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A Primer on the Law and Ethics of Treatment, Research, and Public Policy In the Context of Severe Traumatic Brain Injury

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From the 1976 case of Karen Ann Quinlan¹ to the March 20, 2004, statement of Pope John Paul II,² physicians, lawyers, and theologians have struggled with the legal and ethical implications of treatment and public policy decisions in the context of devastating brain injury. Recent medical

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1. *In re Quinlan*, 355 A.2d 647, 671-72 (N.J. 1976) (holding that “upon the concurrence of the guardian and family of Karen, should the responsible attending physicians conclude that there is no reasonable possibility of Karen’s ever emerging from her present comatose condition to a cognitive, sapient state and that the life-support apparatus now being administered to Karen should be discontinued, they shall consult with the hospital ‘Ethics Committee’ or like body of the institution in which Karen is then hospitalized. If that consultative body agrees that there is no reasonable possibility of Karen’s ever emerging from her present comatose condition to a cognitive, sapient state, the present life-support system may be withdrawn and said action shall be without any civil or criminal liability therefor, on the part of any participant, whether guardian, physician, hospital or others.”). The Karen Ann Quinlan case was followed by a string of well-known cases, including the case of Nancy Cruzan (*Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261 (1990)) and, more recently, the Terri Schiavo case (*Schindler v. Schiavo*, 866 So. 2d 140 (Fla. Dist. Ct. App. 2004)).

2. On March 20, 2004, following a Vatican-sponsored symposium on the scientific and ethical issues raised by the persistent vegetative state, Pope John Paul II stated that health care providers are morally obliged to provide food and water to individuals in the persistent vegetative state because such patients “retain human dignity and have a right to be monitored for clinical signs of eventual recovery.” According to the Pope, denying food and water would constitute “euthanasia by omission” because “[t]he administration of water and food, even when provided by artificial means, always represents a natural means of preserving life, not a medical act. Its use, furthermore, should be considered, in principle, ordinary and proportionate, and as such morally obligatory.” See, e.g., Frank Langfitt, *Pope’s Stand on Life Support Unclear for Church Hospitals: Giving Food, Water Moral Obligation*, *Pontiff Says*, BALTIMORE SUN, Apr. 3, 2004, at 1A.

literature proposing an ethical framework for interventional cognitive neuroscience involving patients in states of minimal consciousness³ raises additional legal and ethical issues in the context of clinical research.

Using the Mathew Kosbob case⁴ as a point of departure, this article discusses the legal and ethical issues raised by treatment and research, as well as public policy decisions, involving patients who are either in a persistent vegetative or minimally conscious state. Section I provides background information regarding the Mathew Kosbob case. Section II provides background information regarding traumatic brain injury, including the definition of traumatic brain injury; the levels of initial neurological damage associated with traumatic brain injury; the cognitive, physical, and behavioral changes that result from traumatic brain injury; and the prevalence of traumatic brain injury. Sections III, IV, and V discuss the legal and ethical issues raised by treatment and research involving individuals with brain injuries, as well as related public policy decisions. Section VI suggests certain policies that may minimize the realization of therapeutic failures, limit hospital and physician liability, and help to preserve our limited financial and medical resources.

This article concludes that until physicians can accurately predict which brain injury victims have a measurable chance of benefiting from available treatments and interventions, and until physicians can accurately convey such predictions to families and surrogates, cases involving patients in a persistent vegetative or minimally conscious state are at risk for therapeutic failures including therapeutic illusion, extravagance, futility, neglect, and even nihilism.⁵ A determination of whether a particular treatment or

3. Joseph J. Fins, *A Proposed Ethical Framework for Interventional Cognitive Neuroscience: A Consideration of Deep Brain Stimulation in Impaired Consciousness*, 22 NEUROLOGICAL RES. 273 (Apr. 2000) [hereinafter Fins 1].

4. See *Kosbob v. Alvares* [sic], No. CV960153525S, 2001 WL 1330053 (Conn. Super. Ct. Oct. 11, 2001) (unpublished opinion); *Kosbob v. Alvarez*, 1998 WL 695061 (Conn. Super. Ct. Sept. 25, 1998); *State v. Alvarez*, 778 A.2d 938 (May 29, 2001), *cert. denied*, 2002 U.S. LEXIS 791 (Feb. 19, 2002); *State v. Crawford*, 778 A.2d 947 (May 29, 2001).

5. The phrase "therapeutic illusion" was first coined by K.B. Thomas in 1978. See K.B. Thomas, *The Consultation and the Therapeutic Illusion*, 1 BR. MED. J. 1327 (May 20, 1978). In Thomas' study, two hundred patients with respect to whom no definite diagnosis could be made were randomly selected for one of two procedures. Under the first procedure, the patients were given a symptomatic diagnosis and medications. Under the second procedure, the patients were told that they had no evidence of disease and, therefore, that they required no treatment. Thomas found no difference in outcome between the two methods as judged by the return or not of the patient within one month and the patient's statement that he or she did or did not get better. Thomas argued that when a patient improves after being provided a treatment that has no proven effect and may only be acting as a placebo, the patient's improvement could mislead the physician into thinking that the treatment given was effective. Thomas labeled this phenomenon as the "therapeutic illusion." *Id.* See also Andrew C. Markus, *The Ethics of Placebo Prescribing*, 67 MT. SINAI J. MED. 140, 142 (Mar.

research decision risks one or more therapeutic failures requires a fact-intensive analysis that frequently is frustrated by the treating physician's diagnostic uncertainty and the family's moral ambivalence. In light of such uncertainties, general public policies, such as Pope John Paul II's March 20, 2004, statement that would mandate health care workers' provision of nutrition and hydration to individuals in persistent vegetative states, should be avoided.

I. MATHEW KOSBOB: A TRAUMATIC BRAIN INJURY CASE STUDY

A. Mathew's Attack

On the warm summer evening of July 28, 1995, fifteen-year-old Mathew Kosbob was with some friends in the parking lot of Davenport Ridge Elementary School in Stamford, Connecticut.⁶ Four older teens,⁷ in front of

2000) (noting that K.B. Thomas first labeled the phenomenon as the therapeutic illusion). In this article, the phrase "therapeutic illusion" is used more broadly to include situations in which a patient, family, or physician believes that a particular treatment or research protocol will improve the patient's condition despite the likelihood that such treatment will have no beneficial effect. Stated another way, individuals under a "therapeutic illusion" have false hopes despite the lack of future benefit. Throughout this article, the phrases "therapeutic extravagance," "therapeutic futility," "therapeutic neglect," and "therapeutic nihilism" are also used. "Therapeutic extravagance" will mean the provision of high-cost treatments that offer little or no benefit. "Therapeutic futility" will mean the provision of treatments that offer little or no benefit and, thus, are wasteful. "Therapeutic neglect" will refer to situations in which a patient likely will benefit from the provision of one or more treatments but the patient does not have access to such treatment. Finally, "therapeutic nihilism" refers to situations in which the possible benefits of treatment are not recognized. *See also* Charles E. Rosenberg, *Belief and Ritual in Antebellum Medical Therapeutics*, in *MAJOR PROBLEMS IN THE HISTORY OF AMERICAN MEDICINE AND PUBLIC HEALTH: DOCUMENTS AND ESSAYS* 112-13, 117 (John Harley Warner & Janet A. Tighe eds., Houghton Mifflin 2001) (noting that the phrase "therapeutic nihilism" was christened in mid-nineteenth century America and was used to refer to a handful of European academic physicians whose "self-confident empiricism . . . denied the utility of any therapeutic measure not proven efficacious in clinical trials.").

6. *See* BATTERED BRAINS (Hilltop Productions, 1999) (a video narrated by William J. Winslade, Ph.D., J.D., which describes three traumatic brain injury cases, including Mathew's); Phil Reisman, *Easy Access to Beer Fuels Teens' Drinking Binges*, THE JOURNAL NEWS (Oct. 6, 2002); *Hard Copy: Teen Beating* (Syndicated television broadcast), at <http://www.mathewkosbob.org/videos.htm>; *Day & Date: Message for Mathew* (syndicated television broadcast, July 1997), available at <http://www.mathewkosbob.org/videos.htm>; Brett Freeman, *Mathew Kosbob's Tragedy Is Our Own: A Stamford Family Struggles to Come to Grips with an Incomprehensible Act of Violence*, FAIRFIELD COUNTY WEEKLY (1997), at <http://www.old.fairfieldweekly.com/articles/kosbob.html>.

7. Washington Alvarez, then 17 years-old, Anthony Bellochio, then 16 years-old, Jarrell Crawford, then 18 years-old, and Michael Ponticello, then 17 years-old (the defendants), were arrested soon after the attack. (Although defendant Alvarez had stabbed another person thirty days before he attacked Mathew and had been in jail, his parents had recently bailed

a crowd of approximately twenty other teenagers, jumped Mathew. They punched, kicked, and hit him repeatedly in the head with an empty forty-ounce beer bottle until, and even after, Mathew lost consciousness.⁸ Mathew's attackers also threw two full beer cans at Mathew, which exploded from the force of striking his skull. When Mathew's friends brought him home, Mathew's pupils were already fixed and dilated. Mathew's parents and his two younger brothers, Jeremy and Alex, found Mathew beaten and bloody in the back seat of his car.⁹ Mathew's father called an ambulance, which transported Mathew to the trauma room of Stamford Hospital.¹⁰ According to a 2001 court opinion, "Mathew was neither conscious nor breathing on his own" when he was admitted to Stamford Hospital.¹¹

B. Mathew's Medical History

From his July 28, 1995, beating until his death on November 23, 1998,

him out.) All four of the defendants were initially convicted of kidnapping in the first degree and assault in the first degree. When Mathew died on November 23, 1998, three of the four defendants (Alvarez, Bellochio, and Crawford) were re-charged with manslaughter in the first degree, which carries a maximum eighty-five year sentence. Alvarez, Bellochio, and Crawford ultimately were sentenced to 17 ½ years, 25 years, and 16 ½ years of prison time, respectively. None of these three defendants is eligible for parole. Upon completion of his sentence, defendant Alvarez will be deported to Ecuador. Ponticello has already served his four year sentence. E-mail from William Kosbob, father of Mathew Kosbob (Apr. 12, 2004, 08:01:21 AM PST) (on file with author). See also *State v. Alvarez*, 778 A.2d 938 (May 29, 2001) (addressing whether defendant Alvarez's prosecution for manslaughter in the first degree is barred by the federal constitutional prohibition against double jeopardy when the defendant pleaded guilty to assault in the first degree and was convicted and sentenced on that charge, only later to be charged with manslaughter in the first degree after Mathew died), *cert. denied*, 2002 U.S. LEXIS 791 (Feb. 19, 2002); *State v. Crawford*, 778 A.2d 947 (May 29, 2001) (dismissing defendant Crawford's double jeopardy appeal because defendant Crawford failed to present any "colorable claims of double jeopardy that support this interlocutory appeal."); *Kosbob v. Alvares* [sic], No. CV960153525S, 2001 WL 1330053 (Conn. Super. Ct. Oct. 11, 2001) (unpublished opinion) (awarding \$6,159,877 in civil damages to the Kosbob family); *Kosbob v. Alvarez*, No. CV-960153525A, 1998 WL 695061 (Conn. Super. Ct. Sept. 25, 1998) (unpublished opinion) (denying and granting some of the City of Stamford's motions to strike various counts against it).

8. Reisman, *supra* note 6, at 1.

9. *Id.*

10. The Stamford Hospital, located in Stamford, Connecticut (the Hospital), is a not-for-profit, 305-bed community teaching hospital that has served "Stamford and surrounding communities for more than 100 years. . . . The Hospital maintains an educational partnership with Columbia University College of Physicians and Surgeons for its teaching programs in internal medicine, family practice, psychiatry, obstetrics/gynecology and surgery." *About The Stamford Hospital*, available at http://www.stamfordhospital.org/tsh/tsh_about.html.

11. *Kosbob*, 2001 WL 1330053, at *1 ("Initially admitted to the trauma room at the Stamford Hospital, Mathew was neither conscious nor breathing on his own.").

Mathew was confined to either a hospital or a rehabilitation facility.¹² Initially admitted to the trauma room at Stamford Hospital, Mathew remained there until September of 1995, when he was transferred to Gaylord Hospital in Wallingford, Connecticut.¹³ Sometime within the next month, Mathew was transferred back to Stamford Hospital and then to the Rehabilitation Hospital of Connecticut,¹⁴ where (with the exception of one transfer to and from Saint Francis Hospital and Medical Center (St. Francis Hospital) during April of 1998) he remained until his death.¹⁵

A 2001 court opinion pieces together Mathew's medical history at the Rehabilitation Hospital of Connecticut.¹⁶ In October of 1995, Mathew underwent lumbar surgery and his body began to twist in severe and uncontrollable spasms.¹⁷ In November of 1995, Mathew began to emerge from his coma, but he contracted vein infections and blood clots and required heavy antibiotics including Botulinum toxin injections in order to kill nerve endings and relieve his pain.¹⁸ On January 16, 1996, Mathew completely emerged from his coma and his doctors formally diagnosed him as severely brain injured.¹⁹ Later that month, Mathew underwent an unsuccessful surgery to cut and lengthen his spastic tendons.²⁰ Around that time, Mathew began to experience severe abdominal pain due to chronic pancreatitis.²¹

In February and March of 1996, Mathew continued to experience pain from multiple surgeries and pancreatitis, suffered from an extraordinarily high fever, and was plagued by bedsores and skin infections.²² On April 7,

12. *Id.*

13. Gaylord Hospital, located in Wallingford, Connecticut, is a 109-bed long-term acute care hospital (LTAC) that specializes in the care and treatment of medically complex patients and rehabilitation. As an LTAC, Gaylord Hospital is staffed and equipped to handle the specific needs of acutely ill or chronically disabled patients who require a hospital level of care. Gaylord Hospital also is able to treat those who need rehabilitation for illnesses or injuries related to the brain and nervous system, bones and joints, lungs, and other conditions. *About Gaylord Hospital*, at http://www.gaylord.org/pages/about_gaylord.html (last visited Nov. 23, 2004).

14. *See infra* note 33 for a description of The Rehabilitation Hospital of Connecticut.

15. The court opinions do not state how long Mathew remained at the Gaylord Hospital and The Stamford Hospital until he was transferred to The Rehabilitation Hospital of Connecticut. *See, e.g., Kosbob*, 2001 WL 1330053, at *1.

16. *Id.*

17. *Id.*

18. *Id.*

19. *Mathew Kosbob: 1979-1998*, at <http://www.mathewkosbob.org/Timeline.htm> [hereinafter *Timeline*].

20. *Kosbob*, 2001 WL 1330053, at *1.

21. *Id.*

22. *Id.*

1996, Mathew's doctors predicted that his case was terminal and that he would only live between five and seven more years.²³ From April through December of 1996, Mathew developed chest congestion, blood clots, heart problems, urinary tract infections, trachea infections, persistent vomiting, rectal bleeding that required a blood transfusion, and recurring chronic pancreatitis.²⁴ Mathew also developed a severe blood infection that required chemotherapy and that he lie under a cooling blanket to combat his high fever.²⁵

From January through March of 1997, while Mathew underwent numerous surgeries to reconstruct his small intestine, his surgeons discovered that his intestinal tract was functioning in reverse.²⁶ From April through August of 1997, Mathew underwent numerous surgeries and suffered recurring loss of intravenous access for feeding.²⁷

From September through December of 1997, Mathew's antibiotics no longer staved off infections and fevers.²⁸ He developed pneumonia and suffered from a partially collapsed lung and continued to suffer from abdominal problems, vomiting, lung congestion, skin breakdown, and chronic pancreatitis.²⁹ During this time period, Mathew's physicians began to administer morphine for Mathew's pain.³⁰

In March and April of 1998, Mathew underwent four abdominal surgeries, and Mathew's physicians increased his morphine dosage.³¹ During this time period, Mathew began to gain weight for no known reason.³² In addition, Mathew underwent a five-hour surgery for his externally ruptured small intestine and spent three weeks in the critical care unit at St. Francis Hospital.³³

23. Timeline, *supra* note 19.

24. *Kosbob*, 2001 WL 1330053, at *1.

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.* at *2.

29. *Id.*

30. *Kosbob*, 2001 WL 1330053, at *1.

31. *Id.*

32. *Id.*

33. *Id.* St. Francis Hospital and Medical Center (St. Francis), located in Hartford, Connecticut, licensed for 617 beds, is one of the largest hospitals in Connecticut and the largest Catholic hospital in New England. In 1990, St. Francis became affiliated with Mount Sinai Hospital to create a new regional health care system; it was the first instance of collaboration between a Catholic hospital and a Jewish hospital in United States history. In October of 1995, the two institutions formally merged. In 1995, St. Francis opened The Rehabilitation Hospital of Connecticut on its Mount Sinai Campus. The 60-bed comprehensive medical rehabilitation facility offers major programs in traumatic brain injury, stroke/neurological rehabilitation, industrial rehabilitation/sports medicine and

On June 23, 1998, Mathew was transported back to the Rehabilitation Hospital of Connecticut where he continued to receive various antibiotics for infection, as well as heavy doses of morphine.³⁴ Mathew cried approximately sixteen to twenty hours a day from his pain.³⁵ In October of 1998, Mathew experienced “uncontrolled cell expansion.”³⁶ Mathew had gained over one hundred pounds since the date of his attack.³⁷ Mathew was transferred back to St. Francis Hospital for the replacement of his last intravenous line, which was required because Mathew’s stomach was essentially “useless.”³⁸

Mathew’s condition continued to decline throughout November of 1998.³⁹ His breathing became more difficult and his intravenous line became infected.⁴⁰ After all treatment options had been exhausted, Mathew Kosbob died on November 23, 1998, one month before his nineteenth birthday.

C. Mathew’s Diagnosis and Prognosis: Mathew’s Family’s Reaction

When Mathew began to awaken from his coma in November of 1995, Catherine Bontke, M.D., the Medical Director of the Rehabilitation Hospital of Connecticut at the time, diagnosed Mathew as being in a “near vegetative state”⁴¹ or “one step away from being in a vegetative state.”⁴² Mathew remained in this state for approximately three years until he passed away on November 23, 1998.

In March of 1996, Dr. Bontke gave the Kosbob family a “blunt and brutal prognosis” for Mathew and identified several treatment options.⁴³ One option was to withhold nutrition from Mathew and effectively allow him to starve to death.⁴⁴ A second option was to allow any infections

general rehabilitation, including spinal cord injury and orthopedics. *Saint Francis Hospital and Medical Center at a Glance*, at <http://www.stfranciscare.org/body.cfm?id=25> (last visited Sept. 27, 2004).

34. *Kosbob*, 2001 WL 1330053, at *2. Unfortunately, Mathew’s attending physician at The Rehabilitation Hospital of Connecticut, Dr. Catherine Bontke, died in June of 1998 from a brain aneurism. See *Mathew’s Story*, at <http://www.mathewkosbob.org/> (last visited Sept. 27, 2004).

35. *Kosbob*, 2001 WL 1330053, at *2.

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

41. BATTERED BRAINS, *supra* note 6.

42. Freeman, *supra* note 6, at 2.

43. E-mail from William Kosbob, *supra* note 7.

44. *Id.*

arising in the future to go untreated, a choice that would have excluded the treatment of numerous intravenous infections that plagued Mathew until he died.⁴⁵ A third option was to continue to provide feedings and medical treatments necessary to preserve Mathew's life.

Starvation or allowing an otherwise treatable infection to kill their son were not viable options for Mathew's parents.⁴⁶ Instead, they decided to provide Mathew with the same treatment that their other sons would receive if they were sick.⁴⁷ Thus, if Mathew suffered from an infection and an antibiotic treatment was available to treat it, Mathew would receive the antibiotic.⁴⁸ Likewise, if Mathew's condition required a non-extraordinary medical procedure, Mathew would undergo the procedure.⁴⁹ Mathew's parents did, however, execute a do-not-resuscitate (DNR) order for Mathew because they did not want the members of the hospitals' professional staff, who had grown attached to Mathew, to have to perform chest compressions on their son.⁵⁰ Except for the six weeks initially following Mathew's attack when a respirator breathed for him, Mathew was not placed on any machines that prolonged his life, other than the tubes that provided him with nutrition and hydration.⁵¹ Mathew's parents felt it was their responsibility "to protect and support Mathew and to allow him to make the decision when and how he would move on."⁵²

D. The Cost of Mathew's Medical Care: Prudential Insurance's Coverage

During Mathew's lengthy hospitalization at the Rehabilitation Hospital of Connecticut, Mathew endured more than 25 body scans, 850 intravenous feedings, 455 general surgeries, 25 transfusions, 77 intravenous surgeries, 4,558 laboratory tests, 1,100 x-rays, 18 nuclear medicine scans, 859 requests for "OR assistance," 62,892 prescriptions, 5,200 respiratory treatments, and 8 abdominal surgeries.⁵³ Notably, the treatments and procedures provided at the three other facilities where Mathew received treatment (Stamford Hospital, St. Francis Hospital, and Gaylord Hospital)

45. *Id.*

46. *Id.*

47. *Id.*

48. *Id.*

49. E-mail from William Kosbob, *supra* note 7.

50. *Id.*

51. *Id.*

52. *Id.* As discussed in more detail in Section V, *infra*, Mathew's parents' decision, but for their execution of a DNR order, is consistent with the Pope's Mar. 20, 2004, position.

53. See *Mathew Kosbob's Medical History*, at http://www.mathewkosbob.org/Mathew%20Kosbob's%20Medical%20History_files/frame.htm (last visited Nov. 23, 2004).

are not included in these figures.⁵⁴ The total cost of Mathew's medical care provided by the four different hospitals, numerous physicians, and other health care workers from the day of Mathew's attack until the day he died was \$2,233,496.98.⁵⁵

Throughout Mathew's ordeal, the Kosbobs' health insurance carrier, Prudential Insurance (Prudential), made three attempts to cease payment for Mathew's medical care.⁵⁶ With each attempt, the Kosbob family enlisted the help of television show *Hard Copy* to raise awareness.⁵⁷ Ultimately, because Mathew remained hospitalized for the entire three-year and four-month period from the day of his attack until his death, and because Prudential's contract required Prudential to pay for all hospitalizations, Prudential was legally required to continue coverage.⁵⁸ The Kosbob family does not fault Prudential for trying to save money, but they believe Prudential was required to honor its contractual obligations.⁵⁹

E. Criminal and Civil Lawsuits and Ramifications

The State of Connecticut brought criminal charges against Mathew's four attackers. Three of the defendants are currently serving prison sentences and one defendant has completed his sentence.⁶⁰ The Kosbob family also settled civil lawsuits against two of the defendants in the combined amount of \$6,159,877 (including economic damages of \$2,159,877 and non-economic damages of \$4,000,000).⁶¹ Additionally, the Kosbobs sued the Stamford, Connecticut school system in a civil lawsuit for negligence, which settled for \$750,000.⁶² Mathew's family placed all settlement proceeds into a special fund in Mathew's name (the Mathew Kosbob Memorial Fund) to create after-school activities for Stamford

54. *Id.*

55. *Id.* See also *Kosbob*, 2001 WL 1330053, at *2 (noting that "[m]edical costs for the care and treatment of the decedent exceeded 2.2 million dollars . . .").

56. E-mail from William Kosbob, *supra* note 7. Other than their health insurance, the Kosbob family had no other sources available to pay for the costs of Mathew's hospitalization. If the Kosbob family lost Prudential's coverage, the Kosbob family would have had to "spend down" their assets to become poor enough to qualify for Medicare or Medicaid coverage.

57. *Id.*

58. *Id.* Mathew was never well enough to be moved to a nursing home: "[n]obody would touch his case."

59. *Id.*

60. See *supra* note 7 and accompanying text.

61. E-mail from William Kosbob, *supra* note 7. See also *Kosbob*, 2001 Conn. Super. LEXIS 2963, at *7 (awarding damages).

62. Reisman, *supra* note 6, at 1.

children.⁶³

As a result of Mathew's tragedy, the State of Connecticut enacted a statutory provision known as "Mathew's Law."⁶⁴ Among other things, Mathew's Law exempts victims of crimes and their families from government spend-down rules and requires the State of Connecticut to help pay medical bills incurred by crime victims.⁶⁵

II. TRAUMATIC BRAIN INJURY: BACKGROUND INFORMATION

A. Defining Traumatic Brain Injury

The phrase "traumatic brain injury" refers to injuries where the head of an individual is "hit" (e.g., as in Mathew's case, with kicks, punches, and beer bottles), "is penetrated" (e.g., by a bullet in the case of a gunshot victim), "strikes a stationary object" (e.g., a windshield in the case of a driver who suffers an automobile accident), "or is violently shaken or twisted" (e.g., as in cases of Shaken Baby Syndrome).⁶⁶ More formally, the Brain Injury Association of America (BIA) defines traumatic brain injury as:

[A]n insult to the brain, not of a degenerative or congenital nature, but caused by an external physical force that may produce a diminished or altered state of consciousness, which results in an impairment of cognitive abilities or physical functioning. It also can result in the disturbance of behavioral or emotional functioning.⁶⁷

The BIA further explains that:

A traumatic brain injury occurs when an outside force impacts the head hard enough to cause the brain to move within the skull or if the force causes the skull to break and directly hurts the brain. A direct blow to the head can be great enough to injure the brain inside the skull. A direct force to the head can also break the skull and directly hurt the brain. This

63. *Id.*

64. E-mail from William Kosbob, *supra* note 7.

65. See CON. GEN. STAT. § 54-209 *et seq.* (2003). See *infra* Section V for a discussion of the financial implications of Mathew's Law.

66. WILLIAM J. WINSLADE, *CONFRONTING TRAUMATIC BRAIN INJURY: DEVASTATION, HOPE, AND HEALING* 25 (1999).

67. The Brain Injury Association of America's Board of Directors adopted this definition of traumatic brain injury on February 22, 1986, and always follows the definition with the statement: "This definition is not intended as an exclusive statement of the population served by the Brain Injury Association of America." *CAUSES OF BRAIN INJURY, WHAT IS BRAIN INJURY?*, BRAIN INJURY ASSOCIATION OF AMERICA, available at <http://www.biausa.org/Pages/splash.html> (last visited Sept. 26, 2004).

type of injury can occur from motor vehicle crashes, firearms, falls, sports, and physical violence, such as hitting or striking with an object. A rapid acceleration and deceleration of the head can force the brain to move back and forth across the inside of the skull. The stress from the rapid movements pulls apart nerve fibers and causes damage to brain tissue.⁶⁸

B. Determining Initial Neurological Damage Due to Traumatic Brain Injury

Following a traumatic incident, emergency personnel typically determine the severity of initial neurological injury to the brain by using an assessment called the Glasgow Coma Scale (GCS),⁶⁹ with scores ranging from a low score of 1 to a high score of 15.⁷⁰ A GCS score in the range of 13 to 15 is typically given to individuals who initially demonstrate mild traumatic brain injury, including persons presenting: (1) brief loss of consciousness—usually just a few seconds or minutes; (2) no loss of consciousness, but individual may be dazed or confused; or (3) tests or brain scans appearing normal. Symptoms of mild traumatic brain injury may include headache, fatigue, sleep disturbance, irritability, sensitivity to noise or light, balance problems, decreased concentration and attention span, decreased speed of thinking, memory problems, nausea, depression and anxiety, and mood swings.

A GCS score in the range of 9 to 12 is given to individuals who demonstrate moderate traumatic brain injury, occurring when: (1) a loss of consciousness lasts from a few minutes to a few hours; (2) confusion lasts from days to weeks; or (3) physical, cognitive, and/or behavioral impairments are permanent or last for several months. Persons with moderate traumatic brain injury generally recover fully with treatment or successfully learn to compensate for their residual deficits.⁷¹

Finally, a GCS score of 8 or below usually describes individuals who

68. TYPES OF BRAIN INJURY, LEVELS OF BRAIN INJURY, BRAIN INJURY ASSOCIATION OF AMERICA [hereinafter CAUSES OF BRAIN INJURY], available at http://www.biausa.org/Pages_types_of_brain_injury.html (last visited Nov. 16, 2004).

69. *Id.* See also Bryan Jennett and M. Bond, *Assessment of Outcome after Severe Brain Damage: A Practical Scale*, 1 LANCET 480 (1975).

70. Many hospitals use variations of the GCS or have developed their own scales to determine the initial neurological damage due to traumatic brain injury. For example, King's College Hospital in London, England, has used the King's Outcome Scale for Childhood Head Injury (KOSCHI), as a specific pediatric adaptation of the original GCS. See Marion Crouchman, *A Practical Outcome Scale for Paediatric Head Injury*, 84 ARCHIVES OF DISEASE IN CHILDHOOD 120 (Feb. 2001).

71. CAUSES OF BRAIN INJURY, *supra* note 68.

initially demonstrate severe traumatic brain injury. Severe traumatic brain injury occurs when a prolonged unconscious state or coma lasts days, weeks, or months. Severe traumatic brain injury tends to be further categorized by clinicians into five subgroups: (1) coma; (2) vegetative state (including the persistent and permanent vegetative states); (3) minimally conscious state; (4) akinetic mutism; and (5) locked-in syndrome.

Very generally, an individual in a coma is in a state of unconsciousness from which the individual cannot be awakened and in which the individual responds minimally or not at all to stimuli, and initiates no voluntary activities.⁷² Thus, comatose individuals generally are neither awake nor aware. In contrast, an individual in a vegetative state⁷³ demonstrates some arousal usually including eye-opening and general responses to pain, such as increased heart rate, increased respiration, posturing, or sweating. However, these individuals have no ability to interact with their environment.⁷⁴ Individuals in vegetative states have sleep-wake cycles, respiratory functions, and digestive functions.⁷⁵ Thus, patients in a vegetative state may be awake, but not aware.⁷⁶ An individual in a persistent vegetative state (PVS) has remained in a vegetative state for more than a month, and an individual in a permanent vegetative state has

72. Joseph T. Giacino & Nathan D. Zasler, *Outcome after Severe Traumatic Brain Injury: Coma, the Vegetative State, and the Minimally Responsive State*, 10 J. HEAD TRAUMA REHAB. 42 (1995).

73. Bryan Jennett and Fred Plum first identified the syndrome in which the patient was awake but unaware as the vegetative state in 1972. Bryan Jennett & Fred Plum, *Persistent Vegetative State after Brain Damage*, 1 LANCET 734 (1972). Today, the use of the word "vegetative" is controversial. Indeed, Pope John Paul II believes the term is "offensive." See Langfitt, *supra* note 2, at 1A. Despite the medical distinction between the vegetative state and the minimally conscious state, many commentators believe that the word "vegetative" "relegates and degrades those hundreds of thousands of disabled Americans who are minimally conscious to the vegetable field." See, e.g., Fred Charatan, *Pessimism Can Be as Misleading as Optimism*, 327 BRITISH MED. J. 949 (2003). This Article uses the word "vegetative" in order to link the reader to the voluminous literature addressing the topic, and not out of disrespect for individuals who are characterized as awake but not aware.

74. Giacino & Zasler, *supra* note 72, at 42. In 1994, the Multi-Society Task Force on PVS ("Task Force") conducted a systematic review of the published data relating to the persistent vegetative state in a two-part consensus statement that attempted to clarify the medical issues. See Multi-Society Task Force on PVS, *Medical Aspects of the Persistent Vegetative State: Part I*, 330 N. ENG. J. MED. 1499-1508 (1994); Multi-Society Task Force on PVS, *Medical Aspects of the Persistent Vegetative State: Part II*, 330 N. ENG. J. MED. 1572, 1572-79 (1994). The current, leading American text on the persistent vegetative state, which updates the 1994 Task Force's efforts, is BRYAN JENNETT, *THE VEGETATIVE STATE: MEDICAL FACTS, ETHICAL AND LEGAL DILEMMAS* (Cambridge Univ. Press, 2002).

75. Giacino & Zasler, *supra* note 72, at 42.

76. Clare Dyer, *Permanent Loss of Awareness Is Crucial to Diagnosis of PVS*, 327 BRITISH MED. J. 67 (July 12, 2003).

remained in a vegetative state for two years or more.⁷⁷

Compared to an individual in a vegetative state, an individual in a minimally conscious state (MCS) demonstrates primitive reflexes, inconsistent ability to follow simple commands, and an awareness of environmental stimulation.⁷⁸ Over time, neurologists have learned to distinguish between individuals in a vegetative state and individuals in an MCS because the latter group demonstrates inconsistent awareness of themselves and their environment.⁷⁹ Individuals in an MCS are particularly troublesome from an ethical and public policy standpoint because they “exist in a twilight zone without realistic prospects for cure and little hope for recovery,”⁸⁰ and patients may evolve from a coma or vegetative state to the MCS.⁸¹

An individual with akinetic mutism suffers from a neurobehavioral condition that results when the dopaminergic pathways in the brain are damaged, resulting in a minimal amount of body movement, little or no spontaneous speech, eye-opening and visual tracking, and infrequent and incomplete ability to follow commands. An individual with akinetic mutism is different from an individual in an MCS because the lack of movement and speech of individuals with akinetic mutism does not result from neuromuscular disturbance.⁸² Finally, individuals with locked-in syndrome have a rare neurological condition in which they physically cannot move any part of their body except for their eyes. Individuals with locked-in syndrome are conscious and able to think, and sometimes can learn to use vertical eye movements and eye blinking to communicate with

77. Giacino & Zasler, *supra* note 72, at 40. Different physicians and, perhaps, different countries define the length of time which must pass before an individual is classified as being in a permanent vegetative state differently. For example, a 2003 statement from the Royal College of Physicians (Great Britain), classifies a vegetative state as permanent when it has lasted for six months in non-traumatic cases and one year in trauma cases. Dyer, *supra* note 76, at 67.

78. Giacino & Zasler, *supra* note 72, at 43.

79. Joseph T. Giacino et al., *The Minimally Conscious State: Definition and Diagnostic Criteria*, 58 *NEUROLOGY* 349, 349 (Feb. 12, 2002) (noting that minimally conscious patients “demonstrate inconsistent but discernible evidence of consciousness.”); Joseph J. Fins, *Constructing an Ethical Stereotaxy for Severe Brain Injury*, 4 *NATURE REVIEWS NEUROSCIENCE* 323, 324 (Apr. 2003) [hereinafter Fins 2]. However, as discussed in more detail in Section III *infra*, the diagnosis of the permanent vegetative state is not always certain. See, e.g., Derick T. Wade, *Ethical Issues in Diagnosis and Management of Patients in the Permanent Vegetative State*, 322 *BRITISH MED. J.* 352 (2001).

80. William J. Winslade, *Research on Minimally Conscious Patients: Innovation or Exploitation?* 19 *J. HEAD TRAUMA REHAB.* 178, 178 (Mar./Apr. 2004).

81. Giacino, *supra* note 79, at 349.

82. Giacino & Zasler, *supra* note 72, at 43.

others and operate environmental controls.⁸³

C. Cognitive, Physical, and Behavioral Changes Caused by Traumatic Brain Injury

When a brain injury occurs, the functions of the neurons, nerve tracts, or sections of the brain can be affected. If the neurons and nerve tracts are affected, they can be disabled, making it difficult to carry messages to the brain. This inability to deliver messages can result in certain cognitive, physical, and behavioral changes; such changes may be temporary or permanent, and may cause impairment or complete inability to perform a function.⁸⁴

The cognitive changes that can result from traumatic brain injury include changes to the memory, decision making, planning, sequencing, judgment, attention, communication, reading and writing skills, thought processing speed, problem solving skills, organization, self-perception, perception, thought flexibility, safety awareness, and new learning.⁸⁵ Although some traumatic brain injury victims only suffer a few of these cognitive changes, Mathew's case illustrates one of the most devastating changes that can occur: an apparent, and ultimately permanent, loss of ability to interact with his environment.

Traumatic brain injury also can cause certain physical changes that can affect muscle movement and coordination, sleep, hearing, vision, taste, smell, touch, fatigue, weakness, balance, speech, seizures, and sexual functioning.⁸⁶ For example, many traumatic brain injury victims must re-learn how to stand, walk, and climb.⁸⁷

Finally, traumatic brain injury can cause certain personality and behavioral changes, including changes in social skills, emotional control and mood swings, behavioral propriety, reduced self-esteem, depression, anxiety, frustration, stress, denial, self-centeredness, anger management, coping skills, self-monitoring remarks or actions, motivation, irritability or agitation, and excessive laughing or crying.⁸⁸ Many traumatic brain injury victims are described as having "very different personalities" than they used

83. *Id.*

84. BRAIN MAPS, WHAT IS BRAIN INJURY?, INJURY ASSOCIATION OF AMERICA [hereinafter BRAIN MAPS], at http://www.biausa.org/Pages/brain_maps.html (last visited Sept. 27, 2004).

85. *Id.*

86. *Id.*

87. BATTERED BRAINS, *supra* note 6 (discussing the case of "Shane," who is re-learning to stand, walk, and climb following a gunshot wound to the head).

88. BRAIN MAPS, *supra* note 84.

to have.⁸⁹

Many individuals who have suffered traumatic brain injury have had their physical conditions stabilized in an acute care hospital and have received some rehabilitation in a rehabilitation hospital. However, these individuals may continue to suffer from permanent problems that interfere with their abilities to successfully reintegrate themselves into their communities. Brent Masel, M.D., president of the Transitional Learning Center (TLC) in Galveston, Texas, explains that organizations like the TLC are needed to help these individuals acquire the skills they need to operate in realistic settings and to successfully re-enter their communities. Dr. Masel specifically notes that “[T]here are a lot of people out there who have a lot to give to society after they have had a head injury and we need to do whatever we can to help these folks.”⁹⁰

Many of the cognitive, physical, and behavioral changes that result from traumatic brain injury require not only acute medical care and lengthy rehabilitation, but also additional case management and social, vocational, recreational, and other forms of services and training. These programs are designed to help the individual reintegrate him or herself back into the community.⁹¹

D. Traumatic Brain Injury Statistics

Although traumatic brain injuries cause the deaths of approximately 50,000 Americans each year,⁹² many individuals like Mathew survive, at least temporarily, and suffer varying, and often multiple, functional defects⁹³ that last for weeks, months or even years. “[T]he broad spectrum of outcomes goes from full recovery to death, with a range of disabilities,

89. BATTERED BRAINS, *supra* note 6 (discussing the case of Laurie Sepulvado who suffered a traumatic brain injury after a car accident, and who is described as having a “very different personality” than she used to have).

90. *Id.*

91. Adeline Hodgkinson, *Service Utilization Following Traumatic Brain Injury*, 15 J. HEAD TRAUMA REHAB. 1208, 1208 (Dec. 2000) (explaining that “[f]or community integration to succeed, many people with TBI will require access to a variety of services, including case management, accommodation, and vocational and recreational services.”).

92. WHAT IS BRAIN INJURY?, BRAIN INJURY ASSOCIATION OF AMERICA [hereinafter WHAT IS BRAIN INJURY?], available at http://www.biausa.org/Pages/what_is_brain_injury.html (last visited Sept. 27, 2004). See also MONITORING TRAUMATIC BRAIN INJURY: WHAT IS THE PUBLIC HEALTH ISSUE?, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, [hereinafter MONITORING TRAUMATIC BRAIN INJURY] available at <http://www.cdc.gov/programs/injury01.htm> (last visited Nov. 23, 2004).

93. WINSLADE, *supra* note 66, at 25.

many of them horrendous, in between.”⁹⁴ Recent statistics show that approximately 90,000 Americans each year suffer traumatic brain injury and are left with long-term disabilities, most of which are preventable.⁹⁵ Every twenty-one seconds, one person in the United States sustains a mild, moderate, or severe traumatic brain injury.⁹⁶ The annual cost of new cases of traumatic brain injury in the United States is between \$9 and \$10 billion, and lifetime costs per person with traumatic brain injury have been estimated to be between \$600,000 and \$1,875,000.⁹⁷ Unfortunately, traumatic brain injury is the leading cause of long-term disability in children and young adults in the United States.⁹⁸

Traumatic brain injury has been described as a “silent epidemic” that is “underfunded and underappreciated as a threat to the public health.”⁹⁹ The popularity of the Susan G. Komen Foundation Run for the Cure, the MS150 bike ride, and the red ribbon demonstrate the public’s awareness of and support for breast cancer, multiple sclerosis, and HIV/AIDS, respectively. In contrast, the public is not nearly as alert to traumatic brain injury, although the total number of Americans who sustain traumatic brain injuries each year has been estimated to be greater than the combined number of Americans who: (1) are diagnosed with breast cancer each year (176,300); (2) are diagnosed with multiple sclerosis each year (10,400); and (3) contract HIV/AIDS each year (43,681).¹⁰⁰

94. *Id.* at 29.

95. PREVENTION AND EDUCATION, BRAIN INJURY ASSOCIATION OF AMERICA, *available at* <http://www.biausa.org/Pages/home.html> (last visited Sept. 25, 2004); CTRS. FOR DISEASE CONTROL AND PREVENTION, TRAUMATIC BRAIN INJURY IN THE UNITED STATES: A REPORT TO CONG. (December 1999), *available at* <http://www.neuroskills.com/index.shtml?main=/tbi/congsurv.shtml> (last visited Sept. 25, 2004). A 1999 Report to Congress authored by the Centers for Disease Control and Prevention [hereinafter Report] estimates that 5.3 million Americans currently live with a disability resulting from traumatic brain injury. The Report does not, however, identify the severity of such disabilities or the number of mild, moderate, or severe brain injuries that contributed to such disabilities.

96. WHAT IS BRAIN INJURY?, *supra* note 92.

97. Fins 2, *supra* note 79, at 323. *See generally* DOROTHY P. RICE, ELLEN J. MCKENZIE & ASSOCIATES, COST OF INJURY IN THE UNITED STATES: A REPORT TO CONG. (Institute for Health & Aging at the University of California San Francisco, Injury Prevention Center, School of Hygiene and Public Health, The Johns Hopkins University, 1989), *available at* http://www.cdc.gov/ncipc/pub-res/cost_of_injury/intro-ch1.pdf (last visited Sept. 25, 2004) (identifying the magnitude of the economic effect of injury on the United States in statistical and human terms and reporting the economic impact resulting from the failure to deal with injury as a major threat to public health, and identifies).

98. Fins 2, *supra* note 79, at 323.

99. *Id.*

100. FACTS AND STATS, BRAIN INJURY ASSOCIATION OF AMERICA, *at* http://www.biausa.org/Pages/facts_and_stats.html (last visited Sept. 25, 2004); MONITORING TRAUMATIC BRAIN INJURY, *supra* note 92. The Centers for Disease Control and Prevention estimates that 1.5 million Americans each year sustain a traumatic brain injury. Of this

III. THE LAW AND ETHICS OF TREATMENT

Emergency personnel, physicians, and hospitals usually provide emergency stabilizing treatment and various forms of intensive life-sustaining treatment, rehabilitation, and nursing care to individuals like Mathew who present with severe traumatic brain injuries. This section explores the legal and ethical implications of providing treatment to patients who are in a persistent vegetative or minimally conscious state.

A. *The Patient's Ability to Pay for Treatment*

Following a traumatic brain injury, the first step toward recovery usually includes the provision of medical stabilizing treatment, followed by additional critical, rehabilitative, or nursing care.¹⁰¹ As noted above, the total cost of the medical care provided to Mathew by his four hospitals and his numerous physicians and other health care providers was \$2,233,496.98.¹⁰² Although Prudential Insurance satisfied Mathew's financial obligations to his various health care providers, many patients have neither health insurance nor other financial resources to pay the lifetime costs of caring for an individual who has suffered a traumatic brain injury.¹⁰³

Unfortunately, "the quality, quantity, and duration of rehabilitative care depend on what financial resources are available rather than on what will most benefit a victim of traumatic brain injury."¹⁰⁴ Thus, one roadblock that frequently stands in the way of a recovering traumatic brain injury victim is his or her inability to pay for needed treatment or rehabilitation.¹⁰⁵ Although many states have established programs that provide some treatment and rehabilitation services to individuals with traumatic brain injury, these services frequently are insufficient: "for those who are not insured, have exhausted their insurance benefits, or have left rehabilitation

number, approximately 1.1 million (75%) have sustained concussions or other forms of mild traumatic brain injuries. See also NAT'L CTR. FOR INJURY PREVENTION AND CONTROL, REPORT TO CONG. ON MILD TRAUMATIC BRAIN INJURY IN THE UNITED STATES: STEPS TO PREVENT A SERIOUS PUBLIC HEALTH PROBLEM, CTRS. FOR DISEASE CONTROL AND PREVENTION at 1 (September 2003), available at http://www.cdc.gov/Migrated_Content/Report/TBI_Report_to_Congress_on_MTBI_Sept_2003.pdf (last visited Sept. 25, 2004) (noting that "[a]ccording to existing data, more than 1.5 million people experience a traumatic brain injury (TBI) each year in the United States. Of them, as many as 75 percent sustain a mild traumatic brain injury—or MTBI.").

101. WINSLADE, *supra* note 66, at 34-39.

102. See *supra* note 56 and accompanying text.

103. See RICE, *supra* note 97, at 86.

104. WINSLADE, *supra* note 66, at 13.

105. *Id.* at 52.

facilities to live with their families or in the community, state services are often grossly inadequate, terribly fragmented, and shamefully inefficient.”¹⁰⁶

Although codes of medical ethics establish idealistic opinions and principles such as “each physician has an obligation to share in providing care to the indigent,”¹⁰⁷ and “[a] physician shall support access to medical care for all people,”¹⁰⁸ these ideals do not take into account the numerous competing interests physicians and other health care professionals face in dealing with other health care providers, health care administrators, managed care organizations, commercial and private third party payors, and state and federal agencies that pay for health care.¹⁰⁹ Although Mathew’s physicians and hospitals were able to provide most of the care Mathew required using the reimbursement received from Prudential, many health care professionals who would like to treat indigent patients must balance their ethical obligations with obligations to third-party health care professionals and financial constraints. Ultimately, many physicians and other health care providers will not be able to live up to the high ethical expectations of organizations such as the American Medical Association,¹¹⁰ and many indigent patients will not have access to costly treatments for traumatic brain injury.¹¹¹ Such results may be characterized as “therapeutic neglect,” which refers to situations in which patients likely to benefit from the administration of one or more treatments do not have access to such care.¹¹²

In many cases, treating and rehabilitating individuals who have suffered

106. *Id.*

107. AM. MED. ASS’N, CODE OF MED. ETHICS E-9.065 (2001) [hereinafter CODE OF MEDICAL ETHICS]. See also *id.* at E-10.01(6) (2001) (“The patient has a basic right to have available adequate health care. Physicians, along with the rest of society, should continue to work toward this goal.”).

108. See AMERICAN MEDICAL ASSOCIATION PRINCIPLES OF MEDICAL ETHICS IX (2001) [hereinafter PRINCIPLES OF MEDICAL ETHICS].

109. See generally ALBERT R. JONSEN ET AL., CLINICAL ETHICS: A PRACTICAL APPROACH TO ETHICAL DECISIONS IN CLINICAL MEDICINE 163-180 (5th ed., McGraw Hill, 2002) (discussing whether economic issues such as the financing of care and cost-containment methods should influence medical decision making).

110. See CODE OF MEDICAL ETHICS, *supra* note 107; PRINCIPLES OF MEDICAL ETHICS, *supra* note 108.

111. See, e.g., BATTERED BRAINS, *supra* note 6 (discussing the case of “Shane,” whose physician believes that he “will get where he wants to be” if they can access the necessary medical resources).

112. See *supra*, note 5; see, e.g., J.M. Teno, *Do-Not-Resuscitate Orders and Hospitalization of Nursing Home Residents: Trumping, Neglect, or Shared Decision-Making at the Eleventh Hour*, 52 J. AM. GERIATRIC SOC. 159-60 (Jan. 2004). Situations involving therapeutic neglect arise not only in brain injury cases but also in numerous other health care settings including, but not limited to, the nursing home setting.

severe traumatic brain injuries could save taxpayers the higher costs associated with providing a lifetime of custodial care to individuals left untreated. However, insurance coverage of brain injury treatment and rehabilitation is not without consequence. Health insurance companies that make million-dollar payouts for single brain injury cases may have to raise their premiums and lower their coverage, affecting other enrollees, including future traumatic brain injury victims.¹¹³

B. Providing Emergency Treatment to Traumatic Brain Injury Victims

Emergency personnel generally provide severe traumatic brain injury victims like Mathew with sufficient initial emergency care (including initial examination and necessary stabilizing treatment) without regard to insurance status or ability to pay. Indeed, the federal Emergency Medical Treatment and Active Labor Act (EMTALA) and its implementing regulations,¹¹⁴ as well as analogous state laws,¹¹⁵ generally require Medicare-participating hospitals that offer emergency services to provide an appropriate medical screening examination and necessary stabilizing treatment to any individual who presents for treatment. Thus, when the ambulance brought Mathew to the trauma room at Stamford Hospital on the evening of July 28, 1995, federal law prohibited the hospital, its physicians, professional staff, and administration from refusing to treat or stabilize Mathew because of any questions regarding his insurance status or ability to pay.¹¹⁶ EMTALA imposes stiff sanctions, including civil monetary penalties of up to \$50,000 per violation and administrative sanctions

113. See, e.g., Dan L. Crippen, Health Care Costs and Insurance Coverage, Address Before the Subcommittee on Employer-Employee Relations Committee on Education and the Workforce and U.S. House of Representatives (June 11, 1999), available at <http://www.cbo.gov/ftpdocs/13xx/doc1324/061199.pdf> (last visited Sept. 25, 2004) (noting that mandated health insurance benefits may contribute to higher health insurance premiums and lower coverage rates).

114. 42 U.S.C. § 1395dd (West 2003); 42 C.F.R. § 489.24 (2001).

115. See, e.g., FLORIDA STAT. ANN. § 395.1041(3) (West 2003) (requiring every general hospital in the State of Florida that has an emergency department to provide emergency services and care for any emergency medical condition when any person requests emergency services and care or emergency services and care are requested on behalf of a person by an emergency medical services provider who is rendering care to or transporting the person or another hospital, when such hospital is seeking a medically necessary transfer); NEV. REV. STAT. § 439B.410(1) (West 2003) (providing that each hospital in the State of Nevada “has an obligation to provide emergency services and care, including care provided by physicians and nurses, and to admit a patient where appropriate, regardless of the financial status of the patient”); 25 TEX. ADMIN. CODE § 133.44 (West 2003) (requiring Texas hospitals to screen and stabilize patients on whose behalf emergency treatment is requested).

116. As discussed in text accompanying note 58 *supra*, Prudential Insurance paid for Mathew’s three years and four months of hospitalization. However, many traumatic brain injury victims are not so lucky.

including exclusion from the Medicare and Medicaid Programs, upon hospitals and their emergency and on-call physicians who fail to comply with EMTALA's requirements.¹¹⁷

However, under federal law, once a hospital has stabilized an individual (*i.e.*, the hospital has provided such medical treatment as is necessary to assure, within reasonable medical probability, that no material deterioration of the individual's condition is likely),¹¹⁸ the hospital is no longer required to provide medical services without regard to the individual's insurance status or ability to pay. Indeed, on September 9, 2003, the Centers for Medicare and Medicaid Services (CMS) formally amended EMTALA's implementing regulations to clarify that the requirement to screen, treat, and stabilize patients without regard to their insurance status or ability to pay formally ends once the hospital stabilizes the patient or admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition.¹¹⁹

In part because of EMTALA and analogous state laws, the initial examination and stabilizing treatment provided to indigent individuals with traumatic brain injuries might be roughly equivalent to those provided to well-insured or financially resourceful individuals with similar traumatic brain injuries. However, once a hospital stabilizes an individual, the inequities in treatment provided to insured and uninsured patients become

117. See 42 U.S.C. § 1395dd(d)(1)(A) (hospitals with 100 or more beds risk civil monetary penalties of up to \$50,000 per EMTALA violation, and hospitals with less than 100 beds risk civil monetary penalties of up to \$25,000 per EMTALA violation); see 42 U.S.C. § 1395dd(d)(1)(B) (emergency department and on-call physicians who fail to comply with EMTALA's requirements also face significant civil monetary penalties of up to \$50,000 per violation and administrative sanctions (including exclusion from federal health care programs like the Medicare and Medicaid programs) for actions that violate EMTALA); 42 U.S.C. § 1395dd(d)(2)(A).

117. 42 U.S.C. §§ 1395dd(e)(3)(A)-1395dd(e)(3)(B) (West 2003) (EMTALA also establishes a private cause of action for patients injured due to EMTALA violations. Thus, patients injured by an EMTALA violation may sue a hospital (although not a physician) in a civil action and may collect damages and equitable relief, as appropriate, under the applicable state law). *Id.* § 1395dd(d)(2)(A).

118. 42 U.S.C. §§ 1395dd(e)(3)(A)-1396dd(e)(3)(B).

119. See 68 Fed. Reg. 53262 (Sept. 9, 2003), *to be codified at* 42 C.F.R. § 489.24; in cases in which the hospital admits the individual as an inpatient, EMTALA's obligations no longer apply, although the September 9, 2003, amendments do clarify that the hospital must continue to provide care to its inpatients in accordance with the federal Conditions of Participation for Hospitals (COPs). See 42 C.F.R. Part 482 (entitled "Conditions of Participation for Hospitals"). Although the COPs establish certain standards to which hospitals must adhere with respect to their various services and departments, no regulatory provision within the COPs requires hospitals to provide uninsured patients with any treatment beyond the initial screening and stabilizing treatment.

increasingly evident.¹²⁰ A not infrequent result is the therapeutic neglect of those patients without health insurance or other financial resources.

C. *The Law and Ethics of Informed Consent to Treatment*

When an individual with a traumatic brain injury requires treatment or rehabilitation, the individual's physician generally has a legal and an ethical obligation to present accurate medical facts to the individual, make recommendations regarding the management of the patient's care, and help the patient make choices from among the therapeutic alternatives available, consistent with good medical practice.¹²¹ With respect to traumatic brain injury victims who are minors, like fifteen-year-old Mathew, most state laws have adopted statutory or regulatory provisions identifying those individuals (*e.g.*, parents, legal guardians, or managing conservators) who may consent to treatment on behalf of the minor child.¹²²

When a severe traumatic brain injury victim presents to a hospital's emergency department, he or she likely will be unconscious or otherwise incapable of consenting to treatment. Generally, physicians are permitted to provide emergency care without first obtaining an individual's informed consent if the individual is unable to communicate because of a life-threatening injury, accident, or illness.¹²³

120. WINSLADE, *CONFRONTING TRAUMATIC BRAIN INJURY*, *supra* note 66, at 84-88.

121. *See generally* RUTH FADEN ET AL., *A HISTORY AND THEORY OF INFORMED CONSENT* (Oxford University Press 1986); JONSEN ET AL., *supra* note 109, at 47-103 (addressing patient preferences and informed consent); TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 77-103 (5th ed. 2001) (discussing the meaning and justification of informed consent); MARSHA GARRISON & CARL E. SCHNEIDER, *THE LAW OF BIOETHICS: INDIVIDUAL AUTONOMY AND SOCIAL REGULATION*, 27-150 (Thomson West/American Casebook Series 2003) (discussing the principle of autonomy and the example of informed consent). Physicians who fail to obtain the informed consent of patients to treatment may be liable under state law if an exception to the requirement for consent does not apply. *See, e.g.*, ALASKA STAT. § 09.55.556 (2003); FLA. STAT. ANN. § 766.103 (West Supp. 2003); LA. REV. STAT. ANN. 40:1299.40 (West 1995); TEX. CIV. PRAC. & REM. CODE ANN. § 74.101 (West Supp. 2003); VT. STAT. ANN. TIT. 1 § 1909 (1976). Some states have established medical disclosure panels that are responsible for identifying the specific risks that must be disclosed to patients undergoing certain medical procedures. *See, e.g.*, LA. REV. STAT. ANN. § 40:1299.40E (West 1995) (establishing the Louisiana Medical Disclosure Panel); TEX. CIV. PRAC. & REM. CODE § 74.102 (Vernon 2003) (establishing the Texas Medical Disclosure Panel).

122. *See, e.g.*, *Moss v. Rishworth*, 222 S.W. 225 (Tex. Comm'n. App. 1920); *Browning v. Hoffman*, 111 S.E. 492 (W. Va. 1922); *Bishop v. Shurly*, 211 N.W. 75 (Mich. 1926); *Zoski v. Gaines*, 260 N.W. 99 (Mich. 1935); *Sullivan v. Montgomery*, 279 N.Y.S. 575 (N.Y. City Ct. 1935); *In re Hudson*, 126 P.2d 765 (Wash. 1942).

123. *See, e.g.*, CAL. PROF. & BUS. CODE ANN. § 2397 (West Supp. 2004) (exception to informed consent for physicians who treat patients in emergency situations); CONN. GEN. STAT. ANN. § 17a-81 (West 1979) (exception to parental consent for emergency treatment situations involving children); FLA. STAT. ANN. § 401.455(1)(b) (West 1995) (exception to

Some individuals with traumatic brain injury who receive medically stabilizing treatment regain full consciousness, and thus, the ability to consent to future treatment and rehabilitation. However, other individuals, like Mathew, may stay in a minimally conscious or vegetative state and remain incapable of consenting to additional medical treatment or rehabilitation. With respect to those individuals who remain incapable of consenting to additional treatment, physicians may be guided in their treatment decisions by an advance directive, if one exists, in which the individual identifies in writing his or her desire to have life support administered, withheld, or withdrawn.¹²⁴ Unfortunately, very few traumatic brain injury victims have executed advance directives.¹²⁵ As a result, physicians, family members, and surrogates struggle to make appropriate treatment decisions.

D. The Law and Ethics of Treating Patients in the Persistent and Minimally Conscious States

Treatment decisions are made especially difficult by the diagnostic uncertainties that plague physicians who treat patients in a PVS or MCS. Mathew's case is a perfect example of such diagnostic uncertainty. Mathew's attending physician at the Rehabilitation Hospital of Connecticut, Dr. Bontke, reportedly determined Mathew was in a "near vegetative" state and that Mathew was "one step away from being in a vegetative state."¹²⁶ In addition, newspaper and media reports discussing Mathew's case explain

informed consent for patients in emergency situations); TEX. HEALTH & SAFETY CODE ANN. § 773.008 (Vernon 2003) (establishing an exception to the general rule of informed consent if the individual is unable to communicate because of an injury, accident, or illness or is unconscious and suffering from what reasonably appears to be a life-threatening injury or illness).

124. State laws establish the requirements relating to the form and content of advance directives. *See, e.g.*, ALA. CODE §§ 22-8A-4 – 22-8A-11 (relating to "Advance Directive for Health Care; living will and health care proxy"); ARK. CODE ANN. § 20-17-214 (2003) (Arkansas Rights of the Terminally Ill or Permanently Unconscious Act); FLA. STAT. ANN. 765 (West 2003) (Florida Health Care Advance Directives law); MD. CODE ANN. HEALTH-GEN. I. § 5-601 (Maryland Health Care Decision Act); TEX. HEALTH & SAFETY CODE ANN. Chapter 166 (Vernon) (Texas Advance Directives Act). *See also* Angela Fagerlin & Carl E. Schneider, *Enough: The Failure of the Living Will*, 34 HASTINGS CTR. REPORT 30, 31 (Mar./Apr. 2004), available at http://www.thehastingscenter.org/Pdf/Publications/Hcr_Mar_Apr_2004_Enough.Pdf (noting that "the law of every state provides for advance directives, almost all states provide for living wills, and most states have at least two statutes, one establishing a living will type directive, the other establishing a proxy or durable power of attorney for health care").

125. *See, e.g.*, Fins 1, *supra* note 3, at 276 (discussing the fact that very few people have executed medical powers of attorney); Fagerlin & Schneider, *supra* note 124, at 32 (stating that roughly eighteen percent of the population has a living will).

126. *See* Kosbob, 2001 WL 1330053, at *2.

that Mathew would sometimes smile at his parents and while listening to the famous song by Celine Dion, "Because You Loved Me."¹²⁷ Both Dr. Bontke's statements, as well as Mathew's reactions, if they were not simple reflexes, suggest a condition slightly better than an actual vegetative state, perhaps even a low-functioning minimally conscious state. However, medical publications definitively identifying the MCS did not appear until 1995 (the year Mathew was attacked),¹²⁸ and medical publications developing practice guidelines for the assessment and management of the minimally conscious state did not appear until 1996 and 1997 (one and two years before Mathew died).¹²⁹ Frequent debates about the diagnosis and meaning of the MCS continued to appear throughout 2002.¹³⁰ Thus, one may argue that emerging diagnostic criteria, when applied to Mathew's condition, resulted in a then-medically current diagnosis, albeit imprecise. Without diagnosing Mathew's condition retrospectively, this section addresses the law and ethics of providing life-sustaining treatment to patients who are in either a vegetative state or an MCS.

1. The Importance and Implications of Precise Diagnoses

The precise diagnosis of a vegetative state or an MCS is overwhelmingly important for purposes of treatment, research, and public policy. Although individuals in a vegetative state recover the cyclical alteration of arousal patterns, and thus, have some brainstem function (in contrast to whole brain death), vegetative individuals are not conscious. In contrast, individuals in the minimally conscious state do demonstrate some degree of consciousness,¹³¹ although some minimally conscious individuals have suffered diffuse structural damage comparable to patients who are in the persistent vegetative state. These minimally conscious individuals would still be considered "hopelessly damaged" in the view of Harvard anesthesiologist and bioethicist H.K. Beecher, although they do not suffer from permanent loss of consciousness.¹³² Therapeutic efforts to restore

127. See *Day & Date: Message to Mathew*, *supra* note 6 (identifying Mathew's response to his parents and Celine Dion's music).

128. See *supra* note 79 and accompanying text.

129. Michael W. O'Dell et al., *Standardized Assessment Instruments for Minimally-Responsive, Brain-Injured Patients* 6 *NEURO REHAB* 45-55 (1996); Pilon & Sullivan, *Motor Profile of Patients in Minimally Responsive and Persistent Vegetative States*, 6 *BRAIN INJURY* 421-37 (1996).

130. See *supra* notes 81, 82 and accompanying text. See also Lang et al., *Cognitive Processing in Patients in Vegetative State and Minimally Conscious State*, 16 *J. PSYCHOPHYSIOLOGY* 228 (2002).

131. *Fins 2*, *supra* note 79, at 324.

132. *Id.*

cognitive function to some of these individuals may be as futile as in the case of patients in a persistent vegetative state.¹³³

However, the low-level functioning of a minimally conscious individual cannot necessarily be equated to overwhelming structural damage.¹³⁴ An individual with minimal consciousness near the borderline of emergence may show “a wide preservation of distributed networks that selectively activate in response to spoken language.”¹³⁵ These latter individuals may have a neuronal substrate that might support and sustain additional cognitive recovery.¹³⁶ Since these individuals are neither permanently unconscious nor necessarily “hopelessly damaged,” *à la* Beecher, some clinicians believe that they may warrant additional evaluation.¹³⁷ Thus, the ability to diagnose with clarity the precise state of individuals who have suffered severe traumatic brain injury is immensely important.¹³⁸

Assuming that clinicians can accurately distinguish between and diagnose vegetative and minimally conscious states,¹³⁹ such distinctions have “profound ethical significance.”¹⁴⁰ For example, a clinician who has diagnosed an individual as persistently vegetative may need to initiate a discussion with the individual’s family regarding futility and the need for palliative care given the fact that “the extent of the [individual’s] injury virtually precludes the potential for demonstrable benefit” from available treatments and interventions.¹⁴¹ On the other hand, a clinician who has diagnosed an individual as minimally conscious may need to consider whether the individual should be a candidate for additional study and treatment, as discussed *infra* in Sections IV and V.¹⁴² The ability of a physician to accurately diagnose and distinguish vegetative and minimally conscious states raises additional issues as well. For example, if clinicians proceed to identify minimally conscious individuals for whom additional treatment may be appropriate, have those clinicians minimized the value of

133. *Id.*

134. *Id.*

135. *Id.*

136. *Id.* at 324-25.

137. Fins 2, *supra* note 79, at 325.

138. *Id.*

139. See, e.g., Tom Buckley, *Withdrawal of Tube Feeding in a Patient with Persistent Vegetative State Where the Patient’s Wishes Are Unclear and There Is Family Dissension*, 8 CRITICAL CARE 79 (2004) (identifying the difficulty of securing a precise diagnosis with respect to the particular case under review: “[t]here is some controversy regarding the extent of her brain damage; some doctors have diagnosed her as being in a PVS whereas others disagree.”).

140. Fins 2, *supra* note 79, at 325.

141. Fins 1, *supra* note 3, at 275.

142. Fins 2, *supra* note 79, at 325.

the lives of the persistently vegetative individuals who will not be considered for treatment?

2. Factors That May Contribute to the Endless Provision of Futile Care

Infrequent, but nevertheless dramatic, cases involving individuals diagnosed (sometimes incorrectly) as vegetative but who ultimately regain consciousness support our culture's common belief that physicians and families should "never give up hope" or discontinue artificial life support.¹⁴³ However, these beliefs are at odds with the current evidence-based clinical literature. Only a very small percentage of individuals in true persistent vegetative states actually regain consciousness. Although adults generally "have a 50 percent chance and children a 60 percent chance of recovering consciousness from a PVS within the first 6 months,"¹⁴⁴ adults have less than one half of one percent (*i.e.*, .005) chance of regaining consciousness after spending six months in a persistent vegetative state.¹⁴⁵ In addition, the tiny percentage of such patients who do regain consciousness also may fall back into a vegetative state.¹⁴⁶ Traumatic brain injury that is severe enough to result in the individual remaining in a persistent vegetative state for several months also usually causes the individual to struggle with permanent cognitive, neurological, physical, and emotional disabilities upon regaining consciousness.¹⁴⁷ One certainly may argue that, "[e]ven those who believe in the sanctity of life would hesitate to embrace an existence with such limitations."¹⁴⁸ However, health care providers "not infrequently find themselves in the conundrum of providing futile care to a hopelessly ill patient."¹⁴⁹ "This is a frustrating endeavor, at a minimum, which is worsened when the prospects of continuing futile care seem

143. William J. Winslade, *What to Do with Our Real-Life Rip Van Winkles?*, HOUSTON CHRON., Apr. 11, 1996, at 25A [hereinafter *Rip Van Winkle*] (discussing the case of Gary Dockery, the forty-two year old Tennessee policeman who, in 1996, emerged from a persistent vegetative state after seven and one-half years). See also END OF LIFE CARE: MIRACLES: A NON-COMPREHENSIVE COMPENDIUM OF CASES OF PATIENTS WHO HAVE AWAKENED AND/OR IMPROVED FOLLOWING A DIAGNOSIS OF PERSISTENT VEGETATIVE STATE, IRREVERSIBLE COMA OR DEATH, at <http://www.all.org/issues/eol07.htm> (identifying thirty similar cases).

144. TRAUMATIC BRAIN INJURY: HOPE THROUGH RESEARCH, NAT'L INST. OF NEUROLOGICAL DISORDERS AND STROKE, NAT'L INSTS. OF HEALTH, PUB. NO. 02-158, (2002), available at http://www.ninds.nih.gov/health_and_medical/pubs/TBI.pdf.

145. *Rip Van Winkle*, *supra* note 143, at 25A.

146. *Id.*

147. *Id.*

148. *Id.*

149. Stanley A. Nasraway, *Unilateral Withdrawal of Life-Sustaining Treatment: Is It Time? Are We Ready?* 29 CRITICAL CARE MEDICINE 215 (Jan. 2001).

endless.”¹⁵⁰

Our culture’s common belief that physicians and families should never stop treating patients may be attributed to several factors. First, physicians and families often suffer from “therapeutic illusions,” a phenomenon first labeled by K.B. Thomas.¹⁵¹ According to Thomas, therapeutic illusions arise when a patient improves after a treatment with no proven effect and the administering physician attributes the improvements to such treatment.¹⁵² In this article, the term “therapeutic illusion” is used more broadly to include situations in which a patient, family, surrogate decision maker, or physician believes that a particular treatment or research protocol will improve the patient’s condition despite the likelihood that such treatment will have no beneficial effect. Individuals suffering from therapeutic illusions may not want to discontinue one or more treatments because of the unrealistic hope that such treatments will be beneficial.¹⁵³

Second, many hospital administrators and health care professionals mistakenly believe that the failure to do everything possible to save the life of a patient risks legal liability and bad publicity.¹⁵⁴ Third, our culture

150. *Id.*

151. *See* Thomas, *supra* note 5.

152. *Id.*

153. The prevalence of therapeutic illusions is better understood in light of prospective studies showing that family members of patients diagnosed as clearly vegetative failed to understand (or simply refused to acknowledge) the patient’s true state, despite the health care team’s valiant and repeated attempts to explain the patient’s actual condition. One study involving patients in a persistent vegetative state showed that: “a large number of family members think that the patients are either semiconscious, sleepy or conscious. Most of them also think that the patients can feel pain and have emotion.” Ashok Karnik, *Persistent Vegetative State: Family Members’ Understanding and Reaction to It*, 118 CHEST 276S (2000) (discussing the results of a study involving family members of patients with PVS who responded to a questionnaire, which attempted to establish their understanding of the PVS, their perception of the patient’s consciousness, emotions and awareness of the surroundings, their views about the treatment being given to the patient and the impact of the whole situation on the respondent’s emotional state and the family as a whole). The researchers in this study concluded that additional family education is needed to dispel misconceptions regarding the persistent vegetative state.

154. Courts have upheld physicians’ decisions to unilaterally withdraw life-sustaining treatment from patients. *See infra* note 170. In addition, state advance directive laws may contain immunity provisions that protect health care professionals who comply with advance directives in good faith. *See, e.g.*, FLA. STAT. ANN. § 765.109 (“A health care facility, provider, or other person who acts under the direction of a health care facility or provider is not subject to criminal prosecution or civil liability, and will not be deemed to have engaged in unprofessional conduct, as a result of carrying out a health care decision made in accordance with the provisions of this chapter.”); N.J. STAT. ANN. § 26:2H-73(a) (“A health care representative shall not be subject to criminal or civil liability for any actions performed in good faith and in accordance with the provisions of this act to carry out the terms of an advance directive.”); OHIO REV. CODE ANN. § 1337.15(A) (“an attending physician of a principal is not subject to criminal prosecution or professional disciplinary action and is not

demonstrates a robust current of vitalism, defined as the value system that holds that any human life is precious and should be biologically prolonged as long as possible and at any cost.¹⁵⁵ Fourth, because technological advances in trauma care make it possible for physicians and emergency personnel to save the lives of many individuals who have suffered very severe traumatic brain injury, and some individuals believe that discontinuing treatment wastes all of the trauma team's hard work.¹⁵⁶ Finally, hospital administrators and physicians arguably have a vested financial interest in prolonging the lives of individuals with any form of health insurance coverage. Together, these factors may contribute to a seemingly endless provision of maintenance care:

But the heroic urge to rescue, so fitting for emergency situations, exerts a prolonged influence in our health care system. Aggressive intervention to save the lives of trauma victims is often followed by stubborn resistance to withdrawing care, even when it is obvious that the continuation of life-sustaining procedures is futile. Once we've initiated rescue in a medical setting, we seem unable to stop. . . . [h]aving pulled a trauma victim back from the brink of death, we seem unable to accept the fact that our medical system may not be able to help that person resume any but the most technical semblance of a life.¹⁵⁷

A careful analysis of Mathew's case, however, does not reveal a significant influence of any of these factors. First, neither Dr. Bontke, Mathew's attending physician, nor Mathew's parents had unrealistic expectations in Mathew's case. Indeed, several news and television reports capture Dr. Bontke confirming that Mathew likely would never regain awareness of himself or his environment, and stating that Mathew would likely die within seven years.¹⁵⁸ Despite Mathew's parents' statements linking Mathew's smiles with their visits and Celine Dion's music, and Mr.

liable in damages in a tort or other civil action for actions taken in good faith and in reliance on a health care decision when all of the following are satisfied . . . "); TEX. HEALTH & SAFETY CODE § 166.044(a) (stating that "[a] physician or health care facility that causes life-sustaining treatment to be withheld or withdrawn from a qualified patient in accordance with this subchapter is not civilly liable for that action unless the physician or health care facility fails to exercise reasonable care when applying the patient's advance directive.").

155. WINSLADE, *supra* note 66, at 117. See also Richard McCormick, *Theology and Bioethics*, HASTINGS CTR. REPORT 5, 10 (Mar./Apr. 1989) (explaining that "the Catholic tradition has moved between two extremes: medicomoral optimism or vitalism (which preserves life with all means, at any cost no matter what its condition) and medicomoral pessimism (which actually kills when life becomes onerous, dysfunctional, boring).").

156. WINSLADE, *supra* note 66, at 116 (noting that the health care system "does an outstanding job of snatching them back from sudden and untimely death.").

157. *Id.*

158. See *Day & Date: Message to Mathew*, *supra* note 6.

Kosbob's statement that he had "hope" in light of Mathew's young age, in several television reports Mathew's mother clearly articulated her understanding that "Mathew's prognosis [was] horrible," and that he was dying "a long, slow, horrible death."¹⁵⁹ In addition, Mathew's father clearly stated, while Mathew was still technically alive, that "[h]e never expected his son to die so young."¹⁶⁰ Mathew's parents executed a do-not-resuscitate (DNR) order and refused the administration of mechanical assistance other than feeding. Thus, neither Dr. Bontke nor Mathew's parents appeared to be therapeutically illusioned. Dr. Bontke's March 1996 "blunt and brutal prognosis," as well as Dr. Bontke's identification of two available options for the Kosbob family (*i.e.*, discontinuing feeding and discontinuing the provision of antibiotics necessary to fight Mathew's future infections), support the conclusion that Dr. Bontke was neither persuaded by concerns for professional liability nor unduly influenced by financial incentives.

Mathew's parents ultimately concluded that it was their "job . . . to protect and support Mathew and to allow him to make the decision when and how he would move on."¹⁶¹ To the extent Mathew's parents believed that Mathew's life was precious, that Mathew retained human dignity, and that Mathew had the right to be monitored for clinical signs of eventual recovery until he passed away notwithstanding numerous medical interventions, Mathew's parents' decision exhibits strains of vitalism and is generally consistent with the Pope's current position.¹⁶²

3. The Law and Ethics of Continuing and Discontinuing Treatment

If an individual who has suffered a severe traumatic brain injury has documented his or her preference for the withholding or withdrawal of life-sustaining treatment in an advance directive, then the ethical principle of autonomy¹⁶³ and the legal doctrines of self-determination and informed consent,¹⁶⁴ generally would require the physician to adhere to the

159. *Id.*

160. *Id.*

161. E-Mail from William Kosbob, *supra* note 7.

162. *See supra* text accompanying note 158. *See also infra* Section V, discussing the Pope's current position.

163. BEAUCHAMP & CHILDRESS, *supra* note 121, at 57-104 (discussing the ethical principle of respect for autonomy); JONSEN ET AL., *supra* note 109, at 48-49 (discussing the ethical significance of patient preferences and autonomy); GARRISON & SCHNEIDER, *supra* note 121, at Chapters 1, 2, 3, 4, and 7 (discussing the principle of autonomy).

164. GARRISON & SCHNEIDER, *supra* note 121, at Chapters 1, 2, 3, and 4 (discussing the legal doctrines of self determination and informed consent); 42 U.S.C. § 1395cc(f)(1)(A)(i) (the federal Patient Self Determination Act); 42 C.F.R. § 489.102 (federal regulations implementing the Patient Self Determination Act). *See also* Peter A. Singer et al., *Hospital Policy on Appropriate Use of Life-Sustaining Treatment*, 29 CRITICAL CARE MED., 187, 188

individual's preference as documented in his or her advance directive. Similarly, if an individual with traumatic brain injury has documented his or her preference for the administration of life-sustaining treatment, then the ethical principle of "respect for autonomy," as well as the legal doctrine of self-determination, would require the physician to consider, or give weight, to that choice, even if the physician would not consider the quality of the traumatic brain injury victim's life worth living.

The trickiest situation results when an individual in a persistent vegetative or MCS has not documented his or her preference for life-sustaining treatment, as in Mathew's case. If the individual's physician has determined that the individual's condition virtually precludes the potential for demonstrable benefit through life-sustaining treatment or other interventions, but the individual's family or surrogate decision-maker requests such treatment, no widely accepted ethical and legal framework exists to govern decision-making. To make matters more confusing, in many cases in which the patient's family has sought treatment and the physician has objected based on his or her belief that the treatment offers no medical benefit, the courts have ruled in favor of the family.¹⁶⁵ Accordingly, as discussed in more detail in Section V below, policy development plays an important role in guiding the practice of physicians.¹⁶⁶

In cases involving patients like Mathew who suffer from severe traumatic brain injuries, one certainly could support, both legally and

(Jan. 2001) (stating that "[a] competent refusal of treatment must be respected based on the ethical principle of respect for persons and the legal doctrine of self-determination and informed consent.").

165. Judith F. Daar, *Medical Futility and Implications for Physician Autonomy*, 21 AM. J.L. & MED. 221, 230-232 (1995). Statutory law upholding a physician's and hospital's unilateral right to withhold or withdraw treatment. In *Gilgunn v. Massachusetts General Hospital*, several physicians decided to unilaterally withdraw therapy from a comatose, elderly, ventilator-dependent, critically ill patient. In doing so, the physicians followed a fair process for futility determination, which included consultation with other physicians and with the hospital ethics committee. Numerous attempts to communicate with the family and to help them comprehend the dire medical situation of their mother were unsuccessful. The ventilator was unilaterally removed and the patient died. The family sued the physicians and the hospital, alleging intentional infliction of emotional distress. The fourteen-member jury found that the defendants' decision to unilaterally withdraw care was in accordance with accepted standards of medical practice despite demands for further treatment. *See also* Nasraway, *supra* note 149, at 215 & n.10 (discussing *Gilgunn v. Mass. Gen. Hosp.*). *But see* Conservatorship of Wendland, 28 P.3d 151, 153-154 (Cal. 2001) (holding that before a patient's conservator can withdraw a patient's life-sustaining nutrition and hydration, the conservator is required to prove, by clear and convincing evidence, either that the patient wished to refuse life-sustaining treatment or that to withhold such treatment would have been in his best interest).

166. Singer et al., *supra* note 164, at 187.

ethically, the decision to shift the intent of care toward comfort and closure. Arguments in favor of such a shift include: (1) continuing treatment that provides no benefit to the patient constitutes therapeutic futility;¹⁶⁷ (2) continuing treatment may unnecessarily prolong suffering for the patient and his or her family;¹⁶⁸ and (3) continuing expensive treatment, without any proof that the patient will benefit from such treatment, is therapeutically extravagant.¹⁶⁹ Withdrawing or withholding care based in whole or in part on the costs of such care is known as bedside rationing.¹⁷⁰ When the benefits of a particular treatment are minimal and the costs of that treatment are high, bedside rationing has been identified as one way to preserve limited medical and financial resources and avoid therapeutic extravagance.¹⁷¹

When a case such as Mathew's involves diagnostic uncertainty, the continuation of treatment is legally and ethically permissible. Indeed, one may argue that in cases involving minimally conscious patients who are near the level of emergence, the failure to provide treatment may constitute therapeutic nihilism, which we define as the failure to recognize the possible benefits of treatment.¹⁷² As discussed in more detail in Section IV *infra*, to the extent a minimally conscious individual could potentially benefit from additional treatment or intervention (including emerging brain stimulation techniques), an ethical analysis may support the provision of

167. See, e.g., CODE OF MEDICAL ETHICS, *supra* note 107, at E-2.035 (addressing futile care). See also Thomas, *supra* note 5 (defining therapeutic illusion).

168. A.Y. Goh & Q. Mok, *Identifying Futility in a Paediatric Critical Care Setting: A Prospective Observational Study*, 84 ARCHIVES OF DISEASE IN CHILDHOOD 265, 265 (2001) (stating that "[i]t is important, both from an ethical as well as an economic viewpoint, for physicians to recognize the limits of intensive care, as it may lead to unnecessary prolongation of suffering for children and their families."). Indeed, many of the news and television reports reveal Mathew's parents' and two other children's overwhelming and intense suffering. E.g., *Day & Date: Message to Mathew*, *supra* note 6.

169. See Thomas, *supra* note 5 (defining therapeutic extravagance as the provision of high-cost treatments that offer little or no benefit).

170. See, e.g., Peter A. Ubel & Susan Goold, *Recognizing Bedside Rationing: Clear Cases and Tough Calls*, 126 ANNALS INTERNAL MED. 74, 74 (1997) (discussing bedside rationing).

171. See generally DAVID M. EDDY, CLINICAL DECISION MAKING: A COLLECTION OF ESSAYS FROM THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (Jones & Bartlett Publ'rs 1996) (discussing the balance between quality and cost and physician responsibilities relating to health care rationing).

172. Whether a particular patient presents a case of therapeutic futility or therapeutic nihilism is not always clear. For example, in the context of cardiovascular disease in an octogenarian, one physician has explained, "[t]here is a fine balance between therapeutic nihilism and therapeutic futility when treating elderly people." John Campbell, *Cardiovascular Disease in the Octogenarian and Beyond*, 318 BRIT. MED. J. 1015 (1999) (book review).

such intervention. Unfortunately, a determination of whether a particular treatment decision constitutes therapeutic futility or extravagance at one extreme, or therapeutic nihilism on the other, requires a fact-intensive analysis and the resolution of any diagnostic uncertainty.

IV. THE LAW AND ETHICS OF RESEARCH

The Brain Injury Association of America emphasizes that traumatic brain injury is one of the primary challenges to clinicians and scientists and stresses that the complexity of traumatic brain injury only intensifies the need for research.¹⁷³ Research involving emerging techniques of neuromodular (*i.e.*, deep brain) stimulation may offer hope for individuals who are in the MCS but have widely preserved neural networks.¹⁷⁴ Because some physicians, families, and surrogates may refuse to terminate life-sustaining treatment provided to individuals in minimally conscious states, research may also provide “a flicker of hope as well as a humane response to [minimally conscious patients].”¹⁷⁵ This section examines the traditional and advanced legal and ethical principles that apply to research involving patients in persistent vegetative and minimally conscious states, the law and ethics of surrogate decision-making for such patients, and the law and ethics of deep-brain stimulation.

A. *Traditional Legal and Ethical Research Principles*

Although research offers hope for the future of individuals with traumatic brain injury, utilizing human subjects in research certainly is not without conflict. Researchers must ensure that federally-sponsored research involving human subjects is approved by an institutional review board

173. Several research efforts relating to traumatic brain injury already are underway. For example, the Traumatic Brain Injury National Data Center (TBINDC) at Kessler Medical Rehabilitation Research and Education Center is the coordinating center for the research and dissemination efforts of the Traumatic Brain Injury Model Systems (TBIMS) program, which is funded by the National Institute on Disability and Rehabilitation Research (NIDRR). The TBIMS program consists of sixteen additional comprehensive systems of care distributed throughout the United States that conduct innovative research and provide “model” care to persons who experience traumatic brain injury. TRAUMATIC BRAIN INJURY MODEL SYSTEMS NATIONAL DATA CENTER, *About the TBIMS Centers*, available at http://www.tbinc.org/main_centers.php (last visited Oct. 15, 2004). The TBIMS program seeks to improve the lives of persons who experience traumatic brain injury, their families and their communities by creating and disseminating new knowledge about the course, treatment and outcomes relating to their condition. ABOUT THE TBI NATIONAL DATA CENTER, TRAUMATIC BRAIN INJURY MODEL SYSTEMS NATIONAL DATA CENTER, at http://www.tbinc.org/registry/about_registry.php (last visited Oct. 15, 2004).

174. See, *e.g.*, Fins 1, *supra* note 3, at 275.

175. Winslade, *supra* note 80, at 178-79.

(IRB) and satisfies the legal standards set forth in the federal Department of Health and Human Services' (or other appropriate agency's) protection of human subjects regulations, frequently referred to as the Common Rule.¹⁷⁶ The Common Rule requires IRBs to determine that research projects meet several criteria.¹⁷⁷ In addition, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, individuals with mental disabilities, or economically or educationally disadvantaged persons, additional safeguards must be included in the study to protect the rights and welfare of the subjects.¹⁷⁸ The Common Rule does not, however, contain any provisions that specifically regulate research involving individuals who are cognitively impaired.¹⁷⁹

Incorporated in the broad categories of respect for persons, beneficence, and justice, the Belmont Report establishes additional ethical principles to which researchers must adhere.¹⁸⁰ Under respect for persons, the Belmont Report states that researchers have an ethical duty to ensure that research subjects enter into studies voluntarily and with adequate information to be

176. The federal Department of Health and Human Services' protection of human subjects regulations are set forth at 45 C.F.R. Part 46 (2003).

177. For example, the federal Department of Health and Human Services' protection of human subjects regulations require IRBs to determine that, under the research project: (1) risks to subjects are minimized; (2) risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result; (3) selection of subjects is equitable; (4) informed consent is sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, 45 C.F.R. § 46.116; (5) informed consent is appropriately documented, in accordance with, and to the extent required by, 45 C.F.R. § 46.117; (6) the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects; and (7) the research plan has adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. 45 C.F.R. § 46.111(a)(1)-(7) (2003). For a detailed discussion of the evolution of IRBs and their role in research regulation, see Richard S. Saver, *Medical Research Oversight From the Corporate Governance Perspective: Comparing Institutional Review Boards and Corporate Boards*, 46 WM. & MARY L. REV. (forthcoming 2004).

178. 45 C.F.R. § 46.111(b).

179. OFFICE OF EXTRAMURAL RESEARCH, NAT'L INSTS. OF HEALTH, RESEARCH INVOLVING INDIVIDUALS WITH QUESTIONABLE CAPACITY TO CONSENT: POINTS TO CONSIDER 1 (Mar. 11, 1999), available at <http://grants.nih.gov/grants/policy/questionablecapacity.htm> [hereinafter QUESTIONABLE CAPACITY] ("Unlike research involving children, prisoners, pregnant women, and fetuses, no additional Department of Health and Human Services (DHHS) regulations specifically govern research involving persons who are cognitively impaired.").

180. NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, DEP'T OF HEALTH, EDUC., AND WELFARE, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Apr. 18, 1979), available at <http://www.ohsr.od.nih.gov/guidelines/Belmont.html> (last visited Oct. 15, 2004) [hereinafter THE BELMONT REPORT].

able to give their informed consent to their participation.¹⁸¹ This ethical duty is based on the principle that autonomous persons are capable of deliberating about personal goals and responding accordingly.¹⁸² The principle of respect for persons also requires protection of individuals with diminished autonomy or capacity.¹⁸³ Although some individuals are in need of greater protection, including individuals who lack the capacity to make their own decisions,¹⁸⁴ other individuals require little additional protection beyond assuring their participation in research activities is undertaken freely and with awareness of any possible adverse consequences.¹⁸⁵ Finally, the principle of respect for persons requires seeking the permission of other parties in order to protect a subject with limited capacity from harm.¹⁸⁶ Subjects with limited capacity are respected by acknowledging their own wishes and by employing third parties to ensure the subjects' well being.¹⁸⁷

The Belmont Report explains that the extent of the protection afforded to the research subject should evaluate the risk of harm in relation to the likelihood of benefit.¹⁸⁸ For example, if an individual with traumatic brain injury has no cognitive deficits but does suffer from a physical impairment such as spasticity, and a potential research protocol would simply involve the tracking of the progress of the individual with spasticity before, during, and after participation in a coordinated plan of rehabilitation and education, then the risk of harm would appear small and the likelihood of benefit may be moderate to great. On the other hand, if the proposed research involved an emerging brain stimulation technique, the risks to the traumatic brain injury victim would be more likely and could potentially outweigh the likelihood of benefit.

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.* See NAT'L BIOETHICS ADVISORY COMM'N, *Research Involving Persons with Mental Disorders that May Affect Decision Making Capacity* (Dec. 1998) [hereinafter PERSONS WITH MENTAL DISORDERS], available at <http://www.georgetown.edu/research/nrcbl/nbac/capacity/TOC.htm>. To the extent that the cognitive disabilities of Mathew, or any other similarly situated traumatic brain injury victim, result in the lack of capacity of that victim to make choices, the National Bioethics Advisory Commission (NBAC) likely would be very protective of such individual in accordance with its report. In its report, the NBAC recommends that investigators undertake a capacity assessment process and, at a minimum, require investigators to specify the method by which prospective subjects' decisional capacity will be evaluated and the criteria for identifying incapable subjects.

185. THE BELMONT REPORT, *supra* note 180.

186. *Id.*

187. *Id.*

188. *Id.*

B. *The Law and Ethics of Surrogate Decision-Making*

Potential research subjects who have suffered traumatic brain injuries frequently suffer from cognitive disabilities, and therefore, will have questionable capacity to consent to participation in research. In cases of severe traumatic brain injury such as Mathew's, the potential subject is clearly incapable of consenting to participation in research. Thus, the question arises: how can a severe traumatic brain injury victim legally and ethically be enrolled in a research study? Frequently, surrogate decision-makers are identified as one solution to this legal and ethical problem.¹⁸⁹

Several legal and ethical issues relating to the use of surrogate decision-making for studies involving traumatic brain injury victims exist. The first issue is whether the potential surrogate needs to be formally designated as a legal guardian before he or she is considered qualified to make a decision about the brain injury victim's participation.¹⁹⁰ If a formal designation is not required, can state legislation authorizing family members (and, in a few states, friends) to make certain treatment decisions on behalf of relatives be used to confer authority for research participation decisions as well?¹⁹¹ Or, can research participation authority be assigned to a person based simply on that person's status as a close relative or trusted

189. THE BELMONT REPORT, *supra* note 180. Individuals with questionable capacity (or clear incapacity) to consent may have a family member and/or LAR [legally authorized representative] serve as a surrogate, with this role documented during the consent process. QUESTIONABLE CAPACITY, *supra* note 179, at 3. The NIH panel further recommended that the surrogate's research decisions reflect, whenever possible, the individual's views prior to the period of incapacity. *Id.*

190. THE NAT'L COMM. FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, RESEARCH INVOLVING THOSE INSTITUTIONALIZED AS MENTALLY INFIRM 11-20 (1978) [hereinafter MENTALLY INFIRM].

191. See, e.g., TEX. HEALTH & SAFETY CODE § 313.004(a) (West 2003):
If an adult patient in a hospital or nursing home is comatose, incapacitated, or otherwise mentally or physically incapable of communication, an adult surrogate from the following list, in order of priority, who has decision-making capacity, is available after a reasonably diligent inquiry, and is willing to consent to medical treatment on behalf of the patient may consent to medical treatment on behalf of the patient: (1) the patient's spouse; (2) an adult child of the patient who has the waiver and consent of all other qualified adult children of the patient to act as the sole decision-maker; (3) a majority of the patient's reasonably available adult children; (4) the patient's parents; or (5) the individual clearly identified to act for the patient by the patient before the patient became incapacitated, the patient's nearest living relative, or a member of the clergy.

State legislation such as the Texas Consent to Medical Treatment Act recognizes that important health-related decisions for persons lacking decisional capacity may be appropriately assigned to relatives such as a parent or spouse; one could argue that decisions regarding research participation also may be assigned to such relatives. *Id.*

individual?¹⁹²

A second issue concerns permitting competent individuals to designate their surrogate decision-makers in advance, with the written authorization of a specific person to act on their behalf in the event future incapacity. In theory, such a document (one could call it a “research power of attorney”) could ensure that the autonomous views of an individual who sustains a traumatic brain injury are honored regarding who may be best suited to act on his or her behalf for such decisions. As a practical matter, however, few, if any, individuals who currently suffer from traumatic brain injury made any attempt to designate a person who may act in their best interests.¹⁹³ As a further matter, the fact that very few people have executed general medical powers of attorney suggests that even fewer people may be inclined to execute a research power of attorney. Finally, research powers of attorney cannot be executed by the large population of individuals who currently suffer from severe traumatic brain injuries since they are now incompetent for purposes of legal decision-making.

A third issue relates to whether an individual’s designation as agent in an existing medical power of attorney may confer similar authority for research participation decisions.¹⁹⁴ Again, as a practical matter, very few

192. Support for this last alternative, at least with respect to relatives, comes from the long-held tradition in health care of relying on families to make decisions for incompetent individuals, and the belief that relatives are most likely to make decisions in accordance with the incompetent individual’s values, preferences, and interests. A policy allowing close relatives and friends to make research participation decisions would be easy to administer and has been a common practice in some research settings. For example, policy guidelines adopted by the Alzheimer’s Disease Centers state that “[u]nless there is statutory or case law to the contrary, family members should be recognized as having surrogate authority without prerequisite appointment as guardians or proxies through the use of instruments such as durable powers of attorney.” PERSONS WITH MENTAL DISORDERS, *supra* note 184, at n. 130 (citing Marshall B. Kapp, *Proxy Decision Making in Alzheimer’s Disease Research: Durable Powers of Attorney, Guardianship, and Other Alternatives*, 8 ALZHEIMER’S DISEASE AND RELATED DISORDERS 28, 34 (1994)).

193. See, e.g., Fins 1, *supra* note 3, at 276 (noting that “only 15%-20% of Americans have an advance directive that could lead to the designation of a legally authorized representative”); Fangerlin & Schneider, *supra* note 124, at 32 (noting that roughly eighteen percent of the population has a living will) (citing L.L. Emanuel, *Advance Directives for Medical Care; Reply*, 325 NEW ENG. J. MED. 1256 (1991)).

194. One certainly could argue that the choice of an agent under a medical power of attorney demonstrates the principal’s high degree of trust in the agent and that such trust entitles the agent to make research participation decisions on behalf of the principal. Indeed, the Department of Clinical Bioethics of the National Institutes of Health has adopted a policy allowing medical powers of attorney to make some research decisions for subjects. See DEP’T. OF CLINICAL BIOETHICS, NAT’L INSTS. OF HEALTH, POL. NO. M87-4, CONSENT PROCESS IN RESEARCH INVOLVING IMPAIRED HUMAN SUBJECTS (2003), available at <http://push.cc.nih.gov/policies/PDF/M87-4.pdf> (Fig. 1 notes that if the subject is capable of understanding the existence of his or her medical power of attorney and the level of risk is minimal, then the agent under the medical power of attorney may make research

current and future traumatic brain injury victims have executed general medical powers of attorney that may be adapted to the research context.

Each of the above alternatives raises questions about the accuracy with which the victim's surrogate will express the values and preferences of the brain injury victim. In addition, potential ethical conflicts of interest arise between the brain injury victim and the potential surrogate because those most likely to act as surrogates are family members who may view the traumatic brain injury victim's participation in the research as a way to "lighten the burden of care-giving or lead to treatment from which the family member may benefit."¹⁹⁵ Two empirical studies have found that some family members are willing to allow their incompetent relatives to be entered in a research study even though they thought the relative would refuse if competent and despite the fact that the family member would refuse to enroll in the research study personally.¹⁹⁶

In a December 1998 report entitled "Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity," the National Bioethics Advisory Commission (NBAC) considered all of the above options and made several recommendations relating to surrogate decision-making.¹⁹⁷ The NBAC's recommendations, which have not yet been adopted or rejected by the Department of Health and Human Services, endorse the idea of prospective authorization.¹⁹⁸ Under a prospective authorization, a person who has the capacity to make decisions about participation in research gives authorization to a particular class of research if its risks, potential direct and indirect benefits, and other pertinent conditions have been explained. Based on the prospective authorization, a legally authorized representative (LAR) may enroll the subject after the subject has lost the capacity to make decisions, provided the LAR is available to monitor the subject's recruitment, participation, and withdrawal.¹⁹⁹

However, for reasons similar to those relating to research powers of attorney, prospective authorizations are impractical. Not many individuals are likely to execute an authorization to enroll themselves in a particular

participation decisions).

195. PERSONS WITH MENTAL DISORDERS, *supra* note 184, at Chapter 3 (quoting Edward W. Keyserlingk et al., *Proposed Guidelines for the Participation of Persons with Dementia as Research Subjects*, 38 PERSP. IN BIOLOGY AND MED. 346 (1995)).

196. *Id.*

197. *See id.* (reporting findings concerning the issues surrounding research on persons with mental disorders, including specific recommendations concerning the adoption of surrogate decisionmakers).

198. *Id.* at Recommendation 13.

199. PERSONS WITH MENTAL DISORDERS, *supra* note 184, at Recommendation 13.

research study before they lose their capacity to make decisions.

The NBAC also endorses the use of LARs or persons authorized to make treatment decisions for incapacitated persons for research enrollment decisions.²⁰⁰ Researchers may feel that the NBAC's recommendations are too legalistic or burdensome, and may prefer the suggestions set forth in a 1999 report of a panel of the National Institutes of Health (NIH), permitting individuals with impaired capacity to choose a family member or representative to serve as a surrogate for research decisions provided the representative's role is documented throughout the consent process.²⁰¹ Importantly, both the NBAC and NIH recommendations require someone other than the researcher to have the authority to make decisions on behalf of incapacitated persons regarding enrollment in research studies. This requirement is intended to protect vulnerable persons from exploitation, to protect researchers from the appearance of impropriety, to diminish the credibility of claims that subjects are being exploited, and to enhance the integrity of research and facilitate the process of recruitment.

C. Advanced Research Ethics Principles: Conflicts of Interest Arising out of the Dual Role of Clinician/Researcher

Physicians have a primary duty of loyalty to their patients.²⁰² In the context of therapeutic research, physician researchers also have a duty to carry out their research in a rigorous, scientific manner. Additionally, physician researchers are subject to secondary influences and interests, which can result in one or more conflicts of interest.²⁰³

In therapeutic research, the primary interests of the physician researcher include the patients' best interests (and patients generally expect physicians to be focused primarily on their care, even when they are enrolled as research subjects), the collection of accurate data, and the physician researcher's rigorous pursuit of his or her research. The secondary interests of the physician researcher encompass all other interests including, but certainly not limited to, tenure, authorship and publication, fame, additional research and grants, and the financial interests of both the physician researcher and the study's sponsor. Such financial interests may lead to direct or indirect institutional pressure to conduct research, or to include

200. *Id.*

201. QUESTIONABLE CAPACITY, *supra* note 179, at 3.

202. *See, e.g.*, CODE OF MEDICAL ETHICS, *supra* note 107, at E-10.015 ("Within the patient-physician relationship, a physician is ethically required to use sound medical judgment, holding the best interests of the patient as paramount.").

203. *See* BLACK'S LAW DICTIONARY 271 (5th ed. 1979) (defining a conflict of interest as a "clash between public interest and the private pecuniary interest of the individual concerned").

patients in clinical trials (which may jeopardize appropriate informed consent and subject selection procedures), or institutional review board pressure to approve research. Secondary financial interests have influenced some researchers to violate standards of informed consent and to falsify data with respect to inclusion of subjects.²⁰⁴ These scandals highlight the need for more stringent review of the research process.

Financial conflicts of interest may have an even greater long-term impact on the existence of research relating to traumatic brain injury. When research institutions depend heavily on private funding and individual researchers are pressured to obtain and maintain such funding, less lucrative research projects may be delayed or shelved indefinitely. For example, a brain researcher may be pressured to participate in a clinical trial assessing the effectiveness of an expensive drug that may help repair damaged brain tissue or help the brain re-route functions once handled by cells. On the other hand, a brain researcher may have little financial incentive to research the effect of a well-coordinated plan of treatment, rehabilitation, and education regarding the prognosis of indigent individuals with traumatic brain injury. Although some commercial sponsors support non-lucrative research and clinical care interventions, many commercial sponsors are less likely to be interested in research that will not be financially profitable. One result may be that investigators who conduct vitally important, but not ultimately financially profitable, research may have difficulty recruiting patients because of the volume of industry-sponsored research.

Physician researchers can assuage the negative effects of conflicts of interest by being mindful of the multiple roles of clinician and investigator and by adhering to certain procedures and safeguards designed to protect the welfare of potential research subjects. First, physician researchers should only agree to participate as investigators in clinical trials when the investigation relates to the physician's scope of practice and area of medical expertise. The physician researcher should have adequate training in the conduct of research and should participate in protocols that are scientifically sound.²⁰⁵ For example, emerging techniques relating to deep brain stimulation may offer hope for brain injury victims who are in a minimally conscious state and have widely preserved neural networks; however, a debate exists about whether deep brain stimulation research is scientifically sound.²⁰⁶ Thus, any physician researcher who considers investigating such techniques must make his or her own determination regarding the

204. See, e.g., Saver, *supra* note 177 (discussing the Jesse Gelsinger research scandal).

205. CODE OF MEDICAL ETHICS, *supra* note 107, at E-8.0315 (entitled "Managing Conflicts of Interest in the Conduct of Clinical Trials").

206. See *infra* Part IV.D.

soundness of such controversial techniques.

Second, physicians should be familiar with the ethics of research and should agree to participate in clinical trials only if they are satisfied that an institutional review board has reviewed the protocol, that the research does not impose undue risks upon research subjects, and that the research conforms to government regulations including, but not limited to, the Common Rule. Although many physicians who engage in research are well aware of, and rely on, the IRB process, physicians who engage in research also have an independent ethical obligation to avoid mere reliance on institutional review board approval if such reliance would not be in the best interests of their patients.²⁰⁷

Third, when a physician has treated or continues to treat a patient who is eligible to enroll as a subject in a clinical trial that the physician is conducting, the informed consent process must differentiate between the physician's roles as clinician and investigator.²⁰⁸ The informed consent process should also disclose the nature and source of funding and financial incentives offered to the physician researcher, including information on uncertainties that may exist regarding funding of treatment for possible complications that may arise during the course of the trial. One way to ensure that the patient understands the distinction between the physician's role as a clinician and the physician's role as an investigator, as well as the nature and source of financial interests faced by the physician researcher, is to require an independent third person who is shielded from the financial interests faced by the physician researcher to obtain the patient's informed consent for participation in the clinical trial. This person, or another unbiased individual, could also stand in the role of the "research subject advocate"²⁰⁹ and be responsible for responding to concerns of research

207. See PRINCIPLES OF MEDICAL ETHICS VII, *supra* note 108, at 4 (providing that physicians shall "regard responsibility to the patient as paramount"). See also CODE OF MEDICAL ETHICS, *supra* note 107, at E-10.015 and E-8.031 (providing that "a physician is ethically required to . . . [hold] the best interest of the patient as paramount" and that the "[a]voidance of real or perceived conflicts of interest in clinical research is imperative if the medical community is to ensure objectivity and maintain individual and institutional integrity"); Trudo Lemmens & Paul B. Miller, *The Human Subjects Trade: Ethical and Legal Issues Surrounding Recruitment Incentives*, 31 J.L. MED. & ETHICS 398, 406-07 (2003). Researchers, physicians, and others involved in research are obliged to familiarize themselves with research ethics guidelines and to treat these as binding professional standards governing their personal involvement in all research-related activities.

208. CODE OF MEDICAL ETHICS, *supra* note 107, at E-8.0315 (addressing "Managing Conflicts of Interest in the Conduct of Clinical Trials").

209. See, e.g., Kathleen M. Neill, *Research Subject Advocate: A New Protector of Research Participants*, 10 ACCOUNTABILITY IN RESEARCH: POLICIES AND QUALITY ASSURANCE 159 (July-Sept. 2003) (explaining that in 2001, the National Center for Research Resources directed the 78 General Clinical Research Centers to develop a Research Subject

subjects, providing additional information to research subjects, and acting as an intermediary between the research subject and the investigators. Research subject advocates may be a valuable tool for protecting research institutions from exploiting research subjects, enhancing the integrity of the research, and facilitating the process of subject recruitment.

Fourth, any financial compensation the physician researcher receives from the sponsors of the clinical trial should be commensurate with the efforts of the physician researcher performing the research and should not exceed the fair market value of the investigation services provided by the physician.²¹⁰ The rate of compensation per patient should not vary according to the volume of subjects enrolled by the physician, and the offering of compensation must meet other existing legal requirements.²¹¹

Fifth, physician researchers should ensure that their clinical trials include provisions for the funding of subjects' medical care in the event of complications associated with the research.²¹² Physician researchers should ensure that they do not bill third party payors when they have received funds from the research sponsor that cover the expenses related to conducting the trial.²¹³

Sixth, when entering into contracts to perform research, physician

Advocate (RSA) position. According to Neill, "[t]he RSA role actualizes the ethical principles of respect for persons, justice, and beneficence that are the foundation of the protection of research participants.").

210. CODE OF MEDICAL ETHICS, *supra* note 107, at E-8.0315. The theory underlying this argument is similar to the theories that underlie the federal anti-kickback statute and the federal Stark Law which, very generally, prohibit physicians from receiving remuneration or engaging in financial relationships in which: (1) the remuneration exchanged between the parties exceeds the fair market value of any services provided by the physician; or (2) the remuneration exchanged between the parties is based on the volume or value of patient referrals for government health care program services. See the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (2000 West Supp. 2004); 56 Fed. Reg. 35,952 (July 29, 1991); 57 Fed. Reg. 52,723 (Nov. 5, 1992); 61 Fed. Reg. 2122 (Jan. 25, 1996) ("safe harbor" regulations interpreting and implementing the anti-kickback statute). See also the Federal Stark Law, 42 U.S.C. § 1395nn (2000 West Supp. 2003); 60 Fed. Reg. 41,914 (Aug. 14, 1995); 63 Fed. Reg. 1,659 (Jan. 9, 1998); 66 Fed. Reg. 856 (Jan. 4, 2001); 69 Fed. Reg. 16,053 (Mar. 26, 2004) (regulations interpreting and implementing the Stark law).

211. See CODE OF MEDICAL ETHICS, *supra* note 107, at E6.0315 (addressing "Fee Splitting: Referral to Health Care Facilities," and explaining that it is unethical for physicians to accept payment solely for referring patients to research studies).

212. *Id.*

213. CODE OF MEDICAL ETHICS, *supra* note 107, E-8.0315. Researchers who bill third party payors for the provision of health or medical services when they have received funds from a research sponsor to conduct a clinical trial may violate, or subject themselves to, civil, criminal, and administrative penalties under the federal Mail and Wire Fraud statutes (18 U.S.C. §§ 1341, 1343 (2000 West Supp. 2002)), the federal civil False Claims Act (31 U.S.C. § 3729(a) (2000)), and the federal Civil Money Penalties Law and implementing regulations (42 U.S.C. §§ 1320a-7a(a)(1)(E) (2000); 42 C.F.R. § 1003.102(a)(6) (2003)).

researchers should determine that the contractual requirements do not unduly delay or otherwise obstruct the publication of the research results.²¹⁴

In summary, physician researchers who have multiple relationships with patients, their families, other health care providers, hospital administrators, employers, third party payors, managed care organizations, federal and state governments, and pharmaceutical or other companies that sponsor research will, without a doubt, face numerous conflicts of interest. Physician researchers may be able to lessen the negative effects of some of these conflicts if they follow proposed guidelines.

D. The Law and Ethics of Deep Brain Stimulation Research

1. An Introduction to Deep Brain Stimulation and its Psychosurgery Predecessor

Assuming that clinicians can distinguish between, and accurately diagnose, vegetative and minimally conscious states, and that intervention is justified in some cases, the legal and ethical implications of research investigating such interventions must be analyzed.²¹⁵ Although no therapy to restore consciousness currently exists, Dr. Nicholas Schiff and his colleagues at the Weill Medical College of Cornell have collected clinical and experimental data to support the hypothesis that using emerging neuromodulation techniques will remediate chronically impaired cognitive function.²¹⁶ The data shows that, although persistently vegetative patients did not benefit cognitively from deep brain stimulation (most likely because they all had an overwhelming loss of functional integration),²¹⁷ a physiological effect, including a wide activation of the cerebrum, as illustrated by marked elevation in cerebral metabolic rates during stimulation, did result.²¹⁸ If deep-brain stimulation is applied to minimally

214. CODE OF MEDICAL ETHICS, *supra* note 107, at E-8.0315 (addressing “Managing Conflicts of Interest in the Conduct of Clinical Trials”). Under the AMA’s Code of Medical Ethics, clinician/researchers, research institutions, and commercial and governmental funding agencies have an ethical obligation to balance their research “portfolios” and to work together to ensure that promising, although not necessary financially profitable, research is not delayed. *See generally* Lemmens & Miller, *supra* note 207 (discussing the AMA’s prohibition of finder’s fees because they are unethical).

215. *Fins 2*, *supra* note 79, at 325.

216. *Id.*

217. *Id.*

218. *Id.* *See also* Martha J. Farah & Paul Root Wolpe, *Monitoring and Manipulating Brain Function: New Neuroscience Technologies and Their Ethical Implications*, 34 HASTINGS CTR. REPORT 35, 41 (May/June 2004) (noting that deep brain stimulation has been used to improve mental function or mood in patients with medically intractable neuropsychiatric illnesses).

conscious individuals with widely preserved neural networks, the theory is that such networks might sustain recovery.²¹⁹

Dr. Schiff and his colleague, Dr. Joseph J. Fins, are concerned, however, that an accurate assessment of deep brain stimulation is threatened by reports in the lay press linking neuromodulation to the crude psychosurgeries and the therapeutic adventurism of W. Freeman, a popular advocate of the therapeutic use of lobotomy.²²⁰ According to Dr. Fins, many of these reports have ignored the complete and accurate history of psychosurgery, including The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research's (National Commission) reports on psychosurgery which, importantly, did not find that psychosurgery had been used for social control, political purposes, or as an instrument for racist repression, as had been alleged.²²¹ Dr. Fins emphasizes that the National Commission did not ban psychosurgical procedures, but instead found "sufficient evidence of efficacy of some psychosurgical procedures to endorse continued experimental efforts as long as strict regulatory guidelines and limitations were in place."²²² According to Dr. Fins, the National Commission's conclusions are important to remember in an effort to prevent any negative views of psychosurgery from coloring research involving emerging neuromodulation techniques in minimally conscious patients.²²³

2. The NBAC's Protectionist Stance

One may view the NBAC's current stance regarding research involving persons with mental disorders that may affect decision-making capacity as protective of potential research subjects.²²⁴ In its December 1998 report addressing this very issue, the NBAC suggested constraining neuromodulation research in individuals with impaired decision-making capacity if "more than minimal risk and no demonstrated prospect of direct medical benefit"²²⁵ existed. "Specifically, the NBAC would permit potentially therapeutic research to proceed with appropriate prospective authorization or surrogate consent, but would severely restrict non-therapeutic Phase I device trials or invasive studies designed to elucidate

219. Fins 2, *supra* note 79, at 325.

220. *Id.*

221. *Id.*

222. *Id.* at 325-26.

223. *Id.* at 326

224. *Id.*

225. Fins 2, *supra* note 79, at 325.

the neurophysiology of the injured brain.”²²⁶ According to Dr. Fins, the NBAC’s current stance raises concern because “many cases of interventional cognitive neuroscience will be difficult to classify as either a therapeutic trial or a non-therapeutic investigation.”²²⁷

Although the United States Department of Health and Human Services (HHS) has not decided whether it will adopt the NBAC’s recommendations, Dr. Fins believes that the NBAC’s recommendations demonstrate a risk-averse attitude with respect to research that could stall or, even worse, prevent neuroscientific advances meant to benefit the very population that the HHS and the NBAC has sought to protect from harm.²²⁸ However, individuals with traumatic brain injury should be included in the neuromodulation research precisely because they have the cognitive dysfunction under investigation.²²⁹

Arguably, the NBAC’s protectionist stance in its December 1998 report is contrary to the fiduciary ethic to enhance access to new interventions that might prove efficacious.²³⁰ “[T]o put it in the language of ethical principles, why have the obligations of distributive justice been so subsumed by an ethic of non-maleficence?”²³¹ Perhaps the silent epidemic of traumatic brain injury, coupled with the lay press’ disregard of the scientific differences between psychosurgery of the past and current neuromodulation technique, “have led to an underappreciation of potential benefits and an overstatement of risks.”²³²

3. Dr. Fins’ Application of Risk-Benefit Principles to Persistently Vegetative and Minimally Conscious Patients

A traditional ethical analysis of deep-brain stimulation research would require the involvement of human subjects in the studies to be justified in accordance with the principles set forth in the Nuremberg Code. Such an analysis would require, among other things, a finding that the hypothesis was robust enough to allow human research (*i.e.*, that “the experiment [is] designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment”). With respect to this issue, Dr. Fins has concluded that:

226. Fins 1, *supra* note 3, at 274.

227. *Id.*

228. Fins 2, *supra* note 79, at 326.

229. Fins 1, *supra* note 3, at 275.

230. Fins 2, *supra* note 79, at 326.

231. *Id.*

232. *Id.* at 325-26.

Having performed probative animal studies and established the theoretical basis for the hypothesis that deep brain stimulation may prove beneficial in improving cognitive function in patients with traumatic brain injury, investigators would be justified in asserting that a clinical trial of this technology had therapeutic intent.²³³

Once therapeutic intent has been demonstrated, investigators still must establish that the possible benefits are proportionate given the foreseeable risks. Stated another way, even if a benefit would occur, if the risks are relatively disproportionate and thus, the intervention too dangerous, the investigators should not proceed.²³⁴ Deep brain research generally would include the use of magnetic resonance imaging, positron emission tomography scans, and of course, stimulation of the brain using electrodes. According to Dr. Fins, the riskiest part of the research, the placement of the electrodes needed to initiate the deep-brain stimulation, has become routine treatment for Parkinson's disease, and has resulted in a mortality of less than one percent, as well as a morbidity between two and three percent.²³⁵ Thus, Dr. Fins argues that the risk associated with the placement of the deep-brain stimulators is not disproportionate to the theoretical benefit.

Finally, once the involvement of human subjects in deep-brain stimulation is scientifically justified, participants must be selected. Selection of subjects must take into consideration harm and the net risk-to-benefit ratio. For example, selecting only persistently vegetative individuals for a clinical trial involving deep-brain stimulation would be problematic because "the extent of their injury virtually precludes the potential for demonstrable benefit."²³⁶ Stated another way, if the placement of deep-brain stimulators is assumed to have some level of risk, even though one could argue that it has a low likelihood of injury in addition to the patient's current persistent vegetative state, and persistently vegetative patients are assumed to have a low likelihood of benefiting from deep-brain stimulation, then the selection of persistently vegetative patients may not yield a positive net risk-to-benefit ratio.²³⁷

On the other hand, minimally conscious individuals can suffer additional harm through the placement of deep-brain stimulators because "[i]nsertion of stimulators has the potential to produce additional injuries which may lead to cognitive deterioration."²³⁸ Minimally conscious individuals also,

233. Fins 1, *supra* note 3, at 275.

234. *Id.*

235. *Id.*

236. *Id.*

237. *Id.*

238. *Id.* The Neuroscience Center at the Cleveland Clinic identifies some of the risks

however, have a “greater theoretical possibility of benefiting from placement of deep brain stimulators”²³⁹ because minimally conscious patients have better preserved brain activity that allows for some interactive behavior and awareness.²⁴⁰ In light of these variables, Dr. Fins concludes that the risk-to-benefit ratio may be more favorable with respect to minimally conscious individuals than with respect to persistently vegetative individuals: “for these reasons, subjects in a minimally conscious state may be best positioned for participation in initial clinical trials.”²⁴¹

E. Conclusions Regarding the Role of Persistently Vegetative or Minimally Conscious Patients in Research

Before a particular patient may be enrolled in a research study, the physician researcher must adhere to all of the legal requirements set forth in the Common Rule and other applicable statutes and regulations, as well as the ethical principles set forth in the Belmont Report and other pertinent ethical guidelines. Whether a particular patient should be involved in a research study will require an exceptionally fact-intensive application of the legal and ethical principles to the particular patient’s case. In cases involving minimally conscious patients near the level of emergence, one could argue that the failure to permit such patients’ enrollment in research studies which may improve their prognosis constitutes therapeutic nihilism. On the other hand, any situation in which a patient like Mathew Kosbob is being considered for enrollment in a research study must account for, and honestly address, the family’s or surrogate’s potential therapeutic illusions. The physician researcher must ensure that the family or surrogate

associated with deep brain stimulation:

There is approximately a two to three percent chance of brain hemorrhage that may be of no significance, or may cause paralysis, stroke, speech impairment or other major problems. This means that for every 100 patients who undergo surgery, two or three will experience a permanent or severe complication. However, this also means that many patients will have no complications. There is a 15 percent chance of a minor or temporary problem. Rarely, infections can occur.

NEUROSCIENCE CTR., CLEVELAND CLINIC, DEEP BRAIN STIMULATION, *available at* <http://www.clevelandclinic.org/neuroscience/techniques/dbs.htm> (last updated Mar. 8, 2004).

239. Fins 1, *supra* note 3, at 275.

240. *Id.*

241. *Id.* Deep-brain stimulation raises additional ethical issues not identified by a simple risk-to-benefit ratio analysis. Specifically, the risk-to-benefit ratio discussed in this Section IV assumes that any gain in consciousness by the minimally conscious individual is a positive development. However, patient distress could result from partial recovery of cognitive function: “Imagine lifting a minimally conscious patient into a state of self-awareness in which s/he became painfully aware of the seriousness and scope of injury. In such a scenario, restoration of self-awareness could lead to suffering.” *Id.* at 276.

understands the actual risks to which the patient will be subjected, as well as the actual degree of benefit that is expected to result. To the extent that the proposed research is designed to seek scientific knowledge intended to lay the groundwork for future therapeutic discoveries, but the actual degree of benefit to the research subject is nonexistent, the family or surrogate must be made to understand that the subject will likely incur absolutely no benefit as a result of participating in the clinical trial and that the potential benefit may only affect future brain injury victims. Only in situations in which the families or surrogates can attest to understanding that their loved one will likely incur absolutely no benefit should non-therapeutic, scientific research be considered.

V. THE LAW AND ETHICS OF PUBLIC POLICY

Public policy discussions addressing treatment and research for severe traumatic brain injury victims such as Mathew should address, at a minimum, whether the resources allocated to traumatic brain injury treatment and research are justified on the basis of fairness, scientific merit, therapeutic effectiveness, and usefulness to the individuals and populations served. As discussed, codes of medical ethics provide that physicians are ethically obligated to recommend treatments that are in their patients' best interests and those that will enhance the quality of their patients' lives.²⁴² Policies addressing the allocation of limited resources, however, have the potential to limit the ability of physicians to fulfill their stated ethical obligations.²⁴³ To safeguard the interests of patients in decisions regarding the allocation of limited resources, the following criteria are usually considered: the likelihood of benefit; the urgency of need; the change in quality of life; the duration of the benefit; and in some cases, the resources necessary for successful treatment. According to professional codes of ethics, non-medical criteria, such as the patient's ability to pay, age, social worth, any perceived obstacles to treatment, patient contribution to illness, or past use of resources, should not be considered.²⁴⁴

Professional codes of ethics also recommend that hospitals and other health care institutions disclose their resource allocation policies and procedures to the public, and that such policies and procedures be subject to regular peer review within the medical profession.²⁴⁵ Because the treating

242. CODE OF MEDICAL ETHICS, *supra* note 107, at E-10.015 (1994) (addressing the "Patient-Physician Relationship").

243. CODE OF MEDICAL ETHICS, *supra* note 107, at E-2.03 (1994) (addressing "Allocation of Limited Medical Resources").

244. *Id.*

245. *Id.*

physician's primary duty of loyalty is to his or her patient, professional codes of ethics also suggest minimizing or eliminating the treating physician's conflict of interest with the prohibition of the treating physician from participation in the resource allocation decision-making process.²⁴⁶ Finally, patients denied access to resources should be informed of the reasoning behind the decision.²⁴⁷

Some theologians believe that life-sustaining treatment should be provided to patients like Mathew Kosbob as a matter of public policy. Although Pope John Paul II certainly may identify with this policy,²⁴⁸ not all representatives of the Roman Catholic Church are in agreement. For example, theologian Richard McCormick has explained that life may not be an absolute value because "there are higher goods for which life can be sacrificed (glory of God, salvation of souls, service of one's brethren, etc.)" and because "not all means must be used to preserve life."²⁴⁹ McCormick references Pius XII who addressed the International Congress of Anesthesiologists in 1952, stating:

A more strict obligation would be too burdensome for most people and would render the attainment of the higher, more important good too difficult. Life, health, all temporal activities are in fact subordinated to spiritual ends.²⁵⁰

Based on Pius XII's statement, McCormick concludes that "[e]xcessive concern for the temporal is at some point neglect of the eternal."²⁵¹

Despite his predecessor Pius XII's statements to the International Congress of Anesthesiologists in 1952, Pope John Paul II told the World Federation of Catholic Medical Associations on March 20, 2004, that health care providers are morally obliged to provide nutrition and hydration to patients in persistent vegetative states.²⁵² In his speech, the Pope specifically explained that "even such people retain human dignity and have a right to be monitored for clinical signs of eventual recovery"²⁵³ and asserted that the phrase "persistent vegetative state" is degrading: "he is and

246. *Id.*

247. *Id.*

248. *See infra* notes 256-61 and accompanying text.

249. McCormick, *supra* note 155, at 9.

250. *Id.* at 9-10.

251. *Id.* at 10.

252. *See, e.g.,* Frank Langfitt, *Pope's Stand On Life Support Unclear for Church Hospitals: Giving Food, Water Moral Obligation, Pontiff Says*, *BALT. SUN*, Apr. 3, 2004, at 1A.

253. *Id.*

will always be a man, never becoming a ‘vegetable’ or ‘animal.’”²⁵⁴ According to the Pope, “[d]enying food and water would constitute ‘euthanasia by omission’ The administration of water and food, even when provided by artificial means, always represents a natural means of preserving life, not a medical act. . . . Its use, furthermore, should be considered, in principle, ordinary and proportionate, and as such morally obligatory.”²⁵⁵ Because no one knows when a patient in a vegetative state might awaken, the Pope further argued that “the evaluation of the probability, founded on scarce hope of recovery after the vegetative state has lasted for more than a year, cannot ethically justify the abandonment or the interruption of minimal care for the patient, including food and water.”²⁵⁶ The Pope’s solution to the problems raised by individuals in a persistent vegetative or minimally conscious state is to “commit more money to find cures for them.”²⁵⁷

Pope John Paul II and others who advocate the absolute provision of life-sustaining treatment to severe traumatic brain injury victims are ignoring several important factors, including the previously expressed desires of patients and their families, the social consensus in the United States protecting the right to refuse medical treatment, the immense physical and mental suffering endured by patients and their families, and the overwhelming costs associated with the intensive care that is required for severe traumatic brain injury victims. Arthur Caplan, the Director of the Center for Bioethics at the University of Pennsylvania, persuasively argues that nothing could be more cruel or disrespectful of human dignity than forcing patients to endure medical treatments they do not want.²⁵⁸ The Pope’s position also takes away the discretion that family members and surrogates should have to decide that a particular patient has simply had enough.

254. Nicole Winfield, *Pope Declares Feeding Tube Removal Immoral*, GUARDIAN UNLIMITED, Mar. 20, 2004.

255. See, e.g., Langfitt, *supra* note 2.

256. Winfield, *supra* note 254.

257. *Id.*

258. Arthur Caplan, *Must We All Die with a Feeding Tube? Pope’s Directive Undermines Patients’ Medical Rights*, MSNBC.COM (April 6, 2004), available at <http://www.msnbc.msn.com/id/4669899/> (last visited Oct. 15, 2004):

The Pope’s aim in reminding us that all people, even those in permanent comas or vegetative states, are human beings deserving of compassion and care is important. But he is wrong about what confers dignity on the sick and the dying. It is not about artificially feeding them against their will, but about finding ways to let their will be respected. . . . No one should be forced to endure medical treatment that they do not want. Nothing could be more cruel or disrespectful of human dignity.

Additionally, the financial implications of the Pope's statement must be considered. The intensive care unit (ICU), where most traumatic brain injury victims are treated, is extremely costly. ICU daily bed charges are up to five-hundred percent higher than regular hospital bed charges and can consume up to twenty percent of a hospital's total expenditures.²⁵⁹ The "intensive care unit symbolizes the dilemma of modern healthcare – good outcomes can be achieved for the most critically ill, but at a great expense."²⁶⁰ While accounting for only thirteen percent of all patients, patients in adult intensive care consume up to thirty-two percent of total resources.²⁶¹ Patients in vegetative states are particularly likely to utilize limited intensive care resources for long periods of time.

As a result of Mathew's tragedy, the State of Connecticut enacted a statutory provision known as "Mathew's Law."²⁶² Among other things, Mathew's Law exempts victims of crimes and their families from government spend-down rules and requires the State of Connecticut to help pay medical bills incurred by crime victims.²⁶³ Laws such as Mathew's Law contribute to states' already constrained budgets and may compromise the provision of care in the future. Indeed, many physicians argue that if our society continues to ignore the "increasing speeds in the healthcare resource allocation patients and families have come to enjoy," all levels of health care have the potential to become compromised.²⁶⁴ Physicians further emphasize that society cannot afford to continue expensive artificial life support for every person that has been accurately diagnosed as being in a persistent vegetative state in light of current scientific findings that such injury "virtually precludes the potential for demonstrable benefit" from any treatment or interventions.²⁶⁵ Society may be able to better use the financial and medical resources that would have been spent providing artificial life

259. Goh & Mok, *supra* note 168, at 265.

260. *Id.* at 265. See also David Crippen & Leslie Whetstone, *ICU Resource Allocation: Life in the Fast Lane*, 3 CRITICAL CARE R47, R47 (1999) (explaining that "[t]wo and a half decades later we find ourselves . . . searching for a speed limit that will restrict excessive and capricious allocation of scarce healthcare resources. Distributive or social justice with regard to healthcare is particularly difficult given the Western mentality that healthcare, from immunizations to experimental fertility treatment, is a basic human right; a right sacrosanct from the clutches of rationing, the very antithesis of democracy as we know it. . . .").

261. *Id.*

262. E-mail from William Kosbob, *supra* note 7.

263. See CONN. GEN. STAT. ANN. § 54-209-54-210 (West 2002).

264. *Id.*

265. *Id.* See also *Rip Van Winkle*, *supra* note 143, at 25A ("We cannot afford to wager years of expensive time, money and energy on tens of thousands of virtually hopeless unconscious patients on the minute possibility that a handful may miraculously speak to us.").

support to individuals with no measurable hope of recovery by allocating resources to less severely injured traumatic brain injury victims who have maintained or regained their consciousness and have the potential and desire to live good lives. For example, studies of adult intensive care indicate significant potential cost savings of \$2 million to \$5 million per year, per hospital could be achieved by identifying and terminating care that is futile.²⁶⁶

The problem, of course, is predicting which patients have measurable hope of recovery.²⁶⁷ Neuropsychologist Joseph Giacino at the Weill Medical College of Cornell University spent more than fifteen years developing ways to objectively measure how people recover from comas.²⁶⁸ According to Dr. Giacino and his associates, the ideal prediction model would be easy to use, and would have high sensitivity and high specificity even when used on patients managed by different protocols, times and places.²⁶⁹ Current outcome predictors commonly used include: age, Glasgow Coma Scale score, papillary reactivity, early hypoxia and hypotension, brain stem reflexes, and CT findings, including analysis of effacement of basal cisterns and ventricles, presence of midline shift based on the position of the third ventricle, subarachnoid hemorrhage, and tissue tear hemorrhages.²⁷⁰ Additionally, a variety of outcome prediction models exist.²⁷¹ Although physicians apply some of these models in the emergency room after initial resuscitation, they generally will not employ these models for decisions regarding an initial course of treatment, including withdrawal of treatment, because many of the models have high rates of false pessimistic results.²⁷² However, physicians use these models to rationalize the utilization of limited resources or to counsel the patients' families.²⁷³ Physicians like Dr. Giacino continue to conduct retrospective analyses in order to develop models that will more accurately predict patient outcomes.²⁷⁴

266. Goh & Mok, *supra* note 168, at 267 (noting further that relatively small amounts of resources were consumed in futile pediatric intensive care unit).

267. Pillai et al., *Outcome Prediction Model for Severe Diffuse Brain Injuries: Development and Evaluation*, 51 NEUROL. INDIA 345 (2003).

268. Carl Zimmer, *What If There Is Something Going on In there?* N.Y. TIMES MAGAZINE, Sept. 28, 2003, at 52-56.

269. Pillai, *supra* note 267, at 345.

270. *Id.*

271. *Id.* Common models used include the Narayan Logistic model, the Choi's Logistic model, Klauber's Logistic model, Glasgow-Liege model, the Choi Classification and Regression model, and the NIMHANS model.

272. *Id.*

273. *Id.*

274. Pillai, *supra* note 267, at 345 (finding that "[a]lmost all of the patients older than 45

VI. CONCLUSIONS

Until physicians can completely and accurately predict which traumatic brain injury victims have a realistic chance of benefiting from available treatments and research interventions, and until physicians can accurately convey such predictions to families and surrogates, patients in persistent vegetative and minimally conscious states will continue to be at risk for therapeutic failures. An extremely fact-intensive analysis is necessary in order to resolve a physician's diagnostic uncertainty.

The administration, withholding, or withdrawing of artificial life support for an individual of uncertain diagnosis, such as Mathew Kosbob, is legally and ethically permissible. However, the provision of life support should not be established as a general rule by any religious institution, federal or state statute or regulation, or by any internal policy or procedure implemented by a hospital or health care organization. As a matter of public policy, the wishes of traumatic brain injury victims with little hope of substantial cognitive recovery should pervade the course of treatment administered by their treating physicians, whether an advance directive has been executed or not. Physicians, family members, or surrogates should make every effort to honor patient preferences in decisions to withhold or withdraw life support, including the administration of artificial nutrition and hydration. Any policy failing to do so risks an unethical imposition of the policy maker's values over the patient's value system.

However, although a severe traumatic brain injury victim, family member, or surrogate may advise the treating physician to administer, withhold, or withdraw life support, the physician must follow appropriate policies and procedures before responding to such directives. All health care institutions, whether large or small, should adopt a policy addressing the administration, withholding, or withdrawal of life-sustaining treatment which must include due process for futility decisions and should include additional safeguards for other decisions.

Additionally, physician researchers must adhere to all of the legal requirements set forth in the Common Rule and other applicable statutes and regulations, as well as the ethical principles set forth in the Belmont Report and other applicable ethical guidelines before enrolling a patient in a

years (91%) had an unfavorable outcome as compared to those younger except for those younger than 10 years. . . . The nature of trauma was not a significant predictor of outcome. . . . [T]he GCS sum score, the motor score and the verbal response score were all highly significant predictors of poor outcome. Ninety-six percent of the patients with absent papillary light reflect were found to have a poor outcome. The horizontal oculocephalic reflect when absent was also found to be a significant predictor of poor outcome, with 98% having a poor outcome.”).

research study. Moreover, the physician must account for, and honestly address, the family's or surrogate's current or potential therapeutic illusions. Physicians who engage in research must ensure the family or surrogate's understanding of the actual risks to which the patient will be subjected, as well as the actual degree of benefit expected to result. The family or surrogate must also be informed if the subject will incur absolutely no benefit as a result of participating in a clinical trial, *i.e.*, if the study is designed primarily to benefit future brain injury victims. Only after families or surrogates confirm their understanding should scientific research be considered. Physicians and researchers can minimize therapeutic failures, limit professional liability, and preserve limited medical and financial resources by improving communication with family and surrogates. First, the treating physician or a third party should explain thoroughly, repeat, and continually reinforce the patient's realistic expected outcome based on the current evidence-based clinical literature. Allied health professionals and other caregivers who treat the patient should be familiar with the treating physician's diagnosis, predictions, and expectations, and should provide consistent information to family members and surrogates.

Second, treating physicians may wish to consider meeting with the patient's family on a regular basis, to provide accurate updates and to reinforce appropriate expectations.²⁷⁵ For example, at the Tufts-New England Medical Center (Tufts), the physicians associated with the Surgical Intensive Care Unit invite families of severely brain-injured patients to join the physicians on multidisciplinary rounds. During the rounds, the family can "witness the entire team meticulously weighing the many problems posed by the catastrophically ill patient."²⁷⁶ The physicians at Tufts "think that this experience both reinforces realistic expectations and strengthens our credibility with and trust by the family for providing complicated care."²⁷⁷ In addition, the physicians at Tufts believe that sharing the burden of decision making with the family members and surrogates creates a patient-focused consensus, which helps family members to understand that the best solutions may involve letting go of their loved ones and ceasing life-sustaining intervention.²⁷⁸

Third, in cases in which physicians and family remain in disagreement regarding the patient's prognosis, a time-limited trial may be appropriate.

275. Nasraway, *supra* note 149, at 217.

276. *Id.*

277. *Id.*

278. Thomas J. Prendergast & Kathleen A. Puntillo, *Withdrawal of Life Support: Intensive Caring at the End of Life*, 288 JAMA 2732 (Dec. 4, 2002).

In a time-limited trial, the physician agrees to provide ongoing, aggressive therapy for a certain period of time, perhaps three to seven days, and measures the patient's response to the therapy at the end of the trial. The implicit expectation is that the family will agree to withdraw therapy if the patient has demonstrated no progress from the therapy.

Fourth, any resource allocation decisions must be made in a forum open for public scrutiny. The participants, procedures, and deliberations relating to the limitation or cessation of health care services should be accessible to all involved in the decision-making process.²⁷⁹ Fifth, the patient's family or surrogate must have access to an internal appeals process, which is essential to ensure continuous refinement of decisions in response to changing information, complex circumstances, and competing values.²⁸⁰ Giving families, surrogates, and other interested parties leave to appeal can be educational, builds trust, and maintains the accountability of the decision-making process.²⁸¹

Professional and hospital liability can be minimized by ensuring that: (1) each hospital or health care organization has a written policy that clearly identifies the process for administering, withholding, or withdrawing life-sustaining treatment, including artificial nutrition and hydration, to individuals in the persistent vegetative or minimally conscious state; (2) the policy incorporates any procedures set forth in the applicable state futility act;²⁸² (3) the hospital, physicians, allied health professionals, and other employees and workforce members properly adhere to hospital policies and procedures; and (4) the hospital and the physicians thoroughly document their compliance with such policies and procedures, especially any due process relating to the patient or family.

Mathew Kosbob's tragic story illustrates the range of legal and ethical issues that must be considered by physicians, researchers, families, and surrogates involved in traumatic brain injury treatment or research decision-making. To resolve these issues, physicians must continue communicating the actual risks and benefits of proposed treatment and research activities and families and surrogate decision-makers must use this information to make decisions that are in the best interest of the patient.

279. Duncan S. MacLean, *Setting Limits Fairly: Can We Learn to Share Medical Resources?* 4 J. AM. MED. DIR. ASSOC. 224, 225 (2003).

280. *Id.*

281. *Id.*

282. See, e.g., ALA. CODE §§ 22-8A-4 – 22-8A-11 (Supp. 2003); ARK. CODE ANN. § 20-17-214 (Michie Supp. 2003); FLA. STAT. ANN. Chapter 765 (West 2003); MD. HEALTH-GEN'L § 5-601; TEX. HEALTH & SAFETY CODE ANN. Chapter § 166 (Vernon 2000); W. VA. CODE ANN. § 16-30-1 (Michie 2001).

