For Everything a Season

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Robert G. Whiteman ("Bob") was a graduate of the Columbia University Bioethics Program and this featured article is in memory of him, commemorating his enthusiasm and dedication to the program.

"No man is an island entire of itself…any man's death diminishes me, because I am involved in mankind. And therefore never send to know for whom the bell tolls; it tolls for thee."[a]

Across the span of history, death has always been imbued with cultural importance. We are all grounded in the deep individual desire to retain control over our lives and bodies. Why should we be any less desirous of maintaining a dignified control over that time when we are to depart our lives? As Dworkin suggests: "Death has dominion because it is not only the start of nothing but the end of everything, and how we think and talk about dying—the emphasis we put on dying with 'dignity'— shows how important it is that life ends *appropriately,* that death keeps faith with the way we want to have lived."[1]

The ineluctable truth that "there is a time to be born and a time to die"[b] has presented challenges to medical science to push back the moment of death for millennia. Not much more than a generation ago, the principle tool of life extension was the respirator which more often than not lost out to the processes of disease and organ failure. Today, the ability to sustain biological life beyond useful or even cognitive purpose raises questions about when enough is enough—is medical science prolonging the process of living or prolonging the process of dying? This creates a legal and ethical question of what happens when a physician believes that continuing a current treatment will neither cure nor benefit the patient and wishes to discontinue such treatment but the patient or the family members disagree with the physician's determination and proposed course of action.[2] The concept of "futility" arose as an attempt to resolve or to avoid disputes like this and reflects a perceived need by doctors to limit patient or family autonomy and justify a decision withdraw or not initiate life-sustaining medical treatment (LSMT).[3]

Medical Futility

The central issue in most futility cases is not whether it is possible to extend the patient's life but whether the life should be extended. Such disputes involve "moral conflicts concerning our most deeply held beliefs about the value of life, about which there inevitably are diverse and incommensurable views within a pluralistic society."[4]The dispute over the legal duties owed to patients requesting LSMT judged futile by doctors has proven intractable and reached a bioethical stalemate because no consensus has emerged regarding what constitutes "futile" medical treatment.[5] While there have been many attempts to define medical futility as a form of professional, scientific assessment, none have been universally accepted as an objective test and "futility still remains inherently and unavoidably subjective."[6]

Historically, the concept of medical futility is present in Hippocratic writings, which suggested three major goals for medicine: cure, relief of suffering, and refusing to treat those who are overmastered by their diseases.

However, the extraordinary advances in medicine over the last several decades particularly the development of cardiopulmonary resuscitation, which ultimately caused death to be redefined, both patients and physicians could legitimately question what it meant to be "overmastered" by illness.[7]

What is futile care?

This is a highly complex and emotionally charged question with no easy or always satisfying answer. In fact some intensive care unit (ICU) workers believe the term *futile care "*should be expunged" from their vocabulary because "(*a*) that the term is not an objective determination, (*b*) that it depends on the goals that an intervention is meant to achieve, and (*c*) that applying it to a given patient runs the risk of creating a self-fulfilling prophecy."[8] The American Medical Association (AMA) through its Council on Ethical and Judicial Affairs[9] has weighed in on this difficult issue and suggested that a patient's care is futile when nothing further can be done medically to cure the patient; the patient is going through the dying process. When this occurs, the AMA Code requires physicians to act in accordance with their own value judgments and to not "prolong the dying process without benefit to the patient or to others with legitimate interests." The AMA Code also states that "patients should not be given treatments simply because they demand them."[9]

Taking the Bull by the Horns

Virtually every state has attempted to deal legislatively with the dilemma of futile or medically inappropriate treatment[10] but only Texas has developed a statutory procedure that attempts to bring the medical futility process to a finite conclusion.[2] For over a decade, by virtue of the Texas Advance Directives Act (TADA)[11] doctors in Texas have had the statutory authority, essentially 10 days after the concurrence by a hospital ethics committee, to discontinue LSMT of a patient even over the patient's or surrogate's objection. Judicial intervention is not authorized to review the decisions of the physician or ethics committee which appear to be unreviewable and is limited to granting an extension of time in which to find another facility to treat the patient. If the procedure has been properly followed, the physicians and the ethics committee are granted complete criminal, civil and administrative immunity.[12]

The Texas Advance Directive Act of 1999[11]

The TADA combines several prior laws dealing with end-of-life decisions into a single statute and makes numerous changes including provisions for a living will and definitions of terminal and irreversible illness.[13] Most importantly, the law establishes a legally sanctioned extrajudicial process for resolving disputes about end-of-life decisions. This mechanism for dispute resolution may be used in response to a surrogate, living will, or medical power of attorney request to either "do everything" or "stop all treatment" if the physician feels ethically unable to agree to either request. As explained by Dr. Robert Fine[c] of Baylor, the co-author of the statute, "a 'medical futility' conflict is a situation in which the physician is asked to 'do everything' but feels that withdrawal of treatment is most appropriate; a 'right to die' conflict is a situation in which the physician is asked to stop all treatment but feels that it should be maintained."[7]

As Dr. Fine has explained, in practice, TADA comes into play "only when (1) the patient is declared terminally or irreversibly ill, (2) the patient is unable to make his or her wishes known, (3) the surrogate is demanding treatment that the responsible physician believes is medically inappropriate, and (4) the responsible physician asks that the process be invoked." He also observes that while physicians are not obligated to follow this process, if they don't, they would lose immunity for the decision to withdraw disputed treatment.[14]

Although the TADA is lengthy and deals with a variety of end-of-life issues, the key (and most controversial) section has to do with the procedure for resolving cases of medical futility.[15] The key provisions of this section are:[16]

1. The physician's refusal to comply with the patient's or surrogate's request for treatment must be reviewed by a hospital-appointed medical or ethics committee of which the attending physician is not a member and during the pendency of the process, the disputed treatment must continue.

2. The family must be given 48 hours' notice and be invited to participate in the committee consultation process.

3. The ethics consultation committee must provide a written report detailing its findings to the family and must include this report in the medical record.

4. If the ethics consultation process fails to resolve the dispute, the hospital, working with the family, must make reasonable efforts to transfer the patient's care to another physician or institution willing to provide the treatment requested by the family.

5. If after 10 days from the time the family receives the ethics consultation committee report no such provider can be found, the physician and hospital are no longer obligated to provide life sustaining treatment.

6. The patient or surrogate may request court intervention but only to attempt to obtain a court-ordered time extension of the 10 day period which can only be granted if the court finds that the extension would provide a reasonable likelihood of finding another treatment provider in the additional time.

7. If the family does not seek a time extension or the court does not grant one, life sustaining treatment may be withdrawn by the treatment team with immunity from civil and criminal prosecution.

It should be noted that while the TADA provides a mechanism by which futile medical treatment may be withdrawn, this is not mandatory but permissive and that palliative or comfort care should be continued.[14]

Positive Results and Strengths

One of the most positive aspects of the TADA, is that it recognizes and attempts to resolve the conflicts that can arise between the competing autonomies of the patient and the physician. It provides a mechanism by which the physician's individual integrity is protected against having to render treatment which she believes is medically inappropriate or morally unacceptable by requiring transfer to another caregiver while at the same time avoiding a unilateral decision by the physician on withdrawing disputed care.[17]

Rather than trying to specifically define the elusive "medical futility", the law fosters a process-based approach, as suggested by the AMA guidelines, by which each case is individually evaluated first by the physician and then by the ethics committee. As a practical matter, if the committee agrees with the physician's assessment and no other caregiver can be found to render the treatment in question, this collective agreement in essence has established a "community standard" of medical futility[18] as well as providing physicians the "safe haven" of immunity from civil or criminal entanglements for doing that which they deem to be medically and ethically correct.

The process seems to have provided an additional, perhaps initially unintended, benefit to the patients' families of providing a mechanism by which they do not have to bear the emotional burden (and potential guilt) of authorizing the death of a loved one even though it may in fact what they believe should occur. As Dr. Fine has reported concerning his own experience with the TADA: "We have had many conversations with families who said in essence, 'If you are asking us to agree with the recommendation to remove life support from our loved one, we cannot. However, we do not wish to fight the recommendation in court, and if the law says it is OK to stop life support, then that is what should happen'."[7] It may also have given a level of comfort to physicians by defining a process and granting immunity from actions that had previously been accomplished in the shadows and which have now become more explicit and increased by 67%.[7]

In a survey of 197 returned surveys from members of the Texas Hospital Association (THA) in 2007, Smith *et al* reported that of those cases that utilized the TADA process, most of the cases were resolved before the 10-day waiting period because "patients died, patients or representatives agreed to forgo the treatment in question, or patients were transferred" and that cessation of requested life-sustaining treatment occurred in only a small number of cases.[10]

Criticisms, Concerns and Ethical Issues

As Law Professor Thomas Mayo[d], of SMU the other co-author of the statute notes, "two of the most persistent and insightful critics" are Dr. Robert Truog and Professor Thaddeus Mason Pope whose essential objection is that the TADA "is procedurally deficient because of the absence of minimal due-process safeguards against biased, substantively flawed, or otherwise inappropriate decision-making by treating physicians."[19] They argue that because there is no provision for judicial review of a decision by a hospital ethics committee which they imply is biased because it is staffed by "insiders" and therefore not independent, it fails to meet basic standards of procedural fairness.[19] This concern about the composition of the ethics review committee and the procedural process is shared by Pope some of whose concerns were that decisions on life-sustaining treatment were being made "outside the shadow of the court system" by an in-house committee whose decision was "final and unreviewable."[20]

In a lengthy legal treatise on the TADA[e], O'Callaghan concluded that the statute would be found to be unconstitutional on the grounds of a denial of 14th Amendment due process protections because: "(1) the statute's failure to set forth a standard limiting the doctor's discretion with regard to the denial of LSMT authorizes arbitrary deprivations of the patient's liberty and life guarantees; (2) the hospital's ethics committee is not a neutral, unbiased adjudicator of the dispute; and (3) the balance of interests indicates that the patient is due formal procedural protections in the adjudication of this dispute.[21] It should be noted that to date, no decision has declared the TADA to be unconstitutional.

In response to the basic objections raised, Professor Mayo has argued that "the due-process criticism starts off right but ends up seriously wrong."[19] He noted that it was a conscious judgment of the statute advisory panel to provide for "an intramural ethics committee review of 'futility disputes'" because: 1) members of the ethics committee bring an expertise to the issues that trial judges generally don't have; 2) ethics committee members may not include physicians with subject patient care responsibility and there is no reason to assume that such a committee would simply be a "rubber stamp" of the attending's decision "short of a deep seated distrust of hospital workers and volunteers"; and 3) while judges may be experts at legal due process, there is nothing to suggest that they "should be the gold standard for decision-making in end-of-life disputes."[19]

Professor Mayo argued further that although nothing in the principally disputed section (§166.046) specifically provided for judicial review, neither does it preclude it and in the advisory panel's discussion of the TADA, it was understood that judicial review would be available through the usual leagal routes in Texas and the panel even considered making the procedure explicit in the statute but rejected that option as unnecessarily redundant.[19] Finally, he argued that notwithstanding any perceived limitation on the courts power to intervene or extend time periods, Texas courts clearly have the inherent power to intervene and preserve the status quo and would be "highly unlikely" to "allow a patient to die in a contested case" pending their evaluation of the merits and jurisdiction and that most courts when presented with a dispute under the TADA, have not hesitated to issue a temporary injunction until the issues-including the existence of a cause of action and subject-matter jurisdiction could be sorted out.[19]

Point-Counterpoint-Rebuttal

In a summary of the main procedural and ethical disagreements surrounding the TADA, a spirited "Point-Counterpoint" debate in the literature occurred in 2009 between Dr. Fine, the proponent of the TADA and Dr. Robert Truog a noted bioethicist from Harvard who was critical of some of its provisions. Dr. Truog had expressed his concerns two years previously by observing that what made the TADA effective was also what created its greatest problem because: "It relies on a due-process approach that is more illusory than real and that risks becoming a rubber-stamp mechanism for systematically overriding families' requests that seem unreasonable to the clinicians involved."[16]

Dr. Fine in his point[14], argued that the TADA "effectively and ethically resolves disputes about medical futility" and that although the statute TADA does not include the words "medical futility" it "does recognize the concept with the term *medically inappropriate treatment."* He noted that attempts to resolve "futility conflicts" should start with the "foundational rule of good communication" and that "palliative care and clinical ethics consultants may be helpful." He referenced a report made to the Texas legislature in 2005 from multiple hospital ethics committees concerning the involvement if the TADA which found that: "of 2,922 ethics consults, including an estimated 974 futility consults, only 65 10-day letters were issued. Of those 65 cases, 11 patients were transferred within 10 days, 22 patients died during the 10-day period, 27 patients had the disputed treatment withdrawn, and 5 patients had treatment extended and/or were transferred later."[14]

Dr. Truog in his counterpoint[22] continued to raise concerns about the procedure and argued that the TADA "is ethically flawed...medical futility disputes must be resolved by a fair process." He felt that "the most fundamental flaw with TADA is that it specifically excludes the involvement of the courts, ceding all of the authority to the hospital ethics committee or medical review committees." He continued his procedural objections by arguing that an aggrieved family had "no options for appealing the decision of the ethics committee" and the court's power was limited to "granting an extension of time for the family to locate an alternative care provider" but "only if there is a reasonable likelihood that such a provider can be found, which is often unlikely." He agreed that keeping cases out of court was "a distinct advantage" but suggested that the ethics committee composition was flawed because it "fails to bring the diversity of the community into the deliberative process." As a result of what he apparently believed was an ethics committee bias, he found it to be "no surprise, then, that in 47 futility cases described in one report from Texas, the ethics committee agreed with the clinicians > 90% of the time." In addition, Dr. Truog felt that there was a socioeconomic bias present because the TADA was invoked most often in urban hospitals so that "the law may therefore be disproportionately applied to people who have been denied, or at least believe they have been denied, beneficial medical treatments that are available to others. These families may believe that, once again, they are being deprived of treatment that is not only beneficial, but indeed life sustaining." Dr. Truog then suggested that the fair thing to do would be to "level the playing field" by taking the decisional authority out of the hands of the hospital ethics committee and placing it into the hands of the judicial system. He concluded his arguments by suggesting that "TADA essentially accepts a tradeoff between a solution that effectively resolves a relatively small number of hard cases in exchange for a process that summarily dismisses some of the most fundamental protections that our society has entrusted to the legal system. In my view, such a compromise does not reflect either our constitutional principles or our ethical ideals"[22]

Dr. Fine in his rebuttal[23] observed that the major argument raised against the TADA was that it "excludes the involvement of the courts and may be unconstitutional." He specifically disputed that assertion and argued that "the law does not exclude the courts, but directs the court to review matters it is most qualified to judge: compliance with procedure, not medical decision making." As concerns the constitutional argument, he pointed out that in a recent TADA case, *Gonzalez,* the court-appointed guardian of the infant patient argued that the TADA did *not* violate either the state or Federal constitution and that "no court has declared TADA unconstitutional after 10 years of use." He also pointed out that Dr. Truog's assertion that "judges provide more diversity and less potential bias than ethics committees" seems to overlook the fact that "judges secure their position either through political appointment or election" and that a judge "no matter how wise, cannot match the collective wisdom or diversity of an ethics committee and does not have expertise in medical decisions." He also challenges the socioeconomic bias assertion of Dr. Truog by suggesting that no evidence to support the claim was presented and challenged the accuracy of the conclusion suggested by Dr. Truog's 47 case examples [that the ethics committee agreed with the clinicians > 90% of the time] by noting that 37 of the 47 futility cases were resolved by ethics consultations prior to resorting to the full dispute process and that of the remaining 10 cases which were heard by the ethics committee, the committee agreed with the physician in 6 cases and not in the other 4 so that this "60/40 split is hardly bias!"[23]

Some Proposed Amendments to the TADA

Professor Mayo, in response to the concerns and criticisms surrounding the statute, proposed a number of modifications to the law in an effort to assuage its critics and keep its essential purpose intact:[19]

Judicial review- If it were necessary to preserve the essential structure of the law…from a finding of unconstitutionality, the availability of judicial review could be made more explicit. As a starting point, "reasonable medical judgment" could be added…[to provide] a basis for substantive review of the medical decision-making involved in the case.

Limit the scope of the immunity available -If there is doubt about the availability of judicial review …the broad immunity …is one of the principal reasons for that doubt. The immunity from criminal liability should be preserved, as should the immunity from disciplinary action byappropriate licensing boards, but the immunity from civil liability could be limited to monetary damages, making it clear that injunctive relief would still be available as a remedy.

Limit the scope-**.** The law should be limited to apply only when the patient lacks decision making capacity. …In addition, [the law] should be limited to disputes over treatment decisions for "qualified patients"--that is, to patients who have been certified to have a terminal or irreversible condition.

*Require a prior informal dispute-resolution-style ethics consultation***.** Many Texas hospitals seem to have gravitated toward a two-step process, even though it is not required bythe statute. It should be required of all hospitals, however, as a "best practice" that would give all parties a chance to find an acceptable middle ground without going directly to the formal statutory process.

*Extend the time deadlines***-**The time limits could easily be extended to provide a minimum number of weekdays' (rather than calendar days') notice before the review consult occurs (five) or during which the attempt to transfer shall take place (ten). At a minimum, the law should encourage facilities to be flexible in applying the time requirements… in order to meet the reasonable needs of families and to avoid treating minimum time requirements as setting upper limits.

Require hospitals to offer another informal dispute-resolution style ethics consult after the expiration of the ten-day waiting period- The ten-day waiting period may develop potentially significant information, even if no transfer has been arranged. The patient's condition may have changed, or it may have stayed the same. Treatment alternatives may have been tried with various outcomes. And the fact that no provider has been found who is willing to accept the transfer is a significant fact in itself. Any or all of this new information might contribute to an agreed-upon resolution of the end-of-life treatment dispute. Afollow-up ethics consultation should be considered a "best practice" unless it is rejected by the surrogate decision maker.[19]

Conclusions

Perhaps technology has gone too far. We've overcome the natural order of life by overriding the natural processes of death possibly beyond that which was reasonable. There was a general sense in medicine to do everything one could to preserve life in the hopes that some heroic intervention might restore a loved one to us against the odds of nature. Now it seems that perhaps all that science can do has become more than nature was meant to bear.

It is clear that while the TADA is not perfect, “it does provide a mechanism for dealing with irreconcilable conflicts between physicians and patients and/or their surrogates regarding end of life care.”[2] Even its most persistent

critic, Dr. Troug recognizes its value in addressing "both the financial implications of providing allegedly inappropriate care and the concerns of clinicians who must endure the moral burdens and burnout associated with being compelled to provide treatments they believe are ethically wrong."[26]

As Professor Mayo has written, "Unilateral withdrawal of life-sustaining treatment should not be done casually and should never be a first resort to settle end-of-life treatment disputes. Proper regard for the values of the patient and the choices of the surrogate decision maker should ordinarily counsel a slow process that ends in unilateral action only as a last resort." [19]

In the most recent session of the Texas legislature, there was an attempt to amend the TADA by the "Patient and Family Treatment Choice Rights Act of 2011" whose proposed amendments are aimed at ensuring that "when an attending physician is unwilling to respect a patient's advance directive or a patient's or family's decision to choose the treatment necessary to prevent the patient's death, life-sustaining medical treatment will be provided until the patient can be transferred to a health care provider willing to honor the directive or treatment decision." [27] In other words, the 10 day rule would be removed and LSMT could not be withdrawn by the physician over objection. As of this writing, the bill has been "left pending in the subcommittee." [28]

The medical decisions "to withdraw or withhold intensive care treatment are complex and value laden."[3] In view of the changing face of medical intervention possibilities, precise guidance as to when this can be done has been elusive and perhaps that is as it should be. It has been ethical at least since the AMA guidelines of 1999 for physicians to decline to provide LSMT when by the exercise of their own professional judgment, they believe such treatment is either medically inappropriate or futile for the overall benefit of their patient. In that sense it almost seems that the TADA simply confirms what is already permitted and its real benefit is the "safe harbor" immunity it provides to physicians from legal entanglements for exercising their professional judgments for their patients' best interests.

Ultimately, there's no escaping that human judgment must be used to evaluate whether any patient's condition is terminal and whether further medical intervention is futile by simply prolonging the dying process. While I would agree that the best person for the role of ensuring that proper legal due process is a judge, trained and experienced in the operation of the law, it seems just as clear that the best arbiter of the status and effects of a medical condition are the trained experts in that field—the physicians themselves.

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[a] John Donne Meditation XVII.

[b] *Ecclesiastes*3:1

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[e]For an extensive legal treatise on the claim that the statute is unconstitutional, see O'Callaghan, N. (2008). Dying for Due Process: The Unconstitutional Medical Futility Provision of the Texas Advance Directives Act. *Baylor Law Review, 60*, 527; and O'Callaghan, N. (2009). When Atlas shrugs: may the State wash its hands of those in need of life-sustaining medical treatment. *Health Matrix, 18*, 291.