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Law

Legal Briefing: Healthcare Ethics Committees

Thaddeus Mason Pope

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ABSTRACT

This issue's "Legal Briefing" column covers recent legal developments involving institutional healthcare ethics committees.[1] This topic has been the subject of recent articles in JCE.[2] Healthcare ethics committees have also recently been the subject of significant public policy attention. Disturbingly, Bobby Schindler and others have described ethics committees as "death panels."[3] But most of the recent attention has been positive. Over the past several months, legislatures and courts have expanded the use of ethics committees and clarified their roles concerning both end-of-life treatment and other issues. These developments are usefully grouped into the following eight categories:

1. Existence and availability
2. Membership and composition
3. Operating procedures
4. Advisory roles
5. Decision-making and gate-keeping roles
6. Confidentiality
7. Immunity
8. Litigation and court cases

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EXISTENCE AND AVAILABILITY

The history of ethics committees is familiar to the readers of this journal. The origins of ethics committees date to the therapeutic abortion committees, dialysis allocation committees, and early institutional review boards (IRBs) of the 1960s.[4] The use of ethics committees received a major boost in 1976. That year, the *Quinlan* court suggested that ethics committees, rather than courts, should review decisions to withhold or withdraw treatment as "a general practice and procedure."[5]

The original concept was, in application, more of a "prognosis committee" comprised of physicians.[6] But that quickly evolved into a multidisciplinary committee.[7] Ethics committees received a further boost in 1983, when the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research endorsed the use of committees in its widely influential report, *Deciding to Forgo Life-Sustaining Treatment.*[8] Indeed, the President's Commission even published a

model statute on the role and function of ethics committees as an appendix to its report.

But the President's Commission's invitation to mandate the establishment and use of ethics committees was not widely accepted across the United States.[9] The following year, in 1984, the Department of Health and Human Services promulgated regulations that only "encouraged" providers to establish "Infant Care Review Committees."[10] Ethics committee statutes were enacted by only a handful of states, including Maryland, New Jersey, Colorado, New York, Texas, and Massachusetts.[11] But perhaps more notable than these laws was the ethics committee mandate in the private, although influential, accreditation standards of the Joint Commission.

Apart from this handful of statutes, legal support and guidance for ethics committees is sorely lacking in the United States.[12] And this situation is not unique to the United States. A dearth of legal support and guidance also exists in other countries. Ethics committees are now legally mandated in only a few nations. Among these are Israel, Taiwan, the Spanish state of Andalucia, Norway, Alberta, and Singapore.[13] And research ethics committees in Belgium[14] and Greece[15] are charged with serving clinical ethical functions in addition to their core IRB functions.

Maryland

In 1986, Maryland became the first state to enact legislation requiring the creation of "patient care advisory committees."[16] The statute now provides that "each hospital and each related institution shall establish . . . a patient care advisory committee."[17] Recognizing that this requirement might be burdensome for smaller facilities, the statute permits a committee to function: "(1) solely at that related institution, (2) jointly with a hospital advisory committee, or (3) jointly with an advisory committee representing no more than 30 other related institutions."[18]

New Jersey

New Jersey quickly followed Maryland. In 1990, New Jersey amended its hospital licensing standards to require that each hospital "have a multidisciplinary bioethics committee, and/or prognosis committee(s), or equivalent(s).[19] This requirement arguably extends to long-term care facilities, because the state's Advance Directive Act requires each healthcare institution to "establish procedures and practices for dispute resolution."[20]

Indeed, New Jersey later amended the licensing standards for both long-term care facilities[21] and home health agencies,[22] to clarify that the required procedures for considering disputes may include "consultation with an institutional ethics committee, a regional ethics committee or another type of affiliated ethics committee, or with any individual or individuals who are qualified by their background and/or experience to make clinical and ethical judgments." New Jersey also extended the ethics committee mandate to its psychiatric and mental health facilities.[23] And the state Bureau of Guardianship Services is required to consult with an ethics committee, especially in "critical areas of decision-making" such as a medical procedure that entails "major, irrevocable consequences" like amputation or organ transplantation.[24]

Like the Maryland statute that allows joint and shared committees, New Jersey regulations recognize "Regional Long Term Care Ethics Committees." These committees, which are approved by the Office of the Ombudsperson for the Institutionalized Elderly (OOIE), "provide to the long-term care community expertise of multi-disciplinary members who offer case consultation and support to residents and health care professionals who are facing ethical dilemmas."[25] While decisions to withhold or withdraw life-sustaining treatment from an elderly, incapacitated resident of a long-term care facility must normally be reported to the OOIE, the decisions need not be reported when they have been reviewed by an approved ethics committee.[26] This seems to be a reasonable delegation of the OOIE's responsibility.[27]

Colorado

In 2010, Colorado enacted significant amendments to its Medical Treatment Decisions

Act. But both the current law and the original 1992 law provided for ethics committees in a section on proxy decision makers. The statute provides: "The assistance of a health care facility's medical ethics committee shall be provided upon the request of a proxy decision-maker or [potential proxy decision maker] whenever the proxy decision-maker is considering or has made a decision to withhold or withdraw medical treatment."[28] Like Maryland, the Colorado law recognizes that the requirement might be burdensome for some facilities. Accordingly, the statute further provides: "If there is no medical ethics committee for a health care facility, such facility may provide an outside referral for such assistance or consultation."

New York

In 2010, New York finally enacted its long-awaited and much-anticipated Family Healthcare Decisions Act (FHCDA).[29] While the centerpiece of the statute was its recognition of default surrogates, the FHCDA also requires each hospital and nursing home to "establish at least one ethics review committee." As in Maryland and Colorado, this requirement can be alternatively satisfied by "participat[ing] in an ethics review committee that serves more than one hospital."[30] Furthermore, recognizing that many facilities already had an ethics committee, the FHCDA allows a hospital to "designate an existing committee, or subcommittee thereof, to carry out the specified functions of the newly mandated ethics review committee," so long as that committee satisfies the statutory composition and operational standards.

Texas

In contrast to the broad mandates in Maryland, New Jersey, Colorado, and New York; Texas's mandate applies only to residential facilities of its Department of Mental Health and Mental Retardation. Since 1996, Texas has required that an ethics committee "be established by each facility."[31] As in other states, Texas also permits a committee to be established "multi-institutionally in cooperation with other health care providers, e.g., local hospitals, serving the same geographical area."

Massachusetts

Like Texas, Massachusetts requires ethics committees in only particular practice settings. Specifically, Massachusetts requires that neonatal intensive care units (NICUs) provide "ethics committees for review of complex patient care issues with a focus on parental involvement in decision making."[32]

"Baby Doe" Regulations

In 1982, disabled newborn Baby Doe died in Bloomington, Indiana, after his parents declined treatment. In response to this case, the Reagan Administration enacted federal laws to protect disabled infants.[33] Among these, the U.S. Department of Health and Human Services (DHHS) issued regulations encouraging the establishment of "Infant Care Review Committees."[34] The committees would assist in developing standards, policies, and procedures for providing treatment to disabled infants, and also assist in making decisions concerning medically beneficial treatment in specific cases. While the DHHS recognized the value of such committees, it only encouraged, but did not require, them.

The Joint Commission

There are only a handful of state laws and no federal laws mandating the existence and availability of ethics committees. But there is direction from the third source of healthcare regulation, private accreditation.[35] The Joint Commission, an independent, not-for-profit organization, is the nation's predominant standards-setting and accrediting body in healthcare.[36] Joint Commission accreditation is critically important both to a healthcare facility's certification for Medicare and Medicaid and to its licensing in many states. Consequently, most facilities took action when, in 1992, the Joint Commission amended its accreditation standards to require a "mechanism" for considering ethical issues.[37] "[H]ospital ethics committees have been the most common response to [this] mandate."[38]

Israel

Ethics committees are far more established in the United States than elsewhere. But they

are mandated by the laws in several other nations. For example, in Israel, the Patient Right's Act of 1996 directs the Director General of the Ministry of Health to appoint ethics committees.[39] At least 15 such committees have been established.[40]

Taiwan

In January 2011, the Taiwanese Legislative Yuan ratified amendments to the Hospice and Palliative Care Act.[41] Previously, life support for an incapacitated patient could be terminated only if a patient's family could prove that the patients had previously expressed a wish not to be resuscitated. Under the new law, the patient's family can jointly sign a request to stop life-sustaining medical treatment. But an independent ethics committee must first review and approve the request before it is carried out.

Andalucia

In 2010, the Parliament of the Spanish state of Andalucia enacted the Bill of Rights and Guarantees Concerning the Dignity of Terminally Ill Persons.[42] The law radically reformed end-of-life treatment, giving patients new rights, including the right to receive (1) accurate and understandable information about diagnosis and prognosis, (2) treatment for pain, and (3) comprehensive palliative care at home. The new law also mandates that all health facilities either have, or be linked to, an ethics committee.[43]

Norway

In 2000, the Norwegian Parliament approved a recommendation by the Ministry of Health and Social Affairs to require the establishment of clinical ethics committees.[44] The requirement is now for each hospital trust to have a clinical ethics committee. This means that one committee may cover more than one hospital. Unfortunately, the role of these committees is not well-defined, and a sufficient number of cases have not been referred to them.[45]

Singapore and Alberta

Both Singapore and Alberta have recently amended their anatomical gift acts and specified a role for ethics committees to assure the integrity of donations. In 2009, Singapore amended its Human Organ Transplant Act (HOTA) to permit living organ donors to receive compensation for expenses.[46] HOTA requires that hospitals performing such transplants establish ethics committees to scrutinize the proposed payment arrangements. It is the job of the ethics committees to ensure that donations are free from undue influence, coercion, emotional pressure, and financial inducement.[47]

In 2009, Alberta enacted a new anatomical gift act[48] and promulgated regulations[49] to implement the law. These regulations require that an "independent assessment committee" be established for the purposes of approving a donation by a minor. The role of this committee is to ensure (1) that the minor agrees to the donation without coercion and understands the nature and consequences of the donation, (2) that only regenerative tissues or organs are to be donated if the minor is under 16, (3) that the donation process poses a minimal risk, and (4) that all adult members of the recipient's immediate family have been eliminated as potential donors.

MEMBERSHIP AND COMPOSITION

The existence of ethics committees is mandated by several states, by the Joint Commission, and by several foreign nations. But it is not always clear what exactly these laws require. Many do not adequately specify the membership and composition of the committee. Colorado, Massachusetts,[50] and the Joint Commission are completely silent on both the size and diversity of committees. Requirements in other jurisdictions are usually minimal. Most laws require at least five members from different disciplines. But the appropriate composition for any particular committee depends on the precise role(s) that committee serves.

New York

The most comprehensive requirements concerning the composition of a healthcare ethics committee are found in the 2010 New York FHCDA. The statute requires that "ethics review

committees" in hospitals include at least five members who have demonstrated an interest in or commitment to patients' rights or to the "medical, public health, or social needs of those who are ill."[51] The committee must be "interdisciplinary." At least three members "must be health or social services practitioners, at least one of whom must be a registered nurse and one of whom must be a physician." At least one member must be a "person without any governance, employment or contractual relationship with the hospital."

The FHCDA's ethics committee composition requirements are a little different for residential healthcare facilities. Specifically, a facility must offer the residents' council of the facility (or of another facility that participates in the committee) the opportunity to appoint up to two persons to the committee. Neither of these two persons may be a resident of, or a family member of, a resident of the facility. Both must have "expertise in or a demonstrated commitment to patient rights or to the care and treatment of the elderly or nursing home residents through professional or community activities, other than activities performed as a health care provider."[52]

Maryland

Maryland requires that each "patient care advisory committee" consist of at least four members. These members must include (1) a physician not directly involved with the care of the patient, (2) a registered nurse not directly involved with the care of the patient, (3) a social worker, and (4) the chief executive officer or a designee from each hospital and each related institution. The statute permits the committee to consist of as many other individuals the facility chooses. The statute specifically suggests including representatives of the community, ethical advisors, and clergy.

Texas

The mandated ethics committee for Texas mental health facilities must consist of at least seven members. The members of a mental health facility committee must include (1) one facility physician; (2) one consulting physician; (3) one facility registered nurse from the individuals' unit who has knowledge of the individual and his or her condition; (4) a member of the clergy; (5) an attorney not affiliated with the facility or the Texas Department of Mental Health and Mental Retardation (TDMHMR); (6) a facility social worker; and (7) a representative of a family members' group or a representative of an advocacy group.[53]

The committee may also include the following additional members, as available (8) an additional consulting physician; (9) an additional facility registered nurse; (10) medical support staff, such as a physical therapist, clinical pharmacist, clinical psychologist, or occupational therapist; (11) a consulting social worker; (12) a rights representative; (13) additional representation by family members and advocacy organizations; and (14) other knowledgeable persons, as appropriate.

New Jersey

While New Jersey law does not specify the composition of hospital ethics committees, it does specify the composition of other ethics committees. For example, the ethics committees with which Bureau of Guardianship services must consult, before consenting to a "critical decision," must be certified as competent for such reviews.[54]

Similarly, ethics committees in the developmental disability context must include at least five members.[55] Members must have "knowledge, experience and/or training regarding ethical issues pertaining to end-of-life care and the unique characteristics of individuals with developmental disabilities."[56] The regulations encourage, but do not require, including (1) a non-attending physician, (2) a non-attending nurse, (3) a social worker, (4) a member of the clergy, (5) an ethicist, (6) a lawyer, (7) at least one member of the community interested in and experienced with individuals with developmental disabilities, and (8) a licensed healthcare professional with expertise in the medical concerns of the individual.

"Baby Doe" Regulations

The DHHS encourages, but does not require, providers to establish Infant Care Review Committees (ICRCs), but DHHS regulations do outline an advisory model. The model ICRC con-

sists of at least seven members; a member of the facility's organized medical staff must serve as chairperson,[57] and the other six may include (1) a practicing physician (for example, pediatrician, neonatologist, pediatric surgeon); (2) a practicing nurse; (3) a hospital administrator; (4) a lawyer; (5) a representative of a disability group or a developmental disability expert; and (6) a lay community member. Furthermore, in connection with review of specific cases, one member of the ICRC must be designated to act as "special advocate" for the infant.

Israel

The Israel Patient's Rights Act requires that ethics committees comprise five members. The chairman of the committee must be a person fit to be appointed district court judge. He/she is selected from a list of such persons drawn up by the Minister of Justice. The other four members include: (1-2) two specialist physicians from different specializations, (3) a psychologist or social worker, and (4) a representative of the public or person of religious authority.[58]

Andalucia

In December 2010, the Andalucia Ministry of Health promulgated regulations implementing the ethics committee mandate in the Bill of Rights and Guarantees Concerning the Dignity of Terminally Ill Persons, which had been passed in April 2010. These regulations direct that committees must be comprised of 10 members, one-half of whom are to be healthcare providers.[59] All members have four-year terms, and there are other detailed appointment rules. For example, there must be balanced representation of men and women. The committee must include (1) physicians, (2) nurses, (3) administrators, (4) lawyers, (5) members of the public, and (6) a member of the research ethics committee. At least one person must be an accredited expert in bioethics.[60]

Taiwan

The 2011 amendments to the Taiwanese Hospice and Palliative Care Act require that a hospital ethics committee must approve family decisions to withhold or withdraw life-sustaining treatment when there is no express consent from the patient. At least one-third of the members of the committee must be comprised of both members of the public and of ethical and legal experts.[61]

Alberta

The Alberta "independent assessment committee" for approving organ donations from minors must have a minimum of three members. One must be a physician, and one must be a psychologist or psychiatrist. No person who has had any association with the donor or the recipient that might influence the person's judgment may be a member of the committee.

Singapore

The Singapore living donor transplant law (HOTA) requires that every hospital transplant ethics committee consist of at least three people. At least one member must be a medical practitioner who is not employed or otherwise connected with the hospital. At least one member must be a lay person.[62] In addition, the Ministry of Health (MOH) has been implementing regulations under HOTA.[63] The MOH has reconstituted the committees to include new members and more perspectives.

OPERATING PROCEDURES

While some ethics committee laws are silent on membership and composition, many more are silent on operating procedures. For example, Massachusetts requires only that the facility have "written policies and procedures for . . . functioning of the ethics committee."[64] New Jersey requires only that the committee (1) participate in the resolution of patient-specific bioethical issues and (2) participate in the formulation of hospital policy related to bioethical issues and advance directives. But these laws provide no direction or guidance on content. They provide no direction as to what the policies and procedures should address.

Maryland

Ethics committees in Maryland are encouraged to engage in education and policy func-

tions. Specifically, they should "educate represented hospital and related institution personnel, patients, and patients' families concerning medical decision-making." They should also "review and recommend institutional policies and guidelines concerning the withholding of medical treatment."[65] The focus of the statutory operational requirements concerns the committee's case consultation function.

Maryland requires that, in appropriate cases, a committee inform its deliberations by consulting (1) all members of the patient's treatment team, (2) the patient, and (3) the patient's family. In a case involving the options for medical care and treatment of a child with a life-threatening condition, the committee must also consult "a medical professional familiar with pediatric end-of-life care, if a medical professional with this expertise is not already a member of the committee."[66] The statute further provides that "the petitioner may be accompanied by any persons the petitioner desires."[67]

The Maryland statute requires not only informed deliberation, but also transparency in case consultation. The statute mandates the committee to make a good faith effort to apprise interested parties about their rights with respect to the committee. The interested parties include: (1) the patient, (2) the patient's immediate family members, (3) the patient's guardians, and (4) any individual with a power of attorney to make a decision with a medical consequence for the patient. The committee must apprise the individuals of their right to (1) be a petitioner, (2) meet with the committee concerning the options for medical care and treatment, and (3) receive an explanation of the basis of the committee's advice.[68]

New York

The 2010 New York FHCDA requires "ethics review committees" to "adopt a written policy governing committee functions, composition, and procedure."[69] The FHCDA provides that ethics committee members and consultants must have access to the medical information and medical records necessary to perform their functions. The required procedures vary depending on the specific task that a committee is asked to perform. In certain situations,[70] when an ethics committee is convened to review a decision by a surrogate to withhold or withdraw life-sustaining treatment, the following procedures are required. First, a person connected with the case may not participate as an ethics review committee member in the consideration of that case. Second, the ethics review committee must respond promptly, as required by the circumstances, to any request for assistance. Third, the committee must permit persons connected with a case to present their views to the committee, and to have the option of being accompanied by an advisor when participating in a committee meeting.

Like Maryland, the New York FHCDA requires not only informed deliberation, but also transparency. The ethics committee must promptly provide certain notice to (1) the patient, when there is any indication of the patient's ability to comprehend the information; (2) a surrogate; (3) other persons on the surrogate list who are directly involved in a decision or dispute regarding the patient's care; (4) any parent or guardian of a minor patient who is directly involved in a decision or dispute regarding the minor patient's care; (5) an attending physician; (6) the hospital; and (7) and other persons the committee deems appropriate.

This required notice includes information about (1) the ethics committee's procedures, composition, and function; (2) any pending case consideration concerning the patient; and (3) the committee's response to the case, including a written statement of the reasons for approving or disapproving the withholding or withdrawal of life-sustaining treatment. In addition, the committee's response to the case must be included in the patient's medical record.[71]

Texas

In contrast to Maryland and New York, the Texas mental health regulations are comparatively thin. They require only two things. First, "decision-making concerning recommendations to be made by the ethics committee must be by consensus." Second, "each consultation with the ethics committee shall be documented in the individual's record."[72]

"Baby Doe" Regulations

In its regulations encouraging the establishment of ICRCs, the DHHS outlines a model ICRC. The suggested operational procedures are very detailed and cover four categories of ICRC functions: (1) prospective policy developments, (2) retrospective record review, (3) maintenance of records, and (4) prospective case review. There is not the space here to review the procedures for all these functions. I shall focus on those procedures for the prospective review of specific cases.

The regulations suggest that, in addition to regularly scheduled meetings, interim ICRC meetings will take place under specified circumstances to permit the review of individual cases. A hospital must, to the extent possible, require that life-sustaining treatment be continued until its ICRC can review the case and provide advice.[73] These interim ICRC meetings must be convened within 24 hours (or less if indicated)[74] (1) when there is disagreement between the family of an infant and the infant's physician as to the withholding or withdrawal of treatment, (2) when a preliminary decision to withhold or withdraw life-sustaining treatment has been made in certain categories of cases identified by the ICRC, (3) when there is disagreement between members of the hospital's medical and/or nursing staffs, or (4) when otherwise appropriate. In addition, interim ICRC meetings must take place upon the request of any member of the ICRC, hospital staff, or the parent/guardian of an infant.[75]

Interim meetings must be open to the affected parties. The ICRC must ensure (1) that the interests of the parents, the physician, and the child are fully considered; (2) that family members have been fully informed of the patient's condition and prognosis; (3) that family members have been provided with a listing that describes the services furnished by parent support groups and public and private agencies in the geographic vicinity to infants with conditions such as that before the ICRC; and (4) that the ICRC will facilitate family members' access to such services and groups.

Finally, to ensure a comprehensive evaluation of all options and factors pertinent to a committee's deliberations, its chairperson must designate one member of the ICRC to act, in connection with that specific case, as "special advocate" for the infant. The special advocate's job is to ensure that all considerations in favor of the provision of life-sustaining treatment are fully evaluated and considered by the ICRC.

Andalucia

The December 2010 regulations for Andalusian clinical ethics committees specify various procedural requirements.[76] For example, the committees must be accredited, and once accredited, the committee must prepare and approve internal rules of operation for transmission to the accreditation body. The committee must meet at least four times annually. Minutes must be taken at each meeting. And resolutions must be adopted by a majority of not less than two-thirds of those present.

Singapore

Hospital transplant ethics committees in Singapore have a narrow and precise job: to grant or deny authorization for the removal of a specified organ from the body of a living person. To grant such authority, the committee must be satisfied that (1) the person from whom the specified organ is to be removed has given consent; (2) the person is not mentally disordered, and, notwithstanding the person's age, is able to understand the nature and consequence of the medical procedures he or she has to undergo as a result of donation of the specified organ; and (3) the person's consent is not given pursuant to a prohibited contract or arrangement, and is not given or obtained by virtue of any fraud, duress, or undue influence.[77]

The statute also requires committees to follow procedures issued by the Ministry of Health. So far, these include that approval shall be valid only for 60 days. If one committee denies authorization, that decision is binding on all other committees. It has been providing training to help committee members conduct their assessments. And it is providing a platform for the committee members at different institutions, to meet and share their experiences, to compare notes, and to learn best practices.

ADVISORY ROLES

In 1984, John Robertson developed an organizational framework for ethics committees.[78] The framework has two dimensions. First, it is either optional or mandatory to consult the committee. Second, it is either optional or mandatory to follow the ethics committee's advice. The classic model is optional-optional. A provider need not consult an ethics committee; if the provider does, she or he need not follow the ethics committee's recommendation (if it even makes one). But there has been movement to optional-mandatory, mandatory-optional, and even mandatory-mandatory. In this section I provide examples of the optional-optional and mandatory-optional models. In these models, whether or not an ethics committee must be consulted, its recommendation is merely advisory.[79] In the next section I provide examples of the optional-mandatory and mandatory-mandatory models.

Maryland

On request, Maryland ethics committees must give advice concerning the options for medical care and treatment of an individual with a life-threatening condition.[80] The Maryland statute specifically anticipates the situation in which a provider for an incapacitated patient believes that an instruction regarding life-sustaining procedure is inconsistent with generally accepted standards of patient care. In such a situation, the provider must petition an ethics committee for advice.[81]

New Jersey

As in Maryland, a key role for New Jersey ethics committees is the resolution of patient-specific bioethical issues. Committees must provide a forum for patients, families, and staff to discuss and to reach decisions on ethical concerns relating to patient care.[82] Specifically, the statute anticipates disagreement among the patient, healthcare representative, and attending physician concerning either (1) the patient's decision-making capacity or (2) the appropriate interpretation and application of the terms of an advance directive to the patient's course of treatment. In such an event, the statute encourages parties to resolve the disagreement by means of procedures and practices established by the healthcare institution, including, but not limited to, consultation with an institutional ethics committee.[83]

West Virginia

As In Maryland and New Jersey, West Virginia requires providers to use an ethics committee as an informal mediator. Specifically, the statute requires that when there is a conflict between a surrogate's decision and the patient's best interest, "the attending physician shall attempt to resolve the conflict by consultation with [among other means] an ethics committee."[84]

New York

In New York, an ethics committee must consider and respond to any healthcare matter presented to it by a person connected with the case.[85] There are two situations in which a matter must be referred to the committee. The first is when an attending physician objects to a decision to withhold or withdraw life-sustaining treatment and does not transfer the patient.[86] The second situation is when an attending has actual notice of certain objections or disagreements that cannot otherwise be resolved.[87]

Whether voluntarily or mandatorily consulted, the ethics committee's response may include: (1) providing advice on the ethical aspects of the proposed healthcare, (2) making a recommendation about the proposed healthcare, or (3) providing assistance in resolving disputes about the proposed healthcare.[88] The FHCDA confirms that recommendations and advice by the ethics review committee are "advisory and nonbinding," except in three specific situations described in the next section.[89]

Texas

The Texas Mental Health Services regulations provide that consultation with an ethics committee may be sought for any treatment decision, but should be sought in three situations. First, consultation should be sought when an individual is unable to give direction regarding

the withholding or withdrawal of life-sustaining treatment, and has no legal guardian or other person legally designated to make such a decision. Second, consultation should be sought when a decision regarding the withholding or withdrawal of life-sustaining treatment is to be made and there is a conflict between or among the decision makers.[90] Third, consultation should be sought when less than "maximal therapeutic effort" will be made to reduce morbidity and mortality.[91]

Pennsylvania

New Pennsylvania mental health regulations provide that, in reaching decisions about appropriate care, it "may be helpful" to use "hospital ethics committees to review situations."[92]

DECISION-MAKING AND GATE-KEEPING ROLES

Most ethics committees remain optional-optional, which appropriately leaves treatment decisions to the joint decision making of physician and patients/surrogates. But some states have given ethics committees certain decision-making authority. This is appropriate, especially in circumstances when there are obstacles to effective joint decision making. Hawaii, for example, defines an "ethics committee" as "an interdisciplinary committee appointed by the administrative staff of a licensed hospital, whose function is to consult, educate, review, and *make decisions* regarding ethical questions, including decisions on life-sustaining therapy." The Hawaii statute does not specify exactly what sorts of decisions a committee will make. But the statutes in other states do.[93] Indeed, several states have delegated several authoritative roles to ethics committees: (1) making treatment decisions for patients without surrogates, (2) adjudicating futility disputes, (3) gate-keeping and check-pointing, (4) adjudicating surrogate "ties," and (5) adjudicating other disputes.

Making Treatment Decisions for Patients Without Surrogates

A frequent issue confronting ethics committees is making treatment decisions for patients without surrogates. Facilities across the United States, and even within the same state, take varying approaches to this problem.[94] Some facilities permit an attending physician to make the decision.[95] Other facilities require the appointment of a guardian. Texas law requires the concurrence of a second physician, who is not involved in treatment of the patient or "who is a representative of an ethics or medical committee of the healthcare facility."[96] Arizona requires a physician to consult with and obtain the recommendations of an ethics committee.[97]

But some states give ethics committees broader and more direct authority for such decisions. For example, Alabama,[98] Arkansas,[99] Georgia,[100] and Tennessee[101] place ethics committees right into the priority list of default surrogates. If no family member or "close friend" is reasonably available, then an ethics committee can be a patient's surrogate. A similar rule in California long-term care facilities permits treatment decisions for incapacitated patients without surrogates to be made by an "interdisciplinary team."[102] Similarly, Iowa established a statewide network of "local substitute medical decision-making boards." That law permits a "county board of supervisors" to "appoint and fund a hospital ethics committee to serve as the local decision-making board."[103]

In contrast to these states, in which ethics committees have the decision making authority of a regular surrogate, in Florida, ethics committees have a narrower role. For surrogate-less patients in a persistent vegetative state, life-prolonging procedures may be withheld or withdrawn only with approval of a "medical ethics committee of the facility where the patient is located." This committee must conclude that (1) the condition is permanent, (2) there is no reasonable medical probability for recovery, and (3) withholding or withdrawing life-prolonging procedures is in the best interest of the patient.[104]

Adjudicating Futility Disputes

Like treatment decisions for un-befriended elders, futility disputes also comprise a significant portion of ethics committee cases.[105] Uniquely, in Texas, the ethics committee may be the forum of last resort in a futility dispute.

If a Texas careprovider cannot reach consensus with a surrogate in a conflict over inappropriate or non-beneficial treatment, the provider can commence a multi-stage review process.[106] The first stage entails giving the surrogate at least 48-hours' notice of an ethics committee meeting. Second, the committee reviews the treating physician's determination. Third, if the committee agrees that the disputed treatment is inappropriate, the surrogate is given the committee's written decision. Fourth, the provider is obligated to continue providing the disputed treatment for 10 days, and to attempt to transfer the patient to another provider who is willing to comply with the surrogate's treatment request. Fifth, if the patient has not been transferred, then the provider may unilaterally stop treatment on the 11th day. Providers who follow the Texas law's prescribed notice and meeting procedures are immune both from disciplinary action and from civil and criminal liability.[107]

Both Idaho and New Jersey have recently considered adopting the unilateral refusal provisions in the Texas law. An Idaho bill was passed unanimously by the state senate, but died in the house.[108] In New Jersey, a joint brief by the New Jersey Hospital Association and the Medical Society of New Jersey asked the Appellate Division of the state Superior Court to adopt these provisions.[109] In late 2010, the court denied that request.[110]

Gate-Keeping and Check-Pointing

The original function of an ethics committee was one of gate-keeper.[111] Certain healthcare decisions cannot be implemented without consulting (and often without the approval of) an ethics committee. Ethics committees continue to play this gate-keeping and check-pointing role. For example, in a Texas mental health facility, behavioral interventions using highly restrictive interventions and aversive techniques such as faradic stimulation (with electric current) require the documented written approval of an ethics committee.[112]

In Massachusetts, in 2005, Haleigh Poutre was hospitalized with severe brain injuries after she was beaten into a coma by her stepfather Jason Strickland. The Department of Social Services[113] assumed custody for Poutre . It moved to terminate Poutre's life support after physicians declared she was in a persistent vegetative state. The Massachusetts Supreme Judicial Court approved this request.[114] But Poutre's condition then improved; she could breathe on her own and follow simple commands.[115] In the wake of this high-profile case, the Massachusetts child welfare system came under intense scrutiny.[116] In an effort to address discovered weaknesses in the system, a new statute provides that proceedings in end-of-life cases require, among other things, a "written recommendation from the ethics committee of the hospital at which the child is a patient."[117]

Ethics committees serve several gate-keeping roles in New York. First, in a residential healthcare facility, a surrogate has the authority to refuse life-sustaining treatment (other than cardiopulmonary resuscitation—CPR) only if the ethics committee, or a court of competent jurisdiction, reviews the decision and determines that it meets statutory standards.[118] Second, an emancipated minor patient with decision-making capacity has the authority to decide about life-sustaining treatment only if an ethics committee approves the decision.[119] Third, in a general hospital, if an attending physician objects to a surrogate's decision to withdraw or withhold medically provided nutrition and hydration, the decision may not be implemented until the ethics review committee reviews the decision and determines that it meets statutory standards.[120]

In Israel, a physician may invoke therapeutic privilege and withhold information that is important for informed consent, if an ethics committee agrees.[121] The committee must confirm that giving this information is likely to cause serious harm to a patient's mental or physical health. In some situations, ethics committee consultation is also required to withhold medical records from a patient or to disclose those records without a patient's consent.[122]

Adjudicating Surrogate "Ties"

In Maryland, if surrogates with equal decision-making priority disagree about a healthcare

decision, then either an attending physician or one of the default surrogates must refer the case to the institution's ethics committee. A physician who acts in accordance with the recommendation of the committee is not subject to liability for any claim based on lack of consent or authorization for the action.[123] Indeed, this role is not unique to Maryland. In Delaware, for example, an ethics committee can decide similar disputes.[124] As in Maryland, the attending physician, acting in accordance with the committee's recommendation, is not subject to civil or criminal liability or to discipline for unprofessional conduct.[125]

Adjudicating Other Disputes

In Israel, an ethics committee can (paternalistically) authorize treatment over a patient's objections when certain conditions obtain.[126] The committee must confirm that (1) the patient has received sufficient information to make an informed choice, (2) the treatment is anticipated to significantly improve the patient's medical condition, and (3) there are reasonable grounds to suppose that, after receiving treatment, the patient will give "retroactive consent."

CONFIDENTIALITY

In many states, the proceedings and deliberations of an ethics committee are confidential. In Maryland, for example, they are treated the same as other medical review committees.[127] This means that they are "not discoverable and are not admissible in evidence in any civil action."[128] The advice of an advisory committee concerning a patient's medical care and treatment become part of a patient's medical record and have all the protections afforded such records. Other states, including Ohio[129] and Texas,[130] similarly protect ethics committee confidentiality.

The 2010 New York FHCDA provides that "notwithstanding any other provisions of law, the proceedings and records of an ethics review committee shall be kept confidential and shall not be released by committee members, committee consultants, or other persons privy to such proceedings and records."[131] The FHCDA further provides that "the proceedings and records of an ethics review committee shall not be subject to disclosure or inspection in any manner." Specifically, "no person shall testify as to the proceedings or records of an ethics review committee, nor shall such proceedings and records otherwise be admissible as evidence in any action or proceeding of any kind in any court or before any other tribunal, board, agency or person." There are a few exceptions.[132] Notably, the FHCDA does not prohibit a patient, a surrogate, other persons on the surrogate list, or a parent or guardian of a minor patient from voluntarily disclosing, releasing, or testifying about committee proceedings or records.

IMMUNITY

Related to concerns over the confidentiality of ethics committee proceedings is concern over immunity. Laws conferring legal immunity can be broken into two categories: (1) those that protect the committee and committee members, and (2) those that protect individuals acting pursuant to the committee's recommendation.

Immunity of the Committee Itself

Many states confer immunity on an ethics committee, on its members, and on the institution in which a committee is situated. For example, the Florida statute provides: "The individual committee members and the facility associated with an ethics committee shall not be held liable in any civil action related to the performance of any duties required in this subsection."[133] Similarly, in Maryland, neither an ethics committee nor a member may be held liable in court for the advice given.[134] "A person that assists one or more hospitals or related institutions . . . may not be held liable in court for any advice given in good faith . . . and the committee and its members may not be held liable for any advice given in good faith."[135]

Likewise, in New York, no person shall be subject to criminal or civil liability, or be deemed to have engaged in unprofessional conduct, for acts performed reasonably and in good faith as a member of, as a consultant to, or as a participant in an ethics committee meeting.[136]

Other states have similar provisions, including Alabama,[137] Georgia,[138] Hawaii,[139] Massachusetts,[140] and Montana.[141] Furthermore, even when ethics committees are not specifically and expressly afforded immunity, they arguably have it by virtue of being a type of medical quality review committee.[142]

Immunity for Following the Advice of the Ethics Committee

Some states have afforded immunity not only to ethics committes, but also to healthcare providers who carry out the recommendations or decisions of an ethics committee. In Hawaii, for example, the statute provides: "There shall be no civil liability for . . . any acts done in the furtherance of the purpose for which the . . . ethics committee . . . was established. . . ."[143] Conversely, physicians typically need not follow the advice of an ethics committee and are not automatically liable for such contravention. However, just as the concurrence of an ethics committee helps establish the appropriateness of a physician's actions, contravention can suggest the opposite.[144]

The Singapore anatomical gift act provides: "Anything done by the transplant ethics committee of a hospital, a member of the transplant ethics committee, or any person acting under the direction of the transplant ethics committee or the Director, in good faith for the purposes of the exercise of the functions of the transplant ethics committee or in accordance with this Act, shall not subject the member or person personally to any action, liability, claim or demand."[145]

LITIGATION AND LIABILITY

Ethics committees regularly serve two important roles with respect to the courts. First, through serving advisory and decision-making functions, ethics committees preclude the need to resort to court. Second, even when cases do reach court, ethics committees often obtain significant deference from courts.[146] Less common is a third relationship that ethics committees have with courts. Sometimes, ethics committees are themselves the targets of legal action.[147] Other times, careproviders are sued for failing to use or for misusing an ethics committee.

Classic U.S. Cases

Perhaps the most famous case involving an ethics committee was that brought by Elizabeth Bouvia in 1986. After winning the right to refuse her feeding tube from a California court of appeal, Bouvia sued Los Angeles County, seeking $10 million in medical malpractice damages for force-feeding her. She also named the 14 members of High Desert Hospital's bioethics committee that had approved the procedure.[148]

Apart from *Bouvia*, ethics committees have typically been named defendants in medical futility cases. The four classic cases are (1) *Gilgunn v. Massachusetts General Hospital*, (2) *Bryan v. Rector and Visitors of the University of Virginia,* (3) *Bland v. CIGNA*, and (4) *Rideout v. Hershey Medical Center*.[149] In *Gilgunn,* the claim for negligent infliction of emotional distress proceeded to a jury, which returned a verdict for the providers.[150] In *Bryan,* the plaintiff's EMTALA (Emergency Medical Treatment and Active Labor Act) claim was dismissed.[151] But both *Bland* and *Rideout* settled, presumably with cash payments to the plaintiffs.[152]

Recent Futility Cases

In late 2009, nine-month-old Gabriel Palmer was diagnosed with a rare disease that affected the growth of his windpipe. East Tennessee Children's Hospital (ETCH) told Palmer's family that it "was going to cease Gabriel's respirator, medications, pulse oximeter and milk feeding because they considered his care futile." ETCH further stated that the facility ethics committee "would meet soon to make the formal decision of withdrawal of treatment, but that the decision was a foregone conclusion." The infant's mother filed a lawsuit, naming not only the hospital, but also the members of the ethics committee. The lawsuit claimed that ETCH's "inappropriate intervention" violated the Tennessee Health Care Decisions Act.[153] In response, the hospital apparently reversed position and agreed to provide the disputed treatment.[154]

Failure to Use an Ethics Committee

In two recent cases, one in Maryland[155] and one in Texas,[156] a plaintiff claimed that a hospital was negligent for failing to consult an ethics committee. In each case, there was conflict regarding the appropriate treatment for a patient. Each plaintiff alleged that a reasonably prudent careprovider would have consulted an ethics committee under the circumstances. Both cases were resolved on other grounds. But, as laws increasingly specify advisory and adjudicatory roles for ethics committees, it arguably becomes negligent to not use them.

Over-Reliance on an Ethics Committee

While some providers have been sued for failing to use an ethics committee, others have been sued for overusing an ethics committee. In two recent cases, on in Seattle and one in Montreal, an ethics committee was charged with playing too great a role. In 2004, Seattle Children's Hospital determined that it was ethically permissible to perform a hysterectomy and other interventions on Ashley, a severely disabled six-year-old girl. The interventions were performed. But, in 2006, the Washington Protection and Advocacy System (WPAS)[157] investigated the hospital.[158] WPAS concluded that the surgery violated Ashley's constitutional and common-law rights, because Washington courts had earlier ruled that sterilization of a developmentally disabled person requires court approval.

Court approval was never sought, in large part because ethics committee review and approval was thought to be sufficient.[159] In May 2007, WPAS reached a settlement agreement with the hospital.[160] One provision of the settlement agreement requires that an ethics committee to include one or more individuals who are advocates for individuals with developmental disabilities. In addition, Children's must bring in appropriate internal and external experts whenever it considereds issues that affect individuals with developmental disabilities.

In Montreal, Marie-Eve Laurendeau gave birth to Phebe Mantha in November 2007. After a difficult delivery involving perinatal asyphxia, Mantha was transferred to Montreal Children's Hospital in serious condition and put on life support. Physicians told Mantha's parents that their daughter had little chance for survival and advised them to take her off respiratory support and hydration. Her parents agreed. But the hospital's ethics committee (comite' d'ethique) later met without the parents and decided to continue treatment. In 2009, the parents filed a $3.5 million lawsuit arguing that the ethics committee never informed them that it actually had no decision-making power.[161] The case is still pending.

Retaliation for Using an Ethics Committee

Jeffrey Datto, a medical student expelled from Thomas Jefferson University in Philadelphia, brought a federal lawsuit challenging the termination. In 2005, Datto discoverd that a patient had been given an inappropirate injection that cased an amputation. Datto noted the error on the patient's chart. Datto's rotation supervisor reprimanded him and attempted to remove the note. Datto took the incident to the ethics committee. But the supervisor was angry about this and Datto received a failing grade. He alleged that his expulsion was, in part, retaliatory. He claimed that the university expelled him because he brought this patient safety issue to the attention of the ethics committee.[162]

Compliance with Directives for Catholic Health Care Services

Ethics committees have become entangled not only with civil law, but also with canon law. Sister Mary Margaret McBride was an administrator and key member of an ethics committee at St. Josephs Hospital in Phoenix, Arizona. In November 2009, she approved an abortion for a woman with pulmonary hypertension. Because the abortion was necessary to save the life of the mother, McBride determined that it was permitted under the Ethical and Religious Directives for Catholic Health Care Services. But Phoenix Bishop Thomas Olmsted disagreed. In May 2010, he excommunicated McBride. And, in December 2010, he removed the "Catholic" designation from the hospital.[163]

CONCLUSION

The life of ethics committees has run roughly parallel with the life of alternative dispute resolution (ADR). Scholars have described the growth of ADR as falling into three developmental stages: (1) experimentation, (2) implementation, and (3) regulation.[164] That model can be adapted to ethics committees: the experimentation stage, from roughly 1975 to 1992; and the implementation stage, from roughly 1992 to 2010. It is time, now, to move to the regulation stage.

NOTES

1. This article focuses on only those clinical ethics committees formed by and for healthcare institutions. It does not discuss non-institutional and quasi-governmental committees such as: (1) substitute decision-making boards in Iowa and New York, (2) euthanasia regional review committees in the Netherlands, or (3) the ethics committee of the Vermont Division of Disability and Aging Services. This article also does not discuss research ethics committees and IRBs.

2. D.B. Mishkin and G. Povar, "The District of Columbia Amends Its Health-Care Decisions Act: Bioethical Committees in the Arena of Public Policy," *The Journal of Clinical Ethics* 16, no. 4 (Winter 2005): 292-8.

3. B. Schindler, "The Truth about Death Panels," *http://www.clmagazine.org/backissues/2010ND_deathpanels.pdf*, accessed 25 February 2011.

4. T.M. Pope, "Multi-Institutional Healthcare Ethics Committees: The Procedurally Fair Internal Dispute Resolution Mechanism," *Campbell Law Review* 31, no. 2 (2009): 257-332.

5. *In re Quinlan,* 355 A.2d 647, 669 (N.J. 1976).

6. *In re Jobes*, 529 A.2d 434, 447-48 (N.J. 1987); *In re Peter*, 529 A.2d 419, 428 n.12 (N.J. 1987); *In re Conroy*, 486 A.2d 1209 1227-8 (N.J. 1985).

7. *In re Torres*, 357 N.W.2d 332 (Minn. 1984).

8. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Deciding to Forgo Life-Sustaining Treatment: Ethical, Medical, and Legal Issues in Treatment Decisions* (Washington, D.C.: U.S. Government Printing Office, 1983): 169-70; *http://bioethics.georgetown.edu/pcbe/reports/past_ commissions/deciding_to_forego_tx.pdf,* accessed 25 February 2011. Ethics committees were also endorsed by leading professional medical associations. For example, in 2005, UNESCO adopted the Universal Declaration on Bioethics and Human Rights. Article 19 calls for the establishment of "independent, multidisciplinary, and pluralist ethics committees." *http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/*, accessed 25 February 2011.

9. It was not widely accepted elsewhere either. Ethics committees in the United Kingdom, for example, have no statutory basis and little clarity or consistency. C. Coulter, "No Overall Policy on Operation of Ethics Bodies in HSE Hospitals," *Irish Times,* 22 December 2010, 8.

10. 45 *C.F.R.* § 84.55(a).

11. Legislation is hardly a necessary condition. Most hospitals and many long-term care facilities across the United States have ethics committees, even where no regulation requires them.

12. While there are few statutes or regulations requiring ethics committees, the use of ethics committees has been endorsed by the courts in many states. See note 4 above.

13. Many nations employ the term "ethics committee" to describe what would be identified as an "institutional review board" in the United States. Such committees are outside the scope of this article. Still, even with this caveat, my list of countries with clinical ethics committees is not exhaustive.

14. T. Meulenbergs et al., "The Current State of Clinical Ethics and Healthcare Ethics Committees in Belgium," *Journal of Medical Ethics* 31, no. 6 (2005): 318-21.

15. J.F. Peppin and M.J. Cherry ed., *Regional Perspectives in Bioethics* (Lisse, The Netherlands: Swets and Zeitlinger, 2003), 156-8.

16. See Act of May 27, 1986, ch. 749, 1986 Md. Laws 2841 (codified as amended at Md. Code Ann., Health-Gen §§ 19-370 to 374); P.C. Hollinger, "Hospital Ethics Committees and the Law: Introduction," *Maryland Law Review* 50, no. 3 (1991): 742-5. Nursing homes were not included until 1990. See Act of May 29, 1990, ch. 545, 1990 Md. Laws 2376 (codified as amended at Md. Code Ann., Health-Gen § 19-370(e)).

17. Md. Health-Gen. Code § 19-371(a).

18. Md. Health-Gen. Code § 19-371(b).

19. N.J. Admin. Code § 8:43G-5.1(h) (including as hospital licensing standards: "The hospital shall have a multidisciplinary bioethics committee . . . .").

20. See N.J. Stat. Ann. § 26:2H-65(a)(5) (requiring all healthcare facilities to establish an institu-

tional dispute resolution mechanism to deal with issues surrounding advance directives); N.J. Admin. Code § 8:39-9.6(i) & (j) (requiring long-term care facilities, residential care facilities, and home health agencies to maintain a mechanism for dealing with ethical dilemmas).

21. N.J. Admin. Code §§ 5:27A-4.15, 8:39-9.6(i)-(l), 8:43-4.15(a), 8:43H-5.3(a).

22. N.J. Admin. Code § 8:42-6.3(a).

23. N.J. Admin. Code §§ 10:8-2.1(f) & N.J.A.C. 10:32-1.5(a)(9).

24. N.J. Admin. Code §§ 10:45-4.1(b)(3)(vi), 10:45-4.1(b)(5)(xi), 10:45-4.3(b)(3), 10:48B-7.1 to 7.5.

25. N.J. Admin. Code §§ 10:48B-2.1 & 15A:3-2.2.

26. N.J. Admin. Code § 15A:3-2.3(d)(6).

27. I have served on one of the largest regional committees, the Tri-State Regional Ethics Committee (TREC). This committee has the integrity and competence to review decisions regarding life-sustaining medical treatment. *http://www.njtrec.org,* accessed 7 March 2011.

28. Colo. Rev. Stat. § 15-18.5-103(6.5).

29. A.7729-D; S.3164-B (2010), codified at N.Y. Pub. Health Code Article 29-CC.

30. N.Y. Pub. Health Code § 2994-m(1).

31. 25 Tex. Admin. Code §§ 405.60(a), 405.53(4) & (5).

32. Mass. Code Reg. 130.650(E)(2)(u).

33. Symposium, "The 25th Anniversary of the Baby Doe Rules: Perspectives from the Fields of Law, Health Care, Ethics, and Disability Policy," *Georgia State University Law Review* 25, no. 4 (2009): 801-1175.

34. 45 *C.F.R.* § 84.55; 49 Fed. Reg. 1622 (1984).

35. R.I. Field, *Health Care Regulation in America: Complexity, Confrontation and Compromise* (New York: Oxford University Press, 2007).

36. "Facts about the Joint Commission," *http://www.jointcommission.org/assets/1/18/The_Joint_Commission_3_10.pdf,* accessed 7 March 2011.

37. Joint Commission, *2011 Comprehensive Accreditation Manual for Hospitals (CAMH): The Official Handbook* § LD.04.02.03 ("1. The hospital has a process that allows staff, patients and families to address ethical issues or issues prone to conflict. 2. The hospital uses its process to address ethical issues or issues prone to conflict."). This provision was formerly in section RI.1.1.6.1 (in 1992) and in RI.1.10 (in 2007).

38. See E.L. Csikai, "The Status of Hospital Ethics Committees in Pennsylvania," *Cambridge Quarterly of Healthcare Ethics* 7, no. 1 (1998): 104-7. Canadian facilities have similarly responded to accreditation standards by Accreditation Canada, formerly known as Canadian Council on Health Services Accreditation. Similarly, German facilities have responded to the Kooperation für Transparenz und Qualität im Gesundheitswesen. A. Dörries, "Implementing Clinical Ethics in German Hospitals: Content, Didactics and Evaluation of a Nationwide Postgraduate Training Programme," *Journal of Medical Ethics* 36, no. 12 (2010): 721-6. Similarly, the Ethical and Religious Directives for Catholic Health Care Services No. 37 provides: "An ethics committee or some alternate form of ethical consultation should be available to assist by advising on particular ethical situations, by offering educational opportunities, and by reviewing and recommending policies." *www.usccb.org/bishops/directives.shtml*, accessed 25 February 2011.

39. Israel Patient's Rights Act of 1996, sec. 24, *http://waml.haifa.ac.il/index/reference/legislation/israel/israel1.htm*, accessed 25 February 2011.

40. N.S. Wenger et al., "Hospital Ethics Committees in Israel: Structure, Function and Heterogeneity in the Setting of Statutory Ethics Committees," *Journal of Medical Ethics* 28, no. 3 (2002): 177-82.

41. K. Liu, "Bill Promotes Life with Dignity for Taiwan's Terminally Ill," *Taiwan Today,* 11 January 2011.

42. Ley de Derechos y Garantías de la Dignidad de la Persona ante el Proceso de la Muerte, *http://noticias.juridicas.com/base_datos/CCAA/an-l2-2010.html*, accessed 25 February 2011.

43. Ley Article 27 (comité de ética del centro). The statute specifies that the composition, operation, and accreditation procedures of the committees will be established by regulation. Regulations were promulgated in December 2010. Decree 439/2010, "Regulating Bodies and Health Care Ethics of Biomedical Research in Spain," Article 12, 14 December 2010, *http://www.derecho.com/l/boja/decreto-439-2010-14-diciembre-regulan-organos-etica-asistencial-investigacion-biomedica-andalucia/impresion.html*, accessed 25 February 2011. Legislation modeled on Andalucia's is being considered in other provinces and at the federal level.

44. R. Førde and T.W.R. Hansen, "Involving Patients and Relatives in a Norwegian Clinical Ethics Committee: What Have We Learned?" *Clinical Ethics* 4, no. 3 (2009): 125-30.

45. S. Holm, "Clinical Ethics Committee in Norway - Highly Recommended by the Norwegian Parliament," *http://www.ethics-network.org.uk/international/clinical-ethics-committee-in-norway-highly-recommended-by-the-norwegian-parliament*, accessed 25 February 2011.

46. Singapore Human Organ Transplant Act § 15B(1), *http://statutes.agc.gov.sg*, accessed 25 February 2011.

47. Similar to Singapore, under the People's Republic of China Regulation on Human Transplantation Act (April 2007), commercial donation is permitted. Voluntariness is confirmed by the Committee on Clinical Application of Technology and Ethics of Human Transplantation. D.W. Hanto, "Ethics Committee Oversight of Living Related Donor Kidney Transplantation in China," *American Journal of Transplantation* 8, no. 9 (2008): 1765-8.

48. Alberta Human Tissue and Organ Donation Act, S.A. 2006, c.H-14.5.

49. Alberta Human Tissue and Organ Donation Regulation, Alta. Reg. 196/2009(5).

50. Massachusetts requires that a neonatal intensive care unit (NICU) have policies and procedures for committee membership. But it does not dictate the content of those policies and procedures. 105 Code Mass. Regs. 130.650(E)(3).

51. N.Y. Pub. Health Law § 2994-m(3).

52. N.Y. Pub. Health Law § 2994-m(3).

53. 25 Tex. Admin. Code § 405.60(b).

54. N.J. Admin. Code §§ 10:45-4.3(c) & 10:48B-2.1.

55. N.J. Admin. Code § 10:48B-3.1. The committee must have: (1) knowledge, experience, and/or training regarding ethical issues pertaining to end-of-life care decision making; (2) the ability to be available for case consultation in a prompt and expeditious manner proportionate to the urgency of the situation; and (3) knowledge, experience, and/or training regarding the nature and characteristics of individuals with developmental disabilities. An absolute minimum of three members must be involved to provide consultation for any case. While this is a small group, it is a majority of the five-person minimum membership. Unfortunately, most ethics committee regulations are silent on quorum requirements.

56. N.J. Admin. Code § 10:48B-1.1(a)(3).

57. 45 *C.F.R.* § 84.55(f)(2).

58. Israel Patient's Rights Act of 1996, sec. 24A.

59. Decree 439/2010, see note 43 above.

60. The regulations also establish a central "Committee on Bioethics of Andalucia," that will issue advice and provide coordination for both clinical and research ethics committees. Governing Council of Andalucia, "Andalusian Patients Will Have a Line of Direct Consultation with Professionals in Situations of Ethical Conflict," 14 December 2010, *http://www.juntadeandalucia.es/servicios/noticias/detalle/31419.html*, accessed 25 February 2011.

61. "Presidential Decree Updating, Deleting, and Amending Provisions of the Hospice Palliative Care Act," 26 January 2011, *http://www.lawtw.com*, accessed 25 February 2011.

62. Singapore Human Organ Transplant Act, sec. 15B(2), *http://www.moh.gov.sg/mohcorp/legislations.aspx?id=1672*, accessed 25 February 2011.

63. *http://www.moh.gov.sg/mohcorp/parliamentaryqa.aspx?id=23060*, accessed 25 February 2011.

64. Mass. CMR 130.650(E)(3)(e). The regulations also require that the newborn's record include documentation of "the process used to make decisions where ethical questions are raised, including parental involvement in the process." Mass. CMR 130.650(E)(4)(f).

65. Md. Health-Gen. Code § 19-373.

66. Md. Health-Gen. Code §19-372(a).

67. Md. Health-Gen. Code § 19-372(b).

68. Md. Health-Gen. Code § 19-374(b). Any information or document that indicates the wishes of the patient shall take precedence in the deliberations of the advisory committee.

69. N.Y. Pub. Health Law § 2994-m(1).

70. These situations include: (1) a surrogate decision to withdraw life-sustaining treatment from a patient in a residential healthcare facility, (2) a surrogate decision to withdraw life-sustaining treatment from a patient in a hospital if the physician objects, and (3) a decision of an emancipated minor patient to withdraw life-sustaining treatment, and (4) a request by a person conneced with the case to help resolve a treatment dispute. N.Y. Pub. Health Law § 2994(m)(4).

71. N.Y. Pub. Health Law § 2994-m(4)(6).

72. 25 Tex. Admin. Code § 405.60(d).

73. 45 *C.F.R.* § 84.55j(3).

74. The ICRC may provide for telephone and other forms of review when the timing and nature of the case, as identified in policies developed by the ICRC, make the convening of an interim meeting impracticable.

75. The ICRC must have procedures to preserve the confidentiality of the identity of persons making such requests, and such persons must be protected from reprisal. When appropriate, the ICRC or a designated member will inform the requesting individual of the ICRC's recommendation.

76. Decree 429/2010, Article 13, see note 43 above.

77. Singapore HOTA, see notes 62 and 63 above.

78. J.A. Robertson, "Ethics Committees in Hospitals: Alternative Structures and Responsibilities," *Quality Review Bulletin* 10 (1984): 6-10; J.A.

Robertson, "Ethics Committees in Hospitals: Alternative Structures and Responsibilities," *Issues in Law and Medicine* 7, no. 1 (1991): 83-91.

79. While the advice of an ethics committee might officially be only advisory, the advice may have the *de facto* effect of being mandatory. S.M. Wolf, "Ethics Committees and Due Process: Nesting Rights in a Community of Caring," *Maryland Law Review* 50, no. 3 (1991): 798-858.

80. Md. Health-Gen. Code § 19-374(a)

81. Md. Health-Gen. Code § 5-612(a).

82. The committee may partially delegate responsibility for this function to any individual or individuals who are qualified by their backgrounds and/or experience to make clinical and ethical judgments.

83. N.J. Stat. Ann. § 26:2H-66.

84. W.V. Code § 16-30-5(d).

85. N.Y. Pub. Health Law § 2994-m(2)(a).

86. N.Y. Pub. Health Law § 2994-f(1).

87. N.Y. Pub. Health Law § 2994-f(2). If an attending physician has determined that a patient lacks decision-making capacity and the practitioner consulted for a concurring determination disagrees, then the matter must be referred to an ethics committee if it cannot otherwise be resolved. N.Y. Pub. Health Code § 2994-c(3)(d).

88. N.Y. Pub. Health Law § 2994-m(2)(b).

89. N.Y. Pub. Health Law § 2994-m(2)(c).

90. 25 Tex. Admin. Code §§ 405.55(a)(3) & 405.60(c).

91. 25 Tex. Admin. Code § 405.54(b)(6).

92. Department of Public Welfare, "Procedures for Surrogate Health Care Decision Making," 41 *Pennsylvania Bulletin* 352 (15 January 2011), codified at 55 Pa. Code § 6000.1014(e)(3).

93. See note 4 above.

94. N. Karp and E. Wood, *Incapacitated and Alone: Healthcare Decision-Making for the Unbefriended Elderly* (Washington, D.C.: American Bar Association Commission on Law and the Elderly, 2002); "Medical Decision Making for Incapacitated Patients without Surrogates," presentation at the ASBH Annual Meeting, Panel Session 411, 24 October 2010.

95. E.D. Isaacs and R.V. Brody, "The Unbefriended Adult Patient: The San Francisco General Hospital Approach to Ethical Dilemmas," *San Francisco Medicine* 83, no. 6 (2010): 25-6.

96. Tex. Health & Safety Code §166.039(e).

97. Ariz. Rev. Stat. § 36-3231(B).

98. Ala. Code § 22-8A-11(d)(7).

99. Ark. Rev. Stat. § 36-3231(B).

100. Ga. Code Ann. § 31-39-4(e)(2).

101. Tenn. Comp. R. & Regs. 1200-8-11-.12(16)(h)(1).

102. This IDT must oversee the care of the resident, utilizing a team approach to assessment and care planning. The IDT's membership must include: (1) the resident's attending physician, (2) a registered professional nurse with responsibility for the resident, (3) other appropriate staff in disciplines as determined by the resident's needs, and, (4) when practicable, a patient representative, in accordance with applicable federal and state requirements. Cal. Health & Safety Code § 1418.8(e). The constitutionality of this provision was upheld in *Rains v. Belshe*, 32 Cal. App. 4th 157 (1995).

103. Iowa Code § 135.29 ("[T]he local substitute medical decision-making board may act as a substitute decision maker for patients incapable of making their own medical care decisions if no other substitute decision maker is available to act."); Iowa Admin. Code § 641-85.3.

104. Fla. Stat. Ann. § 765.404(2). "If there is no medical ethics committee at the facility, the facility must have an arrangement with the medical ethics committee of another facility or with a community-based ethics committee approved by the Florida Bioethics Network."

105. T.P. Gonsoulin, "A Survey of Louisiana Hospital Ethics Committees," *Laryngoscope* 119 (2009): 330-40.

106. Tex. Health & Safety Code Ann. § 166.046.

107. Tex. Health & Safety Code Ann. § 166.045.

108. Idaho S.B. 1114 (60th Legisl.) (passed Senate 3 March 2009).

109. Brief of Amici Curiae New Jersey Hospital Association, Catholic Healthcare Partnership of New Jersey, and Medical Society of New Jersey, *Betancourt v. Trinitas Hospital,* No. A-003-849-08T2 (N.J. Super. A.D. 2009).

110. *Betancourt v. Trinitas Hospital*, 1 A.3d 823 (N.J. Super. A.D. 2010).

111. For example, the antecedents to today's ethics committees served as gate keepers that would grant or deny permission to perform an abortion, or to conduct research with human subjects.

112. Tex. Admin. Code § 404.166(f).

113. This department is now called the Department of Children and Families.

114. *In re Care and Protection of Sharlene*, 445 Mass. 756, 840 N.E. 2d 918 (17 January 2006).

115. M. Underwood, "Chance of Recovery Rare, but Possible, Says Brain Doc," *Boston Herald*, 28 February 2008.

116. Massachusetts Executive Order No. 471, "Establishing the Governor's Special Panel for the

Review of the Haleigh Poutre Case," 3 February 2006.

117. Mass. Stat. ch.119 § 38A.

118. N.Y. Pub. Health Law § 2994-d(5)(B).

119. N.Y. Pub. Health Law § 2994-e(3).

120. N.Y. Pub. Health Law § 2994-d(5)(c)

121. Israel Patient's Rights Act of 1996, § 18(C)-(D).

122. Israel Patient's Rights Act of 1996 §§ 13(D) & 20(A)(4)-(5); see note 40 above; S. Glick, "Unlimited Human Autonomy: A Cultural Bias," *New England Journal of Medicine* 336, no. 13 (1997): 954-6.

123. Md. Health-Gen. Code § 5-605(b)(1)

124. An ethics committee can adjudicate in the event "an individual specified . . . claims that the individual has not been recognized or consulted as a surrogate or if persons with equal decision making priority . . . cannot agree who shall be a surrogate or disagree about a health-care decision."

125. Del. Code, tit. 16 § 2507(b)(8).

126. Israel Patient's Rights Act of 1996 § 15(2).

127. Md. Health-Gen. Code § 19-374(e).

128. Md. Health Occupations Code § 1-401(d).

129. Ohio Rev. Code § 2305.24.

130. Tex. Health & Safety Code §§161.031-.032.

131. N.Y. Pub. Health Law § 2994-m(6).

132. These exceptions include cases in which: a committee approves or disapproves of the withholding or withdrawal of life-sustaining treatment pursuant to 2994-d(5) or 2994-e(3). In such cases, ethics committee proceedings and records may be obtained by, or released to, the department. Also, nothing prohibits the state commission on quality of care and advocacy for persons with disabilities or any agency or person within or under contract with the commission that provides protection and advocacy services from requiring any information, report, or record from a hospital in accordance with the Mental Hygiene Law.

133. Fla. Stat. Ann. § 765.404(2).

134. Md. Health-Gen. Code § 19-374(c).

135. Md. Health-Gen. Code § 19-374(d).

136. N.Y. Pub. Health Law § 2994-o.

137. Ala. Code § 22-8A-4.

138. Ga. Code Ann. § 31-39-4 & -7.

139. Haw. Rev. Stat. § 663-1.7(b) ("There shall be no civil liability for any member of . . . ethics committee, . . . or for any person who files a complaint with or appears as a witness before those committees . . . .").

140. Mass. Stat. ch.112 § 56(a).

141. Mont. Code § 37-2-201.

142. Tenn. Code Ann. § 63-6-219; Del. Code, tit. 24 § 1768(a) ("[M]embers of other peer review committees . . . whose function is the review of . . . medical care, and physicians' work, with a view to the quality of care and utilization of hospital or nursing home facilities . . . are immune from claim, suit, liability, damages, or any other recourse, civil or criminal, arising from any act, omission, proceeding, decision, or determination undertaken or performed, or from any recommendation made. . . .").

143. Haw. Rev. Stat. § 663-1.7(b). Interestingly, Maryland affords immunity for "failing to carry out the advice of an advisory committee" if "the advice given is inconsistent with the written policies of the hospital or related institution." Md. Health-Gen. Code § 19-374(f).

144. See note 4 above.

145. Singapore Human Organ Transplant Act § 15A(4).

146. See note 4 above.

147. G. Magill et al., "ASBH Task Force Report On Ethics Consultation Liability," 24 October 2004, a report available online to members of ASBH, *www.asbh.org,* "Membership," "ASBH Members Only," "Committee and Task Force Reports and Links," "Ethics Consultation Liability Task Force"; D. Hoffman and A. Tarzian, "U.S. Health Care Ethics Committees," in *Legal Perspectives in Bioethics,* ed. A.S. Iltis et al. (New York: Routledge, 2008), 46-67; M.P. Aulisio et al., *Ethics Consultants: From Theory to Practice* (Baltimore: Johns Hopkins, 2003), 120; S.B. Rubin and L. Zoloth, *Margin of Error: The Ethics of Mistakes in the Practice of Medicine* (Hagerstown, Md.: University Publishing Group, 2000), 355-60; S.M. Staubach, "What Legal Protection Should a Hospital Provide, If Any, to Its Ethics Committee," *HEC Forum* 1, no. 4 (1989): 209-20; J.C. Fletcher and E.M. Spencer, "Ethics Services in Healthcare Organizations," in *Introduction to Clinical Ethics, 2nd ed.,* ed. J.C. Fletcher et al. (Hagerstown, Md.: University Publishing Group, 1997), 257-75; J.L. Bernat, *Ethics Issues in Neurology* (Philadelphia: Lippincott Williams & Wilkins, 2008), 116-7.

148. K. Murphy, "$10 Million in Damages Sought: Malpractice Allegation Is Added to Bouvia's Lawsuit," *Los Angeles Times,* 8 October 1986; J.C. Fletcher and K.L. Moseley, "The Structure and Process of Ethics Consultation Services," in *Ethics Consultation: From Theory to Practice,* ed. M. Aulisio et al., (Baltimore: Johns Hopkins University Press, 2003), 109-10.

149. Hoffman and Tarzian, see note 147 above, 61-2.

150. J.J. Paris et al., "Use of a DNR Order over Family Objections: The Case of Gilgunnn v. MGH," *Journal of Intensive Medicine* 14 (1999): 41.

151. *Bryan v. Rectors & Visitors of University of Virginia*, 95 F.3d 349, 352-3 (4th Cir. 1996). The plaintiff refilled in Virginia state court but voluntarily dismissed that action. *Bryan v. Rectors & Visitors of the University of Virginia,* No. CL-95-060 (Fauquier County, Va. Cir. Ct. Nov. 27, 1995) (Order of Nonsuit).

152. *Rideout v. Hershey Medical Center*, 30 Pa. D. & C. 57 (1995); *Bland v. Cigna Healthplan of Texas*, Inc., No. 93-52630-A (Harris County Tex. Dist. Ct., Apr. 25, 1995).

153. *Palmer v. East Tennessee Children's Hospital Association*, No. 176535-2 (Knox County Chancery Ct., Tenn. Nov. 23, 2009).

154. M. Edwards, "Treatment to Continue for Baby with Rare Syndrome," 23 November 2009, *http://www.volunteertv.com/home/headlines/71924162.html*, accessed 25 February 2011.

155. *Neustadter v. Holy Cross Hospital of Silver Spring*, 28 No. 10 Verdicts, Settlements & Tactics art. 19 (Oct. 2008). In September 2010, the Maryland Court of Appeals heard arguments on an unrelated issue: the malpractice trial was held without the plaintiff who could not attend for religious reasons.

156. *Giron v. Baylor University Medical Center*, No. 06-02257-M (298th Judicial District, Dallas, Tex.), on appeal, No. 05-09-00825-CV (5th Ct. App.).

157. WPAC is now called Disability Rights Washington.

158. Washington Protection and Advocacy System, "Investigative Report Regarding the 'Ashley Treatment,' " 8 May 2007, *http://www.disabilityrightswa.org/home/Full_Report_InvestigativeReportRegardingtheAshleyTreatment.pdf*, accessed 25 February 2011.

159. D.S. Diekema and N. Fost, "Ashley Revisited: A Response to the Critics," *American Journal of Bioethics* 10, no. 1 (2010): 30.

160. WPAS Report, Exhibit T, para. 5.

161. See C. Lewis, "Hospital Sued for Keeping Infant Alive," *National Post,* 14 March 2009. A similar case recently arose in Ireland. Terminally ill cancer patient Michele Harte claims that the ethics committee at Cork University Hospital denied her right to have an abortion. The hospital claims that its ethics committee "guided" but did not "instruct" medical staff. C. O'Brien, "Hospital Says Ethics Body Did Not Instruct Staff," *Irish Times,* 22 December 2010. Interestingly, this sort of disclosure is specifically mandated in New York. N.Y. Pub. Health Law § 2994a-m(4)(b)(III))A).

162. *Datto v. Harrison*, Nos. 09-2064 and 09-2549 (E.D. Pa. 9 September 2009) (order on motion to dismiss). Two state court actions were settled in summer 2010. But the federal case is still proceeding. *Datto v. Harrison,* Nos. 081001063 and 071205181 (Philadelphia County Court of Common Pleas) (filled 2008).

163. R. Stein, "Religious Hospitals Spark Controversy with Limits on Care," *Boston Globe,* 30 January 2011.

164. K.K. Kovach, "The Evolution of Mediation in the US: Issues Ripe for Regulation May Shape the Future of Practice," in *Global Trends in Mediation,* ed. N. Alexander (Dordrecht, The Netherlands: Kluwer, 2006).