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At the Bedside

Taking Patients' Values Seriously

Edmund G. Howe

Three articles in this issue of *The Journal of Clinical Ethics* discuss choices that patients sometimes make: purchasing a kidney illegally overseas, repeatedly seeking *in vitro* fertilization (IVF) despite increased risks, and altruistically donating an organ to a stranger. It's been argued that careproviders should feel morally obligated to remedy issues like these, rather than strive only to treat the patients we see to the best of our ability. This argument appears, for example, in discussions about whether careproviders should attempt to "game the system" for their patients. Many say careproviders should not game the system, but instead should try to change the system to help all patients.

There is no doubt that careproviders have a lot to offer — probably more than anyone else — in attempts to reform the healthcare system. When they do become involved in public policy, however, they may do so at a price. In my introduction to this issue of *JCE*, I will consider how, when careproviders choose to take on the larger issues, they may risk losing their capacity to take patients seriously.

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PATIENTS WHO BUY KIDNEYS ILLEGALLY OVERSEAS

In "What Should We Do with Patients Who Buy a Kidney Overseas?" Marie-Chantal Fortin, Delphine Roigt, and Hubert Doucet describe several concerns careproviders have had in Canada when patients who have kidney failure purchase organs overseas. The authors report that this involves 30 to 50 Canadians each year and that this is, experts estimate, 3 to 5 percent of those who would benefit from kidney transplants.

In Canada, buying an organ is a criminal act. It violates a number of important ethical values, the three most important of which follow:

1. As noted above, it's against the law.
2. Should the patients later develop medical complications, they may use up limited resources that other patients may need more, which may violate the principle of justice.
3. Perhaps most importantly, purchasing an organ exploits the vulnerability of those worse-off, who sell their organs; presumably they wouldn't be willing to do this if they weren't badly off.

Fortin and her co-authors relate that, as a consequence of these ethical "wrongs," some careproviders may feel they no longer want to treat patients who buy organs, so long as the careproviders can help patients find another physician and patients are not in a medical emergency. Should careproviders withdraw from caring for patients based on a belief that buying an organ overseas is immoral?

On the one hand, careproviders are free to follow the dictates of their moral conscience. From this perspective, this becomes just another instance of a careprovider withdrawing from a patient's care — for example, a careprovider who believes in the absolute sanctity of human life may opt to transfer the care of a patient who chooses to "go off" a respirator.

On the other hand, it could be argued that careproviders who wish to transfer the care of a patient who breaks the law to purchase a human organ cross a long-held professional boundary that many may see as sacrosanct: usually when a person commits a crime, it is the responsibility of the state, not the careprovider, to judge and possibly punish the person. A careprovider who withdraws medical care for this reason (we would hope) would not *intend* this to be a punishment, but, regardless, it is. Patients may experience the loss of their careprovider, and of the relationship, greatly. Patients may also feel much worse about themselves as a result. Fortin and colleagues point out that there are some instances in which "all" careproviders believe that they must never discriminate against a patient — for example, based on racial, sexual, or political views. The authors also note, rightly, that careproviders should treat patients who commit murder. Why, then, might an exception be made for a patient who purchases a human organ? Fortin and colleagues give additional reasons: for instance, a careprovider who treats such a patient may be seen as contributing to a continuation of this illegal practice.

Yet regardless of whether this can or cannot ultimately be justified, withdrawing care may cause the blurring of important realities regarding patients. When careproviders — or any citizens — address a question of public policy, at some point they must consider other patients who will be affected by the policy. Whenever persons are "lumped together" in this way, it is possible to oversimplify who each of the affected persons are, and thus to stereotype them. This can result in serious negative effects. First, it may cause the greater society to see members of the group in an inaccurately "reduced" way. Second, society tends to view its members as either like the majority, and thus part of the majority, or as unlike the majority, and thus as "marginal" or as "outsiders." Because careproviders have authority and a great deal of influence in regard to what "society" thinks, when careproviders respond to patients in a way that suggests that the patients are different, it may add greatly to that negative effect. Patients may become labeled, and the labels may become self-fulfilling prophecy: patients may become increasingly marginalized due to a process that is wholly outside their control. Patients who seek kidneys illegally, in particular, may be mislabeled by society as "criminals" in *all* respects, and careproviders who withdraw their care may increase the degree to which the greater society sees and treats these patients as social pariahs. Peter L. Berger and Thomas Luckmann are among those who have helped us understand how members of society may label and ostracize persons; as a result of this process, they say, "all men, once socialized" may become "traitors to themselves."[1]

Careproviders, in this way, may become traitors to their patients, to themselves, and to their profession. Oversimplifying and stereotyping a group of patients — which may be necessary in considerations of the ethics of public policies — may distort a careprovider's clinical view of a patient. Then, even if the careprovider still can interact with the patient in the same way, the careprovider's moral judgments of the patient may change how the careprovider feels toward the patient — and the patient may sense this. In response, the patient may lose trust in the careprovider.

The fact is that patients who buy organs *are* criminals. Still, we may be able to see *some* dis-

tinctions that separate these patients from persons who commit serious crimes. Patients who buy organs commit this crime to prolong their life. This may be seen as a selfish act, but it may also have been done to benefit the patients' loved ones, such as young children. Further, Fortin and colleagues tell us, some patients who purchase organs see this as a "win-win" situation: they believe, as some claim, that people who sell an organ do it to serve their own interests. Of course, while they well may believe it, this is also a rationalization.

Still, there may be distinctions that separate such rationalizations from those of others who commit more serious crimes. Fortin and colleagues tell us, for example, that some transplant surgeons report that if they were in the same situation, they might consider purchasing an organ.

My point is not that this crime should be viewed as different, nor that any exceptional factors should "count" as moral, much less legal, excuses. My intent is to illustrate how considerations of this kind can become blurred for careproviders. There are several reasons why careproviders should not transfer the care of these patients. First, they would abandon their medical role, which requires careproviders to unconditionally accept patients and *always* be there for them, regardless of what they may have done. Second, as noted above, transferring patients to another careprovider may have serious adverse social effects; even if it doesn't contribute to the labeling and marginalization of patients, it may cause the patients to feel worse. All patients, including patients who break the law, need careproviders' unconditional care and support. The patients may, in this regard, rightly see careproviders as their only "court," and perhaps even refuge of last resort. Careproviders who withdraw care are not able to offer patients this potentially pivotal and life-changing role.

If, however, careproviders lose respect for patients when they buy a kidney, careproviders may not be able to serve in this role. Careproviders who feel profound disrespect for these patients might most benefit them by withdrawing from their care. These careproviders would not do this to serve their own moral conscience, however; they would do this to provide patients maximal benefit. To protect patients from harm, they might tell patients, "I'm not sure I can help you now, due to my feelings in response to what you have done. Still, what helps you the most remains the most important thing to me. I just don't have control over these feelings, and I'm sorry." Saying something like this could make a difference in how patients respond.

If careproviders don't want to withdraw from these patients, what *can* they do? Stated more generally, what can careproviders do when patients make big mistakes, even including committing a crime? Much. Here are two examples.

First, careproviders can explicitly acknowledge that making big and small mistakes is something that we all do, careproviders and patients — and when it comes to erring, patients should never feel isolated and alone. For example, one of my patients told me that he had "permanently blown" his relationship with his teenage son. No small loss. I responded, "One of the most painful things in life for me — probably for all of us — is when we do something we later regret, and we can't undo it. I imagine it is something like this now for you." On hearing this, the patient changed his mind, and decided that he would not yet give up on trying to be close to his son.

To "validate" patients means to tell them that *something* in what they have done, in *some* way, makes *some* sense. We might say to a patient who bought an organ, for example, "Of course you want to live longer if you can. Wanting this makes sense." We might add, "I can even imagine how I could rationalize away sound arguments against it, without knowing I was doing that." Adding the last sentence is to give a patient the "benefit of the doubt" — greatly. The patient might respond, "Yes, this is what happened," truly or falsely, or "No, this isn't what happened," truly.

It doesn't matter. Most likely patients already know, at some level, that they have erred, and rationalized it. In any case, for careproviders to say that patients rationalize their actions

is implicitly a moral judgment, and saying this won't change patients' subsequent response. In fact, it may make it more likely that patients won't change their response. If careproviders give patients the benefit of the doubt, patients are likely to remember that their careprovider "accepted" them at this time and continued to believe that they *still* had another, "higher" side. I recall as a child having done something that made *everybody* angry. One neighborhood child said, though, "I'm sure he didn't mean it." Obviously, I remember that to this day!

PATIENTS WHO SEEK *IN VITRO* FERTILIZATION

In "As Sure As Eggs? Responses to an Ethical Question Posed by Abramov, Elchalal, and Schenker," Deborah Sarah Ferber reports on careproviders' response — or rather lack of response — to that article on IVF. Ten years ago, Abramov, Elchalal, and Schenker described several "downsides" or worst side-effects from IVF, which included women having a 20-fold increase in the incidence of so-called ovarian hyperstimulation syndrome (OHSS). (The syndrome can involve loss of the ability to urinate, blood clots resulting in strokes, and liver and kidney failure.) Ferber reports that the article by Abramov, Elchalal, and Schenker received little comment in the medical literature, even though it depicted what Ferber calls a "state of emergency." Based in part on these side-effects, Ferber describes how patients may seek IVF even at extreme personal risk and expense, and comments that patients who seek and continue to seek IVF, given these risks, may have a problem that is emotional rather than solely physical.

Ferber acknowledges that she is not a careprovider, but a cultural historian. Her raising these concerns is important, because careproviders who have this information may be wiser and better address these possibilities with their patients. Conversely, should careproviders act on this, it may present certain risks. For example, careproviders might come to assume that their patients probably seek IVF because they are depressed, and so could become less sensitive to their patients' other possible motivations, such as wanting to become pregnant because they find it uniquely meaningful. Research indicates that some women do seek IVF for this reason, even though it may make them feel *more* depressed.[2] They may feel, for example, extremely guilty because they are aware that they could choose to adopt.[3] As this is the case, when careproviders participate in shaping public policy, it is important, *clinically*, that they not assume that patients' desire for IVF — or desire for any treatment, for that matter — is psychiatric illness, regardless of the degree to which this seems logical. Should they do this, patients may (rightfully) resent them, and then listen to little, if anything, they say.

What may be most difficult for careproviders to imagine is that women pursue IVF because becoming pregnant is singularly meaningful to them, and they will pursue it, even given the risks that Ferber describes. This may seem irrational, but, in other contexts, persons have made similar choices throughout time. A classical example is that of warriors who are willing to die so they are well remembered, as described by Homer in the *Iliad*. Many patients report a similar quest for meaning in their later years. I recall, for instance, a patient who forgot to change his clocks one spring to Daylight Savings Time. That fall, he became highly anxious; the summer had passed, he said, as if he hadn't existed. What bothered him most was that he could not do anything that he considered meaningful. This critically important aspect of many persons' reality, rational or not, was identified by Shakespeare, whose work is considered timeless and universal, with good reason. He writes,

> Like as the waves make towards the pebbled shore,
> So do our minutes hasten to their end.
> . . .
> Nativity, once in the main of light,
> Crawls to maturity . . .[4]

Another example that illustrates the need for careproviders to stay aware of patients'

unique need for meaning is a medical practice that is less common and far more controversial than IVF, so-called cosmetic plastic surgery procedures on women's vaginas.[5] Some women seek this surgery to tighten their vagina after it becomes stretched from childbirth. Women may do this for their husbands, to improve their relationships with them, but some say they do it for themselves. As one might expect, when women say they do this to please their husbands, some become enraged. Perhaps it brings to mind the unconscionable status of women in the past, as exemplified by Henry the VIII's beheading his wives when they did not deliver a surviving male heir.

This discomfort or ambivalence furthers the purpose of this article, which is to suggest that even if careproviders strongly oppose a practice as a matter of a medical policy, their strong feelings may inadvertently rob them of the capacity to provide optimal clinical care. For example, a physician suggests women may seek vaginoplasty due to an underlying psychiatric illness called "body dysmorphic disorder."[6]

Careproviders may miss the fact that, for some patients, pleasing their husbands may be more important than anything else. If careproviders feel repulsion at this, even if they don't express it, their patients may still perceive it. This may cause patients to consider their careprovider worthy of contempt. Some careproviders may see these responses as wholly irrational. If so, they may want to consider the arguments of the late philosopher G.E.M. Anscombe. She saw *intention* as all-important, and viewed what persons connote to often be as important as, or more important than, the content of what they say.[7] If we can't see how pleasing a partner could be most important to patients, and, moreover, we can't respect it as a choice, it may eliminate our capacity to help those patients.

This possibility is illustrated by considering a different group of patients who undergo vaginoplasty: patients who have a vagina created for them, perhaps in part to please a partner, when they change their gender from male to female.[8] In these cases, careproviders take due pride in being able to perform surgery for patients in a way that most helps them. Why might this differ from similar surgery for women? One common error in thinking is to allow ourselves to think of others only in terms of what they *should* do. In this instance, for example, careproviders may believe that a husband should love his wife just as she is! Of course, people often don't "work" as we think they should. Thus, vaginoplasty may be exactly what some women want it to be: it may improve their life, whether or not others think it *should*.

How does this apply to careproviders who treat patients who repeatedly seek IVF? When careproviders do not judge or stereotype their patients, they can improve clinical outcomes. For example, careproviders can help IVF patients prepare for the possibility that IVF will fail. First, careproviders can help their patients expect the worst. Second, they can help patients learn how best to handle failure, should it occur. Careproviders can repeatedly say to patients that if they will feel disappointed if they do not become pregnant, it may be because they have allowed themselves to have overly positive expectations. Careproviders can advise patients that, before IVF succeeds (or fails), whenever they feel hope, they can say silently but firmly to themselves, "Whoa. I am expecting something that may never occur."

Secondly, careproviders can tell patients that no matter how much they prepare themselves, if IVF fails, they will feel sad; a voice within them may say over and over, "How sad! How could this happen to you?" Careproviders can tell patients that, rather than be in pain and try to "fight" hearing this voice, they can limit their pain by doing the opposite. For example, patients can learn to "quantify" various aspects of this voice each time they hear it; they could note how loud or how shrill it seems on a scale of 1 to 5, for example. "Quantifying" in this way can reduce pain remarkably. This technique can be effective even when the pain is wholly physical, as from cancer, much like a woman's counting during contractions may distract her from pain during labor.

The "success" of this approach is stated nowhere more clearly than by the writer and

social critic Simone Weil, who said the following about how she became able to "distance" herself from pain she had due to headaches: "I was able to rise above this wretched flesh, to leave it to suffer by itself, heaped up in a corner. . . ."[9] Careproviders can tell patients that they may practice this strategy any time during the IVF procedure that a voice inside them introduces "its" doubts. Careproviders can suggest that patients can get better and better at this, the more they practice. If they don't support their patients in seeking IVF, careproviders may not be able to convey these skills effectively. This is true for patients who have a vaginoplasty; this procedure, like IVF, can fail and have highly adverse side-effects.

PATIENTS WHO DONATE ORGANS TO STRANGERS

Finally, David Steinberg, in "How Much Risk Can Medicine Allow a Willing Altruist?" asks whether there should be a socially based process to help decide when persons should be able to donate organs — and, if they are allowed to donate, who should receive the organs. It is obvious that those potential donors act primarily to benefit others. They do not expect to gain anything — unlike someone who purchases an organ and so lives longer, or someone who has IVF and so is able to bear a child that is biologically her own.

Steinberg notes the perspective of Aaron Spital, who believes that when donors are "relatives and intimates," they should be allowed to accept greater risks than they should when they donate to strangers, because *they are likely to derive more benefit in the first instance*. The point I wish to make is that this view might be problematic for careproviders to adopt. First, it overlooks the meaning that potential donors may find in donating to strangers. Second, it assumes that those who donate to strangers will receive a benefit; but, as discussed above in regard to IVF, those who donate to strangers may give even when doing so makes them feel worse.

Usually, people who help others — especially their loved ones — feel good about it. When careproviders assume that a person would like to donate simply because a loved one will benefit, it may alienate the potential donor, and even enrage him or her (and, I would say, with good reason). Why? Because, briefly, this assumption regards the donor as less of a person than she or he is. This kind of assumption may oversimplify and "reduce" the motivation of a potential donor. It also ignores a donor's strengths, and presumes that, as a person, a donor is more limited than she or he may actually be. As Steinberg notes, in fact, individuals may want to donate, especially to a stranger, with the reason that all human beings belong to an "extended family." Why might careproviders not share this belief? One possibility is that careproviders may presume that others "work" emotionally as they do, and thus couldn't choose freely to be so altruistic.

Should careproviders encourage the view that donors must be self-interested at best, or emotionally impaired at worst, society may come to adopt that view. In fact, the desire to donate an organ to a stranger may be the "highest" moral response a person can have. One of life's most important and real philosophical questions is, in this regard, how someone such as myself can live — having many things — knowing that others who are badly off greatly suffer — while it is possible that I could change this. In regard to this question, I think of the answer of the Australian philosopher Peter Singer. He states that he believes that all of us who can give to relieve other's significant suffering *should* give, unless this would cause to us or our loved ones a comparable burden.[10] Singer "walks the walk." He doesn't eat animals that he believes have the capacity for sentience and can suffer, and he continually strives to update his knowledge, based on new scientific findings, of which kinds of animals these are. Singer also gives a substantial portion of his income to help others who are much "worse-off," and he acknowledges that, in comparison to what he believes that he and others should do, he fails.

Some believe that we, as humans, unlike other animals, have acquired a unique capacity

to give to other persons who aren't closely related to ourselves.[11] The "highest" moral use of this unique human capacity may be giving an organ to a stranger, not because we believe we will benefit, but because we believe, like Singer, that this is right. Pope John Paul II said, for example, that donating an organ for transplantation constitutes "the highest act of love for one's neighbor."[12]

Careproviders who don't or can't see this may lose the opportunity to help patients as much as they could. For example, patients may donate an organ and learn that it "failed." Even if this doesn't happen, patients may fear that it will. Either way, careproviders can help. They can point out to patients that there may be a gain that they can't acquire in any other way. The gain cannot compensate for the loss of a "failed" transplant, but there may still be a "silver lining," and it may be most profound. This is that donors may, as a result of having experienced this loss, gain a depth of perspective regarding their life and of living that they simply couldn't have acquired in any other way. They couldn't acquire this, even by trying.

This is stated, perhaps, as clearly as anywhere by Simone Weil. Speaking of her own gain from having had severe headaches she wrote, "I was suffering from splitting headaches; each sound hurt me like a blow. . . . This experience enabled me by analogy to get a better understanding of the possibility of . . . love in the midst of affliction."[13] This can even happen in response to giving birth to an infant with severe special needs. For example, Barbara Collins is the mother of such a child. She says, "This has given me a sense of what's important. I can't empathize anymore with my friend whose day is ruined because the cleaning lady didn't show up!"[14] Another poignant and compelling example is given by Marianne Rogoff, who has written about her and her husband's life with their daughter Sylvie, who died while still a baby. Sylvie's doctors said just days after she was born that she would be "better off dead,"[15] and Sylvie died several months later. Rogoff writes that she and her husband read the Anne Tyler novel, *The Accidental Tourist*.[16] In the novel, Rogoff relates, "Out of the blue, a victim of random violence, [Macon Leary's] child is killed. Since the death, he is no longer the same man. . . . He blames himself. Macon Leary has to learn how to change, be altered by experience, and transformed."[17] Given these accounts, careproviders may be able to tell patients and donors, that, following a profound loss, they may experience this kind of transformation. But could they say this to a person who would like to donate an organ to a stranger if they believed that the person would like to donate mostly or solely to benefit only him- or herself?

CONCLUSION

My intention in writing this has been to help careproviders avoid the risk that their patients will no longer see them as a refuge of last resort. Second, I hope that careproviders will not contribute to the greater society losing sight of who patients really are, and "lead the way" for society to accurately appreciate the strengths of all patients. Finally, I hope that even when careproviders become engaged in public policy, they can retain a capacity to help the patients as much as they possibly can.

Patients who seek kidneys illegally are, in addition to committing a criminal act, trying to lengthen their lives. Women who seek *in vitro* fertilization, especially those who do this "over and over," may not do it because they are depressed; they may do it *in spite of feeling guilty for not adopting*, because it is more important than anything else in their life could be *to them*. This is also true for women who undergo a vaginoplasty for their husbands, and for men who seek to become women, to better satisfy not only themselves, but their sexual partners. They may do this because this is most important *to them*, and, thus, their quests are worthy of careproviders' respect and support.

Persons who donate an organ, especially to a "stranger," may not do it to benefit themselves; they may, even, be physically and emotionally harmed by donating. Even knowing this, they may continue, nonetheless, *because this is what they believe they should do*. Society can see all

these persons as *less* than they are, and what careproviders say about specific groups of patients may significantly influence what persons in society believe. If patients are mislabeled, they may become marginalized; careproviders may have contributed to this result. To help their patients and society most, careproviders must retain a capacity to see the kinds of patients they write about realistically. If they can take patients' most deeply felt needs seriously, they may also be able, clinically, to help them to the greatest extent possible.

NOTES

1. P.L. Berger and T. Luckmann, *The Social Construction of Reality* (New York: Anchor Books, 1966), 170.

2. As one patient who was not having success with IVF said, "The feeling of failure was so painful! It was not only the pain in my body but also a strong assault on my feelings." T. Su and V. Chen, "Transforming Hope: The Lived Experience of Infertile Women Who Terminated Treatment After In Vitro Fertilization Failure," *Journal of Nursing Research* 14, no. 1 (March 2006): 46-54, p. 50.

3. P. Orenstein, *Waiting for Daisy* (New York: Bloomsbury, 2007), 200.

4. W. Shakespeare, "#60," *Shakespearean Sonnets*, ed. B.A. Mowat and P. Werstine (New York: Washington Square Press, 2004), 125.

5. S.G. Boodman, "Cosmetic Surgery's New Frontier," *Washington Post*, Health Section, 6 March 2007, F1, F5. Since this procedure was first recorded in 2005, there have been 793 performed in the U.S. in this year. One physician who "invented or popularized" this procedure has done 3,000 over the past 12 years. Ibid. No doubt there are good reasons careproviders should be concerned about this. One doctor says that there is "absolutely zero scientific literature" that supports this procedure "even doing only what those doctors doing this purport that they do." Another doctor reports that she has treated several women who have had complications resulting from this procedure. This includes painful intercourse. Ibid.

6. Ibid., F5.

7. G.E.M. Anscombe, *Intention* (Oxford: Blackwell, 1963).

8. G. Liguori, et al., "Laparoscopic Mobilization of Neovagina to Assist Secondary Ileal Vaginoplasty in Male-to-Female Transsexuals," *Urology* 66, no. 2 (August 2005): 293-8.

9. R. Coles, *Simone Weil* (Reading, Mass.: Addison-Wesley, 1987), 118; see also E. Panagopoulou, "Emotionally Expressive Coping Reduces Pregnancy Rates in Patients Undergoing In Vitro Fertilization," *Fertility and Sterility* 86, no. 3 (September 2006): 672-7, in which the author suggests, on the basis of data, that this technique that involves distraction and "distancing" may work better for patients who have failed IVF than these patients "emotional expressing" and working through their grief, p. 676.

10. P. Singer, *Writings on the Ethical Life* (New York: HarperCollins, 2000), see, particularly, 110-3, and 258-9.

11. I. Semeniuk, "How We Tell Right from Wrong," *New Scientist* (3 March 2007): 44-5.

12. M. Banasik, "Living Donor Transplantation — The Real Gift of Life," *Annals of Transplantation* 11, no. 1 (2006): 4-6, p. 5. I think, when contemplating this question of what we should all do for "strangers," of a scene from the movie *Suddenly Last Summer* (1959). Elizabeth Taylor and Montgomery Clift are having dinner in a country club-like setting on one side of a high glass wall. On the other side of this glass wall, outside the country club, are poor persons, crowded against the glass panel. Their faces are jammed and mashed against it as they look in and on those inside. J.L. Mankiewicz, *Suddenly Last Summer* (New York: Columbia Pictures, 1959), movie.

13. Coles, see note 9 above, p. 118.

14. R. Simons, *After the Tears* (San Diego, Calif.: Harcourt Brace Jovanovich, 1987), 79.

15. M. Rogoff, *Sylvie's Life* (Berkeley, Calif.: Zenora Books, 1995), 18.

16. A. Tyler, *The Accidental Tourist* (New York: Knopf, 1985).

17. Rogoff, see note 15 above, p. 87.

Features

How Much Risk Can Medicine Allow a Willing Altruist?

David Steinberg

INTRODUCTION

With the advent of live organ donation, the traditionally low risk permitted altruists in medicine escalated to include death. In 2005 there were 6,020 live kidney donors, 302 live liver donors, and nine live pancreas, intestine, and lung donors combined.[1] Although data is limited, a live kidney donor assumes a mortality risk of about 0.04 percent[2] and the donor of a lobe of liver a mortality risk of 0.2 percent or higher.[3] The probability of death would increase if organs were retrieved from donors with medical risk factors or if surgery was performed in low volume or at lesser skilled transplant centers. Although the available information may be imperfect, recent data confirms that live organ donation is associated with donor risk.[4] That low risk could translate to painful reality was illustrated in the well-publicized deaths of liver donors Danny Boone and Mike Hurwitz.[5] In addition to deaths, there may be serious complications. Serious donor complications in transplantation of the right lobe of the liver include bile leak or stricture in 6 percent, the need for blood transfusion in 4.9 percent, re-operation in 4.5 percent, major postoperative infection in 1.1 percent, and rehospitalization in 8.5 percent.[6] The death or injury of a healthy altruist is disturbing, and a reason to confront this difficult question: How should the amount of risk that medicine can impose on a willing altruist be determined?

RISK AND RELATIONSHIP

In many transplant centers, live kidney donation by altruistic strangers has become accepted practice.[7] Donation by altruistic strangers may be approximated by the number of living unrelated anonymous donors reported by the United Network for Organ Sharing (UNOS) and the Organ Procurement and Transplantation Network (OPTN), which, for 2005, consisted of 68 kidney donors and five liver donors; in 2000 there were 20 kidney donors and one liver donor.[8]

Donation by altruistic strangers has led to debate over whether the permissible amount of

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risk imposed on an altruist should be determined by the relationship between donor and recipient. It has been claimed that familial and other intimate relationships entail inherent obligations so that "what is supererogatory between strangers may be expected between family members" and other intimates.[9] Lainie Friedman Ross claims intimates have a *prima facie* obligation to donate organs and, for that reason, advocates that intimates should be permitted to accept greater risk than strangers.[10] Although it is descriptively correct that many people feel an obligation to donate an organ to an intimate, the translation of those emotions into a moral obligation inappropriately conflates what is with what ought to be. Although intimates may have mutual obligations, it has not convincingly been demonstrated that organ donation is one of those obligations. We strongly respect personal autonomy in matters of bodily integrity and should be reluctant to impose an obligation on intimates to donate an organ or perform some other dangerous altruistic act. Although sound ethics does not necessarily make for appropriate legislation, the absence of momentum for laws that obligate organ donation between intimates suggests a lack of widespread support for this position.

The American Society of Transplant Surgeons, which accepts the retrieval of kidneys from altruistic strangers, does not approve the more dangerous retrieval of a lobe of a liver unless the donor is "emotionally related to the recipient."[11] I suspect that this position is based on the higher risk of liver donation and concern that inappropriately motivated altruistic strangers will escape detection. Although a competent and stringent evaluation should be mandatory for all altruists who are willing to assume substantial risk, there is no theoretical reason to exclude altruistic strangers. Although they are nominally strangers, people may feel a sense of kinship with their intended beneficiaries and "in a cosmic sense consider all human beings to be an extended family."[12] Many religions emphasize the interconnectedness of all persons under a supreme being.[13] Buddhist belief considers the separation between ourselves and others to be illusory.[14] Thomas Nagel notes that logic dictates "we must recognize other persons as persons in fully the same sense in which one is a person oneself."[15] Some altruists, such as rescuers of Jews during the Holocaust, were found to have provided assistance at considerable personal risk because of a belief in "the common humanity of all people."[16] In contrast, related individuals such as spouses and siblings may have troubled relationships. The importance of relationship is expressed in the higher percentage of people who are willing to donate to an intimate or relative compared with those willing to donate to a stranger;[17] however, the nominal nature of a relationship, in itself, does not provide a reliable basis for determining permissible altruistic risk.

RISK AND DONOR BENEFIT

Aaron Spital believes that the justification for live organ donation must be "benefits for the potential donor that are sufficient to offset the risks for the donor."[18] He notes that intimates obtain "the inestimable benefit of seeing a loved one restored to health and then having that person available for sharing the joys of life."[19] Spital claims that relatives and intimates should be allowed to accept greater risk because they are likely to derive more benefit from helping each other.[20]

It has not been proven that donor benefit, in general, is higher for related and emotionally bonded individuals than it is for altruistic strangers.[21] Spital correctly notes that the nature of donor benefit is "psychological and emotional" and "cannot be quantified precisely."[22] Difficulty in the quantification of donor benefit is a serious problem for a justification that defines a continuum of acceptable donor risk that increases with donor benefit; also, it is not obvious how to weigh psychosocial benefits against the qualitatively different parameter of medical risk. Were the potential psychosocial benefits worth the risk that Mike Hurwitz took when he donated a lobe of his liver to his brother in an operation that cost his life? We don't know how to perform these calculations. Also, as il-

lustrated in the Hurwitz and Boone cases, donor benefit is more realistically considered a potential benefit; donors who die reap no benefit, and some donors regret their donation.[23] Because the rewards of altruism in medicine are psychosocial, uncertain, and at best vaguely quantified — and significant material benefits are inconsistent with altruism — donor benefit should not be the barometer used to set the permissible level of altruistic risk.

CUMULATIVE RISK AND BENEFIT

The calculus of medical decision making entails the weighing of risk and benefit and the selection of options likely to provide benefits that outweigh the attendant risks. Individual risk-benefit calculations are flawed in altruism because the person who accepts the medical risk is not the person who reaps the medical benefit.[24] These calculations can, however, be performed on a wider scale that measures cumulative medical benefit and cumulative medical risk on the affected population. Live organ donation is publicly accepted and currently best justified because its cumulative medical benefit far outweighs its cumulative medical risk. Compared to deceased donor organ transplantation, live organ donor transplantation is associated with an outcome that is generally better, reduced patient waiting time and recipients who are generally healthier at the time of transplantation. Although one healthy person in about 400 may die after donating a lobe of a liver, many more lives are salvaged.

There is a direct relationship between risk and benefit in liver and kidney transplantation. The higher risk of liver retrieval is taken to save a life because there is no procedure comparable to dialysis to keep patients with advanced liver disease alive; whereas the lesser risk of kidney retrieval spares dialysis but typically is not immediately lifesaving. The permissible risk to an altruist may be less apparent when the beneficiary's prognosis is uncertain, such as when a previously resected malignancy has, with only some degree of probability, been cured. To be consistent with the goals of medicine, an altruistic intervention must provide benefit to its population of beneficiaries that overwhelmingly outweighs the risks to its population of altruists.

THE ARBITERS OF PERMISSIBLE RISK

Potential organ donors (and altruists in other arenas of medicine) and the professional transplant community (or other purveyors of medical altruism) are the current arbiters of acceptable altruistic risk. Although they check and balance each other, both are imperfectly positioned to establish appropriate standards. Potential altruists can set the upper limit of risk because, if they deem the risk to be too high, they can refuse to participate; however, their role in setting the standards of altruistic risk is problematic, because altruists may be subject to the internal coercion of conscience, family pressures, and rational deliberation — for better or for worse — and can be overwhelmed by emotion.[25] Zell Kravinsky, a man who had already donated one of his kidneys, set the barometer of risk too high when he volunteered to donate his remaining kidney. Transplant centers appropriately refused his request.[26]

Conflicts of interest may exist for medical providers. For example, the professional transplant community employs altruism as a means to save or improve lives. The protection of donors is a vital concern, but it may risk subordination to the goal of obtaining more organs when that goal subtly conflicts with moderating altruistic risk. The reverse is also possible; inordinate fear of donors' deaths or injuries might cause the inappropriate rejection of an altruistic intervention. An important reason that the determination of acceptable altruistic risk should not wholly reside in the medical community is that these decisions entail value judgments for which medicine has no special expertise.

ABSOLUTE LIMITS

The requirement that the cumulative medical benefit of an altruistic act far exceed its cu-

mulative medical risk is a necessary but insufficient limitation. The retrieval of all organs and tissues from a healthy live donor could save more people than the one doomed altruist; yet few of us would endorse participation in such blatant human sacrifice. But where should we set the limit? Is a 1 percent risk of death excessive? Or should we accept a 2 or perhaps a 3 percent risk?

In general, people have the right to determine what is done to their own body. If a person chooses to accept a high risk of death and swim against a forceful current to save a drowning child, that decision will likely be considered morally laudable, if not heroic. It does not, however, follow that a similar degree of risk can be imposed on medical altruists, because altruism in medicine requires the participation of morally accountable healthcare professionals. Retrieval of the heart from a parent who is willing to die to save a child entails certain death and would blatantly challenge the time-honored medical dictum "Do no harm." Lower levels of altruistic risk are also problematic. A 2 percent risk of death in an altruistic intervention that will ultimately be performed on hundreds or thousands of people will, with near statistical inevitability, result in deaths. Similar considerations apply to the imposition of serious harm.

I propose as the guideline for determining altruistic risk that the cumulative medical benefit of an altruistic intervention overwhelmingly outweigh its cumulative medical harm, and that some absolute level of permissible risk is not exceeded. The claim that an altruist's personal autonomy should take precedence over a healthcare professional's duty to avoid inflicting harm must take account of both the harm of any specific action and the broader consequences of weakening the principles that constrain healthcare professionals from hurting people. If significant numbers of people die or are harmed in altruistic medical interventions, physicians will appropriately be seen as violating the Kantian dictum to avoid using a person as means to an end, and trust in the protective role of medicine will erode. A license to inflict excess harm in the sphere of altruism might facilitate cavalier risk taking in other areas of medical practice. For these reasons, there should be limits on the amount of risk that may be imposed on medical altruists.

A PROPOSED PROCESS

A process is required to translate this proposed general guideline for determining permissible altruistic risk for practical application. How do we determine whether the cumulative medical benefit of an altruistic intervention overwhelmingly outweighs its cumulative medical risk? How do we quantify the appropriate limit for altruistic risk? Ethical theory has limitations and cannot provide a quantitative answer. The risk to an altruistic donor is medical; the benefits to the donor are psychosocial. These, like "apples and oranges," are incommensurable parameters and cannot quantitatively be weighed one against the other.[27] The quantification of acceptable risk is beyond the capability of ethics and must be decided by another mechanism. A process is necessary. Because medical altruism in its various forms affects many people and has societal implications, its conundrums should be resolved, at least in part, as matters of public policy.

The public or its representatives, in some appropriate forum, would be informed by the medical community of the anticipated risk and benefit of specific transplant or other interventions based on altruism. In transplantation, a registry will need to be established to track donors' morbidity and mortality. Decisions would be made behind a "veil of ignorance" that could be similar to that described by John Rawls.[28] Ideally, involved citizens would be blind to whether they or their intimates were destined to be asked to perform the relevant altruistic act or would be its beneficiary, and thus would be motivated to justly represent the interests of both altruists and beneficiaries.

Participation by the medical community would be critical but not exclusive. The mechanism for involving the public would present pragmatic challenges, but some form of participation, perhaps similar to the employment of

community members on institutional review boards (IRBs) or ethics committees, should be feasible. The public would judge protocols and not make case-by-case decisions. They would set the upper limit of acceptable morbidity and mortality for a liver transplant or a lung transplant or some other altruistic act. Whether the public would accept more or less risk than the medical community would be a matter for empirical inquiry. Although it might limit its decision-making powers, involvement of the citizenry would be helpful in transplants and in other areas of medicine that involve altruism. If there were a mishap, such as the unavoidable death of a healthy organ donor, the burden on the medical community would be eased. The emotional impact on the transplant team might not be altered, but external criticism would be muted because the transplant would have been endorsed by a public cognizant of the risks.

ACKNOWLEDGMENT

This work was supported by a grant from the Karp Family Foundation, in memory of Harold Karp.

NOTES

1. *http://www.optn.org/latestData/rptData.asp,* accessed 17 January 2006.

2. In a three-year period from 1999 to 2001, of 15,782 kidney retrievals from live donors, seven deaths were reported for a rate of one death for every 2,255 donors (0.04 percent). This is data as of 19 April 2002, reported to the Organ Procurement and Transplantation Network and provided by the United Network for Organ Sharing.

3. R.S. Brown et al., "A Survey of Liver Transplantation from Living Adult Donors in the United States," *New England Journal of Medicine* 348 (2003): 818-25; O.S. Surman, "The Ethics of Partial-Liver Donation," *New England Journal of Medicine* 346 (2002): 1038; J.F. Trotter et al., "Adult to Adult Transplantation of the Right Hepatic Lobe from a Living Donor," *New England Journal of Medicine* 346 (2002): 1074-82.

4. Based on OPTN data as of 19 August 2005, supplied by the United Network for Organ Sharing, for the period 25 October 1999 to 31 May 2005, of 34,433 living kidney donors, there were 23 deaths (eight within the first week of donation); of 2,115 liver donors, there was one death; of 181 lung donors, there were no deaths; when live pancreas, intestine, and kidney-pancreas donors are added to live kidney and liver donors for a total of 36,762 live organ donors, 24 deaths were reported. Based on OPTN data as of 23 June 2006, in 2005, of 308 reported living liver donors, 15 required rehospitalization in the first six weeks postdonation; and of 307 reported living liver donors, five required re-operation during the first six weeks postdonation. In 2005, of 6,325 reported live kidney donors, 90 required rehospitalization in the first six weeks postdonation; and of 6,333 reported cases of live kidney donation, 26 required re-operation in the first six weeks postdonation.

5. C. Miller et al., "Fulminant and Fatal Gas Gangrene of the Stomach in a Healthy Live Liver Donor," *Liver Transplantation* 10, no. 10 (2004): 1315-9; "New Protection Eyed for Living Organ Donors," *Boston Globe,* 31 March 2005; *http://www.lodepp.org/default.html,* accessed 13 July 2005; "New Yorker Dies After Surgery To Give Liver Part to Brother," *New York Times,* 15 January 2002; "A Healthy Patient Dies In A Hospital," *New York Times,* 15 March 2002.

6. Brown, see note 3 above.

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10. L.F. Ross, "Solid Organ Donation Between Strangers," *Journal of Law, Medicine and Ethics* 30 (2002): 440-5; L.F. Ross et al., "Should All Living Donors Be Treated Equally?" *Transplantation* 74, no. 3 (2002): 418-26.

11. *http://www.asts.org/livingliverdonorupdated.cfm,* accessed 12 July 2005.

12. A.S. Daar, "Strangers, Intimates, and Altruism in Organ Donation," *Transplantation* 74, no. 3 (2002): 424-6.

13. S.G. Post, "The Tradition of Agape," in *Altruism and Altruistic Love* (Oxford University Press, 2002), 51-64.

14. L.F Habito Ruben, "Compassion out of Wisdom: Buddhist Perspectives from the Past toward the Human Future," in *Altruism and Altruistic Love* (Oxford University Press, 2002), 362-78.

15. T. Nagel, *The Possibility of Altruism* (Princeton, N.J.: Princeton University Press, 1970).

16. S.P. Oliner and P.M. Oliner, *The Altruistic Personality* (Free Press, 1988); P. Hallie, *Lest Innocent Blood Be Shed* (New York: Harper Perennial, 1994), 131.

17. In several informal surveys, I found a much greater proportion of people willing to donate to a relative or an intimate than to a stranger; 97 percent of Australian nephrologists would donate a kidney to a family member, but only 4 percent would donate a kidney to a stranger: J. Cunningham et al., "Australian Nephrologists' Attitudes Towards Living Kidney Donation," *Nephrology Dialysis Transplantation* 21, no. 5 (2006): 1178-83.

18. A. Spital, "Donor Benefit Is the Key to Justified Living Organ Donation," *Cambridge Quarterly of Healthcare Ethics* 13 (2004): 105-9.

19. A. Spital, "Justification Of Living Organ Donation Requires Benefit For The Donor That Balances The Risk: Commentary On Ross Et Al.," *Transplantation* 74 (2002): 423-4.

20. Ibid.

21. J. Kahn and A.J. Matas, "What's Special About The Ethics Of Living Donors? Reply To Ross Et Al.," *Transplantation* 74, no. 3 (2002): 421-2; J. Kahn, "Commentary: Making the Most of Stranger's Altruism," *Journal of Law, Medicine and Ethics* 30 (2002): 446-7.

22. See note 18 above.

23. E.M. Johnson et al., "Long-Term Follow-up of Living Kidney Donors: Quality of Life After Donation," *Transplantation* 67 (1999): 717-21; N. Weizer et al., "Suicide by Related Kidney Donors Following The Recipient's Death," *Psychotherapy and Psychosomatics* 51 (1989): 216.

24. Donors' risk may also be psychological or financial.

25. C.H. Fellner and J.R. Marshall, "Kidney Donors — The Myth of Informed Consent," *American Journal of Psychiatry* 126 (1970): 1245-51; H.M.E. Karrfelt et al., "To Be or Not To Be a Living Donor," *Transplantation* 65 (1998): 915-8.

26. "An Organ Donor's Generosity Raises The Question of How Much Is Too Much," *New York Times,* 17 August 2003.

27. M. Powers, "Bioethics As Politics: The Limits of Moral Expertise," *Kennedy Institute of Ethics Journal* 15, no. 3 (2005): 305-22.

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Living Donor Transplantation: The Perfect Balance of Public Oversight and Medical Responsibility

Maryam Valapour

Each year more individuals are added to the transplant waitlist than are transplanted.[1] In the past decade, 84,871 individuals have died or become too sick to be transplanted while waiting for an organ.[2] Living donor (LD) organ transplantation offers the only alternative for those individuals who are unlikely to survive until a deceased donor (DD) becomes available. Even among patients with end-stage renal disease who do have a lifesaving alternative — dialysis — as the waiting times grow longer, a significant number are dying on the waitlist.[3] Not only does a transplant offer better survival and quality of life compared to dialysis for the kidney recipient, an LD transplant provides better outcomes than a DD transplant.[4] In 2001, the total number of LDs surpassed DDs in the United States.[5]

However, LD transplantation has a significant disadvantage — unnecessary risk to the donor. Defining acceptable risk for LDs is the topic addressed by Steinberg in this issue of *The Journal of Clinical Ethics*. He argues for the active involvement of the citizenry in this area where medicine depends on the altruism of members of society. Steinberg proposes a process in which community members would represent the interests of the public and would set thresholds of acceptable risk with the medical community in LD organ transplantation.

Organ transplantation is one area in medicine in which there is great national public oversight already, either through direct involvement or through federal oversight on behalf of the public. The federally regulated U.S. Organ Procurement and Transplantation Network (OPTN), the organization responsible for tracking all transplants and developing policies and procedure for organ recovery, distribution, and transplantation is planning on expanding its role to follow LD transplants and outcomes. It also has an active Living Donor Committee who works at improving LD transplantation for the donors.[6] One of their key goals is to minimize donors' risk by evaluating LD program outcomes. Five of the 26 members of the LD committee are members of the general public.[7]

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On the research front, the National Institutes of Health (NIH) funded the Adult to Adult Living Donor Liver Transplantation Cohort Study (A2ALL) in 2002[8] and the Renal and Lung Living Donors Evaluation Study (RELIVE) in 2006,[9] which are multi-center trials that will study medical and psychosocial outcomes of LD liver, kidney, and lung donation. These trials were started in response to not only the calls by the medical community, but also the public for scientifically rigorous data on the incidence of potential risks of organ donation.

Living organ donation may be increasing; however, this is entirely due to kidney donors, who represent 95 percent of all LDs.[10] Perioperative mortality for living kidney donation is 0.03 percent,[11] and morbidity, including minor complication, is less than 10 percent.[12] Despite such small risks, the scientific community continues to study risks of kidney donation to minimize morbidity for the altruistic donor. In addition, the transplant community has proven to be quite conservative in adopting the potentially riskier LD liver and lung transplantation, which account for less than 1 percent of each of those transplants.[13] While there have never been any reports of mortality for LD lung donors, only one case was performed in the U.S. last year.[14]

So, we have to ask, what would direct public oversight in reviewing protocols at a local level really offer to the LD? Would it result in a safer donor environment or would it legitimize risky behavior by transplant programs? Could such oversight limit innovation that is crucial to the longevity of our society by random selection of allowable percent risk early in the course of developing new surgical techniques? Public oversight at a national level has served society well by urging the OPTN to follow outcomes of LDs and the NIH to fund more studies of the outcomes of live organ donation. In addition, the transplant community has shown great restraint in adopting transplants that have higher associated morbidity.

Living donor transplantation is an area of medicine in which an appropriate balance of public oversight with the medical and scientific communities' sense of responsibility to healthy donors has resulted in a system that is both innovative and conservative. Further public oversight is not needed.

NOTES

1. Based on the U.S. Organ Procurement and Transplantation Network data as of 19 January 2007.

2. Ibid.

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4. F.G. Cosio et al., "Patient survival after renal transplantation: I. The impact of dialysis pre-transplant," *Kidney International* 53, no. 3 (1998): 767-72; H.U. Meier-Kreische et al., "Effect of waiting time on renal transplant outcome," *Kidney International* 58, no. 3 (2000): 1311-7.

5. See note 1 above.

6. *www.optn.org.*

7. Ibid.

8. K.M. Olthoff et al., "Outcomes of 385 adult-to-adult living donor liver transplants: a report from the A2ALL consortium," *Annals of Surgery* 242 (2005): 314-25.

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10. See note 1 above.

11. W.H. Bay and L.A. Hebert, "The living donor in kidney transplantation," *Annals of Internal Medicine* 106, no. 5 (1987): 719-27; J.S. Najarian et al., "20 years or more of follow-up of living kidney donors," *Lancet* 340, no. 8823 (1992): 807-10; A.J. Matas et al., "Morbidity and mortality after living kidney donation in 1999-2001: A survey of United States transplant cen-

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13. See note 1 above.

14. Ibid.

Reply to Valapour, "Living Donor Transplantation: The Perfect Balance of Public Oversight and Medical Responsibility"

David Steinberg

Maryam Valapour, in her commentary on my article, "How Much Risk Can Medicine Allow a Willing Altruist?" in this issue of *The Journal of Clinical Ethics,* misinterprets the nature of my article as critical of the transplant community and as a call for direct public oversight.

I have great respect and admiration for the fairness and transparency of how transplants are performed in this country and do not criticize that system. In fact, much of my data was supplied by UNOS (the United Network for Organ Sharing).

What I examine is the theoretical question of how the level of permissible risk to altruists should be determined, including altruism in arenas other than transplantation. I agree with Valapour that it is important to evaluate donors' outcomes. The difficult philosophical question I broach is, How do we judge the data? For example, if a hypothetical altruistic act is found to have a mortality of 0.8 percent, how do we decide whether that is too high a risk, too low a risk, or an acceptable risk?

I claim that medical professionals have no special expertise to make this type of value judgment. I disagree with the positions that acceptable risk should be related to the nominal nature of the donor-recipient relationship, and that the benefit to donors is an appropriate parameter to judge acceptable altruistic risk. I argue that ethics can provide, as a guideline, that the cumulative medical benefit of an altruistic act should overwhelmingly exceed its cumulative medical harm, and that there should be an absolute limit to permissible risk. I claim — as have several philosophers[1] — that ethics has limitations, and that to quantify acceptable risk a process (admittedly pragmatically difficult) should employ a segment of the general public who are positioned to make a fair judgment behind "a veil of ignorance."

All of my positions on this issue should be subject to debate. Unfortunately, Valapour did not present any counter argument beyond the irrelevant statement that "further public oversight is not needed."

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NOTES

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What Should We Do with Patients Who Buy a Kidney Overseas?

Marie-Chantal Fortin, Delphine Roigt, and Hubert Doucet

INTRODUCTION

Worldwide, there is a growing discrepancy between the demand and supply of kidneys for transplantation. Canada is no exception to this rule. As a result of this shortage, waiting lists and times to transplant are becoming longer:[1] in Toronto, for example, the average waiting time for a cadaveric transplant was seven years in 2005.[2] Considering that time spent on dialysis may decrease patients' chances for survival and make them unsuitable for transplantation, some feel compelled to seek other alternatives.[3] One of these is to go overseas, buy a kidney, have it transplanted, and then come home for long-term follow-up care. Experts estimate that every year, 30 to 50 Canadians buy kidneys abroad — between 3 percent and 5 percent of all renal transplants performed.[4] Over the past few years, the media have made public many cases of "transplant tourism." For example, Canadian newspapers published articles on a Chinese website advertising transplant opportunities for foreigners, as well as a Canadian firm offering help to Canadians wanting to buy a kidney from living donors in Pakistan.[5] Although buying kidneys abroad is not yet a widespread practice, there are indicators suggesting it will become increasingly so. This raises a number of issues that can be encapsulated in the question: "What should we — as nephrologists, hospital staff, and the transplant community — do with Canadian patients who buy a kidney overseas?"

In recent years, nephrologists at the Centre Hospitalier de l'Université de Montréal (CHUM) have been confronted with cases of transplant tourism. Some of their end-stage renal disease (ERSD) patients have gone to Pakistan, India, China, or to countries in the Middle East for a

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renal transplant, while others are seriously considering it. Even though, as in Canada, the sale of organs is prohibited in these countries, there is still a black market for kidneys. The CHUM transplant team felt ethically uncomfortable with these patients' actions.

Searching for guidelines in this difficult matter, the CHUM team submitted the case to their Clinical Ethics Committee (CEC). One of the main issues raised revolves around the fact that the doctors felt they were colluding in an illegal and immoral act, which made them uncomfortable and called into question their doctor-patient relationship. The other principal concern was the acceptability of the sale and traffic of organs. The questions brought to the CEC may be summarized as follows:

1. How can/should one react toward patients who have probably committed an act that is considered illegal in Canada?
2. How can one reconcile a physician's duty to ensure the follow-up care of these patients with his or her uneasiness regarding the sale of organs?
3. What is the appropriate attitude to adopt with patients suspected of buying organs, when we have no tangible evidence?
4. Can we refuse to monitor these patients?
5. Can the doctor or the institution do something to prevent this practice?

The CEC conducted an extensive review of the literature on the subject. The only recommendation found was issued by the ethical committee of the Établissements français des greffes in 2003. It stated that even though selling and purchasing an organ in France or overseas is illegal, the transplant physician cannot refuse to treat and monitor patients who return to France with such a transplant.[6] Surprisingly, no national or international ethical or clinical recommendations were found on the issue of follow-up care for patients who have bought and have been transplanted with a kidney overseas. Before offering recommendations on appropriate attitudes to adopt, the CEC had to summarize the ethical issues at stake, review the arguments regarding the selling and trafficking of organs, and propose an ethical framework. This article describes the reasoning of the CEC and its resulting conclusions.

ETHICAL FRAMEWORK

Before making any recommendations on this issue, it was important for the CEC to understand the complexity of the sale and trafficking of organs, and its meaning in the Québec medical context. To do so, legal arguments, medical data, cultural issues, and ethical arguments and values were studied.

FACTS AND ARGUMENTS ABOUT THE SALE OF ORGANS

Legal arguments. There seems to be an international consensus on the prohibition of any form of commodification of organs, as witnessed by statements issued by the World Medical Association, the World Health Organization, and the American Society of Transplantation.[7] In Québec and Canada, the sale or purchase of organs is illegal. Sections 3, 10, 19, and 25 of the Civil Code of Québec proclaim the right of all persons to the inviolability and integrity of their body, the requirement of free and enlightened consent for any interference with their body, and, more specifically, the gratuitousness of any alienation of a part or product of their body.[8] The Québec Charter of Human Rights and Freedoms also enforces the principle of non-commodification of the human body by proclaiming the right of every person to dignity. No matter how universal these principles may seem, however, they are only enforceable if the sale of an organ is conducted in Québec. There is apparently no sanction if the sale and transplantation are performed in another country, where they are legal. There would have to be an international agreement strictly prohibiting the sale of human organs to enforce extraterritorial sanctions. Recently in Canada, Bill C-49, An Act to Amend the Criminal Code (Trafficking in Persons) came into effect, making it a criminal offense to force or threaten a person to have an organ or piece of tissue removed, as well as to offer financial or other material re-

wards in the knowledge that this would result in the trafficking of the person. It also states that the victim's consent to trafficking is never a valid defense.[9] Since the amendment is recent, its interpretation and application in transplant cases will need to be followed.

In the United States, since 1984, the National Organ Transplant Act states that the sale of body parts is illegal and constitutes a criminal offense.[10] The validity of this prohibition is often called into question.[11] Nevertheless, nothing is stipulated about buying organs outside the U.S. Recently, the United Network for Organ Sharing (UNOS) Ethics Committee endorsed a statement that condemns "transplant tourism" and encourages the transplant community to adopt "ethically defensible" policies.[12] However, UNOS did not clarify what it meant by "ethically defensible" policies.

In 2003, the Council of Europe was the first to make a recommendation about organ trafficking. In its report, it encourages countries to struggle against this practice. The council states that it should be considered criminal to be involved in any way in the trafficking of organs. It would therefore be legitimate for countries to take legal action against a patient who illegally buys an organ, or against a doctor who provides information on how to purchase an organ or who agrees to provide follow-up care to a patient who has purchased an organ. Moreover, the council invites countries receiving organs, that is, countries whose citizens have gone abroad to buy an organ, to refuse to reimburse the illegal transplantation and pay for follow-up care, except in cases of emergency.[13] In 2004, the United Kingdom passed the Human Tissue Act, which was fully implemented in September 2006. This law prohibits commercial dealings in human material for transplantation, and states that a person commits an offense if she or he is involved in any way with organ traffic (purchasing, selling, or advertising).[14]

To this day, Iran is the only country to have made public its experience with a legalized and institutionalized market for organs. It is important to note that this institutionalized market does not allow transplant tourism. In fact, organs are procured from Iranians and given exclusively to Iranians. It is impossible for foreigners to receive a kidney from living unrelated Iranian donors.[15]

Position of the World Health Organization. In its most recent resolution on "Human Organ and Tissue Transplantation" (2004), WHO urged its members to take measures to protect vulnerable populations from transplant tourism. It also requested the WHO Director General to provide support to countries that are trying to prevent organ trafficking and transplant tourism.[16] However, it does not suggest any practical means to achieve this goal. In a previous report (2003), WHO members suggested, as a possible solution, assigning organ trafficking the same legal status as pedophilia.[17]

Medical context. Living-donor nephrectomy is associated with low mortality (0.03 percent) and morbidity rates, and it is not connected with an increased risk of ESRD or mortality compared to the general population.[18] It is important to keep in mind that these data are from developed countries. Transplant teams who are participating in organ trafficking are not reporting their complications. Moreover, in countries known for organ trafficking, donors do not receive any follow-up care, so the incidence of ESRD remains unknown.[19]

While the complications for the sellers of kidneys are unknown, there have been reports of complications for patients who buy organs. For instance, there have been documented cases of HIV and hepatitis among patients who bought a kidney in India.[20] In Toronto, where 20 Canadian patients went overseas to buy kidneys, a higher rate of complications than usual was observed, with worse outcomes in terms of graft survival compared to patients receiving transplants from living donors at home. These complications included infections with antibiotic-multiresistant bacteria, disseminated fungemia, and tuberculosis.[21] The transplant team of the University of Minnesota reported similar results in 2006 from 10 patients who underwent renal transplantation in Pakistan, China, and Iran. Complications occurred in six out of 10 patients. In this report, graft and patient survival were

good (one graft loss and no patient deaths).[22] An Australian study reported similar results in patient survival and complications following a renal transplantation performed abroad.[23] It is of concern that when the complications are infections, it becomes a public health issue: the introduction of new pathogens, such as a new strain of antibiotic-multiresistant bacterium, represents not only a threat to the transplanted patient, but also to the entire community, in terms of costs, resources, et cetera.

Cultural context. *India.* In India, renal transplantation is very often the only solution to ESRD. For the majority of ESRD patients, dialysis is too expensive and unavailable. Though most renal transplantations are conducted using kidneys bought from living donors, organ sale remains controversial.[24] Some authors disagree with Western condemnation of the existence of an organ market in India, saying that ethics are context-based and that the Western position is paternalistic and ethnocentric.[25]

The Indian Transplantation of Human Organs Act was adopted in 1995 by most state governments. The bill was passed in the context of a police investigation into organized organ trade. In terms of prison sentences and fines, the law makes the purchasing of organs punishable.[26] Despite the legislation, there is still a market for organs.[27]

A 2002 study interviewing Indians who had sold a kidney reported the following.

- Brokers are almost always involved in the transactions,
- Poverty is the principal motivation for selling an organ (96 percent of organs are sold to pay off debts),
- Women comprise the majority of the sellers,
- The amount the seller received was less than promised,
- The sellers' socio-economic status did not improve after the sale (in fact, it was often worse than before the transaction),
- Of the sellers interviewed, 79 percent said that they would never recommend the practice of selling a kidney to someone else.[28]

Iran. As stated previously, Iran is the only known country where organ selling is legal. In Iran, procuring organs from a brain-dead patient was not permitted until 2001; renal transplantation could only be done from living donors.[29] A governmental organization acts as a broker between seller and buyer. Since the legalization of organ selling, there have been no more waiting lists for renal transplantation.[30]

A study interviewing Iranian kidney sellers showed similar results to the Indian study cited previously.

- Poverty is the principal reason for selling kidneys,
- Most sellers were not able to reimburse their debts from the moneys from the sale,
- Of the sellers interviewed, 76 percent would agree to a prohibition on paid organ donation.[31]

The studies in these two countries indicate that current modes of organ selling are not an effective way to fight exploitation or to alleviate poverty among people in Third World countries.[32]

Canada. In Canada and Québec, organ donation has always been considered solely altruistic.[33] The Canadian healthcare system is based on solidarity, which might explain why organ donation is associated with virtues of altruism, generosity, and charity. The metaphor of the "gift of life" prevails. However, no public debate exists on the subject. In its recent report (2004), the Québec Commission de l'éthique de la science et de la technologie suggests that accepting paid organ donation could lead the population to distrust transplantation professionals and could adversely affect other organ donation programs (living and cadaveric). It also argues that any form of compensation or retribution would constitute an infringement of the law as well as an unacceptable practice from an ethical perspective.[34]

Considering the way healthcare and services are reimbursed in Canada, transplant tourism raises other questions: Should the public health insurance system reimburse patients who buy a kidney overseas, since it is presumably eco-

nomically advantageous for the system to have more patients transplanted? However, if patients who come back need to be hospitalized for complications resulting from transplantation, is it really cheaper for the system in the long run? Would it be legally and ethically defensible for the healthcare system to refuse to pay for the follow-up care of patients who have committed illegal acts abroad? Would this be a means to dissuade patients from going abroad? Is it nonsensical to ask these questions in the context of the Canadian healthcare system? Does the notion of reimbursing anything related to transplant tourism not negate the philosophy underlying the healthcare system? These questions are all highly relevant to this topical debate. In 2005, a decision handed down by the Supreme Court of Canada authorized the use of private health insurance in instances when the public system is unable to deliver care in a reasonable time frame (the *Chaoulli* decision).[35] With this decision, the Supreme Court sent a very strong message to provincial governments to rapidly strengthen their healthcare systems and improve their management of waiting lists and times. Despite the fact that the Supreme Court decision applies only in Québec, on 17 August 2005, the Canadian Medical Association adopted a resolution supporting it.[36] Could this decision have an impact on the transplant situation? For now, the response of the Québec government outlines three specific measures:

1. Guaranteed waiting periods for certain elective cases (tertiary cardiology and radio oncology, as well as hip, knee, and cataract surgery) should be expanded as resources become available and regulated;
2. Development of "affiliated specialized clinics," run by private partners, to complement public service offerings, and from which public establishments may purchase certain services already provided in the public system, without cost to patients; and
3. Allowing citizens to purchase private insurance for hip, knee, and cataract surgeries.[37]

If transplantation were to be added to the list of these procedures, however, the availability of the resource would remain problematic. It might then be considered acceptable for the healthcare system to pay for patients to purchase a kidney overseas when the waiting period for receiving a transplant exceeds a certain limit. Considering the social, economic, and political repercussions of these issues, it is beyond the scope of the CEC to find answers. The CEC believes these issues should be publicly debated and addressed at the governmental and legislative levels.

ETHICAL DELIBERATIONS

After looking closely at the facts and data related to organ selling and trafficking, the CEC considered the values, professional ethics, and ethical principles involved.

Values. In any ethical deliberation, the values at stake need to be analyzed. Moreover, facts and values are often closely interlinked. Emotions should also be considered, because they influence judgments and perceptions of moral dilemmas, and are part of doctors' and patients' narratives. Moral action is rarely absolutely rational and principle-based; emotions, common sense, and intuition are also involved.[38] In the following paragraphs, the values of patients and doctors will be examined; however, further studies are needed on such narratives around the issue of transplant tourism.

Patients waiting for a transplant. Waiting times for renal transplants for ESRD patients are growing. Some patients die while waiting (6 percent in the U.S. and 2 percent in Québec).[39] Dialysis is associated with much suffering. Some patients are so exhausted from dialysis that they are driven to seek other alternatives, such as buying a kidney. Some patients told the transplant team that buying a kidney abroad is a "win-win" situation: they will be free from the constraints of dialysis and they believe the transaction will help someone who is poor. The transplant team felt that most of the patients were not adequately informed of the legal status of the transaction, the conditions of the purchase, the associated medical risks, and the potential consequences for themselves and the sellers. If patients who plan to buy a kidney

abroad are not properly informed of the risks and the consequences of their action, can they really be held accountable?

Transplant physicians. During the meetings with the CEC, some members of the CHUM transplant team expressed distaste for organ buying, and saw it as an exploitation of poor and vulnerable people who thought they would benefit from selling their kidney — a situation that team members did not want to encourage. Since trust is a cornerstone of the doctor-patient relationship, some doctors felt deceived by those patients who did not tell them about their plans to buy a kidney. Some of them also felt betrayed when a patient went ahead with the purchase, despite their advice to the contrary. Nevertheless, members of the transplant team said they would not want to act as whistle-blowers. On the other hand, transplant physicians understood the suffering and exasperation of some of their patients on dialysis. Perhaps if they were in the same position, they would look into all the options, including buying an organ. However, the transplant team also knows that transplantation is not a panacea, and that it should be done in proper conditions with full knowledge of the associated risks.

Professional ethics. When physicians in Québec are faced with any type of ethical dilemma, one of the first documents they should consult is the Québec Code of Ethics of Physicians.[40] The Code of Ethics of Physicians was adopted by the Collège des médecins du Québec and the Québec legislature. The Collège des médecins du Québec is the medical professional corporation constituted by the Medical Act.[41] This act states, "All the physicians qualified to practise the medical profession in Québec constitute a professional order called the 'Collège des médecins du Québec' . . . ."[42] According to the act, the corporation and its members shall be governed by the Professional Code, which is the provincial regulation authorizing professional corporations to adopt a code of ethics and to oversee its application.[43] The mission of the Collège des médecins du Québec is to promote quality medicine and to protect lay persons, as well as supervise the practice of medicine by its members. It is also in charge of granting the exclusive right to practice medicine, ensuring that its members are suitably trained and qualified.[44]

The regulations of the Code of Ethics of Physicians are legally binding, unlike the American Medical Association Code of Medical Ethics, for instance, which is an ethical guide, rather than a law. The Québec Code of Ethics of Physicians is subject to periodic review to ensure that it reflects social, cultural, and political changes in Québec society. A physician may not exempt him- or herself (even indirectly) from a duty or obligation contained in the Code of Ethics. However, the code might not be as helpful in regulating the doctor-patient relationship when the patient is on a waiting list for a transplant. In the Québec context, it appears that the actual therapeutic contract or agreement between a transplant physician and a patient begins only after the transplant has been performed. Before the procedure, the transplant medical team assesses the patient and decides whether or not she or he is a suitable candidate. There seems to be a tacit agreement between the medical team and the patient on the waiting list as to their respective obligations; for example, the transplant team commits to the agreement for as long as the patient remains a suitable candidate for transplantation. Therefore, the transplant doctor is not the treating doctor while the patient is on the waiting list; the treating doctor is the nephrologist in the referral center.

The code allows for conscientious objection on the part of a physician, but it does not present clear guidelines as to how or when this right may be exercised. In fact, if a doctor is feeling uncomfortable, based on moral or ethical grounds, to provide some form of treatment or procedure to the patient, she or he is allowed, under certain circumstances, to end the relationship and refer the patient to another physician. For example, a Roman Catholic physician who wants to refuse to perform an abortion has the professional and legal obligation to refer the patient and help her find another physician. In the meantime, the physician must assume re-

sponsibility for the patient until a new physician is found. Such conscientious objection must not be related to the nature of the patient's illness or to his or her standards of behavior. A physician may not, for instance, refuse to examine or treat a patient based on criteria that would be considered discriminatory such as race, sexual orientation, or political views. Physicians must also inform patients of their personal views and advise the latter of the consequences of not receiving professional care, when such care may be appropriate. In cases of emergency, however, physicians must provide assistance and care, regardless of their personal views.[45] If conscientious objection involves declining a treatment that the patient is entitled to receive — based on the physician's moral, ethical, or religious beliefs[46] — one might question whether a refusal to follow up on patients who purchased an organ abroad actually constitutes such a case. Is a patient entitled to receive elective follow-up care, considering that the commodification of bodies is illegal in Canada? The question is debatable.

That being said, one must realize the difficult situation that transplant doctors may find themselves in: on the one hand, they have the individual right to refuse to treat a patient based on their belief that buying an organ overseas is immoral, provided they inform the patient and help him or her to find another physician; on the other hand, they are obliged to treat in emergency situations — even though the patient may have made a deliberate choice to purchase an organ, with full knowledge of the risks involved. One may wonder, too, about the definition of "emergency": is this an acute rejection, an infection, or other life-threatening disease, such as a stroke or myocardial infarction? At what point does a health condition cease to be an emergency? What, if anything, becomes of a doctor's duties toward a patient from then on? Referring solely to the Québec Code of Ethics of Physicians remains an unsatisfactory method to resolve these quandaries and effectively support a doctor's natural response: to provide care and assistance to people who are suffering. *This response is a key imperative of the medical profession.*

As mentioned previously, doctors cannot discriminate against a patient, for example, by refusing to treat a murderer. Is refusing to treat a patient who bought an organ abroad discrimination of the same moral order as refusing to treat a murderer? This question was raised during discussions between the transplant team and the CEC. Of course, the situations are comparable, because the patient has done something illegal. However, in the case of the murderer, the doctor is not involved in the illegal act, whereas in the case of the organ buyer, the follow-up care of the transplant physician is directly related to the illegal act. Thus, by providing care to a patient who has purchased an organ, the transplant team may be perceived as supporting organ trafficking and encouraging disadvantaged individuals to undergo a nontherapeutic intervention.[47] Also, ensuring the donor's safety and welfare is a golden rule in procuring organs from living donors,[48] but when the procurement is performed illegally or without any information or guarantees concerning the donor's condition, care, and safety before and after the procedure, it becomes a concern for the transplant community.

Thus, even though professional regulations offer some guidance, there are still many unanswered questions. For example, if the transplant team disagrees with the buying of organs overseas and informs all the patients on its waiting list, would it be legally and ethically acceptable to refuse to monitor the patient afterwards? Do the nephrologists in the referral centers have a role to play in preventing the purchase of organs overseas? Moreover, since there are not a lot of doctors who are involved in the field of renal transplantation, what happens if all of the doctors refuse to deliver follow-up care? As discussed previously, although these questions require answers, they would be more appropriately addressed through public debate.

Ethical principles. *Injustice and exploitation.* In the context of the physician-patient relationship, some nephrologists might feel un-

comfortable with a patient suspected of buying an organ in the Third World, on the basis of the argument of injustice and exploitation of vendors. However, since it is difficult to prove such a suspicion, doctors do not want to play a policing role.

As discussed before, organ trading is considered exploitative in Canadian society[49] and organ trading is often criticized by Western intellectuals on these grounds. Some argue that permitting the sale of organs could help donors by giving them the money necessary to escape exploitation.[50] They also argue that we live in societies that allow economic disparities, so there is no breach of the principle of justice.[51] On the other hand, those opposed to the trafficking and marketing of organs also state that available research does not demonstrate that selling an organ leads to less exploitation (Indian and Iranian studies).[52]

The CEC feels that exploitation is a solid argument for prohibiting selling and trafficking. However, it is essential to better identify the values at stake and to propose a framework that goes beyond the exploitation argument, since this argument cannot serve as the sole basis for a doctor to refuse to treat a patient.

Commodification of the human body. Reification of the human body means viewing the body as a material resource in economic and market terms.[53] Selling and purchasing organs leads to reification of the human body by making human beings fungible and turning them into collections of spare parts.[54] This idea is criticized, mostly by American intellectuals who promote autonomy over all other ethical principles. For them, prohibiting the selling of organs undermines human dignity because it prevents the expression of autonomy. Since it is legal in some countries to sell either blood or ova, why would a kidney be any different?[55] One must then consider the invasiveness, risks, and consequences of a phlebotomy versus a nephrectomy.

The commodification of organs goes against the philosophy and principles of social solidarity underlying the Québec and Canadian healthcare systems, as demonstrated by the legal prohibition of the direct sale of gametes.[56] In addition, organ transplantation in Canada and Québec is based on altruism, not market values; it would thus not be surprising for nephrologists to condemn the purchase of organs and to refuse to be "party" to this act, as the human body should not be for sale.

Some have proposed conditions for an "ethical market" of organs.[57] It is beyond the scope of this article to address this issue, which should be the subject of public and governmental debate.

CEC RECOMMENDATIONS

FOR THE DOCTOR-PATIENT RELATIONSHIP

As the situation has been presented to the CEC, there are two problems to address:

1. The patient who is suspected of purchasing a kidney and undergoing transplantation abroad; and
2. The patient who is planning to do so.

The following recommendations must be understood in their social and cultural context, keeping in mind common understandings of the attributes of a "good" doctor, which include humaneness, diligence, consciousness, empathy, and professionalism. For the first problem, the CEC stated that it could be ethically acceptable for the doctors in CHUM's transplantation team who felt most uncomfortable with those patients to refuse to monitor them in elective clinics if they could confirm that another physician who specializes in renal transplantation would do so. However, in emergency situations, doctors cannot discriminate against patients and must provide care in accordance with the Québec Code of Ethics of Physicians.

For patients who are planning to buy an organ overseas and who inform a transplantation team of their intention, there are still many questions that need to be answered. Nonetheless, the CEC recommends that doctors inform their patients of their personal views on the matter, as well as the legal and medical consequences, for both themselves and the sellers, of buying organs. For the CEC, providing such information

is one of the roles of the "good" doctor. It is also a way of ensuring the minimal requirements of informed consent, and could ultimately be a way to dissuade patients from going overseas to buy a kidney. Also, information on the purchase of organs abroad and the position of the transplant team on the issue must be communicated to all ESRD patients waiting for a transplant, thus helping them to make an informed decision.

Furthermore, doctors cannot refuse to treat these patients in emergency situations or in elective clinics, unless another doctor agrees to provide follow-up care, again in accordance with the Québec Code of Ethics of Physicians. Finally, the CEC should help doctors and transplant teams clarify their values and positions on the subject by giving them tools for the analysis of ethical issues.

FOR THE HOSPITAL AND THE TRANSPLANTATION COMMUNITY

For the CEC, it appears of the utmost importance that everyone involved in transplantation promote organ donation. An increase in organ donation will reduce the gap between supply and demand for organs, and the option of purchasing an organ abroad will not seem so attractive. Moreover, it is important that clinicians do not present renal transplantation as a miracle or a panacea to their patients. If patients are well informed of the risks and benefits (not only the benefits) of transplantation, they might not seek alternatives such as buying a kidney overseas.

The CEC also believes that organizations such as Québec Transplant, the Canadian Society of Transplantation, and other professional medical associations should lead the organ traffic debate, particularly regarding the consequences for Canadians who participate in it.

For the CEC, organ sale remains ethically unacceptable in the current context. Some clinicians disagree with this position. They condemn organ trafficking, but are open to an institutionalized organ market as a way to address the shortage. It is beyond the scope of this article to discuss the issue of an ethical organ market.

Finally, as noted previously, many issues raised by transplant tourism are beyond the purview of the CEC, as they require a public debate, with governmental and legislative involvement. The CEC obviously encourages all initiatives in this direction.

CONCLUSION

In conclusion, the question posed by the clinicians to the CEC — "What should we, as nephrologists, hospital staff, and the transplant community, do with Canadian patients who buy a kidney overseas?" — is extremely complex. All angles of this question need to be considered: legal, social, cultural, political, and ethical. However, for the CEC, the way this illicit organ market currently operates is unethical in the Canadian and Québec contexts.

Having offered these recommendations, there are still many questions that need to be answered. The CEC, for one, still needs a better understanding of the values of the doctors, medical teams, and patients waiting for a transplant with regard to organ trafficking and transplant tourism, as well as their perceptions of the role they play in the situation. As we have seen previously, the CEC position on an organ market seems to differ from that of some clinicians. To better explore the position of clinicians on the issue of organ traffic and an organ market, the CEC or the hospital could encourage research projects aimed at gathering clinicians' narratives.

The CEC also recommends informing ESRD patients about organ trafficking. However, who should provide this information? What kind of information should be given? Is there a risk that such information might encourage patients to buy a kidney? Should the information target some cultural groups, considering the Toronto experience, which indicates that patients who bought organs overseas have a variety of cultural backgrounds? Furthermore, what should the role of CHUM be in this issue? For the CEC,

these questions open up very interesting avenues for future research.

Finally, considering the nature of our public health system, and the way that resources are allocated and patients are referred for transplantation in Québec, the legal aspects remain to be detailed as to the different levels of responsibility, depending on whether a doctor is the "treating nephrologist" or the "transplant nephrologist." This might bring us to question the level of independence that physicians really have when they are confronted with the dilemma of treating patients who are involved in illegal acts. Also, the recent *Chaoulli* decision may affect the organization of the system and access to transplantation.

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In Vitro *Fertilization*

As Sure As Eggs? Responses to an Ethical Question Posed by Abramov, Elchalal, and Schenker

Deborah Sarah Ferber

INTRODUCTION

In September 1999 a group of Israeli *in vitro* fertilization (IVF) researchers (Yoram Abramov, MD, Uriel Elchalal, MD, and Joseph G. Schenker, MD) published a debate article in the journal *Human Reproduction* questioning the ethics of using high doses of ovulation stimulation drugs for fertility treatment.[1] The article, "Severe OHSS: An 'Epidemic' of Severe OHSS: A Price We Have To Pay?" considered the widespread aim of obtaining high numbers of eggs in assisted reproductive technology (ART) treatment regimes in relation to the commercial goal of fertility clinics to establish a reputation for high rates of success. The authors proposed that these institutional and commercial goals might expose patients to an increased risk of the severe form of the most common iatrogenic complication of fertility treatments, ovarian hyperstimulation syndrome (OHSS). Using statistics on the side-effects of fertility drugs, the authors provided a new collection of long-term data from Israeli clinics to support their claims. The article suggested that rates of OHSS could be understood by reference to the increased use of high-yield drug regimens and the widening use of ART. In aligning the ethics of decisions made at the clinical level with a broader question about the aims of ART practitioners, they challenged their colleagues to reappraise the legitimacy of the current high levels of drug stimulation. In essence, the authors were posing a cultural question in a clinical context.

This kind of reflective approach is unusual in ART literature,[2] and the present study proposes that an analysis of the responses to the article by Abramov and colleagues provides an opportunity to examine the ethical culture in which ART is practiced. Since the article by Abramov and colleagues was unusual in arguing for a cultural shift, it seems timely, after around seven years, to follow up its reception in the literature. How was it received? Did it convince colleagues? I will propose that, by analyzing the responses — or indeed the ab-

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sence of responses — to this article, it may be possible to trace, at least partially, an "ethical profile" of current ART practice. Beyond this, I will address a more general cultural question: What happens when, from the midst of a professional group, someone challenges some of the cherished assumptions of that group?

Bioethical writing about ART has tended to ignore the persistent reporting of dangerous complications from the routine use of fertility drugs, and ethical debate is, with some exceptions,[3] largely preoccupied with issues of rights: of egg donors and embryos, for example.[4] These debates tend to rehearse vexed ethical questions, often with public policy in mind, but by and large they do not address the clinical realities of ART. I will therefore seek, as a third aim, to contribute to a broader understanding of what constitutes a bioethical inquiry.

This is not a philosophical study: I am a cultural historian, and this article is primarily a qualitative analysis. Lest the impression be given that saying something is "qualitative" is simply a way of justifying bias, I should make clear that this research arises from a concern for the welfare of women suffering OHSS during fertility treatment. There is a vast sub-literature on OHSS within reproductive technology reporting, most of which has historically concerned the refinement of clinical protocols that aim to either diminish or forestall the syndrome. However, it is rarely suggested that one way to diminish the incidence of OHSS would be to practice restraint in the administration of fertility drugs. Yet this is what Abramov, Elchalal, and Schenker did. Such an argument naturally runs hard up against the view that patient autonomy is the gold standard for judging clinical ethical practice, and that doctors who worry about the effects of their drugs might be seen in this light as being paternalistic. However, unless the practice of medicine is to be regarded as no different from that of technicians in auto repair, I suggest that there is, and should be, room for doctors' concerns about patients' safety to be set alongside nostrums about autonomy that simplify a complex clinical and ethical scenario.

APPROACH AND METHODS

I will begin by describing the findings and ethical claims of Abramov, Elchalal, and Schenker. Then I will describe how many published studies in subsequent IVF research did not cite their article, and how many did, through April 2006. I will consider the basis for citing the article: whether it was to endorse the authors' views directly, challenge them, or for another reason. Further, I will suggest that, in all the articles examined, the language and argumentation, as well as some of the clinical scenarios described, provide an insight into clinicians' and researchers' ways of thinking about OHSS. Because I did not know what to expect when I began this inquiry, I have built my categories of analysis around the material as I found it. Inevitably this approach has been informed by the priorities that I brought to the study; I argue nonetheless that anyone making an analysis on the basis of ethical concerns about women's health might come up with similar results. To that extent, the nature of the inquiry makes the exercise repeatable.

BACKGROUND: OHSS

Most fertility treatments use drugs to stimulate a female client's ovaries to make them produce more than the usual single monthly egg. In IVF, egg and sperm are combined in the laboratory to form an embryo or embryos. Women who will be inseminated *in utero* are also generally given fertility drugs to increase the number of mature ova in their bodies prior to insemination. All fertility drug protocols involve a degree of hyperstimulation of the ovaries.[5] While most of the drugs that are administered as part of medical treatment are intended to return the body to normal and stable functioning, fertility drugs are an intentional intervention designed to induce an abnormal response. However, the relative difficulty of precisely controlling ovarian response to fertility drugs, combined with a widespread view that maximizing the number of ova per treatment cycle is the most desirable outcome of a treatment, has led

to the regular occurrence of ovarian hyperstimulation syndrome (OHSS). Minimizing cost has also been identified as a factor.[6] The "underlying [physiological] mechanism" for OHSS is "capillary hyperpermeability mediated by ovarian-derived vasoactive substances."[7] In leading the body to create perhaps 10, 20, or even 50 times the mature egg follicles it usually does,[8] fertility drugs introduce a hormonal imbalance that can result in morbidity and the risk of mortality. A predisposition among certain IVF clients to conditions such as polycystic ovary syndrome has made it possible to identify some clients who are at a higher than normal risk; however, there is no single indication for OHSS other than the drugs themselves.

Three categories of OHSS have been determined by clinicians: mild, moderate, and severe. Estimates vary widely as to the incidence of OHSS in all its forms, but it has been stated that up to 10 percent of all cycles result in some form of OHSS.[9] Severe forms (0.2 to 1.0 percent) often require hospitalization to avert potentially lethal effects, and many patients with moderate cases of OHSS are also hospitalized.[10] Fauser and colleagues reported in 1999 that at least 5,000 women per year worldwide suffered serious OHSS.[11]

The biological changes that characterize severe OHSS have been described as "profound systemic vascular dysfunction, with increased vascular permeability, loss of fluid into the third space and intravascular dehydration."[12] This can produce "massive ovarian enlargement, ascites, pleural effusion, oliguria, haemoconcentration and thromboembolic phenomena."[13] In lay terms, OHSS appears to arise as a result of the overstimulation by exogenous (externally administered) hormones of those endogenous (naturally occurring) ovarian hormones that affect the ways in which fluids circulate in the body. The ovaries swell and blood vessels and other means of containment of fluid become permeable; fluids seep into inappropriate passages, and necessary fluids fail to follow their normal paths, which can lead, for example, to an incapacity to urinate, blood clots (including stroke), fluid in the abdomen or lungs, or liver or kidney failure. Depending on the intensity of the toxic effect, patients experience symptoms including abdominal distension, pain, nausea, vomiting, diarrhea, and inability to breathe.[14]

A notable rise in the incidence of OHSS has occurred since the mid-1980s in the wake of the introduction of complex drug protocols, involving the suppression of the normal ovulatory cycle and re-stimulation of the ovaries. Deployment of a series of drugs, usually by daily injection over a period of weeks, has tended to supersede the use of drugs such as clomiphene citrate, the "fertility drug" of the 1960s and 1970s. The more common procedure, increasingly favored in IVF since the mid-to-late 1980s, is to introduce so-called GnRH analogs, which act to suppress the normal pituitary stimulation of the ovaries and hence suppress natural ovulation. This "false menopause," sometimes preceded by administration of contraceptives, requires the subsequent use of drugs such as human menopausal gonadotrophin (hMG): a blend of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), or FSH alone, to induce the production of multiple egg follicles. Once eggs approach maturity, clients are generally administered with human chorionic gonadotrophin (hCG) to stimulate the final maturation and the release of eggs from their follicles.[15] The use of this protocol makes control of a woman's ovulation easier, making it less likely that a treatment cycle would need to be cancelled. The rise in OHSS appears to be a consequence of increased numbers of egg follicles developing following the use of high doses of hMG/FSH, and thence an increase in the number of mature follicles that respond to the added stimulation of hCG.

There is no dispute in the literature that OHSS is iatrogenic.[16] Debate revolves, however, around whether a large number of eggs should be the main criterion for clinical success, or whether lower numbers of eggs might provide an equal likelihood of successful pregnancy.[17] A further tension seems to lie in the choice by many clinics to obtain a large number of eggs that can be frozen as embryos and retained for

later use by a client if the initial round of treatment fails.[18] While certain categories of clients are at greater risk of OHSS, reduced doses of hMG/FSH and hCG can nonetheless contribute decisively to reduced rates of the condition across the board.[19] The problem lies in the tension between competing clinical goals.

THE CASE MADE BY ABRAMOV, ELCHALAL, AND SCHENKER: CLINICAL FINDINGS AND ETHICAL CLAIMS

Abramov, Elchalal, and Schenker examined the period 1987 to 1996 in 16 out of 19 tertiary care facilities in Israel, and considered the medical records of all patients hospitalized for severe OHSS. They found that 78 percent of the patients "were undergoing IVF, while the rest received conventional ovulation induction treatments."[20] The remaining 22 percent appeared to include cycles of egg donation, not only induction of non-IVF ovulation; 94 percent of those with severe OHSS who received IVF had undergone pituitary suppression followed by exogenous gonadotrophins. In total, 2,902 patients were hospitalized for moderate OHSS and 209 for severe OHSS. In other words, of 73,492 cycles of IVF performed in the survey period, around one in 25 resulted in the client's hospitalization for OHSS in some form, and 2.8 per 1,000 clients, or slightly more than one in 500, led to hospitalization for severe OHSS. The authors do not mention the possibility that severe cases may have been treated without admission to a hospital, but this would have been an unusual scenario, given that more than 10 times the number of severe cases were admitted to a hospital for only moderate OHSS.

For the period in question, the authors noted a six-fold increase in the use of IVF to treat infertility alongside a 20-fold increase in the incidence of severe OHSS. They related this increased likelihood of a client contracting severe OHSS to "a more liberal use of ovulation induction medications."[21] In turn, they identified "the over-utilization of high-dose gonadotrophin protocols" with increasing competition between fertility clinics, and argued that "oocyte and embryo numbers [were] considered as main (*sic*) criteria for . . . success."[22] They identified this development with the increased use of cryopreservation and possibly with expanded egg donation programs, in which numbers are an intrinsic aspect of "success," largely separable from the pregnancy outcome of the clients. (That is to say, a "successful" round of egg donation might result in 20 or more pregnancies, none of them necessarily in the donor.) They concluded by setting out their ethical challenge: "we should ask ourselves how far we are willing to go in treating infertility, and where we should draw the line so that life is not endangered."[23] The authors rejected as questionable two often-cited prophylactic interventions, intravenous albumin and "coasting" or withholding administration of gonadotrophins, and urged "revision of the eligibility criteria for extracorporeal fertilization treatments as well as serious reconsideration of the currently used ovulation induction regimens."[24] This last proposal regarding eligibility criteria appeared to refer to IVF clients who were most physiologically vulnerable to OHSS, or perhaps to egg donors who constituted a growing client class — or to both.

The authors' emphasis was on the possibility of restraint in the administration of drugs and on limiting the number of clients. They deliberately asserted a direct connection between clinical practice and commercial priorities, to challenge the ethical thinking of their colleagues. I determined what I see as the article's distinctive ethical thrust, on the basis of its title, posed as a question to colleagues, and on the explicit challenge to consider the possibility of losing the "competitive edge" by reconsidering who is treated and with what level of pharmaceutical intensity. The article can, in that way, be distinguished from the majority of OHSS-related literature, which, while concerned with patient care, generally assumed that OHSS is a given in routine IVF. That is, most of the literature on OHSS appeared to be produced in the context of discussion of its occurrence, rather than focusing on the instance of its occurrence. The analysis here of responses

to and citations of Abramov, Elchalal, and Schenker takes its cue from the authors' own emphasis. Thus, even the articles that considered patient care, but neither addressed directly the ethical concern raised by the authors, nor appeared to examine the ethics behind the levels of intervention they described, I will treat as having ignored the primary aim of the article by Abramov and colleagues.

CITATIONS AND RESPONSES

An internet search using the Thomson Scientific ISI Web of Knowledge cited reference search on "Abramov, y*"; 1999, on 9 April 2006, yielded 21 references, plus two that were bibliographically defective (one gave an incorrect page reference for the original article[25] and another is referred to as "in press" for *Human Reproduction* 1999, even though this article appeared immediately following Abramov, Elchalal, and Schenker, in the same issue[26]). For the purpose of comparison, it is noteworthy that a U.S. Library of Medicine PubMed search for "ovarian hyperstimulation syndrome" for the period September 1999 to April 2006 yielded 681 references. If Abramov, Elchalal, and Schenker can be regarded as equivalent to the declaration of a state of emergency in the field, the number of articles that are traceable because of their prioritization of OHSS, but that ignored the article, makes this citation rate possibly the most significant finding of the present study. (It should be noted that a 1996 article by IVF coinventor Robert G. Edwards, written with Rogerio Lobo and Phillippe Bouchard,[27] which argued in a similar vein, elicited more than 70 citations, which suggests that an investigation of those responses, similar to the present pilot study, would be of value. In this regard, it is important to note that Edwards and J.C. Emperaire observed with disappointment in 2004[28] that the clinical scene appeared not to have heeded the earlier calls.)

I found that the 23 published responses and citations can be divided into the following four categories.

- Those that explicitly endorsed or reiterated the ethical stance of Abramov, Elchalal, and Schenker (n = 2);
- Those that expressed implicit or partial support (n = 4);
- Those that explicitly contested their claims (n = 2); and
- Those that ignored their specific ethical claims and cited the article for some other reason (n = 15).

Two articles explicitly endorsed or reiterated the claims of Abramov, Elchalal, and Schenker. In these, tone is of some import, as the articles also contained something of the urgency expressed by the Israeli authors. Jan Roest made the most robust statement of support, asserting "It seems time for a change in approach,"[29] specifically advocating that fewer follicles be stimulated. Roest stated, "One can seriously wonder whether the criteria for the application of ART are used strictly enough."[30] Edwards (with Emperaire) continued his campaign for more "friendly" drug regimes, arguing in this case that it is "Time to revolutionize the triggering of ovulation."[31] This article cites Abramov, Elchalal, and Schenker, although not directly in the context of its argument.

Partial support was expressed by Michael A. Graf and Robert Fischer, who wrote, "We read with interest the article on severe ovarian hyperstimulation syndrome (OHSS) and fully agree with the authors that overuse of high dose gonadotrophin stimulation protocols . . . has led to a rise in moderate and severe OHSS."[32] They nonetheless advocate the use of a clinical response, the value of which is questioned by Abramov, Elchalal, and Schenker. George B. Inge, Peter R. Brinsden, and Kay T. Elder gave implicit support, questioning the value of high-yield egg recruitment, while Mohamed Aboulghar and Ragaa Mansour endorsed the value of low-dose protocols, and Meike L. Uhler and colleagues urged "preventative strategies . . . to avoid . . . OHSS."[33]

Two articles explicitly refuted the claims of Abramov, Elchalal, and Schenker at the level of

interpretation of data and regarding the validity of the argument they raised.[34] (See below for further discussion.) The remaining articles ignored the ethical challenge posed by Abramov, Elchalal, and Schenker, expressing concern about the effects of OHSS on female patients but mostly arguing for active clinical responses to the present situation.[35] This type of article appears to be the most typical representative of the existing OHSS literature. To the extent that these citations did not embrace the argument for restraint, they might be seen as missing the authors' intended point.

LANGUAGE AND ARGUMENTATION

Examining the language and argumentation of scientific literature is not a particularly original undertaking, but it seems worthwhile when considering a contemporary clinical scenario in which healthy patients are endangered by the treatment choices of their doctors. Some of the usages and arguments identified here across these studies are "generic" to ART literature; others relate specifically to the responses to Abramov, Elchalal, and Schenker.

Abramov, Elchalal, and Schenker's subtitle for an article clearly written out of sympathy for the plight of female patients ("A price we have to pay?") may perhaps have been suggested by the journal's editors. Nonetheless, the use of the word "we" conveys a sense of a closed shop or a limited ethical horizon, and is not likely to be directed to the women whose health the article concerns, rather to other members of the medical and scientific professions likely to read the journal. In fact, there is no sense in which the "price" of OHSS is paid by the clinicians. As one of the supportive articles noted, OHSS is "caused by doctors and paid for by patients."[36]

Controlled ovarian hyperstimulation (COH; sometimes referred to as COS, controlled ovarian stimulation) is the clinical term for the use of fertility drugs, but it seems to be a misnomer for the procedure. As the literature indicates, there is a large number of cases in which a decidedly uncontrolled response occurs. (One article, not among those that cited Abramov, Elchalal, and Schenker, explicitly acknowledged this irony and placed the word "controlled" in inverted commas.[37]) The word "syndrome" is a relatively neutral term, which could refer either to a collection of externally created symptoms or to endogenous symptoms, but several of the authors went further in using the language of disease and epidemiology to describe manifestations of OHSS. Annick Delvigne and Serge Rozenberg referred to the "Epidemiology and prevention of ovarian hyperstimulation" and to the "prevention of . . . disease."[38] Trifon Lainas and colleagues referred to "grade 4 disease,"[39] while Zouhair O. Amarin argued that radical surgical intervention was necessitated in extreme OHSS emergencies, given "that recovery was not just part of the natural disease process."[40] While it could be argued that these are simply technical ways of talking about any physiological occurrence as it develops and subsides in a person's body, and should not be seen as significant when understood in lay terms, the use of "disease" rather than the more neutral term "condition," for example, nonetheless may serve to reinforce the idea of OHSS as an external phenomenon, with an origin that is out of the hands of the clinician. Indeed, as a way of describing the effects of the drugs, OHSS "toxicity" or even "poisoning" might be as valid as the term "syndrome."

From another view, while the word "epidemic" was used rhetorically and with some sense of irony in the original article, this characterization was challenged by one of the two articles that actively opposed it. Robert G. Forman argued, "They describe an 'epidemic' of OHSS. An epidemic would be defined as a widespread occurrence, or spread, of a disease. Even if the authors' estimation of a tripling of the number of cases of OHSS over a 10 year period is correct, this could hardly be considered an 'epidemic.' "[41] One team reported "a woman with severe male factor infertility."[42] The use of IVF for male factor infertility (in this case constituting around 40 percent of the clinic's caseload) is a notable development in the indications for an invasive procedure on women, but the use here of the word "severe"

referring to the husband's condition, while describing interventions in relation to the woman, is revealing. It shows how far infertility — a "cultural" illness — is perceived as shared by two people, even as its treatment has major physical dangers for only one.

Of the 23 articles, 13 failed to note that OHSS is caused by doctors.[43] Instead, it was referred to variously as: "an important complication of COH";[44] "one of complications of ovulation stimulation";[45] "a complication of supraphysiologic ovarian stimulation";[46] "the most serious complication of controlled ovarian stimulation";[47] and "one of the common complications in ovarian stimulation with gonadotrophin."[48] In relation to the responses of clients' bodies to their treatments, two articles used terminology that implicitly shifted accountability from the clinician to the client: Andre C.D. van Loenen and colleagues wrote about "poor responders"[49] and Delvigne and Rozenberg referred to "rebel cases" of OHSS.[50]

Perhaps more importantly, the choice of words that were used in the articles to describe the frequency of OHSS indicates a point at which scientific interpretation and questions of language overlap. While the figures used in several of the articles varied quite widely on the global incidence of OHSS (0.2 to 1.0 percent;[51] up to 10 percent;[52] approximately 10 percent[53]) and of severe OHSS (0.2 to 1.0 percent;[54] 0.2 to 2 percent;[55] 0.5 to 5 percent;[56] 0.6 to 14 percent[57]), verbal characterizations of the frequency of OHSS and severe OHSS in some cases appeared to be identified according to an arbitrary or selective use of terms. For example, one referred to OHSS (of any type) as "common" (Osamu Tokuyama and colleagues, citing incorrectly the figure of 0.2 to 1.0 percent[58]) and another referred to severe OHSS as "rare," while citing a rate of up to one in 20.[59]

The two articles that actively opposed the ethical proposition put forth by Abramov, Elchalal, and Schenker appeared to seek, principally, to relativize the adverse effects of ovarian hyperstimulation. Forman stated: "To put the data into perspective, severe OHSS has to be considered as one of the complications of ovulation stimulation and, in particular, of IVF treatment. Other potential life-threatening complications occur with similar frequency."[60] The author then cited the high rates of ectopic pregnancy and multiple pregnancy associated with IVF. The argumentative force of this is blunted, I suggest, by the admission that IVF, a treatment identified as dangerous by Abramov, Elchalal, and Schenker, is only made to seem more so when its other major risk factors are described. Forman continued: "Very few medical interventions are risk-free and severe OHSS will remain a complication of IVF cycles despite all attempts at prevention."[61] This ignored the clinical difference between IVF and most other medical interventions, which aim, generally, to remedy a physical problem, rather than solve an emotional one through physical means. R.S. Mathur and Julian M. Jenkins similarly committed what might be called a category error when they suggested that the absence of deaths in Abramov, Elchalal, and Schenker's figures for OHSS could have been interpreted favorably in the light of statistics for maternal mortality that were not specifically related to fertility treatments.[62] It ignored that maternal mortality is not — or, not by definition — caused by doctors.

Pursuing the view of the figures cited by Abramov, Elchalal, and Schenker as a positive, rather than a problem, Forman notes the lower number of severe cases of OHSS in their study compared to the global figures they cited, and claimed, "I would regard their data as being reassuring rather than a cause for concern."[63] This reassurance appears to be essentially the expression of a preference about how to interpret the same statistics about clients' suffering. For Mathur and Jenkins, this approach led to two conclusions: the first represented patients' consent as the benchmark by which medical ethics are judged. "Patients need to be counselled about the risk of developing OHSS and its consequences, but in the end must be free to make an informed decision regarding the most effective treatment for their problems."[64] One might be led to ask: under what circumstances would patient consent *not* be the baseline for argument in defense of a treatment? Abramov, Elchalal,

and Schenker posed the question of the ethical burden on clinicians, not only on clients, and in this way suggested that informed consent should not be regarded as the overriding standard for deciding on the treatment to be undertaken. My argument is that informed consent, understood in this way, is highly problematic in that it puts a possibly unfair onus on the client as the person responsible, when the clinician is doing something that his or her colleagues have suggested is unethical. To imagine that the point-of-consent is the only ethical moment of substance in ART is to deny, among other things, the need for and the significance of clinicians' own prior deliberations. The second conclusion of Mathur and Jenkins was a simple assertion of interpretative preference. Emphasizing the non-physiological aspects of IVF and the question of funding, they stated: "Certainly the risk of OHSS must not be used as an argument to deny funds or restrict access to assisted conception programmes which have the potential to alleviate the misery of childlessness."[65]

FURTHER OBSERVATIONS

Several of the articles described clinical scenarios and recent developments in the treatment of OHSS that raised very serious questions about the directions of ART and suggested that there is a real loss of perspective about the meaning of patient care in ART. The "pre-emptive" electrode cauterization or laser vaporization of healthy ovaries has been performed in numerous instances to permanently destroy follicles in clients' ovaries that contributed to the production of the hormonal response symptomatic of OHSS. Discussed by several of the articles,[66] this so-called "surgical pre-treatment"[67] was presented as being among the current choices that were available to reduce the incidence of OHSS. Indeed, one article bewilderingly used the opportunity provided by Abramov, Elchalal, and Schenker to promote electrocautery as a response of choice.[68] Surgically inflicting irreversible damage on women's bodies in the name of preventing the natural response to a dose of drugs surely poses an ethical problem, which points back to the original question posed by Abramov, Elchalal, and Schenker: "How far should we go?" Surely the answer has to be "Not that far."

In two emergency cases that led to similar irreversible results, a clinician removed (or caused to be removed) a substantial section of the ovaries of two women who suffered from severe OHSS.[69] The author, Amarin, admitted that the decision to remove a segment of the clients' ovaries (30 percent from each ovary in each woman) might have been interpreted as an aggressive treatment, but justified it on the basis of its lifesaving nature. In a narrow sense, this is, of course, true. But such horrendous scenarios seem to call for a greater degree of soul-searching for more responsible initial treatments, as proposed by Abramov, Elchalal, and Schenker. Another article, by Uhler and colleagues, described the near-fatal experience of a woman who was hospitalized for 47 days with critical OHSS and spent a further 30 days in rehabilitation clinics following emergency treatment for a perforated duodenal ulcer.[70] The article was inconclusive about the relative causal weight that should have been attached to the OHSS itself, and to the subsequent risky surgical interventions used in response to it. The scenarios described in both articles made clear that, in all three cases, the women concerned came near to death, the ovaries of each swelled to the size of a softball, and approximately 2.5 to 5 liters of excess fluid were drained from their peritoneum. Each report mentioned the patients' stress (in the context of determining clinical scenarios): Amarin reported that a patient's "severe anxiety associated with invasive monitoring and multiple medical therapies in the intensive care unit" was a factor in the decision to proceed to laparotomy and bilateral partial oophorectomy,[71] and Uhler and colleagues reported that the "profound stress associated with the combination of critical OHSS and subsequent required complex care as well as the diagnosis of *H. Pylori* [a bacterial condition that can cause stomach ulcers] were likely the causative factors of her perforated duodenal ulcer."[72]

(However, "stress" in the second example may have been intended to mean the purely physical effect of the treatments.)

The existence of the vast literature of OHSS heightens awareness of the largely experimental nature of much IVF treatment. One of the articles described a prospective trial of three different stimulation regimes that had been carried out on 38 IVF patients, which gave no indication that the patients were advised that they were part of a trial, nor that they gave consent for this, nor did the authors refer to ethical clearance on the part of their institution.[73] That article was nonetheless in the minority in admitting the experimental nature of the clinical choices. (One further article thanked its participants.[74]) Most did not describe what the clinics were doing as experimental. While it could be argued that the analysis of clinical case notes in the interests of patients' welfare did not constitute experimentation, as such, the existence of a vast body of medical research literature, and the likelihood that such publishing is smiled upon at the institutions at which the authors were employed, together with the apparent competition between new approaches as they were carried out at the clinical level, makes a *de facto* "evidence-based" case for the largely experimental nature of much of this clinical culture. In effect, the literature of OHSS documents the explosion of a patient-funded research culture.

Moreover, it has been noted by a group of concerned practitioners that the fact that IVF is carried out largely in the private sector — "an environment not usually focused on well-conducted clinical trials" — along with the influence of the pharmaceutical industry and the relative lack of direct research funding, leads to "the early implementation of poorly validated strategies."[75] Two articles studied here refer to the possible under-reporting of cases of OHSS, which suggests something of the limits of self-regulation.[76] This situation also goes some way to explaining why research choices appear to have generally not included studies on the long-term effects of OHSS, including its psychological effects, nor indeed studies of the long-term effects of the drugs on those women who did not contract OHSS.[77] (Such a narrow focus is not unique to the ART industry: a 2004 article in *New Scientist* on the subject of the risks of IVF made no mention of the potential risk of ovarian hyperstimulation syndrome to mother or child.[78] Adhering to the traditional notion that the central issue in any discussion of reproductive technology is the sought-for child, the article lazily discusses only one survey of the health outcomes of children born through IVF and ICSI — intra-cytoplasmic sperm injection — rather than taking the five minutes required to do a PubMed or web search on a subject such as "*in vitro* fertilization risks.")

These research questions are, therefore, also fundamentally ethical questions. If there is no demonstrable will among clinicians to pursue these concerns, and if their priorities continue to be to promote the success rates of their own clinics, where will the impetus come from to answer questions about the long term? Divisions between clinicians and endocrinologists appear to exist,[79] and it seems that those practitioners who have been drawing attention to the risks of the drugs are the senior members of the profession, including Robert G. Edwards, René Frydman, and Joseph G. Schenker.[80] This "senatorial" initiative suggests both something of the anxiety created by ever-new drug regimes and the widening indications for IVF, and may be a crucial factor in bringing about change in a largely self-regulating industry.

DISCUSSION

The article by Abramov, Elchalal, and Schenker should be lauded as a valuable example of medical introspection. It is a modest but sincere attempt to flag to the community of ART researchers that there is an ethical question at stake, implicitly *even when* women are agreeing to undergo these procedures. If the question was: *What happens when, from the midst of a professional group, someone challenges some of the cherished assumptions of the group?* The answer might appear to be: *Not a great deal.* But it's important to note that, in this

small exercise of ethical profiling, there are many signs of genuine debate and genuine critique. The critics in the profession are substantially in the minority, but they are present, when even 10 years ago, scarcely a sound was made, while the statistics presently available were mounting up in the clinical context.

I think it is possible to use this survey to provide a preliminary "snapshot" or cross-section of the research culture in which the clinical realities of OHSS arise. It is possible, at least, to suggest that such a seemingly low impact for an article that presents statistics about iatrogenic harm speaks either of a greater preoccupation with producing research literature than reading it, or of an alarming level of indifference, a "tin ear" to ethical pleas coming even from within the sector. The small number of articles that responded directly to Abramov, Elchalal, and Schenker, in the terms in which it posed its question, similarly speaks of a high level of selective reading. The impression that a lay reader gains is of a large medical culture that is extremely productive in terms of clinical intervention, yet apparently unwilling to confront the realities of the harm these interventions are causing. How can this situation come about? I have argued here that selective reading of the clinical literature, and secondarily, the ways in which language and argumentation are used, can help to maintain a degree of cultural insularity, something that can, in turn, contribute to what has been referred to elsewhere as "culturally induced moral ignorance."[81]

In many ways, the article by Abramov, Elchalal, and Schenker might be compared to that written by Henry K. Beecher in 1966,[82] as an attempt both to challenge and, to some extent, to "blow the whistle" on colleagues. Several of Beecher's examples similarly came from clinical reports, rather than from prospective, designed research trials. While figures such as Beecher are rightly celebrated, it is easy to forget that exposés only become exposés after a long process of examination, and that the passage to reform is seldom instantaneous, and certainly cannot be assumed to be going to occur. For the purposes of bioethics teaching among trainee health professionals, this is an important lesson. When history is represented as a *fait accompli,* it is very difficult to escape from the conviction that what happened was always going to happen. Yet in the present instance, none of the researchers whose writing has been addressed here appears to have been tempted to go, for example, to the mainstream media, nor indeed to any governing body that may exist in their country to say, "we need regulation." Whistle-blowing does not always or automatically entail major institutional change.

Generally ART regulation and the ethical debate that accompanies it have been so dominated by debate about the status of the embryo — again, a political and politicized question — that the clinical realities and severe risks of ART tend to be ignored. The article by Abramov, Elchalal, and Schenker is a relatively rare example in which the risks of OHSS are aligned directly with the ethical questions that surround IVF. Such alignment was attempted in some government investigations[83] and was briefly mentioned in a policy-oriented monograph on egg donation.[84] Most feminist responses to ART have tended to overlook the basic clinical features of ART, preferring to address ethical questions about the apportioning of rights and the question of female giving.[85] The exception to this are the early contributions made by so-called radical feminists, who drew attention to problems with IVF drugs in the 1980s and early 1990s.[86] It is a great irony that the dominant theme in the reproductive technology culture — that all men and women, as "health consumers," have a right to access whatever means may be necessary to have a child to call biologically their own — should almost totally obliterate informed discussion about the physical/psychological health status of women whose reproductive rights are ostensibly so paramount.

A final reflection: if the problem of OHSS persists, that is, if the production of high egg yields is still almost universally considered ethical, it may only be a matter of time before maturation of eggs *in vitro,* a possibility researched since the 1980s, but still relatively rare,[87] will be heralded as the solution to the problem. The

seriousness of OHSS will finally be acknowledged, once the technological means to avoid it has been found. Should this occur, it must not be forgotten that ART clients — as many as 100,000 of whom will have suffered from excessive stimulation — are likely to have donated many of the eggs and much of the ovarian tissue used in the research to make this procedure feasible.[88]

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The author has no competing interests that are relevant to this article. This is a literature survey that required no ethical clearance.

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NOTES

1. Y. Abramov, U. Elchalal, and J.G. Schenker, "Severe OHSS: An 'Epidemic' Of Severe OHSS: A Price We Have To Pay?" *Human Reproduction* 14, no. 9 (1999): 2181-3. The present article addresses mainly the question of eggs used for primary IVF treatment and for IVF using donor eggs. The donation of eggs for laboratory research, such as the production of embryonic stem cells, naturally raises questions relevant to the ethical issues discussed by Abramov, Elchalal, and Schenker, but would require a much lengthier discussion than is possible here.

2. R.G. Edwards, R. Lobo, and P. Bouchard, "Time to Revolutionize Ovarian Stimulation," *Human Reproduction* 11, no. 5 (1996): 917-9; R.G. Edwards, R. Lobo, and P. Bouchard, "Why Delay the Obvious Need for Milder Forms of Ovarian Stimulation?" *Human Reproduction* 12, no. 2 (1997): 399-401; J.C. Emperaire and R.G. Edwards, "Time to Revolutionize the Triggering of Ovulation," *Reproductive BioMedicine Online* 9, no. 5 (2004): 480-3; F. Olivennes and R. Frydman, "Friendly IVF: The Way of the Future?" *Human Reproduction* 13, no. 5 (1998): 1121-4; B.C. Fauser et al., "Minimal Ovarian Stimulation for IVF: Appraisal of Potential Benefits and Drawbacks," *Human Reproduction* 14, no. 11 (1999): 2681-6.

3. Royal Commission on New Reproductive Technologies (Canada), *Proceed With Care: Final Report of the Royal Commission on New Reproductive Technologies,* 2 vols. (Ottawa: Minister of Government Services, 1993), 1:391-424, 527-34; Task Force on Life and the Law, *Assisted Reproductive Technologies: Analysis and Recommendations for Public Policy* (New York: New York State Task Force on Life and the Law, 1998), 42-57.

4. See C.B. Cohen, ed., *New Ways of Making Babies: The Case of Egg Donation,* commissioned by the National Advisory Board on Ethics in Reproduction (Bloomington, Ind.: Indiana University Press, 1996), especially the chapter by Rosemary Tong, "Toward a Feminist Perspective on Gamete Donation and Reception Policies," pp. 138-155; K. Rothenberg, "Feminism, Law and Bioethics," *Kennedy Institute of Ethics Journal* 6, no. 1 (1996): 69-84.

5. M.A. Aboulghar and R.T. Mansour, "Ovarian Hyperstimulation Syndrome: Classifications and Critical Analysis of Preventive Measures," *Human Reproduction Update* 9, no. 3 (2003): 275-89, p. 275.

6. Emperaire and Edwards, "Time to Revolutionize the Triggering of Ovulation," see note 2 above.

7. See note 1 above, p. 2181.

8. Edwards, Lobo, and Bouchard, "Time to Revolutionize Ovarian Stimulation," see note 2 above, p. 917.

9. P.E. Egbase, "Severe OHSS: How Many Cases are Preventable?" *Human Reproduction* 15, no. 1 (2000): 8-10, p. 8.

10. See note 1 above; see note 9 above, p. 8.

11. Fauser et al., see note 2 above, p. 2681.

12. R.S. Mathur and J.M. Jenkins, "Is Ovarian Hyperstimulation Syndrome Associated with a Poor Obstetric Outcome?" *British Journal of Obstetrics and Gynaecology* 107, no. 8 (2000), 943-6, p. 943.

13. See note 5 above, p. 275.

14. See note 1 above, p. 2181; A. Delvigne and S. Rozenberg, "Epidemiology and Prevention of Ovarian Hyperstimulation Syndrome (OHSS): A Review," *Human Reproduction Update* 8, no. 6 (2002): 559-77, p. 559.

15. Task Force on Life and the Law, see note 3 above, pp. 47-9.

16. Delvigne and Rozenberg, see note 14 above, p. 559.

17. G.B. Inge, P.R. Brinsden, and K.T. Elder, "Oocyte Number Per Live Birth in IVF: Were Steptoe and Edwards Less Wasteful?" *Human Reproduction* 20, no. 3 (2005): 588-92.

18. Edwards, Lobo, and Bouchard, "Time to Revolutionize Ovarian Stimulation," see note 2 above, p. 917; see note 1 above, p. 2182.

19. See note 5 above, p. 285.

20. See note 1 above, p. 2181.

21. Ibid.

22. Ibid., 2182.

23. Ibid.

24. Ibid.

25. T. Lainas et al., "Administration of Methylprednisolone to Prevent Severe Ovarian Hyperstimulation Syndrome in Patients Undergoing In Vitro Fertilization," *Fertility and Sterility* 78, no. 3 (2002): 529-33.

26. R.S. Mathur and J.M. Jenkins, "Patients Should be Allowed to Weigh the Morbidity of OHSS Against the Benefits of Parenthood," *Human Reproduction* 14, no. 9 (1999): 2183-5. I thank Heather Wolffram for detecting this discrepancy.

27. Edwards, Lobo, and Bouchard, "Time to Revolutionize Ovarian Stimulation," see note 2 above.

28. Emperaire and Edwards, "Time to Revolutionize the Triggering Ovulation," see note 2 above.

29. J. Roest, "Severe OHSS: An 'Epidemic' Caused by Doctors," *Human Reproduction* 14, no. 9 (1999): 2183.

30. Ibid.

31. Emperaire and Edwards, "Time to Revolutionize the Triggering of Ovulation," see note 2 above.

32. M.A. Graf and R. Fischer, "Severe OHSS: An 'Epidemic' of Severe OHSS: A Price We Have to Pay?" *Human Reproduction* 14, no. 12 (1999), p. 2930.

33. See note 17 above; see note 5 above, p. 285; M.L. Uhler et al., "Perforated Duodenal Ulcer Associated with Ovarian Hyperstimulation Syndrome," *Human Reproduction* 16, no. 1 (2001): 174-6, p. 175.

34. See note 26 above; R.G. Forman, "Severe OHSS: An Acceptable Price?" *Human Reproduction* 14, no. 11 (1999): 2687-8.

35. See note 9 above; see note 12 above; A. Delvigne and S. Rozenberg, "Preventive Attitude of Physicians to Avoid OHSS in IVF Patients," *Human Reproduction* 16, no. 12 (2001): 2491-5; M. Filicori and G.E. Cognigni, "Roles and Novel Regimens of Luteinizing Hormone and Follicle-stimulating Hormone in Ovulation Induction," *Journal of Clinical Endocrinology and Metabolism* 86, no. 4 (2001): 1437-41; L. Shanner and J. Nisker, "Bioethics for Clinicians: 26. Assisted Reproductive Technologies," *Canadian Medical Association Journal* 164, no. 11 (2001): 1589-94; O. Tokuyama et al., "Vascular Endothelial Growth Factor Concentrations in Follicular Fluid Obtained from IVF-ET Patients: A Comparison of hMG, Clomiphene Citrate, and Natural Cycle," *Journal of Assisted Reproductive Genetics* 19, no. 1 (2002): 19-23; see note 25 above; Delvigne and Rozenberg, see note 14 above; A. Raziel et al., "Increased Early Pregnancy Loss in IVF Patients with Severe Ovarian Hyperstimulation Syndrome," *Human Reproduction* 17, no. 1 (2002): 107-10; A.C.D. van Loenen et al., "GnRH Agonists, Antagonists, and Assisted Conception," *Seminars in Reproductive Medicine* 20, no. 4 (2002): 349-64; P.Y. Liu and D.J. Handelsman, "The Present and Future

State of Hormonal Treatment for Male Infertility," *Human Reproduction Update* 9, no. 1 (2003): 9-23; Z.O. Amarin, "Bilateral Partial Oophorectomy in the Management of Severe Ovarian Hyperstimulation Syndrome — an Aggressive, but Perhaps Life-saving Procedure," *Human Reproduction* 18, no. 4 (2003): 659-64; E. Aktan et al., "Effects of Coasting on the Outcome of Intracytoplasmic Sperm Injection-Embryo Transfer Cycles," *Australian and New Zealand Journal of Obstetrics and Gynaecology* 44, no. 4 (2004): 298-301; R. Klemetti et al., "Complications of IVF and Ovulation Induction," *Human Reproduction* 20, no. 12 (2005): 3293-300; E. Thyzel et al., "Age Dependent Assessment of TFPI Levels in Follicular Fluid of Women Undergoing IVF," *Clinica Chimica Acta* 361, no. 1-2 (2005): 176-81.

36. See note 29 above, p. 2183.

37. Fauser et al., see note 2 above, p. 2682.

38. Delvigne and Rozenberg, see note 14 above, p. 572.

39. See note 25 above, p. 531.

40. Amarin, see note 35 above, p. 662.

41. Forman, see note 34 above, p. 2687.

42. Raziel et al., see note 35 above, p. 109.

43. See note 12 above; see note 17 above; see note 25 above; Forman, see note 34 above; see note 32 above; Filicori and Cognigni, see note 35 above; Liu and Handelsman, see note 35 above; Shanner and Nisker, see note 35 above; Tokuyama et al., see note 35 above; Uhler et al., see note 33 above; van Loenen et al., see note 35 above; Klemetti et al., see note 35 above; Aktan et al., see note 35 above.

44. Van Loenen et al., see note 35 above, p. 356.

45. Forman, see note 34 above, p. 2687.

46. See note 12 above, p. 943.

47. Uhler et al., see note 33 above, p. 174.

48. Tokuyama et al., see note 35 above, p. 19.

49. Van Loenen et al., see note 35 above, p. 354.

50. Delvigne and Rozenberg, see note 14 above, p. 572.

51. Tokuyama et al., see note 35 above, p. 21.

52. See note 9 above, p. 8.

53. Amarin, see note 35 above, p. 659.

54. See note 1 above, p. 2181.

55. Amarin, see note 35 above. This figure appears to be cited for IVF only.

56. Delvigne and Rozenberg, see note 14 above, p. 559.

57. See note 25 above, p. 529.

58. Tokuyama et al., see note 35 above, p. 19. Their citation refers to Abramov, Elchalal, and Schenker (see note 1 above, p. 2181), which gives this figure for severe OHSS only, not for all forms.

59. Delvigne and Rozenberg, see note 14 above, p. 559.

60. Forman, see note 34 above, p. 2687.

61. Ibid., 2688.

62. See note 26 above, p. 2185.

63. Forman, see note 34 above, p. 2687.

64. See note 26 above, p. 2185.

65. Ibid.

66. See note 5 above; see note 9 above; Delvigne and Rozenberg, see note 14 above; Amarin, see note 35 above, p. 662.

67. Delvigne and Rozenberg, see note 14 above, p. 572.

68. See note 9 above, p. 9.

69. Amarin, see note 35 above.

70. Uhler et al., see note 33 above.

71. Amarin, see note 35 above, p. 661.

72. Uhler et al., see note 33 above, p. 175.

73. Tokuyama et al., see note 35 above, pp. 19-23.

74. See note 25 above, p. 533.

75. Fauser et al., see note 2 above, p. 2685.

76. Forman, see note 34 above, p. 2687; Raziel et al., see note 35 above, p. 109 (citing Forman).

77. See note 26 above, p. 2184.

78. J. Randerson, "IVF Seems Safe But Only Time Will Tell," *New Scientist* 184, no. 2471 (30 October - 5 November 2004): 10-11.

79. Edwards, Lobo, and Bouchard, "Why Delay the Obvious Need?" see note 2 above.

80. Edwards, Lobo, and Bouchard, "Time to Revolutionize Ovarian Stimulation," see note 2 above; Edwards, Lobo, and Bouchard, "Why Delay the Obvious Need?" see note 2 above;

Emperaire and Edwards, "Time to Revolutionize the Triggering of Ovulation," see note 2 above; Olivennes and Frydman, see note 2 above; see note 1 above.

81. U.S. Department of Energy, *Advisory Committee on Human Radiation Experiments: Roadmap to the Project,* chap. 4, *http://www.eh.doe.gov/ohre/roadmap/achre/chap4_2.html,* accessed 12 July 2005.

82. H.K. Beecher, "Ethics and clinical research," in *Bioethics: An Anthology,* ed. H. Kuhse and P. Singer (Malden, Mass.: Blackwell Publishing, 1999), 421-8.

83. See note 3 above.

84. Cohen, see note 4 above, pp. 272-3; cf. A.D. Gurmankin, "Risk Information Provided to Prospective Oocyte Donors in a Preliminary Phone Call," *American Journal of Bioethics* 1, no. 4 (2001): 3-13.

85. Rothenberg, see note 4 above; Tong, see note 4 above.

86. R. Klein, *The Exploitation of a Desire* (Geelong: Women's Studies Summer Institute, distributed by Deakin University Press, 1989); R. Rowland, *Living Laboratories: Women and Reproductive Technologies* (Bloomington, Ind.: Indiana University Press, 1992).

87. See note 32 above; P. Curtis, "Better than sex — IVF clinic claims to beat nature at its own game," *Guardian*, 30 December 2006, *http://www.guardian.co.uk/print/0,,329673062-110418,00.html*, accessed 23 March 2007.

88. Indeed, in December 2006, subsequent to this article's acceptance the previous June, a new society was formed, the International Society of Minimally Assisted Reproduction, with this specific aim in mind. See *http://www.naturalcycle.ord*, accessed 23 March 2007.

Is Subfertility a Medical Condition?

Jeroen D. Kok

We need to consider this question when we address the ethical issues brought to our attention by Ferber. The view on the problem of subfertility varies strongly from one person to another. Where some will judge the inability to achieve pregnancy to be a case of bad luck or even not a problem at all, others will perceive or experience it as a nuisance, a dysfunction of the body, a disability, or maybe even a disease. To the last group, the author's statement that *in vitro* fertilization (IVF) is a physical solution to merely an emotional problem could be offending. Whatever someone's view on subfertility is, it will strongly affect the way and the degree that this individual will appreciate solutions to it, including advantages and disadvantages or risks related to these solutions.

In healthcare systems in the majority of Western Europe, reproductive medicine is not driven by commercial interests or by the desire to make money by creating "babies-on-demand." Therefore, because a physician does not have to weigh the best interests of patients against the need or desire to work more time-efficiently or more cost-efficiently, he or she can carefully select patients and treatments *lege artis.* Thus, the risk of overtreating subfertile couples with unnecessary, early, or overly aggressive IVF treatments should be low. For commercial subfertility institutes, where profitability and unconditional customer satisfaction prevail, this remains to be seen. Against that background and with the rising number of commercial and private fertility clinics worldwide, I share the concern for "overtreatment" implied by Ferber.

The fact remains that patients who are attending subfertility clinics are genuinely suffering from their childlessness.[1] Typically in our clinic, by the time an infertile couple would decide, in concert with their physician, to proceed with IVF, they will have gone through a difficult and lengthy period (often of several years) of extensive testing and less invasive but unsuccessful treatments. Only by then it is, without a question, in their best interest to be offered a safe and efficient, in terms of (cumulative) live birth rate, IVF treatment. To achieve this, at least some degree of ovarian stimulation is required, because having more than one oocyte available creates a level of redundancy

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to compensate for loss encountered at several critical stages in an IVF treatment, such as fertilization.

In this context, research is being done to predict the individual threshold and sensitivity to these stimulatory hormones, potentially allowing the development of individually tailored stimulation regimes.[2] Until this results in usable and reliable knowledge and techniques, standardized stimulation protocols will be used, meaning we will continue to encounter cases in which ovaries turn out to be more strongly stimulated than desired, especially in the first treatment cycle.[3] Regretfully, this brings along the risk of OHSS, a side-effect that is taken very seriously by those who are professionally involved, as judged by both the amount and content of the literature on the background, aetiology, ethics, consequences, prevention, and treatment of OHSS.[4] Nevertheless, there can never be enough awareness of the fact that severe OHSS is potentially lethal.

In the desire to improve the help given to subfertile patients, research focuses on every step of IVF treatment, including ovarian stimulation,[5] with the aim of finding the optimal treatment. Optimal, in this context, implies the painful awareness of our limitations and that every treatment has its side-effects, and that the benefits of a treatment should be weighed carefully against its disadvantages. It also implies that the "optimal treatment" is dynamic in nature. That is to say, the "optimal treatment" is questioned, modified, reevaluated, and updated constantly, based on newly gained insight and knowledge. The article by Abramov and colleagues[6] is valuable because it warned of a potentially rising trend in the incidence of OHSS. Additionally, it presented an attractive opinion based on rather raw statistics, and it concluded with an appeal for reconsideration of ovarian stimulation strategies. This has nothing to do with "blowing the whistle," but it is an example of expression of the typically more implicit self-reflection that is characteristic for medical research. The proof of this, for instance, can be seen in the increasing numbers of articles that discuss or even advocate for mild or minimal stimulation regimes[7] following the period in which maximizing the number of oocytes obtained was considered beneficial. It explains why the appeal by Abramov and colleagues did not evoke the reaction Ferber expected, but this does not mean their message was being ignored.

The above-mentioned trend toward milder stimulation and IVF treatments is not only visible in the literature, but also in the daily practice of our clinic. Rough data from the period 1996 to 2002 indicate that the mean number of oocytes obtained in the first treatment cycle dropped from almost 11 to less than eight. The number of cases in this group with more than 20 oocytes obtained after ovarian stimulation decreased from more than 8 percent to less than 2 percent in this period, and I assume this decreasing trend has continued since.[8] Because we increasingly aim for mild ovarian stimulation (and single embryo transfer), in our clinic, cases with more than 20 oocytes after ovarian stimulation are considered a rarity nowadays.

A physician should, on pure medical and ethical grounds, carefully assess the benefits, drawbacks, and risks when determining whether a patient is eligible for IVF. The patient should be well informed about all these considerations. When the risks are acceptable to both the professional and the patient, there are no ethical objections to proceed with a carefully performed IVF treatment, if that is the best possible treatment for the patient's involuntary childlessness.

NOTES

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2. B. Imani et al., "Prediction of the Individual Follicle-Stimulating Hormone Threshold for Gonadotropin Induction of Ovulation in Normogonadotropic Anovulatory Infertility: An Approach to Increase Safety and Efficiency," *Fertility and Sterility* 77, no. 1 (January 2002): 83-90.

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Some Reflections on IVF, Emotions, and Patient Autonomy

Deborah Sarah Ferber

Finding precise analogies between new and traditional medical interventions is always a judgment call.[1] *In vitro* fertilization (IVF), it could be argued, appears to occupy a category of its own, because it is, on the one hand, a life-quality enhancing treatment that enables some otherwise potentially childless women to bear children, but one that routinely presents a risk by multiplying ova (making it different from other life-quality enhancing treatments, such as reconstructive surgery) and that, on the other hand, poses this risk while not treating a life-threatening condition.[2] I wish to address this question in the context of clarifying some points raised in the commentaries of Jeroen Kok and Edmund Howe regarding my analysis of the responses to the article by Abramov and colleagues.[3]

I was brought up short by Professor Kok's sentence about my comments possibly offending IVF patients, something I did not intend and very much wish to avoid. While he says (not quite accurately) that I refer to infertility as "merely" emotional, his comment did make me think of those patients rendered infertile because of some physical problem, such as pelvic scarring through sexually transmitted diseases or surgery, prior removal of ovaries or other reproductive organs because of cancer, or other causes. From that point of view, Professor Kok is quite right to pull me up.

By referring to infertility as a problem in the "emotional" sphere, I intended to distinguish infertility from a physical condition, even though it is often caused by one. That infertility is not life-threatening in no way diminishes its significance for the person or persons involved, but it could be argued that it imposes different questions for the caregiver, who has the responsibility of using potentially lethal drugs to address the condition. (If clients were able to obtain all the relevant clinical materials on the internet, some greater ethical onus would arguably revert to the drug companies.) I was trying therefore to draw attention to the potential for a shift in the ethical calculus on the basis of the particular nature of the intervention. The distinction I sought to make is that there might be grounds for a differential ethical reading of ovarian hyperstimulation syndrome

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(OHSS) because of the distinctive nature of IVF and particularly because, according to Abramov and colleagues, there seems to be room for downward adjustment in drug regimes without loss of overall benefit to clients. In this light, Professor Kok also provides heartening preliminary figures on more conservative stimulation regimes.

In relation to Dr. Howe's comments in "Taking Patients' Values Seriously," which appears at the beginning of this issue of *The Journal of Clinical Ethics,* I should also make clear that I use the term "emotional" not as a euphemism for any form of mental difficulty, such as depression, rather in reference to the emotional dimension of life, which relates to the fulfillment of hopes for oneself and one's relationships. I would never imagine a pathology in someone seeking to have a child through the available means, nor indeed in grieving if these means do not work. Whether the stresses that can accompany fertility treatment might exacerbate a pre-existing disposition, or, if the treatment does not succeed, herald an intense emotional response, are different questions from the more straightforward one I was posing.

On the question of clinical analogies, it is important to examine the points at which the continuum might break down between assessment of the risks posed by a treatment for a physical illness (such as insertion of a coronary bypass), a treatment in response to one's own infertility, or, indeed, at one further remove, the supply of donor eggs to treat someone else's infertility, or again, the donation of eggs for experimentation. For some, there is no line to draw and the ethical questions would remain the same at every point along that scale: this would be the standard argument from autonomy. For others, there might be a different set of issues to be addressed at each point. Where the line is drawn is fundamentally a cultural choice: Abramov and colleagues, for example, make specific reference to the cultural pressure of commercial goals as potentially posing a risk in the clinical context. Yes, they do propose a "paternalistic" response to this situation,[4] but, at the other end of the spectrum, where they identify patients at risk, lies the so-called "informative" model, that is, the view that informed consent alone shapes all the relevant ethical questions, a view that arguably might imply the abdication of a degree of clinical responsibility.[5]

There is a risk that merely asserting the priority of autonomy can also function to shut down debate. But if autonomy is to be the guiding principle, it would seem to place greater, not less, onus on the forums of medical and public debate, to open out the terms of reference for ethical discussion of the risks of IVF. In order to make informed consent truly informed, it might also put greater onus on caregivers to pursue more systematically longitudinal analysis of the physiological effects of IVF treatment.

In the end, however, the client's wishes must remain the gold standard, and in this I am ignoring, at least for present purposes, those contributions to debate that problematize the meaning of autonomy for different women in different cultural contexts.[6] Indeed, in my article, I hoped to withdraw altogether from discussing the question of motivations for seeking IVF, as my immediate subject was the clinical culture partially represented in medical journals.[7] For convenience, I sought to consider this culture in relation to the idea of a stable and unproblematic autonomy principle, which, if it is to stand, might reasonably be accompanied by redoubled efforts to chart the ethical landscape in ways that recognize that different types of clinical interventions can raise new questions within the caregiver culture.

I hope to have indicated here, then, that I would wish neither to trivialize nor to pathologize the emotional lives of those people who are seeking or undergoing, or who have undergone, IVF treatment.

NOTES

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Clinical Care

Ethical Considerations in Clinical Care of the "VIP"

Thomas Schenkenberg, Neil K. Kochenour, and Jeffrey R. Botkin

The illnesses and injuries of celebrities are daily fare in the public media and most experienced clinicians can recount personal encounters with celebrity "VIP" patients. While obvious ethical violations with regard to confidentiality may occur simply as a result of the temptation to impress others, more complex, unrecognized ethical challenges can arise due to conflicts between legitimate, but competing, values and goals. The majority of these ethical issues arise when the clinician's standard approach is significantly altered as a result of the VIP's social status rather than being determined by the clinical features of the presenting situation.

"VIP," an acronym that typically translates to "very important person," would be more usefully understood, in the clinical context, as "very *influential* person." The word "important" indicates valid and inherent significance, consequence, or value. Whether a given celebrity is "important" depends on whether the requirements of the definition of "important" are met. The word "influential" indicates that an effect has been exerted on others. In the clinical context, the effect would be a significant change in the clinical approach.

A working definition of a "medical VIP" is suggested as follows.

- Any individual whose personal (non-clinical) characteristics significantly change the clinical approach of the clinician, or
- Any individual whose clinical or personal characteristics are such that the clinician's personal interests or the interests of others produce a significant alteration in the patient's care. We add this second element to account for the special care provided to patients with conditions that are of personal interest to a particular clinician or when treating a patient in a preferential manner could produce a beneficial effect for others.

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This definition is very broad and, indeed, any given patient might have an idiosyncratic characteristic that could unduly influence a given clinician. It is the potential ubiquity of these influences that points to the need for reflection and analysis.

Although alterations in the standard of care for a celebrity VIP would typically be intended to result in superior care, a medical VIP's nonclinical characteristics (for example, expressed racism) could affect the clinician's approach in a negative way and could incline a given clinician to provide a lesser standard of care than is customary. Of course, some alterations in the standard of care that are intended to be beneficial, may, in fact, not be beneficial.

THE CUSTOMARY STANDARD OF CARE AND EXAMPLES OF ALTERATIONS IN THE STANDARD OF CARE FOR VIPS

The experienced clinician's standard approach for providing optimal clinical care has been developed on the basis of hard-won training and experience. Of course, practitioners commonly adjust their standard protocol because of special clinical considerations. Many social and regulatory forces also influence care, for example, the Health Insurance Portability and Accountability Act (HIPAA), the Emergency Medical Treatment and Active Labor Act (EMTALA), institutional policy, the requirements of third-party payers, accreditation guidelines, and quality assurance concerns. The focus here is on changes made in care that are based on the patient's VIP status.

Clinicians and institutional administrators commonly make "accommodations" with regard to meals, special rooms, and conveniences for celebrity patients and benefactors.[1] Accommodations for celebrity VIPs may also include matters that are directly related to clinical care, such as the seniority of attending staff, special support personnel, scheduling of diagnostic studies, scheduling surgery, and avoiding students' participation in providing care.

Changes in the standard protocol might also occur as a result of interaction between clinical issues and the personal interests of the clinician, or the interests of others. For example, a clinician with a personal interest in a certain disease might make special arrangements (outside a research protocol) for a patient with the condition.

To the uninitiated, including the celebrity VIP, it may appear that there are only advantages associated with being a VIP patient. However, certain important disadvantages can also accrue. The history or physical exam may be less thorough than for the typical patient.[2] The VIP may receive excessive or fewer diagnostic studies. The VIP may be undertreated or overtreated in a manner that varies from the customary.[3] The usual confidentiality rules might be held in abeyance. Self-indulgent demands by the VIP may lead to physician-assisted substance abuse because the clinician does not or cannot effectively counter the demands.

The VIP's pursuit of multiple opinions or the "ultimate expert" can complicate care. The Ayatollah Khomeini was said to have been attended by 40 Iranian physicians. In 1979 the exiled, self-proclaimed Shahanshah of Iran received medical care from eight medical teams from six countries. At the time of Francisco Franco's death, one attending physician observed that there were so many physicians in the hospital room that there was scarcely room for the patient.[4] The VIP's pursuit of the highest ranking or most well-known clinician may not result in identifying the most qualified clinician. The intervention of a high ranking clinician in caring for the VIP, when the high ranking clinician is not regularly involved in the type of technical care required, has been called the "chief syndrome."[5] This type of upward transfer of clinical authority within a hospital hierarchy might be encouraged by high-level administrative personnel who may attempt to influence frontline clinicians with requests for preferential care for a VIP.[6]

Case reports describing the care of "famous patients" demonstrate that medical and surgical care has been delayed due to social and political considerations. Public statements, as well as information given to the VIP patient, have

been postponed and deceptive. For example, Evita Perón was described as the "victim of the VIP syndrome" in the misdiagnosis of her cervical cancer and the failure to inform her of her diagnosis.[7] In 1985, amidst significant political turmoil, delayed surgical interventions (eventually seven in number) for diverticulitis by "rival teams of surgeons" for Brazilian President-Elect Tancredo Neves led to the conclusion that "he died of high status."[8] It has been argued that the demands of high political office compromise the quality of medical care and that being a political VIP can be dangerous "not only for the health of the leader but also for the well-being of the nation," as in the case of delayed hospitalization for President Dwight David Eisenhower, after his left anterior wall myocardial infarction in 1955.[9] The anticipated, potential negative effect on the public of news of certain types of illnesses in political figures has resulted in the observation that there is a medical-political paradox: "to get the best medical treatment can be politically fatal, to subordinate medical considerations to political considerations can be medically fatal."[10]

While associates of the celebrity VIP may rush to gain access to special medical/surgical care for the celebrity, psychiatric problems may be ignored or denied in their earlier stages or even deceptively referred to as "exhaustion."[11] This, in turn, may lead to delayed or inferior quality mental health care for celebrities, followed by frantic efforts to secure exceptional care when psychiatric symptoms become too severe to ignore.[12]

The literature also points to special categories of VIPs such as "the doctor as patient," which produce significant alterations in the quality of care.[13] One anecdotal report describes a prominent physician who reportedly taped a note to his chest prior to an operation at his own hospital saying that he wanted to be treated just like anybody else.[14]

ETHICAL CONSIDERATIONS

Achieving excellent treatment for one's patient, advancing knowledge, improving medical training, increasing financial support for an institution, engendering a positive public image for an institution, enhancing societal well-being, and advancing ones's personal career are all accepted, legitimate goals. Ethical conflicts arise in the care of the medical VIP when those goals compete with each other or compete with other positive goals such as maintaining a proper standard of care for all patients, proceeding with care on the basis of truly informed consent, honoring the principle of distributive justice, avoiding conflicts of interest, and, of course, maintaining patients' confidentiality. We will discuss two milieus, the emergency department and psychiatric settings, in which ethical issues related to the care of the VIP have been debated in the literature. We will then review general ethical considerations related to the VIP, to other patients, to the clinician, and, finally, with regard to institutional and societal impact.

EMERGENCY DEPARTMENT

Many authors have found preferential care for VIPs in the emergency department to be unacceptable because the nature of the care may be based on social status rather than clinical need, and would thus fail "the test of fairness."[15] Such special care in the emergency department may harm other patients due to longer waiting times and increased discomfort and risk as they wait. If a celebrity VIP or healthcare administrator receives special care in the emergency department, she or he will not appreciate the average patient's experiences. This inherent dishonesty "robs other emergency department users of the benefits that might occur were VIPs subjected to visits more like theirs."[16] In the long run, the system fails to benefit from the feedback that might come from those who are in the best position to effect change.[17]

Conversely, it has been argued that care of the celebrity VIP in an emergency room setting *should* include special accommodations due to the special needs of the VIP and to maintain the standard of care for other patients. Suggested accommodations include having a senior physician take control of the situation when the VIP

is seriously ill, calling in additional staff, admitting a VIP to in-patient care when an ordinary patient would not be admitted, and possibly diverting regular patients to other facilities.[18]

Most authors conclude that, with regard to care in the emergency department, the best care is routine care. The care received by Ronald Reagan following a 30 March 1981 assassination attempt and the care received by Pope John Paul II following a 14 May 1981 assassination attempt have been described as very similar to the care that would have been provided in the respective emergency rooms of George Washington University Hospital and Gemelli Hospital for any person with a gunshot wound; the care they received has been described as a model of how VIP care should be conducted in the emergency department.[19]

PSYCHIATRIC SETTINGS

Applying the principle that "the best care is routine care" may not be possible or advisable when the VIP's care is provided in other settings.[20] For example, an in-patient psychiatric hospitalization involves a longer length of stay, more complex interactions with numerous staff, more group activities, and represents different challenges from those found in the emergency department.[21]

The presence of a VIP in an in-patient psychiatric unit can have considerable, negative effect on the staff, other patients, and the therapeutic milieu. As a result, other patients and the VIP himself or herself may not receive optimal treatment because of alterations in the fundamental nature of the milieu, patient-to-patient relationships, and staff-to-patient relationships. Celebrity VIPs in a psychiatric setting or in longer term medical settings may suffer an even greater loss of self-esteem and loss of control than the typical patient, and the resulting dependency, loss of influence, and passivity may be especially troublesome to them.[22] Treatment of unusually influential patients, including physicians, in a psychiatric hospital has led to another use of the term "VIP syndrome," that is, a pattern that involves increased pressure on the treating staff (sometimes created by the desires/expectations of the staff themselves rather than by the patient), isolation of the patient, increased demands by the patient, and "very likely eventual therapeutic failure," with suicides and premature discharge against medical advice.[23] The in-patient psychiatric treatment of Ernest Hemingway when he was ill with a paranoid alcoholic depression at the age of 62 was described as overly personal and as treating Hemingway as "the very famous author" rather than as "the very ill patient."[24] Such overly personal interaction between the staff and the patient may have inadvertently contributed to Hemingway's eventual suicide four days after discharge from a second hospitalization.[25] The "special" care of Secretary of State James F. Forrestal's severe psychiatric disorder (depression, paranoia, and suicide threats) involved less aggressive treatment and less supervision than was typical in that era and may have contributed to Forrestal's suicide by jumping from a VIP tower suite on the sixteenth floor of the Bethesda Naval Hospital in 1949, a room that was not equipped to house suicidal patients.[26]

EFFECTS ON THE VIP

Clearly, when "special" care for the medical VIP results in worse care (intended or unintended) for the VIP, the stated purpose of care has been compromised. Such a possible outcome of "special" care is rarely openly recognized and perhaps never discussed with the patient. The nature of a true "informed consent" discussion with a VIP in this regard, that is, outlining the possible risks of "special" care, would be difficult; although, in principle, such a patient should be apprised of the increased risks associated with care that deviates from the norm.

In attempting to achieve a proper standard of care for the VIP, it is clear that, at times, the needs of the VIP actually exceed the needs of the typical patient, and the clinical process should be adjusted accordingly. For example, caring for a VIP raises special considerations with regard to confidentiality.[27] Ideally, the VIP has the same right to confidentiality as other patients. When the VIP patient is a serial killer

or an impaired head of state, the responsibilities of the clinician with regard to confidentiality become very complex.[28] Deception has often been employed in actions and statements concerning the healthcare and health status of VIPs, especially heads of state.[29] Remarkable attempts have been made by unauthorized individuals to acquire medical records, lab results, blood samples, and even slides of fecal matter related to famous and infamous patients, and significant inducements have been offered to staff to take photographs of VIP patients or their remains.[30] Accomplishing a proper level of confidentiality for the VIP requires additional vigilance, effort, and planning on the part of individual staff members and institutions.

While there may be potentially negative issues related to public discussion of a VIP's care, with the VIP's permission, publicity about his or her illness may instead produce positive results. Many celebrity VIPs choose to disclose personal medical information. A great deal of attention has been focused on the disease entities associated with Lance Armstrong, Kitty Dukakis, Michael J. Fox, and Betty Ford. This attention led to increased research and institutional funding, early diagnosis for other patients, improved education for individual patients, better public understanding, and greater compassion for those suffering from the condition.

EFFECTS ON OTHER PATIENTS

Beyond the interests of the VIP, the care of the "ordinary" patient can be affected when the clinician alters his or her pattern of care for a VIP. If the VIP is allowed to "jump the queue" for an appointment or other services, other patients will be displaced and their care might be delayed or restricted, and they will not be informed that their care has been adversely affected in favor of the VIP's care.

EFFECTS ON THE CLINICIAN

Clinicians may be sorely tempted to discuss what they know about the status of a VIP under their care. Indeed, when the issue of VIP care is raised, it is common for clinicians to volunteer stories about VIPs they have seen in the past. In the extreme, this behavior has been referred to as the "star-struck phenomenon," with clinicians so influenced by their own acquired, secondary celebrity status that they have broken confidentiality, apparently for reasons related to their own need for increased status.[31]

Special treatment or the expectations of special treatment from any source for a VIP may also affect staff morale. Staff may resent being asked to participate in the exceptions granted to VIPs because such "special" treatment stands in contrast to their value of "equal treatment for everyone." While some staff may seek inappropriately close association with a VIP, others often describe a VIP in unflattering terms, speak of the burden involved in caring for a VIP, and express relief when a VIP's care is completed.[32]

The care of high ranking political figures carries a wide variety of potential conflicts and risks for the clinician, ranging from demands for inappropriate care, demands for deception, potential loss of prestige for failing to participate (thus "losing" the high status patient), conflicting lines of authority for decisions, and even death, as in the case of Bernhard von Gudden, Ludwig II's psychiatrist, who drowned with his patient under mysterious circumstances in 1886.[33]

INSTITUTIONAL/SOCIETAL IMPACT

The impact of the VIP's requests or needs on the care of other patients often depends on the ability of an institution to manage the administrative complexities created by having a VIP in the facility. For smaller institutions, treating a celebrity VIP is a unique experience. Such institutions may have no formalized plan for handling a celebrity VIP and thus must develop an approach specific to the unique situation that they find themselves in.[34] Using our definition of a medical VIP, however, the presence of a VIP is not particularly uncommon, and, thus, it might be suggested that all institutions, large and small, should be prepared for the ethical challenges of the medical VIP.

The expense involved in accommodating a VIP's additional needs with regard to confidentiality and security represents additional chal-

lenges in terms of organizational ethics. Hospital personnel need explicit directions about any special confidentiality requirements of the VIP. Some institutions have standardized plans for dealing with the media on issues related to celebrity patients.[35] Such plans are reported to minimize the disruption of the regular function of the facility and minimize disruption to the care of other patients, which could occur in the face of thousands of letters and messages to the celebrity, the presence of numerous credentialed and uncredentialed media personnel, and requirement for heightened security.[36]

Institutions have the option of "overstaffing" to accommodate a VIP's requests. Passing these costs for extra care to the VIP, rather than dispersing them to all patients, is a meritorious approach. Developing policies to guide such practices has the advantage of a transparent discussion of the issues and their effects.

Extra consideration for a VIP may lead to the promotion of worthy social goals. Alternatively, as noted above, it has been argued, although not tested, that patients in general will benefit more if a celebrity VIP patient experiences the type of care available to everyone, thus becoming aware of the need for improvement in the delivery of care, with the informed celebrity being in a better position to work for improved care for all.[37] Philanthropy for medical or academic institutions is often fostered when wealthy individuals or their loved ones receive outstanding care.

Some authors have proposed that there may be rare circumstances in which special clinical care for a VIP could have beneficial clinical effects for a large number of people in general, and thus the special care might be justified.[38] For example, it has been proposed that special treatment for a high ranking political figure during a national crisis or for key medical personnel during an epidemic may be justified on the basis of the secondary impact on the welfare of others.[39] Once one opens this line of reasoning concerning the needs of third parties, however, one must be prepared to deal with a very wide range of possible justifications for altering the care of the patient at hand. For example, should the needs of a single mother of four, whose children would benefit if she received preferential care, be given priority over care of an elderly widower?

CONCLUSIONS AND RECOMMENDATIONS

- Special care for a VIP is improper if it results in worse care for the VIP. The potential for unintentionally causing worse care requires special vigilance on the part of the clinician.
- If a significant alteration in the standard of care for a VIP is contemplated, those changes should be reviewed with the VIP. Informing a VIP that he or she will *not* receive "special" care could be advantageous.
- Special care, provided for non-clinical reasons, for a VIP is morally unacceptable if it results in worse care for other patients.
- Possible future benefit to the community, to other patients, or to the institution for treating a VIP in a special manner must be evaluated in the context of the immediate impact on the care of others whose access to care is determined by medical need and fairness. Accommodating VIPs for the purpose of increasing the likelihood of continued or future financial support for the institution or as a reward for past contributions might be justified, as long as other patients are not harmed by the specific measures involved. Benefactors should not assume that they have "paid in advance" for special care if such care comes at the expense of significantly worse care for another patient.
- The increased needs of VIPs with regard to protecting privacy, security, and confidentiality should be recognized.[40] The costs of these accommodations represent a significant challenge to institutional ethics and policy and should not be passed on to regular patients.
- As a result of their VIP status, celebrity VIPs may actually require clinical care that is different from the standard, as in the case of in-patient psychiatric care. The care of other

patients may need to be adjusted beyond the typical standard of care to offset the impact of the presence of the VIP.
- Family/entourage and media influence must be managed with the rights of the patient being paramount.
- The development of institutional policy or a VIP protocol would result in a healthy discussion of the ethical issues involved in the care of the medical VIP.
- Institutional policy should include "blinding" the decision-making process with regard to clinically irrelevant social variables, for example when prioritizing transplant candidates.[41]
- Consultation with the hospital ethics committee may be beneficial if opposing values and viewpoints are difficult to resolve.

The present discussion relates to values that have emerged in contemporary society in the United States, where the general standard of care is high. There is always a degree of "unevenness" in the application of clinical care across patients, across units, and across institutions; but, within an institution, one would hope that such unevenness is not deliberately based on non-clinical factors if harm comes to the patient as a result.

Finally, while anecdotal accounts of celebrity VIP care appear in the literature, there has been very little objective study of the impact of a medical VIP's status on the care he or she receives, on the care that other patients receive, or on the institution. A number of issues might fruitfully be explored, including the types of medical VIPs that produce significant change in the standard of care, how the standard of care is changed, special issues related to confidentiality, risks to VIPs and to regular patients, and whether factors such as the gender of the VIP influence care and institutional preparations for VIPs.

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Persistent Vegetative State

Ethics Consultants' Recommendations for Life-Prolonging Treatment of Patients in Persistent Vegetative State: A Follow-up Study

Ellen Fox, Frona C. Daskal, and Carol Stocking

In 2003, we conducted a survey to learn how ethics consultants would respond to a set of hypothetical clinical cases involving a patient in a persistent vegetative state (PVS), as a follow-up study to a similar survey that was conducted in 1991.[1] The earlier study concluded that "a widespread ethical consensus has emerged only for the easiest cases."[2] It also concluded that the finding of wide variability in ethics consultants' recommendations "suggests a need to clarify standards for ethics consultation."[3]

In the years that separate the two studies, guidelines regarding the appropriate treatment of patients in PVS have been issued by several professional groups, including a Multi-Society Task Force[4] and the American Academy of Neurology[5] in the U.S., and the British Medical Association[6] and the Royal College of Physicians in the U.K.[7] Meanwhile, efforts to clarify ethics consultation standards have included a national consensus conference in the U.S. that resulted in consensus statements on the goals[8] and desired outcomes[9] of ethics consultation, a report on ethics consultation by the Council on Ethical and Judicial Affairs of the American Medical Association,[10] a monograph by the American Society for Bioethics and Humanities (ASBH) entitled *Core Competencies for Health Care Ethics Consultation,*[11] and national guidance on ethics consultation published by the Veterans Health Administration.[12]

In light of these ongoing efforts, we wanted to assess if and how the findings of a 2003 study would differ from those of the 1991 study. Specifically, we addressed: What would ethics consultants recommend in response to PVS cases? To what degree is there consensus? What fac-

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tors influence recommendations? Do recommendations conform to established guidelines? We especially wanted to see whether our findings would suggest increased agreement about the appropriate treatment of PVS patients and/or appropriate ethics consultation practices.

METHODS

SUBJECTS

The sample for the 1991 study consisted of attendees of the annual meeting of the Society for Bioethics Consultation, held in Toronto, Ontario, Canada, in that year. The Society for Bioethics Consultation no longer exists as a separate body, but has been folded into the larger ASBH. For the 2003 study, we surveyed every fourth registrant of the joint meeting of the ASBH and the Canadian Bioethics Society held in Montreal, Quebec, Canada. Whereas in the earlier study questionnaires were handed out at the meeting, in the current study, subjects were sent questionnaires by mail. In both studies, those who did not initially respond were sent two follow-up mailings.

QUESTIONNAIRE

The 2003 questionnaire was very similar to the 1991 questionnaire; relevant differences will be pointed out in the results section below. As in the 1991 study, the questionnaire presented several variations on the case presented in table 1. Seven variations differed only as to the patient's previously expressed wishes and/or the current wishes of the patient's family; an eighth variation asked, "If you were the patient described above, which of the following do you think the ethics consultant should recommend?"

For each variation, respondents were given five options and asked to choose the option that best described what they would recommend on ethical grounds (see table 1). The questionnaire also sought demographic data, including age, sex, religion, education, and professional background. Subjects were asked about their experiences as ethics consultant and ethics committee member and about whether they had completed an advance directive for themselves.

DATA ANALYSIS

Categorical variables were compared using the *chi*-square test of association. As in the earlier study, the degree to which the respondents agreed on a response to each case scenario was expressed as the proportion of agreeing pairs. The degree of agreement on responses across the first seven scenarios was expressed as an overall *kappa.* In addition to coding the questionnaire responses, we constructed a combined variable to distinguish respondents who indicated that, in their role either as a consultant or as a committee member, they had ever made specific recommendations about limiting a treatment for a particular patient.[13] We duplicated Fox's "intensity of LPT" variable by assigning a numeric value of 1 through 4 to the ordinal responses A through D, and then summing the responses across the seven vignettes. Higher scores represented more choices to continue life-prolonging treatments. Associations with the intensity of LPT score were tested using Spearman's rank correlation coefficients. Written comments and responses to open-ended questions were transcribed and later grouped into categories.

RESULTS

CHARACTERISTICS OF RESPONDENTS

Of the 183 questionnaires that were mailed, 117 questionnaires were returned for a response rate of 64 percent. Table 2 is a comparison of the demographic characteristics of respondents from the 1991 and 2003 studies.

A majority of the respondents who answered the eighth variation question, (109 of 117) reported that they had completed some sort of written advance directive; of the respondents, 45 percent (49/109) had an advance directive that specified their preferences about life-sustaining treatment (a treatment directive); 52 percent had an advance directive that designated a proxy decision maker (a proxy direc-

tive); 42 percent had both; and 45 percent had neither.

With respect to experience as ethics consultants or ethics committee members, 69 percent (75/109) of the respondents had ever been members of ethics committees (former study — fs: 81 percent in the past three years), while 35 percent had ever acted as an independent ethics consultant (fs: 62 percent in the past three years). Of the respondents who were consultants and/or committee members, approximately 61 percent served at university hospitals, 26 percent at private hospitals, and 13 percent at public hospitals. Of those respondents, 52 percent indicated that they had experience making recommendations about treatment limitations in their role as an ethics consultant or committee member (fs: 46 percent as an ethics consultant

TABLE 1 The Case, Variations, and Recommendations Used in the Surveys

The case

Imagine that, as an ethics consultant, you are asked about limiting treatment for a theoretical unconscious patient who, you are certain, has no possible chance of ever regaining consciousness and absolutely no awareness of the outside world. Currently, the patient is receiving fluid and nutrition through artificial means as well as routine nursing care, but does not require any other life-prolonging treatments.

The variations

1. The patient left an advance directive which clearly and convincingly states that the patient **did not want** to be kept alive in the event of a permanently unconscious and unaware state. The family **agrees** with discontinuing all life-prolonging treatments.
2. The patient left an advance directive which clearly and convincingly states that the patient **did not want** to be kept alive in the event of a permanently unconscious and unaware state. The family **disagrees** with discontinuing all life-prolonging treatments.
3. The patient left an advance directive which clearly and convincingly states that the patient **wanted** to be kept alive in the event of a permanently unconscious and unaware state. The family **agrees** with continuing all life-prolonging treatments.
4. The patient left an advance directive which clearly and convincingly states that the patient **wanted** to be kept alive in the event of a permanently unconscious and unaware state. The family **disagrees** with continuing all life-prolonging treatments.
5. The patient left no oral or written advance directive of any kind. The family wants all life-prolonging treatments **discontinued.**
6. The patient left no oral or written advance directive of any kind. The family wants all life-prolonging treatments **continued.**
7. The patient left no oral or written advance directive. There are no known family members or friends.
8. If you were the patient described above, which of the following do you think the ethics consultant should recommend?

The possible recommendations

A. Continue routine nursing care but discontinue all treatments necessary for prolonging life.
B. Continue fluid and nutrition through artificial means as well as routine nursing care, but do not provide any additional treatments necessary for prolonging life.
C. Continue fluid and nutrition through artificial means as well as routine nursing care, and in addition provide only the following treatments should they become necessary for prolonging life (circle as many as may apply): antibiotics, acute care hospitalization, blood transfusions, transfer to intensive care unit, dialysis, minor surgery, major surgery, artificial respiration, cardiopulmonary resuscitation, organ transplantation, other (specify).
D. Provide all possible treatments necessary for prolonging life.
E. Other (specify).

in the last three years). Among those who had served as an independent consultant, 16 percent had never made a recommendation to limit treatment; of those who had served on an ethics committee, 27 percent had not done so.

Respondents who had experience making recommendations about limiting treatment (n = 61) differed from those who had no such experience (n = 56) in that the former were younger (p = .006), more likely to be a doctor or nurse (74 percent versus 40 percent, p = .0004), more likely to have a written treatment directive (62 percent versus 22 percent, p <.0001) or proxy directive (69 percent versus 31 percent, p <.0001), less likely to live in Canada (33 percent versus 59 percent), and less likely to think an ethics consultant should recommend life-sustaining treatment for them if they were in PVS (23 percent versus 48 percent, p = .004).

TABLE 2 Comparison of Demographic Characteristics of Respondents

	1991		**2003**	
Characteristic	*n*	%	***n***	**%**
Sex				
Male	71	61	**46**	**42**
Female	46	39	**63**	**58**
Country of residence				
United States	80	70	**83**	**76**
Canada	34	30	**26**	**24**
Age in years				
≤ 40	33	28	**31**	**28**
41-60	69	58	**57**	**52**
> 60	16	14	**22**	**20**
Religion				
Catholic	30	26	**18**	**25**
Protestant	40	34	**32**	**45**
Jewish	14	12	**13**	**18**
Agnostic/atheist/other	32	28	**8**	**11**
Professional background*				
Physician	45	38	**30**	**27**
Nurse or other clinical	20	17	**25**	**23**
Philosopher/ethicist	48	41	**28**	**25**
Theologian or minister	28	24	**6**	**5**
Administrator/other	32	26	**12**	**11**
Attorney	7	6	**9**	**8**

* Percentages exceed 100 due to overlap.

RECOMMENDATIONS OF RESPONDENTS

Table 3 shows the comparative responses to the eight case vignettes as well as the proportion of agreeing pairs for each vignette.[14] The similarity of responses from the entire samples in the two studies is readily apparent. The overall *kappa* for the first seven vignettes in the 2003 data is 0.21. (The analogous *kappa* for the earlier study was 0.17.) Both are indications of very poor agreement.

Nonetheless, compared with the data from 1991, agreement on recommendations for certain vignettes has increased modestly. Vignette one continues to show a strong consensus as to the appropriate recommendation (defined as proportion of agreeing pairs of >.50). This time, however, the proportion of agreeing pairs exceeded .50 for two additional vignettes (five and seven), with a greater percentage of respondents recommending withdrawal of life-prolonging treatment. Of note, the proportion of agreeing pairs did not increase at all and remains very low for both vignettes in which the patient wanted to be kept alive as long as possible (three and four), as well as for vignette six, in which the patient's wishes were not known and the family wanted to continue all life-prolonging treatment. Agreement was also low for the two vignettes in which there was a conflict between the wishes of the patient and the wishes of the patient's family.

While virtually all of the respondents offered specific treatment recommendations for vignettes one and five, approximately 20 percent of respondents selected option E, "Other (specify)," for at least one of the other vignettes. The most common write-in entries among the 212 associated with option E responses were suggestions to resolve the conflict through discussion (35 percent of entries), to delay the treatment decision (19 percent), to attempt to change the family's views (10 percent), or to seek legal counsel (9 percent). A few write-in comments

(4 percent) suggested that ethics consultants should not make recommendations.

An additional 380 comments were received in response to the request that respondents explain or qualify their comments. These most commonly pertained to the patients' wishes (24 percent), the family's wishes (21 percent), futility (14 percent), cost (12 percent), or the best interests of the patient (10 percent). Less than 1 percent of comments suggested that food and fluid are basic care that should not be stopped.

FACTORS THAT INFLUENCE RESPONSES

Only one characteristic, personal preference for life-prolonging treatment in PVS, was significantly related to the intensity of LPT score (respondents who would want an ethics consultant to recommend more intensive life-prolonging treatment for themselves in PVS were more likely to recommend it for a hypothetical patient in PVS, $p = .01$). The intensity of LPT score was not associated with age, sex, country of residence, religion, or having an advance directive.

While the intensity of LPT score did not differ between respondents who had experience making recommendations to limit treatment and those who had no such experience, the two groups did sometimes differ significantly in their responses to individual vignettes, and the outliers generally fell into the latter group. For example, 100 percent of the respondents who had experience making recommendations to limit treatment selected option A in response to the first vignette, compared with 87 percent of those who had no such experience ($p = .03$).

Although patients' wishes were the most commonly cited factor in responses to the request that respondents explain or qualify their recommendations, overall, the responses did not re-

TABLE 3 Comparison of Responses to the Variations in the Case (1991/**2003**)

Variation #	*N* 1991	***N*** **2003**	Patient's wishes[1]	Family's wishes[2]	A: Routine care only 1991 %	A: Routine care only **2003** **%**	B: Fluid + nutrition 1991 %	B: Fluid + nutrition **2003** **%**	C: Additional treatments 1991 %	C: Additional treatments **2003** **%**	D: Everything possible 1991 %	D: Everything possible **2003** **%**	E: Other (specify) 1991 %	E: Other (specify) **2003** **%**	Proportion of agreeing pairs 1991	Proportion of agreeing pairs **2003**
1	115	**104**	No LPT	No LPT	93	**94**	5	**4**	1	**0**	0	**1**	1	**1**	0.87	**0.89**
2	116	**103**	No LPT	All LPT	3	**4**	38	**28**	36	**36**	6	**18**	16	**14**	0.30	**0.43**
3	114	**103**	All LPT	All LPT	50	**59**	24	**20**	6	**4**	0	**4**	20	**13**	0.34	**0.27**
4	116	**103**	All LPT	No LPT	20	**17**	37	**36**	26	**21**	3	**12**	14	**12**	0.26	**0.24**
5	115	**104**	Unknown	No LPT	68	**79**	20	**10**	3	**1**	0	**2**	9	**2**	0.50	**0.68**
6	112	**103**	Unknown	All LPT	12	**11**	43	**28**	24	**31**	2	**10**	19	**20**	0.29	**0.24**
7	115	**102**	Unknown	Unknown	56	**68**	22	**16**	10	**3**	0	**3**	13	**11**	0.38	**0.51**
8	114	**101**	Personal preference[3]		83	**75**	10	**13**	2	**3**	0	**2**	4	**7**	0.71	**0.59**

NOTES

1. PVS patient's wish for life-prolonging treatment (LPT) as expressed in an advance directive.
2. Wishes of the PVS patient's family regarding LPT for the patient.
3. The LPT the respondent thinks an ethics consultant should recommend if the respondent were in PVS.

flect strict adherence to patients' wishes. Only 59 percent of the respondents consistently recommended withdrawal of life-prolonging treatment in cases involving a PVS patient who did not want such treatment (vignettes one and two). For cases involving a PVS patient whose prior wishes were to be kept alive as long as possible (vignettes three and four), only 10 percent of the respondents consistently recommended providing all necessary life-prolonging treatment. Still, patients' wishes had a major impact on the responses. Comparing pairs of vignettes that varied only with respect to patients' wishes, about 81 percent of the respondents changed their recommendations between vignettes one and four, and 76 percent changed between vignettes two and three.

The strong influence of family's wishes is also apparent. Comparing paired vignettes that varied only with respect to family's wishes, 33 percent of our respondents changed their recommendations between vignettes one and two; 32 percent changed between vignettes three and four, and 65 percent changed between vignettes five and six.

Finally, respondents seemed significantly influenced by resource allocation and/or futility concerns. The vast majority of respondents (82 percent) did not recommend providing the PVS patient with all possible treatments necessary for prolonging life even when both the patient and the family wanted the patient kept alive as long as possible.

LIMITATIONS

The findings of this study are limited in several respects. Although our response rate of 64 percent is respectable for a survey study, our respondents were self-selected in that they were all registrants at the same professional meeting. In addition, not all respondents had acted as ethics consultants either independently or as a member of an ethics committee. Therefore, our results may not be generalizable to all ethics consultants.

As in the earlier study, responses to simplified hypothetical cases may not accurately reflect actual behavior. A more detailed account of the patient's case might have resulted in different choices for some of the respondents. The request for a single "recommendation" after each vignette, along with the forced choice between options, does not reflect the usual process of ethics consultation. Our inclusion of an "other" category among the options, and our request to "explain or qualify" each response, allowed the respondents to voice any reservations they might have had about the framing of the questions; however, few did.

DISCUSSION

This study demonstrates wide variability in what ethics consultants say they would recommend for specific hypothetical cases involving a PVS patient. Compared to the 1991 study, the results are strikingly similar overall. Although in a few cases agreement has increased modestly, consensus is still largely lacking.

To better understand the variability of the responses we observed, we examined several well-known consensus statements and guidelines published in the interval between the two studies, and attempted to determine the extent to which responses in this study were consistent with those guidelines.[15] We found that, for difficult cases such as those described in vignettes two through seven of this study, the guidelines were generally too nonspecific and nonprescriptive to suggest a particular best course of action. For example, the Royal College of Physicians suggests that "decisions not to intervene by cardio-pulmonary resuscitation or to prescribe antibiotics, dialysis and insulin *can* [emphasis added] be taken clinically, in the best interests of the patient, after full discussion with those concerned."[16] Similarly, the Multi-Society Task Force on PVS encourages physicians to "work closely with the family to determine the appropriate level of medical treatment," but stops short of saying what should be done in case of conflict.[17]

We also examined several published guidelines, consensus statements, and standards on ethics consultation to see how they might inform our discussion.[18] Almost all caution ethics consultants against imposing their own per-

sonal moral views on others. For example, Fox and Arnold assert, "Certainly, many normative aspects of clinical practice remain controversial, and it is important not to overestimate the extent of prevailing consensus on ethical issues. For many situations there is a range of ethically acceptable alternatives."[19] In a similar vein, the ASBH *Core Competencies* document explicitly rejects an "authoritarian approach," in which the ethics consultant displaces the appropriate moral decision maker and/or excludes relevant parties from the decision-making process, in favor of an "ethics facilitation approach," which involves "the building of morally acceptable shared commitments or understandings."[20]

Indeed, all of the guidelines stress the centrality of the ethics consultant's role in building consensus. For example, Fletcher and Siegler talk about the goal of ethics consultation to foster "a fair and inclusive decision-making process" and "to facilitate resolution of conflicts in a respectful atmosphere with attention to the interests, rights, and responsibilities of those involved."[21] The American Medical Association report on ethics consultation states categorically, "Where there is a dispute, the consultation role is one of negotiation and resolution."[22] And the Veterans Health Administration's national guidance on ethics consultation suggests that ethics consultants should "facilitate moral deliberation" to help the decision maker or makers determine which option is best among the various options that are ethically justifiable.[23]

Thorough elicitation and discussion of the participants' perspectives — and efforts to facilitate a solution that is acceptable to all — are essential to the ethics consultation process. Because clinical cases are so complex, and because the process of ethics consultation is as important as the outcome, it is generally inappropriate for ethics consultants to make specific clinical recommendations that are based only on a brief summary of a case. The best ethics consultants learn from experience that ethics consultation cases are rarely as straightforward as they may initially seem.

Most of the respondents in this study were willing to respond to a request for a recommendation of an "ethically correct" treatment decision even though only minimal case information was presented. In every vignette, respondents had the option to select "E, Other (specify)," but most selected one of the specific treatment options instead. Relatively few pointed out the need to collect additional information, identify the appropriate decision maker, or engage the healthcare team and the family in moral deliberation.

While it is unreasonable to expect that all ethics consultants' responses to clinical vignettes will be the same, it is reasonable to expect that their responses will reflect widely accepted standards. Such standards suggest that ethics consultation is not primarily about prescribing ethical actions, but facilitating an ethical decision-making process. Future research might attempt to assess the use of a systematic approach that includes key steps, such as confirming the adequacy and accuracy of information, identifying the appropriate decision maker, clarifying the full range of ethically justifiable options, and engaging the participants in discussion.[24]

While consultants' responses to this study may differ from their behavior in actual practice, the current study suggests a continued need to clarify and apply standards for ethics consultation, particularly with regard to the role, nature, and effect of ethics consultants' recommendations; how to identify the appropriate decision maker; and the limits to the decision maker's authority.

DISCLAIMER

The views expressed in this article do not reflect the views of the Department of Veterans Affairs or of the United States government.

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NOTES

1. E. Fox and C. Stocking, "Ethics Consultants' Recommendations for Life-Prolonging Treatment of Patients in a Persistent Vegetative State," *Journal of the American Medical Association* 270 (December 1993): 2578-82.

2. Ibid.

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4. Multi-Society Task Force on PVS, "Medical aspects of the persistent vegetative state — first of two parts," *New England Journal of Medicine* 330 (1994): 1499-508; Multi-Society Task Force on PVS, "Medical aspects of the persistent vegetative state — second of two parts," *New England Journal of Medicine* 330 (1994): 1572-9.

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12. *http://www.ethics.va.gov/integratedethics.asp,* accessed 22 March 2007.

13. The corresponding variable in the 1993 study looked at recommendations made as an independent ethics consultant in the past three years.

14. As explained in our 1991 report, "The proportion of agreeing pairs statistic can be understood as follows. Let a randomly chosen respondent make a recommendation for variation 5. The chance that a second randomly selected respondent would agree with the first is 50%, because the proportion of agreeing pairs is 0.50 for that vignette. Although the proportion of agreeing pairs statistic does not adjust for chance agreement, it is clear that no consensus exists when there is only a 50/50 chance that two people will agree. See note 1 above, p. 2580.

15. See notes 4 through 7 above.

16. See note 7 above.

17. Multi-Society Task Force on PVS, "Medical aspects — second of two parts," see note 4 above.

18. See notes 8 through 12 above.

19. Fox and Arnold, see note 9 above.

20. See note 11 above.

21. See note 8 above.

22. See note 10 above.

23. See note 12 above.

24. See note 11 above.

Law

Legal Trends in Bioethics

Sigrid Fry-Revere

I have reconsidered the format of this column since I first wrote it 17 years ago. I have tried to make it more useful by organizing the information with busy readers in mind who may only be looking for information relevant in their jurisdictions. I have given each section a heading that reflects the potential practical ramifications of the material it contains. I have divided entries up by jurisdiction, and underlined the status of the case, regulation, or law. Furthermore, each entry is a very brief synopsis to allow readers to glance through sections quickly and then follow up on their own if a particular development is of interest.

No entry should be relied upon without reading the full text of the law, regulation, or case in question or without checking if any more recent developments have superseded the ones reported here. Also, please remember to be cautious about what entries might or might not be binding in your jurisdiction. Usually, jurisdiction is determined by the location of the medical institution, but that is not always the case. The law of the patient's state of residency, if different than the law where the healthcare institution is located, may also be relevant as may other jurisdictional factors.

This column is called "Legal Trends in Bioethics," so I will begin each section with a brief statement of developing changes. I have avoided legal references and citations in these introductory paragraphs to make them easier to read. Readers who would like references for any part of these paragraphs are welcome to e-mail me if an internet search for such references proves fruitless. Usually these introductory paragraphs will be only two or three sentences long, but, in this, my first "Legal Trends" in almost 15 years, I take the liberty of describing what has happened in a much broader space of time than will be the case in future columns.

The individual synopses given in this first "Legal Trends" are for developments from July through December 2006. Future columns will provide updates in three-month increments.

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

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A ONE-TIME INTRODUCTION TO UNDERSTANDING LEGAL TRENDS IN BIOETHICS

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

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

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

Legislatures and courts, in the area of bioethics, also act under the existence of two contrary presumptions. Legislatures tend to act with a presumption in favor of prevailing moral beliefs. The courts, on the other hand, have the structural and theoretical obligation to protect individuals from majoritarian decisions that unnecessarily violate their constitutionally protected freedoms. They also have an obligation to uphold the separation of church and state. So, in bioethics cases, courts often have to deal with preventing governments, either through legislation or other state action, from imposing moral or religious preferences on individuals who might not agree. Thus courts tend to show greater deference to individual choice than legislatures do, and tend to become more cautious the more divisive the issue.

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

LIFE AND DEATH DECISIONS CONTRARY TO PATIENTS' WISHES

In the last three decades the pendulum has swung from focusing on the right to refuse or withdraw treatment to the right to demand treatment, and now may be stabilizing in recognition of the inherently private nature of such decisions. In the 1970s, 1980s, and early 1990s, most end-of-life treatment disputes involved patients[1] or patients' families seeking support in their efforts to stop treatment. This was reflected in court cases and in the flood of state advance directive legislation and even in a public movement to legalize forms of aid in dying. In subsequent years, this trend reversed, mostly due to the growing political influence of the right-to-life movement. Advance directive laws were amended to make them more restrictive and, while in Oregon the Death with Dignity Act was approved twice by public referendum, similar propositions in other states such as California and Washington failed repeatedly. Suddenly there were more cases in which patients or their surrogates were demanding treatment rather than refusing it.

In just the past few years, however, there has been some resistance to these developments. Several 2005 polls regarding the highly publicized Terri Schiavo case found that Americans were fairly evenly divided on whether Terri's feeding tube should be removed or not, had a slight bias in favor of having her husband rather than her parents make the decision, and consistently felt strongly that the federal government should not be involved.[2] In one poll when people were asked, "If a patient has been in what doctors call a 'persistent vegetative' or coma-like state with no higher brain activity for a significant amount of time, who do you think should make the decision whether the patient should be kept alive or not: The person's par-

ent or other family members, the person's spouse, or the government?" There were only 2 percent of respondents who answered, "The Government."[3]

These results indicate that many Americans believe such decisions should be left to family members, not courts or legislatures. The Schiavo case is too recent for there to be any evidence of a possible new trend in court decisions, but, immediately after these polls were taken, the federal government dropped all discussion of possible "Schiavo" legislation.

It is also worth noting that, while the courts have hesitated to award damages for prolonging life against patients' wishes, they have awarded damages when medical professionals shortened a patient's life against the patient's wishes. In other words, the courts have refused to recognize treatment as "futile" simply because the patient has a bad prognosis. Or, put yet another way, courts have found that patients and families have a right to prolong life even in cases when medical professionals see such efforts as resulting in unnecessary suffering or a waste of resources.

I predict that in the years to come there will be a growing emphasis on keeping end-of-life decisions more private and within the family (however defined).

Recent Cases, July 2006 - December 2006

Louisiana. In *Terry and Flowers v. Red River Center,* the daughters of a deceased patient sued the nursing home where their mother had lived because staff called 911 in violation of what the daughters believed to be a valid do-not-resuscitate order (DNR order). The patient died at the hospital, but her daughters claimed that failure to follow the patient's wishes caused her undue pain and suffering. This court upheld the lower court's finding that all three advance directives issued in the previous six years were invalid: one because the form used required two physicians' signatures and there was only one; the second because it had been executed at another institution and wasn't in the defendant's records; and the third because it was signed by one of the daughters and not the patient herself, and there wasn't any evidence that the patient wanted the daughter to make such decisions for her. 942 So.2d 1238; 2006 La. App. LEXIS 2597 (15 November 2006).

New York. In *In re Matter of Claudia E.E.,* the New York Supreme Court Appellate Division, Third Department ruled that the Mental Hygiene Legal Service (MHLS) did not have the right to revoke its consent to a guardian's request to withdraw a patient's life-sustaining medical treatment simply with a letter. The guardian/sister of a mentally retarded person with Down syndrome and Alzheimer's disease decided to take her sister off the ventilator and feeding tube and transfer her to hospice care. When the patient didn't die, but instead was breathing on her own and feeding herself, MHLS sent a letter revoking its consent. The revocation was not valid because the proper procedure would have been to commence a special proceeding challenging the guardian's decision. 822 N.Y.S.2d 810; 2006 N.Y. App. Div. LEXIS 12512 (19 October 2006).

But in *In re Guardianship of Chantel Nicole R,* the Supreme Court of New York, Appellate Division, First Department ruled that MHLS had the authority to commence a special proceeding to object to a mother of a mentally retarded child making medical decisions for her daughter concerning life-sustaining treatment. 821 N.Y.S.2d 194; 2006 N.Y. App. Div. LEXIS 10922 (21 September 2006).

Recent Laws and Regulations, July - December 2006

Federal. The Advance Directives Improvement and Education Act of 2005 (S. 347/H.R. 2058) is being considered by various congressional committees. At this point, it isn't clear whether or not the act will come to a vote this legislative session. The act, among other things, would require Medicare providers to honor advance directives executed in another state unless the provider can "reasonably demonstrate" that the directive does not express the patient's wishes or directs a form of medical treatment

prohibited by the laws of the state in which the patient is being treated. The Advance Directives Improvement and Education Act of 2005, S. 347/H.R. 2058, 109th Cong. (2005).

California. The California legislature passed and the governor signed on 28 September 2006 a law, effective immediately, to ease the signature requirements for advance directives and durable powers of attorney filed electronically. 2005 Bill Text CA A.B. 2805 (28 September 2006). A.B. 2805, 2005-2006 Assem., Reg. Sess. (Ca. 2006).

Georgia. A bill was prefiled on 13 December 2006 to revise Georgia's advance directive laws. House Bill 24 will be introduced in the 2007 legislature. Among other things, this bill will combine Georgia's living will and durable power of attorney provisions into one form. H.B. 24, 149th Gen. Assem., Reg. Sess. (Ga. 2007). 2007 GA H.B. 24.

New Hampshire. The governor signed a bill (H.B. 656), effective 1 January 2007, that revises New Hampshire's advance directive laws. Among other things, the state's living will, proxy decision making, and DNR statutes have been combined into one form. H.B. 656, 159th Gen. Assem., Reg. Sess. (N.H. 2006).

Also, in New Hampshire as of 1 January 2007, new laws go into effect that set out specific requirements that must be satisfied before an agent may withhold or withdraw life-sustaining treatment. RSA 137-J:10 (2006).

New Jersey. A bill was introduced on 4 December 2006 in the New Jersey Senate to require surrogate decision makers to make healthcare decisions in accordance with a patient's religious beliefs. A similar New Jersey Assembly bill was introduced 9 November 2006. 2006 Bill Text NJ S.B. 2380; 2006 Bill Text NJ A.B. 3514. S.B. 2380, 211th Leg., Reg. Sess. (N.J. 2006); A.B. 3514, 211th Assem., Reg. Sess. (N.J. 2006).

Pennsylvania. Pennsylvania's Title 18 and 20 (Crimes and Offenses and Decedents, Estates, and Fiduciaries) were amended to protect caretakers and individuals or facilities who lawfully comply with a "health care representative's" directions as long as the care-dependent person has been documented by the attending physician to have an end-stage medical condition or to be permanently unconscious. S.B. 628 signed into law on 29 November 2006. 2005 Bill Text PA S.B. 628. S.B. 628, 2005-2006 Leg., Reg. Sess. (Pa. 2006).

Texas. The Texas Department of Aging and Disability Services has promulgated rules that went into effect 1 December 2006 requiring that all home and community support services maintain written policies regarding the implementation of advance directives and give notice to patients or their surrogates if the patient is incapacitated regarding any procedures the agency is unwilling or unable to provide or that the agency withheld in accordance with an advance directive. 40 TAC §97.283 (2006).

Also, on 13 November 2006 a bill was prefiled that would, among other things, provide for transferable physicians' orders, and prohibit healthcare providers or insurance companies from requiring advance directives as a condition for receiving healthcare services. 2007 Bill Text TX S.B. 28.

Interesting Developments in Other English Common Law Countries

Canada. The Manitoba College of Physicians and Surgeons, which oversees Manitoba's doctors, published a report in October 2006 proposing policies that give physicians the authority to stop or withhold medical treatment under certain circumstances even if the patient or family disagrees. The College of Physicians is still considering whether or not to implement the report's recommendations. *http://www.cpsm.mb.ca/about/news/2006/10/16/38189_0610160758-046?pageNumber=1.*

THE RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

Pre-Birth (Abortion, Fetuses, Embryos, and Stem Cells)

There isn't an ethical or political topic more prone to semantic manipulation than abortion and the related issues of fetal rights and stem-

cell research. People immediately make assumptions based on an author's word choices. I do it myself, but I want very much to be objective in my representation of the law relevant to these issues. So, in an attempt to give as objective a representation as possible, I will do two things: First, in my synopses, I will try to use the same vocabulary and tone reflected in the particular case, law, or regulation at issue. And, second, I'm going to disclose my personal beliefs so the reader can filter out any biased wording that might slip in.

I am morally pro-life, but politically pro-choice. My moral conviction is that human identity begins with our genes. That means, for me, a new individual begins at conception. This being said, I'm also a firm believer in the constitutional goals and philosophical origins of our political system. Historically, in recognition of the pluralist nature of our society, our system was set up to protect individuals with minority moral perspectives from having the exercise of their beliefs restricted by those who believe otherwise. The more divisive an issue, the harder our courts must work to protect minority points of view. I feel very strongly that abortion is morally wrong except under very limited circumstances and that all human life should be accorded a certain degree of respect. However, I also realize that these views are not shared by all, and that, while they have a strong religious history, they are not supported by our own legal history or by the principles of the U.S. Constitution.

Even if U.S. jurisprudence recognized each new human individual as a person under the law at all stages of development (which it doesn't), there simply are no historical or legal precedents in English or American law that justify treating the pre-born with equal status to other persons. Children, at every stage of development, have always had fewer rights than adults, particularly fewer rights vis-à-vis their parents. In every culture, children's rights, and the corresponding legally supported freedom to go against their parents' wishes, increase as the child matures. Infants have fewer rights than children who can walk and talk; children who are mobile have fewer rights than those who have reached puberty; children who have merely reached puberty have fewer rights than those who exhibit maturity. U.S. law, in the past, has adhered to the logic of this sliding scale of maturity even when considering the rights of children earlier in their development. Newborns have more rights than viable fetuses; viable fetuses have more rights than not-yet-viable fetuses, and all fetuses have more rights than embryos, blastocysts, or human life at the point of conception. Never in the history of English or U.S. law has a child at any stage of development been treated as *prima facie* having the same legal standing as a parent. Thus, the legal issue is *not* whether fetuses should be treated as equal persons under the law (that is, as with discrimination against racial minorities and women, we now need to abolish discrimination against the pre-born). The real issue is: What level of rights should be accorded the pre-born, using a traditional sliding scale of rights that is based on relative maturity?

To understand the legal debate over abortion and related issues, it is important to realize that there actually are two debates: One is the moral, religious, and philosophical debate about personhood. The other is a debate over how far those who hold either extreme of a wide range of moral perspectives should be allowed to compromise the integrity of our legal system (constitutional and common law) in order to have their own particular moral perspective become law.

The trend over the last 15 to 20 years has been a slow erosion of abortion-related rights. Some of the laws passed carry moral weight but have little effect on eroding our legal system, for example, the battle over parental notification laws. However, the partial-birth abortion debate now being waged in the U.S. Supreme Court could have a significant effect on our legal system because it could potentially change the historical relative rights of women vis-à-vis their fetuses.

The November 2006 elections gave some indication that more Americans than in the past wish the government to step back and be less

involved in pre-birth decisions. As with end-of-life decisions, more Americans seem to be indicating that these morally divisive issues should be decided privately and not by the government. This being said, most legislatures are rather evenly divided between pro-choice and pro-life advocates.

I predict that the U.S. Supreme Court will declare partial-birth abortion bans that do not include an exception for cases in which the mother's life is in danger unconstitutional, but will imply that the states are free to regulate abortion and related rights beyond what was previously allowed.

Recent Cases, July 2006 - December 2006

Federal. Pending cases. Decisions expected from the U.S. Supreme Court in the spring of 2007 include *Gonzales v. Carhart,* 05-380, and *Gonzales v. Planned Parenthood,* 05-1382. These cases challenge the constitutionality of the Partial-Birth Abortion Ban Act of 2003. In 2000, the U.S. Supreme Court held a Nebraska law banning partial-birth abortions unconstitutional because it didn't include an exception to the ban for when a woman's health is in danger. Since then, Congress passed its ban on partial-birth abortions that also doesn't include an exception for when a mother's health is in jeopardy, so the issue is once again before the Court. One major difference is that the Court's composition has changed since 2000. In 2000 Justice Sandra Day O'Connor cast the decisive fifth vote. Today, Justice Samuel Alito, who has written in the past that the Constitution does not protect the right to an abortion, sits on the Court in her place. If the Partial-Birth Abortion Ban Act of 2003 is found constitutional, it will ban the procedure in all states, whether or not individual states passed or defeated such laws on the state level.

California. *In People Advocate v. Independent Citizen's Oversight Committee,* the California Superior Court upheld the validity of Proposition 71, but plaintiffs plan to appeal. 2006 WL 1417983 (Cal. Superior Ct. 2006) (upholding the constitutionality of Proposition 71).

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

Recent Laws and Regulations, July - December 2006

Federal. On 24 August 2006, the U.S. Food and Drug Administration (FDA) approved Plan B®, an emergency contraceptive, for over-the-counter sale to women ages 18 or older. Plan B® is still available by prescription only to women under 18. Application No. 21045/S011 (24 August 2006). Press Release, U.S. Food and Drug Administration, "FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older. Prescription Remains Required for Those 17 and Under," 24 August 2006, *http://www.fda.gov/bbs/topics/NEWS/2006/NEW01436.html,* accessed 26 January 2007.

California. In 2004, California voters approved Proposition 71 and the raising of $3 billion through state bonds to fund stem-cell research, including embryonic stem-cell research. California Health & Safety Code §125290.10. That bond issue hasn't taken place because there is a lawsuit challenging the constitutionality of the proposition and the proposed system for administering the funds. In *People's Advocate v. Independent Citizen's Oversight Committee,* the California Superior Court upheld the validity of Proposition 71, but plaintiffs plan to appeal. 2006 WL 1417983 (Cal. Superior Ct. 2006) (upholding the constitutionality of Proposition 71).

Hawaii. On 26 April 2006, the governor signed into law a bill that codifies the protections of *Roe v. Wade.* H.B. 1242, 23rd Leg., Reg. Sess. (Haw. 2006) (to be codified at Haw. Rev. Stat. § 453-16).

Illinois. Two bills were introduced in the Illinois legislature in December 2006: One would allocate $25 million annually for the next

five years to stem-cell research, including embryonic stem-cell research (H.B. 1039); the second would ban human cloning and the sale of human embryos (H.B. 1038). H.B. 1039, 94th Gen. Assem., Reg. Sess. (Ill. 2006); H.B. 1038, 94th Gen. Assem., Reg. Sess. (Ill. 2006).

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

Also in Michigan, bills were introduced last August as a unit called the "Coercive Abortion Protection Act," that, among other things, would make it criminal to coerce a person into having an abortion. The act also includes a requirement for "coercion and intimidation screening." H.B. 5879, 93rd Leg., Reg. Sess. (Mich. 2006); H.B. 5880, 93rd Leg., Reg. Sess. (Mich. 2006); H.B. 5881, 93rd Leg., Reg. Sess. (Mich. 2006); H.B. 5882, 93rd Leg., Reg. Sess. (Mich. 2006); H.B. 5883, 93rd Leg., Reg. Sess. (Mich. 2006). 2005 Bill Text MI H.B. 5879 (26 July 2006).

Missouri. In the November 2006 election, Missouri voters passed an amendment to the state constitution, the Missouri Stem Cell Research and Cures Initiative, that guarantees that any stem-cell research allowed under federal law is also allowed in Missouri. Mo. Const. of 1945, art. III, § 38(d) (2007).

New Jersey. On 20 December 2006, the governor signed a bill that approves a state bond issue to borrow $270 million for expansion of human embryonic stem-cell research. (S 1471). N.J. P.L. 2006, c. 102. N.J.S.A. 34: 1B-21.31-36.

South Dakota. The state legislature enacted a law that makes it a class five felony for any person to "knowingly administer to, prescribe for, or procure for, or sell to any pregnant woman any medicine, drug, or other substance with the specific intent of causing or abetting the termination of the life of an unborn human being." The law contained a narrow exception in instances in which an abortion is necessary to preserve a woman's life. H.B. 1215, 81st Leg. Assem., Reg. Sess. (S.D. 2006). The U.S. Court of Appeals for the Eighth Circuit stayed enforcement of the act (see entry above), but while it was being litigated, a voter referendum on the November 2006 ballot rejected the new law.

After Birth (Premature Infants, Newborns, and Children)

Legislative considerations of children's rights have fluctuated over the years based on political issues that really had little to do with the actual welfare or maturity of children. This is still true today. The courts have worked to mediate the effects of such political pressures, but not always successfully. Examples are the ongoing debates over religious exceptions to child abuse laws, over parental notification when minors seek abortions, and over the proper treatment of premature or handicapped infants.

I have seen some shift in legal arguments in favor of holding that a child's best interest cannot be judged independently of its family unit, that is, that there should be more of a presumption in favor of parental decision making unless it is absolutely clear that the parent does not have the child's best interest in mind. I think this development parallels developments in other areas of bioethics, in which it is clear that a growing number of Americans feel that, in a pluralistic society, there needs to be sphere reserved for private family decision making with as little government interference as possible.

I predict that this trend will grow, but very slowly, and, while a few isolated court cases will reflect this shift toward family decision making, it will take much longer for other branches of government to accept more of a hands-off approach.

Recent Cases, July 2006 - December 2006

I have not reported any child abuse cases here because those that I found that were de-

cided or filed in the last six months didn't involve any out-of-the-ordinary medical issues. Usually, if medical treatment was involved at all, it was that the parents were accused of neglect for not providing adequate medical care. While these cases are often horrific, they don't involve any new ethical issues.

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

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

Ohio. In *Cincinnati Women's Services Inc. v. Taft,* the court held that a provision of Ohio law that required a woman seeking an abortion to have an in-person meeting with a physician at least 24 hours prior to receiving an abortion for informed consent purposes was constitutional, but that a provision that limited minors seeking a judicial bypass to parental-consent requirements to one petition for such bypass per pregnancy was unconstitutional. No. 05-4174 (6th Cir. 13 November 2006) *Cincinnati Women's Services v. Taft,* 468 F. 3d 361; 2006 U.S. App. LEXIS 28049 (6th Cir. 2006).

Recent Laws and Regulations, July - December 2006

Federal. Two congressional bills failed in December 2006. The first (H.R. 6099) would have required that a woman seeking an abortion be told that "there is substantial evidence that the process of being killed in an abortion will cause the unborn child pain" and that she has the option of anesthetizing the fetus before the abortion. Another bill that hasn't left committee is H.R. 522, which would have extended the Fourteenth Amendment to guarantee "right to life" for "each born and pre-born human person." Given the new Democratic majority in Congress, it is not likely that either of these bills will be up for a vote in the near future.

Illinois. The Illinois Supreme Court announced 18 September 2006 that it will issue rules necessary to implement the state Parental Notice of Abortion Act. Ill. S. Ct. M.R. 21173. Until the court issues rules, the act remains unenforceable because the court needs to specify the procedures by which minors can seek judicial waivers under special circumstances. The Illinois Supreme Court holds its annual Rules Committee meeting every January.

Oklahoma and Utah. On 16 March 2006, Utah's governor and on 20 May 2006 Oklahoma's governor signed bills that add a parental consent requirement to their states' existing parental notification laws applicable in cases in which minors seek abortion. H.B. 85, 56th Leg., 2006 Reg. Sess. (Utah 2006) (to be codified in

Utah Code Ann. § 76-7-304) (Enacted 1974) (Last Amendment 2006); H.B. 1686, 50th Leg., 2006 Reg. Sess. (Okla. 2006).

Interesting Developments in Other English Common Law Countries

England. The Nuffield Council on Bioethics, in a report published in November 2006, recommended that premature babies born before 22 weeks not be resuscitated regardless of the parents' wishes. Babies born between 22 and 23 weeks of age should only be treated if the parents insist and the doctor agrees.

ORGAN AND TISSUE PROCUREMENT

Medical innovations in transplantation have been spectacular; unfortunately, we are stuck in a vicious cycle in which demand far outstrips supply. The organ and tissue industry, plagued by the inequities of altruistic donation on one hand and profits in the billions on the other, is fraught with abuses that range from a black market to the negligent cutting of corners in a rush to profit.

I predict a proliferation of court cases and regulation in an attempt to stem the tide of abuses, and a move to a system of presumed consent to organ donation, in an attempt to increase the supply of organs and human tissue. For various reasons, these measures will solve little in the long run. Even lifting the prohibition on the sale of organs and tissue will not solve the problem for long. Perhaps stem-cell therapies or some other "medical miracle" will eventually solve the organ shortage.

Recent Cases, July 2006 - December 2006

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

Connecticut. In *Miller v. Hartford Hospital, et al.,* the Superior Court of Connecticut for the Middlesex Judicial District held that under Connecticut law human tissue is not a product for the purposes of product liability law. 2006 Conn. Super. LEXIS 2835 (19 September 2006).

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

New Jersey. Action being initiated. A law firm in New Jersey is organizing a first-of-its-kind class action suit against Biomedical Tissue Services of Ft. Lee, New Jersey, for selling contaminated tissue samples. *http://www.monheit.com/biomedical-tissue; http://www.oshmanlaw.com/pharmaceutical litigation/tainted tissue.html,* accessed 24 January 2007.

New York and New Jersey. The King's County District Attorney arrested and indicted a funeral home director and several others in February 2006 for illegally selling stolen body

parts. Media Release, Office of the District Attorney, Kings County (23 February 2006). Since then, several others, from as many as seven funeral homes in New York and New Jersey, have been added to the original indictment. *http://www.usatoday.com/news/nation/2006-10-18-stolenbodyparts_x.htm; http://transcripts.cnn.com/TRANSCRIPTS/0610/18/cnr.06.html,* accessed 28 January 2007.

Recent Laws and Regulations, July - December 2006

Colorado. The first-person consent rule (also present in the new Uniform Anatomical Gift Act) went into effect in Colorado on 6 August 2006. The law prohibits any disposition of an individual's remains after death that is contrary to the deceased's written wishes. Col. Rev. Stat. 15-19-102 (2006).

Michigan. On 31 December 2006, Michigan's governor vetoed a bill (H.B. 6292) that would have provided a tax incentive (up to $200 in tax credits) for people who donate money to umbilical cord blood stem-cell banks. The governor stated the money would be better spent on stem-cell research.

New Jersey. A bill was introduced in October 2006 that would require the New Jersey Motor Vehicle Commission to share organ donor information with federally designated organ procurement organizations. Currently the bill is in committee and is expected to be voted on later in this legislative session. 2006 Bill Text NJ A.B. 3137 (19 October 2006).

Also in New Jersey, a bill was withdrawn from further consideration that would have amended the New Jersey Anatomical Gift Act to require that those involved in organ procurement not ask for an anatomical gift if they have reason to believe that the gift would be contrary to the decedent's wishes or religious beliefs. The amendment further would have barred the anatomical gift if a person who is listed in the state list of potential surrogates indicates that such a gift would be contrary to the decedent's wishes or religious beliefs. 2006 Bill Text NJ S.B. 2378 (4 December 2006).

New York. On 16 August 2006, the governor signed into law three bills to amend driver licensing laws. One requires that "organ donor" be prominently printed on the front of organ donors' licenses. The other requires that each donor so designated be registered in the New York State Organ and Tissue Donor Registry. 2005 Bill Text NY A.B. 11883, A.B. 2995, 228th Leg. Sess., Reg. Sess. (N.Y. 2006); A.B. 11883, 229th Leg. Sess., Reg. Sess. (N.Y. 2006).

Also in New York, on 16 August 2006, the governor signed into law an act requiring the transplant council to complete a study on the issues surrounding the implications of presumed consent for organ and tissue donation. 2005 Bill Text NY A.B. 11842. A.B. 11842, 229th Leg. Sess., Reg. Sess. (N.Y. 2006).

On 16 August 2006, the New York governor signed into law a bill that allows reduction in federal adjusted gross income of up to $10,000 to anyone who donates one or more of his or her organs to another human being. 2005 Bill Text NY A.B. 3072. (16 August 2006). A.B. 3072, 229th Leg., Reg. Sess. (N.Y. 2006).

Pennsylvania. The governor signed on 2 July 2006 a law that requires Pennsylvania businesses to provide up to five days paid leave for organ and bone marrow donors. The law further clarifies that this leave is in addition to any other personal or sick leave allowed the employee by the employer, and that, if such leave is provided, the employer qualifies for the state donor tax credit. 2005 Bill Text PA H.B. 153 (Act No. 2006-65, 2 July 2006). H.B. 153, 189th Gen. Assem., Reg. Sess. (Pa. 2006).

Rhode Island. The governor signed on 10 July 2006 a law requiring the state medical examiner and his designees to share all information necessary to facilitate organ and tissue donation with federally designated organ procurement organizations and other nonprofit federally registered eye and tissue banks. 2005 Bill Text RI S.B. 2616 (10 July 2006). S.B. 2616, 2005-2006 Leg. Sess., Reg. Sess. (R.I. 2006).

South Carolina. A bill has been prefiled for the 2007 legislative session that would require all patients to indicate, at the time of admission to a hospital, whether or not they are an

organ or tissue donor, or both, and, if not, whether the patient or the patient's family would be willing to discuss organ or tissue donation, or both, should the patient become a potential donor during his or her stay in the hospital. 2007 Bill Text SC S.B. 131 (6 December 2006). S.B. 131, 117th Gen. Assem., Reg. Sess. (S.C. 2006).

Other. The National Conference of Commissioners on Uniform State Laws has revised its Uniform Anatomical Gift Act. The 2006 version was released on 13 July 2006. Most notably, the new version supports first-person consent. The document states that, in all cases, the express wish of the donor should take precedence over any wishes expressed by the family. Uniform laws are model documents that must be adopted by individual states before they have any force of law.

INFORMED CONSENT

In the last three decades, the documentation of informed consent has developed from a valuable form of evidence to a near meaningless formality. As consent forms become more complicated and less comprehensible, courts have begun to consider violations of informed consent as actionable, in and of themselves, as opposed to being simply one element showing negligence in malpractice suits. Mere documentation of consent is no longer always enough. *Informed* consent is starting to take on a legal life of its own. Violations of informed consent are not only an indication of negligence (a claim requiring a proof of damages) but also an affront to human dignity and/or a breach of fiduciary obligation, both of which can now sometimes be claimed without evidence of actual damages, that is, the physical or emotional harm required in malpractice claims.

As medical innovations and the availability of experimental treatments multiply exponentially, physicians and researchers are under ever-greater pressure to succeed. That pressure sometimes creates a conflict of interest with the traditional role of physician as healer — the traditional view of physician as one with the patient's best interest at heart. Patients and their families also have unrealistic expectations with respect to the curative potential of experimental treatments. These factors, along with the ever-more-complicated nature of medicine, make it important that the informed consent process actually works, that it helps ensure informed decision making, and not merely serves as a meaningless legal formality.

In this area of the law, legislatures, government agencies, and the courts have all been working, albeit slowly, toward the goal of trying to make the informed consent process more comprehensible. Opposition to such advances usually comes from medical institutions and practitioners already overburdened with legally required paperwork.

I predict that new advances in documentation technologies will eventually be used to satisfy everyone. For example, the informed consent process could include the electronic recording of a patient's verbal responses to questions designed to verify comprehension.

Recent Cases, July 2006 - December 2006

Federal. Ongoing litigation. In *Ryan v. Staten Island Univ. Hospital, et al.,* the U.S. District Court for the Eastern District of New York agreed to hear a claim for malpractice, fraud, and violation of New York State consumer protection and public health laws. The plaintiff claims, among other things, that she and her husband were lured from their home in Florida for treatment of his pancreatic cancer by numerous misrepresentations, including a claim that the treatment proposed had a 95 percent success rate. 2006 U.S. Dist. Lexis 88313 (intermediary finding regarding discovery issue, 5 December 2006).

Florida. In *Pope v. Winter Park Healthcare Group, Ltd.,* the Florida District Court of Appeals held that the hospital was responsible for assuring that the patient received the information necessary for informed consent, even if the procedure in question was performed by a physician not employed at the hospital. The court found that the duty of informed consent rests

with the hospital, even in the case of independent contractors. 939 So. 2d 185; 2006 Fla. App. Lexis 16605 (Fla. Dis. Ct. App., 5th Dist., 6 October 2006).

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

Michigan. In *Compton v. Pass,* the Michigan Court of Appeals ruled that failure to inform plaintiff of the option to undergo a sentinel node procedure instead of an axillary dissection wasn't the proximate cause of her permanent axillary cording and lymphedema. The court granted summary judgment for defendant. No. 260362 (Mich. Ct. App. 22 August 2006).

Mississippi. In *Cleveland v. Mann,* the Mississippi Supreme Court ruled that an informed consent form that included a provision compelling arbitration in the case of disputes was not unconscionable. The patient had signed and initialed the document, there was bold type indicating that a right to a trial would be waived, and there was time between the signing and the surgery for the patient to reconsider. These facts were enough to override the patient's lack of education or inability to read and understand the agreement. Miss. Supreme Ct. No. 2005-CA-00924-SCT; 2006 Miss. LEXIS 467 (31 August 2006).

Texas. In *Gray v. Woodville Health Care Center,* the Court of Appeals of Texas, Eighth District, held that a family didn't have a case for malpractice or wrongful death. The court did not discuss informed consent or the meaning of "hospice" care, but analyzed the case purely along traditional notions of malpractice. The facts, however, clearly indicated a misunderstanding as to the meaning of "hospice" care. The family consented to having the patient transferred to hospice care, but was shocked to find that the patient died the day after transfer; in their minds it was negligent for the patient's physician to order most treatments stopped in conjunction with the transfer. 2006 Tex. App. LEXIS 6904 (3 August 2006).

Recent Laws and Regulations, July - December 2006

California. On 29 September 2006, the governor vetoed a bill passed by the California legislature that would have amended the Health and Safety Code to include special informed consent provisions for participants in biomonitoring experimentation. Of special interest were the requirements that participants be informed and consent to the intended use of any biospecimen, including any potential patentable pharmaceuticals or other products, and that participants have full access to all laboratory reports and final research results. 2005 Bill Text CA A.B. 1062 (31 August 2006). A.B. 1062, 2005-2006 Gen. Assem., Reg. Sess. (Ca. 2005).

Rhode Island. On 3 July 2006, a bill amending the state informed consent laws took effect without the governor's signature. The new law (P.L. No. 2006-225) allows for an exception to informed consent requirements in the case of experimental procedures being tested in emergency settings. No informed consent is required if the patient is unable to consent due to a life-threatening condition. 2005 Bill Text RI H.B. 8073; 2005 Bill Text RI S.B. 2613 (7 July 2006). H.B. 8073, 2005-2006 Leg., Reg. Sess. (R.I. 2006); S.B. 2613, 2005-2006 Leg., Reg. Sess. (R.I. 2006).

UNCONVENTIONAL TREATMENT

As in other areas of bioethics, a significant number of people are disillusioned with the government's ability to make wise decisions regarding the appropriateness of care. Twenty years ago, Americans had more faith in both doctors and the government, when it came to protecting the population from the hazards of developing pharmaceuticals and technologies.

In recent years, some of this faith has eroded. Citizens are not only questioning and challenging the government, but also suing to take certain decisions out of government hands.

I predict that few plaintiffs will be successful in their challenges to government authority, but that challenges will increase and, with time, some will begin to bring about change.

Recent Cases, July 2006 - December 2006

Federal. Ongoing case. In *Abigail Alliance v. Eschenbach,* the U.S. Court of Appeals for the District of Columbia Circuit granted the FDA's petition to rehear the question of standing *en banc.* The court had previously held that the lower court erred in dismissing the Alliance complaint. The circuit court found that the Alliance case had standing and a due process interest in self-determination that protected the pursuit of promising new drugs. The issue in the case is whether individuals should have the right to purchase drugs before full approval by the FDA. Oral arguments are scheduled for 1 March 2007. 2006 U.S. App. LEXIS 28834 (21 November 2006) Rehearing *en banc* granted 21 November 2006 (Case # 04-5350).

Washington. In *State of Washington v. Tracy,* the Washington State Supreme Court held that the recognized Washington State compassionate-use defense, for those arrested for the use of marijuana who claim to possess the drug for medical reasons, does not apply if the "qualifying doctor" is not a Washington State doctor. In this case, the defendant had a medical marijuana card issued by a California doctor and an authorization for use issued by an Oregon doctor. Her convictions were upheld. 158 Wn. 2d 683; 2006 Wash. LEXIS 883 (Wash. 2006).

Recent Laws and Regulations, July - December 2006

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

THE RIGHT TO ACCESS AND CONTROL MEDICAL INFORMATION

One of the biggest changes in the last 30 years has been the ease with which information can be transmitted and stored, and with that comes privacy concerns.

I predict that errors in transmitting information by e-mail will lead to some interesting cases, and perhaps even regulation in the near future. Are your e-mail communications encrypted? Are you sure when you press that send button that your response is reaching the correct person, and only that person? As wonderful as new technologies are, it is important to pause and think about how best to use them.

Like e-mails, data storage on computers and computer systems isn't as secure as some people think. Experimental data or hospital records, particularly now that there is a movement to create nationwide medical information systems, might be vulnerable. Some private companies are providing their clients with "memory sticks," replete with all their medical records, ready to plug into any doctor's or hospital's computer either to be printed or downloaded. Giving patients memory sticks is cheaper than linking all U.S. medical providers electronically, and is also safer from a privacy perspective.

Recent Cases, July 2006 - December 2006

California. Pending litigation. *Taus v. Loftus, et al.* is a case in which a child abuse victim gave permission (at age 17) — and so did her father — to be interviewed, and for the taped interview to be shown for "educational pur-

poses." A case study was published that referenced "Jane Doe," but other identifying information was disclosed when the researcher gave presentations about the case, including videotaped interviews with the subject in which the subject's first name was used by the researcher, and the city where the subject lived as a child was disclosed. Based on this information, in conjunction with information disclosed in the researcher's published case study, reporters discovered more about the case and published allegedly defamatory remarks about the subject and the researcher's claims regarding her recovery of repressed memories. 2005 Cal. App. Unpub. LEXIS 3048, 22 media L. Rep. 1545. *Taus v. Loftus, et al.,* 2006 CA S. Ct. S133805 (appeal).

Recent Laws and Regulations, July - December 2006

Federal. The FDA is collecting comments on a proposed project for the "Development of an Electronic System for Reporting Medication Errors and Adverse Drug Events in Primary Care Practice." 71 Fed. Reg. 74537 (12 December 2006).

The FDA has also issued a request for information regarding "Improving Health and Accelerating Personalized Health Care Through Health Information Technology and Genomic Information in Population — and Community-Based Health Care Delivery Systems." 71 Fed. Reg. 64282 (Nov. 1, 2006).

California. On 30 September 2006 the governor signed into law the Local Pandemic and Emergency Health Preparedness Act of 2006. This act, among other things, authorizes local public health officials to demand and receive medical information regarding patients from healthcare providers and health insurance plans without first obtaining patient authorization. 2005 Bill Text CA S.B. 1430 (31 August 2006). S.B. 1430, 2005-2006 Leg., Reg. Sess. (Ca. 2006).

Iowa. There is a bill pending before the Iowa state legislature to implement electronic health records systems incrementally throughout the state. H.B. 2637, 81st Gen. Assem., 2nd Sess. (Iowa 2005).

MEDICAL TESTING

There are no new trends in the handling of medical testing issues. The ethical questions associated with the accuracy of tests, proper reporting of results, and the risks associated with certain types of disclosure have not changed. This is, however, an important section to include in "Legal Trends," because, as genetic testing improves, some very difficult ethical questions, with correspondingly difficult policy questions, will arise. As testing becomes a more reliable predictor of a person's potential for sickness or health (as well as a predictor of other things as well) there is a danger that some people will put too much stock in genetically identified propensities and act, legislate, or regulate accordingly.

Recent Cases, July 2006 - December 2006

Ohio. In *Galland v. Meridia Health Sys. Inc.,* the Ohio State Court of Appeals held that a five-year-old child who was stuck by a used needle from an unidentified patient could not comprehend HIV enough to be emotionally distressed by the thought that she might have contracted AIDS. The court also summarily dismissed the parents' claim of emotional distress, stating that, under Ohio law, the damage suffered by bystanders must be severe and debilitating for recovery to be possible and there was no evidence that the parents' damages were that severe. No. 23163 (Ohio Ct. App. 20 September 2006); 2006 Ohio 4867, 2006 Ohio App. LEXIS 4785.

In *Bright v. Family Med. Found. Inc.,* the Ohio State Court of Appeals upheld a finding of malpractice against a medical facility and doctor for using a lidocaine bottle contaminated with HIV. The bottle had been used to numb the plaintiff's foot after being used on another patient with AIDS. No. 05AP-835 (Ohio Ct. App. 28 September 2006); 2006 Ohio 5037; 2006 Ohio App. LEXIS 4947.

Recent Laws and Regulations, July - December 2006

Federal. The U.S. Department of Health and Human Service Centers for Disease Control and Prevention (CDC) published a document on 22 September 2006 that recommends HIV screening for all patients in all healthcare settings unless the patient declines such testing. The document is a little unclear with respect to whether it is recommending "presumed consent" or "notice with an option to opt-out." At several points in the document it is stated that "HIV screening is recommended after the patient is notified that testing will be performed unless the patient declines." In other parts it is stated that "general consent for medical care should be considered sufficient to encompass consent for HIV testing." "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings." 55 (RR14):1-17 (22 September 2006).

In *Hickman v. Laboratory Corp. of America Holdings Inc.,* the Abingdon Federal District Court for the Western District of Virginia found that a medical worker who was stuck with a needle who then received a "false positive" HIV result could not recover from the lab that tested her blood. The plaintiff's smoking and taking of fertility drugs were intervening factors that could have caused her anxiety. Her claims for emotional distress due to breach of express warranty or negligence were summarily dismissed. VLW 006-3-429 (6 October 2006) and VLW 006-3-4769 (9 November 2006); 2006 U.S. Dist. LEXIS 82119 (W.D. Va. 2006).

Ohio. A bill was introduced on 28 November 2006 in the Ohio state legislature to limit the liability of hospitals, among other things, for the genetic screening of newborns. 2005 Bill Text OH H.B. 692. H.B. 692, 162nd Gen. Assem., Reg. Sess. (Ohio 2006).

DECISION-MAKING CAPACITY/COMPETENCY

Decision-making capacity and competency continue to be among the most vexing practical questions in clinical ethics. Philosophically, determining capacity doesn't seem all that difficult: Does the person understand the consequences of his or her decision? However, in reality, the situation is often very different. Judgment is impaired either temporarily or permanently by pain, by medication, by emotional insecurities, by the potentially coercive nature of experts or family members, and by illness itself.

One major development over the last 30 years is that most legal and medical professionals, even if not the public, now understand that the standard for determining capacity in the medical context is different than the standards applied in conservatorship or criminal proceedings. Also, while not anywhere near perfect in its application, it is now generally recognized that advance planning with respect to healthcare decisions is wise. When patients are unconscious or express wishes consistent with their advance directives, the capacity to make healthcare decisions is a non-issue; the advance directive, if valid, should be followed. Only if a patient expresses inconsistent wishes or gives other signs of possible diminished or compromised capacity does an evaluation of the ability to comprehend the consequences of a healthcare decision become important.

I predict that over the next few years scientific advances in our understanding of cognitive functions will make determinations of capacity less subjective and take some of the anguish out of situations in which a patient's capacity to make healthcare decisions is in doubt.

Recent Cases, July 2006 - December 2006

California. In *In re Gregory A.,* the California Appeals Court upheld a lower court's decision to appoint a conservator. The plaintiff sought denial of reappointment of a conservator, claiming that the lower court applied the wrong standard when it decided that a conservator was necessary. The appointment was upheld on the grounds that the plaintiff was, in fact, presently disabled because he had a history of resisting taking his medication and "re-

quired constant prompting." The court found that the plaintiff sufficiently lacked "insight into his mental illness" to justify a conservator. No. A113587 (Cal. Ct. App. 7 November 2006). *In re Gregory A.,* 2006 Cal. App. Unpub. LEXIS 10119 (Cal. Ct. App. 2006).

Recent Laws and Regulations, July - December 2006

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

California. The California legislature is considering revisions to the state conservatorship and guardianship laws. The Jones Omnibus Conservatorship and Guardianship Reform Act of 2006 is the newest version of Assembly Bill 1363, which was first introduced in 2005 and has undergone almost a dozen amendments. A vote is anticipated in 2007. 2005 CA A.B. 1363 (22 August 2006); A.B. 1363, 2005-2006 Gen. Assem., Reg. Sess. (Ca. 2005).

PALLIATIVE CARE AND PAIN CONTROL

Issues of palliative care for the elderly and for newborns will become increasingly divisive. Baby boomers, who have now experienced having children and their elderly relatives struggling with debilitating illnesses, will demand changes. They will demand changes for their grandchildren and for themselves.

After a flurry of concern and consequent regulations, laws, and cases involving handicapped newborns in the 1980s, there was a lull in politically airing such concerns until the recent Bush administration made the protection of infants (at all stages of development) from the potential ill-intent of parents and doctors one of its missions. The U.S. Federal Born-Alive Infant Protection Act became law in 2001, and, in 2005, DHHS Secretary Mike Leavitt promised to enforce any violations of the Born-Alive Infant Protection Act or the federal Emergency Medical Treatment and Labor Act, which, he states, requires aggressive treatment to try to save the life of every child born alive, no matter how young or under what circumstances. The American Academy of Pediatrics and many physicians don't adhere to these standards. Instead, they believe that, at times, it is acceptable for parents in consultation with the infant's physician to limit or cease treatment if they believe doing so would be in the child's best interest. As yet, this inconsistency in policy and practice hasn't led to any noteworthy cases.

Usually when asked, "What is a 'good death'?" most people respond, "A peaceful, painless death, preferably at home." Yet only 20 percent of people die at home, and how many of those deaths are peaceful or painless is debatable. Most people die in hospitals, and, of those, more than in the past are demanding that everything be done to save their lives. The divide between those who believe life of any kind is valuable and those who believe some forms of life aren't worth living is great, and both sides mistrust the healthcare community to carry out their wishes.

I predict that the more divisive these issues become, the more likely it will be that governmental bodies will leave such decisions up to individuals and their families. Judges who are now squeamish about finding for plaintiffs in wrongful-life cases will do so more frequently, first at the end of life but eventually also at the beginning. The violations found will be trust-

based: a failure of a professional duty to "care," expressed either through concepts of informed consent or professional responsibility.

Recent Cases, July 2006 - December 2006

California. Pending case. In *Ross v. Raging Wire Telecommunications, Inc.,* the Supreme Court of California agreed to hear a case in which the plaintiff was fired from his job when he began smoking marijuana as part of his medical treatment. The treatment was prescribed by his physician and is legal in California. It is alleged that plaintiff's doing so while off-duty did not affect his job performance, and that firing him was a violation of the established California body of law that protects disabled workers. *Ross v. Raging Wire Telecommunications, Inc.,* No. S138130 (Cal. 2005).

Recent Laws and Regulations, July - December 2006

Federal. In December 2006, H.R. 6099 failed to pass the House. The bill would have required that a woman seeking an abortion be told that "there is substantial evidence that the process of being killed in an abortion will cause the unborn child pain" and that she has the option of anesthetizing the fetus before the abortion.

Interesting Developments in Other English Common Law Countries

England. The Nuffield Council on Bioethics, in a report published in November 2006, recommended that premature babies born before 22 weeks not be resuscitated regardless of the parents' wishes. Babies born between 22 and 23 weeks of age should only be treated if the parents insist and the doctor agrees.

DEFINITION OF DEATH

Twenty years ago, the struggle was still to help the general public, judges, government officials, and some medical professionals understand and accept the concept of "brain death," or, more precisely, the concept of death as determined by the complete and irreversible cessation of all the functions of the entire brain. At the time, patients on ventilators or cardiovascular support seemed to be alive because their lungs and hearts were still functioning, albeit with mechanical support. It took time to accustom people to the notion that such patients are really corpses because they have no chance of recovering any brain function.

In recent years, there has been a push to return to more classical criteria for death: irreversible cessation of circulatory and respiratory functions. This movement is driven primarily by transplant physicians who seek to harvest organs while they are most viable. A growing general mistrust in the medical profession and the need for rushed decision making in such situations is once again making people uncomfortable. Now, many feel that a patient isn't truly dead until the brain stops functioning, even if such cessation is unquestionably going to happen given that the patient's heart and lungs have already irreversibly stopped. People don't understand why in one decade they are told that death comes with brain death and in the next decade that it is acceptable to harvest a person's organs even before brain death because the lungs and heart have stopped functioning. People are asking themselves: Is such organ procurement vivisection? Does a patient with a still-functioning brain sense what is going on? Do such patients feel pain?

These questions need to be addressed and answered to the public's satisfaction, otherwise their already diminished faith in the medical profession will diminish further.

Recent Cases, July 2006 - December 2006

Texas. *Grotti v. State of Texas,* 2006 Tex. App. Lexis 10018 (17 November 2006). The court overturned a jury verdict that held that a doctor had caused a patient's death by occluding the patient's endotracheal tube (ET) after 60 minutes of coding the patient with little success. At the time of the occlusion, the patient's respiration had slowed to three or four respira-

tions per minute; she had no heart sounds or pulse, but some electrical activity on the monitor. The court found that (1) the evidence contrary to the verdict demonstrates that the patient experienced irreversible cessation of her spontaneous respiratory and circulatory functions prior to 21:50 (the time of the occulation), and (2) her respiratory efforts between 20:50 and 21:50 were insufficient to maintain life. It is pretty clear, given the facts of this case, that there wouldn't have been a trial if the defendant doctor had simply withdrawn the patient's ET tube, rather than holding her finger over it until the patient stopped moving. (The physician had occluded the ET tube for five minutes.)

Recent Laws and Regulations, July - December 2006

New Jersey. The New Jersey Board of Medical Examiners has published a proposed rule, 17360 NJAC 13:35-6A, entitled "Declarations of Death Upon Neurological Criteria State ID: 38 NJR 2021." The comment period ended 14 July 2006. It is unclear when the final rule will be published.

Wisconsin. The Wisconsin Department of Health and Family Services has enacted new rules that were effective on 1 December 2006 that require that a prescribed form be filled out by physicians, technicians, and tissue bank employees. When organs and tissue, other than cardiovascular tissue, are removed from decedents, the form requires details regarding the time and cause of death, the types of organs/tissues requested, and the tests done to determine the appropriateness of transplantation. CR 06-076 (Ref. Wisconsin 20742) (31 October 2006).

OVERSIGHT: PATIENT TRUST

There is no doubt that we are in a general crisis of trust. In the last 20 years, the public has become more cynical with respect to many social institutions, including government and the healthcare industry. David Shore, founder of the Harvard School of Public Health's Trust Initiative, has been arguing for half a decade that the healthcare industry needs to make the engendering of trust both internally and with respect to the public a top priority.[4]

In the absence of functional internal mechanisms to reduce clerical and medical error, employee burn-out, and iatrogenic illness, the public will demand governmental intervention. It is my prediction that healthcare organizations will do too little too late, and there will be a drastic increase in governmental regulation of healthcare.

Recent Laws and Regulations, July - December 2006

California. A bill has been introduced in the California Assembly to establish an Office of Patient Advocate in the State Department of Public Health. 2007 Text CA A.B. 52 (4 December 2006); A.B. 52, 2007-2008 Gen. Assem., Reg. Sess. (Ca. 2007).

HIV

Twenty years ago, HIV was probably the most explosive bioethics topic, but today, while still very important, the issues involved are no longer novel. In addition to the law mentioned below, please look in two sections above, "Medical Testing" and "Unconventional Treatment." There are some cases involving HIV mentioned in those sections as well.

Recent Laws and Regulations, July - December 2006

New Jersey. On 19 December 2006, the governor signed a bill establishing a needle-exchange program in six cities. The bill also provides $10 million for state drug-treatment programs. P.L. 2006, c.99; N.J.S.A. 26:5c-25 through 26:5c-25.

CONSCIENTIOUS OBJECTIONS (HEALTHCARE PROVIDERS)

Sometimes in the rush to protect patients' rights, people forget that the rights being protected are individuals' rights; everyone has a

constitutionally protected right to act in accordance with his or her personal moral convictions, even medical professionals. If the right that a patient is exercising requires that someone act to help, then the potential for conflict becomes obvious. In most cases, a healthcare employer can decide, as a condition of employment, whether or not employees will be obligated to perform certain procedures or provide certain information that they might find morally objectionable. The employee can then accept the conditions, renegotiate, or decide to work elsewhere. In situations in which laws have made specific performance mandatory, such as emergency treatment situations, employees and employers have fewer options. If an employer accepts, or the law requires, provisions for medical conscientious objectors, then procedures must be established to accommodate both the objecting medical professional and the patient.

The best way to approach questions of conscientious objections by healthcare professionals is to implement policies for dealing with potential problems before they arrive. Employers and clinical ethics committees need to be aware of the issues involved, educate themselves on their legally permissible options, and then, after creating policies regarding medical conscientious objectors, educate staff regarding those policies.

While several bills on this issue were introduced a year ago or more, none have been introduced or passed within the last six months.

NOTES

1. The term "patient," when not referring to a particular patient, is henceforth used to include the patient and any decision maker appointed either by the patient or by operation of law to act for the patient.

2. This website includes the polling results from 11 polls taken between 1 March 2005 and 27 November 2005, *http://www.pollingreport.m.*

3. Ibid., Fox News/Opinion Dynamics Poll, 1-2 March 2005.

4. D. Shore, ed., *The Trust Crisis in Healthcare: Causes, Consequences, and Cures* (New York: Oxford University Press, 2007).

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The Journal of Clinical Ethics has prepared worksheets and consent forms for authors to use in obtaining informed consent from patients, patients' representatives, and/or patients' families, which may be obtained from the editorial office using the contact information listed at the top of these instructions for authors.

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PEER-REVIEW PROCESS

The majority of articles published in *The Journal of Clinical Ethics* have been subjected to double-blinded peer review. That is, the manuscripts are reviewed by experts who agree to review materials for the journal without remuneration; some of the reviewers are members of the Editorial Board. Members of this Board receive a complimentary subscription to the journal but receive no other compensation.

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The editorial staff welcomes questions and comments, which may be addressed to Leslie LeBlanc, Executive Editor, at the address listed above.

REFERENCES

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1. J.L. Smith, R.M. Miller, Jr., and W.C. Callahan, "Tracking the Virus in Africa: The Etiology of AIDS," Journal of AIDS Epidemiology 124, no. 6 (June 2006): 1147-59.

2. L. Greene and W.K. Nelson, "The Ethics of Care," in Principles of Nursing Science, vol. 2, ed. W.K. Nelson (Plano, Tex.: Nursing Administration Press, 2007): 122-4; T.M. McCall et al., "Cost-Effectiveness v. Total Patient Care: Who Wins?" Health Care Administration Quarterly 6, no. 2 (Summer 2007): 150-6.

3. See note 1 above, pp. 1127-8.

4. Ibid., 1148.

5. Greene and Nelson, "The Ethics of Care," see note 2 above.

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