IN THE SUPREME COURT FOR THE STATE OF TENNESSEE
AT NASHVILLE

PATRICIA P. ASHE,	)	
	)	**Davidson County Circuit**
Plaintiff/Appellant	)	**Court Case No. 95C-58**
	)	
v.	)	**Court of Appeals Case No.**
	)	**01A01-9710-CV-00563**
	)	
RADIATION ONCOLOGY ASSOCIATES;	)	**Supreme Court Case No.**
and STEVEN L. STROUP, M.D.,	)	**05101-9902-CV-00033**
	)	
Defendants/Appellees	)	

PLAINTIFF/APPELLANT'S SUPPLEMENTAL BRIEF

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Comes now the Plaintiff/Appellant, by and through the undersigned counsel, and pursuant to Rule 11 of the Tennessee Rules of Appellate Procedure, files this Supplemental brief in support of Plaintiff's Appeal.

SUMMARY OF ARGUMENT

Every person has the sovereign right to decide what shall be done with his or her own body. This right of autonomy and personal choice is strongly protected in Tennessee in cases involving medical surgeries and procedures by treating the failure to obtain a patient's informed consent as a battery. The rule of *Cardwell v. Bechtol*, 724 S.W.2d 739 (Tenn. 1987) is sound and in conformity with well- reasoned law and policy. This appeal raises a question of first impression in Tennessee concerning proof of causation in informed consent cases. Only two states, Tennessee and Pennsylvania, continue to treat a physician's failure to obtain informed consent as a battery; however, this is a distinction to be prized and guarded. Tennessee should not eviscerate the law of informed consent by adopting a causation test requiring the plaintiff to prove, *post hoc*, that consent would have not been given if the physician had provided the disclosures and information required by law. An after-the-fact inquiry into a patient's decision-making process by asking "what might have happened if there had been informed consent" is not honestly justiciable. Such a mythical causation requirement is also inherently at odds with Tennessee's analysis of informed consent cases under a battery theory. Tennessee's statutory and case-law framework for informed consent cases relies upon physician *experts* to define and limit the duty of

disclosure and scope of information. When a physician fails to obtain the patient's informed consent, as established by competent expert proof, the patient's consent is void *ab initio* and any procedure that follows is wrongful. Plaintiff urges this Court to follow the holding of the Pennsylvania Supreme Court in *Gouse v. Cassel*, 532 Pa. 197, 615 A.2d 331 (1992) that a plaintiff is not required to prove that a causal relationship exists between a physician's or surgeons's failure to disclose information and the patient's consent to undergo surgery or treatment. Recovery under the theory of informed consent should not require "what would have happened if" causation proof because it is the conduct of the unauthorized procedure that constitutes the tort (battery) and the causal harm that matters is that the *wrongful procedure itself caused injury*.

STATEMENT OF FACTS[1]

Patricia Ashe underwent radiation therapy in 1994 to her chest (an area in the mediastinum that included the spinal cord within the radiation field) for treatment of a cancerous lung tumor. The Plaintiff presented expert evidence through Dr. Carlos A. Perez, the Director of the Radiation Oncology Center at the Mallinckrodt Institute of Radiology at Washington University of Medicine in St. Louis. (TE 273). Dr. Perez practices radiation oncology at Barnes and Jewish Hospitals in St. Louis and is the editor and author of the leading medical school textbook on radiation oncology.[2] Dr. Perez

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[1] Plaintiff's opening brief set forth an extensive statement of facts. In this supplemental brief, Plaintiff will focus on those facts relevant to the informed consent issue.

[2] CARLOS A. PEREZ & LUTHER W. BRADY, PRINCIPLES AND PRACTICE OF RADIATION ONCOLOGY (2d ed. 1992):

"The need to obtain informed consent for treatment is based on the patient's right to

testified that the recognized standard of care required patients undergoing radiation therapy to the lung to be informed of the risk of radiation paralysis (TE 301). Importantly, Dr. Perez explained that the standard of care for radiation treatment required limiting the radiation dosage to 4500 rads. The defendant (Dr. Stroup) used a dose of **5000** rads to the chest tumor. Dr. Perez testified that at Washington University in St. Louis spinal cord doses do not exceed 4500 and that patients receive a written consent form that specifically discloses to patients the potential for radiation damage to the spinal cord and paralysis (TE 303). Dr. Perez testified that at doses of 4500 or below the risk of developing radiation paralysis to the spinal cord was approximately 0.2% (TE 306). In this case, however, the MRI and isodose curves established (without dispute) that Ms. Ashe actually received, at the area of paralysis on her spinal cord, a dose of 5250 (TE 306). Dr. Perez, therefore, opined that Ms. Ashe's radiation injury was dose-related (TE 307) and that if she had received a dose within the standard of care of 4500 or less she would not have suffered radiation paralysis (TE 306-307). Dr. Perez further explained that the risk of spinal cord injury for the doses which Ms. Ashe received (5250) was in the range of 1%-2% (TE 306).

> self-determination and the fiduciary relationship between the patient and the physician. The law requires that the treating physician adequately apprise every patient of the nature of the disease requiring treatment, the recommended course of therapy and the details regarding it, alternative treatments available, benefits of recommended treatment, and all minor and major risks (acute and late effects) associated with the recommended therapy. It is always advisable to discuss the informed consent contents in the presence of a witness and have that person sign the informed consent form or the chart verifying that the information was discussed with the patient. . . It is extremely important for the radiation oncologist and the staff to spend as much time as needed to ensure that the patient, and if necessary, the relatives understand all aspects of the radiation therapy, particularly the specific description of its various potential deleterious effects." (pp. 49-50)

Defendants' own expert witness, Dr. Julian Rosenman, Professor of Radiation Oncology at the University of North Carolina in Chapel Hill, admitted that Ms. Ashe's spinal cord received a dose of 5250 at its highest point with the lowest cord dose at 4750 (TE 522, 526). Dr. Rosenman also explained that because Ms. Ashe received a dose of 5250 at approximately 209-210 rads per session as opposed to 200, this higher fractionated dosage resulted in an actual biological dose of 5400 (TE 548-549).

Defendants' physicist expert, Dr. Timothy Schultheiss, who served as the Director of Radiation Physics at the Fox Chase Cancer Center in Philadelphia, Pennsylvania, testified that at doses of 5000 or less, the risk of radiation injury was approximately two-tenths of a percent (TE 613). Dr. Schultheiss admitted that at dosages of 5700 to 6100 the probability radiation paralysis was five percent (5%). (TE 621). When asked to offer an opinion on what the risk of radiation injury was at a dosage range of 5250 to 5400 Dr. Schultheiss hesitated and testified he would need time to think about it (TE 624). Upon further questioning he stated, "Let me guess on that one for a minute." (TE 625). After consideration, Dr. Schultheiss testified that the risk was under one percent (1%). On further cross examination Dr. Schultheiss admitted that published medical literature indicated that at 5000 rads or more there was a five percent (5%) risk of radiation paralysis (TE 639-640). In his own writings, Dr. Schultheiss had written that very few radiologists would in practice employ a higher dose than 4500 rads to the spinal cord (TE 641). Dr. Schultheiss concluded that doses above 5000 rads in a particular clinical situation could be given if the patient is properly informed of the risks and consequences of paralysis. (TE 642). At Dr. Schultheiss's

cancer center in Pennsylvania, lung cancer patients receive written consent forms that specifically identify the potential for radiation damage to the spinal cord.[3]

At trial, the Defendants also offered the video tape deposition testimony of Dr. Leonard Prosnitz, a radiation oncologist at Duke University. (Prosnitz Depo., p. 7). Dr. Prosnitz estimated the risk of radiation paralysis at dosages between 4000 to 5000 at less than one-half of one percent and maybe less than two-tenths of a percent. (Prosnitz Depo., p. 27). Dr. Prosnitz testified that he did not believe that the standard of care required informing patients of the risk of radiation paralysis at dosages of 5000 rads. (Prosnitz Depo., p. 31). He stated:

> "I think its a negative from an emotional point of view. I think you can get people so worried that they are so afraid, that A, **they may not do the right thing that you want them to do**, and/or B, they'll worry excessively and have a lot of anxiety that they don't need to have." (Prosnitz Depo., p. 32) (emphasis supplied).

[3] (Prosnitz Depo, Ex. 6, "Fox Chase Cancer Center, Radiation Therapy Information Sheet, Lung").

HISTORICAL BACKGROUND

The doctrine of informed consent has roots that reach far back in law, jurisprudence and philosophy. Blackstone's COMMENTARIES ON THE LAWS OF ENGLAND (1765) begins at chapter one with "*The Absolute Rights of Individuals,*" noting, "The right of personal security consists in a person's legal and uninterrupted enjoyment of his life, his limbs, his body, his health and his reputation."[4] Blackstone cited MAGNA CARTA as the basis for the right of personal security:

> "Both the life and limbs of a man are of such high value in the estimation of the law of England that it pardons even homicide if committed *se defendendo* or in order to preserve them. For whatever is done by a man, to save either life or member, is looked upon as done with the highest necessity and compulsion."[5]

In 1859 John Stuart Mill, in ON LIBERTY, wrote:

> The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a significant warrant. . . Over himself, over his own body and mind, the individual is sovereign.[6]

In a fundamental sense the concept of what is a "right" and what law is all about evolve from the acceptance of the sanctity of an individual's freedom to control his or her own body and make up his or her own mind. Immanuel Kant, in his work, THE SCIENCE OF RIGHT, defined the "rights" of persons and the meaning of what is "mine" by reference to the concept of bodily consent: "Anything is *mine by right*, or is rightfully

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[4] WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND (1765), Book I, Chapter I, p. 68 (Baker, Voorhis and Co. 4th ed. 1938).

[5] *Id.* at 69.

[6] JOHN STUART MILL, *On Liberty* (1859) in UTILITARIANISM. ON LIBERTY, ESSAY ON BENTHAM, (Meridian Books, 1962), p. 135.

mine, when I am so connected with it, that any other person who should make use of it without my consent, he would do me a lesion or injury."[7] Hegel's PHILOSOPHY OF RIGHT also defined a right "in the first place" as the "immediate embodiment of freedom" pursuant to a man's "immediate existence within himself."[8] Hegel stressed that "It is only through the development of his own body and mind, essentially through his self-consciousness and apprehension of itself as free, that he takes possession of himself and becomes his own property and no one else's."[9] Accordingly, for Hegel, slavery was "absolutely unjust" because a person's mind and body must be "inherently free."[10]

The protection of an individual's bodily autonomy and right to self-determination in the doctor-patient setting received firm judicial support in a 1914 opinion, *Schloendorff v. Society of New York Hospital,* 211 N.Y. 125, 105 N.E. 92 (1914), by Judge Benjamin Cardozo, then sitting on the Court of Appeals of New York:

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages.[11]

Schloendorff v. Society of New York Hospital involved a surgeon who exceeded the scope of consent (for an exploratory surgery) and performed a "medical battery" by

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[7] IMMANUEL KENT, *The Science of Right,* in 42 GREAT BOOKS OF THE WESTERN WORLD 403 (1987).

[8] GEORG WILHELM FRIEDRICH HEGEL, *The Philosophy of Right* in 46 GREAT BOOKS OF THE WESTERN WORLD 21, 26 (1987).

[9] *Id.* at 26.

[10] *Id*.

[11] *Schloendorff v. Society of New York Hospital,* 211 N.Y. 125, 105 N.E. 92, 93 (1914).

removing a fibroid tumor.[12] Despite the best of medical intentions, and without the need for any proof of fault, the law is well-recognized that a physician is held liable under these circumstances :

> The problem of the validity and the extent of a plaintiff's consent frequently arises in connection with surgical operations on patients who are unconscious. . . If he has given valid consent to a particular operation, and the surgeon in the course of the treatment discovers the desirability of extending the operation to another area, the mere medical indication will not justify the surgeon in going ahead. Unless the consent given prior to the operation was sufficiently general in its terms, or unless an unforseen emergency has arisen during the operation that allows the assumption that the patient would consent if he could be asked, the surgeon by extending the operation exceeds the express or implied consent and may be held liable for battery.[13]

The further development of the law, to embrace the concept of "informed consent" by recognizing that patients have an absolute right to receive **information** and **disclosures** in connection with medical procedures received profound stimulus in the wake of Word War II, Nazi doctors and the Nuremberg Tribunal.[14] The NUREMBERG CODE (1949) declared in uncompromising fashion in its first principle that:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have the legal capacity to give consent, should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching or other ulterior form of constraint; **and should have sufficient knowledge and comprehension of the elements of the**

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[12] *See Blanchard v. Kellum*, 975 S.W.2d 522 (Tenn. 1998) (expert proof not required if physician acts without consent so as to commit medical battery).

[13] 28 THE NEW ENCYCLOPEDIA BRITANNICA 742, *Torts, Survey of Modern Tort Law, Personal Injury* (15th ed. 1987).

[14] *See* J. Katz, "*The Consent Principle of the Nuremberg Code: Its Significance Then and Now,*" in GEORGE J. ANNAS & MICHAEL A. GRODIN, THE NAZI DOCTORS AND THE NUREMBERG CODE 227 (1992).

subject matter involved as to enable him to make an understanding and enlightened decision.[15]

In the United States, even after the Nuremberg experience, physicians continued to deprive human beings of their fundamental right to informed consent. The TUSKEGEE STUDY OF UNTREATED SYPHILIS IN THE NEGRO MALE (1932-1972)[16] and the COLD

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[15] *Id.* (emphasis supplied).

[16] *See America's Dirty Little Secret Bad Blood: The Tuskegee Syphilis Experiment*, http://www.aabhs.org/tusk.html ("In 1932 the American Government promised 400 men - all residents of Macon County, Alabama, all poor, all African American - free treatment for Bad Blood, a euphemism for syphilis which was epidemic in the county. Treatment for syphilis was never given to the men and was in fact withheld. The men became unwitting subjects for a government sanctioned medical investigation, The Tuskegee Study of Untreated Syphilis in the Negro Male, The Tuskegee Study, . . . lasted for 4 decades, until 1972. . . What has become clear since the story was broken by Jean Heller in 1972 was that the Public Health Service (PHS) was interested in using Macon County and its black inhabitants as a laboratory for studying the long-term effects of untreated syphilis, not in treating this deadly disease.")

WAR HUMAN RADIATION EXPERIMENTS (1944-74)[17] are perhaps the most infamous examples of modern American failures to heed the rights of patients to informed consent. The nation's social policy on informed consent continues to grow out of these experiences. On May 16, 1997, President Clinton issued a formal apology at the White House to the surviving participants of the Tuskegee study and called for greater research and training in the area of bioethics and informed consent:

> [W]e commit to strengthen researchers' training in bioethics. We are constantly working on making breakthroughs in protecting the health of our people and in vanquishing diseases. But all our people must be assured that their rights and dignity will be respected as new drugs, treatments and therapies are tested and used. So I am directing Secretary Shalala to work in partnership with higher education to prepare training materials for medical researchers. They will be available in a year. They will help researchers build on core ethical principles of respect for individuals, justice and **informed consent**, and advise them on how to use these principles effectively in diverse populations.[18],[19]

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[17] Department of Energy, *Final Report of Advisory Committee on Human Radiation Experiments* (1995) at:http://tis.eh.doe.gov/ohre/roadmap/achre/index.html. This report details how between 1944 and 1974 the federal government authorized 4,000 human radiation experiments, the majority of which involved exposing patients, without their knowledge or consent, to radioactive isotopes to "map the human metabolism." These experiments occurred in Tennessee, at Oak Ridge and Vanderbilt Univeristy Medical Center where physicians and scientists exposed patients to radiation without their consent. The experminents only came to light in 1994 when an invesigative journalist for the ALBUQUERQUE TRIBUNE, Eileen Welsome, published a Pulitzer Prize winning series of articles that revealed that 18 people had been injected with plutonium. *See* 52 BULL. OF ATOMIC SCIENTISTS No. 1 "*The Verdict:No Harm, No Foul,*" (January/February 1996) at http://www.bullatomsci.org/issues/1996/jf96/jf96gordon.html.

[18] Full text of President Clinton's apology available at: http://www.pub.whitehouse.gov/urires/I2R?urn:pdi://oma.eop.gov.us/1997/5/16/11.text.1 (emphasis supplied).

[19] A recent study in the journal SURGERY examined 616 consent forms for surgical procedures from hospitals throughout the United States. The researchers at Penn State University concluded, "The majority of surgical/procedural informed consent forms used by U.S. Hospitals are complex and are not easily understood by the average patient. In addition, the majority of reviewed consent forms do not list the specific benefits or potential complications of the planned surgery/procedure." K. Cooper, T. TenHave & D. Tully, *The Readability of Currently Used Surgical/Procedure Consent Forms in the United States,* 123 SURGERY 496-503 (1998).

On October 3, 1995, President Clinton offered the United States Government's apology for the deprivations of human liberty that occurred during the COLD WAR HUMAN RADIATION EXPERIMENTS:

> While most of the tests were ethical by any standards, some were unethical, not only by today's standards, but by the standards of the time in which they were conducted. They failed both the test of our national values and the test of humanity.
>
> In one experiment, scientists injected plutonium into 18 patients without their knowledge. In another, doctors exposed indigent cancer patients to excessive doses of radiation, a treatment from which it is virtually impossible that they could ever benefit.
>
> **Informed consent** means your doctor tells you the risk of the treatment you are about to undergo. **In too many cases, informed consent was withheld.** Americans were kept in the dark about the effects of what was being done to them. The deception extended beyond the test subjects themselves to encompass their families and the American people as a whole, for these experiments were kept secret. And they were shrouded not for a compelling reason of national security, but for the simple fear of embarrassment, and that was wrong.
>
> So today, on behalf of another generation of American leaders and another generation of American citizens,the United States of America offers a sincere apology to those of our citizens who were subjected to these experiments, to their families, and to their communities.
>
> [T]here are **regulations** that **establish proper informed consent** and ensure that experiments are conducted ethically. **But** in overseeing this necessary research, **we must never relax our vigilance.**
>
> **The breathtaking advances in science and technology demand that we always keep our ethical watchlight burning.** No matter how rapid the pace of change, it can never outrun our core convictions that have stoodus so well as a nation for more than 200 years now, through many different scientific revolutions.
>
> **I believe** we will meet the test of our times that as science and technology evolve, **our ethical conscience will grow, not shrink. I**nformed consent, community right-to-know, our entire battery of essential human protections all these grew up in response to the health and humanitarian

> crises of this 20th century. They are proof that we are equal to our challenges.[20]

The principle of civil liability for a physicians' failure to obtain informed consent entered American medical malpractice law in 1957 in a California decision, *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees,* 317 P. 2d 170, 181 (Cal. Dist. Ct. App. 1957) and in the Florida case of *Chambers v. Nottebaum,* 96 So. 2d. 716 (Fla. Dis. Ct. App. 1957). As Professor William McNichols of the Oklahoma Law School wrote in a 1995 law review article:

> Beginning in the late 1950s, the first cases began to appear in which the courts allowed patients to recover tort damages when physicians wrongfully failed to disclose information about the risks involved in a proposed course of medical treatment. **The theory, however was battery.** Such courts viewed consent to treatment obtained without adequate risk disclosure as legally ineffective consent. They viewed risk nondisclosure situations as analogous to and an extension of those battery cases where consent was fraudulently obtained. Allowing a patient to recover under a battery theory, rather than under a negligent malpractice theory, had several important advantages. First and most importantly, battery did not require the patient to prove by an expert medical witness that the defendant had deviated from an accepted standard of care. **Second, battery did not require the patient to prove that he would have refused the treatment if he had been given proper information.** Third, battery would entitle the patient to recover damages even if the operation didn't have a "bad result." Fourth, as an intentional tort battery might have entitled the patient to an instruction in punitive damages, which would not be available in an action based upon negligence.[21]

Professor McNichols then recounts how, in 1960, after having introduced the battery-informed consent analysis for inadequate risk disclosure into American law, courts began to change course and adopt a negligence standard, replete with a subjective or

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[20] Remarks By President William J. Clinton in acceptance of Human Radiation Final Report (October 3, 1995) at: http://www.ohre.doe.gov/ohre/roadmap/whitehouse/appa.html.

[21] W. McNichols, *Informed Consent Liability in a "Material Information" Jurisdiction: What Does the Future Portend?"* 48 OKLA. L. REV. 711, 714-15 (1995)(citations omitted; emphasis supplied).

objective standard for causation.[22] In a footnote to this article; however, McNichols notes, "A small minority [of states] still consider such actions to sound in battery. *See e.g., Gouse v. Cassell,* 615 A. 2d 331, 335 (1992)(rejecting negligence-type causation analysis elements because action is one for battery)."[23] In fact, Tennessee and Pennsylvania are the **only** two states that continue to hold that informed consent claims sound in battery.[24],[25]

Under negligence analysis, in the 1970s, the doctrine of informed consent further developed with the landmark case of *Canterbury v. Spence,* 464 F.2d 772 (D.C.Cir.), *cert denied,* 409 U.S. 1074 (1972). *Canterbury v. Spence,* established a patient-oriented standard for disclosure (the material risks that would constitute reasonable disclosure under the circumstances) and an objective test for causation (would a reasonably prudent patient have consented if disclosures were made). Today courts applying negligence law in informed consent cases are split on whether a patient-oriented

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[22] *Id.* at 715 and 730; *see e.g, Natanson v. Kline,* 186 Kan. 393, 350 P. 2d 1093 (Kan. 1960).

[23] *Id.* at 715 n. 22.

[24] DAVID LOUISELL & HAROLD WILLIAMS, 3 MEDICAL MALPRACTICE § 22.03 at 22-9 (1998) ("In **Pennsylvania and Tennessee**, however, the courts continue to hold that informed consent claims sound in battery.")(emphasis supplied).

[25] *See also* FOWLER V. HARPER, FLEMING JAMES, JR. & OSCAR S. GRAY, THE LAW OF TORTS § 3.10 n. 20 (2d ed. 1986); John H. Derrick, *Medical Malpractice: Liability for Failure of Physician to Inform Patient of Alternative Modes of Diagnosis or Treatment,* 38 A.L.R. 4th 900 (1985); Laurent B. Frantz, *Modern Status of Views as to General Measure of Physician's Duty to Inform Patient of Risks of Proposed Treatment,* 88 A.L.R. 3rd 1008 (1978); 61 AM. JUR. 2D, *Physicians, Surgeons, and Other Healers* §§187(Generally) , 256 (Surgical Operations). Many states enacted reform statutes in the 1970s that altered the trespass on the case/battery view of informed consent and specifically imposed the negligence causation requirement. *See e.g.,* TEX. REV. CIV. STAT. ANN. art. 4590i § 6.02 (West Supp. 1998)(imposing negligence causation standard); and compare:*Bowers v. Talmage,* 159 So. 2d 888 (Fla. Dis. Ct. App. 1963) (battery theory) with FLA.STAT.ANN. § 766.103 (Florida Medical Consent Law)(West 1997).

standard of disclosure controls as opposed to a professional (expert) standard.[26] In addition, in those jurisdictions applying negligence principles, most apply an objective standard for causation.[27]

TENNESSEE'S LAW OF INFORMED CONSENT, BASED UPON A BATTERY THEORY, SOUNDLY PRECLUDES THE IMPOSITION OF A CAUSATION ELEMENT THAT WOULD REQUIRE THE PLAINTIFF TO SHOW A CAUSAL RELATIONSHIP BETWEEN A PHYSICIAN'S FAILURE TO DISCLOSE INFORMATION AND THE PATIENT'S CONSENT TO UNDERGO SURGERY OR TREATMENT

Under the battery theory of informed consent there is no causation requirement other than to prove that the procedure performed pursuant to the "defective consent" caused injury. As stated in 1998 in the leading treatise on the law of medical malpractice by Professor David Louisell of the University of California Law School at Berkeley and Harold Williams, M.D., LL.B:

> A major distinction between negligence and assault and battery involves the element of causation. Under the negligence theory, the plaintiff must show that but for the defendant's failure to properly inform him of the nature of treatment, its risks, and alternatives, the plaintiff would not have consented to the treatment. **In battery, however, the plaintiff is only required to prove the occurrence of an unconsented touching. . . . Where a battery remains the sole basis for informed consent claims, the plaintiff is not required to establish that he would have refused the treatment if properly informed by the physician.** [Citing *McDonald v. United States*, 767 F. Supp. 1295, 1312 (M.D. Pa. 1991)(applying Pennsylvania law)]. Conversely, in a negligence action, the plaintiff must

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[26] W. McNichols, *Informed Consent Liability in a "Material Information" Jurisdiction: What Does the Future Portend?"*48 OKLA. L. REV. 711 at 716 notes 30-31 (1995).

[27] *Id.* at 730.

> prove that actual damages occurred as a result of the failure of disclosure."[28],[29]

Because the gravamen of the tort of battery is the non-consensual bodily contact -- a *trespass on the case* -- the inquiry into whether a reasonable patient would have consented anyway misses the point. It was wrongful, tortious (and a battery under Tennessee law and the Plaintiff's expert evidence) for Dr. Stroup to administer radiation therapy to Ms. Ashe's spinal cord without advising her of the risk of permanent paralysis.[30] Defective consent is simply no consent. *Cardwell v. Bechtol,* 724 S.W.2d 739, 751 (Tenn. 1987): "[F]ailure to give such information is not the type of omission that results in negligence, but rather it negates consent for the treatment. Without consent,

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[28] DAVID LOUISELL & HAROLD WILLIAMS, 3 MEDICAL MALPRACTICE § 22.03 at 22-11-12 (1998) (emphasis supplied).

[29] *See also* FAY A. ROZOVSKY, CONSENT TO TREATMENT, A PRACTICAL GUIDE, (2d ed. 1990) ("The negligence theory cannot, however, be perceived as an easy way for plaintiff's lawyers to secure significant judgments. Proving causality or that a patient would have foregone surgery had she been properly informed is difficult to establish to the satisfaction of a judge or jury."); W. McNichols, *Informed Consent Liability in a "Material Information" Jurisdiction: What Does the Future Portend?"*48 OKLA. L. REV. 711, 714-15 ("Second, battery did not require the patient to prove that he would have refused the treatment if he had been given proper information"); J. Katz, *Informed Consent--Must it Remain a Fairy Tale?* 10 J. OF CONTEMPORARY HEALTH LAW AND POLICY 69 (1994) ("Battery law, based on unauthorized trespass, gives doctors only one defense -- that they have made an adequate disclosure."); *cf. Wilkerson v. Mid-America Cardiology,* 908 S.W. 2d 691 (Mo. Ct. App. 1995)(causation discussed in a negligence informed consent case versus battery).

[30] *See ZeBarth v. Swedish Hospital Medical Center*, 81 Wash. 2d 12, 449 P.2d 1 (1972)(radiation paralysis injury to the spinal cord as a result of radiation therapy for Hodgkin's disease; judgment for failure to obtain informed consent (as to risk of injury) affirmed); David Gooden, *Radiation Injuries—Ionizing Radiaton*, 14 AM. JUR. PROOF OF FACTS 3D, 85, 98-99 (1991)("The medical practice of radiation therapy can result in the occurrence of severe sequelae (complications) in up to five to ten percent of patients. . . For acute radiation injuries. . . the court should find for defendants **if there is proper informed consent** and no malpractice."); Fred Luhman, *Physicians Use of Excessive Radiation*, 17 AM JUR. PROOF OF FACTS 575 (1978)(emphasis supplied).

the treatment constitutes a battery."[31] In a "medical battery" if a physician exceeds the scope of operative consent and in a non-emergency setting perfoms a new or different operation, the plaintiff is not required to prove that if the physician had stopped the operation, awoke the patient, and asked for consent, that a "reasonable patient" would have refused consent.[32] Likewise, Pennsylvania has applied this analysis and result to informed consent battery cases in *Gouse v. Cassel*, 532 Pa. 197, 615 A.2d 331 (1992); *Taylor v. Albert Einstein Medical Center,* No. 03787, 1998 WL 880887, (Pa. Super. Ct. 1998); *Rowinsky v. Sperling*, 452 Pa. Super., 215, 223-225, 681 A.2d 785 (Pa. Super. Ct. 1996), *appeal denied,* 547 Pa. 738, 690 A.2d 237 (1997); *Boutte v. Seitchik,* 719 A.2d 319 (Pa. Super. Ct. 1998); and *Shaw v. Kirschbaum*, 653 A.2d 12, 15-16 (Pa. Super. Ct. 1994), *appeal denied*, 664 A.2d 812 (Pa. 1995). Pennsylvania law recognizes that: "Recovery on the theory of informed consent is permitted regardless of causation because it is the conduct of the unauthorized procedure that constitutes the tort."; *Moure v. Raeuchle*, 529 Pa. 394, 402, 604 A.2d 1003, 1007 (1992).[33]

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[31] It is worth recalling that in the sentences immediately preceding the stirring statement in *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 105 N.E. 92 (1914) of every human being's right to determine what shall be done with his or her body, Judge Cardozo observed, "In the case at hand, the wrong complained of is not merely negligence. It is trespass." *See also Gray v. Grunnagle*, 423 Pa. 144, 223 A.2d 663 (1966) (failure to warn of risks of spinal operation is a battery where paralysis results); *Belcher v. Carter,* 13 Ohio App. 2d 113, 234 N.E.2d 311 (Ohio Ct. App. 1967)(failure to warn of danger of radiation is a battery).

[32] Thus if a patient consents to right ear surgery and during surgery the physician decides, albeit for sound medical reasons, that the left ear needs surgery, the surgeon commits a battery if without reviving the patient he operates on the left ear. *Mohr v. Williams*, 95 Minn. 261, 104 N.W. 12 (1905).

[33]Pennsylvania law does not codify, or apply by judicial decision, an expert standard for disclosure of information and risks. In 1997, the Pennsylvania legislature condified the duty of disclosure is informal consent cases in 40 PA. STAT. ANN. §1301.811-A (1997) requiring informed consent in cases involving surgery, anesthesia, radiation therapy, chemotherapy, blood transfusions, insertion of a surgical device or appliance, experimental medications, experimental devices, or using an

As noted in Plaintiff's discussion of the history of the law of informed consent, Tennessee did not take a "turn in the road" as did most other jurisdictions in the 1960s and 1970s and meld informed consent cases into negligence law. In a thoughtful opinion of the Supreme Court of California, *Cobbs v. Grant,* 8 Cal. 3d 229, 104 Cal. Rptr. 505, 502 P.2d 1 (1972) Justice Mosk noted:

> Dean Prosser surveyed the decisions in this area [battery versus negligence in informed consent cases] and concluded, "The earliest cases treated this as a matter of vitiating the consent so that there was liability for a battery. . ."
>
> Although this is a close question, either prong of which is supportable by authority, the trend appears to be toward categorizing failure to obtain informed consent as negligence. . .
>
> [This trend towards negligence] reflects an appreciation of the several significant consequences of favoring negligence over a battery. . .
>
> [M]ost jurisdictions have permitted a doctor in an informed consent action to interpose a defense that the disclosure he omitted to make was not required within his medical community. However, expert opinion as to community standard is not required in a battery count, in which the patient must merely prove failure to give informed consent
>
> and a mere touching absent consent.[34] Moreover, a doctor could be held liable for punitive damages under a battery count, and if held liable for the intentional tort of battery might not be covered by his malpractice

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approved medicine or device in an experimental manner. The Pennsylvania courts continue to apply the battery theory. *Morgan v. MacPhail*, 550 Pa. 202, 704 A.2d 617 (1997).

[34] It will be immediately realized that this concern or reason for moving to a negligence theory is inapplicable in Tennessee since expert testimony is required by Tennessee separate statute on informed consent that requires expert proof of the community standard of care for disclosure of information TENN. CODE ANN.§ 29-26-118 (1980).

> insurance.[35] Additionally, in some jurisdictions the patient has a longer statute of limitations if he sues in negligence.[36], [37]

Tennessee has chosen to respect and safeguard patient autonomy by giving patients the deciding vote in matters that affect their lives. By contrast, the states that departed from the battery analysis and employed a negligence causation analysis have been strongly criticized by eminent scholars and critics for undermining a patient's right of autonomy through a mythical and unworkable inquiry into a plaintiff's decision-making process after the fact.[38] Professor Aaron Twerski (reporter for the ALI's 1998 RESTATEMENT (THIRD) OF THE LAW OF PRODUCTS LIABILITY) and Professor Neil Cohen chastised the "myth of causation" in informed consent cases in a 1988 article in the University of Illinois Law Review[39]:

> The classic tort model for informed consent litigation, while simple in theory, is seriously flawed in practice. The model depends on constructing a causal bridge between the absence of the information and the decision of the plaintiff to proceed with the therapy or use the product. Except in

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[35] These concerns by Justice Mosk are also not manifested in Tennessee. Under *Cardwell v. Bechtol* physicians have remained insured and punitive damages may only be awarded for truly exceptional misconduct under *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896 (Tenn. 1992).

[36] *Cobbs v. Grant*,8 Cal. 3d 229, 104 Cal. Rptr. 505, 502 P.2d 1 at 8 (1972).

[37] Actually the doctrinal difference between informed consent cases and negligence cases continues to permit courts to apply separate statutes of limitations, or dates, under the discovery rule. *See Gaston v. Parsons*, 318 Or. 247, 864 P. 2d 1319 (1994).

[38] *See e.g.*, A. Twerski, N. Cohen, *Informed Decision Making and the Law of Torts: The Myth of Justiciable Causation*, 1988 U. of Illinois L. Rev. 614 n. 29 (1988); PAUL S. APPELBAUM, CHARLES W. LIDZ & ALAN MEISEL, INFORMED CONSENT at 122 (1987)("By conditioning the availability of compensation on the congruence between the patient's own decision and what a so-called reasonable person would have decided, the objective test undercuts a patient's right of self-determination."); JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT 79-80 (1984); Koopersmith, *Informed Consent: The Problem of Causation*, 3 MED. & LAW 231 (1984).

[39] A. Twerski, N. Cohen, *Informed Decision Making and the Law of Torts: The Myth of Justiciable Causation*, 1988 U. OF ILLINOIS L. REV. 607 (1988).

> the most blatant situations, the causal relationship between inadequate information and plaintiff decision making is, we shall demonstrate, not practically justiciable. The law does and can only consider the information the health professional or product vendor should deliver. It does not and cannot consider the multitude of factors that influence the way people actually make decisions. To decide causation without looking at the latter is wholly illusory. On the other hand to insist on such an inquiry would involve the courts in the kind of investigation of human behavior that would seriously compromise the judicial process. . . [40]
>
> One might expect that if informed consent was not obtained, the courts would have recognized a cause of action for battery on behalf of the ill-informed patient. If the physician violated a duty to inform the patient of risks and alternatives to the recommended therapy such that consent was effectively voided ab initio, then the doctors' touching of the patient was unwanted and offensive. [Citing, in a footnote, *Cardwell v. Bechtol*] Nonetheless, the vast majority of courts have refused to adopt this approach.[41]

These authors also conclude that the "rubric of battery" best protects the dignitary interest of autonomy.[42] Reading these observations on the law of informed consent by Professors Twerski and Cohen simply reaffirms the wisdom and resolve of this Court's opinions in *Cardwell v. Bechtol*, 724 S.W.2d 739 (Tenn. 1987) and *Shadrick v. Coker*, 963 S.W.2d 726 (Tenn. 1998). The negligence approach to informed consent was the wrong turn in the road. By adhering to the battery theory in informed consent cases in clear and unmistakable language, this Court, and Pennsylvania, have avoided (or actually solved) the "causation dilemma" in informed consent/negligence cases. The "but-for" causation test of the law of negligence is inapposite to cases involving battery and non-consensual invasions. It is no defense, and indeed of no moment, for a defendant to say, after the fact, "Oh well, even though my harmful, wrongful or

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[40] *Id.* at 608.

[41] *Id.* at 611.

[42] *Id.* at 616.

offensive contact hurt you, if I had asked you beforehand for consent, you, or certainly a reasonable person, would have consented."[43] Application of the "but-for" test in informed consent cases trammels on the paramount right of patient autonomy and forgives the harm resulting from a wrongful and unlawful procedure.[44]

Moreover, the "but-for" test, even in the law of negligence, is neither comprehensive nor exclusive as a test for causation. For example, where there are two causes at work and either of them, alone, would have been sufficient to bring about the result (as in the classic "twin fires case"), the "but-for" test does not work since each defendant could argue the injury would have occurred anyway.[45]

The Pennsylvania Supreme Court's decision in *Gouse v. Cassel*, 532 Pa. 197, 615 A.2d 331 (1992), and subsequent Pennsylvania decisions, are entirely consistent with Tennessee's battery theory of informed consent. Physicians today are well aware of the need to obtain a patient's informed consent to surgery or therapeutic treatment involving bodily invasion. The American Medical Association's Council on Ethical and Judicial Affairs has directly addressed the issue of informed consent:

> E-8.08 Informed Consent.
>
> The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient should make his or her own determination on treatment. The

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[43] For example, if a passerby touches or takes liberties with a person asleep on a park bench in an offensive way, it is of no consequence that the unconscious person, if awoken, might have consented to the touching. The law recognizes the primacy of the individual's right to autonomy and protects the dignitary interest under the law of trespass on the case and battery.

[44] FAY A. ROZOVSKY, CONSENT TO TREATMENT, A PRACTICAL GUIDE, 82 (2d. ed. 1990) ("[I]t is the provision of treatment based upon inadequate disclosure that causes the harm.").

[45] *See Anderson v. Minneapolis, St. Paul & Sault St. Marie R.R. Co.*, 146 Minn. 430, 179 N.W. 45 (1920).

> physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic social policy for which exceptions are permitted: (1) where the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent; or (2) when risk-disclosure poses such a serious psychological threat of detriment to the patient as to be medically contraindicated. Social policy does not accept the paternalistic view that the physician may remain silent because divulgence might prompt the patient to forego needed therapy. Rational, informed patients should not be expected to act uniformly, even under similar circumstances, in agreeing to or refusing treatment. Issued March 1981. (I, II, III, IV, V)[46],[47]

The American Medical Association's House of Delegates has reaffirmed the duty to obtain informed consent:

> H-140.989 Informed Consent and Decision-Making in Health Care
>
> (1) Health care professionals should inform patients or their surrogates of their clinical impression or diagnosis; alternative treatments and consequences of treatments, including the consequence of no treatment; and recommendations for treatment. Full disclosure is appropriate in all cases, except in rare situations

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[46] American Medical Association, Council on Ethical and Judicial Affairs, *Current Opinions of the Council on Ethical and Judicial Affairs*, *Opinions on Practice Matters* E8.08 (1992). (AMA policies available by download at: http//:206.189.190/ad-com/polfind/announce.htm.

[47] *See also,* statements on informed consent by other authoritative medical bodies: American Hospital Association, Board of Trustees,*Patient Bill of Rights* (1992), http://www.aha.org/resource/pbillofrights/html. ("The patient has the right to obtain from his physician complete current information concerning his diagnosis, treatment and prognosis in terms the patient can reasonably be expected to understand. . .The patient has the right to receive from his physician information necessary to give informed consent prior to the start of any procedure/treatment.") American College of Physicians, *Ethics Manual* (1992); American Medical Association, C*ode of Medical Ethics: Fundamental Elements of the Patient-Physician Relationship* (1992)("The patient has the right to receive information from physicians and to discuss the benefits, risks and costs of appropriate treatment alternatives. . . . The patient has the right to make decisions regarding the health care that is recommended by his or her physicians. Accordingly, the patient may accept or refuse any recommended medical treatment") at http://www.ama-assn.org/ethic/fundelms.htm; President's Commission For The Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, MAKING HEALTH CARE DECISIONS (1982) (patients have the right to receive all relevant information prior to treatment). These and other authorities on informed consent are discussed at length in a clinical textbook prepared by several professors from the University of Virginia School of Medicine: JOHN C. FLETCHER, *et al*., INTRODUCTION TO CLINICAL ETHICS (1995).

> in which such information would, in the opinion of the health care professional, cause serious harm to the patient.
> (2) Individuals should, at their own option, provide instructions regarding their wishes in the event of their incapacity. Individuals may also wish to designate a surrogate decision-maker. When a patient is incapable of making health care decisions, such decisions should be made by a surrogate acting pursuant to the previously expressed wishes of the patient, and when such wishes are not known or ascertainable, the surrogate should act in the best interests of the patient.
> (BOT Rep. NN, A-87; Reaffirmed: Sunset Report, I-97)[48]

From a fairness and fault perspective there is a strong basis for invoking battery liability since, under Tennessee law, there must be expert proof that the physician did not make the informed consent disclosures required by the standard of care.[49] Thus, a patient whose consent was obtained in a sub-standard and ill-informed manner may rightfully rely upon the law of battery for protection. As Shakespeare put it in 1601, "I'll have an action of Battery against him if there be any law in Illyria."[50]

CONCLUSION

Patricia Ashe consented to radiation therapy to her chest without any disclosure or discussion by her radiation oncologist of the known risk of permanent paralysis from radiation injury to the spinal cord. The Plaintiff introduced expert evidence and

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[48] American Medical Association, *House of Delgates Opinion H-140.989*(1997). These and other AMA policies are available by download at: http://www.ama-assn.org/ad-com/polfind/announce.htm (search="informed consent").

[49] Indeed there is a more compelling rationale to impose battery liability without negligence causation proof in informed consent cases than in "medical battery" cases. In the informed consent case the physician must be shown to have been a wrongdoer (by failing to provide the information required by expert testimony under the standard of care). In a medical battery case there is no need for expert proof and despite the best medical care and medical judgment the law imposes battery liability on the basis of a violation of the patient's right of personal autonomy.

[50] WILLIAM SHAKESPEARE, *Twelfth Night*, act iv., scene 1, lines 32-33 in THE YALE SHAKESPEARE (Barnes & Noble 1993).

testimony that the risk of radiation paralysis was between 1-2% and in some reported studies as high as 5% at the doses Ms. Ashe received. The trial court granted a directed verdict for the Defendants on the informed consent claim applying a subjective but-for causation test. The Court of Appeals reversed and remanded and announced an objective but-for causation test. Under this Court's opinions in *Cardwell v. Bechtol*, 724 S.W.2d 739 (Tenn. 1987) and *Shadrick v. Coker*, 963 S.W.2d 726 (Tenn. 1998), however, the law of battery applies to informed consent cases and the Plaintiff is not required to prove that she would have refused the treatment if properly informed by her physician. There are compelling reasons to eschew negligence analysis and treat informed consent cases as a *trespass on the case* -- as a battery. As therapies and medical advances race forward the law must vigilantly safeguard the absolute right of the individual to make an informed decision concerning medical treatment.

The Plaintiff respectfully prays that this Honorable Court hold, consistent with the authorities discussed herein, that in an informed consent case the theory of battery applies in the State of Tennessee and that the plaintiff is not required to establish that she would have refused the treatment if properly informed by the physician. Plaintiff further prays that this Court direct a verdict in favor of the Plaintiff on the issue of causation, there being no dispute that the radiation therapy caused the Plaintiff's paralysis.[51] Finally, Plaintiff prays that the case be remanded for trial on the issue of whether the Defendant physician failed to obtain the Plaintiff's informed consent to radiation therapy as this issue was pretermitted by the trial court's entry of a directed verdict on the informed consent claim at the close of the Plaintiff's proof.

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[51] The Plaintiff moved for a partial summary judgment on the issue of causation since there was no disputed issue of fact on the question of whether the radiation therapy caused Ms. Ashe's paralysis (TR 19-37).

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document has been hand-delivered to the following:

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on this the 15th day of March, 1999.

_____
David Randolph Smith