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At the Bedside

When, If Ever, Should Careproviders Give Moral Advice?

Edmund G. Howe

In this issue of *The Journal of Clinical Ethics*, in "Of More than One Mind: Obstetricians-Gynecologists' Approaches to Morally Controversial Decisions in Sexual and Reproductive Healthcare," Farr Curlin, Sira Dinner, and Stacy Tessler Lindau report that some obstetricians and gynecologists share moral views with patients. For instance, one doctor said, "I can't in good conscience tell [the patient] where to go" to get an abortion. Another said he may tell patients why he believes abortion may harm them.

The question of when — if ever — careproviders should share their own moral views with patients may arise in numerous situations. For example, many careproviders routinely tell their patients what they *should* do to maximize their health. Common examples are telling patients to stop or to reduce their drinking, to eat less, and to stop smoking.[1] Some patients consider these behaviors to be highly enjoyable, and thus *personal* choices regarding how they want to live their lives; as a consequence, patients may see this kind of advice from a careprovider as not only medical, but moral!

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The "medical/moral" advice that careproviders give may go far beyond behaviors such as drinking, eating, and smoking. The doctor mentioned above, who tells patients about the harms of abortion, is an example; careproviders may go further in the advice they give their patients if they believe that they should always treat the *whole* patient, rather than just treating the "disease." Patients may agree: patients may feel offended, in fact, if they find out that their careprovider believed that he or she *could* have helped them by giving advice, but didn't.

Careproviders *and* patients, then, may believe that in some contexts careproviders *should* give moral advice, at least when it could significantly benefit a patient's physical or emotional health. But *should* careproviders share their moral views, and, if so, when? As articles in this issue of *JCE* illustrate, there is controversy regarding this question. Frank Chervenak and Laurence McCullough, in "Professional Responsibility and Individual Conscience: Protecting the Informed Consent Process from Impermissible Bias," answer emphatically, "No." They believe that careproviders who share their moral views may be a "peril" that could "undermine the profession of medicine from within." In contrast are the doctors mentioned above, who feel that they should share their moral views.

Edmund Pellegrino, physician and internationally renowned ethicist, writes in this issue

of *JCE* that physicians must maintain their personal spiritual and moral integrity. He states, "Physicians opposed to abortion are morally entitled to refuse and give reasons for doing so clearly and honestly without demeaning the patient."[2] This would seem to support the tack taken by the first obstetrician-gynecologist mentioned above, who tells patients that it is not possible, "in good conscience," even to refer them to someone else. Those who favor sharing their moral views may do so for a different reason; for instance, they may want to enhance a patient's autonomy, by enabling the patient to have additional views "on the table." These obgyns may want to maximally benefit the patient.

In this introduction, I will discuss whether careproviders should share medical-moral views, and, if they should, how far they should go. I will not describe what careproviders should do, nor where careproviders should "draw the line" along a medical/moral spectrum, with behaviors clearly related to patients' health — drinking, eating, and smoking — on the one end, and behaviors that may affect patients' emotional well-being — including almost any behavior — on the other. Instead, I shall discuss a third option that may enable careproviders to bypass having to make this kind of decision.

In this issue of *JCE,* David Kozishek and Elizabeth Bogdan-Lovis, in "Beliefs, Boundaries, and Self-Knowledge in Professional Practice Careproviders," write that it is possible for careproviders to avoid having to choose between "protecting patients' autonomy from the threat of paternalism" and "defending physicians' rights to follow the guidance of their conscience." Kozishek and Bogdan-Lovis suggest that careproviders may be able to go beyond having to choose between being morally neutral or expressing their moral views; they propose that careproviders can "re-imagine" their relationship with patients as one in which patients and careproviders are able to engage in a moral dialogue that is open and honest enough that careproviders don't have to be concerned with choosing to share moral views. The authors assert that this conceptual shift can replace careproviders' need to balance these two "competing rights" by providing "the moral space necessary" for patients and careproviders to have an "increased mutual understanding instead of resolution of conflicting principles." Is this view realistic? If it is, how could this best be achieved? These are the questions I will focus on in the following discussion.

THE TWO TRADITIONAL ETHICAL OPTIONS

REMAINING NEUTRAL

When careproviders give moral advice, it may unintentionally serve to disrespect and harm patients. This is especially likely when the advice extends outside the usual scope of medical care. Accordingly, careproviders have conventionally believed that they should *not* share their own moral views. Chervenak and McCullough make this clear in the historical introduction to their article. The core deontological and consequential values underlying this traditional neutrality are generally well known. Careproviders who share their views may violate patients' vulnerability, caused by their illness. When careproviders do this, they also may impose their moral views on patients.

When careproviders share their moral views, they may strongly affect patients. Patients may not feel as free to make ethical decisions; for example, patients' decision making may be clouded by anxiety that they previously didn't experience. Their anxiety may be due to new uncertainty or even new guilt. Or patients may feel offended when careproviders share their own moral views; some patients may feel so offended that they won't return. The loss of the patient-careprovider relationship may be *most* critical. Worse still, patients may generalize this negative feeling to all careproviders and avoid other careproviders whom they need to see for other pressing medical reasons.

In addition to these arguments, there are other, more subtle concerns that careproviders should also recognize. First, even when careproviders have exceptional medical knowledge and experience, *these* sources of exceptional expertise *don't* enable them to have better "ethical answers." This is equally true of experts in ethics, who have exceptional skill in ethical *analysis*. This skill doesn't enable them, *either*, however, to determine which of two *reasonable* ethical outcomes is better. This conclusion is, I believe, self-evident from how ethicists typically

respond. That is, even the most skilled ethicists often reach different conclusions. There is a reason for this discrepancy: ethics, as a discipline, provides no method for deciding which of two reasonable ethical answers is more morally valid.[3] For this same reason, it may be problematic for careproviders to share their moral views with patients. The preferable ethical course for careproviders may be to leave moral decisions *entirely up to patients*, as Chervenak and McCullough suggest.

Second, even though careproviders' moral advice may, *in general*, be sound, it may not apply to *any individual patient*. It may not be possible to understand any *one* patient well enough to be able to give advice that "hits the mark." This may be the case, in part, because when persons make moral decisions, they take into account innumerable conscious and unconscious experiences. They may make decisions much as persons fill in a crossword puzzle,[4] that is, they don't rely solely on logic, but also use their intuition. Careproviders may use this understanding of how decisions are made to benefit patients. They can assure patients that they, alone, are the best qualified to make moral decisions for themselves. Patients may not have previously considered themselves as "best in the world" at anything, and careproviders can help patients by imagining a strength that the patients have, and then sharing this with patients. I will discuss this further below.

Third, when careproviders give patients moral advice, it may be degrading to patients if it appears that the careproviders see patients as less deep and complex persons than they are. Gabriele Marcel experienced this when he was working for the Red Cross in France during World War I. He identified missing persons and informed their families. Families contacted him daily, asking him if he had any information about a French soldier or another person. "Nothing," Marcel wrote, "could have immunized me better against the power of effacement possessed by the abstract terms which fill the reports of journalists and historians of the war."[5]

There is evidence that some patients resent careproviders when they give moral advice, even to quit smoking.[6] Thus careproviders should think twice before giving advice, *even when patients ask for their moral view.* I recall a time that I didn't hesitate to share my views, and I still regret it. A patient, an adult, told me that he had spoken "harshly" to his parents, and asked me if I thought what he'd said was "cruel." I thought that if I hesitated, the patient would think that I was hedging, and this would be worse than whatever I said. Well, it wasn't. I said, "Well, *yes*!" and the patient was floored. He is still my patient, but my responding as I did remains a source of distrust to this day.

SHARING MORAL VIEWS

Careproviders may enhance patients' autonomy and benefit them by giving patients new food for thought. Such advice may be literally lifesaving. An example is when careproviders tell patients that they should stop or reduce their drinking.[7] Patients who drink too much risk losing their marriage, job, and even their life. Careproviders may tell patients to stop or cut back on drinking even in an ER setting,[8] *even when careproviders have no prior patient/careprovider relationship and have little time*. It is obvious that drinking strongly affects patients' health, but careproviders may be able to give advice that is less concerned with physical safety but may still benefit patients greatly.

For example, what if the philosopher Martin Heidegger had met with his physician prior to deciding to join the Nazi Party? That Heidegger made this and similar choices later harmed his reputation and, for many, the significance of his work.[9] Let us suppose that Heidegger's physician saw Heidegger's choice as immoral, gave him advice, and thus enabled Heidegger to change. The physician could have regarded this advice as affecting Heidegger's emotions, and, although it would have been outside the scope of "usual medical care," it would have benefited Heidegger immensely.[10]

ATTITUDES CAREPROVIDERS MUST ACQUIRE AND CONVEY

Kozishek and Bogdan-Lovis propose that careproviders and patients can acquire the ability to talk about moral issues openly. I recommend, to accomplish this, that careproviders acquire and convey certain *attitudes.* These attitudes can be best modeled by imagining an ideal family, since family members tend to care for

one another to an exceptional degree. Ideally, family members share experiences spontaneously, and don't have first to ask what is ethically justifiable. This is what Kozishek and Bogdan-Lovis propose. Is such spontaneity possible for careproviders? I offer an experience of my own in this regard.

I saw a patient who had been in the intensive care unit recovering from a brain infection. During this time, his wife and children hadn't been able to visit him. When I saw him, he had recovered and was making plans to return home. He told me he planned to stop and visit an old friend whom he hadn't seen in many years on his way home. When I heard this I winced, because I imagined how his wife and children might feel if they learned that he hadn't come home directly to them, and I told him this, spontaneously. "Thanks," he said. "I'd never thought of that."[11] He went home directly, and later told me that he was *very* glad that he had.

I spontaneously told the patient what I thought. This anecdote conveys how careproviders who want to establish a re-imagined relationship might respond to patients. When I winced at hearing the patient's original plan to visit a friend rather than go right home, I responded to "just a feeling." Careproviders who would like to respond to their patients as a member of an ideal family might do this, too. The three most important attitudes that careproviders can adopt are best exemplified by how ideal parents would respond.

First, children need to know that their parents unconditionally love them and that, *regardless of what they do*, their parents won't abandon them. Ideal parents may be the *most* loving when their children are at their very *worst*. Careproviders may have to do this, too. In the next section I will provide an example of how careproviders can go the extra mile for patients.

Second, children need their parents to see their strengths. How might ideal parents do this? Let us suppose, here, that a child wants to join a baseball team but his (or her) parents anticipate that the child will be, by far, the worst player on the team. The parents could say before their child joins the team, "You know, we are proud that you want to be on the team. Even if you are the worst player on the team, we will be proud. In fact, if you are, we will be *even prouder* of you than if you are the best player." "Why?" the child might ask, "Why might you be even *prouder*?" "Because," the parents might say, "if you are the *best* on the team, that would be easy. What is much harder is to be the worst, but to still play!" In the next section, I will describe an intervention in which careproviders can tell patients about a strength they have.

Third, children need to know that parents know and respect that they have *different* values. This may be most difficult for parents, because they have the competing interest in "instilling" in their children good moral views. Consider, however, this instance. An adult daughter comes to her parents and tells them she's pregnant. Suppose that her parents believe that she might be considering an abortion. How, ideally, might they respond? They might say, even if they oppose abortion, "We know that with *your* strengths, you will do well *whatever* you decide. Please tell us any way we can help." Why might parents say this? Because this may be the only way they can expect to be able to maintain open communication with their child when she needs their support.

This may be the case also for careproviders. If careproviders do share their moral views with patients, patients may choose not to share their medical concerns with physicians in the future, but share with someone else instead. Given this risk, how can careproviders not share their moral views, but, at the same time, help patients change their moral views? In the next section I will consider how careproviders can do this by only asking questions.

If careproviders acquire these attitudes, they will treat patients more like their own family members. This may be a degree of commitment that many careproviders do not want to establish, but it may be necessary, to establish the kind of re-imagined relationship that Kozishek and Bogdan-Lovis describe.

SPECIFIC INTERVENTIONS

When careproviders have a strong relationship with their patients, they may be able to benefit the patients to a greater extent, because patients may be much more likely to listen to and reflect on what their careproviders say. An example of this is when careproviders gave pa-

tients advice that they should lose weight. Some patients viewed their careproviders positively or negatively — not on the basis of what their careproviders said — but on the basis of whether they thought that their careproviders felt empathy toward them.[12] If there is a strong relationship, careproviders may be more able to preserve relationships with patients should they give advice and the patients feel offended. Careproviders can't know in advance how patients will respond. Thus, the only way is to "minimize damages" when they give advice by trying, beforehand, to form strong relationships. Sometimes, however, careproviders do not feel empathy for their patients.[13] When this happens, perhaps it is not possible to establish the kind of relationships these patients need. The interventions I describe below don't require careproviders to always feel empathy, however, careproviders can use them at any time, including when they don't feel as empathic as they might want.

GOING THE EXTRA MILE

The first intervention involves careproviders taking an opportunity to go the extra mile for patients. Careproviders can imagine and then take the opportunity to do more than might be expected, from taking slightly more time to benefit a patient or acting as a patient's advocate. An example of an intervention that is not particularly burdensome is to knowingly accept some amount of greater stress to benefit a patient in a way that is not essential to his or her care. I think of a junior staff member who told me of the stress he experienced whenever he chose to "lobby" his attending on behalf of his patients. Some patients might conclude that they would do without the benefit if the junior staff member was not there to lobby for them.

An example of an intervention requiring somewhat more burden is for careproviders to make themselves more available by giving patients their home or cell phone number. I remember, in this regard, being at a dinner with a careprovider who took a phone call from a patient and missed the main course and dessert. She told me that she gave her patients her cell phone number because she thought that this gave them better care. I have considered her effort to be the state of the art ever since.

A third example that requires a great deal of burden is when careproviders go against their professional boundaries to serve patients. A careprovider may have the opportunity to do this, for instance, when a medical service can't schedule a new appointment for a patient for months, because it has an extremely long waiting list. Careproviders in this situation may get better results for such patients by contacting the service themselves. They may tell the service that unless the service can "fit the patient in" sooner, they fear that it could become grounds for a patient to bring a suit, because health problems that could be prevented with an earlier appointment might ensue. This may cause the service to make an earlier appointment.

All three of these interventions would be things that careproviders would do for members of their family.

To make extra efforts like this, careproviders first must be able to imagine them. They can do this by trying to imagine, with every patient, what they would do if the patient were a member of their family. Beyond this, there is a more radical intervention that careproviders should habitually perform: if they imagine something they would do — but won't or can't — they should explain to their patients why they won't or can't. Doing this conveys to patients, even when careproviders don't feel particularly empathic, that they are committed to patients, at least to this extent. This is what they would do for their families.

There are downsides to going the extra mile. First, opportunities may simply not exist for some patients. Second, when careproviders do go the extra mile, they may not be able to tell some patients what they have done, as some patients may suspect that their careprovider is merely trying to impress them, and it is not possible to strengthen the relationship in this way. Third, the strain making extra efforts may cause careproviders to resent patients, consciously or unconsciously. Such resentment can easily occur outside our awareness. I recall, for example, a time that one of my patients acted badly and, as a result, spent the night in jail. I remember feeling only "good" when I learned he would be released after only one night. Afterward, it dawned on me that I could have easily tried to call the patient while he was in jail. I would

have done this for a family member. In retrospect, I believe that I didn't call because I unconsciously felt angry. As a result, I was not there when the patient needed assistance most.

UNDERSTANDING AND COMMUNICATING A STRENGTH

Leston Havens is a psychiatrist who has directed the training of Harvard psychiatric residents for decades. He has pioneered approaches that careproviders can use to establish strong relationships, even when there is no prior relationship and little time.[14] Once grasped, Haven explains, these steps can be "accomplished with surprising speed."[15] In general, careproviders must first try to "meet the patient." Careproviders must "seek simply to think, feel, and experience what is happening as the patient is thinking, feeling, and experiencing it."[16]

The first of these steps is to understand. This enables patients to see their careproviders more as an ally. If careproviders can then share with their own moral view, patients may be more likely to see the careprovider as trying to help them. One way in which careproviders may be best able to understand patients is to scan their own experience to find a feeling like theirs. For example, I once was trying to understand the feeling of a patient who wanted to die. I was able to recall being on a whale watch ship near Maine, when I felt such extreme nausea that I thought, if this doesn't stop, I want to die.

Once a careprovider understands, the next step is to share the understanding with the patient. As Havens says, this "understanding must be *communicated back to the patient* for the alliance to begin. . . ."[17] Careproviders can then check whether they truly understand; this also conveys to patients that careproviders want to understand. A good way to see if careproviders understand is to self-disclose. This is an unusual intervention, but it can have exceptionally positive effects.[18] Self-disclosure may be particularly important when the patients are from a minority culture, because they may especially want to know that their careprovider is a "real person" before they develop trust.[19] There are many different types of disclosures that careproviders can make; they might disclose a feeling that echoes the patient's experience. Careproviders might say, for example, "When I was in a situation like yours, I felt scared, especially because I, too, didn't know how things would turn out for me."[20] Self-disclosure may be particularly beneficial because it may enable patients to "normalize" what they are experiencing.[21] The effect may be quite profound, as illustrated in this case. A patient avoided doing something he'd needed to do for years and now had crippling anxiety as a result. He felt depressed and suicidal, particularly because he knew he had brought this all on himself. I assured him (at greater length than related here), "I do this too. And then I feel enraged at myself that I've caused my own problem." When I finished, the patient smiled. "Until now, I've seen you as someone who had it all together," he said, "and believed I could never be like you. Now I know I *can*."

The third step that Havens suggests is to help the patient find a strength. Havens writes, "The widespread concentration on pathology . . . is not only demoralizing, but *it deprives clinicians of an ally*."[22] He and a colleague write elsewhere, "The patient needs to feel that the two of us, together, with our *strengths*, are facing this predicament."[23] Careproviders can *always* find such strengths. To best do this, careproviders may find it helpful to ask themselves what they imagine their patients are trying to achieve.

An example illustrating how careproviders can always find a strength is a patient I saw who felt inordinately emotionally attached to inanimate objects. I realized that this patient had exceptionally warm relationships with all of the members of her family. I said, "Of course! How could this *not* be! You have the most exceptional capacity to empathize. This is why, I think, that you have such exceptionally close relationships with your husband and children. Your capacity to care has simply spilled over!" The patient said that she was now able to see herself as gifted. Moreover, for the first time, she felt *equal.* She has flourished. Whenever persons have vulnerabilities, they also have corresponding strengths.

ASKING, NOT TELLING

Recent advances in medical knowledge indicate that the best way to treat persons who drink to excess is *not* to tell them what is "wrong with them," rather, careproviders should ask patients what they see as the pros and cons of their

drinking.[24] This same approach also has been used successfully with patients who have what might be called "highly destructive" moral or religious views. Most importantly, this approach has enabled patients in these situations to make not only new choices that were beneficial to them, but choices that were still within what *they* viewed as *their own* moral or religious framework.

Destructive religious views might lead patients to refuse lifesaving treatment because they feel that they should be punished; or they may lead patients to "disown" an adult child because the child is gay, or to stay in a marriage with a partner who beats them. How is it possible to help patients with these beliefs? Griffith and Graby write, "The most useful questions are often those in which the clinician in essence lends . . . to the patient the clinician's [insights] . . . by embedding them within questions."[25] More specifically, careproviders can ask patients indirect questions, for example, "What do you think *God* would think in response to what you are doing?" or "What do you think you would do if you *didn't* think that God had this view?"

Here is an example of how such indirect questions may be beneficial. A patient I saw was feeling despair after her mother died. She felt this way, she said, because she believed she could never be even "half the person" her mother had been. I asked, "What would *your mother* say about this?" She responded, suddenly brighter, "Oh, *she* would strongly disagree with me. *She* would say that I am just as worthy as she is, because I, too, have a wonderful family and friends."

I was almost moved to tears by her account of her mother's wisdom, and I told her so. She said, "Maybe I'm not such a failure after all."

CONCLUSION

In this introduction I've pointed out extremely strong reasons that careproviders should *not* share their moral views with patients. On the other hand, I've also pointed out that if careproviders do share their views, they may enhance patients' autonomy and benefit them. Whether or not careproviders do this, and the degree to which they may help patients depends on whether they have a prior, strong relationship with their patients.

To foster strong relationships, careproviders may have to treat patients almost as they would treat members of their own families. I have also indicated how careproviders can establish such relationships: going the extra mile — or telling patients why they can't or won't go the extra mile, understanding patients, telling patients about a strength that they have, asking patients questions about their moral views.

What should careproviders do? The last word on this should be Lester Havens's. He states that our patients need us "to risk being extended in how we think and how we work . . . if we are careful to follow the patient, and do not attempt to lead, we can afford to venture beyond the familiar."[26]

NOTES

1. L.I. Solberg, M.V. Maciosek, and N.M. Edwards, "Primary Care Intervention to Reduce Alcohol Misuse/Ranking Its Health Impact and Cost Effectiveness," *American Journal of Preventive Medicine* 34, no. 2 (February 2008):143-52; K.I. Pollak et al., "Empathy Goes a Long Way in Weight Loss Discussions," *Journal of Family Practice* 56, no. 12 (December 2007): 1031-6; T. Pilnick and T. Coleman, " 'I'll Give Up Smoking When You Get Me Better': Patients' Resistance to Attempts to Problematise Smoking in General Practice (GP) Consultations," *Social Science and Medicine* 57, no. 1 (July 2003): 135-45; J. Litt, "How to Perform Effective Smoking Cessation Advice in Less than a Minute Without Offending the Patient," *Australian Family Physician* 31, no. 12 (December 2002): 1087-94.

2. E.D. Pellegrino, "Commentary on 'Of More than One Mind'," in this issue of *JCE.*

3. An example of this is the conflict between the values of the sanctity of life and of relieving a patient's suffering. These premises are well summarized in A.L. Caplan and E.J. Bergman, "Beyond *Schiavo,*" *The Journal of Clinical Ethics* 18, no. 4 (Winter 2007): 340-5; and A. Fiester, "Mediation and Moral *Aporia*," *The Journal of Clinical Ethics* 18, no. 4 (Winter 2007): 355-6.

4. S. Hack, *Evidence and Inquiry* (Malden, Mass.: Blackwell Publishers, 2001), 84.

5. G. Marcel, *The Philosophy of Existentialism* (New York: Citadel Press, 1963, written in 1947), 199.

6. Pilnick and Coleman, " 'I'll Give Up Smoking When You Get Me Better'," see note 1 above; K. Treadway, "The Code," *New England Journal of Medicine* 357 (2007): 1273-5.

7. Solberg, Maciosek, and Edwards, "Primary Care Intervention to Reduce Alcohol Misuse," see note 1 above.

8. R. Asseltine, "The Impact of Screening, Brief Intervention, and Referral for Treatment on Emergency Department Patients' Alcohol Use," *Annals of Emergency Medicine* 50 (2007): 699-710.

9. Heidegger spoke to a friend "at the turn of 1931-2," and this friend then recorded in his diary that Heidegger was becoming a National Socialist, like his wife. "I would never have believed it," the friend comments. R. Safranski, *Martin Heidegger,* trans. E. Osers (Cambridge, Mass.: Harvard University Press, 1998), 227.

The theologian Reinhold Niebuhr said, "One of the most fruitful sources of self-deception in the ministry is the proclamation of great ideals and principles without any clue to their relation to the controversial issues of the day." R. Niebuhr, *Leaves from the Notebook of a Tamed Cynic* (New York: Harper & Brothers, 1930), 191-2, cited in D.R. Davies, *Reinhold Niebuhr: Prophet from America* (New York: MacMillan, 1948), 13.

10. Heidegger had a "physical and mental breakdown" in the spring of 1946. He said that he had "broken down" at the " 'inquisitional hearing' " in December 1945. Safranski, *Martin Heidegger,* see note 9 above, p. 351.

11. It may be interesting to note here that some persons who have damage to their brains may tend to make decisions more on the basis of utility than on other values. They may, for example, take *less* into account their own or others' feelings, much as this patient did in this case. M. Koenigs et al., "Damage to the Prefrontal Cortex Increases Utilitarian Moral Judgments," *Nature* 446 (19 April 2007): 908-11.

12. Pollak et al., "Empathy Goes a Long Way in Weight Loss Discussions," see note 1 above. Some patients might assume this, for instance, if they saw that their careproviders were themselves overweight.

13. Should careproviders take time when a patient in the hospital dies to "formally mourn"? See Treadway, "The Code," see note 6 above.

14. L.L. Havens, "The Best Kept Secret: How to Form an Effective Alliance," *Harvard Review of Psychiatry* 12 no. 1 (2004): 56-62.

15. Ibid., 57.

16. L.L. Havens and S.N. Ghaemi, "Existential Despair and Bipolar Disorder: The Therapeutic Alliance as a Mood Stabilizer," *American Journal of Psychotherapy* 59, no. 2 (2005): 137-47, p. 138.

17. Emphasis is in Havens. Havens, "The Best Kept Secret," see note 14 above, p. 56.

18. S. Knox and C.E. Hill, "Therapist Self-Disclosure: Research-Based Suggestions for Practitioners," *Journal of Clinical Psychology* 59 (2003): 529-39, p. 529. I am indebted to my daughter, Chelsea Howe, for referring me to work by Clara Hill.

19. Ibid., 535.

20. Ibid., 530.

21. Ibid., 531.

22. Havens, "The Best Kept Secret," see note 14 above, p. 57.

23. Havens and Ghaemi, "Existential Despair and Bipolar Disorder," see note 16 above, p. 142.

24. This is known as motivational interviewing. It is now used in numerous fields. See, e.g., B. Everett et al., "Pragmatic Insights into a Nurse-Delivered Motivational Interviewing Intervention in the Outpatient Cardiac Rehabilitation Setting," *Journal of Cardiopulmonary Rehabilitation and Prevention* 28, no. 1 (January/February 2008): 61-4.

25. J.J. Griffith and L. Graby, "Brief Psychotherapy at the Bedside: Countering Demoralization From Medical Illness," *Psychosomatics* 46, no. 2 (March - April 2005): 109-16, p. 111.

26. Havens, "The Best Kept Secret," see note 14 above, p. 61.

Features

Of More than One Mind: Obstetrician-Gynecologists' Approaches to Morally Controversial Decisions in Sexual and Reproductive Healthcare

Farr A. Curlin, Shira N. Dinner, and Stacy Tessler Lindau

INTRODUCTION

The American College of Obstetricians and Gynecologists notes that obstetrician-gynecologists (ob/gyns) are presented with "complex ethical questions" related to sexual practices, contraception, treatment of infertility, pregnancy and termination of pregnancy, and reproductive genetics and that "it is important for physicians to improve their skills in addressing ethical decisions."[1] At stake with respect to physicians' ethical decisions are both patients' access to legally permitted medical interventions and physicians' integrity in view of personal and professional ethical commitments. Yet despite continuous debates in academia,[2] law,[3] policy,[4] and the popular media,[5] little is known about how ob/gyns deal with these complex issues in the decisive arena of the clinical encounter.

Questions regarding how ob/gyns *should* navigate moral complexity relate to a long-standing debate regarding whether, and to what extent, physicians ought to influence patients' medical decisions. This debate ranges over many subjects and invokes a variety of ethical principles and norms. Yet the heart of the debate concerns what it means to both seek patients' good and respect patients' autonomy when making medical decisions. On the one hand, few today would defend physicians' paternalism as an ethical model for decision making (apart from medical emergency or a patient's incapacity to consent). Paternalism can violate a patient's right to self-determination,[6] and problematically assumes that the physician and patient share the same criteria for judging which medical decision is best.[7] Such criteria are ambiguous in a pluralistic culture, particularly with respect to morally complex issues like sexual and reproductive healthcare.[8]

On the other hand, bioethicists from a range of perspectives have argued that the pendulum has swung too far away from paternalism toward a form of patient autonomy that markedly restricts the physician's moral agency and re-

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sponsibility and at times requires physicians to violate their own sense of moral integrity.[9] Quill and Brody, for example, critique models in which "the physician should objectively answer questions but avoid influencing the patient to take one path or another, even if the physician has strong opinions or if the patient asks for advice."[10] Such models, they suggest, "make the physician an obstacle to rather than a resource for medical decision making."[11]

Between the two poles of overweening paternalism and unmitigated patient autonomy, bioethicists have proposed frameworks for decision making in which the patient makes the final choice, but that choice is informed by a dynamic interaction in which patient and physician exchange their ideas, experiences, and values.[12] It is not clear how these models work in the context of sexual and reproductive health concerns, in which the patient's experience is often complicated by vulnerability, fear, anxiety, and even shame.

Despite the moral complexities that are central to ob/gyn practice, little is known regarding how ob/gyns go about medical decision making in areas of ethical complexity and whether current patterns reflect particular ethical ideals. This study aims to identify the ways that practicing ob/gyns navigate the intersection of their own convictions, patients' preferences, and professional expectations when they address ethically complex issues in sexual and reproductive healthcare.

METHODS

We conducted one-to-one, in-depth, semi-structured interviews with a purposive sample of 19 practicing ob/gyns. Semi-structured interviews are often used to explore individuals' situated and complex decisions and experiences in order to better understand how they explain and justify those decisions and experiences.[13] We began with informal contacts and used snowball sampling (a method in which respondents identify additional respondents) to deliberately recruit practicing ob/gyns from a spectrum of geographic regions and moral traditions (religious and secular).[14] As the study progressed, a mainstream approach emerged that was endorsed by the majority, but not all, of the participants. To deepen the investigation of alternative approaches, we deliberately sought, in the latter half of the study, to interview physicians who were more or less critical of this mainstream approach. Qualitative researchers commonly employ such *purposive* sampling strategies to define the dimensions along which the concepts of interest vary.[15]

After informed consent was obtained, interviews were conducted in person or by telephone. These interviews lasted an average of one hour and were designed, as Crabtree notes, to "elicit narratives detailing the informant's conception of the identified domains."[16] Rather than asking ob/gyns about their general approach to medical decision making, interviewers asked participants to focus on those areas of clinical practice that they find ethically complex or problematic. Our interview guide, shown in table 1, was constructed and revised based on insights from an in-depth evaluation of the

Table 1. Interview Guide

Question 1: "Do you encounter clinical situations in your practice that you find ethically complex or problematic?"
If physician responds "No," ask specifically about:
- Contraception
- Preconception counseling
- Abortion
- Maternal-fetal medicine
- Sexuality

If physician responds "Yes," ask the following, as indicated by the context:
- "What kinds of situations are these?"
- "How do you deal with or approach such situations?"
- "What do you think are the patient's expectations in that setting? Are those fair?"
- "What do you think are the expectations of the profession of ob/gyn for how you should respond in such settings? Are those fair?"
- "How do you deal with conflict between your own convictions, professional or colleagues' expectations, and patients' wishes?"

Question 2: "How would you describe your own religious convictions or commitments, if any?"
Question 3: "How do you think your religious commitments [or 'moral commitments' if physician not religious] shape your approach to the care of patients' sexual and reproductive health concerns?"

literature, pilot interviews, and review by expert colleagues.

Interviews were tape-recorded and transcribed verbatim. Transcripts were analyzed by employing an iterative process of textual analysis in the following manner. After the fifth interview, SD and FC independently coded the full transcripts by identifying and labeling discrete units of text that referred to one or more concepts relevant to the study purpose. They met together subsequently to develop consensus and to create a working codebook of categories, subcategories, and concepts. A third investigator (SL) independently coded two manuscripts to check for consistency and adequacy of the codebook. Utilizing qualitative analysis software (Atlas TI – Scolari/Sage), all prior and subsequent transcripts were coded according to the codebook formulations. At various points throughout the study, the three investigators employed an inductive approach to the data to identify emergent themes, relationships, and patterns among them. Following the principle of *constant comparison,* the investigators examined each new transcript in relation to the prior ones to ensure that the codebook and our evolving interpretation of the findings reliably followed from the data.[17] Finally, representative quotations were chosen to tangibly demonstrate the themes identified; these are noted parenthetically in the results section by participant number using the notation (Px), where "x" corresponds to the participant number as indicated in table 2.

To strengthen the credibility of the findings, strategies commonly used in qualitative research were employed.[18] The authors, before data collection and during analysis, candidly acknowledged to one another their own judgments about how physicians should navigate areas of moral complexity in the clinical encounter and then engaged their disagreements as resources to prevent one-sided analysis.[19] Among the authors, views spanned the spectrum reflected in the

Table 2: Characteristics of Participants

Participant	Age	Gender	Practice Setting	Region	Religious Affiliation
P1	66	Male	Private	West	Roman Catholic
P2	45	Male	Academic	Midwest	Jewish
P3	66	Male	Private	Midwest	Jewish
P4	72	Male	Private	Midwest	Jewish
P5	42	Male	Private	Midwest	Roman Catholic
P6	46	Male	Private	Southeast	Evangelical Christian
P7	63	Male	Religious hospital	Midwest	Methodist
P8	39	Female	Private	Southwest	Protestant
P9	57	Male	Private	Midwest	Jewish
P10	61	Female	HMO	Northeast	None
P11	33	Female	Academic	Northeast	Hindu
P12	44	Female	Private	Northeast	Protestant
P13	39	Female	Private	Northwest	None
P14	60	Male	Religious hospital	Midwest	Protestant
P15	66	Male	Private	Midwest	Roman Catholic
P16	50	Male	Private	Northeast	Roman Catholic
P17	44	Female	Private	Midwest	Evangelical Christian
P18	45	Male	Academic	Midwest	Roman Catholic
P19	42	Female	Private	Midwest	Roman Catholic

The interview numbers in this table correspond to those cited in the text. Religious affiliations are as defined by the participants themselves. To protect confidentiality, the order does not correspond precisely to the order in which interviews were conducted, and the ages of participants have been altered at random by +/- 0-3 years.

study sample. Bringing to bear multiple perspectives in data analysis and interpretation strengthens the credibility of the findings and is known as investigator *triangulation*.[20] Additionally, interviews were conducted until *theoretical saturation* was reached — a point after which subsequent interviews produced no substantial new themes.[21] This study was approved by the University of Chicago Institutional Review Board.

RESULTS

The characteristics of participants are listed in table 2. All participants described patients as the *final* decision makers in contexts of moral complexity. Yet participants disagreed about the proper scope of physician involvement in the decision-making process, particularly when patients and physicians disagreed about what should be done.

The majority of participants held that, in contexts of moral complexity, patients should ideally make informed, deliberate, personal decisions that are not unduly influenced by others, particularly physicians. We term this the *mainstream approach* because even its critics agreed that it predominates within contemporary ob/gyn practice. Ob/gyns who endorsed this ideal sometimes suggested that the good of the patient is either difficult to know or can only be known by the patient: "What may be right for one person may not be right for another. The thing about medicine is that there's usually no right or wrong answer" (P12). In light of ambiguity about the patient's good, the ob/gyns should avoid making moral judgments: "As a provider or physician, that you are called to offer service or help people and not judge or instruct them morally" (P12). Ob/gyns should rather "inform patients to the full extent" (P11) by providing all pertinent medical data and by disclosing all available medical options. As one noted, "I would just tell [the patient] that it's [prenatal genetic screening] available, give her the statistics . . . and let her decide" (P16). If a physician cannot provide the service requested, then he or she is "obliged to refer [the patient] and let her know about another doctor out there who might be willing to help" (P2).

Further emphasizing patient autonomy, these ob/gyns said that they make efforts to prevent undue outside influences from impinging on patients' voluntary decisions in areas of moral complexity. At times, they question the influence of patients' family members or sexual partners: "I asked her, 'Why are you doing this [seeking an abortion]? Is this for you or for your partner or for other people?' . . . she was being swayed by her family and her partner's family" (P12). And although these ob/gyns "help people explore their own feelings and evaluate the pros and the cons," they try to do so "without directing them one way or to any particular decision" (P13). Even if asked for advice (for example, about selective reduction of a multiple gestation), one explained, "I would put the ultimate decision back up to them. I probably would not say what I would do" (P11).

Ob/gyns who endorsed the mainstream approach, as a general rule, did describe situations in which they could not go along with patients' requests. For example, if a patient requests something that the physician believes will cause medical harm, the physician might invoke the responsibility of the medical profession to determine which interventions are medically indicated: "There certainly are limits. You certainly don't just do whatever the patient requests or demands if it's something that you consider totally medically inappropriate" (P14). Or, if a patient's request violates a widely held societal norm, the physician might invoke that norm. For example, several implied what one physician noted regarding sex selection: "I do draw the line at toying or playing with nature and biology" (P11). In other contexts, some appealed to the moral authority of the profession, noting that colleagues and/or the standards of the American College of Obstetricians and Gynecologists (ACOG) would not support what the patient requests.

Yet those who were more supportive of the mainstream approach noted that cases in which they refused patients' requests were exceptions to the general rule of honoring patients' wishes, and they typically added that they would offer to refer a patient to another physician if they could not come to agreement. The following quotation demonstrates the way that patient

autonomy was emphasized as the ideal even when it was not fully carried out: "I realize this is an amazingly paternalistic thing to think [that a 19-year-old unmarried woman should not have in vitro fertilization], and I don't usually think like that. . . . As a general rule, my default is always to be the exact opposite. I'm here to provide services as long as they're not hurting anybody" (P2).

For some ob/gyns, boundaries to the mainstream approach arise in the most routine aspects of patient care. In our sample these were, with few exceptions, Roman Catholic or Evangelical Christians who experience frequent tensions between their patients' wishes and their own convictions about sexuality and reproduction. These ob/gyns talked about being obligated to make judgments about which medical decisions are more and less morally right, and they described their efforts to influence patients to make choices that the physician believes are in the patient's best interest. They justified their divergence from the mainstream approach by challenging its premises or reinterpreting its implications.

For example, several said that they fulfill the obligation to fully inform patients about medical options by talking to patients about the ostensible harms of those medical decisions that the ob/gyn judges to be immoral. One said that, unlike "many doctors," he informs patients that abortion may hurt them in the "long term" by influencing "depression, suicide rates, cancer, possible risk of infertility in the future, emotional and mental distress, as well as social distress between the partners" (P5). These ob/gyns often do not see their own influence as a threat to the patient, but rather as a force that countervails other societal pressures. They therefore challenge influences "from people, from society, and from [patients'] partners" that may lead patients to do something that the physician does not believe "is in their best interest" (P19).

Although they conceded that patients make the *final* decisions, these ob/gyns do not always avoid being directive in their counsel. One described his approach this way: "I think one of our jobs is to help counsel patients, to uncover for them the truth, to point out to them the lies that they are subjected to, or to make sure that they are informed before they end up going down a wrong course of action" (P18). Others said they probe patients' motivations and thought processes: "I ask them questions. How do you feel about it? What do you think? . . . And then I sometimes ask, 'Are you interested in any suggestions?' "(P6).

Paradoxically, these ob/gyns at some points justified the influence of their own biases, and at other points said that they make every effort to be unbiased. For example, one ob/gyn said, "I would work very hard to keep my life bias [referring to the topic of abortion] out of this discussion, but . . . the flaw in the system, from my personal perspective, is that the politically correct bias isn't represented as a bias. It is totally inherent in the system . . . I am getting more comfortable saying, 'Well, by the way, I'm in the minority here, and I hope that this won't affect my ability to care for you, but my bias is on the other side of this issue' " (P17).

When they are not able to persuade patients, these ob/gyns may clarify their boundaries by explaining to patients why they will not provide or participate in what the patient has requested. Some will make their proscriptions explicit up-front. For example, an ob/gyn who will not prescribe contraceptives said, "When [patients] call to make an appointment, they are told . . . 'You should know that she does not prescribe the birth-control pill [or] Depo [depot medroxyprogesterone] shot [or] place IUDs . . .' We actually rattle all that off — the whole laundry list" (P19). Yet if a patient requests a medical intervention that the ob/gyn does not support, the ob/gyn may refuse to provide a referral for the patient. Such refusals were described most often in reference to abortion. One ob/gyn explained, "I've told patients, 'You are doing something I don't agree with, so I can't in good conscience tell you where to go' " (P8). Others say they defer problematic requests by having the patient talk with or be seen by a colleague. One described her ambivalence about telling patients to talk to someone else in the office: "It is an indirect referral . . . it is a line I have to draw, but it is also living in an information era. They can easily access this information" (P17).

All of the supporters of the alternative approaches eventually described the religious roots of their objections to certain medical de-

cisions. Yet they tended to initially justify their approaches in nonreligious and even morally neutral terms. When they did articulate moral judgments, these ob/gyns generally justified them by reference to uncontroversial concepts, such as a commitment to the patient's medical good, the physician's obligation to do no harm, or the Hippocratic Oath, rather than by reference to particular religious commitments or traditions. As the following quotations demonstrate, this pattern at times seemed to obscure the sources of the physicians' counsel.

> [Talking to patients about sexuality] is easy because the science works for me. I don't have to say anything about my values. (P17)

> Even though I'm a Christian, [patients] are not coming to see me for my faith. They are coming to see me for medical care, so I try and keep it on a medical level. (P19)

> It is not very often that I have to bring in my Catholic beliefs although that is definitely what forms my beliefs. (P5)

DIFFERENT APPROACHES YIELD DIFFERENT CONCLUSIONS

Participants disagreed sharply regarding what patients expect from their physicians in morally complex clinical scenarios. Those who more strongly endorsed the mainstream approach said that patients neither expect nor desire moral counsel from their ob/gyns. Several noted what one expressed in this way: "I haven't ever been in a situation that I can remember that the person didn't already have her mind made up [about having an abortion] when she came in" (P2). Others commented that even undecided patients would prefer for their physicians to stick to the medical facts and empathically support the choice the patient makes: "[A patient expects me] to outline the options, to go over the complications, to let her and her significant other know that ultimately it's their decision, not my choice" (P3).

Those who believed that patients do not expect directive counsel also believed that patients are unlikely to be influenced by such counsel, particularly regarding sexual behaviors. Noted one, "Chances are no matter how long I talk to [the patient] and tell her what I think is important, she's still going to have sex, and she's still going to get pregnant, and she's still going to get sexually transmitted diseases" (P2). Most participants focused instead on preventing medical harms that may accompany sexual activity: "When they do get involved with multiple partners then I feel I do need to counsel them. I talk to them about protection for pregnancy and sexually transmitted diseases" (P7).

Physicians who challenge patients about their sexual behavior were more ambivalent about what patients expect. They acknowledged that patients are often surprised — "They tell me that no one has ever had this discussion with them" (P18) — and that some women are unlikely to change their sexual behavior regardless of what her physician says. Yet several argued that many patients are looking to their physicians for directive counsel. One described his perception this way: "I think most of them are looking for guidance, direction . . . and truth in an ethical situation. They're looking for insight . . . and help. They are in a situation and they are coming to you saying, 'What would you do?' " (P6). Others said that even when patients were not looking for advice, their counsel "has caused some patients to take a hard look at some of the decisions that they have made" (P5). As such, they expect to influence those who are "on the fence," if not those who have "made up their mind" (P19).

Across the board, participants seemed cautious to avoid the impression that they were *imposing* their values on their patients or that they were acting without compassion. Those who followed the mainstream approach often commented that they would not make or disclose moral judgments about patients' decisions, because to do so would be "judgmental" (P2, P3, P4, P9, P12, P13), and a breach of professional boundaries. One noted, "I think that for a physician to superimpose his or her moral standing on that patient is not the right thing to do professionally" (P10).

Supporters of alternative approaches tried to distinguish making moral judgments from lacking compassion toward patients. They justified their approaches as consistent with a commitment to the patient's long-term good (P5).

One ob/gyn invoked a religious concept to express an idea that several mentioned in other terms: "You are your brother's keeper to a certain extent . . . and when you see your brothers and sisters going the wrong way . . . you have an obligation, I believe, to at least voice your concern about that behavior" (P18). Some supporters of the alternative approach argued that they were not imposing their values on patients, but rather were trying to live out their own commitments with integrity: "Just as I do not ask my patients to compromise their morals and ethics, I will not compromise on mine" (P18).

All participants said that they willingly continue to care for patients regardless of moral disagreements, even after patients go elsewhere to obtain a service that the ob/gyn has refused to provide. Yet two ob/gyns did note that they had found it difficult at times to care for patients who had had an abortion. One described a conversation with such a patient the following way: "I told her . . . 'I'm having a hard time with this. I'll take good care of you. However, if I feel like I cannot act competently, I'll have you talk with one of my partners.' We've worked through it, but I thought my job as her physician was to let her know that I might have some issues, that we would have to see how it goes" (P19).

Supporters of alternative approaches said that, for the most part, patients have been "understanding" (P5) and "respectful" (P19) regarding their boundaries and "grateful" (P17) to hear their opinions. Yet they acknowledged that some patients avoided them altogether and that, as one put it, "The [patients] that transfer care are the ones that are upset" (P19).

IMPLICATIONS FOR THE PROFESSION OF OBSTETRICS AND GYNECOLOGY

Both subscribers to and critics of the mainstream approach to morally complex medical decisions agreed that the latter are in the minority among ob/gyns. The critics said that at times they feel ostracized from and alienated by the rest of the profession, and they expressed deep disappointment with and frustration toward what they judge to be the majority's "politically correct" (P17) and "irresponsible" (P6) approach to sexual and reproductive health.

Those in the mainstream charged their critics with "inflicting" (P12, P13), "imposing" (P9) and "forcing" (P3) their values on patients and thereby violating professional boundaries. One concluded, "If they want to become priests or ministers and practice religion that's fine, but they shouldn't be practicing medicine" (P3). Those who followed the mainstream approach were most disturbed by refusals to refer patients for what are legal medical interventions, actions one described as "breaking a professional code of responsibility to the patient" (P2).

Despite their differences, it seemed that the physicians try to work together peaceably as colleagues. Several mainstream ob/gyns expressed what one summarized this way: "I don't have much patience for [physicians of the alternative approach], but I would not want them to do anything that they could not do in conscience" (P4). Those outside the mainstream noted that they have been able to work out collegial relationships that allow them to practice conscientiously. "[My colleagues] have come to the understanding that I am not compromising anybody's care and that I am just serving a different part of the community that feels more in line with my beliefs" (P5).

DISCUSSION

Interviews with a geographically and religiously diverse purposive sample of practicing ob/gyns revealed two different narratives about the process of medical decision making in the context of moral complexity. The narrative of those who follow the mainstream approach emphasizes the primacy of patients' autonomy, and its adherents aim to maintain moral neutrality in their counsel if not also in their own minds. When dilemmas arise, moral decisions are referred to the patient. In contrast, an alternative approach is described wherein ob/gyns address moral complexity by engaging strategies such as persuasion, sharing of personal values, reference to a moral authority, or clarification of boundaries to influence the decisions that patients ultimately make. Some — in our sample most were Roman Catholic and Evangelical Christians (though other Roman Catholic and Protestant Christians in our sample em-

ployed a mainstream approach) — engaged a directive, persuasive approach to medical decision making even for routine matters in sexual and reproductive healthcare.

To characterize these approaches as rigid for given physicians over time would both oversimplify and overstate our findings. In fact, our data suggested that individual physicians may vary their approach in relation to factors such as the quality and history of the patient-physician relationship, the individual patient's circumstances, experience, and the practices of their professional partners or colleagues. Finally, the participants were clearly aware that, among ob/gyns, there are differing approaches to areas of moral complexity. While some expressed animosity or disdain toward the approaches of those who differed from them, others stated that they could practice compatibly even with colleagues who disagreed on these basic issues. This latter observation corroborates previous findings.[22]

Our findings suggest that, for practicing ob/gyns, debates about the proper role of the physician in medical decision making are complicated by concerns about personal moral integrity and by disagreements about how the patient's best interest can best be known and protected. The familiar rubric of paternalism versus autonomy usually presumes that physicians at least are agreed about the patient's best interest, even if the patient is not so persuaded. Yet, with respect to morally controversial aspects of sexual and reproductive healthcare, ob/gyns who all profess to be committed to the patient's best interest apparently disagree about what that interest entails. Some defer to patients' judgment and accommodate patients' requests so long as those requests are in accord with professional medical standards. Others encourage patients to make what the physician believes to be, based on convictions the patient may not share, morally "admirable"[23] medical decisions. These differences undoubtedly shape the care that patients receive in areas of moral complexity.

Siegler has argued that the clinical encounter has always been less a neutral exchange than a dynamic process of mutual influence and negotiation, which culminates in a *physician-patient accommodation*.[24] One danger in that process, particularly in areas of moral disagreement, is that "mutuality" will devolve toward coercive or patronizing paternalism.[25] Against that tendency, Childress and Siegler recommend three procedural safeguards.[26]

The first procedural value is *disclosure:* ob/gyns must not withhold information that is relevant to the patient's decision, and they must be *candid* about their own biases.[27] Quill and Brody argue that an open dialogue, "in which the physician frankly admits his or her biases, is ultimately a better protector of the patient's right to autonomous choice than artificial neutrality would be."[28] In that respect, it would be better for ob/gyns who endorse the alternative framework to be explicit about what their commitments are than to misrepresent those commitments or to leave them operative but undisclosed. Some authors have suggested that disclosure should occur prior to initiation of the physician-patient relationship, for example, via a sign posted in a waiting room, a brochure sent to prospective patients in advance of a visit, or via phone when the patient calls for an appointment — a practice reported by a few of the ob/gyns in our study.[29]

The second procedural value is *voluntariness:* the patient must not be coerced.[30] Some suggest that physicians may unduly influence patients by disclosing their own moral judgments. Chervenak and McCullough have argued, for example, that with respect to abortion, "No judgments about the morality of those decisions should be expressed to the pregnant woman, for whom the obstetrician acts exclusively in the role of physician, not private person."[31] In contrast, Thorp and Bowes, in defending the "pro-life" perinatologist, argue that any ob/gyn is justified in "forthrightly announcing his or her worldview, as long as the patient understands the point of view (biases) held by her counselor."[32] Although they disagree about whether physicians' moral judgments should be disclosed, they share the judgment that the physician-patient relationship should "never be used to coerce a patient into complying with her physician's morality."[33]

A clear point of tension among our participants was whether an ob/gyn ever has sufficiently compelling reasons to justify not counseling about or referring a patient for a legal

medical intervention to which the ob/gyn objects (the case of abortion was most often referenced in our interviews). In the articles we consider here, the bioethicists do not definitively answer this question. Childress and Siegler say that, in such situations, physicians "may" have a duty to inform patients about other physicians who would provide what the patient requests,[34] and Quill and Brody comment that physicians are "perhaps" obligated to facilitate the transfer of care.[35] Yet these authors do suggest that disclosure and voluntariness are prerequisites to and necessary conditions for the final safeguard — that all negotiations between physicians and patients end in a *mutually acceptable accommodation.*[36]

It is not clear that a mutually acceptable accommodation is always possible if a physician will not counsel about or refer for a particular medical intervention. Siegler allows for a physician to refuse to participate in that which "would violate his personal sense of responsible conduct," so long as "the patient's emergency health care needs are attended to."[37] A point of debate is to what extent "health care needs" would include, for example, providing postcoital contraception or abortion to a woman who cannot readily access another physician because of her limited resources, the practice location, or the acuity of her medical condition.[38] Moreover, Siegler suggests that, at points of deep disagreement, the only possible accommodation may be a termination of the particular physician-patient relationship.[39] Others have noted that, in decisions related to pregnancy, such accommodations may be regarded by patients as acts of coercion or abandonment, particularly in the absence of alternative and accessible sources for care.[40] The issue becomes particularly acute with respect to women who have been the victims of sexual violation or assault.

Disclosure, voluntariness, and the negotiation of acceptable accommodations all protect against paternalistic abuses of physician power. Yet even the best procedural safeguards can be circumvented or distorted if ob/gyns, whatever their moral frameworks, are not sufficiently committed to their patients' good. Ultimately, deliberative and interactive models for medical decision making depend on ob/gyns being *caring* physicians who put their patients' interests before their own.[41] Creativity, honesty, and flexibility within the individual patient-physician relationship are required to find accommodations that require neither the physician nor patient to violate their own integrity. Physicians must be, in Thomasma's words, motivated by conscience rather than the superego and must have "a healthy appreciation for moral ambiguity."[42]

Our study has important limitations. First, qualitative methods are powerful for generating rich descriptions of the ways that ob/gyns think about this complex topic, yet they do not allow any statistical inference regarding how the themes we found are distributed within the broader population of physicians. Second, the analysis and interpretations are those of the authors. It remains possible that somewhat different interpretations might emerge with different investigators and a different sample, and future studies are warranted to see if our findings are corroborated by other investigators in other settings.

In conclusion, our findings suggest that, within the one profession of obstetrics and gynecology, there are different and dissonant ideas about how a caring physician should approach medical decision making in areas of moral ambiguity. These differences have implications for ob/gyns and their patients. The intensity of rhetoric used by some ob/gyns to describe others suggests that these are sensitive and charged issues. In light of that, ob/gyns might take up respectful discourse about their disagreements by starting with the apparent fact that they are often able to work together and accommodate one another as colleagues, even in the same practice groups.

Moreover, our study suggests that in the area of sexual and reproductive healthcare, patients' experiences, and potentially their medical decisions, may differ based on the ethical approaches of their ob/gyns, a hypothesis supported by data from a recent national survey.[43] This observation may have important implications for how women approach the selection of a physician, where such choice is available, and for maximizing harmony between patients and physicians in medical decision making. Simultaneously, this observation should caution ob/gyns against the real possibility of harm that

could result from alienating or abandoning a patient in need, particularly one who cannot access other care due to limitations in personal or practice setting resources. As such, we hope our study will spur further deliberation and inquiry about the appropriate forms of physician-patient communication in contexts where patients' and physicians' moral judgments conflict.

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NOTES

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Commentary on "Of More than One Mind"

Edmund D. Pellegrino

In modern pluralistic societies conflicts in moral belief and practice are becoming more commonplace. Often they can be peacefully negotiated by avoidance of certain relationships, compromise, or mutual respect. At other times, the nature of the human relationship is such that the mechanisms for resolving conflicts become themselves ethically problematic.

This is the case in the physician-patient relationship when patients demand a treatment or procedure that physicians judge to be morally damaging to their personal or professional integrity. Curlin and colleagues' article in this issue of *JCE* surveys the ways a small sample of physicians of varying moral and religious persuasions confront this conflict.[1] Curlin sampled obstetrician-gynecologists. Surveys of other specialties describe similar ethical conflicts.[2]

Physician-patient moral conflicts are especially significant in obstetrics and gynecology. Here sociocultural conflicts surrounding abortion, *in vitro* fertilization, and a variety of techniques of assisted reproduction, et cetera, are of the most morally divisive.[3] Recently these conflicts were exacerbated by publication of an opinion of the ethics committee of the American College of Obstetrics and Gynecology, which stated that physicians who cannot in conscience provide reproductive services that patients request must refer patients to another physician who will.[4] That the U.S. Secretary of Health and Human Services later challenged this policy is significant, but not entirely reassuring.

The ACOG committee's recommendation must be seen against the background of a more general trend to demand moral neutrality of physicians, that is, a separation of personal from professional ethics. This is part of a trend toward erosion of conscientious objection as a right of physicians who refuse to compromise their personal moral integrity.[5] The questions Curlin's and other surveys raise are more than questions of procedures physicians should follow to confront conflict with patients. They are moral questions of the gravest significance.

Is the right of conscientious objection a natural right, that is, a right based in human dignity? Or is it a *prima facie* right that can be overridden by the autonomy owed to patients? Are not physicians persons worthy of equal respect? Do they not also have a claim to autonomy? Is it not more consistent with human rights to protect the autonomy of both patients and physicians? Autonomy is a reciprocal, not a unilateral, principle. Can the principle of autonomy be used to violate autonomy? If physicians are entitled to respect for their moral and professional integrity, can they be compelled to act against conscience and refer patients to someone who will provide an abortion? Is this not an act of complicity with what many physicians consider a seriously offensive moral act?

Curlin's article and other surveys are important sources of data about what *is* done, but not about what *ought* to be done. Surveys cannot answer normative questions. They provide valuable data about the kinds and prevalence of ethical issues that arise in clinical practice. Agreement on a "mainstream" set of procedures does not confer moral probity on those procedures, or by itself compel others to participate.

This is not the place to evaluate the statistical questions raised by Curlin's survey. He and his coauthors are aware of some of them. What

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can be questioned is the conclusion from the practices of 19 physicians of varying moral persuasions that there is a "mainline" approach. Does this imply that the mainline opinion has a certain moral weight? The moral questions raised by the survey cannot be resolved by majority opinion, even in a democracy.

The "mainline" opinion asserts that physicians who oppose abortion, or any other procedure on moral grounds have but one choice: to refer to another physician not opposed. Those who will not refer, on grounds of moral complicity in an intrinsically wrong act, are cited as being "judgmental," preachy, imposing their will on others, or abandoning the patient. Explaining the reasons for one's refusal, saying when asked what he or she would advise, or suggesting alternatives are prohibited.

One can agree with the mainline view that respects the right of ultimate choice to rest with the patient. Prohibition of coercion or derogation of the patient is a moral requisite. But there must be equal regard for the right of physicians to refuse. They must not be coerced by threats of loss of certification, or disciplinary action if they dissent from the mainline course.

Physicians opposed to abortion are morally entitled to refuse and give reasons for doing so clearly and honestly without demeaning the patient. Explanations must be given with respect for the patient. Physicians can answer questions about the reasons for refusal and acknowledge that people may differ without demeaning the person who differs. They must absorb patiently the reproach of patients or "mainstream" colleagues. They are bound to give reasons without sanctimonious self-righteousness. But physicians cannot knowingly assist in abortion by making a referral. Physicians opposed to abortion cannot "abandon" a patient once they have entered a professional relationship with her. They should refer her to an obstetrician known to be competent for needed non-abortion care. It is the patient's responsibility to negotiate her demands freely with other obstetricians.

Physicians who cannot morally perform an abortion must always treat patients compassionately while making their own moral position clear. This is the case also for other procedures of dubious moral probity. Physicians may find a procedure unacceptable but must never treat patients with less than the respect their human dignity demands. Physicians must learn to respect the human person, even while disagreeing with her request or demand for a morally questionable procedure. Indeed, speaking one's mind to another without castigation is more respectful of the other than a refusal to do so.

Early disclosure of a physician's objection to abortion or other procedure usually subsumed under the rubric "reproductive technology" is mandatory. Indeed, obstetricians who have objections should make them known before entering a professional relationship with a patient. A brochure stating what treatments and procedures a physician will not do should be available to patients and posted in a visible place. As in any other potential conflict, prevention is the best course. It is recommended even by those arguing physicians should be morally neutral.[6]

Dissenting physicians should offer to continue seeing a patient if needed. They should treat the complications of procedures they find objectionable. Elective or selective abortions are not true medical emergencies. In true medical emergencies, physicians have the duty to provide medically indicated care guided by their conscientious assessment of what is in the patient's best interest.

NOTES

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Professional Responsibility and Individual Conscience: Protecting the Informed Consent Process from Impermissible Bias

Frank A. Chervenak and Laurence B. McCullough

In their article "Of More than One Mind: Obstetrician-Gynecologists' Approaches to Morally Controversial Decisions in Sexual and Reproductive Healthcare," Farr Curlin, Shira Dinner, and Stacy Tessler Lindau report the results of a qualitative study of self-reported attitudes of obstetrician-gynecologists toward decision making in the ethically controversial clinical area of reproductive healthcare. Qualitative research is useful for the generation of significant hypothesis. Curlin, Dinner, and Lindau generate such a hypothesis: "within the one profession of obstetrics and gynecology, there are different and dissonant ideas about how a caring physician should approach medical decision making in areas of moral ambiguity." Curlin, Dinner, and Lindau are entirely correct to state: "These differences have implications for ob/gyns and their patients."[1]

In our judgment, the main ethical implication concerns the distinction between professional responsibility to patients and individual conscience.[2] The failure to identify this distinction can and does land physicians, not just obstetrician-gynecologists, in a world of preventable ethical trouble in the informed consent process.

The professional responsibilities of physicians originate in the physician's fiduciary role. The ethical concept of the physician as fiduciary of the patient, and therefore of the physician as a professional, was introduced by two British physician-ethicists in the eighteenth century, John Gregory (1724-1773) of Scotland and Thomas Percival (1740-1804) of England. Gregory wrote the first modern medical ethics in the English language, and Percival the first text entitled "Medical Ethics" in any language. Their work was enormously influential on nineteenth-century medical ethics in Britain, Europe, and North America.[3] The framers of the 1847 *Code of Medical Ethics of the American Medical Association*,[4] the first modern national code of medical ethics, explicitly acknowledge their considerable debt to Gregory and Percival.

Gregory and Percival forged a three-component concept of fiduciary or professional responsibility.

1. The physician should become and remain intellectually and clinically competent by routinely basing clinical judgment, decision making, and behavior on the best available evidence.
2. The physician should use his or her knowledge and skills primarily to protect and promote the health-related interests of patients

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and keep self-interest systematically secondary.

3. Physicians should maintain and pass on medicine to future physicians and patients as a public trust that exists primarily to benefit present and future patients (making research a major component of professional responsibility), not as a private guild concerned primarily to protect the economic and other self-interests of its members.[5]

The first component secures the intellectual integrity of the physician as a professional, the second the moral integrity of the physician as a professional and the third the warrant for public confidence in physicians as a group living out the first two commitments.

Intellectual and moral integrity should guide the physician's role in the informed consent process. From among the technically possible and available alternatives for managing the patient's clinical condition, the physician should identify those for which there is a reliable evidence base of expected clinical benefit. Put more precisely, the physician initiates the informed consent process by identifying the medically reasonable alternatives for the clinical management of the patient's condition. Sources of bias originating in the physician's self-interests, economic and non-economic alike, should be identified and eliminated from this rigorous process of clinical judgment. The result is an expert, not a lay, judgment.

Self-consciously permitting moral values, concerns, or judgments of an individual physician that originate from sources other than expert clinical judgment about what will protect and protect the patient's health-related interests to shape the physician's clinical judgment about medical reasonableness involves impermissible bias in the formation of this crucial clinical judgment. This provides an ethical justification for the well-understood and long-standing ethical consensus about non-directive counseling. It is well understood that a physician's economic self-interest (for example, in self-referral for the performance of obstetric ultrasound examination or a cesarean delivery) counts as impermissible bias. An individual physician's *moral* commitments that originate in sources outside of expert clinical judgment fall into the same category. This judgment is unaltered by the sincerity or intensity of the moral commitments at stake, no matter their origin in a physician's individual moral life.

It is one thing for physicians to restrict their practice on the basis of individual conscience, provided that patients are clearly informed. It is something altogether different for physicians to express individual, conscience-based views about the moral status of the fetus and the morality of abortion in an attempt to influence a pregnant woman's informed decision making.

Medicine is not alone in being a profession that poses challenges to individual conscience. Consider military commanders electing precision aerial bombing of targets where civilians are known to be located, or a religious adviser counseling a penitent about the admitted sexual abuse of a child. Like the professions of arms and the ministry (as well as the law), medicine can become a morally perilous way of life. Failure to manage that peril responsibly, by disciplining individual conscience to the requirements of professional responsibility, will willfully undermine the profession of medicine from within. Not all of the respondents in the study by Curlin, Dinner, and Lindau appreciated this, which is very worrisome indeed.

NOTES

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Beliefs, Boundaries, and Self-Knowledge in Professional Practice

David Kozishek and Elizabeth (Libby) Bogdan-Lovis

INTRODUCTION

"Of More than One Mind: Obstetrician-Gynecologists' Approaches to Morally Controversial Decisions in Sexual and Reproductive Healthcare," usefully describes how a selection of obstetrician-gynecologists (ob/gyns) think and act when navigating between their responsibilities as medical professionals, their patients' healthcare goals, and the moral ground of their own conscience.[1] The issues raised by this study are important to many aspects of medical practice; but from our pedagogical perspective this study is of particular importance for how students learn about patient-physician communication, moral discernment, professional boundaries, and related expectations within medical education. When helping students learn how to listen and communicate effectively in professional practice, it is very helpful to have knowledge of how clinicians, patients, and families actually do communicate with one another: What kinds of things are communicated in the clinical encounter? How are they communicated? Why are they communicated? How are power differentials within the patient-physician relationship negotiated? What is left un-said, un-asked, or un-explained in the clinical encounter — and why? The research by Curlin, Dinner, and Tessler Lindau responds to these important questions.

It should be noted that this study does not claim to map generalizable patterns of behavior, but instead provides insight into the subtle dynamics of the clinical encounter. Most physicians interviewed for the study subscribed to what Curlin, Dinner, and Tessler Lindau call the "mainstream approach." This approach is in keeping with guidance provided by the American College of Obstetricians and Gynecologists (ACOG).[2] We will focus on the issues raised by the participants who subscribed to various "alternatives" to the mainstream approach — alternatives that at times go beyond conscientious objection to intentionally influencing their patients' decision-making process.

We organize our comments within two main themes. First, we discuss how we can best talk about the issues raised by Curlin and colleagues. How should the issues be characterized, and by whom? What language should be used? Which concepts are the most helpful to discuss the role of personal conscience in the healthcare pro-

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fessions? Which concepts are not as useful? We then broaden the discussion about the role of personal beliefs in the clinical setting. Second, we point to background issues in medical education today that shed additional light on the relationship between personal morality and professional responsibility. The background issues revolve around some potentially mixed messages being passed on to students, interns, and residents in contemporary American medical education.

FRAMING THE DISCUSSION

There are two main issues we will discuss in this section. First, we consider which language and concepts are most helpful to think about the role of a physician's conscience in the clinical encounter, and second, we will enlarge the discussion by including nonreligious beliefs as equally important within the patient-physician relationship.

In their introduction, Curlin, Dinner, and Tessler Lindau situate their study directly within the context of an ongoing debate among bioethicists about clinical decision making. The debate is about the proper place to come down between "the two poles of overweening paternalism and unmitigated patient autonomy."[3] While this approach is in keeping with much of the literature on the role of personal conscience in healthcare, we believe that the authors' decision to frame their study in these terms sets the stage for endless discussions (or perhaps merely assertions) about conflicting principles in complex situations, rather than helpful dialogue about the lives involved.

We find it more helpful to take a step back from "respect for patient autonomy" to its parent concept of "respect for persons." This conceptual shift replaces the need to balance competing rights within the patient-physician relationship with the moral space necessary for a dialogue between patient and provider, the end or goal being increased mutual understanding instead of resolution of conflicting principles. Moving beyond the task of protecting patient autonomy from the threat of physician paternalism, or, alternatively, defending physicians' rights to follow the guidance of their conscience from the demands of patient autonomy, to a context of respect for *both* patient and provider, allows for a helpful re-imagining of the relationship — from that of a battleground to that of a meeting ground where open and honest dialogue can occur between the parties.

Despite attempts to limit the role that a provider's conscience plays in clinical care, the reality is that there will always be occasions when physicians consciously or unconsciously follow the guidance of their personal beliefs when working with their patients. The study by Curlin, Dinner, and Tessler Lindau investigates the religiously based dimensions of this dynamic. The quotations provided reveal varying levels of intention, awareness, and action on the part of the respondents who objected to the "mainstream approach" — most of whom did so out of religious beliefs and convictions.

Focusing attention on religious beliefs and the role of a physician's conscience is one way to frame the discussion about personal moral beliefs in the practice of medicine. We find it more interesting to broaden the discussion by looking more closely at how less-apparent beliefs influence behavior. We all have many different kinds of beliefs, biases, and prejudices — only some of which are conscious — that guide our everyday behavior.[4] The beliefs we hold might be religious in nature, but they often are not. For instance, at some level most of us believe that we will live to see tomorrow and as a result we do not act today as though this were our last day of life. Or, imagine an ob/gyn raised by his family to believe that "poor people should not have children that they cannot support." Might that belief — directly or indirectly, consciously or not-quite-consciously — influence the way he practices medicine? The physician may even consciously claim such a belief as a part of his conscience.[5] Is a "secular" belief, bias, or prejudice that leads a physician to try to influence his patients to prevent or end a pregnancy any less worthy of inquiry than a "religious" belief, bias, or prejudice that leads a physician to try to influence her patients to give birth?

Religiously informed moral beliefs are perhaps the most easily ascertained (and therefore studied), but to focus exclusively on them misses much of the complexity of how inner lives guide outer actions. The authors of this

study rely on bioethics literature regarding the role of physicians' personal moral beliefs that calls for transparency and/or disclosure on the part of physicians. This advice presumes that physicians are fully aware of all of their beliefs, and of how they influence their relationships with patients. Indeed, some physicians may steer their patients toward specific choices by presenting their moral preferences as medical advice. They may not be aware that they are acting out of personal moral, rather than professional medical, convictions. For this reason we support respecting providers' appeals to conscience if those appeals are well-reasoned within a moral framework (one not based in fear, hatred, prejudice, violence, et cetera), consciously held, and openly shared as soon as conflicting goals of care become apparent. But we also want to draw a line as clearly as possible between a physician acting in accordance with the leadings of his own conscience and covertly or openly imposing his moral beliefs on his patients — for example, by remaining silent about options for care, steering patients toward particular decisions, or interpreting the "best interest" of his patients in a way that he feels justifies his acting as a moral therapist. If, however, a patient wants to discuss the moral dimensions of her care with her physician, the patient-physician relationship will best be served if her physician is clear about his beliefs on the matter at hand, shares them with his patient, does not appear to be standing in judgment, and does not try to guide the patient to a particular decision out of moral rather than medical concerns.

Like calls for transparency, appeals to concepts such as acting in the patient's best interest or keeping the patient's welfare as a primary goal are open to considerable interpretation. Such appeals are often made with the assumption that their meaning is completely evident. The minority of practitioners in the study who object to the mainstream approach most likely feel quite strongly that they are in fact acting in the patient's best interest and promoting her welfare by guiding her away from what they see as an immoral or dangerous course of action that may cause grave spiritual harm to her (in addition to causing spiritual harm to the physician herself).

IMPLICATIONS FOR MEDICAL PROFESSIONALISM EDUCATION

Our observations emphasize the importance of teaching medical students, interns, and residents the reflective skills necessary to increase their self-knowledge throughout their educational and professional careers. Before a physician can be transparent about her personal beliefs within her professional relationships (be they religious or nonreligious beliefs), she will first need to learn how to become aware of and reflect on what it is that she actually believes, why she believes as she does, how her beliefs might influence the way she practices medicine, and whether she wants to retain, amend, or lay down any of her previously held beliefs. This reflective process can be taught and modeled by skillful educators. Beyond moral beliefs that arise from a physician's conscience, such reflective skills will also help the clinician become aware of unrecognized biases, prejudices, attitudes, or generalizations that might influence the way she relates to particular patients.

The study by Curlin and colleagues also points to a need for medical educators to model behavior for students that will help them learn how to engage in open and respectful dialogue with their patients around passionately held moral beliefs. Such learning takes both courage and a willingness to try to understand the patient's life experience, beliefs, and choices without seeking to change the patient to fit the provider's belief system.

Unfortunately, we see some aspects of contemporary medical education that may be actively working against these educational goals. We will turn now to look at three "mixed messages" we sometimes see being delivered in contemporary medical education. These mixed messages may inhibit students from learning about themselves and from learning the skills necessary for respectful dialogue with their patients about matters of conscience and personal belief.

The first mixed message that students, interns, and residents may experience is that, on the one hand, they are told that they don't have to do anything that their attending physician tells them to do if they think it is wrong or immoral; students are expected to learn how to

develop their own conscience and use it as one source of guidance about what is best in any given clinical situation. But what happens to that same learning when professional medical organizations and medical educators teach that patient autonomy is a higher value than a physician's moral convictions? To us that teaching seems to give students the mixed message that they should listen to and follow their conscience while they are in an educational context, but after they become physicians they need to leave their conscience at the door of the clinic, or at least learn to subvert the guidance of their conscience during interactions with patients. By expecting medical students to develop and follow their inner moral guide or conscience, and expecting practicing physicians not to, medical education is setting physicians up for failure in knowing how to navigate the complexities revealed in the study by Curlin, Dinner, and Tessler Lindau.

Another mixed message is delivered when medical educators stress the need for medical students and residents to learn about, develop, incorporate, and act out of virtues and values integral to medical professionalism. It may become clear to students that some virtues and values — or perhaps particular interpretations of those virtues and values — are considered desirable while others are not. Students quickly discern when to keep quiet about their personal beliefs if they find themselves outside the dominantly held interpretation of values. This learned silence may then be carried into their medical practice and may lead to some of the covert behaviors and attitudes revealed in this study. Likewise, the disconnect between what students are taught about medical professionalism and students' observations of how medical professionals actually behave may lead students to dismiss all values education as irrelevant or hypocritical.[6]

A third potentially mixed message may occur when medical schools teach students that they should support their future patients' religious/spiritual lives because it is believed that doing so will enhance their patients' health and well-being. Yet at the same time students and physicians who have an active religious or spiritual life may get the message that their own religious beliefs or spirituality should not inform the way they practice medicine.

These potentially mixed messages, absorbed during medical education, coupled with shifting relationships of power in the move from student to practicing physician, can result in unhealthy, fractured identities for physicians and confusion about the role of personal beliefs and conscience in the practice of medicine. Most physicians will find a way to live their professional lives in keeping with their conscience. The effect of mixed messages in medical education may be to drive conscience-led decision making underground in the clinical setting. This move underground may then lead to the surreptitious and unreflective imposition of a provider's beliefs on patients' decision making.

CONCLUSION

The study by Curlin, Dinner, and Tessler Lindau provides a glimpse of how some ob/gyns approach moral and medical decision making with (or for) their patients. We have made two points: First, the choice of language and concepts will influence how the discussion of this study unfolds, and, second, the results of the study have great importance for medical education. A principle-based approach with the goal of clear resolution for all complex situations of the sort described in this study will lead to a continuation of a debate that is centered on conflict. In contrast, we suggest that pursuing the goal of increased respect and understanding between patient and provider would better facilitate fully informed and mutually agreed upon decisions.

We believe that teaching medical students to rely primarily on moral principles to frame ethical and moral discussions does them a disservice. At least equally important is the ability to enter into dialogue with patients in a way that is transparent, honest, respectful, open to hearing the truth of their patients' lives, and true to their own deeply held moral convictions. This ability to enter into respectful dialogue presumes our other educational goals: reflective skills that allow ever increasing self-knowledge; and experiences in medical school and residency that model for students and residents the

respect that we hope they will show to their future patients.

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NOTES

1. F.A. Curlin, S.N. Dinner, and S. Tessler Lindau, "Of More than One Mind: Obstetrician-Gynecologists' Approaches to Morally Controversial Decisions in Sexual and Reproductive Healthcare," in this issue of *JCE.*

2. "The Limits of Conscientious Refusal in Reproductive Medicine," *ACOG Committee Opinion* 385 (November 2007), *http://www.acog.org/from_home/publications/ethics/co385.pdf,* accessed 18 April 2008.

3. See note 1 above; see also F.A. Curlin et al., "Religion, Conscience, and Controversial Clinical Practices," *New England Journal of Medicine* 356, no. 6 (8 February 2007): 597-8.

4. For a brief discussion of the possibility of "value neutrality" and "nondirective" counseling in ob/gyn practice see J.M. Thorp, Jr. et al., "Integrity, Abortion, and the Pro-Life Perinatologist," *Hastings Center Report* 25, no. 1 (January 1995): 27.

5. We do not support such a belief or practice, but offer this example to help the reader imagine non-religiously based beliefs that might influence a physician's practice.

6. See for example: A.H. Brainard and H.C. Brislen, "Learning Professionalism: A View from the Trenches," *Academic Medicine* 82, no. 11 (November 2007): 1010-4.

Ethical Issues Concerning Disclosures of HIV Diagnoses to Perinatally Infected Children and Adolescents

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BACKGROUND

Healthcare workers (HCWs) often disagree with caregivers or parents about whether, when, and how to disclose HIV serostatus to perinatally HIV-infected children, yet the critical ethical, moral, and legal issues involved and their interplay have been underexplored. The purpose of this article is to bring attention to this increasingly important issue and the complexities involved, and to provide a framework for considering disclosure-related challenges.

Worldwide, 2.2 million children live with HIV, with 640,000 newly infected each year.[1] In the U.S., more than 9,000 children live with perinatal HIV.[2] Early in the epidemic, when HIV-infected children faced very short life expectancies, few providers were concerned about disclosing the diagnosis to children. However, since the advent of antiretrovirals (ARVs) and their use in children, increasing numbers of HIV-infected children are living longer, often into adolescence and young adulthood. Thus, children are reaching a level of cognitive development that allows them to understand their HIV diagnosis and to participate in treatment decisions, which could affect adherence to often complex medication regimens. Furthermore, older children and adolescents are reaching a level of physical and emotional development that can lead to sexual activity and sexual transmission risks. Sexual transmission is of particular concern among adolescents who may have little sexual experience, and thus may be less familiar with safer sexual practices. If perinatally infected youth are nonadherent, they could potentially transmit drug-resistant virus. Thus, legal guardians/caregivers or parents (all of whom we will refer to below as "parents") of children with perinatally acquired HIV face the difficult tasks of someday telling their child that he or she is HIV infected.

Disclosure of HIV entails telling children that they have a potentially life-threatening, stigmatized, and sexually transmittable illness.

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Thus, parents and healthcare providers often disagree about the timing and appropriateness of disclosure. The American Academy of Pediatrics (AAP) recommends that all adolescents know their HIV status and that disclosure be considered for school-age children as soon as is developmentally appropriate.[3] However, the AAP provided few concrete guidelines to support providers and families in this process (that is, *when* and *how* exactly to tell, how to decide, how to weigh psychosocial effects of disclosure, and whether full disclosure is ever *not* appropriate).

When disagreements occur about whether to disclose — most commonly when a healthcare worker recommends that a child be told, and the parent refuses — critical ethical issues surface. Even when parents and HCWs might concur that the time is right to begin discussing HIV with the child, questions can still arise as to *how* to disclose — for example, what exactly should be said. Clinicians often need help with these issues, and guidelines for both parents and providers can be helpful. But little clear guidance is available.

Commonly, parents delay disclosure until children are at least 10 years old, providing some information about the illness beforehand, without using the terms "HIV" or "AIDS."[4] One study, for example, reports that 50 percent of staff, caregivers, and patients thought disclosure should occur before age 12.[5] Prior research has reported that some parents try to protect their children by attributing the need for medical care to other, more benign, or less stigmatized conditions (for example, asthma or cancer). When full disclosure does occur, the psychological impact on the child and family is not clear. In fact, studies differ dramatically as to whether a higher incidence of psychological and behavioral problems occur among children who have *not* been told about their diagnosis versus children who *have* been formally told.[6] Moreover, critical questions emerge of not just how clinicians *are* addressing these issues, but how providers *should* proceed in these cases. How should clinicians think about balancing the rights of the child *versus* the mother, especially as children grow older? Do the rights of the child ever trump those of the parent, and if so, when and why? Who should disclose the diagnosis to the child? One study found that the majority of patients thought they were told at the right time and by the right person, if the latter were a family member, rather than a healthcare provider.[7]

The broader implications of nonadherence, sexual transmission of HIV, and sexual transmission of drug-resistant strains of the virus necessitate thorough analysis and understanding of these issues. Consideration of these ethical dilemmas varies with the circumstances of the case, and in particular, as we shall see, may shift over time due to psychological, medical, and social developments. Hence, this article explores these areas by presenting a clinically based case to illustrate these considerations in disclosure decision making, and outline the complex issues involved.

Several recent general approaches and theoretical perspectives may be applicable here. Fins and colleagues have suggested models of "clinical pragmatism," drawing on the work of John Dewey, in which in any particular clinical ethical dilemma, both principles and the details of the particular case are considered.[8] Similarly, Dubler has recently suggested approaching ethical conflicts in clinical care using a "mediation model," in which, briefly, a "mediator facilitates a discussion between and among the parties . . . to identify their goals . . . and to generate . . . options."[9] In addition, the American Counseling Association (ACA) has advocated a seven-step ethical decision-making model incorporating the work of several researchers,[10] that suggests, in brief: (a) identifying the problem, (b) referring to and applying the ACA "Code of Ethics," if relevant, (c) determining the nature and dimensions of the dilemma, (d) generating potential courses of action, (e) considering the potential consequences of all options and determining action, (f) evaluating the selected course of action to see if it presents any new ethical considerations, and (g) implementing the course of action.[11] Such approaches have not been applied to perinatal HIV disclosure cases, and we have tried to do so below.

A SAMPLE CASE

We present the following case scenario to illustrate many of these dilemmas. This case is drawn from clinical experience that our team

has had. The names and other potentially identifying details of the case have been changed to protect the identity of the patient and her mother.

PART I

Maria, a 36-year-old HIV-infected Latino woman, gave birth to an HIV-infected daughter, Amelia. Maria does not want Amelia to know that either of them has HIV. Amelia is now 10 years old. Amelia has been told she takes medications for "a problem in her blood." Recently, Amelia says she does not like taking the medication, and occasionally misses doses. The clinic staff have raised the issue of whether Amelia should be told about her diagnosis. In the near future, she will be at the age at which girls often become more interested in boys and/or sexual behavior. Also, her social worker feels that if Amelia knew her diagnosis, Amelia might be more adherent to her medications.

But Maria says that she absolutely does not want her daughter to know. Maria believes Amelia is still too young, and will be emotionally devastated. Maria says that it is *her* responsibility — and only her responsibility — as a mother to "protect" her child and that her daughter is "not ready" to know. Maria says that Amelia is "a good girl" and will not be sexually active until she is married.

The social worker thinks Maria feels very guilty about having transmitted the virus to Amelia. Maria herself became infected through a former boyfriend, who had a history of intravenous-drug use. Still, the staff is concerned and thinks Maria should begin to reconsider.

The staff thus confronted several ethical dilemmas. Does the daughter have a right to know her diagnosis? Does the mother have a right not to disclose the diagnosis to the daughter? Does a mother have a right to the privacy of her own diagnosis, which could be threatened if her daughter learns of her own status? Should the staff ever tell the daughter if the mother does not want them to? If the daughter wants to know more about her condition, what should the staff say? Should she still be told simply that she has "a blood disease"? Are there other approaches the staff can take, and if so, what?

This case is typical of many. Parents often fear that disclosure may distress the child and other family members. Healthcare providers often advocate disclosure, due to the possible psychological and medical benefits for the child, as well as public health concerns (that is, the possibility of transmission to sexual partners).

Legally, there is no clear mandate concerning most of these disclosure dilemmas. Federal and state laws do not appear to explicitly address disclosure of diagnosis to children. Many state laws do protect the privacy of information regarding a person's HIV status, except in very specific circumstances;[12] and these laws may prevent HCWs from informing a child that he or she was perinatally infected with HIV, as such a disclosure would result in violating the confidentiality of the mother's HIV diagnosis. In at least one state (that is, Georgia) a physician may be warranted in telling a child that he or she was perinatally HIV infected, as the law supports a physician's disclosure of a mother's HIV diagnosis to a child, given reasonable belief that the child is at risk of having been infected with HIV.[13]

Other laws that address the rights of a child versus the rights of a parent are worth noting. Generally, laws assume that parents act in the best interests of the child. The law might thus support a parent's decision regarding disclosure. But the law recognizes that in certain circumstances, and for various reasons, parents may not act in their child's best interest. According to the principle of *parens patriae*, protection of the child's welfare outweighs the parents' right to refuse medical treatment for the child,[14] though whether parents nonetheless have a right to refuse disclosure to a child is unclear. The *Storar* case set a precedent that a parent cannot deprive a child from lifesaving treatment.[15] Similarly, Article 10 of the N.Y. State Family Court Act established a legal procedure to protect children from physical, mental, and emotional mistreatment. However, parents often consent to treatment, but not to disclosure to an HIV-infected child. Whether nondisclosure alone ever constitutes mistreatment is debatable. Other legal precedents have granted adolescents some treatment-related autonomy. Adolescents may petition courts for "emancipated minor" status to be eligible for healthcare coverage; or may qualify for "mature minor" status that allows older children who understand the associated risks and benefits to initiate certain treatments without parental consent when parental consent may be difficult to obtain.[16] Yet the case of *McChandless v. State* suggested that physicians should not treat a minor without parental consent when the parents are available within one week, during which time treatment delay

would not alter the outcome.[17] In all states, an adolescent infected with a sexually transmitted disease (STD) such as syphilis can receive treatment without parental notification, but other STDs differ from HIV. Also, in some states decisions about parental notification for STD services is at physicians' discretion.[18] Yet clearly these precedents refer to treatment, not disclosure.

When children are in foster care, only some foster care parents — especially those who have a medical foster home — have legal rights concerning the child's healthcare. Typically, foster care agencies assume responsibility for the child's healthcare, and often require consent from biological parents (or the court) before children receive specialized care. Yet how this responsibility and consent apply to disclosure, and how healthcare teams can best address disclosure to children in foster care, is not clear. The AAP states that test results "should be provided by the child's physician to foster parents, biological parents (if possible), foster care agency and the child (if old enough to comprehend and if disclosure is appropriate to the developmental level of the child)." But this organization does not say when or how foster parents should disclose when the child inquires before being old enough to understand the diagnosis,[19] or when, exactly, a child is old enough.

In short, in facing dilemmas concerning disclosures to children, given the absence of other legal guidance, HCWs must make difficult ethical decisions.

As depicted in table 1, numerous sets of ethical issues arise both for and against disclosure and need to be considered and weighed — related broadly to principles of autonomy, beneficence, nonmalfeasance, and justice. For each of these principles, reasons exist both pro and con. Hence, the specifics of each case play important roles in balancing these issues. These broad categories of concerns overlap, but we use them here to structure and clarify the discussion.

The principle of autonomy might dictate that Amelia has a *right* to know her diagnosis. Yet ethically, minors are capable of giving assent, but not consent,[20] and parents have certain rights and responsibilities over their children's care. Reasons to disclose include the notion that a child has a right to know what is occurring in his or her own body, yet Maria, as a mother, might be said to have autonomy as a parent, with rights to challenge healthcare providers' suggestions. Maria has the responsibility to make decisions about what is in Amelia's best interest, and thus has the right not to disclose the diagnosis to her daughter if no imminent danger exists. Moreover, arguably, Maria has the right potentially to withdraw Amelia from care (if to do so is not imminently life threatening to Amelia).

The principle of beneficence arises here since disclosure could increase the child's sense of autonomy, empowering the child, and facilitating his or her ability to care for him or herself. Knowledge of his or her status could help a child feel more control over certain issues concerning his or her self. Potentially, children who are aware of their status will also not be as angry or resentful about having been kept in ignorance as those who learn only at a later point in their lives.

Yet the ideal of nonmalfeasance might suggest that children have a right to be protected from harsh and painful information that is otherwise not necessary, suggesting they should not be told of their status. Since the infection did not result from the child's behavior, the child should be protected from the psychological and social burdens of this disease, if possible.

Principles of beneficence and nonmalfeasance may be relevant, too, based on medical implications of disclosure decisions. Disclosure may[21] or may not[22] improve children's medication adherence. This difference in findings may be due to various factors; for example, caregiver stress, cognitive functioning,[23] or age of the child.[24] Among other chronic conditions (for example, diabetes and asthma), nonadherence increases as children age.[25] If medication needs to be taken in public, stigma can hamper adherence.[26] Nonadherence may result, too, from parents giving adolescents "too much" responsibility for taking medications, after disclosure. Adolescents may also have difficulty considering the long-term consequences of nonadherence, or may not want to take their medication because it reminds them that they are "not normal," or the pills might result in unintended disclosure to peers.

Table 1. Ethical Principles Involved in Disclosure of HIV Status to a Minor

Principle	Arguments in Favor of Disclosure	Arguments Against Disclosure
Autonomy	• Child has a right to know what is inside his or her own body	• Parent has a right to decide • Parent will have to deal with consequences of disclosure • Parents generally act in the child's best interest • Rights of parent outweigh those of HCW

Beneficence	• Disclosure may empower the child
	• Disclosure may have medical benefits:
	  • Helping with adherence
	  • Encouraging/increasing safer sexual practices
	  • Helping mother's adherence and healthcare
	• Disclosure may have psychological benefits:
	  • Increasing use of psychotherapy/social services by mother and child
	  • Reducing burden of secrecy for parents
	  • Enhancing relationships and bonding between parent and child
	• Disclosure can facilitate parent receiving additional help from HCWs
		• Non-disclosure provides some benefit, protecting child from burden

Nonmalfeasance	• Disclosure can prevent deception of child	• Disclosure may cause medical harms:
		  • Decreasing adherence
		• Disclosure may:
		  • Burden the child psychologically, impairing self-esteem, and increasing anxiety and depression
		  • Increase marginalization/stigma of child and family
		  • Cause parents to feel guilty
		• Child might then disclose the information to others, hurting the family as a whole

Additional Issues that Arise If a Minor Is Sexually Active		
Autonomy	• Sexual partner has a right to know of his or her risk	• Offspring has a right to decide whether to disclose or not to partner
Beneficence	• Disclosure might prompt safer sex	
Nonmalfeasance		• Withholding of information can contribute to partner becoming infected

Justice	• Public health concerns:
	  • Offspring may have additional partners over time to whom he or she can spread HIV
	  • Sexual partners have a right to know risks	

Psychologically, too, disclosure can be beneficial and reduce harm. HIV-infected youth who have not been told of their infection may encounter anxiety and related emotional and behavioral problems, sensing that "something is wrong." Disclosure could thus alleviate some anxiety, and facilitate addressing these worries, since fears of the utterly unknown can be greater than those of a known disease. Disclosure may be helpful, too, by facilitating psychotherapy that can address HIV-related mental health issues, since HIV can then be discussed more directly and openly, rather than hidden. Knowledge of their HIV infection may enable adolescents to cope better with the disease and possible fears of death from HIV. Children unaware of their chronic health condition may experience more anxiety.[27]

Yet disclosure can potentially cause psychological harm, as children may not be equipped to handle the implications of disclosure. *Modified labeling theory* provides a means to understanding some of the psychosocial consequences that might result from disclosure to children: prior to learning of their HIV status, children may have internalized societal conceptions of the meaning of being HIV infected (that is, as associated with risky sex or drug injection).[28] Thus, when children learn they are HIV infected, they may need to integrate their previous identity (of being HIV negative) with a new one (of being HIV positive). As they cope with the news of how they became infected, they may have to reconceptualize their mother's and/or father's identity as well. Modified labeling theory suggests that negative labels lead to negative outcomes for the person labeled. When children expect that they will receive negative labels or stigma for being HIV positive, they may respond in several ways, including *secrecy*, which is likely to be encouraged by some caregivers to avoid stigmatization. Such children may try to avoid any indication that they are different from their peers. HIV-infected children may *withdraw* or keep a comfortable distance from others who are known to be infected. Infected children may choose to spend their free time only with their family, who may actually encourage such isolation. Or, some HIV-infected children may affiliate with each other through treatment groups, but avoid being close to other children. Yet secrecy and withdrawal can lead to isolation, in turn fostering poor self-esteem and mental health problems, including depression. Alternatively, some children may want to divulge their diagnosis within their social networks to educate others or gain acceptance. This may result in increased support or, conversely, ostracization.[29] Disclosure might further marginalize a child already marginalized due to race, socioeconomic status, or HIV-related disabilities, or promote a false sense of friendships and social support.

Cognitively, children may lack the capacity to understand HIV and its implications, in which case disclosure may cause harm. Many children younger than 10 have less fully developed abilities to understand abstract concepts of having a chronic illness, especially if they do not feel ill.[30]

Parents face additional ethical concerns as well. As mentioned earlier, the principle of autonomy would indicate that parents or legal guardians have the right to decide when to disclose to a child, because they may know best when exactly a child is prepared. They will also have to deal with the consequences. But to give caregivers unequivocal authority over disclosure might not always be best, since caregivers might not know or be able to do what is best for their child. Their fears that their child will get angry at them, or that parental sexual or drug use risk behaviors will be disclosed could interfere with their objectivity in considering their child's best interests. HIV-infected parents may also have cognitive or mental health problems that impair their judgment.

Medically, the potential benefits and harms of disclosure on maternal health behaviors have been underexplored. After disclosure, a parent may decrease his or her sense of responsibility for medical monitoring of the child. Yet divulgence of a child's HIV-positive status may also increase tensions due to revelations of prior parental secrets. Psychologically, disclosure to a child may benefit the parent, reducing the burden of keeping the secret, and facilitate support and caregiving. Disclosure may also enhance communication and connectedness between the parent and child, since previously the parent withheld information from the child and may have devoted energy to maintaining se-

crecy. However, following disclosure, if the child divulges the information to others, stigma can increase for the parent and family, adding stress, and possibly fueling maternal guilt, self-hatred, and low self-esteem. Parents may become overwhelmed or burdened by the child's consequent distress. Disclosure could also lead to subsequent divulgence of additional family secrets that parents would prefer remain hidden (for example, concerning a parent's drug use or sexual behavior).

A moral perspective might also argue that the child would only need to know his or her status if he or she is sexually active, and because the child should be abstinent anyway, there is no reason to tell.

Given all of the above considerations and fears that Maria could remove Amelia from their medical care, the staff decided that if Maria did not want Amelia to know, they should not disclose at this time. Rather, they decided to delay disclosure, while working with Maria to determine the best time to move forward with the disclosure process. The staff also decided that if Amelia asked, they would refrain from answering, and instead discuss a plan with Maria, since they felt they should never lie about the diagnosis if Amelia inquired about it. Amelia did not ask for additional information about her "blood disease."

PART II

Amelia is now 13 years old. She says that many girls she knows have boyfriends, but she denies that she is dating or romantically involved.

The staff again become concerned, and speak with Maria about telling Amelia, but Maria still refuses to disclose. Maria doesn't want to upset her daughter who, she feels, seems very well-adjusted. She had spoken to her priest who said that she has a right not to tell Amelia. The staff decide to continue to accede to the mother's wishes.

Six months later, Amelia tells her doctor that she has a boyfriend, but denies having sex. Additional questions now arise as to whether the staff should tell Amelia at this point. Does a 13 year old have a greater right to know than a 10 year old? The staff wrestles with whether Amelia is sexually involved or likely to be in the imminent future.

When a child becomes sexually active, the presence of a third party — the sexual partner — introduces additional complexity into disclosure decisions. Here, the well-being of a third party — the daughter's sexual partner, if one exists — is potentially at stake. The possible harm caused by nondisclosure could now involve the transmission of HIV to the potential sexual partner, since if the adolescent is aware of being HIV infected, he or she may be more likely to engage in safer sex (that is, using condoms). Although safer sex is by no means guaranteed following disclosure, an adolescent who is unaware of his or her HIV infection lacks this critical information, which can potentially help motivate prevention behaviors. Maria may have the right to make decisions about her daughter's well-being, but not the well-being of a boyfriend, if one exists. The staff question whether to believe Amelia that she has not had sex, and decide to believe her, in part because of mutual trust developed over the years. The team thus decides again to respect Maria's decision not to tell, but to continue to encourage Maria to move toward full disclosure.

PART III

Amelia is now 15 years old and has a boyfriend, and tells her doctor that she has had sex with him, but does not always use condoms. The physician decides not to break Amelia's confidentiality about sexual activity, but tells Maria that it is time for Amelia to know her diagnosis, because Amelia is getting older and is at an age where many girls are sexually active and that she could endanger her partner. Maria objects to disclosure and says that Amelia goes to church regularly with her and would not have sex at this age.

The staff then wrestle with whether they should tell Amelia that she is HIV infected, in order to enable her to make informed decisions about whether or not she possibly will expose her boyfriend to HIV sexually. Should the staff encourage Amelia to inform her mother that she is sexually active, so that Maria would be more inclined to let Amelia be told about HIV? Or should the staff tell Maria that Amelia is sexually active, and then attempt to encourage her to inform Amelia of her HIV status? What rights, if any, does the boyfriend have here?

Ethically, the staff should tell Amelia at this point, though the issues here may still be complex. In particular, Amelia may not want to inform or protect the boyfriend. Disclosure alone may be beneficial in decreasing risky behavior — unsafe sex or substance use. However, youth with HIV may hesitate to use condoms, fearing

that they will be seen as "unclean" by partners. Some have likely reached a level of moral development[31] to want to avoid transmitting HIV to others. However, that desire may conflict with their wish to enhance or maintain their own psychosocial well-being or acceptance, or to appear "normal." Additionally, disclosure might cause harm, since offspring may then feel angry about their HIV status, and have diminished hope for their future, leading to risky behavior without much concern about possible transmission to others, as has similarly been suggested among adults.[32] For children with AIDS-related neurological impairments, caregivers and providers need to pay attention to the child's own emerging sexual curiosity and interest, ability to read social cues, and social judgment, when considering what information is appropriate to provide, given the child's level of impairment.[33] These determinations can be complicated, since HIV can also cause "adolescent-onset dementia," with problems in processing speed, memory, executive planning, and judgment[34] that can contribute to transmission of the disease through sexual activity.[35]

On balance, the staff decide at this point to inform Amelia of her HIV status and of the risk that she may have already transmitted HIV to her boyfriend, or could do so in the future if she continued having unprotected sex. The staff inform Maria that they think these discussions are important at this point. Maria, though with some reluctance, finally agrees to staff disclosure. They talk with Amelia about her concerns about telling her boyfriend, and help her to think about encouraging him to get an HIV test (for example, suggesting that Amelia and her boyfriend could go together to get tested for HIV) and to use condoms in the future.

Amelia was very sad for a few weeks, and then grew angry with Maria for not having told her sooner. Amelia intimated that she always knew something was wrong, but was too afraid to ask anyone about it. Maria became concerned that Amelia had started to drink alcohol with her friends and to smoke marijuana.

PART IV

Two months later, Amelia tells her physician that she has not informed her boyfriend that she is HIV infected. She says she doesn't want to tell him because she is ashamed and fears that he will "dump her" if she tells him.

The staff then have to decide what obligation they have to inform the boyfriend that he may have been exposed to HIV. They think they could either tell him or work closely with Amelia to have her inform him or encourage him to get tested and use condoms. The staff wonder if Maria has the right to know that her daughter is putting him at risk, and what obligation Maria has to keep Amelia from endangering him.

Here, the physician could choose to inform the boyfriend. A *Tarasoff*-like "duty to warn" permits HCWs in some states to notify sexual partners whom an HIV-infected patient is likely to have exposed.[36] As of 1999, 31 states had laws regarding partner notification[37] and *Tarasoff* "duty to warn" obligations. But these differ, for example, concerning criminalization of HIV-infected individuals who do not disclose to sexual partners, whether laws refer to "exposure alone" versus resultant infection of others, presence or absence of intent, and degrees of criminality involved (that is, from misdemeanor to attempted murder). Some states prohibit an HIV-infected person from engaging in any sexual activity with an HIV-uninfected person without disclosing, while others prohibit only unprotected penetrative acts.[38] In New York and many other states, legally, such disclosure to the boyfriend is currently at the doctor's discretion. Physicians can tell, but questions still emerge as to whether to do so is in the best interests of the adolescent if she opposes such notification. She may then lose trust in her providers (since her partner may say that he was notified, and he may trace the situation to her). Healthcare providers could also work with Amelia and refer her to a partner-notification program.[39]

DISCUSSION

The exploration presented in this article illustrates how a wide range of ethical principles and other issues arise and need to be taken into consideration and balanced in this case. Yet to weigh these competing pros and cons can be difficult. Ordinarily, the mother's rights to autonomy trump those of the child, since the latter is a minor — if the mother is thought to be acting in the best interest of the child. This an-

alysis illustrates the difficulty of developing definitive "one-size-fits-all" guidelines for these complex scenarios. Each case must be evaluated based on the specifics of the situation, consideration of the full range of concerns presented here, and the potential consequences of all options. Such an approach permits needed flexibility.

We have attempted to present the principles that should be followed when providers confront ethical dilemmas regarding disclosure of a child's HIV diagnosis. Though the articulation of specific, unequivocal rules is impossible, the range of principles highlighted here need to be considered and weighed. Though a utilitarian approach might suggest that the decision should maximize the greatest good for the greatest number, that determination is tricky at best, since the interests of the parties may conflict, and nondisclosure has significant public health consequences. This analysis also elucidates how *moral*, potentially theological, and not just ethical, issues are involved. This analysis suggests potential limits of this ethical framework as well. Specifically, these principles can potentially be interpreted in varying ways that can be subjective and lead in different directions.

Clinically, some centers are no doubt more experienced than others in approaching, addressing, and following up on these issues (for example, assessing whether decisions had the anticipated effect and consequences). Hence, appropriate training for confronting these issues, and involvement of nursing staff, social workers, and psychologists is critical.

Clinicians can aid with disclosure issues in several important ways. First, providers can help parents think about disclosure as a process, rather than a single event or point in time. In this regard, caregivers may require education about the possibility of *partial* disclosure — gradually increasing the child's understanding over time. Parents may also benefit from peer support, speaking with other caregivers concerning disclosure to an HIV-infected child — either individually or in a group.[40] The staff can try to work closely with the parent to optimize trust and minimize potential distrust that may exist. The staff may want to discuss with the mother the findings that it is best for the parent-child relationship if the parent embarks on the disclosure process at some point in the near future, rather than wait until a later point (for example, at age 18 when the provider can disclose to the child without the parent's permission). At that later point, the child might resent the mother for not having previously divulged the information. Nonetheless, even if told by 10 or 11 years of age, the child may still regret not being told earlier. The staff could encourage and assist the mother to develop a future plan for disclosing. When the mother realizes the need to disclose at a concrete point in the future, she may be more inclined to overcome some hesitation or denial regarding the ultimate need for disclosure. The staff might determine whether and what other family secrets exist (for example, concerning maternal drug use, history of trading sex for drugs or money, extramarital sexual relationships, bisexuality in a father) that may underlie or contribute to the mother's current desire for continued secrecy concerning HIV, or whether the caregiver is concerned about ostracism, loss of housing or jobs, et cetera, that might result if the child discloses to others. Social workers and psychologists have skills that can help the parent cope with these issues. Unfortunately, HIV is still highly stigmatized, given its association with disenfranchised groups and sexual and drug risk behaviors, and potential lethality. Once disclosure has occurred, children often benefit from interactions with other HIV-infected children who are aware of their diagnosis, and to discuss coping and future disclosures with others.

Policy makers need to be acutely aware of the questions and nuances involved in HIV disclosure. Tensions arise if the child is psychologically and cognitively — but not legally — old enough to be told. The staff may then arguably, from a purely ethical perspective, be supported in disclosing, but legally be unable to disclose. Hence, potentially, policy makers could consider broadening the concept of emancipated or mature minor so that clinicians can more fully discuss the infection with offspring, even if parents object. Potentially, state laws could also become more uniform, and allow for the development of national guidelines that are more universally applicable.

This case also highlights particular questions for future research. Future studies can ex-

plore the ways children and parents view and approach these issues, and weigh these often-competing considerations; the conflicts families and providers have encountered; and their decision-making processes. Parents and clinicians no doubt vary in how they weigh some of these concerns more than others. In certain cases, clinicians might think that some of these issues are more pertinent than others. Similar topics needing further investigation are whether disclosures to children at particular ages increase or decrease adherence and safer sexual practices,[41] and when disclosure to children can potentially harm or benefit maternal health behaviors. This case highlights the need to develop new models for assessing and supporting children's comprehension of HIV-related information as they age. Future studies can also elucidate children's ability to keep such information secret.

Cultural issues are potentially critical here as well, given the ethnic diversity of families affected by HIV. A family's cultural background might influence decisions concerning disclosure of an HIV diagnosis to a child.[42] Cultures vary in their views and practices concerning discussions of personal or taboo topics. A culturally sensitive, multi-disciplinary care approach tailored to an adolescent's needs and social circumstances is vital — using culturally sensitive language, and clear and effective interpretation.[43]

Given the growing numbers of pediatric HIV cases worldwide, there is a tremendous need for greater understanding and guidance regarding these issues. These concerns are rapidly spreading in the developing world, where issues of autonomy, rights and responsibilities, shame, and secrecy may be framed differently. The substantial stigma in many countries can result in considerable ostracism and isolation of people living with HIV. Research is needed to understand how these issues manifest themselves in different cultural contexts.

We have attempted to shed critical light on the dilemmas posed by disclosure of HIV infection to perinatally infected children and adolescents. Given the rising spread of the pandemic, increased attention to these complexities — how ethical, psychological, medical, and legal concerns can at times conflict and need to be carefully and sensitively assessed — is critical. This attention can enhance patient care and health policy, and will be of ever-rising significance in upcoming years.

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Disclosure of HIV Status to an Infected Child: Medical, Psychological, Ethical, and Legal Perspectives in an Era of "Super-Vertical" Transmission

Charles D. Mitchell, F. Daniel Armstrong, Kenneth W. Goodman, and Anita Cava

INTRODUCTION

More than a quarter century after the discovery of HIV we are still finding our way through thickets of confidentiality, stigma, and access to treatment. In fact and on balance, one could make the case that for all the progress made in the *medical* treatment of persons with HIV/AIDS, we have made a hash of it when it comes to clinical or applied ethics management of HIV cases, particularly in mother-child dyads when either or both is of questionable mental capacity. This is especially troublesome, given the recent appearance of a new and extraordinary population: children who acquired the virus from mothers, who themselves acquired the virus from mothers. In other words, we are now seeing cases of "super-vertical" or grandmaternal transmission. In the presence of high-quality treatments that allow affected children to live long enough to reproduce, HIV has become a malady that is inherited without being genetic.

Against this background, it is still the case that parents are often reluctant to disclose the diagnosis of HIV-1 infection and/or AIDS to an infected child. There are several reasons for this reluctance, most prominently denial, fear of the child becoming depressed or being ostracized because of the stigma, and parental guilt.[1] In states that have enacted strict laws governing the disclosure of HIV-related diagnostic information (often known as "super-confidentiality laws"), these issues are magnified because the disclosure of the HIV status of a child generally involves the simultaneous disclosure of the parents' HIV status. Decisions in this area require a balance among the child's right to know and ability to comprehend the information, and the emotional well-being and privacy rights of parents; in some cases we must take into account the competence of parents to make best-interest decisions for their children. Despite an evolving literature on disclosure of HIV status to children, the clinical and ethical problems raised by this type of case are largely unresolved.

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This report describes a dramatic, albeit not entirely unfamiliar, case that resulted in a change in hospital policy and identified a need to change state law. The case involved an HIV-infected mother who refused to disclose the diagnosis of HIV to her infected child. After its presentation we will discuss the medical, behavioral, ethical, and legal aspects of the case. The case warrants such review because of what it reveals about the problem of HIV disclosure in an era in which we are still sorting out the ethics of access, stigma, and information exchange, and in which children can acquire a dangerous and fraught malady indirectly from their grandmothers.

CASE REPORT

The patient was an adolescent with perinatally acquired, advanced HIV-1 disease marked by profound immunosuppression and multiple medical problems. Both the child and her mother were identified as being HIV-1 infected when the child was two years old. The child then endured recurrent pneumonias, chronic skin infections, failure to thrive, and HIV-1 encephalopathy associated with severe cognitive impairment. The mother, who was the child's only guardian, was in apparent denial regarding both her own and her child's diagnosis. She persistently refused all medical therapy for HIV, and insisted that God would care for her family. She did not belong to any church that prohibited seeking medical care.

As the child's health was failing, the mother finally agreed to start highly active antiretroviral therapy (HAART) — but she did not adhere to the recommended medication regimen and follow-up medical visits despite repeated counseling regarding the consequences of failing to do so. Previous attempts to involve Child Protection Services had failed, apparently because of an evolving trend at the time to support a parent's right to refuse HIV treatment for a minor child. At the same time, legal interpretation of the state law regarding the super-confidentiality of HIV status raised significant legal concerns about disclosure of the child's diagnosis without the mother's consent.

The child was admitted yet again for fever, wasting, and worsening skin ulcerations. The mother adamantly and repeatedly refused permission to disclose the diagnosis to the child, stating that her daughter would be "too sad" if she were to know. Physicians discussed this case with the hospital risk management staff, who opined that the mother's conduct constituted child neglect. After communicating this sentiment to the mother, she agreed to disclose the diagnosis — but not while the child was hospitalized. The mother agreed to bring her daughter in for a follow-up clinic visit so that disclosure could occur. However, mother and daughter missed both this and subsequent clinic visits.

The child was admitted for the last time eight months later, because of recurrent fevers and continued wasting. The mother repeatedly denied to the emergency room staff that her child had AIDS, even though several members of the staff had previously cared for the child. The mother had been given a prescription for a prophylactic antibiotic to prevent *Mycobacterium avium-intracellulare* (MAI) bacteremia the previous year, but she later admitted she was not giving the child the medications. This child had MAI. When asked to bring the medications from home, the mother brought in more than 30 bottles of pills, the majority of which had never been opened. The case was then referred to the state Child Protection Services agency for an investigation of medical neglect. After obtaining judicial authorization, the child was informed of the HIV-1 infection status in a manner that was regarded as appropriate for her age and degree of cognitive impairment. Under court order, the child was then placed in the custody of a relative.

The child's clinical status initially improved once regular antiretroviral therapy began. Despite this initial success, progressive HIV-1 disease complicated by advanced neurological impairment overwhelmed the child. She was transferred to hospice, where she died six months later. She had become a teenager (in conjunction with other facts of the case, any more precise age or even age range could serve to identify her, and so we therefore withhold this datum). Mother, too, later died of AIDS-related complications.

STATEMENT OF THE PROBLEM

Decisions about disclosure of HIV status to children are complex. There is a growing consensus, supported by the American Academy of Pediatrics (AAP), that the benefits of disclosure outweigh the risks.[2] However, in clinical settings, disclosure occurs in a complex context that involves evaluation of the child's medical condition, consideration of (a) medical and psychological effects of disclosing versus not disclosing, (b) a child's cognitive and psychological capacity to comprehend and act upon the information, and (c) the parents' cognitive and psychological capacity to comprehend and act upon the information. These clinical factors are further influenced by statutory law, case law, and institutional policy developed in light of

the law. In most states, disclosure of HIV status is controlled by laws written to apply to adults; caregivers are left to deal with the consequences of insufficient consideration of the effects on decision making related to children and adolescents. Pediatricians inevitably confront cases that simultaneously involve complexities in all of these dimensions, leading to uncertainty about how to proceed medically, psychologically, ethically, and legally. This case illustrates the complexity of this issue.

While this discussion focuses primarily on the mother, and it is usually the mother with whom the medical team interacts, the reasons commonly cited for nondisclosure may come from the father and/or the mother. As was the case here, the mother may be in denial both in regard to her own as well as her child's infection status. If she refuses to accept her own or her child's diagnosis, then she can perhaps avoid having to cope emotionally with this reality. The extent of the mother's denial in this case is evidenced by her repeated refusal in the face of extensive evidence to admit that her child had AIDS. Denial may also be prompted by the stigma associated with AIDS. Because of this stigma, many patients and/or their families adopt denial as their primary means of coping with their infection.

Many mothers refuse to disclose because they fear repercussions from their sex partner and/or (other) family members. These repercussions may assume several forms. The mother might be subject to emotional and/or physical abuse, or she may suffer economic deprivation if her sex partner, who may be a primary source of income, abandons her. Mother might also be afraid of being socially ostracized by her partner, her family, or other support systems (schools, churches, et cetera), or being criminally prosecuted if she knows her infection status and fails to disclose it to her sex partner. She might also suffer from guilt about having infected her own child. Further, as expressed in this case, a mother might have a genuine fear of the child becoming severely depressed by the knowledge of its infection status. Alternatively, the mother might refuse to disclose because in doing so she thereby discloses her own HIV status. In all these respects, HIV is truly a family disease.

MEDICAL COMMENTARY

The American Academy of Pediatrics Committee on Pediatric AIDS recommended in 1999 that the "disclosure of the diagnosis to an HIV-infected child should be individualized to include the child's cognitive ability, developmental stage, clinical status, and social circumstances."[3] The committee "strongly" encouraged the disclosure of HIV-infection status to school-age children, and that symptomatic ("particularly those requiring hospitalization") children and adolescents should be informed of their diagnosis. There are several medical reasons why disclosure of this diagnosis to an infected child should be promoted once a child reaches a certain age, the most prominent being the need to optimize compliance with HAART. While adherence to HAART is demanding, it pales when compared to the regimens required to treat the complications of AIDS if the disease is allowed to progress. In our experience at a major pediatric HIV treatment center, a number of children treated for advanced disease have required 25 or more different medications.

When a regimen becomes this complex, compliance becomes extremely difficult. The critical need for compliance should be emphasized at the start of HAART. Despite some current controversy as to when to start therapy, HAART is most effective when begun before the development of profound immunodeficiency. Continued effort must be made to optimize compliance to minimize the risk of developing HAART resistance and treatment failure. Disclosure remains one of the most useful means of achieving this once a child is sufficiently mature.

Once aware of the diagnosis, a child can assume greater responsibility for her or his own care. This may be essential for children in dysfunctional families or whose caretakers are incapacitated by their own illness. It is important that a child be educated and emotionally accept the diagnosis before being unable (that is, if she or he develops severe cognitive encephalopathy, as was partly the case here) or unwilling (that is, because of issues related to adolescent psychological development) to participate in his or her own medical care. As a greater number of perinatally infected children live longer

and enter adolescence, they must be informed of their status before they become sexually active or engage in other high-risk behaviors (intravenous-drug use, for instance). They must be given the time and the opportunity to make informed and responsible decisions.

The care team must also attend to confidentiality regarding a parent's infection status. At the same time, team members must remember their primary role as advocate for their child patients, and not elevate the rights and needs of the parent over those of the child, especially when life is in the balance. It is a sad perversion indeed when a parent's demands for confidentiality result in a diagnosis of HIV being withheld from a child or adolescent.

The advent of HAART therapy, coupled with the development of a reliable surrogate marker of disease activity (viral load), radically altered our conception of HIV management. Gortmaker and colleagues[4] demonstrated that the use of HAART is associated with a reduction in mortality among HIV-1 infected children and adolescents, duplicating findings previously reported among adults.[5] While such therapy did not exist when the child in our case was diagnosed at age two, the benefits of HAART were readily apparent by the time of death.

What has happened is no less than a major shift in the expectations of treating physicians. While HIV cannot be cured, neither can juvenile onset diabetes (at least without a pancreatic transplant). Like diabetes, HIV infection is a treatable condition. The survival of HIV-infected children is, in some cases, already measured in decades rather than years. These accomplishments underscore the need to make children aware of their status when they are mature enough and before they are neurocognitively impaired.

BEHAVIORAL HEALTH COMMENTARY

As this case demonstrates, disclosure of HIV status to a child who was vertically infected raises a number of complicated issues, including (a) whether the child should be told, (b) what effect disclosure might have on the child's psychological functioning, and (c) whether there are factors associated with the disease in children that may negate any benefits of disclosure and bring into question the capacity of the child to understand and act upon the diagnostic information in a way that benefits his or her health.

Whether disclosure of diagnostic information to a child is helpful or harmful has been, and continues to be, a potential source of conflict between parents and healthcare providers. This is particularly true when the illness is potentially life threatening. Parents feel a need for secrecy and fear their child will experience greater distress when provided this information. Parents often believe their child needs to be "ready" for the information.[6] In the case of vertical transmission, disclosure of the diagnosis to the child represents concurrent disclosure of the mother's diagnosis, something we have seen a mother may disdain out of fear of increased stigma or social isolation[7] for her and/or her children. Factors related to greater parental willingness to disclose to children include recognition of more severe disease-related symptoms[8] and parents' appreciation of their limitations in dealing with the situation.[9]

Research on the effects of disclosure on children's psychological functioning suggests that there are clear benefits for children who know their diagnosis. Reports indicate that as many as 66 percent of children infected with HIV have received either full or partial disclosure, but this disclosure usually occurs two to eight years after initial diagnosis.[10] When disclosure occurs, it has been associated with children's use of more active coping strategies,[11] lower levels of behavior problems,[12] lower levels of aggression, and higher levels of self-esteem.[13] There are developmental issues that may argue for or against disclosure at specific points in time, including the ability of the young child to make discriminating decisions about whom to tell about the disease.[14] For adolescents, decisions about sexual activity and protection of partners are closely related to knowing their diagnosis.[15] Finally, adherence with HAART regimens may be improved if the child knows the reason for the therapy, particularly given the many challenges this treatment presents.[16]

After considering the relative risks and benefits of disclosure for children, the American Academy of Pediatrics recommended disclosure, but also that the disclosure process take

into consideration the child's age, maturity, and developmental challenges.[17]

An issue that is not addressed in the literature, but which arises in this case, is that of the competence of the child, and possibly the parent, to understand and be able to act upon diagnostic information once it is disclosed. One of the known consequences of HIV infection is central nervous system (CNS) disease. AIDS-related dementia in parents who are infected may dramatically affect their ability to make informed decisions on behalf of their children. In addition, the CNS effects of HIV on the cognitive functioning of children have been documented in the school-age years, with particular effects noted in the areas of memory, processing speed, social-emotional regulation, attention, and executive functions such as problem-solving, planning, and organization.[18] As children reach adolescence, more severe cognitive impairment consistent with AIDS-related dementia in adults can be anticipated.[19] Progressive cognitive impairment may work against maturity associated with age in children, creating a situation in which children may be "old" enough to be told, but impaired enough for this information to be meaningless and have no influence on their behavior. In this case report, the child's lack of cognitive capacity added to the complexity of the decision to disclose diagnostic information against the parent's wishes.

While there is substantial evidence that disclosure may be beneficial for children, there are a number of legitimate concerns to be considered when evaluating the risks and benefits of this action. Models are being developed and tested to determine the optimal way to provide diagnostic information to children.[20] Research is clearly needed that addresses the relationship between providing diagnostic information and the cognitive capacity of the child to understand and act upon that information. It may be the case that providing diagnostic information to the "incompetent" child may have no effect at best, and may in fact be harmful. This is a question that should be answered by data, not opinion.

ETHICS COMMENTARY

Of the many ethical issues that arise here, two call for the greatest attention:

- When, if ever, can a claim of parental confidentiality trump a child's right or need to know an HIV diagnosis and treatment plan?
- When, if ever, can a parent's (purported) desire to protect a child from onerous medical news supersede those rights and/or needs?

CONFIDENTIALITY

While privacy and confidentiality are often accorded pre-eminent status in any itemization of the duties of health professionals, they are not absolute. Indeed, there is a well-supported suite of events, circumstances, or situations in which the violation of confidentiality is not only morally permissible — it may be morally obligatory. The instances in which health professionals are morally (and generally legally) required to notify authorities are well known: gunshot wounds, child and elder abuse or neglect, and certain epidemiologic data. There are powerful utilitarian reasons for this: generally, expectations of medical confidentiality are inadequate to override expectations of life, physical safety, necessary public health practice, and so forth.

The case at hand, however, does not involve informing authorities of a case or diagnosis, but informing a *patient* of her diagnosis. Here, any ethical justification to violate the mother's confidentiality and disclose the child's diagnosis must appeal both to public health and to rights of personal self-determination. Note also that the issue is often cast as a duty to warn an innocent third party who faces ongoing or repeated exposure. Even in such cases, it is reasonable to insist on more evidence, more research, and more structured ways of trying to manage decision making in the face of a paucity of empirical data.[21]

The public health argument is based on the fact that adolescents who are unaware of their HIV-positive status might themselves be or become a source of contagion. If adolescents know their HIV status, then, with adequate counseling and other interventions, they will be able to avoid being the source of additional infection. For a generation, policies and laws regarding the disclosure of HIV status have been based on the well-motivated belief that when HIV-positive individuals know their status, they tend to change their behavior in appropriate ways.

The self-determination argument is somewhat more difficult to make in the case of an adolescent, particularly one whose capacity is in question. For instance, it is not unreasonable to doubt (at least a little) the ability of some adolescents to make generally sound decisions about a variety of matters. Still, many pre-adolescents and even children are able to achieve insight and understanding about a variety of maladies and health issues, especially health problems with potentially severe or catastrophic consequences. Moreover, making patients — including pediatric patients — partners in their care is known to improve compliance and a variety of outcomes.

This being the case, the values attached to self-determination and good outcomes should be regarded (all other things being equal) as adequate to set aside the primacy of confidentiality. The law recognizes this in the "privilege to warn" principle, most famously invoked in a California case, *Tarasoff v. Regents of the University of California*, in which a therapist chose to honor the therapist-patient obligation of confidentiality and did not alert his patient's girlfriend of his serious homicidal intentions. Finding the therapist liable, the California Supreme Court invoked an exception to the obligation of confidentiality when necessary to prevent undue hardship and cruelty.[22]

THERAPEUTIC PRIVILEGE

In our case, the mother stated that she wanted to protect her child from the awful news of an HIV diagnosis. This (provisionally) compassionate position must be addressed. It is part of a long tradition in pediatrics and adult medicine to invoke the "therapeutic privilege," or notion that deception may be morally permissible if truth-telling will cause a negative outcome. This belief enjoys more support than evidence permits; indeed, much such "evidence" is anecdotal and episodic. But the price it demands is steep: the erosion of trust, which might be long standing; the loss of an engaged ally in care; and the generally unhappy stance that deception is better than truth-telling, which wears on clinicians as heavily as any professional burden.[23] This is not to suggest that there are no circumstances under which it will be appropriate to deceive children about aspects of a malady. Rather, it lends support to the AAP policy on disclosing HIV to children — namely, a strong recommendation that clinicians undertake such disclosures while simultaneously admitting the possibility of exceptions.

We must take care not to make a virtue out of interpersonal necessity, or even difficulty. It can be quite a challenge to communicate bad news to patients. It would be perverse if we were to allow that difficulty to be used in support of a policy that just happened to free clinicians of the duty to communicate bad news with compassion and understanding. While the literature shows a high prevalence of nondisclosure of HIV status to children, it is not entirely clear if this nondisclosure is for the patients' sake or the clinicians'.[24]

It is difficult to say whether or how a patient's diminished capacity should alter communication strategies. In the absence of outcomes data to guide us, even a little, the best course should be shaped by a "deference toward the standard." That is,

- If there is expert opinion and broad consensus on an issue (and here we have such with the AAP statement and a general movement by psychologists and psychiatrists to make all patients partners in their care); and
- If there is no compelling reason to the contrary (perhaps shaped by the facts of the case); then
- In case of uncertainty, defer to the evolving standard. In this case, that points to greater rather than lesser communication.

From or near the beginning of the HIV/AIDS epidemic it was clear that there was plenty of duty to go around: from patients and parents to clinicians and public health authorities, all parties should adopt stances characterized by trust, candor, and sexual responsibility.[25] What a happy coincidence that values we independently prize would be precisely those needed to impede the transmission of an awful malady.

LEGAL COMMENTARY

The law frequently lags behind what ethics and perhaps best medical practice would suggest. This case illustrates the short time within which even the most innovative legal efforts

become dated. Within a mere 12 years, improved medical treatment has created a new and largely unanticipated class of patient: adolescent survivors of perinatal HIV infection. These patients may well require certain legal rights and protections as individuals, not as minors whose best interests are supposed to be protected by their parents.

Florida enacted one of the very first comprehensive statutes intended to protect rights of HIV-infected individuals. Passed in 1988 and amended several times thereafter, the Omnibus AIDS Act[26] is founded on the notion that "this illness can best be controlled through an informed public that knows how to avoid contracting and transmitting the disease and that voluntarily agrees to be tested."[27] The Florida State Legislature held that this goal would best be achieved by creating strong privacy and confidentiality rights for the patient.

Florida law's requirement for patient consent before both testing and disclosure of test results is almost absolute, with very limited exceptions, largely for public health reasons. So informed consent for testing is not required when federal or state law require a test for sexually transmitted diseases, when a party has been convicted of prostitution or related offenses, for release from prison, or for purposes required by a medical examiner.[28] Other exceptions to the informed consent requirement include specific situations such as organ donation, "bona-fide medical emergencies," autopsies, certain sexual battery cases, anonymous epidemiologic research, to protect medical personnel, and by court order.[29]

Significantly, the Florida State Legislature imposed a heavy burden on any court contemplating overriding the right of a patient to confidentiality of HIV test results. The court must find that there is a "compelling need" for test results that "cannot be accommodated by other means."[30] Further, the legislature instructs courts to "weigh the need for disclosure against the privacy interest of the test subject and the public interest which may be disserved by disclosure which deters . . . future . . . testing or which may lead to discrimination."[31] Indeed, the primacy of patient privacy is further underlined by a provision of the Omnibus AIDS Act that amends a variety of civil rights laws to prohibit discrimination against persons within its ambit. Consequently, Florida was one of the very first states to forbid discrimination on the basis of HIV status in employment, housing, public accommodations, and health/life insurance.[32]

No doubt, the heavy weight of legislative and judicial concern in Florida, a trend-setting state in enacting comprehensive HIV legislation, is squarely in favor of giving the patient control over healthcare information and the right to veto disclosure — in most instances. In the case described here, the mother's dual role as guardian of her adolescent child, HIV infected from birth, and guardian of her personal HIV status, created a conflict of interest that was probably not contemplated by legislators when they attempted to balance patient rights against public responsibilities. The Florida Legislature did not foresee the survival of HIV-infected infants into adolescence and did not provide independent legal protection for them. Accordingly, the law in Florida gives no clear permission to a treating physician to disclose HIV status to an adolescent when so doing would *de facto* result in disclosure of parental status — unless that parent has consented. Hence, in our case, a court order was required when the mother refused to give her permission; this is the last resort for physicians caught in legislative limbo.

Have other states protected adolescent HIV patients, ensuring that they receive adequate and complete information about their status without having to resort to a court order? California and New York, states with comparably comprehensive legislation concerning the privacy and confidentiality of HIV status, reflect some interesting variations. Worth noting is that California specifically provides that the results of an HIV test may be disclosed to a person believed to be the subject's spouse or sexual partner, the subject's hypodermic needle-sharing partner, and/or the county health officer.[33] As long as this disclosure is done according to statutory specifications, the person making such disclosure may not be civilly or criminally liable.[34] Similarly, New York permits disclosure of HIV status to a limited group of "contacts" that does not extend to children or minors.[35] Both statutes reflect the privilege-to-warn principle identified earlier, but neither state would permit physicians in the case under discussion to disclose

to the child, as children are not within the protected group. That the nation's three most comprehensive legislative schemes do not explicitly permit disclosure of HIV status to adolescents, in situations such as these, indicates the state of the law at this time.

It is worth noting, however, that the California statute may afford an alternative avenue to physicians in such a predicament, although research reveals no case law on the issue.

Addressing consent to be tested for HIV status, California law provides that "when the subject of an HIV test is not competent to give consent for the test to be performed, written consent for the test may be obtained from the subject's parents, guardians, conservators, or other person lawfully authorized to make healthcare decisions for the subject. *For purposes of this paragraph, a minor shall be deemed not competent to give consent if he or she is under 12 years of age"* (emphasis added).[36] This provision raises the possibility of giving an adolescent older than the age of 12 years the right not only to consent, but also to receive information — rights not available under Florida law.

It is important, however, to underscore that the age, experience, intelligence, and maturity of a child may be factors in balancing rights and responsibilities. For example, a judge in Bangor, Maine, allowed a mother of an HIV-infected son to refuse treatment for the boy because she feared the powerful drugs would "kill him rather than extend his life . . ."[37] Whether that would be the same outcome were the child an adolescent and able to understand the risks and benefits is an unanswered question.

In a discussion of this issue on a more global level, Hartman[38] suggests that a federal law titled The Younger Americans Act is necessary to protect the emerging and strong interests of adolescents in medical decision making. The scope of her analysis is broad — ranging from fertility to end-of-life issues — but her solution is a more long-range approach that will not resolve immediate and serious medical issues such as the one confronting the physicians in this case. Instead, attention must be focused on the particular and thorny public policy issues presented in the HIV/AIDS arena, in which the task of balancing confidentiality and the right to be informed has a peculiar immediacy.

At the very minimum, this case points to the need for creating a clear and specific statutory exception to the patient's strong right to confidentiality of her or his HIV status. In a circumstance when a patient's refusal to permit disclosure triggers serious health concerns in a person who both has a right and a need to know his or her medical situation, the therapeutic privilege discussed here should be translated into law. Obviously, it must be carefully drawn to prevent abuse and unwarranted breaches of confidentiality. Years of effort to create a public policy that respects private healthcare information must not be undermined by hasty attempts to remedy a serious, apparently unanticipated consequence of this strong policy. Nonetheless, public policy requires nothing less than a remedy in fact to the conundrum presented by this case.

CONCLUSION

This case began when there was no effective treatment for AIDS and the primary focus of HIV-related legislation was to both insure patient confidentiality and protect against discrimination. The treatment and monitoring of HIV disease has since undergone a radical transformation. This change occurred because of the availability of effective antiretroviral therapy and continuing advances in the understanding of the pathophysiology of this disorder. That the child in this case was not able to be treated more effectively was largely due to two factors: the mother's denial and our inability to gather more support for disclosure at an age when the child could have assumed primary responsibility for medical care and before extensive cognitive impairment occurred. These failures stand as sentinels at a gate through which this patient, had she passed, might very well be facing the challenge of telling *her* children of this unhappy diagnosis.

As the clinical realities have changed, so must we work to change the common misconceptions regarding this disease. Adopting a proactive stance toward disclosure should further this goal. A written policy has been instituted

in our hospital that actively fosters disclosure.[39] This policy describes what procedures should be followed should a parent or legal guardian persistently refuse (permission) to disclose the diagnosis of HIV to a child over 12 years of age. It requires that each case be reviewed individually. If there is evidence of medical neglect as evidenced by the parents refusing or failing to comply with HAART despite repeated counseling, then the case must be referred to the Child Protection Services. If not, then the case is presented to the Pediatric Bioethics Committee for review, with the opportunity afforded to the parent or legal guardian to present their arguments for nondisclosure. If the committee concurs that disclosure is in the best interest of the child and the parent still refuses, the case is referred for further legal consultation. If the adolescent is or is about to become sexually active, then he or she can be informed of the HIV diagnosis despite the parent's refusal. At the end of the day, in both law and institutional policy, public health holds the strongest hand.

ACKNOWLEDGMENTS

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NOTES

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17. See note 2 above.

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29. Fla. Stat. §381.004(3)(h)(2-10).

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32. Hartog, *Florida's Omnibus Aids Act,* see note 27 above.

33. Cal. Health & Safety Code §121015-(a) (2001).

34. Cal. Health & Safety Code §121015 (2001).

35. N.Y. Public Health Code Section 2782 § 1(a-o)(1992).

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39. Copies of the policy regarding disclosure can be obtained by contacting the corresponding author at *cmitchell@med.miami.edu*.

Disclosure of HIV Status to an Infected Child: Confidentiality, Duty to Warn, and Ethical Practice

James R. Corbin

INTRODUCTION

What are the ethical and legal imperatives of client confidentiality and safety and how do they impact a decision to disclose a child's HIV diagnosis? This is the issue that Charles D. Mitchell and colleagues as well as Robert Klitzman and colleagues wish to address in their respective works.[1] The authors of each article describe the complexities of disclosure when the child is infected perinatally and the mother does not wish to inform her child, for various reasons. Each set of authors presents stimulating discussion and case material that assists the reader in navigating the ethically and legally murky waters of determining how and when disclosure or nondisclosure is the best practice alternative.

THERAPEUTIC JURISPRUDENCE

Therapeutic jurisprudence is a term coined by David Wexler and Bruce Winick that describes the problem-solving process between two systems: a study of the impact of the system of law on mental health as well as the impact of the social sciences on the law.[2] Wexler and Winick describe a problem-solving process between two systems whose rules and procedures do not always coincide. This concept includes the idea that each system has an impact the other, and dedicates a field of study to this convergence.

The issue of HIV disclosure becomes a matter of best medical practice as well as an issue that has therapeutic, legal, and ethical relevance. Healthcare institutions' bioethics committees are often charged with spanning the divide between ethical imperatives (including client confidentiality, autonomy, beneficence, and nonmalfeasance), moral and legal issues (such as the vicissitudes of *duty to warn,* various state laws, and safety), institutional policies, and best medical practice (including issues of treatment compliance).

The authors of these articles describe how the problem of disclosure has emerged more recently due to improved treatment and the related phenomenon of "super-vertical transmission" — infants who were infected with the virus perinatally who grow up to have children of their own who are in turn infected with the virus.

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THE CONUNDRUM OF CONFIDENTIALITY

One of the issues that is often in contention between these systems is the ethical responsibility to maintain a client's confidentiality. Professionals in each field recognize its importance and have parallel processes in this regard: attorney/client privilege (in the realm of law) and client/clinician confidentiality (in the field of allied healthcare practice). It is one of the basic tenets of therapeutic relationship and one that is an essential agent in the helping process for attorneys as well as clinicians. Indeed, it is clinicians' ethical responsibility to maintain the privacy and confidentiality of our clients and to practice within the confines of the law and in an ethical manner.[3]

The codes of ethics of the National Association of Social Workers and of the Clinical Social Work Association, for instance, outline the values and principles that govern social work practice and guide its profession in making ethical decisions. They compel licensed social workers to maintain clients' privacy and confidentiality except under very specific circumstances.[4]

SUMMARY OF THE *TARASOFF* DUTY — MANDATED REPORTING AND THE DUTY TO WARN

Allied health professionals are often compelled to reveal confidential information about clients when they are a harm to themselves or others. As well, all professionals (mental health, educational, and healthcare) who work with minors are mandated to report incidents of alleged child abuse whether the child-client or parent agrees or not.[5] The California Supreme Court decision in *Tarasoff v. Regents of the University of California* set a standard for practitioners to reveal confidential information in their *duty to warn* others of the potential dangers from a client.[6]

In the majority decision, the court found that the "protective privilege ends where the public peril begins."[7] The decision has a significant impact on the legal requirements for a clinician and certainly impacts clients' confidentiality. If, during the course of treatment, a clinician assesses a client as a danger to someone, the clinician has a duty, and is legally compelled to warn the intended victim.[8]

CASE LAW RELATED TO THE LIMITS OF CONFIDENTIALITY AND PRIVILEGE: A LEGAL ANALYSIS

Often the terms *confidentiality* and *privilege* are used interchangeably to describe the same general phenomenon — keeping information about a client private. However, the two terms can be distinguished from one another. The professional necessity of keeping a client's information private (for attorneys and allied healthcare professionals) is referred to as maintaining a client's confidentiality and is, as Stein notes, "rooted in the ethical codes of each profession as well as in statutory law."[9] On the other hand, privilege "refers to the right to withhold confidential information in a court of law . . . [and] is conferred by the legislature of the courts."[10] In a general sense, the conduct of the professional practitioner must be, as *Tarasoff* states, "measured against the traditional negligence standard of the rendition of reasonable care under the circumstances."[11] State laws vary, so practitioners must familiarize themselves with the appropriate statutes in their state.

The history of confidentiality and how it has been guarded and breached can be traced through pertinent case law. Familiarity with pertinent case law related to confidentiality can also be helpful in guiding practitioners negotiating work with a client, for example, who poses potential danger (through action or inaction). As discussed earlier, the *Tarasoff* ruling in 1976 formed the foundation of case law that guided practice with regard to a clinician's duty to warn others of a client's intent to harm.

However, subsequent rulings have helped to clarify (in most cases) what constitutes such things as *imminent harm*, the *intended victim*, and what actions constitute a warning. The ruling in the case of *Mavroudis v. Superior Court* clarified that threats must pose an "imminent threat of serious danger to a readily identifiable victim."[12] This was further clarified during a subsequent ruling in *Thompson v. County of Almeda* when the court ruled that the threat must be specific.[13] Thus, clinicians should take

heed to their ethical and potential legal obligations to protect others from a patient posing an imminent danger.

It is clear that work with a patient who is noncompliant with treatment or is suspected to be engaging in unsafe sexual practices poses many therapeutic and ethical challenges. Clinicians may be concerned about the liability that a breach of confidentiality may pose. Dickson notes, "When there is no statutory protection, consultation combined with careful documentation should minimize the chances of successful litigation."[14] In many states, mental health practitioners are protected from litigation when they are following, for instance, mandated reporting guidelines. However, clinicians must balance their obligations and be aware of state law and statutes that protect the rights of HIV-infected individuals, for example, the Omnibus AIDS Act.[15]

A careful assessment and consultation with a supervisor or bioethics committee are often the first steps in making an appropriate plan of action. Reamer further outlines steps to be taken by a clinician if the patient poses a threat to another party:

- Consult an attorney who is familiar with state law concerning the duty to warn and/or protect third parties
- Consider asking the client to warn the victim (unless the [professional] believes this contact would only increase the risk)
- Seek the client's consent for the [professional] to warn the potential victim
- Disclose only the minimum amount necessary to protect the potential victim and/or the public
- Encourage the client to agree to a joint session with the potential victim in order to discuss the issues surrounding the threat (unless this might increase the risk)
- Increase the frequency of . . . sessions and other forms of monitoring
- Be available or have a backup available, at least by telephone
- Refer the client to a psychiatrist if medication might be appropriate and helpful or if a psychiatric evaluation appears to be warranted
- Consider hospitalization, preferably voluntary, if appropriate.[16]

Not all clinical situations involving disclosure of HIV status and confidentiality are quite so clear. Work with children is certainly specialized in that clinicians must balance the confidentiality of their clients and address issues regarding safety while simultaneously maintaining an appropriate alliance with their caregivers and/or legal guardian(s).

PRACTICAL IMPLICATIONS FOR CLINICAL PRACTICE

So what practical implications do any of these aforementioned guidelines provide? Who, what, when, and how does a healthcare practitioner disclose such information? These are indeed the questions that face clinicians in this situation.

WHO SHOULD DISCLOSE?

The clinician who has the closest working relationship with the client and professional experience with children should be selected to discuss this matter with the child and mother. This decision is both a practical and therapeutic one. Bioethics committees and other multidisciplinary panels should address this important issue and may decide that the treating physician is the obvious and best choice. Other practitioners who are involved in the treatment process and team may be appropriate options as well. For instance, a hospital social worker who has a working knowledge of the case and appropriate training and experience with children and families may be a suitable option because of her or his working knowledge of various macro systems that may be helpful to the family post-disclosure.

WHAT SHOULD BE DISCLOSED?

The simple answer to this question in regard to what information should be disclosed to a child is, *it depends.* It depends on the child's age and developmental level. Therapeutically, the child should know (as soon as the child is able to grasp the concepts of sickness and illness) that he or she has a special condition that requires specialized treatment. All questions that arise from the child should be answered in a straightforward and truthful manner that provides information without overwhelming the

child (particularly, a young child) with unnecessary detail (such as detailed information about how Mother was exposed to the virus). Ideally, this would involve a joint effort by the professionals involved, as well as Mother and/or other immediate adult family (like Father). Of course, this depends on Mother's wishes for her minor child and confidentiality regarding her own status. Medical professionals should be present to answer questions about the course and treatment of any illnesses that arise due to immune deficiency.

If the mother strongly objects, the careprovider or staff should allow this discussion to continue over greater lengths of time, since different persons require different amounts of time to adjust to and accept new stresses that they know will be extremely painful. The time may arise, though, when giving the information can no longer be deferred, as when the child may engage in sex, since it may endanger another, and not be at all what the child would want. Accordingly, the staff should try as best they can to prepare the mother so that she has advance notice that this time will come — and when.

Staff may be rightfully concerned about giving the mother notice, knowing that the mother may use the information to leave and not return. Giving the mother notice that the time will come is, however, the only way to respect the mother's dignity and autonomy. The law may provide a remedy if and when the mother and child disappear, but whether or not it does, and what the remedy may be, may lie outside what the staff can ethically decide. Staff may have no better choice than to be open with such a mother well in advance, regardless of the risk of flight.

WHEN SHOULD DISCLOSURE OCCUR?

Ideally, a mother should be counseled to discuss the advantages (and risks) of disclosure and should have final say in most matters of disclosure, including timing. Little information should be disclosed about the details of the child's health without her consent As our authors indicate, this is really where the issue becomes most critical — for example, what if a mother delays — or worse, refuses to allow disclosure to the child for various reasons. This is when the support of other allied healthcare professionals such as social workers or psychiatric professionals can be of some assistance. These professionals often have the necessary mental health training to address issues of resistance, fear, and anxiety that arise out of this situation and related decision-making processes.

The developmental level and capacities of the child should always factor into the timing of disclosure. However, there exists little evidence that a parent's denial about the child's condition is helpful or even healthy to the child in the long term. The timing of disclosure is even more critical as the child ages, when (as discussed by our authors) a child may become sexually active and risks infecting another child. As suggested earlier, a situation in which a parent chooses not to disclose at this point becomes a matter subject to pertinent legal obligations such as the *duty to warn* an innocent third party. This duty and legal statutes relevant to the situation should be discussed with the mother as part of the disclosure process.

HOW SHOULD THE DISCLOSURE OCCUR?

The disclosure should occur in the professional setting; however, the parent (mother) is the key figure in how this meeting or meetings will transpire. The mother should be counseled about her role in the disclosure and how the professionals involved will make themselves available as sources of support and information. One potential scenario that may arise is a parent's wish to disclose to the child in the home or outside the professional realm. This request should be honored; however, the relative advantages and disadvantages of having other professionals immediately available should also be discussed.

A question that staff might encounter at this point is whether or not they should "check up" to be sure that the child has been informed. It would be ideal to anticipate with the mother, in advance, the future course for herself and her child. Staff could offer to work with the mother to support and work with the child while the child is told, and afterward — regardless of the time and the setting in which this actually takes place.

While there may be room for different views on this, one that seems paramount is for the

child to know that she or he could endanger another by having unprotected sex, so that the child does not do this unknowingly. To allow this to happen to respect the mother's autonomy — notwithstanding legal concerns — seems inhumane. Regardless, the tone and therapeutic aim of the disclosure should be one of support, help-giving, and openness to questions.

CONCLUSION

The ethical, legal, and therapeutic difficulties that arise out of the scenarios described challenge even the most seasoned professional. For this reason, professional collaboration and consultation is critical and can help guide the process in a way that is both practical and therapeutic and within the ethical and legal guidelines of our professions.

NOTES

1. This is a commentary on two articles, "Disclosure of HIV Status to an Infected Child: Medical, Psychological, Ethical, and Legal Perspectives in an Era of 'Super-Vertical' Transmission," by C.D. Mitchell, F.D. Armstrong, K.W. Goodman, and A. Cava, and "Ethical Issues Concerning Disclosures of HIV Diagnoses to Perinatally Infected Children and Adolescents," by R. Klitzman, S. Marhefka, C. Mellins, and Lori Wiener, both in this issue of *JCE*. Some material for this article is adapted from J. Corbin, "Confidentiality and Duty to Warn: Ethical and and Legal Implications for the Therapeutic Relationship," in *New Social Worker* 14, no. 4 (2007): 4-7.

2. The term *therapeutic jurisprudence* and related theory and practice are described in the following sources: D.B. Wexler, *Therapeutic jurisprudence: The law as a therapeutic agent* (Durham, N.C.: Carolina Academic Press, 1990); D.B. Wexler and B.J. Winick, *Essays in therapeutic jurisprudence* (Durham, N.C.: Carolina Academic Press, 1991); D.B. Wexler and B.J. Winick, "Introduction," in *Law in a therapeutic key (*Durham, NC: Carolina Academic Press, 1997), xvii-xx; and B.J. Winick, "The jurisprudence of therapeutic jurisprudence," *Psychology, Public Policy, and the Law* 3, no. 1 (1997): 184-206.

3. Ethical guidelines regarding confidentiality in the behavioral and allied health fields appear in the following sources: American Psychological Association — Committee on Ethical Guidelines for Forensic Psychologists, "Specialty guidelines for forensic psychologists," *Law and Human Behavior* 15 (1991): 655-65; American Psychological Association, "Guidelines for child custody evaluations in divorce proceedings," *American Psychologist* 49 (1994): 677-80; Clinical Social Work Association, *Code of ethics* (Arlington, Va.: Clinical Social Work Association and National Association of Social Workers, 1997); National Association of Social Workers, *Code of ethics* (Washington, D.C.: NASW Press, 1996); Omnibus AIDS Act (Fla. Stat. §381.004); American Academy of Pediatrics Committee on Pediatric AIDS: Disclosure of Illness Status to Children and Adolescents with HIV Infection," *Pediatrics* 103 (1999), 164-6.

4. Clinical Social Work Association. *Code of ethics*, see note 3 above; National Association of Social Workers, *Code of ethics*, see note 3 above.

5. M. Levine and L. Wallach, *Psychological problems, social issue, and law* (Boston: Allyn and Bacon, 2002).

6. *Tarasoff v. Regents of the University of California*, 108 Cal. Rptr. 878 (Ct. App. 1973); reversed and remanded, 13 Cal. 3d 177 (1974); modified, 17 Cal. 3d 425 (1976).

7. Ibid.

8. Levine and Wallach, *Psychological problems, social issue, and law*, see note 5 above.

9. T.J. Stein, *The role of law in social work practice and administration* (New York: Columbia University Press, 2004), 11.

10. Ibid., 105.

11. *Tarasoff v. Regents of the University of California,* 17 Cal.3d 425, 439-440 (1976).

12. F. Reamer, *Social work malpractice and liability*, 2nd ed. (New York: Columbia University Press, 2003), 31.

13. Ibid.

14. D.T. Dickson, *Confidentiality and Privacy in Social Work* (New York: Free Press, 1988), 164.

15. Omnibus AIDS Act (Fla. Stat. §381.004).

16. Reamer, *Social work malpractice and liability*, see note 12 above, p. 41.

Practice

Placebo Use in Clinical Practice: Report of the American Medical Association Council on Ethical and Judicial Affairs

Nathan A. Bostick, Robert Sade, Mark A. Levine, and Dudley M. Stewart, Jr.

INTRODUCTION

The use of placebos in research has received much more attention than has their use in clinical practice. This report is intended to guide physicians' clinical use of placebos in ways that respect patients' autonomy by allowing them to participate actively in the medical decision-making process.

For the purposes of this report, a *placebo* is defined as a substance that the physician believes has no known specific pharmacological activity against the condition being treated. Placebos can be therapeutically beneficial to some patients when they give rise to the so-called *placebo effect.*[1] In general, this refers to a change in the patient's condition that is attributable to the symbolic aspects of the overall care, rather than the medicinal qualities of the substance prescribed by the physician.[2] Although there is some debate as to the origins of the placebo effect,[3] much has been learned in recent years regarding its anatomical and physiological foundations.[4]

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ETHICALLY APPROPRIATE PLACEBO USE

Physicians administer placebos because placebos might relieve the symptoms that cause distress to their patients.[5] Historically, physicians used placebos without patients' knowledge, at a time when they had great latitude in providing treatment without a patient's consent if they believed the intervention to be medically indicated.[6] Accordingly, placebos often were used to relieve pain or other complaints that appeared to have no objective medical explanation.[7] Such use of placebos could convey benefits derived from the placebo effect or from the symbolic affirmation of physicians' willingness to help their patients.[8]

The deception associated with placebo use, however, is now widely viewed as problematic because it directly conflicts with contemporary notions of patient autonomy and the practice of shared decision making.[9] Today, if physicians attempt to deceive patients by representing placebos as pharmacologically active medications, they risk undermining their patients' trust.[10] Loss of trust is a serious consequence because it is a foundational component of the patient-

physician relationship.[11] If trust is undermined, patients may be less satisfied with their physicians and therefore less likely to consult them when making health-related decisions.[12] Moreover, patients may not adhere to treatment recommendations when trust in their physician has been compromised, thereby adversely affecting patients' overall health outcomes.[13]

Deceptive use of placebos poses other potential harms to patients, as well. For example, this use of placebos may mask and potentially delay the treatment of medical conditions.[14] Furthermore, some patients may encounter adverse side-effects resulting from placebo use, an occurrence known as the *nocebo phenomenon*.[15]

Ultimately, the deceptive use of placebos is not ethically acceptable because it may harm patients to a greater degree than it helps them. This is particularly true in cases when placebos are utilized to serve the convenience of the physician rather than to promote the welfare of the patient. Perhaps the most pernicious use of placebos is for mollifying a patient who is demanding, displays a difficult personality, or has a complex problem that has become frustrating to the physician. Placebos should never be used in this way because it is fundamentally inconsistent with physicians' professional obligations to promote patients' welfare and respect the autonomy of patients.

In some instances, it may be most appropriate to forego the use of placebos altogether. Several studies have described placebo-like effects that lead to better health outcomes when physicians are able to comfort and reassure patients presenting with symptoms that do not appear to have a clear medical basis.[16] This seems to work best when physicians establish partnerships with patients that are built on respect and trust, and encourage adherence to treatment plans.[17]

In other instances, physicians may utilize placebos within their clinical practice without relying on the act of deception. In these cases, physicians should make decisions regarding the use of placebos in partnership with their patients.[18] For example, a physician could explain to a patient that a more certain diagnosis or better understanding of his or her condition could be achieved by evaluating the effects of different types of medication, including one that is not pharmacologically active, namely, a placebo.[19] By obtaining the patient's cooperation in this manner, the physician need neither identify which medication is the placebo nor seek specific consent immediately before its administration.[20] This example of shared decision making demonstrates an approach that respects the autonomy of patients and fosters trust within the patient-physician relationship. Moreover, the authorized use of placebos is not expected to significantly diminish their clinical effectiveness as research suggests that little variation in clinical outcomes is observed between patients who are informed that they are to be treated with placebos and patients who are administered placebos in a deceptive manner.[21]

When physicians are faced with significant clinical or diagnostic uncertainty, the authorized use of placebos may prove particularly valuable for conducting single-patient controlled studies, known as *N-of-1 trials*.[22] In these trials, a disease-specific intervention and a placebo are alternated through several treatment cycles; the duration of each cycle depends on the nature of the disease.[23] Such studies can be *single-blinded,* in which only the patient is unaware of which drug is being administered, or they can be *double-blinded,* in which the assignment of treatment is managed by a third person, such as a pharmacist, so neither patient nor physician knows which medication is in use. In either case, the patient keeps a detailed journal of the waxing and waning of symptoms. At the study's conclusion, the physician can differentiate between benefits attributable to the pharmacologically active drug and to the placebo.[24] Throughout this process, the patient's progress should be monitored and the placebo discontinued if the active agent is found clearly to be more effective.[25]

CONCLUSION

Placebos are substances that the physician believes have no specific pharmacological activity against the condition being treated. They may be used in clinical practice to determine a diagnosis or appropriate treatment in the face of clinical uncertainty. Physicians must avoid deception when administering placebos by informing the patient that a placebo may be used.

RECOMMENDATIONS

The Council on Ethical and Judicial Affairs recommends the following.

A placebo is a substance provided to a patient that the physician believes has no specific pharmacological effect upon the condition being treated. In the clinical setting, the use of a placebo without the patient's knowledge may undermine trust, compromise the patient-physician relationship, and result in medical harm to the patient.

Physicians may use placebos for diagnosis or treatment only if the patient is informed of and agrees to its use. A placebo may still be effective if the patient knows it will be used but cannot identify it and does not know the precise timing of its use. A physician should enlist the patient's cooperation by explaining that a better understanding of the medical condition could be achieved by evaluating the effects of different medications, including the placebo. The physician need neither identify the placebo nor seek specific consent before its administration. In this way, the physician respects the patient's autonomy and fosters a trusting relationship, while the patient still may benefit from the placebo effect.

A placebo must not be given merely to mollify a difficult patient, because doing so serves the convenience of the physician more than it promotes the patient's welfare. Physicians can avoid using a placebo, yet produce a placebo-like effect through the skillful use of reassurance and encouragement. In this way, the physician builds respect and trust, promotes the patient-physician relationship, and improves health outcomes.[26]

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Placebos: Current Clinical Realities

Rachel Sherman and John Hickner

"In general, the placebo effect disappears when the patient knows he/she is receiving a placebo. This is in itself interesting, but since we believe in telling patients the truth, lying to patients in order to get the placebo effect presents an ethical conundrum."

"The use of placebos would be nullified if the patient knew. To use them when the patient does not know is unethical."

"As a physician trained in an environment which emphasized the importance of trust, and the validation of the individual's symptoms despite unexplainable physiology, I am opposed to the use of placebos even if research were to show benefit. The end does not justify the means."

INTRODUCTION

The power of the placebo effect was recognized in ancient times, as the following quotation from Socrates, according to Plato, illustrates: "[The cure for the headache] was a kind of leaf, which required to be accompanied by a charm, and if a person would repeat the charm at the same time that he used the cure, he would be made whole; but without the charm the leaf would be of no avail."[1]

Placebos remain clinically relevant and philosophically interesting in the twenty-first century. While modern researchers often investigate placebos and the placebo effect within the context of experimental studies, there is little data on the current use of placebos in clinical practice. Our January 2008 study, "Academic Physicians Use Placebos in Clinical Practice and Believe in the Mind-Body Connection,"[2] is the first significant U.S. study on placebo use in clinical practice since 1979,[3] other than a study of medicine interns from a single residency program published in 1999.[4] Nearly half of the Chicago-based academic internists who responded to our survey reported using placebos in clinical practice, and nearly all believe in their therapeutic potential. Yet, the use of placebos outside of clinical trials is a source of ethical tension,[5] as the three physician comments from our survey data (noted above the introduction) also illustrate.

In light of the ethical tension between harnessing the therapeutic power of the placebo and respecting patients' autonomy, and in the context of twenty-first century neuroscience hot in pursuit of the biological substrate of the mind-body connection,[6] the publication of "Placebo Use in Clinical Practice: Report of the American Medical Association Council on Ethical and Judicial Affairs," in this issue of *JCE* is timely. It will, no doubt, stimulate further discourse on the appropriate role of placebos in modern day medical practice. The AMA statement provides an initial set of guidelines regarding the ethical use of placebos and attempts to reconcile placebo use with modern principles of patient au-

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tonomy, informed consent, and non-deceptive therapeutic practices. As a fourth-year medical student and a family physician, neither an expert in medical ethics, we will comment on the AMA placebo statement primarily in the context of physicians' responses to our recent survey. The survey responses provide preliminary U.S. data about the current role of placebos in clinical practice.

EXAMINING THE AMA PLACEBO REPORT IN THE CONTEXT OF CURRENT PHYSICIANS' PRACTICES AND BELIEFS

We surveyed 466 academic internal medicine physicians in the Chicago area in the summer of 2006, and 50 percent responded.[7] We asked physicians about their use of placebos and their knowledge, attitudes, and beliefs about the placebo effect. Physicians defined *placebo* in a variety of ways, but the most commonly agreed upon definition was *an intervention not considered to have a specific effect through a known physiologic mechanism.* Of the physicians we surveyed, 45 percent reported using placebos in clinical practice. Still, 12 percent said that placebo use should be categorically prohibited in clinical practice, while the rest supported the use of placebos in a variety of circumstances, including when research supports its efficacy (46 percent) and if the physician anticipates the placebo will benefit the patient (31 percent). About one in five respondents suggested placebo use was appropriate only after a patient was notified about "receiving a placebo." Of those who reported placebo use, when asked about their personal practice, 4 percent introduced the treatment using the word "placebo." Still, the majority offered information that may have accurately described the nature and purpose of the proposed treatment. For instance, 34 percent introduced the placebo as "a substance that may help you and will not hurt," and 9 percent as "medicine with no specific effect." Another 33 percent individualized their response to this question with statements such as, "This may help you but I am not sure how it works." At the time our data were collected, prior to the AMA report, psychiatrist Walter Brown proposed a way to introduce a placebo to patients that, he believed, avoided concerns about informed consent. Similar to most of our surveyed physicians, Brown's proposal, which he adapted from a previous study, does not explicitly contain the word *placebo:* "These pills do not contain any drug. We don't know exactly how they work; they may trigger or stimulate the body's own healing processes. . . ."[8] According to our study results and Brown's recommendation, specific use of the word *placebo* is not a customary part of current clinical practice.

While our study offers new insight into physicians' behaviors and beliefs, our study is limited by its largely multiple-choice design, and further qualitative research is warranted to gain better insight into the nuances of individual physician's behaviors and attitudes. Still, many physician respondents offered comments that frequently referred to the tension between promoting the placebo effect and non-deceptive therapeutic practices. As a potential solution to what many physicians recognized as an "ethical conundrum," several physicians suggested that placebo use would be appropriate only if the patient agreed to the *possibility* of receiving a placebo. One physician commented, "As in a clinical trial, I would provide a placebo [in clinical practice] only if the patient knew that she/he may receive a placebo during the course of treatment, but may not know at what point during therapy. I think this would allow preservation of the placebo response." The AMA report offers a similar recommendation, stating that the patient must be informed and agree to receive a placebo for medical diagnosis or treatment, but the patient need not know the identity of the placebo at the actual time of use.

IS THE PLACEBO FOR THE PATIENT OR THE PHYSICIAN — OR BOTH?

The AMA report states that placebos "must not be given merely to mollify a difficult patient, because doing so serves the convenience of the physician more than it promotes the patient's welfare." In 1979, Goodwin, Goodwin, and Vogel found that 75 percent of the physicians surveyed had ordered a placebo for "a 'problem patient,' a patient that the nursing staff was complaining about."[9] Although such use of placebos appears to be less common today, 15 percent of our physician respondents did report using placebos "after 'unjustified' demand for

medication," and 6 percent had used a placebo "to get the patient to stop complaining." Rather than prescribing a placebo in these types of circumstances, the AMA encourages physicians to produce a "placebo-like effect through the skillful use of reassurance and encouragement." While reassurance and encouragement are indispensable physician practices and should be taught as a central part of medical schools' training courses on doctor-patient interaction, we believe there may be situations when a prescription for a placebo may *equally* serve the convenience of the physician and provide supplemental therapeutic benefit for the patient. This therapeutic value may be broadly conceived to apply to both disease-specific symptoms as well as personality-dependent emotional states that contribute to a patient's overall health, and may also influence disease-specific health outcomes.

THE USE OF "IMPURE" PLACEBOS

Although the AMA report acknowledges the potential use of pharmacologically active medications as placebos, it does not discuss the ethical implications of this practice. According to the AMA report, a placebo may be defined as a substance that has "no known specific pharmacological activity against the condition being treated." The use of a pharmacologically active medication for non-indicated conditions raises important ethical questions. For the purposes of our discussion, we will refer to pharmacologically active placebos as "impure placebos," a term used by professor of law Adam Kolber, who, in contrast, called a biologically inert substance a "pure placebo." Kolber writes, "Impure placebos can be difficult to detect because the prescribed medication has a pharmacological effect on some illnesses, and doctors may be able to provide plausible-sounding medical rationales for prescribing impure placebos."[10]

Our study found that physicians rarely prescribed "pure placebos." Rather, nearly all of the physicians who said they had prescribed a placebo prescribed "impure placebos." Of the 48 percent of physicians who reported giving at least one type of treatment in a situation when there was no evidence of clinical efficacy. Among the treatments given, 33 percent reported giving antibiotics for viral or other non-bacterial diagnoses, others gave vitamins (20 percent), ibuprofen (12 percent), sub-therapeutic doses of medication (7 percent), and herbal supplements (5 percent). Only a small minority of physicians reported giving what may be considered "pure placebos," such as prepared placebo tablets (2 percent), saline infusions (3 percent), and sugar or artificial sweetener pills (1 percent). These results suggest that the placebos used by physicians in clinical practice are rarely biologically inert substances, or "dummy" pills, which is how they are typically characterized in research trials and in popular culture. Unfortunately, "impure placebos" may have known potential negative side-effects and, in the case of antibiotics, their overuse promotes drug-resistant infections. We believe further dialogue regarding the appropriate use of "impure placebos" in clinical practice is needed.

PLACEBOS AS SYMBOLS OF HEALING

A placebo serves as a symbol of healing that triggers positive therapeutic expectations in a patient. We suggest that the definition of placebos include but not be limited to a "substance," as defined by the AMA report. We suggest the definition of placebos also include interventions or factors that have no known specific clinical efficacy against the condition being treated. Physicians' practices such as wearing a white coat, or the physical examination of the patient (independent of diagnostic purposes) may serve as placebo treatments for patients. As one physician in our study commented, "I have always wondered if the office physical exam is as much a sophisticated grooming ritual to relieve stress rather than obtain diagnostic information. In the outpatient setting it is typically normal but both physician and patient are fairly attached to its performance."

In another example of the symbolic value of a placebo, physician David Watts, a gastroenterologist, poet, and writer, spoke of his experience *prescribing* medication to patients that he also suggested they may not need to take. "There's something about sitting down at the desk and writing it [the medication] out longhand, tearing the prescription from its pad and handing it to him [the patient], taking it down to the pharmacist who brings forth this amber bottle with a childproof cap and 25 small white

excretions of something wonderful. Something about all of that that is just the right amount."[11] This expanded definition of a placebo captures the broader symbolic aspects of patient care that may trigger the placebo effect.

CONCLUSION

As a matter of scientific inquiry, the power of the placebo effect will continue to be researched as an isolated variable, both in formal research studies and during *N*-of-1 clinical trials (trials in which a medication is tested in only one individual). Ultimately, in clinical practice, the separation of placebos and the placebo effect from other forms of therapy is somewhat artificial. In the context of everyday medicine, we believe the symbolic value of placebos and the power of the placebo effect are best served not as isolated therapeutic tools, but rather as integrated aspects of humanistic and holistic patient care. In the year 2008, amidst great technological advances of modern medicine, the purpose of the ancient charm used by Socrates still resonates. "For the charm will do more, Charmides, than only cure the headache. I dare say that you have heard eminent physicians say to a patient who comes to them with bad eyes, that they cannot cure his eyes by themselves, but that if his eyes are to be cured, his head must be treated; and then again they say that to think of curing the head alone, and not the rest of the body also, is the height of folly. And arguing in this way they apply their methods to the whole body, and try to treat and heal the whole and the part together."[12]

POSSIBLE ADDENDA TO THE AMA RECOMMENDATIONS ON PLACEBO

We offer the following as possible additions to the AMA report.

1. Placebos, when used, should be a supplement and not a substitute for a clinically indicated treatment.

2. Placebos may be useful when there is no other effective treatment available for a patient.

3. "Pure" placebos are generally safer than "impure" placebos.

4. Only safe impure placebos should be used (for example, certain vitamins).

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NOTES

The quotations at the beginning of this article are anonymous physicians' quotes from the authors' 2006 survey data.

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Clinical Placebo Interventions Are Unethical, Unnecessary, and Unprofessional

Asbjørn Hróbjartsson

INTRODUCTION

The American Medical Association Council on Ethical and Judicial Affairs (CEJA) has written a report on the clinical use of placebo interventions.[1] The CEJA position, adopted by the American Medical Association House of Delegates, is that placebo interventions are ethically acceptable if the patient is informed about the nature of the treatment, but that the information need not be such that the placebo intervention is clearly identified, nor is it necessary to seek specific consent before its administration. In the following I will argue that this position is not tenable.

WHY AND HOW DO PHYSICIANS USE PLACEBO INTERVENTIONS?

Within the last five years, two large surveys of European or American clinicians have described how often, why, and how physicians treat patients with placebo interventions.[2] Our survey of 772 Danish physicians (with a response rate of 65 percent) found that 86 percent of general practitioners, and 54 percent of hospital-based physicians, said that they had used a placebo intervention at least once in the last year.[3] Half of the general practitioners (48 percent), and 10 percent of hospital-based physicians, said that they had used a placebo intervention more than 10 times within the last year. The most frequent reason given for placebo interventions was "to follow the wish of the patient and avoid a conflict." The most frequent placebo interventions were antibiotics (for example, for viral infections). Placebo interventions were considered ethically acceptable by 46 percent of the respondents.

The other survey, which included 466 academic physicians (with a response rate of 50 percent) at three Chicago-based medical schools, found that 45 percent of the respondents said that they had prescribed a placebo intervention within the last year, and 8 percent had used a placebo more than 10 times in the last year.[4] The most common reason for using placebo given was "to calm the patient" (18 percent). Other reasons included, for example, "unjustified demand for medication (15 percent)," and "to get the patient to stop complaining (6 percent)." In this survey also, the most typical placebo intervention was antibiotics. Half of the respondents (46 percent) thought a placebo intervention was permitted "when research supported its efficacy." The respondents reported that in 4 percent of the cases, patients were informed, "it is a placebo."

The CEJA statement mentions the possibility of "nocebo effects," and thereby probably thinks of placebo interventions as preparations

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containing no active drug, for example saline injections or lactose tablets, so-called "pure placebos." This is in conflict with the findings of these surveys, that the typical placebo is a drug, a so-called "impure placebo," in many cases an antibiotic. The ethical implication is that drugs have harmful effects. For example, antibiotics can result in serious allergic reactions for the individual being treated, and other harms; further, the unjustified use of antibiotics may cause the unnecessary development of bacterial resistance, creating potential problems for future patients who are in true need of antibiotics.

The central section of the CEJA report starts, "Physicians administer placebos because placebos might relieve the symptoms that cause distress to their patients." The statement thereby indicates that placebos typically are initiated for the benefit of patients. The report does state, in the middle of the text, and without a heading of its own, that it is not ethically acceptable to use placebo interventions "to serve the convenience of the physician rather than to promote the well-being of the patient," however, the prominent place given to the presentation of the ethically sound motive of helping the patient portrays the typical ethical situation as a dilemma between two valid ethical principles, that is, between promoting patients' well-being and respecting patients' autonomy. In contrast, the surveys find that placebo interventions typically are initiated for the "convenience" of the physician.

CONVENIENCE PRESCRIPTIONS OF PLACEBO SHOULD BE AVOIDED

Convenience prescriptions of placebo interventions involve two quite different ethical scenarios that are not considered in the CEJA report. The first scenario involves a placebo treatment, for example "to get the patient to stop complaining," without informing the patient that the treatment is a placebo. Such a practice is clearly unethical, as it implies deception that is unbalanced by benevolence, and that carries the risk of harmful effects.

The second scenario involves disagreement about treatment. A patient wants a treatment that the physician thinks is unnecessary because there are no expected additional benefits. The physician clearly states this to the patient, who still wants the intervention. This is not a case of deception, but one of the physician's professional integrity being in conflict with the patient's wishes. Should a physician follow the wish of a patient and prescribe a placebo intervention? (Given that any treatment is a placebo when there is no expected additional benefit beyond that of the treatment ritual.) As stated, potential harmful effects to the individual patient — and, in the case of antibiotics, potential harm to future patients — speak strongly against this practice. Further, to prescribe an intervention only because the patient wants it implies a substantial transformation of the patient-provider relation. Ideally, a possibly imprudent treatment wish of a patient is checked by the physician's professional considerations, and a possibly imprudent treatment suggestion by a physician is checked by the patient's wishes. If a patient's wishes overrule professional considerations, the relation between patient and physician risks being transformed from one of mutual respect and dialogue to one resembling that between customer and shopkeeper.

Still, it is no simple task to decide when a treatment should be considered a placebo and when it is part of a defensive treatment strategy. In the case of antibiotics, one physician may conclude that a fever is viral and therefore consider antibiotics a placebo intervention. Another physician may conclude that the fever is *most likely* viral, but the risk of bacterial infection is not negligible, and will therefore not consider antibiotics to be a placebo intervention. Clearly, from a theoretical point of view, the two situations are very different, but from a practical perspective, they may merge in the inevitable clinical uncertainty. Whether an intervention is considered a placebo or an active treatment depends on a physician's gut feeling about the expected treatment benefit (beyond any effect of the treatment ritual). A physician's gut feeling may be very different from a patient's, and this tension represents a challenge to the physician-patient relationship. It is a challenge, however, that should be met with further dialogue and reconsiderations about the expected benefits and harms, and not by caving in and compromising

professional integrity by prescribing ineffective and potentially harmful drugs.

LITTLE EVIDENCE THAT PLACEBO INTERVENTIONS IN GENERAL HAVE CLINICALLY IMPORTANT EFFECTS

The CEJA report implicitly takes for granted that the effects of placebos are clinically relevant and universal. In the 1950s, it was commonly accepted that the effects of placebo were clinically relevant for many patients who experienced both subjective and objective improving outcomes in many clinical conditions.[5] However, this was a misconception based on flawed methodology. In most cases comparisons had been based on changes from baseline in a placebo group, and not on a more reliable comparison between a placebo and a no-treatment group.

Our review of 114 randomized clinical trials comparing placebo with no-treatment groups found no statistically significant effect on binary outcomes or on continuous-observer reported outcomes.[6] We found that patients who had received a placebo reported somewhat reduced subjective symptoms compared with untreated patients, but it was unclear to what extent this was due to the bias inherent in unblinded trials (for example, reporting bias) and to which extent the effect was real. We also found a statistically significant effect of placebo on pain, but the size of the improvement was modest, corresponding to 6 mm on a 100 mm visual analogue scale. This result was reproduced in 2004, when we updated the review with more than 50 additional trials.[7] Even assuming that an effect of placebo exists beyond the expected reporting bias, for example on pain, we know little about the situations that generate such an effect. Our predicament is that a few clinical trials show substantial effects, and many trials show no effects, or in some cases harmful effects, and there is no clear pattern that explains this variation.

Therefore, based on over 150 trials there is, on average, no evidence of clinically relevant effects of placebo interventions over a broad range of clinical conditions. Therefore, the main ethical argument for placebo prescriptions, that such interventions generally will benefit patients, is highly questionable.

REPLACE PLACEBO TREATMENTS WITH EMPATHIC CONSULTATION STRATEGIES

An intervention, including a placebo intervention, is but one of many components of the patient-provider interaction. It is challenging to study the various components of patient-provider relationships and how the parties interact. Still, reviews indicate that the relation between a patient and a supportive person can have important effects on subjective and objective outcomes. One Cochrane review on the effect of a supportive person on labor concluded that it reduced the number of Caesarean sections, the number of women that needed analgesics, and the number of women with "unpleasant labours."[8] There is no need for placebo interventions. A better alternative is a consultation strategy involving dialogue, empathy, information about relevant facts, and joint decisions about diagnosis and treatments.

The CEJA mentions, "In some instances, it may be most appropriate to forego the use of placebos altogether." It would have been interesting to know CEJA's suggestion of why this is appropriate only in "some instances," and not always.

THE CEJA POLICY ON PLACEBO OPENS THE GATE TO A DANGEROUSLY SLIPPERY AREA

The report states that clinical placebo interventions "may prove particularly valuable for conducting single patient controlled studies, known as *N*-of-1 trials." Such trials are a special version of randomized clinical trials. In this case an individual person with a reasonable stable chronic condition will engage in testing the effect of two or more treatments. Typically, the patient will be blinded, for example by using a placebo, and typically there will be several periods of treatments in a random order. However, *n*-of-one trials are rare, and their ethical problems are basically the ethical problems of clinical trials. Therefore, CEJA's emphasis on n-of-one trials in a report on the use of placebo in clinical practice is misplaced.

Still, the phrase "particularly valuable" has the implication that the report does not restrict use of placebo to *n*-of-one trials. Placebo inter-

vention, according to the report, may be valuable (if not particularly so) outside *n*-of-one trials. One likely scenario envisaged by the CEJA could be a clinician in doubt about a treatment. He or she then discusses this with the patient, and prescribes various medications, including placebos, to try what works best, but without the formal design of the randomized sequences of *n*-of-one trial. However, such an approach is unethical. Without the bias-reducing techniques of randomization of treatment periods, and blinding procedures, informal experimentation has a very high risk of bias. Poorly conducted research is unethical, also when it comes to *n*-of-one trials. From the patient's perspective, it is preferable to either be referred to another physician with more knowledge about the clinical problem or to participate in a properly conducted *n*-of-one trial.

CEJA opens the gate to a dangerously slippery area when they recommend that the information provided to patients need not be such that the placebo intervention is clearly identified nor is it necessary to seek specific consent before its administration. The surveys indicate that physicians, when using placebo interventions, often inform their patients in a purposely vague manner, by stating "this is a substance that may help and will not hurt," or "it's a medication," or "this may help you but I am not sure how it works."[9] This practice is clearly unethical because patients are unaware that they will receive a placebo.

CONCLUSION

The CEJA recommendations are problematic from a clinical, research, and ethical perspective. The recommendations do not address present placebo prescription practices, nor build on systematic reviews of randomized trials comparing placebo with no-treatment. A revised recommendation could include the following:

Clinical placebo interventions are unethical, unnecessary, and unprofessional. Placebo interventions are potentially harmful. First, placebo interventions are often drugs that involve a risk of harmful side-effects. Second, placebo interventions may damage patient-physician trust considerably, because they often involve deception and prescriptions for the convenience of the physician rather than for the well-being of the patient. Randomized trials generally find no effects, or modest subjective effects, of placebo interventions. Placebo interventions could, and should, be replaced by empathic consultation strategies.

NOTES

1. N.A. Bostick et al., "Placebo Use in Clinical Practice: Report of the American Medical Association Council on Ethical and Judicial Affairs," in this issue of *JCE.*

2. A. Hróbjartsson and M. Norup, "The use of placebo interventions in medical practice — a national questionnaire survey of Danish clinicians," *Evaluation & the Health Professions* 26 (2003): 153-65; R. Sherman and J. Hickner, "Academic physicians use placebos in clinical practice and believe in the mind-body connection," *Journal of General Internal Medicine* 23 (2008): 7-10.

3. Hróbjartsson and Norup, see note 2 above.

4. Sherman and Hickner, see note 2 above. The study was published electronically in October 2007, which is considerably later than the drafting of the CEJA report. However, the point here is not the specific study cited, but that none of the several published studies of the clinical use of placebo was discussed in the report.

5. H.K. Beecher, "The powerful placebo," *Journal of the American Medical Association* 159 (1955): 1602-6.

6. A. Hróbjartsson and P.C. Gøtzsche, "Is the placebo powerless? An analysis of clinical trials comparing placebo treatment with no treatment," *New England Journal of Medicine* 344 (2001): 1594-602.

7. A. Hróbjartsson and P.C. Gøtzsche, "Is the placebo powerless? Update of a systematic review with 52 new randomised trials comparing placebo with no treatment," *Journal of Internal Medicine* 256 (2004): 91-100.

8. E. Hodnett et al., "Continuous support for women during childbirth," *Cochrane Database of Systematic Reviews* issue 3 (2007): article no. CD003766, *http://www.cochrane. org/reviews/en/ab003766.html.*

9. Sherman and Hickner, see note 2 above.

Case Commentary

Commentary on "The Case of Mr. A.B.": Dilemmas for a Reason

G. Caleb Alexander

Ethical dilemmas are called *dilemmas* for a reason. Unlike some cases in clinical ethics, which can ultimately be resolved with the gathering of additional facts or the facilitation of greater communication among affected parties, in the article "The Case of Mr. A.B.," we face a true dilemma: should the staff not tell Mr. A.B. about the tragic loss of his daughter prior to a planned bypass surgery, as his family asks? The authors of the case, Peter Sloane and Evan G. DeRenzo, should be commended for highlighting that "refined ethical analysis rarely results in a neat division between what is clearly ethical and what is clearly not."[1]

There are many important dimensions of the problem of truth-telling in medicine (for example, Is lying different than deception?), most of which are far beyond the scope of this commentary.[2] Nevertheless, a few observations follow.

First, the facts are clear, as are the competing principles at stake. Mr. A.B.'s family and the medical team must grapple with a classic tension between beneficence and patient autonomy. Unfortunately, part of what complicates the picture in this setting is the difficulty of knowing how the timing of the delivery of the daughter's death will impact Mr. A.B. The physiologic consequences of grief in the context of his critical illness are not clear, and, of course, given its rarity, this is not the sort of topic that lends itself to rigorous scientific study.

The real crux of the issue here, as with many cases of delivering bad news, is not whether or not the truth should be told, but how it should be told. Respecting Mr. A.B.'s autonomy does not necessitate the delivery of sensitive information without consideration of timing, and a whole host of other contextual factors. Patients don't need to be "hit over the head" with information, and just as with disclosing a terminal diagnosis, clinicians should skillfully deliver information with careful consideration of not only *what* is communicated but *when* it is communicated, *how* it is communicated, *who* is present, and the like.[3] In this case, one helpful consideration to guide when disclosure should take place is how elective the bypass surgery truly is. The less elective the surgery, the less any news of the daughter's death seems material to the decision of whether or not the surgery should be pursued.

The main argument to support postponing disclosure of the daughter's death is Mr. A.B.'s own precarious state. It may be safe to assume that if any patient were to be at increased risk

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of poor outcomes triggered by acute grief, Mr. A.B. would be the one. Even without news of his daughter's death, his comorbid conditions and current clinical instability already put him at serious risk from his bypass surgery. Going into the operating room on a ventilator is never a good prognostic sign, and even Mr. A.B.'s "peak physiologic state" is tenuous.

(As an aside, despite the hardship and grief that this patient will necessarily undergo, how fortunate that he has a family and that they are all on the same page. This consensus is invaluable in helping to negotiate these clinical settings. Nevertheless, the clinician has shared responsibility for the situation. Responsibility for withholding news of the daughter's death cannot be abandoned by the healthcare providers and left to the family alone,[4] even if the patient's children, as Sloane and DeRenzo stated, are "adamant that they would take responsibility for such outcome and would be clear with their father that the decision to delay disclosure was theirs.")

This is a tricky clinical case, and one could argue that there may be more than one ethical resolution to the dilemma that the team and patient's family face. Is it possible that the morally defensible course lies as much in the process that is taken as in the outcome that is reached — a procedural argument that recognizes the vagaries of clinical decisions that at times must be made? Here, the team reached a decision through thoughtful deliberation and careful consultation with the affected parties. True, it is a decision about which reasonable people will disagree. However, this is what characterizes dilemmas in the second-best world in which we live.

EPILOGUE

Although tempting, the ethical standing of the decision to withhold news of the daughter's death should not be judged based on the follow-up to the case that is provided. This follow-up, and the outcome of other similar cases, may be of interest and utility in informing how *future* cases should be navigated. However, whether or not the decision reached in *this* case was an ethical one should be judged based on the information that was available to the decision makers at the time the decision was made. Hindsight is, after all, better than foresight, if not 20/20.

ACKNOWLEDGMENTS

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NOTES

1. P. Sloane and E.G. DeRenzo, "The Case of Mr. A.B.," The Journal of Clinical Ethics 18, no. 4 (Winter 2007), 399-401.

2. M. Sheldon, "Truth telling in medicine," *Journal of the American Medical Association* 247 (1982): 651-4.

3. R.D. Truog et al., "Sudden Traumatic Death in Children: 'We Did Everything, but Your Child Didn't Survive'," *Journal of the American Medical Association* 295 (2006): 2646-54.

4. A. Torke et al., "The doctor-surrogate relationship," *Archives of Internal Medicine* 167 (2007): 1117-21.

Law

Legal Trends in Bioethics

Sigrid Fry-Revere, Sheeba Koshy, Greyson C. Ruback, and John Leppard, IV

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*.

GENERAL INTRODUCTION

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

Each state also has its own constitutional protections, some of which clearly mirror those in the federal Constitution, but others do not.

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

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

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to show greater deference to individual choice than legislatures do, and tend to become more cautious when confronted with divisive issues.

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

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

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

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

INTRODUCTION TO "LEGAL TRENDS IN BIOETHICS" SPRING 2008

This issue of "Legal Trends in Bioethics" extends the scope of what is covered to include not only cases, but also regulatory actions such as fines and other penalties imposed for violation of regulatory requirements. This change reflects a trend, not a recent one, but a long-term trend in the United States to rely more on regulatory discipline through the executive and legislative branches than the traditional route of judicial court action. As reflected in the *Lebron* case discussed in the "Oversight" section below, this trend poses a potential threat to the balance of power between the three branches of government. It also poses a threat to constitutional principles of due process and fairness. Regulatory bodies have the same constitutional obligation to abide by principles of due process and fairness as the judiciary, but unlike the structure of the judicial system, which is constitutionally determined, regulatory bodies are invented and reinvented as needed. It is hard to ensure fairness when regulations and the privileges and obligations they impose are constantly in flux.

The growing trend toward regulatory rather than judicial action is also reflected in the inclusion of a new section for the Department of Health and Human Service Food and Drug Administration (FDA). At the end of last year, Congress passed the largest reform of the FDA since 1997. This reform included a huge increase in the agency's budget and many new responsibilities. Also, the U.S. Supreme Court has acted on several FDA-related cases. Already reported in the last "Legal Trends in Bioethics" but repeated here is a discussion of the *Abigail Alliance* case, in which plaintiffs sought more ready access to drugs for terminally ill patients before final FDA approval. By refusing to hear the case, the U.S. Supreme Court let stand the D.C. Circuit Court's holding that the FDA had the authority to regulate access to drugs, even to the point of denying such access to terminally ill patients for whom such drugs might be the only hope of survival. Another case involving the FDA, *Riegel v. Medtronic*, however, was granted a hearing by the Supreme Court. In *Medtronic,* the issue isn't access to drugs but whether FDA market-

ing approval, based on its evaluation of the safety and effectiveness of a product, protects manufacturers of that product from liability if the product somehow does not meet state standards.

FDA

The FDA is undergoing monumental changes that will affect the field of bioethics both directly and indirectly. The FDA currently has a budget of more than $2 billion and regulates the sale of more than $1 trillion of products annually, including food, drugs, cosmetics, and medical devices. Justin Blum, " 'Inadequacies' at U.S. FDA Risk Lives, Report Says," *Bloomberg.com*, *http://www.bloomberg.com/apps/news?pid=newsarchive &sid=ampdOikmgaIA*, accessed 1 February 2008. And there is no end in sight for growth in both the FDA's budget and its responsibilities. The public mistrusts the medical establishment, the pharmaceutical industry, and new medical technologies, and demands that government agencies like the FDA help it negotiate ever more difficult medical decisions about increasingly useful but hazardous treatments. Understandably, Congress has bowed to public pressure, and this quarter's "Legal Trends in Bioethics" includes a new "FDA" section and a more detailed description of Food and Drug Administration Amendments (FDAA) of 2007 than reported last quarter. Regulations passed to implement the FDAA and other revisions to drug and medical device regulation and related judicial cases will be reported in future entries under this section.

Recent Judicial Cases and Regulatory Actions October - December 2007

The U.S. Supreme Court heard oral arguments on 4 December 2007 in the case of *Riegel v. Medtronic*. The issue before the Court is whether medical device companies selling products approved by federal regulators can be sued under state laws by patients injured by the companies' products. Medtronic asserts that the device in question was approved by the FDA and federal law "preempts" patients from claiming violation of state laws related to safety and effectiveness. S. Ct. (US no. 06-179).

Recent Developments in Law and Regulation October - December 2007

The President signed into law on 27 September 2007 the Food and Drug Administration Amendments Act of 2007. The act greatly expands the FDA's authority. The act includes a target number of $450 million in user fees to be paid by drug companies; this would be an increase over $100 million from previous years. The new user fees will contribute approximately 25 percent of the FDA's current $1.6 billion budget. The act allows the FDA to issue fines of up to $10 million if drug makers fail to complete FDA-requested studies. It strengthens conflict of interest rules for FDA drug safety panels by requiring a reduction of the number of scientists with ties to drug companies by 25 percent over the next five years. It also includes new authority for the FDA to require pharmaceutical companies to track adverse events, regulate pharmaceutical marketing, and expand the pediatric exclusivity provisions of the Best Pharmaceuticals for Children Act for another five years. Also, the FDA Amendments Act instructs the Secretary of the U.S. Department of Health and Human Services (DHHS) to create mandatory registration and reporting requirements for clinical trials to be posted on a national publicly available database, probably on the National Library of Medicine's website *www.clinical trials.gov.* Public Law No: 110-85. Related bills include H.R. 2900 and S. 1082, 110th Leg., Reg. Sess. (2007).

The FDA issued proposed guidelines on 15 November 2007 to increase transparency regarding conflicts of interest for members of its advisory panels. The proposed rules require experts on advisory panels to disclose any financial ties to an industry if an issue involving that industry is before the panel, and to detail the reasons that they still should be allowed to serve on the committee. FDA Press Release, "FDA Announces Steps to Improve Advisory Committee Processes," 15 November 2007, *http://www.fda.gov/bbs/topics/NEWS/2007/NEW01744.html*.

The FDA is preparing new draft guidelines that would allow pharmaceutical and medical device companies to send physicians studies on "off-label uses," that is, non-FDA approved uses,

of medications. Physicians can prescribe medications and medical devices for off-label uses, but the FDA currently prohibits the marketing of drugs and medical devices for unapproved purposes. Under the FDA's draft guidelines, companies can send physicians unabridged reprints of studies on off-label uses of medications published in peer-reviewed medical journals, as long as they are not significantly influenced by the companies or individuals with financial ties to them. A. Wilde Matthews, "FDA and Drug Marketing," *Wall Street Journal*, 1 December 2007, *http://online.wsj.com/article/SB11964 697331 4510201.html,* accessed 11 February 2008. Full text of the draft: *http://oversight. shouse.gov/documents/2007113010 3225.pdf.*

The FDA gave a Seattle company, Targeted Genetics, permission to resume its human tests of an experimental, gene-based arthritis treatment on 26 November 2007. The FDA ordered a hold on the tests after the death of a study participant was determined to be unrelated to the treatment. An inquest into the cause of the patient's death was conducted by Targeted Genetics' own scientists, the National Institutes of Health, and doctors at the University of Chicago. R. Weiss, "Gene Study Therapy is Allowed to Resume," *Washington Post,* 26 November 2007*, http://www. Washingtonpost.com/wp-dyn/content/article/2007/11/25/AR2007112501229. html*, accessed 28 January 2008.

OVERSIGHT: PATIENT TRUST

Some topics previously included in this section are now under the heading "FDA," so please review that section for issues involving government oversight and patient trust directly related to the FDA. Regulatory actions with relevance to bioethics issues by government entities other than the FDA at the federal and state levels are reported here. Also reported here are civil actions that often parallel regulatory actions. Civil suits are filed because, while regulatory actions can result in fines and regulatory relief, they do not result in damages or reparations. For plaintiffs to receive damage awards, they must seek relief in a civil suit. Therefore, for example, Medtronic, Inc. has entries in both the "FDA" and "Oversight" sections.

Recent Judicial Cases and Regulatory Actions October - December 2007

National. The pharmaceutical company Merck, Inc. will settle 27,000 lawsuits by paying $4.85 billion for damages suffered by users of its painkiller Vioxx. Finalization of the agreement requires that 85 percent of all plaintiffs agree to settle. A. Berenson, "Merck Agrees to Settle Vioxx Suits for $4.85 Billion," *New York Times Online*, 9 November 2007, *http:// www.nytimes.com/2007/11/09/ business/09 merck.html?_r=1&scp=3&sq=Vioxx +settlement &st=nyt&oref=slogin*, accessed 28 January 2008.

The device manufacturer Medtronic, Inc. reached a settlement of $114.1 million related to its Marquis line of implanted cardiac defibrillators. Plaintiffs in the suits against Medtronic allege that the company knew for years that there was a potential for defects in the battery used in the defibrillator, but sold them anyway and didn't advise patients that safer devices were available. Medtronic argued that it fulfilled every obligation in terms of reporting the problem. K. Shwiff, "Medtronic to Pay $114 Million in Settling Heart-Device Suits," *Wall Street Journal Online*, 21 December 2007, *http://online. wsj.com/article/SB119827448 805945807.html*, accessed 4 February 2008.

California. The California Department of Managed Health Care fined Health Net $1 million for lying to state investigators about paying employees bonuses based on the number of individual health insurance policies they canceled. California law prohibits insurers from compensating claims reviewers based on their claims decisions. "California Fines Health Net $1M for Lying about Linking Employee Bonuses to Policy Cancellations," *Kaiser Daily Health Policy Report*, 16 November 2007, *http:// www.kaiser network.org/Daily_reports/rep_ index.cfm? DR_ID=48921*, accessed 4 February 2008.

Illinois. The state circuit court of Cook County declared unconstitutional a 2005 state law that caps noneconomic damages in malpractice lawsuits at $500,000 in cases against physicians and $1 million in cases against hospitals. The court ruled that the law violates the separation of legislative and judiciary power.

The case is likely to advance to the Illinois Supreme Court. That court has stuck down state caps on damages in negligence lawsuits twice in the past 30 years. *Lebron v. Gottlieb Memorial Hosp.* (Ill. Cir. Ct. Cook County No. 06-L-12109, 13 November 2007).

Recent Developments in Law and Regulation
October - December 2007

Federal. The President signed into law on 26 December 2007 an omnibus budget package that includes a provision that requires the National Institutes of Health (NIH) to make the results of all NIH-funded studies available to the public free of charge. Under the provision, researchers who receive grants from NIH have to submit final copies of studies accepted for publication in a scientific journal. The results of these studies will be posted in a database available to the public free of charge within one year after publication. Implementation of the program could take up to six months. Public Law No: 110-161.

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

Colorado. The state department of health launched a new web-based Hospital Report Card that details information about hospital performance across the state. Information included in the site includes: the number of patients who died at Denver hospitals after heart-bypass surgery, hip replacement, or other procedures; the number of patients who got bedsores; and the number of surgeries a hospital performed. The Report Card also includes measures of mortality after 11 procedures, three measures of patient safety and data on the volume of 10 procedures at each hospital. K. Human, "State hospital report cards now available," *Denver Post Online*, 28 November 2007, *http://www.denverpost.com/news/ci_7581546*, accessed 1 February 2008.

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

THE RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

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

The abortion issue continues to strain the social and legal fabric that holds the United States together. Interestingly, most of the entries in this section this quarter do not deal with determining the rights of fetuses, but instead with the scope of influence that the pro- and anti-abortion camps can exert. Notably, all of the court cases reported involve constitutional issues such as the First Amendment right to protest, the right of Congress to impose restrictions on abortions — a right that traditionally has been reserved to the states — and the public's right to petition to force a state's attorney general to empanel a grand jury. In the laws section below, there are a few bills dealing directly with the rights of fetuses, but they are outnumbered by bills focused on secondary political maneuvering instead of the heart of the issue.

Recent Judicial Cases and Regulatory Actions
October - December 2007

Federal. A three-judge panel of the Fourth U.S. Circuit Court of Appeals heard oral arguments on 1 November 2007 in the attorney

general's appeal of the Court's previous ruling that a Virginia law permitting "partial-birth" abortions is unconstitutional in light of the U.S. Supreme Court decision in *Gonzales v. Carhart,* which upheld a federal ban on partial birth abortions. *Richmond Medical Ctr. v. Herring* (4th Cir. No. 03-1821).

U.S. District Court for Western Pennsylvania heard arguments on 19 December 2007 in a lawsuit challenging a Pittsburgh ordinance that creates a buffer zone between protesters and healthcare facilities, including abortion clinics. *Brown v. Pittsburgh* (Western PA District Court No. 06-CV-00393, 26 March 2006).

The U.S. District Court for the Eastern District of Pennsylvania ordered a Reading, Pennsylvania, man to stop posting material on the internet deemed threatening to doctors who provide abortion services. The anti-abortion activist had published the address and photographs of a doctor who worked at women's health clinics and made threatening remarks. *Gonzales v. Dunkle* (Eastern PA District Court No. 07-CV-03577, 8 November 2007).

Colorado. Anti-abortion advocates threatened to file suit against the city of Denver on First Amendment grounds because the city refuses to issue the groups permits to demonstrate during the Democratic National Convention scheduled to take place in Denver in August 2008. "Antiabortion Advocates Threaten to Sue Denver for Not Issuing Demonstration Permits for Democratic Convention," *National Partnership for Women and Families Daily Women's Health Policy Report*, 5 November 2007, *http://npwf.convio.net/site/News2?abbr=daily2_&page=NewsArticle&id=7599&news_iv_ctrl=-1&s_oo=D4Tvn MQZLC3oTo5K9b AQTA*, accessed 26 January 2008.

Kansas. Life is for Everyone, a coalition of the anti-abortion groups led by Operation Rescue, submitted a citizens petition to convene a grand jury to investigate whether Planned Parenthood of Kansas and Mid-Missouri's Overland Park, Kansas, clinic Comprehensive Health is complying with state abortion laws. The petition alleges that Comprehensive Health performs illegal late-term abortions, provides false information to state officials, fails to report suspected child abuse, participates in illegal trafficking of fetal tissue, fails to comply with parental notice requirements, and fails to enforce a 24-hour waiting period. National Partnership for Women and Families, "Kansas Judge Selects Grand Jury for Investigation of Planned Parenthood Clinic," 12 December 2007, accessed 1 February 2008.

*A grand jury convened on 30 October 2007 to investigate whether Dr. George Tiller broke a state law concerning late-term abortions. Abortion opponents have garnered enough signatures of registered voters to form a grand jury pursuant to a 1970 state law that allows the public to petition for the calling of a grand jury. Six other states also have laws allowing citizens to petition for a grand jury hearing against the state attorney general's better judgment. Kaiser Family Foundation, "Kansas Abortion Opponents Petition for Grand Jury Investigation of Abortion Provider Tiller," *Kaiser Daily Health Policy Report*, 13 September 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2& DR_ID=47348*, accessed 3 November 2007.

Recent Developments in Law and Regulation
October - December 2007

***Hawaii**. Two bills were held over from the 2007 legislative session that would allow all forms of stem-cell research. H.B. 364, H.B. 1261, 24th Leg., Reg. Sess. (Haw. 2007).

Massachusetts. The state senate passed a bill on 23 October 2007 that would expand abortion clinic buffer zones from 18 feet to 35 feet. The current law, passed in 2000, requires protesters to stay at least six feet away from the clinic's employees and patients and establishes an 18-foot zone within which individuals may not interact with clinic visitors or staff for the purpose of counseling or protesting. S.B. 1353, Gen. Assem., Reg. Sess. (Mass. 2007).

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

New Jersey. A ballot initiative failed that would have allowed New Jersey to borrow $450 million for stem cell research grants in the next

decade. K. Heyboer, "Dissecting the Stem Cell Vote," *Jersey Blogs*, 8 November 2007, *http://blog.nj.com/jerseyblogs/2007/11/ disectingthe_stem_cell_vote.html*, accessed 4 February 2008.

***Ohio**. There has been no action on a bill introduced on 19 July 2007 that would prohibit women from undergoing an abortion without the written consent of the father. Should the identity of the father be unknown, women would be required to submit a list of possible fathers to the physician, who would be required to conduct paternity tests and then seek paternal permission to abort. First-time violators would be charged with abortion fraud, a first-degree misdemeanor. Repeat offenders would be charged with a fifth-degree felony. H.B. 287, 127th Gen. Assem., Reg. Sess. (Oh. 2007).

*There has been no action on a bill introduced on 10 July 2007 that would prohibit all abortions in the state, as well as any distribution of mifepristone (the "morning-after pill"). The bill would also increase the penalties for unlawful abortions and abortion trafficking. H.B. 284, 127th Gen. Assem., Reg. Sess. (Oh. 2007).

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

Pennsylvania. A bill passed the state house on 17 July 2007 that provides for umbilical cord blood banking, and is currently in the state Senate Appropriations Committee. The bill requires healthcare practitioners to give pregnant patients information regarding umbilical cord donation. H.B. 874, 191st Gen. Assem., Reg. Sess. (Pa. 2007).

South Dakota. A group of pro-life citizens recently filed a petition to collect signatures for a South Dakota ballot initiative that would ban abortions with limited exceptions, including cases of rape or incest, to save a woman's life, or in cases of a "substantial and irreversible health risk" of impairment to "a major bodily organ or system." Supporters must collect 16,776 signatures of registered voters by 1 April 2008 for the measure to appear on South Dakota's November 2008 ballot. "Petition Filed for Ballot Initiative in S.D. That Would Ban Most Abortions," *Daily Women's Health Policy Report,* 18 December 2007, *http://npwf.convio.net/site/News2?abbr=daily2_&page=News Article&id=9391*, accessed 1 February 2008.

Wisconsin. A bill is moving its way through various committees in the state legislature. Originally introduced in the state senate on 19 June 2007, the bill would require physicians who perform abortions to take certain steps if a woman seeking an abortion seems to have been coerced into having the abortion or seems to be in danger of being harmed if she declines to have the abortion. The bill is currently in the state senate committee on Health, Human Services, Insurance, and Job Creation. S.B. 218, 1007 Reg. Sess. (Wis. 2007).

Interesting Developments in Other Countries

International. A study conducted by the Guttmacher Institute and the World Health Organization found that abortion rates are similar in countries where the procedure is legal and where it is not legal. Additionally, the study found that the number of abortions worldwide is declining due to increased access to contraception. Kaiser Family Foundation, "Abortion rates similar in countries that legalize, prohibit abortion, study says," *Kaiser Daily Health Policy Report*, 12 October 2007, *http://www.kaisernetwork.org/daily_reports/rep_index. cfm?hint=2& DR_ID=48142*, accessed 26 January 2008.

Brazil. The governor of Rio de Janeiro, Brazil on 24 October 2007 urged the government to legalize abortion. The governor said legal abortions could help reduce violence in the city. In Brazil, abortion is banned except in cases of rape or to save the life of the pregnant woman. Kaiser Family Foundation, "Legalizing Abortion in Rio de Janeiro, Brazil, Could Help Reduce Violence, Governor Says," *Kaiser Daily Health Policy Report*, 26 October 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm? hint=2&DR_ID=48455*, accessed 26 January 2008.

The Brazilian government plans to increase the number of free birth control pills it provides

at state-run clinics from 20 million to 50 million in 2008. A. Downie, "Brazil doles out 'morning after' pills: The country's most populous state now offers the contraceptive pills at metro stops in a battle to limit illegal abortions," *Christian Science Monitor*; *http://www.csmonitor.com/2007/1120/p07s02-woam.html.*

Britain. The British Parliament's Select Committee on Science and Technology reported on 31 October 2007 that there is "no scientific basis" for lowering the 24-week gestational limit on legal abortion in the country. The report also recommends the elimination of a requirement that women seeking abortions obtain the signature of two doctors prior to undergoing the procedure. Although the committee's report is not binding, it is expected to influence Britain's abortion debate in the coming months. Kaiser Family Foundation, "U.K. Parliamentary Committee Releases Recommendations on Gestational Limit on Abortion, Other Related Regulations," *Kaiser Daily Health Policy Report*, 1 November 2007, *http://www.kaisernetwork.org/daily_ reports/rep_index.cfm?hint=2&DR_ID=48581*, accessed 26 January 2008.

The Human Fertilisation and Embryology Bill was introduced in the House of Lords on 17 January 2008. The bill would amend the Human Fertilisation and Embryology Act of 1990 by changing the legal definition of parenthood in cases involving assisted reproduction and provides for regulation of procedures that combined several human embryos. It has progressed through the first sitting of the Report Stage, with a second scheduled for 21 January 2008. Amendment proposals seeking changes to current abortion law are expected to be introduced. Bill being considered by the House of Lords: HL 2007/08 6. The entire text of the bill can be found at *http://www. publications. parliament.uk/pa/ld200708/ldbills/006/08006.i-iv.html*.

The Human Genetics Commission released recommendations for regulation of the sale of personal genetics tests on 4 December 2007. Read more about this in the "Right to Access and Control Medical Information" section.

India. The Indian Council of Medical Research and the Department of Biotechnology issued guidelines on 8 November 2007 governing stem cell research and cloning procedures throughout the republic. The regulations, which come after five years of deliberation, provide a nationwide ban on human cloning, and apply strict requirements on similar research. Research using embryonic stem cells, as well as research using fetal/placenta cells, is allowed, but consent must be obtained from the donor. Additionally, the Drug Controller-General of India will be charged with registering the specific blood banks. Violators of the new regulations would face stiff penalties including heavy fines and possible incarceration. Sanjay, "Stem Cell Research: Human Cloning Prohibited," *Merinews*, 8 November 2007, *http://www.merinews.com/catFull.jsp?articleID= 127572*, accessed 26 January 2008.

Slovakia. The Slovakian Constitutional Court denied a petition in December 2007 to outlaw abortion. Although the Court ruled against a request by the Christian Democratic Party's request to make abortion illegal, it did reduce the limit on the procedure from the twenty-fourth week of pregnancy to the twelfth week. L. Lesña, "Court upholds abortions in first 12 weeks," *Slovak Spectator,* 10 December 2007, *http://www.spectator.sk/articles/view/30150/court_upholds_abortions_in_first_12_ weeks.html*, accessed 1 February 2008.

The **United Nations** General Assembly's Human Rights Committee voted against an amendment to a draft resolution to place a moratorium on the death penalty that would have urged member states to "take all necessary measures to protect the lives of unborn children." The U.S. voted in favor of the anti-abortion amendment, along with Iran, Egypt, Syria, Zimbabwe, and several other countries. C. Parsons, "UN Panel votes for death penalty moratorium," *Reuters*, 15 November 2007, *http://africa.reuters.com/wire/news/usnN15331328.html*, accessed 4 February 2008.

The United Nations University Institute for Advanced Studies issued on 10 November 2007 a report calling for a legally binding international ban on human reproductive cloning that would allow for therapeutic research such as stem-cell techniques. The report also advises countries that intend to allow human cloning research to prepare by explicitly granting human clones the same individual rights as all citizens, to prevent "potential abuse, prejudice and

discrimination." C. Kuppuswamy et al., "Is Human Reproductive Cloning Inevitable: Future Options for UN Governance," *UNU-IAS Publications*, 10 November 2007. The full report can be found at *http://www.ias.unu.edu/resource_centre/Cloning_9.20B.pdf*.

The **Vatican**. At the twenty-fifth International Congress of Catholic Pharmacists on 29 October 2007, Pope Benedict XVI spoke in favor of a right to conscientiously object to dispensing drugs such as emergency contraception, which can prevent pregnancy if taken up to 72 hours after sexual intercourse. Kaiser Family Foundation, "Pope Benedict Says Pharmacists Have Right To Conscientiously Object To Fill Emergency Contraception," *Kaiser Daily Health Policy Report,* 31 October 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=48544*, accessed 26 January 2008.

Vietnam. A series of studies released on 29 October 2007 by the United Nations Population Fund reports there is a cultural preference for male children in Vietnam. The reports found that there are approximately 110 boys for every 100 girls. The preference for male children is established in other countries in the region including India and China. This is "further tipping the balance between the sexes in Asia." For decades, Vietnam has had a two-child-per-family policy. In 2003, the country banned fetal sex selection, but many physicians continue to defy the law and tell couples the sex of their fetus. The dearth of women in the region has increased social unrest and sex trafficking of women. Kaiser Family Foundation, "Cultural Preference for Male Children in Vietnam Increasing Gender Imbalance in Asia, UNFPA Reports Say," *Kaiser Daily Health Policy Report*, 2 November 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=48612*, accessed 26 January 2008.

AFTER BIRTH (PREMATURE INFANTS, NEWBORNS, AND CHILDREN)

There are no cases, bills, laws, or regulations to report for this section for this issue of "Legal Trends in Bioethics." But there is one thought-provoking news item that is worth noting: the Kaiser Family Foundation reports that 2006 saw the highest number of recorded births in the United States since 1961, nearly 4.3 million. The Kaiser Foundation article states that experts attribute the steep rise in U.S. births to a decrease in contraceptive use, a decrease in abortion access, poverty, religious beliefs, cultural demographic changes, and lower levels of education. Kaiser Family Foundation, "Women's Health Policy: U.S. Experiences Highest Number of Recorded Births in 2006 Since 1961," *Kaiser Daily Health Policy Report,* 17 January 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=49893*, accessed 26 January 2008.

HEALTHCARE COVERAGE

There is a growing debate in Congress and across the U.S. on legislation that would provide paid medical leave to all workers. Democratic presidential candidates Senators Hillary Rodham Clinton and Barack Obama have voiced their support for the idea. The Bureau of Labor Statistics reports that 43 percent of U.S. workers, or about 50 million people, do not receive paid medical leave benefits. Kaiser Family Foundation, "Paid Medical Leave Legislation Gains Momentum," *Kaiser Daily Health Policy Report,* 12 November 2007.

The American College of Physicians (ACP) said that the U.S. government should provide universal health coverage, but indicated that both single- and plural-payer systems should be considered. The group based its recommendations on an analysis of healthcare systems in the U.S. and 12 other industrialized nations. It found that although a single-payer healthcare system has lower administrative costs than a pluralistic system, the latter provides consumers with more choices and has more support in the U.S. Kaiser Family Foundation, "American College of Physicians Endorses Two Approaches to Achieve Universal Coverage," *Kaiser Daily Health Policy Report,* 4 December 2007.

Recent Judicial Cases and Regulatory Actions October - December 2007

Federal. The Medicare Rights Center filed suit in the U.S. District Court for the Southern District of New York on 26 November 2007, charging that the DHHS should not deny cover-

age for "off-label" use of prescriptions. The plaintiff was using a fertility drug as a cancer treatment and Medicare refused to pay for the treatment because the drug was not approved as a cancer treatment. Such "off-label" use is common in the medical profession and is based on clinicians' experience, published guidelines, and research findings in medical journals. "Off-label prescriptions" are typically not used unless conventional therapies are ineffective. J. Young, "Advocates Sue over Medicare Drug Coverage Exclusions," *The Hill*, 28 November 2007, *http://thehill.com/business—lobby/advocates-sue-over-medicare-drug-coverage-exclusions-2007-11-28.html*, accessed 28 January 2008.

California. The Second District Court of Appeals for the State of California ruled 4 December 2007 that canceling individual health insurance policies for omissions or mistakes on applications after claims are submitted is prohibited under state law. The court also held that insurers cannot cancel a member's policy if they do not attach a copy of the application to the policy. *Ticconi v. Blue Shield of California* (Ca. 2d Ct. App. No. B190427, 4 December 2007).

Nebraska. A lawsuit was filed in the Lancaster County District Court on behalf of Sandra Cartwright, alleging that state employees living in predominately Black areas are offered inferior health insurance coverage. J. Funk, "Lawsuit: State discriminated against blacks with insurance choice," *Lincoln Journal-Star*, 5 November 2007, *http://www.journalstar.com/articles/2007/11/05/news/nebraska/doc472e5be94739f900866308.txt*, accessed 4 February 2008.

Recent Developments in Law and Regulation
October - December 2007

Federal. The President vetoed a State Children's Health Insurance Program (SCHIP) expansion bill on 3 October 2007. On 18 October 2007, the House, tried, but failed to override the presidential veto. The bill would have provided an additional $35 billion in funding to the program over the next five years, bringing total spending to $60 billion annually. State Children's Health Insurance Program Reauthorization Act, H.R. 976, 110th Cong., 1st Reg. Sess. (2007).

*There has been no action on a bill that would provide universal health insurance to all U.S. residents. The AmeriCare Health Care Act would create AmeriCare, a program that would use Medicare to provide health insurance to U.S. citizens who don't receive coverage through their employers and whose annual income falls below 300 percent of the federal poverty level. On 9 July 2007, the bill was referred to the Subcommittee on Health, Employment, Labor, and Pensions, where it is still pending. H.R. 1841, 110th Leg., 1st Reg. Sess. (2007).

Alaska. There has been no action on a universal healthcare proposal introduced 10 September 2007 at a special late summer hearing of the Senate Health, Education, and Social Services Committee. The bill, called the Mandatory Universal Health Care Act, would require all state residents to obtain health coverage, with the state subsidizing plans for low-income residents. It would create a healthcare board that determines which medical services are covered under the subsidized program and would certify private coverage plans that meet state requirements. The board would also oversee the Alaska Health Fund, funded by both the state and the federal government, as well as contributions from employers and employees. A sliding-scale voucher system would be funded by the tax revenues collected to pay for the program. Residents would be able to use the vouchers to obtain coverage from the Alaska Health Care Clearinghouse, a "marketplace" for various certified policies. S.B. 160, 24th Leg., Spec. Sess. (Alaska 2007).

California. A bill was introduced in the state Assembly on 11 September 2007 that is proposing a new plan that would increase tobacco taxes to increase state revenues and, as a separate measure, mandate health insurance. Families for whom insurance costs amounted to more than 6.5 percent of annual family income would receive subsidies to pay for insurance. The plan has the support of the California Medical Association and is expected to be supported by Governor Arnold Schwarzenegger. AB 1X, 2007-2008 Leg. 2d Ext. Sess. (Cal. 2007).

*The governor vetoed a bill on 12 October 2007 that intended to extend healthcare coverage to all state residents. The legislation would have required employers to contribute as much

as 7.5 percent of their payroll to cover the cost of health insurance for employees or pay into a state pool that would provide coverage. In contrast to a proposal from Governor Arnold Schwarzenegger earlier this year, the bill did not include an individual mandate. A.B. 8, 2007-2008 Leg., Reg. Sess. (Cal. 2007).

Colorado. The Colorado Blue Ribbon Commission for Health Care Reform approved a set of recommendations that includes requiring state residents to obtain health insurance or pay a tax penalty. The panel also recommends expanding eligibility for state health programs. The panel's recommendations will be presented to state lawmakers on 31 January 2008. The package would cost approximately $1.1 billion and would expand coverage to 696,000 of the state's 792,000 uninsured residents. Kaiser Family Foundation, "Colorado Commission Recommends Health Care Plan Similar to Massachusetts," *Kaiser Daily Health Policy Report*, 21 November 2007.

Louisiana. The Coalition of Leaders for Louisiana Health Care proposed a plan that would cover uninsured adults whose incomes fall below 200 percent of the federal poverty line. The proposal hopes to divert money from the charity hospital system to a free-market model in which patients could present insurance cards to the doctor of their choice. K. Moran, "Health Care Execs float plan for the uninsured," *The Times Picayune*, 5 December 2007.

Wisconsin. The governor announced the details of BadgerCare Plus, a new health insurance plan for children effective 1 February 2008. Under the plan, families whose children are not eligible for existing state programs would be able to buy health insurance for a child for $120 to $822.36 a year, depending on the families' income. G. Boulton, "State Moves on Health Insurance for Children," *Milwaukee Journal-Sentinel*, 7 November 2007, *http://www.jsonline.com/story/index. aspx?id=683937*, accessed 28 January 2008.

VACCINES

The only news on the issue of vaccines is still that most of the bills introduced to mandate vaccination for human papillomavirus (HPV) have failed or stalled. Since Merck's HPV vaccine was first approved in June 2006, more than two dozen states considered mandating HPV vaccinations for school attendance. As of the end of 2007, only Virginia and the District of Columbia require HPV vaccination for school enrollment, but there are still a few states considering mandating the vaccine and those are listed below.

Recent Developments in Law and Regulation October - December 2007

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

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

***Wisconsin**. A public hearing was held on 17 0ctober 2007 in the state senate for a bill that would require schools to provide parents with information about the HPV vaccine. The bill directs the Department of Public Instruction, in conjunction with the Department of Health and Family Services, to distribute information that includes the recommendations made by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention. An identical bill is currently being considered by the state assembly. S.B. 252, A.B. 492, 2007 Reg. Sess. (Wis. 2007).

Interesting Developments in Other Countries

At the third annual Clinton Global Initiative conference in New York City, Merck announced that it will donate at least three million doses of its HPV vaccine Gardasil to women in developing countries. Half a million women

are diagnosed with cervical cancer annually, and about 80 percent of the cases and deaths are among women in developing countries because of limited screening and treatment. Kaiser Family Foundation, "Merck to Donate Three Million Doses of HPV Vaccine Gardasil to Developing Countries," *Kaiser Daily Health Policy Report*, 28 September 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ ID=47829*, accessed 26 January 2008.

ORGAN AND TISSUE PROCUREMENT

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

Recent Judicial Cases and Regulatory Actions October - December 2007

Federal. The Charlie W. Norwood Living Organ Donation Act was signed into law by the President on 21 December 2007. The act amends the National Organ Transplant Act to clarify that the act's provisions prohibiting the transfer of human organ for use in human transplantation for valuable consideration does not apply to human organ paired donation and similar practices. It ensures that criminal penalties do not apply to human organ paired donation. Public Law No: 110-144.

Recent Developments in Law and Regulation October - December 2007

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

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

***Maine**. There has been no action on a bill introduced on 17 March 2007 that would adopt the 2006 Uniform Anatomical Gift Act without changes since the bill was carried over to the 2008 session. 123rd Leg. Sess. L.D. 1505, 123rd Leg., Reg. Sess. (Me. 2007).

***Michigan.** A bill to amend the state's anatomical gift act passed the state house on 4 December 2007 and is currently in the Senate Committee on Health Policy. H.B. 4940, 94th Leg., Reg. Sess. (Mich. 2007).

***Missouri.** There has been no action on a bill introduced on 1 February 2007 to adopt the 2006 Uniform Anatomical Gift Act without changes. The bill is currently in the Missouri House Health Care Policy Committee. S.B. 496, H.B. 723, 94th Gen. Assem., 1st Reg. Sess. (Mo. 2007).

***New Jersey**. There has been no action on a bill introduced on 9 January 2007 to amend the state's anatomical gift act. A.B. 3909, 2007 Gen. Assem., Reg. Sess. (N.J. 2007).

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

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

***Washington.** There has been no action on a bill introduced on 24 January 2007 to amend the state anatomical gift act. The bill is currently under consideration in the state senate. H.B. 1637, 60th Leg., 2007 Reg. Sess. (Wash. 2007).

INFORMED CONSENT

Recent Judicial Cases and Regulatory Actions October - December 2007

***Federal.** The U.S. Supreme Court heard arguments on 4 December 2007 in the case of *Charles R. Riegel, et ux v. Medtronic, Inc.* The case involves an angioplasty procedure in which a catheter balloon reportedly burst, causing complications for the patient. Medtronic claims it should not be susceptible to suit under state law because the device had complied with federal regulations to receive FDA approval. A decision

in the case is expected shortly. *Charles R. Riegel, et ux v. Medtronic, Inc.* S. Ct. (U.S. No. 04-0412).

UNCONVENTIONAL TREATMENT

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

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

Recent Judicial Cases and Regulatory Actions October - December 2007

***Federal**. The U.S. Supreme Court denied certiorari on 14 January 2008 in *Abigail Alliance v. Von Eschenbach*. By refusing to hear the case, the U.S. Supreme Court allows the lower court decision to stand. The U.S. Circuit Court of Appeals for the District of Columbia had decided that terminally ill patients do not have a constitutional right to access medications that have not been approved by the FDA. The Abigail Alliance and the Washington Legal Foundation argued that terminally ill patients who did not qualify for participation in clinical trials or otherwise qualify to obtain experimental drugs through existing FDA access programs should have a right to purchase the drugs directly from pharmaceutical companies and take them under the supervision of their own physicians. The U.S. District of Columbia Court of Appeals did not recognize this "other right to life" argument, and the Alliance has decided to appeal to the U.S. Supreme Court. S. Ct. (U.S. no. 07-444).

*****The Federal District Court for the Central District of California on 20 November 2007 granted defendants' motion to dismiss for failure to state a claim in the case of *Americans for Safe Access v. Department of Health and Human Services and Food and Drug Administration*. The suit was filed by the Americans for Safe Access against the DHHS and the FDA for allegedly violating the federal Administrative Procedure Act by publicly releasing "false and misleading statements" about the benefits of the use of medical marijuana. Plaintiffs called for the DHHS and the FDA to retract and correct statements it made that there are no sound scientific studies supporting the medical use of marijuana. *Americans for Safe Access v. Department of Health and Human Services and Food and Drug Administration*, No. 007-01049 (C.D. Ca., filed 21 February 2007).

***Colorado**. The Second District Court for the state of Colorado overturned a state health department policy that restricted providers of medical marijuana to five patients. The decision was in response to a lawsuit against the Colorado Department of Health and Environment claiming its five-patient per marijuana provider rule was arbitrary and unfair. *Lagoy v. Colorado* (Colorado 2d District Court No. 07-CV-6089, 15 November 2007).

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

Recent Developments in Law and Regulation October - December 2007

***Delaware.** A bill to allow freestanding birth centers to hire certified professional midwives is not moving through the state legislature and may be permanently stalled. Under current law, midwives working in a freestanding birth center, whether certified professional midwives or certified nurse midwives, must have a backup agreement with a physician who has hospital admitting privileges and is available around the clock for consultation and referrals. A registered nurse with adult and infant resuscitation skills also must be present for each delivery. H.B. 106, 144 Gen. Assem., Reg. Sess. (Del. 2007).

LIFE-AND-DEATH DECISIONS

Recent Judicial Cases and Regulatory Actions October - December 2007

Montana. A suit was filed in the state First Judicial District Court on 1 November 2007 seeking declaratory judgment and injunctive relief that would prohibit law enforcement officials from prosecuting physicians who assist mentally competent terminally ill patients by facilitating medication that allows the patients choice in ending their life. The suit makes reference to rights expressed in Montana's Constitution including rights to privacy, individual dignity, due process, equal protection under the law, and the "right to seek safety, health, and happiness in all lawful ways," and seeks to prove that charging any such physician with a crime is, therefore, unconstitutional. Plaintiffs hope the decision will clarify state law on the issue of a patient's right to choose how and when to die. *Baxter et al. v. Montana,* (Mt. 1st Dist. DV 2007 787, 1 November 2007), *http://www.compassionandchoices.org/localgroups/mt/documents/BaxtervMTComplaint10-17-07.pdf*.

Recent Developments in Law and Regulation October - December 2007

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

New Hampshire. A bill is moving its way through various committees that would require an original copy of any advanced directive, instead of a copy as allowed under current law, to be used by careproviders as an indication of a patient's wishes. The bill, introduced on 4 January 2007, was referred to the House Judiciary Committee and is expected to be considered before 21 February 2008. H.B. 40 2007-2008 Leg., Reg. Sess. (Nh. 2008). Full text of the bill can be found at *http://www. gencourt.state.nh.us/legislation/2008/HB0040.html.www.legis.state.wi.us/2007/data/SB-151.pdf*.

Interesting Developments in Other Countries

International. A study sponsored by the University of Utah and conducted in collaboration with medical health professionals in Oregon and the Netherlands was released in late September 2007. The study, published in the October issue of the *Journal of Medical Ethics*, found no evidence that "vulnerable" groups were more likely to seek access to physician-assisted suicide measures. The study, conducted in Oregon and the Netherlands, compared "the elderly, women, the uninsured (inapplicable in the Netherlands, where all are insured), people with low educational status, the poor, the physically disabled or chronically ill, minors, people with psychiatric illnesses including depression, or racial or ethnic minorities," relative to background populations, and found that the only factor that showed a "heightened risk" was in people with AIDS. M. Battin, "Legal physician-assisted dying in Oregon and the Netherlands: evidence concerning the impact on patients in 'vulnerable' groups," *Journal of Medical Ethics* 33 (October 2007): 591-7.

Canada. The College of Physicians and Surgeons of Manitoba formally released a final statement "Withholding and Withdrawing Life-Sustaining Treatment" on 30 January 2008. The stated purpose of the document is to stipulate the ethical obligations of physicians, to emphasize open communication to achieve consensus, and to provide conflict resolution strategies when consensus cannot be reached. Of particular interest are the procedures delineated in the event that consensus cannot be reached. The "minimum goal" of life-sustaining treatment is defined as "the maintenance of or recovery to a level of cerebral function that enables the patient to: achieve awareness of self; and achieve awareness of environment; and experience his/her own existence." If the "minimum goal is not realistically achievable" and the physician concludes that life-sustaining treatment should be withheld or withdrawn, he or she must "if pos-

sible" consult with another physician. If that consulted physician disagrees, the consulting physician must either provide the treatment or transfer the patient to someone who will. But if the consulting physician agrees (or "it is not possible to consult with another physician"), treatment may be withheld or withdrawn once the "patient/proxy/representative" is advised of (1) the consulted physician's agreement or the fact that a consultation could not be obtained, and (2) the location, date, and time at which treatment will be withheld or withdrawn. If the minimum goal is achievable, there is no consensus and the physician believes the best course of action is to withhold or withdraw treatment, a consultation with a second physician becomes mandatory, and implementation, even with the consultant's agreement, becomes more complicated.

The statement also includes procedures for implementing DNAR (do not attempt resuscitation) orders and for emergency situations when communication between physician and patient/proxy/representative cannot occur. College of Physicians and Surgeons of Manitoba, "Statement: Withholding and Withdrawing Life-Sustaining Treatment," no. 1602 (30 January 2008). (The authors thank Pat Murphy, Clinical Ethicist at St. Boniface General Hospital in Winnipeg for sending us this document.)

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

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

Recent Judicial Cases and Regulatory Actions October - December 2007

Federal. The U.S. District Court for the District of Maine issued a preliminary injunction on 21 December 2007 against a new state law that sought to restrict medical data companies from accessing prescription information. The court relied heavily on an April 2007 ruling by the U.S. District Court for the District of New Hampshire that struck down a similar New Hampshire law, declaring that the statute violated the First Amendment by preventing the transfer of truthful commercial information. Both cases are now on appeal at the 1st U.S. Circuit Court of Appeals in Boston. *IMS Health Corp. et al. v. Rowe*, No. cv-07-127-B-W (D. Me. 21 December 2007). *IMS Health Corp. et al. v. Ayotte,* Appeal No. 07-1945 (U.S. 1st Circuit Ct. 14 August 2007). The full text of the Maine ruling can be found at *http://www.med.uscourts.gov/Opinions/Woodcock/2008/JAW_01022008_1-07-cv127_IMS_V_MAINE.pdf*. (Also, see below how Vermont is trying to avoid this type of litigation through new legislation.)

Recent Developments in Law and Regulation October - December 2007

Federal. The President signed into law a reauthorization bill for Medicaid, Medicare, and SCHIP on 29 December 2007, despite the removal of an information technology mandate that the administration had requested. DHHS had sent congressional leaders a letter that suggested that the President's approval was conditioned on the inclusion of an expansion of certified electronic health technologies. S.B. 2499, 110th Cong., 1st Reg. Sess. (2007). Health Data Management, "I.T. Mandate out of Medicare Bill," *HDM Breaking News*, 21 December 2007, *http://www.healthdatamanagement.com/news/mandate_legislation_Medicare25383-1.html*, accessed 30 January 2008.

House Speaker Nancy Pelosi held a closed meeting with Oregon Governor Ted Kulongoski and others on 27 November 2007 to discuss, among other things, Oregon's place in leading the charge to establish a centralized electronic health records (EHR) database. H. Esteve, "Pelosi says health care change can start here," *Oregonian*, 28 November 2007, *http://www.oregonlive.com/oregonian/stories/index.ssf?/base/news/1196222112166530.xml&coll=7*, accessed 30 January 2008.

DHHS announced on 29 October 2007 the launching of a new pilot program that plans to enlist 1,200 physicians across the country to institute a system for electronic health records in return for increased Medicare reimbursements. Officials are also suggesting that insurance providers consider similar payment increases. Kaiser Family Foundation, "Physicians Who Adopt Electronic Health Records Will Receive Higher Medicare Payments Under Pilot Project," *Kaiser Daily Health Policy Report*, 30 October 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=48524*, accessed 31 January 2008. This program was launched despite the warnings of Patients Privacy Coalition (a bipartisan partnership of lawmakers, nonprofit organizations, and private corporations) about possible abuses of electronic health record databases considered in comprehensive healthcare reforms. The group asserted any database would provide an open season on individual health information for data-mining companies that could sell the information, resulting in identity theft, fraud, predatory practices, and/or discrimination. E. Pfeiffer, "Bill sought to shield medical data," *Washington Times*, 18 October 2007.

Oregon. The governor announced on 27 November 2007 that the state has received a $20 million grant from the Federal Communications Commission to fund installation of broadband cable at rural health facilities throughout the state. H. Esteve, "Pelosi says health care change can start here," *Oregonian*, 28 November 2007, *http://www.oregonlive.com/oregonian/stories/index.ssf?/base/news/1196222112166530.xml&coll=7*, accessed 30 January 2008.

Vermont. Amendments were accepted to Act No. 80, Vermont's version of prescription restraint legislation. Among other things, the act restricts access to prescriber data for marketing use, and imposes new regulations on pharmacies in an attempt to increase patient privacy and decrease costs. The amendments were made in anticipation of a pending lawsuit, *IMS Health Corp. et al. v. Sorrell,* as similar cases struck down laws in Maine and New Hampshire in 2007 (see entry above under federal cases in this section). The suit asserts the unconstitutionality of the law, as it restricts the transfer of truthful commercial information. S.B. 115, 2007 Gen. Assem., Reg. Sess. *IMS Health Corp. v. Sorrell,* No. 2:2007cv00188 (D. Vt. 29 August 2007.)

Interesting Developments in Other Countries

United Kingdom. The U.K. Human Genetic Commission (HGC) issued in December 2007 recommendations for the regulation of personal genetics tests. The proposals include independent reviews of all tests before they reach the market, banning public advertising for tests with "major health implications," and requiring that such tests only be administered by a health professional. Though the HGC has stressed it does not want to ban any particular tests, in general they support stricter control under oversight by the Medicines and Healthcare products Regulatory Agency. "Tougher gene test regulation call," *BBC News*, 5 December 2007.

HIV/AIDS

Recent Developments in Law and Regulation October - December 2007

***Federal**. Since the end of 2007, all states and the District of Columbia are now required to report their HIV cases by name if they wish to receive funding from DHHS under the federal Ryan White Grant Program. 42 U.S.C. § 201. All states except Hawaii and Vermont have complied, making anonymous HIV testing almost a thing of the past in the U.S.

Thirty members of Congress sent a letter on 6 December 2007 to the Secretary of the Department of Homeland Security calling for the repeal of the HIV/AIDS statutory ban, instead of, as the department proposes, merely streamlining the waiver process for HIV-positive individuals seeking short-term business or tourist visas

to the U.S. The congressional letter sees the department's proposal and the statutory ban as a violation of human rights. The Department of Homeland Security has proposed to shift decision-making authority from the U.S. Citizenship and Immigration Services to the respective U.S. consular offices. The congressional letter prefers a repeal of the statute that would return the decision to the Secretary of Health. B. Lee et al., "Letter to Secretary Chertoff," 6 December 2007. The full letter can be found at *http://lee.house.gov/index.cfm?Content ID=1165&ParentID=0&SectionID=4&SectionTree=4&lnk=b&ItemID=1160*.

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

***California**. The governor signed into law a bill on 12 October 2007 to amend sections of the Health and Safety Code relating to HIV/AIDS. Previously, physicians were required to test pregnant women for HIV unless the test was explicitly refused in writing. This bill removes that stipulation and instead merely requires that women be told that an HIV test is planned and made aware of their right to refuse. Ch. 550. A.B. 682, 2007-2008 Leg., Reg. Sess. (Cal. 2007); Cal. Code Regs. tit. 106 § 120990, 125090, 125107 (2007).

District of Columbia. President Bush signed into law an omnibus spending bill on 26 December 2007 that, among other things, lifts a long-standing ban on the funding of needle-exchange programs within the District of Columbia. The D.C. Department of Health now plans to allocate $1 million to fund needle exchanges. H.R. 2764, 110th Cong., 1st Reg. Sess. (2007). Kaiser Family Foundation, "City Funding for Needle-Exchange Programs in Washington, D.C.," *Kaiser Daily HIV/AIDS Report*, 21 December 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49539*, accessed 27 January 2008.

The D.C. State Board of Education unanimously approved on 13 December 2007 new guidelines for the D.C. schools' health curriculum. The guidelines include grade-specific information about HIV/AIDS and controversial subjects such as "sexual orientation," and "gender identity." Kaiser Family Foundation, "Washington, D.C., Board of Education Approves Health Education Standards That Include HIV/AIDS Information," *Kaiser Daily HIV/AIDS Report*, 17 December 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49433*, accessed 27 January 2008.

D.C. Mayor Adrian Fenty announced plans in November 2007 to help curb the spread of HIV/AIDS within the district. Fenty hopes to triple the number of free condoms distributed by the government by the end of 2008, for a total of three million, and to pressure district hospitals to provide more comprehensive and timely HIV testing to pregnant women. D. Nakamura, "More Testing Pledged On HIV," *Washington Post*, 27 November 2007, B01.

New Jersey. The state legislature passed a bill on 28 December 2007 mandating HIV testing for all pregnant women within the state. The law stipulates two tests, one at the inception of pregnancy and the second during the third trimester. There is an exemption if the mother objects, but any objection will be noted on her medical record, and, in these cases, the newborn will be tested after birth unless a religious exemption is requested. The law will go into effect on 25 June 2008. P.L. 2007, c.218, 2007 Gen. Assem., Reg. Sess., *http://www.njleg.state.nj.us/2006/Bills/PL07/218_.HTM*.

New York. The governor is considering a plan that would mandate the state's HIV-positive Medicaid beneficiaries enrollment in managed-care plans. The plan, still in its initial stages, has drawn scrutiny from Housing Works, an HIV/AIDS advocate, which worries that man-

datory enrollment could prove to be a "large-scale disruption" of the current system, noting that the current HIV Special Needs Plans are only available in New York City, and cater to less than 5 percent of the state's 65,000 Medicaid beneficiaries living with HIV/AIDS. Kaiser Family Foundation, "New York Gov. Spitzer Considers Imposing Mandatory Managed Care Enrollment Among HIV-Positive Medicaid Beneficiaries," *Kaiser Daily HIV/AIDS Report*, 3 December 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49159*, accessed 29 January 2008.

Oregon. The state Department of Human Services launched a pilot project on 1 November 2007 that seeks to provide mental health support service and affordable rental housing to HIV-positive Oregonians living with mental illnesses. See "Mental Health" section below.

Interesting Developments in Other Countries

International. A report released on 2 November 2007 by the Forum for Collaborative HIV Research, a public-private partnership based out of George Washington University, has increased scrutiny on the BCG vaccine, which is used to prevent tuberculosis among children in developing countries. The forum's findings, among other things, suggest that the BCG vaccine may lead to higher susceptibility to illness, and in some cases death among HIV-positive infants. These findings follow the recent changes in policy at the World Health Organization, which stepped back from its former recommendation for the vaccine when its own report, released in May 2007, showed that HIV-positive infants stood a higher chance of developing the BCG disease, a weaker strain of tuberculosis that causes bovine TB. The Forum for Collaborative HIV Research et al., "HIV-TB Co-Infection: Meeting the Challenge," 2 November 2007. The forum's full report can be accessed at *http://www.hivforum.org/uploads/TB/Final%20HIV-TB%20Report.pdf*.

South Asia. The World Bank, in collaboration with the United Nations and private entities, announced the launching on 11 December 2007 of "Tackling HIV and AIDS Stigma and Discrimination," an initiative that seeks to reduce HIV/AIDS stigmatization in Southern Asia by providing numerous grants to small-scale projects that show promise for replication. Grants will be distributed through a competitive award program. Kaiser Family Foundation, "World Bank, Partners Launch Competition in South Asia to Develop Approaches Aimed at Reducing HIV/AIDS-Related Stigma," *Kaiser Daily HIV/AIDS Report*, 13 December 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49377*, accessed 28 January 2008.

China. The Beijing Municipal Health Board issued in November 2007 a new regulation mandating that condoms be provided in all city hotel guest rooms by the end of 2008. The mandate comes after city authorities recorded 973 new HIV/AIDS cases between January and October 2007, 54 percent higher than in 2006. Kaiser Family Foundation, "Beijing Health Bureau Orders Hotels to Provide Condoms in Guest Rooms by End of 2008," *Kaiser Daily HIV/AIDS Report*, 26 November 2007, *http://www.kaisernetwork.org/daily_reports/rep_ index.cfm?hint=1&DR_ ID=49016*, accessed 29 January 2008.

Indonesia. UNESCO and L'Oreal announced on 12 December 2007 the launch of Hairdressers against AIDS, a program designed to stem the spread of HIV/AIDS in Indonesia, a country with an estimated HIV-positive population of 290,000. With the help of the Indonesian AIDS Foundation, the program will work to educate the nation's hairdressers on HIV prevention, and how to educate others in the community. Kaiser Family Foundation, "L'Oreal, UNESCO Launch Campaign That Trains Indonesian Hairdressers To Promote Discussion, Educate People About HIV/AIDS," *Kaiser Daily HIV/AIDS Report*, 17 December 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49432*, accessed 27 January 2008.

Madagascar. The government has already played a role in increasing access to condoms and training teachers on HIV prevention, as well as establishing over 100 testing clinics. In August, the Parliament passed a law protecting HIV-positive people from discrimination, the first of its kind in Africa. Additionally, Madagascar officials distributed 400,000 HIV test kits

in 2007, and hope to provide 90 percent of the HIV-positive population with antiretroviral drugs by the end of 2012. Kaiser Family Foundation, "Madagascar's Response to HIV/AIDS One of 'Most Aggressive' in Africa," *Kaiser Daily HIV/AIDS Report*, 18 December 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49459*, accessed 27 January 2008.

Uganda. The Minister of Health announced in December plans to initiate a program that would provide free circumcision to males throughout the country in an effort to reduce the risk of HIV transmission. Kaiser Family Foundation, "Uganda Plans To Introduce No-Cost, Countrywide Male Circumcision Program to Prevent Spread of HIV," *Kaiser Daily HIV/AIDS Report*, 11 December 2007, *http://www.kaisernetwork.org/daily_reports/rep_Index.cfm?hint=1&DR_ID=49327*, accessed 28 January 2008.

CONSCIENTIOUS OBJECTIONS (HEALTHCARE PROVIDERS AND RELATED PROFESSIONS)

Recent Judicial Cases and Regulatory Actions October - December 2007

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

Michigan. On 30 November 2007, a Detroit-area pharmacist filed suit against Target Corporation, his former employer, alleging that his November 2006 firing over refusal to dispense emergency contraception violated the U.S. Civil Rights Act of 1964 by not accommodating his expressed religious beliefs. *Bundy v. Target Corporation* (U.S. Dist. Court of Eastern Michigan No. 2:2007cv15091, 30 November 2007).

Pennsylvania. The Third Circuit Court of Appeals for the state of Pennsylvania ruled on 21 September 2007 that a Philadelphia clinic did not violate the rights of 16-year-old Melissa Anspach, or the rights of her parents, by providing emergency contraception to Anspach, at her request, in January 2004. In the ruling, Judge Theodore McKee stressed, "[t]he Constitution does not impose an affirmative obligation on the defendants to ensure that children abide by their parents' wishes, values or religious beliefs." *Anspach v. Phila. Dept. of Pub. Health* (Phila. 3d Cir. Appeal No. 05-3632, 21 September 2007).

Recent Developments in Law and Regulation October - December 2007

Connecticut. A law went into effect on 1 October 2007 that requires all licensed healthcare facilities to administer emergency contraception, upon request, to victims of sexual assault unless the woman tests positive for pregnancy. Public Act No. 07-24, 2007 Gen. Assem., Reg. Sess. Roman Catholic officials announced on 27 September 2007 that the state's four Catholic hospitals would abide by and not challenge law in court as some thought they might. Catholic News Service, "Catholic hospitals agree to provide emergency contraception to rape victims," *Catholic Online*, 1 October 2007.

New Jersey. The governor signed into law on 2 November 2007 a bill requiring the state's pharmacies to fill all lawful prescriptions without delay, "notwithstanding sincerely moral, philosophical, or religious beliefs of [the] pharmacist." The act, Public Law 2007, c.199, does have an exception for pharmacies that choose not to carry any particular drug or device, but mandates that in such cases the pharmacist must offer to locate a substitute pharmacy that is "reasonably accessible to the patient" and does stock the drug/device in question. P.L. 2007, c.199, 2007 Gen. Assem., Reg. Sess.

New York. A bill is still pending that was introduced on 2 February 2007 that would amend Section 6810 of the state's education law to prohibit pharmacists from refusing to dispense or refill a prescription based on philosophical, moral, or religious reasons. The bill

was referred to the Committee on Higher Education on 9 January 2008. S.B. 2344, 2007 Gen. Assem., Reg. Sess.

Pennsylvania. Pennsylvania's Independent Regulatory Review Commission adopted proposals on 18 October 2007 to require that hospitals provide emergency contraception to survivors of rape. Hospitals can apply for an exemption on moral grounds, but state legislators are considering a bill, H.B. 288, that would remove the possibility of such an exemption. The bill, however, was re-committed to the Rules Committee on 11 December 2007, and no action on passage is expected in the near future. H.B. 288, 2007 Gen. Assem., Reg. Sess.

Interesting Developments in Other Countries

Slovakia. Slovakia's Ministry of Health has stepped back from previous statements when on 20 September 2007 it announced that it would not strike the "conscience clause" that currently allows medical workers to refuse to perform procedures, such as abortions, that conflict with their religious beliefs. The announcement comes on the heels of strong statements from Pope Benedict XVI and Slovakia's Roman Catholic leadership who seek a strengthened conscience clause. Kaiser Family Foundation, "Slovak Health Ministry Drops Effort To Abolish Clause Allowing Health Workers To Object To Performing Abortions, Other Procedures," *Kaiser Daily Health Policy Report*, 20 September 2007, *http://www. kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=47624*, accessed 23 January 2008.

The **Vatican**. At the twenty-fifth International Congress of Catholic Pharmacists on 29 October 2007, Pope Benedict XVI spoke in favor of a right to conscientiously object to dispensing drugs such as emergency contraception, which can prevent pregnancy if taken up to 72 hours after sexual intercourse. Kaiser Family Foundation, "Pope Benedict Says Pharmacists Have Right To Conscientiously Object To Fill Emergency Contraception," *Kaiser Daily Health Policy Report,* 31 October 2007, *http://www.kaisernetwork. org/daily_reports/rep_index.cfm?hint=2&DR_ID=48544*, accessed 26 January 2008.

MENTAL HEALTH

Recent Judicial Cases and Regulatory Actions October - December 2007

Virginia. The Virginia Supreme Court's Commission on Mental Health Reform issued recommendations on 21 December 2007 following the release of Virginia's Crisis Intervention Continuum Survey 2007. The panel called for expanded out-patient treatment and more specific procedures to monitor patients and enforce current laws. The debate over proposals to strengthen Virginia's preventative out-patient commitment law, which stem from an April incident at Virginia Tech in which a mentally ill student killed 32 students and faculty before killing himself, is expected to intensify once the state's General Assembly convenes in early 2008. C. Jenkins, "N.Y. Law Raises Issues of States' Reach in Patient Care," *Washington Post*, 30 December 2007, C01.

Recent Developments in Law and Regulation October - December 2007

***Federal**. The President signed into law on 5 November 2007 the Joshua Omvig Veterans Suicide Prevention Act. The act directs the Secretary of Veterans Affairs to develop and implement a comprehensive program designed to reduce the incidence of suicide among veterans. Public Law No. 110-110.

*The Paul Wellstone Mental Health and Addiction Equity Act of 2007 is progressing through Congress. Originally introduced on 9 March 2007, the bill would require insurers to cover mental illness at the same level as they cover physical illness. The bill passed both the Committee on Ways and Means and the Committee on Education and Labor on 15 October 2007 and was ordered to be reported to the House as a whole on 16 October 2007. A similar bill, The Mental Health Parity Act of 2007, was passed in the Senate in September. H.R. 1424, S.B. 558, 110th Leg., Reg. Sess. (2007).

The Amyotrophic Lateral Sclerosis (ALS) Registry Act is progressing through Congress. Originally introduced in the Senate on 14 May 2007, the bill would establish a national regis-

try to collect and store data on ALS. The bill was placed on the Senate Legislative Calendar on 4 December 2007. A similar version of the bill passed the House in October. H.R. 2295, S.B. 1382, 110th Leg., Reg. Sess. (2007).

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

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

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

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

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

Recent Judicial Cases and Regulatory Actions October - December 2007

Federal. The U.S. Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society released a draft report on the oversight of genetic testing on 5 November 2007. The report identifies "significant gaps in this oversight system that could lead to harms," and asserts that the FDA has not made clear how efforts to regulate genetic testing will function. The report comes as multiple companies are planning the release of direct-to-consumer genetic test kits, which have faced criticism over their cost, necessity, reliability, and privacy implications. The draft's public commentary period is now closed, and the Committee is set to finalize the report at their next meeting on 12-13 February 2008. Secretary's Advisory Committee on Genetics, Health, and Society, "U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of HHS," Draft Report, 5 November 2007. It is also worth noting that in November, Navigenics Inc. announced the release of Health Compass, a $2,500 direct-to-consumer saliva-based whole-genome scan set for release in early 2008. Another company, 23andme of Mountain View, California, has announced plans for the release of a similar test later in 2008. Winslow, R., "Is There a Heart Attack in Your Future?" *Wall Street Journal*, 6 November 2007, D1.

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

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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. 1151-8.

4. Ibid., 1148.

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

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