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George P. Smith, II, Restructuring the Principle of Medical Futility, 11 J. PALLIATIVE CARE 9 (1995).

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Restructuring the Principle of Medical Futility

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Abstract / This essay surveys the need for a clear and objective definition of medical futility. It is urged that once agreement is obtained for structuring operational guidelines for determining futility, a three-tier decisional structure can be developed for testing whether a given treatment falls within the scope of these guidelines. Under the first tier, the treating physician would be given the primary responsibility for making the determination to withhold treatment on the grounds of futility. While the physician would be under a duty not to prescribe treatment deemed futile, he would be obliged to inform the patient and his family of this decision, including the reasons for it, in order to allow, under the second tier, for an appeal to be taken by the patient or family to the hospital ethics committee. The third tier recognizes a right of limited appeal to the courts.

Résumé / Cet essai porte sur le besoin de définir clairement et objectivement ce qu'est la futilité médicale. En vue de cerner ce qu'est la futilité, il est vivement conseillé, une fois parvenu à établir des lignes directrices qui soient opérationnelles, de créer une structure décisionnelle à trois niveaux afin de vérifier si un traitement donné se situe dans les limites de ces lignes directrices. Au premier niveau, le médecin traitant aurait la responsabilité initiale de refuser un traitement sur la base de sa futilité. Alors que le devoir du médecin consisterait à refuser un traitement jugé futile, il aurait, en retour, l'obligation de faire part de sa décision au patient et à sa famille. Au deuxième niveau, le patient ou sa famille, s'appuyant sur les raisons évoquées, pourrait aller en appel de cette décision devant le comité d'éthique de l'hôpital. Le troisième niveau consacre le droit à un recours limité devant les tribunaux.

INTRODUCTION

Before exploring the etiological structure of the term "medical futility", it is relevant to place the need for this analysis within the recent historical context. Any discussion of the principle of futility presents complex issues and requires an acknowledgement to be made of the limits of health care and of the inevitability of death (1).

THE CONTEMPORARY CONTEXT AND MODERN DILEMMA

In the United States, approximately 1.6 million persons die in hospitals or long-term care facilities each year; approximately 70% of those die as

a result of someone's decision to withdraw or withhold life-sustaining treatment (2). Physicians often make these decisions without clear guidelines and without informing the patient or family (2). Consequently, extraneous factors such as race, wealth, gender, and age of the patient, as well as judgments on the quality of the patient's life and concerns about cost containment, may cloud the physician's decision to withhold or withdraw treatment (3). A clear working definition of futility is needed so that (a) patients and families can be informed that the physician is withdrawing treatment, (b) patients and families have objective criteria against which they may judge the physician's decision to withhold or withdraw life-sustaining treatment, and (c) courts have a standard by which they may judge the physician's action in the context of civil, or even criminal, actions (4).¹

The issue of futility sparks the most discussion when a patient is in a persistent vegetative state (PVS) and/or when a physician writes a "Do Not Resuscitate" order (DNR) (5). When a patient is diagnosed as being in a persistent vegetative state, there is no chance that he/she will regain consciousness or return to a sapient existence (6).

A DNR is ordered when the physician concludes that it is not worth the effort to effect cardiopulmonary resuscitation in the event of cardiac or respiratory arrest (7). The law does not prevent the physician from ordering a DNR (7,8). The problem lies not in the fact that physicians write DNRs, but rather that there are no clear guidelines for making the DNR decision and that patients and families are often unaware whether and why such a decision has been made (9).² The definition of futility proposed in this essay seeks to deal with both the DNR order and the patient in the persistent vegetative state.

DEFINING FUTILITY

While the word "futility" may be understood generally as denoting useless, ineffectual actions lacking in purpose (10), in the profession of

medicine these common understandings of the word are missing. Indeed, more often than not, four *uses* of futility are posited by way of explaining the term and thereby crafting working definitions (11). Even though definitional problems exist, it is recognized that when a medical treatment or intervention is deemed futile, the physician is freed from the moral and the legal duty to provide it (3).

The four recognized clinical uses of futility are as follows (11):

- when a cure is physiologically impossible;
- when the treatment is non-beneficial;
- when the treatment is unlikely to produce a desired benefit;
- when the treatment is plausible but not yet validated.

Physiologically Impossible

One definition of futility adopts the "physiologically impossible" use of the term. A treatment is futile only "when the patient is moribund and will die within hours or days regardless of treatment given" (1). This definition is clearly inadequate. While it is not difficult to justify a decision to withhold or withdraw treatment on such grounds, it is far too narrow and does not cover many situations where the withholding or withdrawing care on the ground of futility would be justifiable. It only bars treatment when all treatment will undoubtedly fail; it is too narrow to permit withholding or withdrawing treatment from a body doomed to existence in a persistent vegetative state. For these reasons the "physiologically impossible" meaning of futility is inadequate.

Non-Beneficial or Unlikely to Produce a Benefit

The second and third uses of futility in the medical profession — that the treatment is futile if it is non-beneficial or that it is unlikely to produce a desired benefit — acknowledge the differences between *effect* and *benefit*. The goal of medicine is to benefit the patient, not merely to physiologically affect the patient (12). "Physicians should distinguish between an effect, which is limited to some part of the patient's body, and a benefit, which the patient has the capacity to appreciate and which improves the patient as a whole" (3,13). For example, nutritional support could have the *effect* of preserving organ systems in a patient in a persistent vegetative state, but fail to *benefit* the patient because this treatment does not restore the patient to a conscious and sapient state (12). Another example that demonstrates the point more explicitly is when a doctor refuses to honor a patient's demand that he be

given a blood transfusion for a simple cold. While the transfusion would certainly have a physiological effect on the patient's body, it would not cure his cold and, therefore, the blood transfusion would not offer him any benefit. Within this framework, then, a treatment that does not offer the patient a benefit, regardless of whether or not it affects the body, should be withheld on the grounds of futility.³

When using this distinction between effect and benefit, it is important to note that giving comfort and palliative care to patients for whom there is no possibility of recovery is a benefit and should not be withheld as futile unless such treatment in fact does not comfort or alleviate pain (12,14). Palliative care does not seek to cure a person's ailment or reverse a terminal prognosis. However, palliative care offers the benefit of alleviating or moderating the patient's pain or discomfort and allows the patient to live out his remaining time in dignity.

The two uses for futility just cited share the same goal of withholding treatment when there is no benefit. Nonetheless, there are differences worth noting. Withholding treatment on the grounds of futility when the treatment is non-beneficial is another way of phrasing the physician's duty not to prescribe treatment that would harm the patient. No balancing is involved — there is merely a prohibition against prescribing harmful treatment.

However, when the physician wishes to withhold treatment on the ground of futility because the treatment is very unlikely to produce a desired benefit, the physician must balance the possible harm against the possible good (3). The factors in the balance are not logical absolutes but rather statistical probabilities of success or harm derived from trials and analysis of hospital data (11). "Futility refers to an expression of success that is either predictably or empirically so unlikely that its exact probability is often incalculable" (12). Medicine is a science but not an exact science. Thus, limiting futility to instances when it can be stated with logical certainty that the treatment would be more harmful than beneficial would unduly restrict its usefulness.

Plausible But Not Validated Treatment

The last use of futility describes the situation when the treatment has not been validated as an appropriate treatment for a given diagnosis. This, however, is not an appropriate ground for withholding treatment. In fact, such experimentation where there is a reasonable likelihood of success should be encouraged. If a physician prescribes a treatment that is not yet validated,

he or she should inform the patient that this is the case. The patient is, in essence, the subject of an experiment, and the physician and hospital must follow the appropriate procedures of medical experimentation (15). Where there is a plausible likelihood that the treatment may benefit the patient, experimentation and documentation should be encouraged so that physicians may assess whether the treatment was effective or futile.

The Schneiderman and Jecker Proposal

Schneiderman and Jecker have proposed the most practical working definition of futility. According to these authors, futility may be defined both quantitatively and qualitatively. Under their definition, if the treatment is either quantitatively or qualitatively futile, no duty exists for the physician to administer it (12,16). They offer criteria for determining both quantitative and qualitative futility, and these criteria are examined below.

The quantitative definition focuses on the probability that an intervention will effectuate a particular outcome and assesses whether that probability falls below a minimum threshold (17). For example, a recent study in *The New England Journal of Medicine* calls for withholding aggressive resuscitation of infants born at 22 weeks gestation (18). By studying the mortality and morbidity of their preterm infants, the authors found that not one of the 20 infants in their study born at 22 weeks gestation survived to hospital discharge, whereas 31 out of 35 of those born at 25 weeks did survive to hospital discharge (18). While aggressive interventions kept the infants born at 22 weeks alive for up to four months, the results show that the doctors were only prolonging imminent death. The only justification for prolonging the death of these infants beyond a few hours was to permit the parents to say goodbye.⁴ In essence, the study concluded that treating preterm infants born at 22 weeks is futile because there is no chance that they will ever be viable. This, then, is a quantitative use of futility.

Schneiderman and Jecker have also sought to give a quantitative definition to futility. They concluded that if in the last 100 cases a given treatment for a given condition has proved to be useless, it is futile and therefore need not be administered (12). While little support for deciding on the number 100 is offered, any number would inevitably be arbitrary; 100 seems reasonable because it is of sufficient size to rule out unknown variables and to minimize the margin of error. Record keeping is encouraged in all

instances, so that treatments that offer no relief in over 100 cases may be deemed futile and need no longer be prescribed. Such a quantitative view may also be seen as making an implicit *rejection* of the use of futility for withholding treatment that is plausible but not yet validated, because a treatment is not deemed quantitatively futile until it has been tried at least 100 times and has failed every time.

Qualitative futility is defined as "any treatment that merely preserves permanent unconsciousness or that fails to end total dependence on intensive medical care". Such a treatment should be withheld (12). The scope of this definition is narrow and appropriately so, because its primary focus is the person in a persistent vegetative state. Since such a person has no chance of regaining consciousness, any treatment that merely sustains him would be qualitatively futile and could thus be withheld. The quality of life of a person in a persistent vegetative state is minimal if there is one at all. By virtue of the diagnosis, there is no chance of recovery. Keeping that person from his destiny and depriving him of a right to die with dignity does not further the goals of medicine.

It is impossible to discuss qualitative futility without discussing quality of life (17,19). However, particular care should be given to ensure that decisions of qualitative futility do not extend beyond the limited definition suggested here. For example, qualitative futility should not be invoked to justify not performing curative eye surgery because the patient has Down syndrome. Such a quality of life decision is inappropriate for the medical profession to make. If it is possible to restore the patient to a sapient state or to free the patient from total dependence on intensive medical care, the physician has a duty to offer the treatment because that treatment benefits the person regardless of the existence of a handicap or disability.

What Futility is Not

When discussing medical futility, it is necessary to discuss what medical futility is *not*. Medical futility is not an act that is impossible to perform (12); it is entirely possible that the physician has both the technology and skill to perform CPR yet rightly refuses to do so on the ground that such treatment is futile (12). A given treatment is also not futile merely because it would subject the patient to extreme pain and a lengthy recovery (20). Nor is a treatment futile if it leaves the patient with a severe mental or physical handicap (20), because the patient or family, rather than the physician, should have the right to bal-

ance the possible harm and good. Allowing a physician to withhold treatment if it is possible or even probable that the patient will be mentally or physically handicapped as a result of such treatment empowers the physician to make quality of life determinations that too greatly infringe on the patient's autonomy. Quality of life decisions made by the physician should be limited to those when there is no chance that the patient can regain consciousness or when there is no chance that the treatment can free the patient from total dependence on intensive medical care.

Futility is Not Hopelessness

Futility must not be used to mask prejudice, such as a refusal to treat an HIV-positive patient for fear of contracting AIDS (3,30). Similarly, futility is not hopelessness. Hopelessness is a subjective determination that the patient will not recover, while futility is an objective determination that there is a low probability of recovery (12,21). It is logically consistent for a patient to have given up hope that a given treatment will be effective when medical data indicate the opposite. It is also logical that a patient will still have hope that a given treatment will work despite all medical data indicating otherwise. However, futility should not be rejected in hopes of a miracle (3), for to do so would carve out an exception to the futility doctrine capable of engulfing the entire theory.

Futility Is Not Medical Experimentation

Futility must also be distinguished from medical experimentation. Under normal circumstances, if a treatment is deemed futile, a physician is under a duty not to administer it (22). If the physician nonetheless wants to administer the treatment for experimental reasons, he/she must obtain informed consent from the patient "to [administer] therapy of no proven benefit [to the patient] with the hope of possibly benefiting [the patient], while serving to advance knowledge in a systematic way" (3). While experimentation should be encouraged to determine which treatments actually benefit patients, a physician must exercise extreme caution when choosing this path and when informing the patient should place particular emphasis on the minimal likelihood that such treatment will be of direct benefit (15). To do otherwise would jeopardize the patient's autonomy.

Futility vs Rationing and Resource Allocations

Medical futility is often confused with resource allocation or rationing. In fact the two differ greatly. When a given treatment is deemed to be futile, it implies that such treatment has no thera-

peutic benefit (12). Futility decisions do not rest on the fact that certain resources may be scarce (17). Rationing, however, implies that although the treatment may provide a therapeutic benefit, concerns of cost and allocation of limited resources dictate that the treatment not be given (3).

It is clear that physicians should not make bedside decisions to withhold or withdraw treatment based on the allocation of scarce resources. Because the US has no universally accepted system for resource allocation (12), there is "no guarantee that any limits a[n] [individual] physician imposes on his or her patients will be equally shared by other physicians and patients in the same circumstances" (12). There are no guarantees that withholding treatment from one patient will result in another patient's receiving medical services (12). Thus, physicians should not make bedside allocation decisions by cloaking them in the veil of futility.

The impropriety of making *bedside* allocation decisions when determining whether or not to withhold treatment does not mean that the futility of a given treatment should not be considered when resource allocation is determined at the macro level, away from the bedside (23,24). In the US today there are at least 10,000 people in a persistent vegetative state, each of whom costs from \$80,000 to \$150,000 a year to maintain (16). According to these figures, over a billion dollars a year is being spent to preserve human beings for whom there is *no* chance of recovery (25). If the US were eventually to turn to explicit resource allocation, undoubtedly this expense would be questioned. It would not be unjustifiable to base resource allocation decisions on the potential success of treatments (26) rather than on social status, gender, race, or ability to pay. The fears of the "slippery slope" (6) associated with bedside resource allocation decisions are greatly mitigated when such determinations are made by society on a macro economic level. Thus, while great care should be taken not to confuse futility with bedside rationing, the futility of a treatment should be considered when and if society turns to explicit health care rationing.

In brief, our society needs a clear working definition of futility that does not confuse futility with impossibility, hopelessness, experimentation, prejudice, or bedside resource allocation. Until the medical profession has such a working definition, the important uses of futility in medical decision making cannot be fully realized.

WHO DECIDES?

There are two questions in the debate over "who decides". The first is: Who decides the objective

standard of futility? Once the standard is established, the question becomes: Who makes the actual bedside decision to withhold treatment based on the objective criteria?

The Objective Standards

Objective standards of futility should be decided in a public forum (17). The medical profession in the US, perhaps through the American Medical Association, should initiate the process by proposing guidelines. Once the medical profession presents a proposal, society would have a chance to respond and express its opinions through the electoral process (3). State legislatures and Congress would either accept the guidelines as proposed by the medical profession or with modifications expressed by their constituencies. Either way, the US would have standards of futility arrived at through a democratic process that, at least in accepted theory, would express the ethical and social values of the nation. The difficult and elusive nature of futility would of necessity mandate that these standards be both reasonable and flexible.

Who Makes the Bedside Decision: A Construct for Decision Making

Once objective criteria for futile treatment have been agreed upon, a three-tiered decision and appeal structure would be established. The treating physician would have the primary responsibility for determining when to withhold treatment on the grounds of medical futility. Once such a decision was made, the patient and/or family would have the right to take a *de novo* appeal to the hospital ethics committee. If the patient and family were not satisfied with the decision of the ethics committee, a limited appeal could be taken to the courts.

Physicians would have the primary responsibility for determining whether a given situation calls for withholding or withdrawing care on the grounds that it falls within the established guidelines (17). The physician's expertise in the field of medicine and his/her detailed knowledge of the facts as the patient's treating physician favor the physician as the appropriate primary decision maker.

Some argue that the patient or family should be able to decide when treatment is futile (27). However, assigning the decision to the physician avoids unnecessary suffering for the patient and family (9,26). The physician is trained to make such decisions and, further, is insulated from the emotional burdens of the patient or family which may make such a determination more difficult or even impossible for them (4).

The fact that the physician is responsible for making the primary futility decision does not free him from his duty to inform the patient. While some authors argue that futility removes both the duty to treat *and* the duty to inform (28), preclusion of a duty to inform infringes too greatly on patient autonomy (29,30). Informing the patient and family of the decision not to administer treatment on the grounds of futility helps patients and families cope with the inevitability of death (28). Furthermore, informing the patient that the physician has made a decision that a treatment is futile permits the patient and family to seek a second opinion or switch to alternative medical care (2). Moreover, informing the patient and documenting the decision ensures that the physician is accountable (28) for futility decisions. Should such decisions be negligently made or should they not be carefully documented, then the physician could be exposed to liability (2). In short, to adequately protect patient rights, the physician must be under a duty to inform the patient of the decision to withhold or withdraw treatment on the grounds of medical futility.

The Basis of Appeal

When a physician charged with the duty of making the primary futility decision informs a patient and family that such treatment will be withheld or withdrawn, the physician must also inform the patient and family of their right to "appeal" such a decision. In the construct proposed, the physician must inform the patient and family that they have a right to a *de novo* review of the physician's primary decision with the hospital ethics committee. In this proceeding the physician would make his case and the patient and family theirs. The ethics committee would then discuss the issues and issue a written decision stating the grounds for its decision. If the ethics committee held for the primary physician, the patient and family would have to seek judicial redress. The basis of appeal would be limited to seeking judicial review of the reasonableness of the decision to withdraw or withhold treatment (12). Ideally, the standard of reasonableness would in turn be shaped and tested by the particular state legislatures and administrative agencies in question, following guidelines of the type offered by Schneiderman and Jecker (12).

Subjective Variability: A Caveat

Although the consultations or evaluations of ethics committees are an important factor in the implementation of this proposed construct (15),

it is well to remember that there is a considerable degree of variability to be found among ethics consultants in dealing with, for example, patients in a persistent vegetative state (31). Indeed, one recent study concluded that consensus among such consultants was not a realistic goal (31). All too often it was found that that standards of evaluation were based on subjective processes that relied on a body of formalized opinion that in turn derived from bodies of knowledge developed from overlapping and potentially contradictory sources, e.g. peer-reviewed literature, recognized experts, professional organizations, and textbooks (31).

Since the strategies of ethics consultants derived from "discussion, negotiation, persuasion, compromise, and delay to resolve conflicts," it was concluded that the real value of ethics consultations was to be found more in their "reconciliatory function" than in their "prescriptive content" (31). This understood, the work and value of ethics committees are not diminished sufficiently to exclude them as a step or insulated level of decision making before appeal to the judicial system.

THE DUTY NOT TO ADMINISTER FUTILE TREATMENT

Jecker and Schneiderman offer three compelling reasons why physicians should have a duty *not* to provide futile treatment. The authors first argue that physicians will use the term as a "subterfuge for rationing, cost containment, or refusals to treat vulnerable patients" (20). If physicians were given the discretion to provide treatment deemed to be futile, patients with the means — either independent wealth or superior insurance — could bypass the doctrine altogether by simply changing physicians. This would drastically limit the usefulness of the futility paradigm, as it would become merely a device for denying treatment to those who could not afford it.

The second argument advances the proposition that since the public looks to the medical community to set medical standards, the making of *ad hoc* assessments of futility by individual physicians rather than the enforcement of objective criteria developed by the medical profession as a whole would be an abdication of professional responsibility (20). Here, both the burden and the responsibility to take action, to mandate uniform treatment for all patients in a given condition, are imposed directly upon the medical profession in order for it to preserve its stature and credibility.

Lastly, it is maintained that offering futile treatments exploits the public's fear of death and exaggerates what medicine and science can achieve (20). This leads to false expectations and inevitable disappointments, which in turn undermine the confidence of the public at large. These arguments support clearly the proposition that physicians should have an affirmative duty *not* to administer futile treatment.

CONCLUSION

There is a need for a clear, objective, working definition of futility. Whatever definition is settled upon, it should not arise arbitrarily but be shaped by free and open discourse between and among the medical profession and socio-legal policy makers. Once guidelines for determining futility have been accepted, ideally utilizing the Schneiderman-Jecker standards, a three-tiered decisional construct for determining whether a given treatment for a given patient falls within the scope of these guidelines may be developed.

Consistent with the construct proposed herein, the treating physician would be given the primary responsibility for the decision to withhold treatment on the grounds of futility. While under a duty not to prescribe treatment he deems futile, the physician would be obligated to inform the patient and the immediate family of this decision. The grounds for the decision would also necessarily be disclosed, allowing the patient or family to take an appeal to a hospital ethics committee. The courts would provide the third and final tier of review and thus be the ultimate decision maker, although this judicial review would be limited to considering the reasonableness of the decision to withdraw or withhold treatment.

In the final analysis, whatever construct for decision making is employed to give firm contours to a contemporary and functional definition of medical futility, it must be recognized that exceedingly complex value judgments underlie any contention that a given life-extending intervention is futile. Thus, the central issue to be raised is "the dispensability of a human life and the relevant standard for that judgment" (32). Ultimately, this complex medico-socio-legal-philosophical-ethical issue can only be resolved by the courts and legislatures. The universal motivating force, however, in all deliberations of this nature should be human compassion and the imperative to bring it to bear upon all levels of discussion of medical futility (33).

Date received, October 26, 1994; date accepted December 19, 1994.

ACKNOWLEDGEMENTS

This essay was researched and first written during 1993, when I was a Visiting Scholar at the Center for the Study of Society and Medicine of the College of Physicians and Surgeons of Columbia University in New York City. I acknowledge the kindness and generous support provided to me by Dr. David J. Rothman, Director of the Center, during my visit. I also acknowledge with pleasure the assistance which I received from my student assistant, John E. Durkin, in preparing this essay. In July, 1994, when I was a Visiting Fellow at the University of Otago Bioethics Research Center, I completed the article in its final form. I thank Professor Alastair V. Campbell, the Director of the Center, for his gracious hospitality during my stay.

NOTES

1. "A treatment that cannot provide a minimum likelihood or quality of benefit should be regarded as futile, and such futile treatment is not owed to the patient as a matter of moral duty" (3).
2. A recent study concluded that individuals suffering from cardiac arrest and meeting distinct criteria should have their rescue efforts terminated at the scene because further treatment would be futile. Specifically, the study concluded that, "Excluding persons with persistent ventricular fibrillation, resuscitative efforts can be terminated at the scene when normothermic adults with unmonitored, out of hospital, primary cardiac arrest do not regain spontaneous circulation within 25 minutes following standard advanced cardiac life support" (34). The study makes the judgment of futility that there is no *benefit* from continuing resuscitation efforts under such circumstances, because in all likelihood patients with such a degree of injury will not live to be discharged from a hospital. The authors point out that if these criteria were widely adopted, there would also be a substantial reduction in futile hospital care (34).

A persistent vegetative state, as defined by the Multi-Society Task Force on PVS, is one that arises one month after acute traumatic or non-traumatic brain injury or presents as a condition lasting at least one month in patients with either degenerative or metabolic disorders or developmental malformations. A patient is considered to be in a state of *permanent* vegetation if therapies aimed at reversing the persistent vegetative state have not been successful and if a diagnosis of irreversibility is made with a high degree of clinical certainty that consciousness will never be regained (35).

3. Section 9 of the Uniform Rights of Terminally Ill Act of 1989 provides that no physician or other health care provider will be subject to criminal or

civil liability or be disciplined for unprofessional conduct if their actions are in accord with *reasonable* medical standards (36).

The Connecticut statutes state more specifically that no liability is imposed for removal or withholding of life support, provided the decision to act accordingly is based on "the best medical judgment of the attending physician in accordance with the usual and customary standards of medical practice" (37).

In 1991, New Jersey became the first state to enact legislation containing a personal religious exemption or conscience clause that requires a physician to pronounce death on the basis of cardio-respiratory criteria (i.e. cessation of all circulatory and respiratory functions) rather than brain or neurological death in those instances where he knows or has reason to believe such is consistent with a patient's religious beliefs (38,39).

4. A federal district court in Virginia (*In the Matter of Baby K*, 1993) held that withholding ventilator treatment from an anencephalic (born without a brain) infant would violate the federal Emergency Medical Treatment and Active Labor Act, the federal Rehabilitation Act of 1973, the Americans with Disabilities Act, and the Child Abuse Amendments of 1984. In 1994 this decision was affirmed on appeal by the Fourth Circuit US Court of Appeals (40).

Among adults and children suffering from a post-traumatic persistent vegetative state for twelve or more months, recovery of consciousness is unlikely. In cases of non-traumatic PVS occurring for three or more months, it is exceedingly rare for recovery to occur. The overall life expectancy for both conditions ranges from 2 to 5 years. Interestingly, when artificial nutrition and hydration are withdrawn from PVS patients, they usually die in 10-14 days (35).

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