

verse populations and less inclusive health care programs, cautioned Joanne Lynn, a senior researcher with the RAND Corporation and director of the Washington Home Center for Palliative Care Studies in Washington, D.C. “There isn’t a huge demand for assisted suicide in good care systems, but there could be a huge demand in much less adequate care systems,” Lynn said.

Psychiatrist Linda Ganzini of Oregon Health and Sciences University agrees that her state’s high-quality system of palliative care is the factor most responsible for keeping the number of assisted-sui-

cide cases low. “Your safety net is your end-of-life care and your hospice care,” she said. “It’s not the safeguards that you build into the law.”

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Terri Schiavo — A Tragedy Compounded

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An interview with Dr. Quill can be heard at www.nejm.org.

The story of Terri Schiavo should be disturbing to all of us. How can it be that medicine, ethics, law, and family could work so poorly together in meeting the needs of this woman who was left in a persistent vegetative state after having a cardiac arrest? Ms. Schiavo had been sustained by artificial hydration and nutrition through a feeding tube for 15 years, and her husband, Michael Schiavo, was locked in a very public legal struggle with her parents and siblings about whether such treatment should be continued or stopped. Distortion by interest groups, media hyperbole, and manipulative use of videotape characterized this case and demonstrate what can happen when a patient becomes more a precedent-setting symbol than a unique human being.

Let us begin with some medical facts. On February 25, 1990, Terri Schiavo had a cardiac arrest, triggered by extreme hypokalemia brought on by an eating disorder. As a result, severe hypoxic-ischemic encephalopathy developed, and during the subsequent months, she exhibited no evidence of higher cortical function. Computed tomographic scans of her brain eventually showed severe atrophy of

her cerebral hemispheres, and her electroencephalograms were flat, indicating no functional activity of the cerebral cortex. Her neurologic examinations were indicative of a persistent vegetative state, which includes periods of wakefulness alternating with sleep, some reflexive responses to light and noise, and some basic gag and swallowing responses, but no signs of emotion, willful activity, or cognition.¹ There is no evidence that Ms. Schiavo was suffering, since the usual definition of this term requires conscious awareness that is impossible in the absence of cortical activity. There have been only a few reported cases in which minimal cognitive and motor functions were restored three months or more after the diagnosis of a persistent vegetative state due to hypoxic-ischemic encephalopathy; in none of these cases was there the sort of objective evidence of severe cortical damage that was present in this case, nor was the period of disability so long.²

Having viewed some of the highly edited videotaped material of Terri Schiavo and having seen other patients in a persistent vegetative state, I am not surprised that family members and others unfamiliar with this condition would interpret some of her apparent alertness and movement as meaningful. In 2002, the Florida trial court judge conducted six days of evidentiary hearings on Ms. Schiavo’s condition, including evaluations by four neurologists, one radiologist, and her attending

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physician. The two neurologists selected by Michael Schiavo, a court-appointed “neutral” neurologist, and Ms. Schiavo’s attending physician all agreed that her condition met the criteria for a persistent vegetative state. The neurologist and the radiologist chosen by the patient’s parents and siblings, the Schindler family, disagreed and suggested that Ms. Schiavo’s condition might improve with unproven therapies such as hyperbaric oxygen or vasodilators — but had no objective data to support their assertions. The trial court judge ruled that the diagnosis of a persistent vegetative state met the legal standard of “clear and convincing” evidence, and this decision was reviewed and upheld by the Florida Second District Court of Appeal. Subsequent appeals to the Florida Supreme Court and the U.S. Supreme Court were denied a hearing.

So what was known about Terri Schiavo’s wishes and values? Since she unfortunately left no written advance directive, the next step would be to meet with her closest family members and try to understand what she would have wanted under these medical circumstances if she could have spoken for herself, drawing on the principle of “substituted judgment.” Some families unite around this question, especially when there is a shared vision of the patient’s views and values. Other families unravel, their crisis aggravated by genuine differences of opinion about the proper course of action or pre-existing fault lines arising from long-standing family dynamics.

Here Ms. Schiavo’s story gets more complex. Michael Schiavo was made her legal guardian under Florida law, which designates the spouse as the decision maker above other family members if a patient becomes irreversibly incapacitated and has not designated a health care proxy. After three years of trying traditional and experimental therapies, Mr. Schiavo accepted the neurologists’ diagnosis of an irreversible persistent vegetative state. He believed that his wife would not want to be kept alive indefinitely in her condition, recalling prior statements that she had made, such as “I don’t want to be kept alive on a machine.” The Schindler family, however, did not accept the diagnosis of a persistent vegetative state, believing instead that Ms. Schiavo’s condition could improve with additional rehabilitative treatment.

The relationship between Mr. Schiavo and the Schindler family began breaking down in 1993, around the time that a malpractice lawsuit revolving around the events that led to Ms. Schiavo’s car-

diac arrest was settled. In 1994, Mr. Schiavo attempted to refuse treatment for an infection his wife had, and her parents took legal action to require treatment. Thus began wide-ranging, acrimonious legal and public-opinion battles that eventually involved multiple special-interest groups who saw this case as a *cause célèbre* for their particular issue. Michael Schiavo was criticized for being motivated by financial greed, and his loyalty to his wife was questioned because he now lives with another woman, with whom he has two children. The Schindlers were criticized for not accepting the painful reality of their daughter’s condition and for expressing their own wishes and values rather than hers.

The right of competent patients to refuse unwanted medical treatment, including artificial hydration and nutrition, is a settled ethical and legal issue in this country — based on the right to bodily integrity. In the Nancy Cruzan case, the Supreme Court affirmed that surrogate decision makers have this right when a patient is incapacitated, but it said that states could set their own standards of evidence about patients’ own wishes.³ Although both the Schiavo and Cruzan cases involved the potential withdrawal of a feeding tube from a patient in a persistent vegetative state, the family was united in believing that Nancy Cruzan would not want to be kept alive in such a state indefinitely. Their challenge, under Missouri law, was to prove to the court in a clear and convincing manner that this would have been Nancy Cruzan’s own wish. The Schiavo case raises much more challenging questions about how to define family and how to proceed if members of the immediate family are not in agreement.

The relevant Florida statute requires “clear and convincing evidence that the decision would have been the one the patient would have chosen had the patient been competent or, if there is no indication of what the patient would have chosen, that the decision is in the patient’s best interest.” Since there is no societal consensus about whether a feeding tube is in the “best interest” of a patient in a persistent vegetative state, the main legal question to be addressed was that of Terri Schiavo’s wishes. In 2001, the trial court judge ruled that clear and convincing evidence showed that Ms. Schiavo would have chosen not to receive life-prolonging treatment under the circumstances that then applied. This ruling was also affirmed by the Florida appeals court and denied a hearing by the Florida Supreme Court. When Terri Schiavo’s feeding tube was removed for the second time, in 2003, the

Florida legislature created “Terri’s Law” to override the court decision, and the tube was again reinserted. This law was subsequently ruled an unconstitutional violation of the separation of powers.

On March 18, 2005, Ms. Schiavo’s feeding tube was removed for a third time. The U.S. Congress then passed an “emergency measure” that was signed by the President in an effort both to force federal courts to review Ms. Schiavo’s case and to create a legal mandate to have her feeding tube reinserted yet again. The U.S. District Court in Florida denied the emergency request to reinsert the feeding tube, and this decision was upheld on appeal. Multiple subsequent legal appeals were denied, and Ms. Schiavo died on March 31, 2005, 13 days after the feeding tube was removed.

This sad saga reinforces my personal belief that the courts — though their involvement is sometimes necessary — are the last place one wants to be when working through these complex dilemmas. Although I did not examine her, from the data I reviewed, I have no doubt that Terri Schiavo was in a persistent vegetative state and that her cognitive and neurologic functions were unfortunately not going to improve. Her life could have been further prolonged with artificial hydration and nutrition, and there is some solace in knowing that she was not consciously suffering. I also believe that both her husband and her family, while seeing the situation in radically different ways, were trying to do what was right for her. Her family and the public should be reassured and educated that dying in this way can be a natural, humane process (humans died in this way for thousands of years before the advent of feeding tubes).⁴

In considering such profound decisions, the cen-

tral issue is not what family members would want for themselves or what they want for their incapacitated loved one, but rather what the patient would want for himself or herself. The New Jersey Supreme Court that decided the case of Karen Ann Quinlan got the question of substituted judgment right: If the patient could wake up for 15 minutes and understand his or her condition fully, and then had to return to it, what would he or she tell you to do? If the data about the patient’s wishes are not clear, then in the absence of public policy or family consensus, we should err on the side of continued treatment even in cases of a persistent vegetative state in which there is no hope of recovery. But if the evidence is clear, as the courts found in the case of Terri Schiavo, then enforcing life-prolonging treatment against what is agreed to be the patient’s will is both unethical and illegal.

Let us hope that future courts and legislative bodies put aside all the special interests and distractions and listen carefully to the patient’s voice as expressed through family members and close friends. This voice is what counts the most, and in the Terri Schiavo case, it was largely drowned out by a very loud, self-interested public debate.

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A New Colonialism? — Conducting Clinical Trials in India

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In January 2005, the government of India enacted a new rule that allows foreign pharmaceutical companies and other interested parties to conduct tri-

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als of new drugs in India at the same time that trials of the same phase are being conducted in other countries. This new rule supersedes a directive of India’s Drugs and Cosmetics Rules that required a “phase lag” between India and the rest of the world. According to the old rule, if a phase 3 study had been completed elsewhere, only a phase 2 study was permitted in India. Even under the new rule, phase 1