

*Health Care Law*

*Mid-Atlantic Ethics Committee Newsletter*

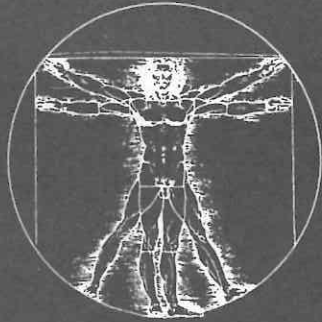
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Mid-Atlantic Ethics Committee  
Newsletter, Fall 1995

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# MID-ATLANTIC ETHICS COMMITTEE

N E W S L E T T E R

A Newsletter for Ethics Committee Members in Maryland, The District of Columbia and Virginia  
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Fall 1995

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## SHOULD PROXY DECISION-MAKERS BE ABLE TO CONSENT TO PARTICIPATION IN MEDICAL RESEARCH FOR INCAPACITATED PATIENTS?

Writing of Baby Fae, whose twenty-day life was marked by an experimental transplant of a baboon's heart, Alexander Capron observed that "Baby Fae's short life will remain with us as a reminder that certain good things—like biomedical research—sometimes go too far." One key protection against research that might go "too far" is genuinely effective informed consent. Long after Baby Fae died, questions remained about the adequacy of the process that led to her parents' consent.

The bedrock principle of informed consent for federally funded research is that "No investigator may involve a human being as a subject in research . . . unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative." This regulation goes on to specify the "basic elements of informed consent," including disclosure of the "reasonably foreseeable risks or discomforts to the subject," "any benefits to the subject or others which may reasonably be

## Letter From the Editor

In this issue, we address a problem that has become a focus of attention in Maryland—whether our current law should be expanded to allow agents or surrogates to consent, on behalf of incapacitated patients, to participation in medical research that may not have a therapeutic benefit for the patient. The Maryland Office of the Attorney General has initiated a study of this question and has issued a letter opinion on the subject. Our feature article, by Jack Schwartz, Chief Counsel for Opinions and Advice in the AG's Office, describes this initiative. The issue also includes comments on the question from two physicians at the National Institute of Mental Health whose research focuses on Alzheimer's Disease and from a philosopher/lawyer from the Institute of Law, Psychiatry and Public Policy at the University of Virginia. As always, we include our case study and comments, Network News, and Calendar. We welcome any comments you might have on the issues presented in the newsletter and hope that you find the information helpful.

Diane E. Hoffmann

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**Diane E. Hoffmann, J.D., M.S.,** Editor  
**Andrea Imredy,** Student Editor  
**Nancy Zibron, M.A.,** Layout Editor

Contributing Editors:

**Louis Breschi, M.D.,** Member, Ethics  
Committee, Franklin Square Hospital  
**John Fletcher, Ph.D.,** Director, Center for  
Biomedical Ethics, University of Virginia  
**Sigrid Fry-Revere, J.D., Ph.D.,**  
Independent Bioethics Consultant  
**Jacqueline J. Glover, Ph.D.,** Philosopher-in-  
Residence, Director, Office of Ethics,  
Children's National Medical Center  
**Edmund G. Howe, M.D., J.D.,** Director of  
Programs in Medical Ethics, Uniformed  
Services University of the Health Sciences  
**Sanford Leikin, M.D.,** Adjunct Medical  
Officer, Office of Protection of Human  
Subjects, National Institutes of Health  
**Joan Lewis,** Coordinator, Washington  
Metropolitan Bioethics Network,  
D.C. Hospital Association  
**Steven Lipson, M.D.,** Medical Director,  
Hebrew Home  
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Hospital and Francis Scott Key  
Medical Center Ethics Committees  
**Jan Vinicky, Ph.D.,** Bioethicist,  
Washington Hospital Center  
**Margot White, J.D.**

**The Institutional Ethics  
Committee Resource Network  
Law & Health Care Program  
University of Maryland School of Law  
500 West Baltimore Street  
Baltimore, MD 21201  
410/706-7191 or 410/706-7239**

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be acted upon without consulting an attorney.

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at Baltimore



## NETWORK NEWS

### Baltimore Area Ethics Committee Network (BAECN)

At the last meeting of the BAECN, on September 21, 1995, Diane Hoffmann spoke on a recent study she conducted on the knowledge and attitudes of outpatient elderly toward advance directives and their ability to complete the Maryland Advance Directives Form. The next meeting of the BAECN will be held on Thursday, November 16, 1995 at 4:30 p.m. at Anne Arundel Medical Center. Speakers will include State Senator John Astle and Dr. David Davis. They will speak on state health care legislation. The BAECN's Task Force on Standards for Education and Ethics Committee Qualifications has been hard at work drafting a proposal for standards to guide each member of the network. A copy of the proposed standards has been sent to every BAECN member for comments and suggestions. For a copy of the proposal, contact Dr. Jack Syme at (410) 368-3020.

### Metropolitan Washington Bioethics Network (MWBN)

In the MWBN's September meeting, speaker Helen Chapple, R.N., C.D.E., M.A., presented "Kevorkian, Suffering and the Doctrine of Double Effect." The program, which provoked intense discussion among the participants, analyzed Dr. Jack Kevorkian's acts of helping terminally ill individuals to commit suicide in the context of the doctrine of double effect. This doctrine acknowledges that one action may have two effects: an intended, beneficial effect and an unintended "side" effect that results in death, often of an innocent. Whereas the traditional version of the doctrine applied only where two lives were involved, a new version of the doctrine is often applied where only one life is involved. Examples of

situations in which the traditional doctrine of double effect applies include killing in self-defense, killing a fetus by giving chemotherapy to a mother diagnosed with cancer, separating conjoined twins when both may not survive the operation, or treating curable cases of a disease first when there is a shortage of curative medicine. A frequently used example of a situation in which the newer version of the doctrine is said to apply is the administration of pain medication that may shorten a patient's life. The questions posed to the audience were to what extent Dr. Kevorkian's behavior can be justified as responsible moral action under either the traditional or the newer doctrine of double effect, and what the implications are for health care providers working with suffering or terminally ill patients. For copies of handouts from the program and a list of references on this subject, call Joan Lewis at (202) 682-1581 or fax your request to (202) 371-8151.

The network's November meeting will focus on the subject of viatical settlements, which involves the purchase of a life insurance policy from a terminally ill individual in exchange for a pay-out of 70 to 80 percent of the policy's face value during the ill person's remaining life. The purchaser of the policy collects the full value of the policy upon the ill person's death. Between 1989 and 1995, the volume of viatical settlements rose from less than \$10 million per year to over \$200 million per year. A recent federal district court ruling ordered one of the nation's largest viatical settlement firms to bring its operations into compliance with federal securities laws and to place the ownership of the policies into the hands of a neutral third party. Despite the ruling, the court found that the viatical process is a legitimate and beneficial one and that there was no evidence of fraud or misrepresentation in this particular case. Panelists for this meeting include the Executive Director of the Whitman Walker Clinic and a representative from a viatical settlement

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## Proxy Decision-Makers

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expected,” and “appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.”

Of course, these regulatory requirements leave open to debate a host of difficult issues. For example: How (and by whom) is it decided that a potential research subject really has the capacity to give informed consent? Does the consent process really inform the potential subject, or is the process distorted by the investigator’s need for subjects and the potential subject’s “therapeutic misconception” — the misplaced belief that the research is really aimed at the subject’s individual well-being? Is attention paid to the issue of continuing consent, long after the forms are signed?

Other unanswered questions involve the “legally authorized representative” who may give informed consent when the research subject cannot. Who is such a representative? The definition in the federal regulations is circular, referring to anyone “authorized under applicable law.” The only such “representative” identified in the regulations is the parent or guardian of a child; the regulations leave to other law the question of who exactly is “legally authorized” to give consent for research participation by subjects, other than children, who are unable to give consent personally. Further, what standards or safeguards should apply to consent by a representative? Presumably, a representative should not have the same authority to give consent as a competent research subject does, but what are the right limits?

No state law addresses these difficult issues comprehensively. Indeed, only a few states have any laws addressing human experimentation and the protection of research subjects. California provides a sketchy answer by authorizing proxy consent on behalf of persons unable to consent personally “for medical experiments related to maintaining or improving the health of the human subject or related to obtaining information about a pathological

condition of the human subject.” If Maryland is typical, laws dealing with proxy consent for health care matters, which were not drafted with research in mind, do not resolve the public policy issues posed by research on incapacitated subjects. The Maryland Health Care Decisions Act recognizes three possible decision-makers for an incapacitated patient: the patient herself, through an advance directive; a health care agent; or a surrogate, and a guardian of the person. Although these three differ in the source and scope of their authority, they have one thing in common. They all make “health care” decisions.

The term “health care” is not defined. However, other provisions in the Act make its meaning clear. It is synonymous with a procedure or course of treatment that relates to the disease state of the particular patient.

This intended scope of “health care” is reflected in the Act’s itemization of factors related to substituted judgment. Health care agents and surrogates are to look exclusively at the consequences if treatment were provided to, or foregone for, that patient. For example, in assessing whether the patient would wish to consent to a treatment were she able to, the agent or surrogate is to consider the patient’s “[c]urrent diagnosis and prognosis with and without the treatment at issue . . .” and any “[e]xpressed preferences regarding the provision of, or the withholding or withdrawal of, the specific treatment at issue or similar treatments.”

This decisional framework, requiring a “health care” judgment framed in terms of the patient’s assumed decision about a treatment, works well enough for some kinds of research. So long as there is an articulable link between the research and a possible improvement in the patient’s condition, then a “health care” decision is possible, and the patient’s hypothesized wishes would be the basis for it.

However, the Act does not authorize an agent or surrogate to consent to a protocol expected to have no present or future therapeutic effect on the patient. Even an advance directive that consents to participation in future research

cannot authorize an agent’s or surrogate’s decision unrelated to potential therapeutic effect on the patient. Altruism is noble, but it is not “health care.”

Likewise, the Act’s “best interest” test is entirely focussed on the impact of a treatment on the patient. A treatment is in the patient’s best interest if “the benefits to the individual resulting from a treatment outweigh the burdens to the individual resulting from that treatment,” taking into account a variety of factors all related to the individual. Under this formulation, participation in a clinical trial might be in the patient’s best interest if, to use the language of the American College of Physicians, “the net additional risk caused by the participation is small, and there is scientific evidence that participation is reasonably likely to offer benefits over standard treatment or no treatment, if none exists.” Even the risk that the patient might wind up in the placebo group of a double-blind, placebo-controlled study might be worth the potential benefit. Asked to consent to the patient’s participation in such a research protocol, the proxy would consider the probability and nature of the benefit, the degree of risk, and the opportunity cost of foregone alternatives. If the proxy consented, the immunity provisions of the Act would apply to those who acted pursuant to the consent.

But suppose there is no scientific evidence that participation is reasonably likely to offer benefits to the patient. The Act’s “best interest” calculus does not include potential benefits to society as a whole, or even to those who might suffer from the same disease in the future. Participation in research of that kind, even with minimal risk, is not a “health care” decision within the meaning of the Act.

Given the seeming shortcomings of current law, the Maryland Attorney General’s Office has organized an informal study of these issues. A group of researchers, academics, ethicists, patient advocates, and lawyers has been meeting to identify the policy questions and the options for responding. When

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## Proxy Decision-Makers

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this working group has drafted a coherent options paper, it intends to open the discussion to all who are interested, through a series of meetings throughout the state. The result of this process, if sufficiently wide agreement could be obtained, might be proposed legislation (for the 1997 session of the General Assembly) on those matters that call for a definitive legal answer.

This task is difficult, and the process may yet founder. Still, the goal — safeguarding research subjects while nurturing the research enterprise — makes the effort worthwhile.

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### References:

1. *When Well-Meaning Science Goes Too Far*, Hastings Center Report, February 1985, at 9.
2. 45 C.F.R. §46.116.
3. Paul S. Appelbaum, Loren H. Roth, and Charles Lidz, *The Therapeutic Misconception: Informed Consent in Psychiatric Research*, 5 Int'l J. of Law & Psychiatry 319 (1982).
4. 45 C.F.R. §46.102(c).
5. 45 C.F.R. §§46.402(d) and (e) and 46.408.
6. Cal. Health & Safety Code §24175(e).
7. Md. Code Ann. Health-Gen. §§5-605(c)(2)(i) and (ii).
8. Md. Code Ann. Health-Gen. §5-601(e).
9. *Cognitively Impaired Subjects*, 111 *Annals of Internal Med.* 843, 845 (1989).

Submitted by  
Jack Schwartz, J.D.  
Chief Counsel, Opinions and Advice  
Maryland Attorney General's Office

## AN ARGUMENT FOR ALLOWING PROXIES TO CONSENT TO PARTICIPATION IN MEDICAL RESEARCH FOR PATIENTS LACKING CAPACITY TO GIVE INFORMED CONSENT

Theoretically, informed consent ensures that subjects fully understand the nature and consequences of

participating in medical research and emphasizes that their participation is voluntary. However, determining what constitutes “informed consent” is often difficult, especially when the research involves cognitively impaired subjects such as patients with Alzheimer’s Disease (AD). We believe that although difficult, it is vitally important to be able to include cognitively impaired subjects in clinical research, and to exclude this large population would be discriminatory. What is needed are guidelines to enable impaired people to participate in both direct and no direct medical benefit research. As we do research with Alzheimer’s disease (AD) patients, we will be drawing from our own experiences as examples for this discussion.

Do we need to study persons without the capacity to give informed consent in no direct benefit research? Maybe they are too vulnerable and the best way to protect their rights and autonomy would be to exclude patients without the capacity to consent to research from participation in no direct benefit research. We argue that such a stance is overly protective and would deny millions of patients and families the hope and associated benefits of involvement in research. In essence, it would deny patients the indirect benefits of research participation, such as the pride in participating in clinical science experiments and the knowledge that one is contributing to the efforts of disease prevention in future generations. Alzheimer’s disease is a large drain on the finances of individual families as well as society, with annual estimates of up to \$48 billion for the direct costs alone. Research participation often provides families and individual patients needed support, medical resources and respite at a time of great need and frustration. As to why Alzheimer subjects are needed for participation in research on the disease, it is important to note that nothing substitutes for human subjects to learn about the etiology and course of an illness. The transgenic mouse is a promising animal model for Alzheimer’s disease, but is in its infant stages of development and is not

currently a substitute for clinical research with actual patients.

If one can assume that it is morally acceptable and humane to include patients without the capacity to give informed consent in clinical research which does not promise direct medical benefit, how might this be accomplished? The Code of Federal Regulations for the protection of human subjects requires that “legally effective informed consent of the subject or the subject’s legally authorized representative” be obtained prior to research. The National Institutes of Health (NIH) Clinical Center borrowed from the legal system and developed the durable power of attorney (DPA) for use in research with cognitively impaired subjects regardless of the prospect for benefit. The DPA is a legal form which gives a designated proxy the ability to make health care and research decisions for a patient who may eventually become incapable of making such decisions for himself or herself. (A proxy is analogous to an agent under the Maryland Health Care Decisions Act.) Having employed this proxy system for health care and research since 1987, when it was first implemented at the NIH, we have had considerable clinical experience with the process of enrolling patients in both benefit and no medical benefit protocols. The key to our ability to include subjects without capacity to give informed consent in clinical research trials is two-fold. First, we ask everyone to designate a health care and research proxy while he/she has the capacity to do so and we include this person in research decisions throughout the research process. Second, we require patients with limited informed consent capacity to give assent, which involves less understanding than consent, even if they have formally executed a DPA in the past.

Although the focus of this article is on AD, designating a health care and research agent for clinical research with subjects at risk of cognitive impairment could be applied to other conditions as well. As possible examples, we believe this approach is adaptable to patients with potential

cognitive decline due to Parkinson's Disease, stroke, and other debilitating diseases. Discontinuing or avoiding biomedical clinical research with these subjects once they become significantly impaired would only impede medical research and not necessarily be in the best interest of patients, patients' families or society. Given our successful experiences utilizing the DPA in AD, we advocate the use of an agent or research proxy decision maker and patient assent for patients who lack capacity to give informed consent to participate in research irrespective of the potential for direct medical benefit. As is always the case in medical research, the greater the risk, the greater the safeguards and supervision by the Institutional Review Board. However, we would not exclude subjects from these studies simply on the basis of cognitive impairment. Rather, we recommend the use of alternative approaches in the informed consent process with cognitively impaired subjects. The DPA is one viable option being pioneered successfully at the NIH. Under the Health Care Decisions Act, other options include the use of surrogates or a living will. These alternatives need further study in research settings.

1. *Annotated Code of Maryland, Health General Article 5-601.*

2. *NIH Publication No. 95-3676: 1994.*

3. *45 Code of Federal Regulations (CFR 46.111(a)(4))*

4. *Fletcher JC, Wichman A. A new consent policy for research with impaired human subjects. Psychopharmacol Bull. 1987;23:382-385.*

5. *Dukoff and Sunderland, Clinical Research with Alzheimer's Disease Patients: Informed Consent and the Use of the Durable Power of Attorney. Submitted 1995.*

6. *Annotated Code of Maryland, Health General Article 5-601.*

Submitted by  
Ruth Dukoff, M.D. and  
Trey Sunderland, M.D.  
National Institute of Mental Health  
Bethesda, Maryland

## AN ARGUMENT FOR LIMITING THE ABILITY OF PROXIES TO CONSENT TO PARTICIPATION IN MEDICAL RESEARCH FOR INCAPACITATED PATIENTS

In recent years, most states have enacted laws allowing substitute or proxy consent to be given for medical care of patients who are not able to consent for themselves. Many statutory schemes now include expanded durable powers of attorney for health care and other advance directives, as well as priority lists of decisionmakers who are authorized to give consent in the absence of a patient's formally stated wishes. These laws extend the principle of patient autonomy, allowing decisions that benefit patients to be made by others who are bound by law to keep patient interests in mind. They can have the simultaneous effect of eroding the powers of physicians, whose interests in pursuing specific therapies for unconscious or impaired patients may be impeded by the necessity of negotiating with health care agents.

No similar legislative trend has occurred to allow substitute consent to clinical research, and we should not be surprised. It is hard to imagine a ground-swell of support for the idea that anyone should be legally designated to "volunteer" another person into an experiment—an event that carries risks both known and unknown while offering benefits that are at best speculative. In the absence of significant demand, are there any policy reasons that would nevertheless provide a basis for supporting legal change in this area?

One powerful argument in favor of allowing proxy consent to research participation is to advance the principle of autonomy. People who wish to participate in research should be allowed to endorse a medical power of attorney allowing them to be enrolled

as research subjects in the context of future cognitive incapacity. They should be empowered to delegate their consent to a trusted agent, and to circumscribe the agent's decisions with whatever conditions they feel appropriate. Taking the risk of entering a research protocol—even one that has the primary objective of increasing medical knowledge and poses no benefit to a particular subject—should not be foreclosed to those willing to choose it. But the law should limit the prerogatives of agents to carrying out the specific wishes of the would-be-volunteer. The fictional concept of substituted judgement is too indeterminate a foundation upon which to build a new structure of proxy consent in the research arena.

But what of the incompetent or never competent: the unconscious, the developmentally disabled, the seriously and chronically mentally ill? Should they be made passive "volunteers" in studies that might benefit society at large?

Benefits to the group from which the "volunteered" subject is chosen might provide a justification for research that poses minimal risk and offers no direct therapeutic benefit. But it is difficult to articulate a general principle that can be invoked in favor of research carrying higher risks. Why would we allow proxy consent for research on incapacitated subjects under conditions prohibited in research on children or other vulnerable groups?

The role of health care proxy is a fiduciary role. In the therapeutic context we have endorsed it as a way of extending autonomy or of facilitating decisions judged to be in the best interest of the patient. Stretching the role to include proxy consent to research participation would similarly stretch the idea of a fiduciary. What person or committee could presume to speak as fiduciary for these subjects when their "best interests" would rule out any unnecessary steps into harms way?

A premier principle of the Belmont Report, a seminal document guiding

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## An Argument for Limiting the Ability of Proxies

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research ethics in the U.S., is that “it is important to distinguish between biomedical research and the practice of accepted therapy.” Yet recent studies suggest that this distinction is often not understood, particularly by seriously ill patients, nor adequately communicated by clinician/researchers—with the troubling consequence that many research subjects believe that they will sustain direct benefit from their participation in research. This misperception endures among ill but otherwise “normal” cognitively functional patients. It is worth keeping in mind as proposals are debated to allow substituted consent for research on cognitively impaired patients. In that context, the blurring of research and therapy would be even more difficult to monitor.

As chair of the Advisory Committee on Human Radiation Experiments, Ruth Faden recently identified several policy areas which “cry out for resolution” by a public body. One such area was the development of guidelines for research involving adults whose competence to consent to participate in research is questionable. In the classes of potential research subjects, the cognitively impaired are among the most vulnerable. Being unavailable for “informed consent,” they cannot invoke the protection of even that problematic and often hollow concept. They should be last in line for research, and only then if the process for their participation is open to public scrutiny including external monitoring of the research

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1. Ruth Faden, “Protecting Human Subjects”  
*Chronicle of Higher Education* 10-20-95.

Submitted by  
Paul A. Lombardo, Ph.D., J.D.  
Institute of Law, Psychiatry  
and Public Policy  
University of Virginia

## Case Presentation

*One of the regular features of the Newsletter is the presentation of a case considered by an ethics committee and how the committee resolved it. Individuals are both encouraged to comment on the case or analysis and to submit other cases that their ethics committee has dealt with. In all cases, identifying information of patients and others in the case should only be provided with the permission of the individual. Unless otherwise indicated, our policy is not to identify the submitter or institution. Cases and comments should be sent to: Editor, Mid-Atlantic Ethics Committee Newsletter, University of Maryland School of Law, 500 W. Baltimore St., Baltimore, MD 21201-1786.*

### Case Study From a Maryland Hospital

K.B. is an 86 year old white female who, other than many years of hypertension, was in good health until recently. She lives independently in a retirement community. However, recently her blood pressure had become more difficult to control and a nephrectomy was done to help control it. Shortly after this she developed renal failure and was started on hemodialysis through an intravenous catheter.

For several months she was getting dialysis three times a week. A couple of weeks prior to receiving the dialysis, she underwent a vascular bypass procedure in the leg and ultimately had a full recovery, after a lengthy hospitalization.

Shortly after discharge, K.B. began feeling poorly. She kept this to herself for several days but eventually called the nephrologist who told her to come to the emergency room. On arrival she appeared ill, had a fever, and had an elevated white blood count. She was ultimately found to have staphylococcal sepsis and was admitted to the hospital. After several days of treat-

ment K.B. continued to get worse, her white blood count and fever remained elevated, and she had a suppressed mental state. Because her prognosis for recovery from the sepsis was poor, dialysis was stopped. Over the next couple of days however, K.B.’s vital signs, white blood count, and fever improved, but she remained unresponsive. K.B.’s surrogate indicated that K.B. would not want to continue dialysis and wanted to be left to die. The nephrologist was concerned about this because during conversations with K.B. before she became unresponsive K.B. expressed a wish to continue.

During the previous couple of months K.B. had repeatedly expressed to her family that she wanted to die. K.B.’s family consisted of her daughter who had been appointed K.B.’s agent through a durable power of attorney for health care, her son-in-law, and her sister, who lived in the same retirement community. They claimed that K.B. was intimidated by doctors, and would always go along with the doctor’s recommendation even if that was not what she wanted to do.

The physician had reason to believe that the surrogate was acting in her own interest and not that of K.B.. She noted several conversations in which the family told K.B. that “you should have died earlier,” and that “if you were a horse we would shoot you.” After a conversation in which K.B.’s sister accused the nephrologist of wanting to continue dialysis only to make money, the doctor decided to call the ethics committee.

An ad hoc patient care advisory committee was formed. They met independently with K.B.’s family, and with the physician. The physician claimed that K.B.’s chance of recovery was around 5% but that she (the physician) felt obligated to K.B. to continue dialysis since during her last conversation with K.B., K.B. wanted to continue the treatment. The doctor wanted to continue dialysis for at least a limited time to see if K.B.’s current condition could be improved.

K.B.’s family expressed reluctance to continue. They noted multiple instances where K.B. did not want to



go on living in her current state, that she would never want to be placed in a nursing home, and reiterated that K.B. would not tell the doctors what she really wanted. How should the ethics committee proceed to resolve this conflict. Should it make a recommendation? If so, what should the committee recommend?

## Case Discussion: Comments From a Philosopher/Ethicist

Conflicts among family members pose some of the most challenging issues for an ethics committee. Even when there is some advance planning, as in this case where a daughter had been appointed as an agent through a durable power of attorney for health care, conflicts about the patient's wishes and the adequacy of the surrogate can still arise. We may all agree with the *presumption* that families are appropriate decision-makers, but it is still difficult to sort out when that presumption ought to be overridden and through what means. How do we determine when a surrogate is acting in his or her own interest and out of unacceptable conflict of interest, rather than out of knowledge about the patient's wishes and genuine care and concern? An ethics committee consultation may be helpful by sorting out what is known about the patient's wishes from multiple sources and challenging what may appear as unacceptable conflicts of interest. The physician and the family disagree about what they think the patient would have wanted. Through an information gathering process, it would be important to learn more about the evidence each party has in support of their claim about the patient's wishes.

As a starting point, it would be important to learn more about the relationship between the nephrologist and the patient. Are her concerns based solely on the last conversations before the patient became unresponsive? Did the patient have capacity at

the time? Does the physician have previous information based on a long-standing relationship? Was she involved in completing the durable power of attorney for health care? Is there a primary care physician who may have additional information about this patient, her wishes, and the circumstances surrounding the naming of the daughter?

Did the physician have first-hand information about the inflammatory conversations where the family said the patient should have died earlier and if a horse, would have been shot? If so, was the issue of surrogacy challenged at that time? What explanation does the nephrologist give for the patient having named her daughter?

A similar line of inquiry with the family would be helpful. What evidence do they have concerning K.B.'s wishes? What explanation do they give for the daughter having been selected? In many jurisdictions, like the District of Columbia and Maryland, the family is the presumed decision-maker. This patient went through the trouble of actually naming her daughter. What is the family's account of this process and its rationale?

As you can imagine, discussion of the possible self-interest on the daughter's part and the possible inappropriate remarks would be sensitive. Given a so-called 5% chance of recovery, what level of animosity would have to be evidenced for a family to be disqualified as an appropriate surrogate?

Here is how I can imagine a best case scenario - meaning the most straightforward. There is a primary care physician who helped K.B. discuss end-of-life issues and helped facilitate the naming of the daughter as the agent under a durable power of attorney for health care. The remark by the family was misheard or exaggerated, and it is clear that K.B. would trust her daughter's judgment of when it was time to stop. The primary care physician confirms the family's view that K.B. would not want to continue if it was unlikely to help or she was "vegetative." The primary care physician also confirms the family's

view that K.B. deferred to physicians which could account for her desire to continue dialysis.

A second scenario would include more ambiguities. There is probably no primary care physician who could offer independent information about K.B.'s wishes or her naming of her daughter as her health care agent. The nephrologist, herself, does not have a long-standing relationship with K.B. The family dynamic is troubled, and "inappropriate remarks" have been validated by a number of other care providers. In a group meeting, the family cannot really account for why K.B. would have wanted to continue dialysis. It is clear they are mistrustful of the physician - but also have some level of concern about the suffering their family member will face. Through a discussion of the 5% chance of returning to her baseline, the family may see the value of a limited time trial of dialysis. Clear parameters for the length of the trial would have to be established. The issue of placement would also have to be addressed. If no one believes she would be able to return to her retirement community, then this would have to be addressed. If the trial of dialysis is to see if K.B. could be returned to a higher level of mental functioning, then the trial seems worth it. If however, K.B. was firm in her belief that she would not want to live in an unresponsive state in a nursing home, and there was *not* a chance to restore mental capacity, then perhaps a trial is inappropriate.

I am trying to imagine what it would take for an ethics committee to recommend that the daughter be disqualified as the surrogate, and another person named. Who, in fact is better situated to speak for K.B.? Perhaps another surrogate would be necessary if the daughter stopped coming to meetings and denied further involvement, or if there was evidence of abuse or neglect. This does not seem to be the case. I believe the ethics committee may be helpful by facilitating further communication between the parties, and supporting either the family's desire to stop now, or some time-limited trial of

*Cont. on page 8*



## Case Discussion

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dialysis, depending on the medical information.

Two concerns or take-home lessons from this case bear repeating. Families are very important and the presumption that they are the appropriate surrogates is strong. We all have conflicts of interest in that we are likely to leave our estates to or inherit from the very loved ones we trust to make our decisions or who trust us to do so. We must be mindful that the standard is not conflict of interest - we all have those - but rather *unacceptable* conflicts of interest. Secondly, it is not true that whatever families say must be followed without question or concern. Ethics committees can be an appropriate mechanism to help explore decisions by families that seem to go against the patient's wishes or interests. And, as always, it is helpful for members of the health care team to document conversations concerning advance planning, so that there is more information should conflicts arise at a later time. The more involved the health care team is in the development and execution of an advance directive, the more likely it is to be helpful

Submitted by:

Jacqueline J. Glover, Ph.D.

Director, Program in Bioethics  
Department of Health Care Sciences

George Washington University  
Director/Philosopher-in-Residence

Office of Ethics  
Children's National Medical Center

## Case Discussion: Comments From a Health Law Professor

Adam Smith's *The Wealth of Nations* is one of those books that people interested in medical ethics rarely read. That is unfortunate, since Smith laid the foundation for modern economics—a subject with which medical ethics now grapples on a daily basis. The first sentence in *The*

*Wealth of Nations* observes that “the greatest improvements in the productive powers of labor, and the greater part of the skill, dexterity, and judgment with which it is anywhere directed, or applied seem to have been the effects of the division of labor.” Such division of labor (known as specialization in medical circles) has had astounding benefits, but it also creates certain hazards, including parochialism, fragmentation, overspecialization, and miscommunication.

In the early days of medical ethics, ethical problems were viewed by all parties as legal disputes, requiring the services of lawyers and judges for resolution. Despite some early (and overly confident) assertions of competence for handling such matters, the legal system turned out to be a rotten way of dealing with ethical disputes. In short order, there was a concerted effort to remove such issues from the universe of “law-type” problems. As lawyers and judges were distanced from the ethics business, a new specialty (and various organizational forms) arose—ethicists, ethics committees, and ethics consultants.

As noted above, one of the trade-offs associated with the division of labor is parochialism. The conventional (and, unfortunately, the too often accurate) wisdom is that all specialists have a tendency to view the problem before them as necessarily arising out of the particular specialty in which they are engaged—and thus remediable by the skills which they have to offer. As a distinguished surgeon once explained it to me, “If the only tool you have is a hammer, everything looks like a nail.”

Those who specialize in ethics are not immune to this tendency. Although this case study resulted from an ethics consultation, and is in a publication directed at those interested in ethics committees, the dispute presents either a straightforward question of law or an example of miscommunication. As such, the dispute does not require the services of ethics committees, ethics consultants, or ethicists.

The case study presents a simple legal question: is the daughter, in legal terminology, a faithless agent? If so,

the physician is obligated to seek a court order setting aside the durable power of attorney. The Court will then appoint someone else as the decision-maker for K.B. If the doctor does not seek a court order, the law requires that the daughter, acting as proxy for K.B., be obeyed. As a legal matter, there is no middle ground. Ethics, as Mae West might have put it, has nothing to do with it.

The evidence supporting the claim that the daughter is a faithless agent is at best unfavorable. Although K.B.'s last expressed wishes to her physician indicated she wished to continue with dialysis, three members of her immediate family stated there had been multiple recent conversations in which K.B. had expressed the opposite. The family further stated that K.B. was intimidated by doctors and would agree with a physician's recommendation, even if it was not what she really wanted. The evidence that the family was pursuing its own interest as opposed to K.B.'s was the accusation that the physician was only pursuing dialysis because of his personal financial gain, and certain candid comments to K.B. about her quality of life. K.B.'s physician may well be frustrated with her family, but that is a long way from the standard for proving the daughter is a faithless agent. Even if K.B.'s doctor believes that the daughter is faithless, the proper response is legal, not ethical.

The exceedingly low probability of recovery could be an additional reason to accept the refusal of treatment. If K.B.'s chances are slim to none and the evidence on faithlessness is equivocal, the fight probably isn't worth the candle. This reasoning is problematic, however pragmatically appealing it might appear. Durable powers of attorney allow principals to designate agents to make decisions for them when they are no longer able to do so, and the law requires that agents be treated like principals. We are not allowed to second-guess competent principals, regardless of the probability of success of a foregone treatment. There is no compelling reason why the same reasoning should not apply to

duly designated agents, in the absence of overwhelming independent proof of faithlessness. Refusal of treatment, standing alone, is not independent evidence of faithlessness—even if the treatment has a high probability of success. Were the default rules otherwise, one could dispense with proxy consent entirely.

The economic implications of identifying and eliminating faithless agents must also be considered. Policing the system costs all parties both money and time. The risk of error is non-zero, even with full adversarial proceedings. There are good arguments for allocating the hazard of faithlessness to the principal, particularly when there has been recent contact between the agent and principal. The candid comments of the family to K.B., which the physician believed were evidence of faithlessness, are, if anything, additional reasons to adhere to the wishes of K.B.'s daughter. It should have been crystal clear to K.B. what the results would be of leaving her daughter as proxy-decision maker, and she did so nonetheless. An open-ended standardless inquiry into faithlessness imposes substantial costs, undermines certainty, and may well lead to less care in selecting agents. Although there may be some marginal cases in which the results are problematic, the best solution may nonetheless be to give duly-designated agents a virtually irrefutable presumption of faithfulness.

Another hazard of specialization which might account for the dispute is miscommunication. It is hard to believe that the physician is planning to continue dialysis for any significant amount of time, given the grim prognosis and his expressed intention "to continue dialysis for at least a limited time to see if the patient's current condition could be improved." K.B.'s family may not realize that the physician is only proposing a temporary trial of dialysis, and may be refusing treatment because they believe the physician plans to continue it indefinitely. It seems unlikely the two sides are that far apart. A few minutes of

discussion might well eliminate the whole controversy.

It has been argued that ethicists, ethics committees, and ethics consultants can serve a useful role by ensuring that the parties to a dispute are talking to - rather than past one another. Although good communication is clearly necessary, one would have thought the logical (not to say ethical and cost-effective) response to miscommunication is to avoid it at the outset instead of calling in the ethics SWAT team in those few situations which have resulted in a stand-off. Miscommunication is not ethics at all—and treating it as such detracts from the credibility of ethicists, ethics committees, and ethics consultants in dealing with genuine ethical issues.

Whether cast as a legal dispute or miscommunication, this case study does not include a problem which the division of labor has allocated to ethicists, ethics committees or ethics consultants. "Shoemaker, stick to thy last" is an old rule - but one which applies to medical ethics as well as shoemakers.

Submitted by  
David Hyman, M.D., J.D.  
Associate Professor  
University of Maryland School of Law

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## Afterword

The family was told by the ad hoc committee that the doctor only wanted to continue dialysis for two more treatments to see if K.B. could improve enough to decide whether or not treatment should continue. The committee also explained that the doctor felt obligated to continue treatment because of K.B.'s previous stated wishes. After hearing this the family agreed to two more days of dialysis.

After two more treatments, K.B.'s mental state significantly improved. She was able to hold a conversation with the nephrologist and her family. After thinking about it for a couple of days, K.B. decided to decline further dialysis, and arrangements were made to place K.B. in hospice care.

## Network News

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firm. The meeting will be held on November 14, 1995 at 4:00 p.m. at Meridian Health Care Center at Aspenwood, Silver Spring, Maryland. For information on the meeting, call Joan Lewis at (202) 682-1581.

## Virginia Bioethics Network (VBN)

The membership and Board of the VBN approved the "Recommendations for Guidelines on Procedures and Process and Education and Training to Strengthen Bioethics Services in Virginia" at the Network's annual meeting in October 1995. The "Guidelines" were written by John Fletcher, Ph.D., Edward Spencer, M.D., Sigrid Fry-Revere, J.D., Ph.D., and Cavin Leeman, M.D. and were debated by the VBN for two years before final approval. The membership and Board have approved the guidelines for public distribution. For more information, call (804) 924-5974.

## West Virginia Network of Ethics Committees (WVNEC)

The WVNEC's recent fora on "Ethical Issues in the Care of the Dying" received great interest, drawing between 100 and 150 participants on each occasion. The program began with a film produced by the Memorial Sloan Kettering Cancer Institute in New York City called "On the Edge of Being: When Doctors Confront Cancer." The film presented interviews with six physicians who had direct experience with cancer, either by developing cancer themselves or by having a close family member who had the disease. In the film, these physicians discussed their experience with the care received by cancer patients, the ethical issues surrounding pain control, the spiritual questions cancer

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## Other News

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patients and their families must grapple with, and the problem and prevention of health care provider burn-out. The 45-minute film sparked a discussion among participants lasting several hours. For information on how to obtain a copy of the film, which is available free of charge, please call Cindy Jamison at (304) 293-7618.

The WVNEC is also planning to hold a workshop on the new organizational ethics standards recently mandated by the Joint Committee on Accreditation of Healthcare Organizations (JCAHO) for hospitals, nursing homes and home care agencies. No date has yet been set. Call (304) 293-7618 for more information.

## Other News and Announcements

**Georgetown University School of Medicine:** The Georgetown University School of Medicine is pleased to announce a new federally sponsored fellowship program in primary care research, with one position per year in the bioethics track. Fellows spend two years taking courses, conducting research, and participating in the activities of the Center for Clinical Bioethics and the Institute for Health Care Research and Policy at Georgetown University. An M.A. degree in Bioethics through the Kennedy Institute of Ethics and the Department of Philosophy is optional. For further information, contact Dr. Daniel Sulmasy, Center for Clinical Bioethics, 238 Building D, Georgetown University Medical Center, Washington, DC 20007 or call Stacy Schultz at (202) 687-1122.

**Center for Biomedical Ethics, University of Virginia:** The Advisory Board and Friends of the Center for Biomedical Ethics offer the STACY BOYLE MATCHING GRANTS for institutions that wish to send participants to the Center's program *Developing Ethics Programs in Long-Term Care* (DEPLTC), to be held April 17-19, 1996 at the University of Virginia in Charlottesville. This three-day program

is designed to facilitate or strengthen the implementation of an ethics program within a long-term care institution. The course is limited to 30 participants. The Center for Biomedical Ethics is also sponsoring the *Developing Hospital Ethics Program* (DHEP), to be held March 25-30, 1996 at the University of Virginia in Charlottesville. This six-day course of study for health care professionals from hospitals and other health care institutions is designed to facilitate or strengthen the implementation of an institutional ethics program within such institutions. The course is limited to 24 participants. For information on either of these programs, please call (804) 924-5974.

**Johns Hopkins University/Georgetown University:** The Johns Hopkins University and Georgetown University are pleased to announce the jointly sponsored Greenwall Fellowship Program in Bioethics and Health Policy, which is supported by the Greenwall Foundation. The two-year funded fellowships include academic course work, a "hands-on" summer internship in health policy, and supervised research leading to at least one publishable manuscript. Fellows have the opportunity to design individualized academic programs, drawing on the resources of the Johns Hopkins School of Public Health, the Department of Medicine at Johns Hopkins School of Medicine, the Georgetown University Law Center, the Kennedy Institute of Ethics at Georgetown University, and the Department of Medicine at Georgetown University. Applicants should have advanced degrees in medicine, nursing, philosophy, law, social sciences or a related field. Applications for fellowship positions that will begin in September 1996 are due by March 1, 1996. Address inquiries and requests for applications to the Greenwall Fellowship Program in Bioethics and Health Policy, Johns Hopkins School of Public Health, 624 North Broadway, Room 513, Baltimore, MD 21205-1996 or fax requests to (410) 614-9567.

**Open Society Institute:** The Open Society Institute, a non-profit foundation that supports the development of open societies worldwide, has initiated the Project on Death in America. The

mission of this new program is to understand and transform the culture and experience of dying in the United States through initiatives in research, scholarship, the humanities and the arts and to foster innovations in the provision of care, public education, professional education and public policy. The Project of Death in America invites proposals for funding that will contribute to understanding and transforming the culture and experience of dying and bereavement in the United States. Applicants are invited to submit proposals for projects in the following areas:

1. The epidemiology, ethnography and history of dying and bereavement in the United States.
2. The physical, emotional, spiritual and existential components in dying and bereavement.
3. The contribution of the arts and humanities.
4. The design, implementation, evaluation and dissemination of new service delivery models for the dying and their network of family and friends.
5. The design, implementation, evaluation and dissemination of educational programs for the public about death and dying.
6. The design, implementation, evaluation and dissemination of educational programs for the health care professions.
7. The shaping of governmental and institutional policy.

The Project also welcomes proposals in areas not listed above. Applicants in the arts and humanities as well as in quantitative sciences are encouraged to apply, as are persons and organizations outside health care networks, without conventional credentials, or without prior experience in applying for foundation grants. The Project is particularly eager to encourage initiatives arising from varied cultural contexts.

For a copy of the program announcement and a description of the application process and timeline, address inquiries to the Project on Death in America, Open Society Institute, 888 Seventh Avenue, 19th Floor, New York, New York 10017 or fax requests to (212) 489-8455.



# CALENDAR OF EVENTS

## NOVEMBER

- 21 Georgetown University Center for Clinical Bioethics, Evangelium Vitae Lecture Series. "God's Law and Civil Law," Kevin Quinn, S.J. 12:00-1:00 pm, at New Research Building Auditorium, Research Building Room WG10, Georgetown University Medical Center, Washington, DC. Call Stacy Schultz at (202) 687-1122.
- 30 University of Maryland Medical System, Medical Humanities Hour. "Perspectives on Surrogate Motherhood," Margaret Little, Ph.D., Dept. of Philosophy, Georgetown University. 4:30-5:30 pm, at Shock Trauma Auditorium, University of Maryland Hospital, Baltimore, MD. Call Henry Silverman, M.D. at (410) 706-6250.

## DECEMBER

- 4 University of Maryland School of Law's Law & Health Care Program Conference, "Proposed Medicare and Medicaid Reforms: A Discussion." 8:00 am-2:00 pm, University of Maryland School of Law, Baltimore, MD. Call (410) 706-3378.
- 6 West Virginia Network of Ethics Committees, Northern Regional Forum. "Resolving Conflicts in Patient Care." At Byrd Health Sciences Center, University of West Virginia, Morgantown, WV. Call Cindy Jamison or Alvin Moss, M.D. at (304) 293-7618.
- 12 Georgetown University Center for Clinical Bioethics, Bioethics Colloquium. "Human Subjects Research: Findings of the Advisory Committee on Human Radiation Experiments," Jeffrey Kahn, Ph.D., M.P.H., Bioethics Program, Medical College of Wisconsin and Advisory Committee on Human Radiation Experiments. 5:00-6:45 pm, Warwick Evans Room, Building D, Georgetown University Medical Center, Washington, DC. Call Stacy Schultz at (202) 687-1122.
- 19 Georgetown University Center for Clinical Bioethics, Evangelium Vitae Lecture Series. "The New Culture of Human Life," Leo O'Donovan, S.J. 12:00-1:00 pm, at New Research Building Auditorium, Research Building Room WG10, Georgetown University Medical Center, Washington, DC. Call Stacy Schultz at (202) 687-1122.

## 1996

### JANUARY

- 9 Georgetown University Center for Clinical Bioethics, Bioethics Colloquium. "Ethics and Managed Care," John Eisenberg, M.D., Dept. of Medicine, Georgetown University Medical Center, and Edmund Pellegrino, M.D., Center for Clinical Bioethics, Georgetown University Medical Center. 5:00-6:45 pm, at Warwick Evans Room, Building D, Georgetown University Medical Center, Washington, DC. Call Stacy Schultz at (202) 687-1122.
- 18 Baltimore Area Ethics Committee Network Meeting. Topic and location TBA. Call Jack Syme, M.D. at (410) 368-3020.
- 19 West Virginia Network of Ethics Committees, Southern Regional Forum. "Resolving Conflicts in Patient Care." At Charleston Area Medical Center, Charleston, WV. Call Cindy Jamison or Alvin Moss, M.D. at (304) 293-7618.
- 19 Georgetown University Center for Clinical Bioethics, Catholic Ethical and Religious Directives Lecture Series. "Social Responsibility," Keven Wildes, S.J., Ph.D. 12:00-1:00 pm, at Warwick Evans Conference Room, Building D, Georgetown University Medical Center, Washington, DC. Call Stacy Schultz at (202) 687-1122.
- 27 Metropolitan Washington Bioethics Network Meeting. "Physician-Assisted Suicide." Time and location TBA. Call Joan Lewis at (202) 682-1581.

### FEBRUARY

- 13 Georgetown University Center for Clinical Bioethics, Bioethics Colloquium. "Clinical Problem-Solving and Sherlock Holmes," William Ayers, M.D., Kennedy Institute of Ethics, Georgetown University. 5:00-6:45 pm, at Warwick Evans Room, Building D, Georgetown University Medical Center, Washington, DC. Call Stacy Schultz at (202) 687-1122.
- 20 Georgetown University Center for Clinical Bioethics, Catholic Ethical and Religious Directives Lecture Series. "Pastoral Care," James Shea, S.J. 12:00-1:00 pm, at Warwick Evans Conference Room, Building D, Georgetown University Medical Center, Washington, DC. Call Stacy Schultz at (202) 687-1122.

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