1982

Informed Consent in Pennsylvania - The Need for a Negligence Standard

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INFORMED CONSENT IN PENNSYLVANIA—
THE NEED FOR A NEGLIGENCE STANDARD

I. INTRODUCTION

The belief that a doctor is under a duty to disclose the collateral risks of a proposed treatment to his patient was first enunciated in this country in 1957. Since then, the doctrine of informed consent has generated considerable controversy in the courts, among legal scholars, and within the health care professions. It constitutes one of the pri-


2. Meisel, The "Exceptions" to the Informed Consent Doctrine, supra note 1, at 415. In Professor Meisel's opinion, the doctrine of informed consent is a source of conflicting viewpoints. Id. He states that although it has been "condemned by the medical profession as a 'myth' and a 'fiction,' it has been generally praised by legal scholars for promoting significant individual rights and has also been well regarded by the plaintiff's bar, though perhaps for less altruistic reasons." Id. The proponents of informed consent contend that the doctrine protects the patient's right to determine his own destiny in medical matters; it promotes his status as an autonomous human being; it guards against overreaching on the part of the physician; it protects his physical and psychic integrity and thus his privacy; and it compensates him both for affronts to his dignity and for the untoward consequences of medical care.

Id. at 414-15 (footnotes omitted).

Opponents of the doctrine of informed consent insist that it wastes valuable time that could be spent in rendering treatment to the ill, in part because patients do not understand what they are told and in part because they do not want to be informed; it undermines the trust which patients need to reposit in their doctors if they are to be successfully treated; and it requires disclosure of information about the possibility of the risks of treatment or failure of the treatment that may lead to a psychologically induced self-fulfilling prophecy.

In addition, the goal of disclosure of information to patients—that they may make their own choice about treatment—is illusory because disclosure can (and indeed usually will) be made by the physician.
mary sources of antagonism between doctors and lawyers, since the issue is most often raised in the context of a lawsuit against the doctor for medical negligence. A patient who has suffered a "bad result" of treatment and is unable to prove that his doctor was negligent now can seek relief on this completely different basis of liability. An allegation in such a way as to assure that the patient agrees to the treatment. Also, some patients have their minds made up . . . and the receipt of information does not change their decision. For other patients, the disclosure of information needlessly frightens them, possibly to the extent that they refuse necessary treatment.

Id. at 415-16 (footnotes omitted). See also 2 D. LOUISELL & H. WILLIAMS, MEDICAL MALPRACTICE ¶ 22.01 (1981).

3. Meisel, The "Exceptions" to the Informed Consent Doctrine, supra note 1, at 413.


5. See Meisel, The Expansion of Liability, supra note 1, at 52-53 n.4.

There is some risk that any procedure, even in the absence of negligence, may not yield the intended result or may end in a "bad result." Id. at 56. "Bad results" of medical intervention may occur either as a result of negligence on the part of the doctor or as a result of "statistical risk." Id. at 54. Unfortunately the problem of distinguishing the two causes of bad results is complicated by the fact that the patient is usually ill or injured before seeking treatment. Id. at 56. Traditionally, a patient who suffered a "bad result" of treatment in the absence of medical negligence could not recover, while a patient whose "bad result" was caused by medical negligence could find redress in the courts. Id. at 56-57. In Meisel's opinion, courts have tried to find ways to compensate all patients who have suffered a bad result, and, for this reason, there has been a slow and almost imperceptible trend toward a system of judicially created strict liability in medical negligence cases. Id. at 57. Meisel sees the doctrine of informed consent as a method by which the courts have been able to circumvent the requirement of negligence and allow the plaintiff to recover. Id. at 58.

Another commentator notes that, because medical technologies often have unwanted side effects, such as iatrogenic illnesses caused by untoward actions of drugs and the risks involved in various diagnostic procedures, the public and the courts seem to be unable to distinguish between true medical negligence and unsatisfactory therapeutic results. See Bennett, Technology as a Shaping Force, in DOING BETTER AND FEELING WORSE—HEALTH IN THE UNITED STATES 125, 132 (J. Knowles ed. 1977). In Dr. Bennett's opinion, the growing number of malpractice suits is the result of unreasonably inflated public expectations regarding what medicine can accomplish. Bennett, supra, at 132. According to Dr. Bennett, these inflated expectations exist partly because the medical profession has not properly educated the public, and partly because of the "Marcus Welby" syndrome, stimulated by television shows in which doctors and hospitals produce a cure in 60 minutes. Id. It is Dr. Bennett's opinion that

"[malpractice," to a very large degree, is a result of technological advances in medicine. This is not meant to imply that the public does not deserve or need to be protected from negligence or incompetence, but that one of the tasks of medicine and society must be to set limits "to the boundless hopes and expectations, constantly escalating which technology has engendered. Advanced technology has promised transcendence of the human condition. That is a false promise, incapable of fulfillment. Human desires are infinite and cannot be achieved by the finite means of technology."

Id. (quoting Callahan, Science: Limits and Prohibitions, 3 HASTINGS CENTER REPORT (1973)).
of the absence of informed consent will not only fortify a weak case of medical negligence, but will also guarantee the plaintiff that his case will reach the jury. In view of this, it is hardly surprising that the percentage of malpractice suits alleging lack of informed consent is increasing.

The notion that a patient must be provided with pertinent information regarding the course of his medical and surgical treatment was borne of a societal change in attitude concerning the nature of the doctor-patient relationship. Many no longer view the patient as a passive entity within a paternalistic and hierarchical medical system. Rather, the patient is now viewed as having the right to determine the direction of his medical treatment, and to base his decisions on accurate information supplied by his doctor. Accordingly, the legal system has developed the concept of informed consent.

6. J. Ludlam, supra note 4, at 6. In Pennsylvania, the questions of what information must be given in order to render a consent informed and whether such a consent was given are always for the jury. See note 91 and accompanying text infra.

One commentator urges that the theory of informed consent is one which should not be indiscriminately relied on by plaintiffs' counsel. See Shrager, The Strategy of Theory Development, Trial, June 1981, at 39. The author sees informed consent as a theory which should generally be reserved for situations in which medical negligence has been ruled out, since “conceptually informed consent deals with the risk of harm which may arise from non-negligent treatment.” Id. at 40, 42. Furthermore, in order for the plaintiff to prevail, the following additional criteria must be present: 1) proof of failure to disclose; 2) injury from a risk not disclosed; 3) elective surgery; and 4) a showing that a reasonable patient, if warned of the risks, would have decided to forego the procedure. Id. at 40.

7. See Meisel, The Expansion of Liability, supra note 1, at 76-77. See also Schneyer, Informed Consent and the Danger of Bias in the Formation of Medical Disclosure Practices, 1976 Wis. L. Rev. 124, 142.

8. For a thorough examination of the recent changes in attitude regarding health care, see Fox, The Medicalization and Demedicalization of American Society, in Doing Better and Feeling Worse—Health in the United States 5, 9-22 (J. Knowles ed. 1977). Fox notes that, during the last few years, many medico-legal decisions of far-reaching importance have been made by the courts and legislatures. Id. at 12-14. Patients have asserted various individual and collective rights—expressed as “health,” “quality of life,” and “quality of death”—to which they feel entitled. Id. This process, in Fox’s opinion, “also involves heightened awareness of a whole range of imperfections, injustices, dangers, and afflictions that are perceived to exist in the society, a protest against them, and a resolve to take action. . . .” Id. at 14.

9. Id. at 20. Fox discusses the attempts which have been made to “destratify” the doctor’s relationship with patients and other health professionals through greater emphasis on a patient’s right to treatment, right to information (relevant to diagnosis, therapy, and prognosis), right to confidentiality, and right to be allowed to die. Id. at 19. In Fox’s opinion, there is reason to believe that the doctor, as a consequence of pressure from outside and within the medical profession, will become less dominant and autonomous and subject to more control. Id. at 21.

10. Id. See R. Shandell, The Preparation and Trial of Medical Malpractice Cases § 5.02 (1981). Shandell states that [i]t is an ancient conceit of the medical profession that ‘the doctor knows best’ and that patients are people of low intelligence, who
The doctrine of informed consent is a direct outgrowth of the common law rules governing the intentional tort of battery. Most jurisdictions which have recognized the doctrine, however, have determined liability using a negligence framework. In contrast, the Pennsylvania courts, while imposing an affirmative duty on the doctor to disclose certain information regarding treatment, have continued to develop the doctrine under the legal rubric of “assault and battery.” The unfortunate result has been a “hybrid” tort, the use of which allows the courts to impose liability on the doctor who breaches his duty to disclose regardless of whether that failure to disclose was the legal cause of the injury. Furthermore, Pennsylvania’s rigid adherence to a theory of liability grounded in battery has led one court to the conclusion that no cause of action for lack of informed consent can lie where the patient cannot possibly understand the complexities involved in medical decisionmaking, and ought not to be given a say about treatment even when it involves the patient’s own body.

From the doctor’s perspective, the issue of informed consent heralds a basic change in his role as a practitioner. See J. Ludlam, supra note 4, at 6. Ludlam notes that many physicians have intellectual difficulty with the idea that the patient not only has the right to participate in and control the medical decision, but that he also has the right to make the “wrong” medical decision. Id. at 2, 8. Doctors are also disturbed by uncertainty regarding what the new duty of disclosure entails. See, e.g., 2 D. Louisell & H. Williams, supra note 2, at ¶ 22.01. Professor Louisell and Dr. Williams note that “as a practical matter, physicians are at a loss to decide exactly what dangers they should disclose, since such dangers, to a physician with a good imagination are literally without number.” Id. See also Zaslow, Informed Consent in Medical Practice, 22 PRAC. LAW. 13 (1976). In Dr. Zaslow’s opinion, most doctors will understand that a patient must be informed of obvious possible complications, such as voice loss after a thyroidectomy, facial palsy following parotidectomy, or paralysis of an extremity—even though these occur in a small percentage of cases. Id. at 17. However, Dr. Zaslow contends that a doctor will be unsure whether he should discuss the less obvious risks, such as wound infections and disruptions, adjacent organ injuries, or peritonitis resulting from poor intestinal healing. Id. In addition, Dr. Zaslow notes that there are complications which are so unusual that the most learned physician could not think of them all. Id. A similar confusion exists in the dental profession where many procedures are elective and there are usually multiple methods of treating any particular condition. See R. Warner & H. Segal, Ethical Issues of Informed Consent in Dentistry 13 (1980).
ment does not involve "touching" the patient.\textsuperscript{14} That this reasoning can lead to inconsistent results is obvious, since a patient will have a cause of action where the risks of surgery or injected medication are not disclosed but will be left without a remedy where there is no disclosure of the risks of oral medication.\textsuperscript{15}

It is the purpose of this comment to examine the law of informed consent and its development in Pennsylvania.\textsuperscript{16} Attention will be focused on the theory of liability that has been employed by the Pennsylvania courts which have dealt with the issue of informed consent.\textsuperscript{17} Finally, an argument will be made that it is appropriate at this time for Pennsylvania to abandon the battery theory in favor of a cause of action grounded in negligence.\textsuperscript{18}

II. The Bases of Liability

Traditionally, a cause of action for failure to procure a patient's consent before treatment was decided under a battery theory of liability.\textsuperscript{19} The patient had to allege and prove only that the doctor engaged in an unprivileged touching without the patient's permission.\textsuperscript{20} The primary compensable harm was the violation of the patient's bodily dignity.\textsuperscript{21} A doctor who was found liable for battery was also deemed to be responsible for any physical ill effects which resulted from the treatment, regardless of whether the treatment was within the standard of care usually observed by members of the profession.\textsuperscript{22} This was the case even where the patient would have consented had he been given the opportunity.\textsuperscript{23}

\begin{thebibliography}{99}
\bibitem{15} For a discussion of Malloy, see notes 71-76 and accompanying text \textit{infra}.
\bibitem{16} See \textit{infra}.
\bibitem{17} See \textit{infra}.
\bibitem{18} See \textit{infra}.
\bibitem{20} McCoid, supra note 19, at 384.
\bibitem{21} See, e.g., Lacey v. Laird, 166 Ohio St. 12, 139 N.E.2d 25 (1956) (plaintiff was awarded the nominal sum of one dollar where an unauthorized operation proved beneficial).
\bibitem{22} See Comment, supra note 19, at 1399 n.18.
\bibitem{23} See McCoid, supra note 19, at 392. Professor McCoid contends that in informed consent cases relying on the battery theory \[\text{the fact that the medical treatment to which there is no consent is not seriously harmful, or is in fact beneficial to the patient, does not excuse the doctor. Further, the fact that the treatment is conducted in accordance with the dictates of good surgery or medicine and is done in a skillful and careful manner does not constitute an excuse.}\]
\textit{Id.}
In the early 1960s, largely as a result of changing social attitudes, courts across the nation began to impose an affirmative duty on the doctor to disclose the collateral risks of a proposed treatment. A new cause of action based on the lack of informed consent was created and was almost universally considered under negligence concepts. This method of dealing with the doctor's failure to disclose possible risks of treatment was consistent with the prevailing view that it was inappropriate to hold a doctor liable for an intentional tort when his wrong was in the nature of an omission and when he acted without an intent to injure his patient. The battery theory was reserved in most states for situations in which doctors willfully performed unauthorized procedures or deviated from the scope of the patient's consent by operating on a part of the body for which consent had not been given.

24. See J. Lieberman, The Litigious Society 81 (1981); R. Shandell, supra note 10, at § 5.03. Little thought was given to the notion that a patient is entitled to make a decision based upon information regarding risks, benefits, and alternatives of proposed treatment until about 1960, when a changed attitude was manifested in a series of decisions across the country. The first decision to discuss the duty to disclose at any length was Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093 (1960).

25. J. Lieberman, supra note 24, at 81. See Meisel, The Expansion of Liability, supra note 1, at 84-86. The birth of the new doctrine and early cases in which negligence concepts were utilized is discussed. Id. (citing Mitchell v. Robinson, 344 S.W.2d 11 (Mo. 1960), aff'd after retrial, 360 S.W.2d 673 (Mo. 1962); Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093 (1960)).


We agree with the majority trend. The battery theory should be reserved for those circumstances when a doctor performs an operation to which the patient has not consented. . . . However, when the patient consents to certain treatment and the doctor performs that treatment but an undisclosed inherent complication with a low probability occurs, no intentional deviation from the consent given appears; rather, the doctor in obtaining consent may have failed to meet his due care duty to disclose pertinent information. In that situation the action should be pleaded in negligence.

Cobbs v. Grant, 8 Cal. 229, 240, 502 P.2d 1, 8, 104 Cal. Rptr. 505, 512 (1972). See also Trogun v. Fruchman, 58 Wis. 2d 569, 599-600, 207 N.W.2d 297, 313 (1973). The Trogun court advanced several reasons why modern courts tend to treat cases based on risk disclosure under negligence concepts: battery is commonly perceived as an act of an antisocial nature; the act complained of in non-disclosure is not within the traditional idea of "touching"; the failure to inform is generally not an intentional act and is thus inconsistent with the requirement that battery be intentional; the doctor's malpractice insurance may not cover assault and battery; and informed consent actions do not appear to be appropriate cases for punitive damage awards. Id.

27. See J. Ludlam, supra note 4, at 23. The author states that "[t]he cases in which the battery theory is properly applied include: where the physician obtains consent to perform an operation, but either exceeds the scope of that consent, misrepresents the severity of the operation, or performs an operation of a substantially different nature." Id. at 23-24 (footnotes omitted).
Under the negligence theory of informed consent, the patient must prove that the doctor failed to disclose pertinent information regarding the nature of a proposed procedure, its risks, and alternatives. In some jurisdictions, the adequacy of this disclosure is judged by what facts are usually disclosed by doctors, but in other jurisdictions, the standard is based on what facts a reasonable person in the patient's situation would want to be told. In addition to proving inadequate disclosure on the part of the doctor, the patient must prove that he suffered an injury and that the injury was causally related to the doctor's failure to inform. The test for causation used in most recent decisions is whether a reasonable patient would have rejected the treatment had he been apprised of the possibility of the risk which materialized.

III. DEVELOPMENT OF THE DOCTRINE IN PENNSYLVANIA

It has long been the law in Pennsylvania that, in the absence of an emergency, failure to procure a patient's consent before an operation renders a doctor liable for a "technical assault." This term was borrowed from courts in other jurisdictions which had coined the term in the early 1900s as a euphemism for battery in cases where doctors were found liable for operating without consent. As an intentional tort, a

28. Id. at 26-32.
29. For an explanation of the two standards of disclosure, see note 48 infra.
30. See J. Ludlam, supra note 4, at 33-36. The requirement of causation has two parts. First, the patient must show that his injury resulted from a risk which the doctor negligently failed to disclose. Second, the patient must show that "but for" this failure to disclose, he would not have undergone the procedure. Id. at 34. See also Shartis, Informed Consent: Some Problems Revisited, 51 Neb. L. Rev. 527, 547 (1972). Under a negligence theory, the patient must prove that he would not have undergone the procedure had he known of the risk, and that, therefore, the doctor's withholding of information was the proximate cause of the injury. Id.
31. See J. Ludlam, supra note 4, at 34. Courts initially used a subjective test for causation in which they attempted to determine what the particular patient would have decided had the risks been disclosed. Modern decisions, however, have tended to utilize an objective test and have tried to ascertain what a reasonable patient in the plaintiff's situation would have decided. Id. For a more detailed discussion of the causation requirement, see notes 56-70 and accompanying text infra.
32. See Moscicki v. Shor, 107 Pa. Super. 192, 195, 163 A. 341, 342 (1932). In Moscicki, the plaintiff, a dental patient, consented to full mouth extractions but insisted that only her lower teeth be removed at that particular visit. Id. at 194-95, 163 A. at 341. The dentist, after administering anesthesia, removed all of the patient's teeth. Id. The superior court held that the jury could consider whether the dentist was liable for "technical assault." Id. at 201-02, 163 A. at 344.
33. Id. at 195-96, 163 A. at 344. The Moscicki court borrowed the term "technical assault" from previous cases in other jurisdictions. Id. (citing Throne v. Wandell, 176 Wis. 97, 101, 186 N.W. 146, 147 (1922); Mohr v. Williams, 95 Minn. 261, 104 N.W. 12 (1905)). In Mohr, the patient con-
cause of action for technical assault exists independently of any action for negligence which may have occurred in the medical treatment itself. The burden of proof in a battery action has always been on the patient to show that the procedure performed was unauthorized.

In 1966, the Supreme Court of Pennsylvania, in Gray v. Grunnagle, followed the nationwide trend by imposing an affirmative duty on the doctor to disclose information to his patient regarding the nature of the proposed treatment and the risks involved. In Gray, the court stated that, in order for a patient's consent to be operative, the consent must be both "informed" and "knowledgeable." Further, the court

sent an operation on her right ear. After she was anesthetized, the physician examined both ears, and finding the condition of the left ear more serious than that of the right ear, decided to operate on the left ear. In response to the doctor's argument that the law of assault and battery was inappropriate to the case, the court stated that the "act of defendant amounted at least to a technical assault and battery." In Gray, the patient underwent an exploratory laminectomy to discover and, if possible, correct the cause of his progressively worsening leg condition. After the exploratory laminectomy was performed by Dr. Grunnagle, a neurosurgeon, the patient was unable to walk. Dr. Grunnagle testified that, while it was his routine practice to advise patients of the serious risks of this type of surgery, he could not specifically remember informing Mr. Gray. He also testified that he believed that he would have an opportunity to decide if he wanted to undergo corrective surgery after the results of the first operation were known. Dr. Grunnagle testified that, while it was his routine practice to advise patients of the serious risks of this type of surgery, he could not specifically remember informing Mr. Gray.


37. Id. The patient in Gray underwent an exploratory laminectomy to discover and, if possible, correct the cause of his progressively worsening leg condition. In this type of operation, an incision is made in the patient's back in the area of the spinal column. The source of the problem is observed and, if possible, corrective measures are taken. After the exploratory laminectomy was performed by Dr. Grunnagle, a neurosurgeon, the patient was unable to walk.

38. Id. at 158, 223 A.2d at 671 (citing Scott v. Wilson, 396 S.W.2d 532 (Tex. Civ. App. 1965)). The Scott court held that consent to an operation
concluded that whether any consent which had been given by the patient met this standard was a question for the jury. The Gray decision made it clear that Pennsylvania was joining those states that required disclosure of pertinent information to the patient. The supreme court in Gray, however, never considered the adoption of a negligence standard for the new cause of action. Instead, the court utilized the intentional tort concepts that had traditionally been employed in lack of consent cases. The court equated uninformed consent with no consent, was of no effect unless it was an “informed and knowledgeable” consent. 396 S.W.2d at 535.

39. 423 Pa. at 167, 223 A.2d at 674. The supreme court did not direct a verdict for the plaintiff even though Dr. Grunnagle testified that he had no recollection of informing his patient of a 10 to 15% risk that he would be in worse condition after the surgery. Id. at 163, 223 A.2d at 672.

40. The only clear holding of Gray was that the trial court had committed reversible error in granting the surgeon’s motion for judgment n.o.v. and that the question of whether Mr. Gray had actually given his consent to the major surgical operation which was performed was a question of fact for the jury. Id. at 167, 223 A.2d at 674. Gray was interpreted in 1970 by a federal court to mean that Pennsylvania courts would require disclosure of information regarding collateral risks and alternatives to the patient. See notes 43-46 and accompanying text infra. Subsequent courts have mechanically adopted that view and it is supported somewhat by the lengthy discussion of the informed consent concept in Justice O’Brien’s opinion. On close examination, however, it is questionable whether the Gray decision constituted a mandate for the requirement of disclosure. Justices Roberts and Cohen concurred with Justice O’Brien’s opinion solely on the ground that the issue of whether the patient consented to a major operation rather than a minor one was for the jury. Chief Justice Bell filed a dissenting opinion in which he argued that the signed consent form constituted a valid agreement between incision is made in the patient’s back in the area of the spinal column. The doctor and patient which authorized the operation. Justice Jones and Justice Eagen also dissented. Id. at 167, 223 A.2d at 675-76. The only issue which commanded a majority of four votes was the issue of whether it was the jury’s role to decide a conflicting issue of fact—whether Mr. Gray consented to major surgery.

The Gray decision created a myriad of unanswered questions. For a commentary written immediately after the decision, see Note, Informed Consent to Surgery—Substitution of Patient’s Subjective Understanding of Nature and Risks of Procedure for Objective Reasonable Man Test?, 71 Dick. L. Rev. 677 (1967). In that author’s opinion, the decision raised questions regarding the value of the consent form, the need for the plaintiff to prove proximate cause, and the standard which would be used in subsequent litigation to judge the validity of the consent given. Id. at 679-81.

41. The written opinion of Gray consisted of no more than the facts of that case, serially arranged quotations from a dated law review article, and opinions from other jurisdictions. The court quoted first from Powell, Consent to Operative Procedures, 21 Md. L. Rev. 189 (1961), for the propositions that the legal relationship between doctor and patient is essentially contractual in nature and that operation without consent constitutes assault and battery. 423 Pa. at 156, 223 A.2d at 669. Next, the court quoted from Bang v. Charles T. Miller Hosp., 251 Minn. 427, 88 N.W.2d 186 (1958). 423 Pa. at 156, 223 A.2d at 669. In Bang, the court held that a patient should be informed of alternative possibilities and given a chance to decide on a course of treatment before the doctor proceeds with an operation. 251 Minn. at 434, 88 N.W.2d at 190. Finally, the Gray court quoted at length from Scott v. Wilson, 396 S.W.2d 532 (Tex. Civ. App. 1965). 423 Pa. at 158, 223 A.2d at 670. The
and, therefore, in its opinion, treatment without disclosure of pertinent information constituted a technical assault.\textsuperscript{42}

\textbf{A. Definition of the Duty: Adoption of the Lay Standard of Disclosure}

Four years after \textit{Gray} was decided, the United States Court of Appeals for the Third Circuit gave further definition to the emerging doctrine of informed consent in \textit{Dunham v. Wright}.\textsuperscript{43} The \textit{Dunham} court stated that, under Pennsylvania law, a patient's consent to surgery was deemed "informed" only if the patient was told of the nature of the procedure and its risks, of alternative methods of treatment and their possibilities of success and inherent risks, and of the possible results of foregoing treatment altogether.\textsuperscript{44} The Third Circuit inferred facts in \textit{Scott} were similar to those in \textit{Gray}-the patient underwent an elective operation and suffered a complication from that surgery. The court held that any consent given was of no effect unless it was informed and knowledgeable, and that operation without such a consent constituted an assault and battery. 396 S.W.2d at 535.

The Powell article, on which the \textit{Gray} court heavily relied, was written before the doctrine of informed consent was generally recognized and did not address the concept of disclosure of collateral risks. Rather, it discussed the treatment of cases in which the doctor operates with no consent or with consent gained by coercion, or in which the doctor operates on the wrong organ or on the wrong person, or in which he performs an illegal operation. See Powell, supra, at 192-208. A footnote in the article recognized that assault and battery concepts may not be applicable in cases in which consent is given but the doctor fails to inform the patient of the risks. Powell, supra, at 190 n.4.

42. 423 Pa. at 159-60, 223 A.2d at 671. See 1 S. Pegalis \& H. Wachsmann, \textit{American Law of Medical Malpractice} §2:15 (1980). The authors discuss the rationale that the failure to disclose a risk negates consent. Id. at 96. They state that this result flows from the tort law concept that consent is ineffective when it is based on a mistake known to the defendant or is obtained by misrepresentation. Id. The authors note, however, that there are relatively few reported decisions based upon this theory. Id. (citing Gray v. Grunnagle, 423 Pa. 144, 223 A.2d 663 (1966); Shulman v. Lorner, 2 Mich. App. 705, 141 N.W.2d 348 (1966); Bang v. Charles T. Miller Hosp., 251 Minn. 427, 88 N.W.2d 186 (1958)).

43. 423 F.2d 940 (3d Cir. 1970). In \textit{Dunham}, the patient was seriously ill with a toxic thyroid and she was referred to the defendants, who were specialists, for thyroid surgery. Id. There was testimony that her condition was continually deteriorating and that surgery was her only hope of survival. The patient died immediately after surgery. Id. at 942. The court of appeals held that 1) the district court had sufficient evidence to send the issue of consent to the jury, and 2) the trial judge was not required to rule as a matter of law that no emergency existed. Id. at 947.

44. 428 F.2d at 943-44. The Third Circuit noted that, in \textit{Gray}, the supreme court "adopted the approach of jurisdictions that have tried to give substance to a patient's right to decide for himself what surgical procedures he wishes to undergo." Id. at 944. The Third Circuit also noted that these jurisdictions considered consent to be effective only if made after the patient has been advised of the possible consequences and risks inherent in the particular operation. Id. The court further noted that, although it had not been "clearly articulated," a careful analysis of the rationale of the cases
from Gray that under Pennsylvania law a doctor should never withhold from his patient information about possible complications of surgery. 45

relied upon by the court in Gray indicated that "before a patient will be deemed to give an informed consent, it may be necessary that he know the alternative methods of treatment available to him and the inherent dangers and possibilities of success of such alternatives." 46

In Dunham, the plaintiffs framed their complaint in terms of negligence and the trial judge charged the jury accordingly. 47 The Third Circuit, however, restated settled Pennsylvania law—a surgeon who operates without authorization is charged with an assault. 48 The court recognized that "[s]ome jurisdictions consider an action against a physician who operates without an informed consent as one sounding in negligence" and observed that the treatment of a physician's failure to disclose under negligence principles had been approved in a recent extensive law review article. 48 (citing Plante, supra note 1).

Most decisions involving informed consent have turned on the duty to disclose collateral risks of proposed surgical or corrective surgery rather than on the risks of foregoing treatment. Recently, however, in a controversial and much criticized opinion, the Supreme Court of California held that, even if a procedure is risk-free and diagnostic in nature, the doctor must inform his patient of possible adverse effects of refusing the procedure. Truman v. Thomas, 27 Cal. 3d 285, 611 P.2d 902, 165 Cal. Rptr. 308 (1980). The Truman court held that the doctor was liable for not disclosing risks of foregoing a diagnostic procedure where the patient refused a pap test and later developed cervical cancer. 48

45. 423 F.2d at 944-45. The Dunham court noted that it was not necessary for the doctor to give his patient a recital of medical casebook theory—he need only disclose possible alternatives for that particular patient. 48 at 946.

It was not immediately clear whether the Gray and Dunham courts promulgated a requirement that is fulfilled by the doctor's act of conveying information regarding treatment to his patient or whether the doctor must be sure that his patient understands the information in order to discharge his duty. See Meisel, The Expansion of Liability, supra note 1, at 113-23. Courts have failed to distinguish between the two concepts: "Judicial opinions use words like 'informed,' 'disclose,' 'tell,' 'know,' and 'understand' almost interchangeably without any apparent realization that the physician’s disclosure of information does not assure the patient's understanding of that information." 48 at 114 (footnotes omitted). Professor Meisel uses passages from Dunham as an example:

[B]efore a patient will be deemed to give an informed consent, it may be necessary that he know the alternative methods of treatment available to him and the inherent dangers and possibilities of success of such alternatives . . . . If a patient's decision is to be a knowing and intelligent one, he must understand in addition to the risks of the suggested surgery, the possible results of the failure to chance it. A complete understanding of the consequences of foregoing the operation would seem necessarily to include a consideration of the alternative treatment for the patient's disease or condition.

Some jurisdictions considering the duty of a physician to disclose to a patient the hazards of surgery have given broad discretion . . . . [I]n Pennsylvania a consent is "informed" only if the patient knows what is apt to happen to him.

47. 423 F.2d at 940, 944 (3d Cir. 1970) (emphasis added by Meisel). In Meisel's opinion, the confusion in language may be largely semantic (since "informed" can function as a verb or adjective), but it "betrays a deeper uncertainty on the part of the courts as to the true
nature of the obligation imposed by the doctrine of informed consent, and even more fundamentally with the purposes served by the doctrine itself." Id. at 116. Where the issue has been specifically considered, however, courts have held that the doctor discharges his duty to disclose when he makes a reasonable attempt to convey the necessary information to the patient. See notes 54 & 55 infra.

46. 423 F.2d at 946. The Third Circuit held that even though the evidence of an emergency was meager, the trial judge was not required to rule as a matter of law that no emergency existed. Id. at 947. A dissenting judge stated that, in his opinion, the facts of the case did not establish an emergency, since the patient had been in the hospital for over 30 days prior to the operation and this afforded the doctor adequate time in which to obtain a consent. Id. at 948 (Seitz, C.J., dissenting).

The emergency exception to the requirement of disclosure has long been recognized by the Pennsylvania courts. See, e.g., Gray v. Grunagle, 423 Pa. 144, 155, 223 A.2d 663, 668-69 (1966); Smith v. Yohe, 412 Pa. 94, 106, 194 A.2d 167, 174 (1963); Moscicki v. Shor, 107 Pa. Super. 192, 195, 163 A. 341, 342 (1932). The Moscicki court noted that "where a patient is in possession of his faculties and in such physical health as to be able to consult about his condition, and where no emergency exists making it impracticable to confer with him, his consent is a prerequisite to a surgical operation by his physician." Id.

Certain exceptions, or defenses, have not yet been considered by the Pennsylvania courts but have been recognized in other jurisdictions. For instance, an exception has been found where the existence of the risk was a matter of common knowledge and awareness of the risk could be imputed to the patient. See, e.g., Wilkinson v. Vesey, 110 R.I. 606, 627, 295 A.2d 676, 689 (1972). Courts have also found an exception where it could be shown that the patient requested that he not be informed. See, e.g., Cobbs v. Grant, 8 Cal. 3d 229, 245, 502 P.2d 1, 12, 104 Cal. Rptr. 505, 516 (1972). For a thorough discussion of the concept of waiver as it applies to the law of informed consent, see Meisel, The "Exceptions" to the Informed Consent Doctrine, supra, note 1, at 458-60. Some states have recognized the defense by statute. See, e.g., N.Y. PUB. HEALTH LAW § 2805-d(4)(b) (McKinney 1977); UTAH CODE ANN. § 78-14-5.2(c) (1977). The duty to disclose has also been suspended where the patient is unable to give consent due to mental or physical disability. 1 S. PEGALIS & H. WACHMAN, supra note 42, at 101. For a discussion of this "incompetency" exception, see Meisel, The "Exceptions" to the Informed Consent Doctrine, supra note 1, at 439-53.

The defense to the disclosure requirement which has received the most attention from courts and scholars is the "therapeutic privilege." J. LUDLAM, supra note 4, at 38. This doctrine allows the doctor to withhold information from his patient if knowledge of the facts would cause the patient's condition to deteriorate. Id. For a discussion of the therapeutic privilege, see Meisel, The "Exceptions" to the Informed Consent Doctrine, supra note 1, at 460-70. In Meisel's opinion, if the therapeutic privilege is not "severely circumscribed in its scope, it threatens to swallow the general obligation of disclosure, thereby depriving the patient of all decisional authority." Id. at 461.

Pennsylvania courts have said that it is never the prerogative of the doctor to screen out possible complications of surgery. See, e.g., Sauro v. Shea, 257 Pa. Super. 87, 93, 390 A.2d 259, 262 (1978). However, it has been argued that some accommodation of the doctrine of therapeutic privilege seems inevitable. Fala, The Law of Medical Malpractice in Pennsylvania, 36 U. PITT. L. REV. 203, 251 (1974). The Pennsylvania legislature has incorporated the privilege, in the form of an affirmative defense, into the Health Care Services Malpractice Act. See PA. STAT. ANN. tit. 40, § 1301.103 (Purdon Supp. 1982-1983). For the complete text of this section, see note 55 infra.
In Cooper v. Roberts, the Superior Court of Pennsylvania was confronted with the task of defining the standard to be used in determining, in any particular case, what information need be disclosed. The prevailing view, that a doctor must disclose those facts which would be disclosed by a reasonable practitioner, was considered and rejected by the Roberts court, which theorized that the patient's right to know should not depend on standards developed by the medical community. Instead, the court adopted a lay standard—a formulation that required the doctor to disclose those facts, risks, and alternatives which a reason-

47. 220 Pa. Super. 260, 286 A.2d 647 (1971). In Roberts, the patient sought damages for the perforation of her stomach during the performance of a gastroscopic examination. Id. at 262, 286 A.2d at 648. The doctors described the nature of the procedure. There was no indication, however, that they informed the patient of collateral risks. The device used, a fiberscope, had been in use for five years at the time of the examination in 1962, and during those five years, there had been no reported punctures. Id. at 263, 286 A.2d at 648. Furthermore, the fiberscope was considered an improvement over its forerunner, the semi-rigid scope, which had an incidence of perforation of approximately 0.0004%. Id. The trial resulted in a jury verdict for the defendant doctors. 220 Pa. Super. at 262, 286 A.2d at 648.

The superior court, however, held that the trial judge erroneously charged the jury to weigh the defendants' disclosure against that disclosure which a reasonable practitioner would make. Id. at 267, 286 A.2d at 650. It would be better, the court believed, to judge the adequacy of the physician's disclosure by what a reasonable patient would want the doctor to disclose. Id.

48. Id. For a discussion of the two standards presently in use, see 1 S. Pegalis & H. Wachman, supra note 42. Two schools of thought have emerged to measure the scope of the physician's duty and the jury must be instructed as to which standard will be used to judge the doctor's disclosure. Id. at 98. According to the "professional" standard, a doctor must disclose only the information that other reasonable practitioners in the same or similar circumstances would have disclosed. Id. This standard, based on collective professional judgment, is the law in at least 20 jurisdictions. Id. at 99.

Other jurisdictions, reflecting judicial doubts as to the appropriateness of a professional standard for measuring the physician's duty to disclose, have adopted a "lay standard" of reasonableness, which mandates that the doctor disclose that information which a reasonable patient would consider significant to his decision. Id. at 99-100. Fourteen jurisdictions have adopted this standard. See Meisel, The Expansion of Liability, supra note 1, at 96 n.128. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972), is a frequently quoted case that adopted the lay standard. Meisel, supra note 1, at 95-96. See also Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972); Wilkinson v. Vesey, 110 R.I. 606, 295 A.2d 676 (1972).

At least eight jurisdictions have considered the lay standard and refused to adopt it. See Meisel, The Expansion of Liability, supra note 1, at 96 n.128.

49. 220 Pa. Super. at 266-68, 286 A.2d at 650-51 (citing Dow v. Kaiser Found., 12 Cal. App. 3d 488, 90 Cal. Rptr. 747 (1970); Berkley v. Anderson, 1 Cal. App. 3d 790, 82 Cal. Rptr. 67 (1970)). The Roberts court reasoned that it would be hard to determine from the testimony of a physician-expert what the community standard was, since he would testify to either "what he would have done under similar circumstances, or what he thinks another practitioner should do under such circumstances, neither of which supplies an adequate definition of the 'community standard.'" 220 Pa. Super. at 267, 286 A.2d at 650. The court also noted that it considered the plaintiff's difficulty in finding a doctor to testify. Id.
able person in the patient's situation would consider material to his decision regarding whether to undergo treatment. The Roberts court reasoned that this objective standard would allow the patient to be the arbiter of his own treatment without requiring the doctor to be a mind-reader of his patient's subjective thoughts. Finally, the Roberts court noted that the adoption of the lay standard of disclosure eliminated the need for expert testimony on the issue of what risks would normally be disclosed by members of the professional community.

Neither Gray nor Dunham clearly distinguished between the doctor's giving of information and the patient's subjective understanding of that information. Jurisdictions that have considered the issue, however, have uniformly held that the doctor's duty is discharged when he conveys the relevant information to his patient, and Pennsylvania de-

51. Id. If the lay standard is employed, the plaintiff will be relieved of the necessity of producing expert medical testimony on the issue of what doctors usually disclose. The lay standard does not, however, completely dispense with the plaintiff's need for medical testimony. See 1 S. PEGALIS & H. WACHMAN, supra note 42, at 102. The jurors, in determining what information they, as reasonable people in the patient's situation, would want disclosed, will need to hear medical testimony explaining the nature of the procedure, its risks and alternatives. Id. Generally the plaintiff will still have to produce expert medical testimony which supplies this information. Id. It may sometimes be possible, however, for the plaintiff's counsel to establish the requisite facts through the admissions and concessions of the defendant doctor. Id. The plaintiff will also need to produce expert medical testimony to show that his injury was a result of the procedure in question. J. LUDLAM, supra note 4, at 33.

Jurisdictions which recognize the lay standard permit the defendant to introduce expert testimony of his compliance with an applicable medical standard, but evidence of such a standard is not conclusive. Id. (citing Wilkinson v. Vesey, 110 R.I. 606, 295 A.2d 676 (1972)). Accord Trogun v. Fruchtman, 58 Wis. 2d 569, 207 N.W.2d 297 (1973). The Wilkinson court explained how expert testimony could be utilized:

By our absolving the patient of the need to present medical testimony reflecting a community standard of disclosure, we do not mean to prevent the physician from introducing evidence of such a standard, if one exists, nor does it eliminate the need for a witness with the proper expertise whose testimony will establish the known risks involved in the procedure in controversy.

110 R.I. at 626, 295 A.2d at 688. See also Salis v. United States, 522 F. Supp. 989 (M.D. Pa. 1981). In Salis, the district court allowed experts to testify that a patient would normally have been apprised of the perils of the operation in question. Id. at 999 n.14. The court noted that the evidence was admitted not to establish a "community standard of disclosure" but as probative of the fact that the risks were foreseeable to the defendants. Id. For a discussion of the role of expert testimony in informed consent cases, see Greenwald, Oh, Didn't I Tell You?—A Look at Informed Consent, TRIAL, June 1982 at 54.

53. For a discussion of the two distinct concepts, see note 45 supra.
54. See, e.g., Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972). In Canterbury, the District of Columbia Circuit recognized the distinction, ex-
Cisions have wisely refused to delve into the subjective area of what a particular patient "knew." 55

plaining that in duty-to-disclose cases attention is more properly focused on the nature and content of the physician's divulgence than on the patient's understanding. Id. at 780 n.15. The court noted that the physician discharges his duty to disclose

when he makes a reasonable effort to convey sufficient information although the patient, without fault of the physician, may not fully grasp it . . . Even though the factfinder may have occasion to draw an inference on the state of the patient's enlightenment, the fact-finding process on performance of the duty ultimately reaches back to what the physician actually said or failed to say.

Id.


In 1975, in response to a perceived medical malpractice crisis, the Pennsylvania Legislature enacted the Health Care Services Malpractice Act. PA. STAT. ANN. tit. 40, §§ 1301.101 to .1006 (Purdon Supp. 1982-1983). The purpose of the act was to establish a system whereby litigants could receive a prompt determination of their medical negligence claims and to make professional liability insurance available at a reasonable cost. Id. at § 1301.102. A mandatory, non-binding system of arbitration was established by the act, however, in Mattos v. Thompson, 491 Pa. 385, 421 A.2d 190 (1980), the Pennsylvania Supreme Court declared § 1301.309, which gave the arbitration panel "original exclusive jurisdiction," to be an unconstitutional infringement on the right to a jury trial. Id. at 396, 421 A.2d at 195-96. The Attorney General of Pennsylvania stated, in an opinion issued to the Administrator for Arbitration Panels for Health Care that, except for § 1301.309, the provisions of the act remained intact. Attorney General Official opinion No. 80-2 (Oct. 14, 1980), reprinted in 10 Pa. Bull. 4279 (Nov. 1, 1980). This left the provisions which dealt with insurance viable but, after Mattos, the panel for arbitration remained in existence only to handle claims submitted to it by all parties voluntarily.

The legislature included in the act a definition of informed consent, the wording of which makes it clear that the doctor's duty was to be considered discharged upon his disclosure of pertinent information:

"Informed consent" means for the purposes of this act and of any proceedings arising under the provisions of this act, the consent of a patient to the performance of health care services by a physician or podiatrist: Provided, that prior to the consent having been given, the physician or podiatrist has informed the patient of the nature of the proposed procedure or treatment and of those risks and alternatives to treatment or diagnosis that a reasonable patient would consider material to the decision whether or not to undergo treatment or diagnosis. No physician or podiatrist shall be liable for failure to obtain an informed consent in the event of an emergency which prevents consulting the patient. No physician or podiatrist shall be liable for failure to obtain an informed consent if it is established by a preponderance of the evidence that furnishing the information in question to the patient would have resulted in a seriously adverse effect on the patient or on the therapeutic process to the material detriment of the patient's health.


Except for the provision of a "therapeutic privilege," which affords a defense to the doctor who withholds information where the patient could be
B. The Requirement of Causation: Inconsistent with a Battery Theory

Under a traditional battery theory of liability, while the patient must prove that the doctor's "touching" caused his injury, the patient need not prove a causal link between the doctor's failure to disclose information and the decision to undergo the procedure in question. Recently, federal courts applying Pennsylvania law have required proof of this latter aspect of causation in informed consent cases. Pennsylvania courts, however, have never required this showing.

In Bowers v. Garfield, the patient suffered a complication of surgery, the risks of which had not been disclosed. The United States District Court for the Eastern District of Pennsylvania held that, in order to recover, the patient must prove a causal relationship between the doctor's failure to disclose and the injury complained of. Finding no Pennsylvania case law dealing with the issue of causation, the district court looked to the law of other jurisdictions and stated that it was following the weight of modern authority in requiring proof of causation. The Bowers court further concluded that, if the highest harmed by disclosure, this definition merely codified pre-existing common law. The scope of the doctor's duty is defined using the lay standard but the provision does not address—and therefore has no impact on—the underlying theory of liability. See Meisel & Kabnick, Informed Consent to Medical Treatment: An Analysis of Recent Legislation, 41 U. Pitt. L. Rev. 407, 529 (1980). For a discussion of the act and its history, as well as possibilities for the future, see Jones, Medical Malpractice Litigation: Alternatives for Pennsylvania, 19 Duq. L. Rev. 407 (1981).

Since the act itself states that the definition of "informed consent" is to be used "for the purposes of this act and of any proceedings arising under the provisions of this act," it is not clear, after Mattos, whether Pennsylvania courts would feel compelled to recognize the provision which creates a therapeutic privilege. Dentists are not included in the act's definition of "health care provider" and have therefore never been affected by the act. Id.

56. For a discussion of the causation requirement, see notes 30 & 31 and accompanying text supra.


58. 382 F. Supp. at 504. The plaintiff had had nine pregnancies, five of which had terminated in miscarriage. She had undergone tubal ligation for the purpose of sterilization. Id. at n.1. She consulted the doctor for recurrent bleeding and, after examination, he recommended removal of her uterus. Id. at 504. As a result of the surgery, the plaintiff developed an abnormal opening between her vagina and bladder which was successfully repaired by a subsequent operation. Id.

59. Id.

60. Id. at 506.

61. Id. The court observed that the preeminent case on this issue was Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972).

62. 382 F. Supp. at 505. The court rejected the plaintiff's contention that proof that the failure to disclose caused the injury complained of was unnecessary and irrelevant. Id. at n.3. In the opinion of the court, this stance was clearly against the weight of modern authority on the issue of
court of Pennsylvania were to consider the issue, it would opt to judge this causation by an objective standard of whether a reasonable person would have undergone treatment rather than a subjective standard of whether the patient himself would have undergone treatment.\(^6\) Accordingly, the court approved the jury charge that the requisite causal connection existed only if, after disclosure of material facts, a reasonable person in the patient's situation would have decided against treatment.\(^4\)


\(^4\) 382 F. Supp. at 506. In Bowers, the jury determined that a "reasonable woman," if informed of the risks and alternatives, would have undergone the operation. \(\text{Id. at 505.}\) The plaintiffs argued that, if considered at all, the causation requirement should have been framed as a subjective test —whether the plaintiff herself would have undergone the operation had she been fully informed of the risks by the defendant. \(\text{Id. at 505.}\) The court noted that the superior court in Roberts had used an objective standard when it mandated that the doctor must disclose information which a reasonable person would consider material. \(\text{Id. (citing Cooper v. Roberts, 220 Pa. Super. 260, 286 A.2d 647 (1971)).}\) Consequently, the court reasoned, the Pennsylvania courts, if faced with the decision, would choose to promulgate an objective test for causation just as they had done for the standard of disclosure. 382 F. Supp. at 506. In adopting an objective test, the court also relied heavily on the Canterbury opinion:

> We think a technique which ties the factual conclusion on causation simply to the assessment of the patient's credibility is unsatisfactory. . . . When causality is explored at a post-injury trial with a professedly uninformed patient, the question whether he actually would have turned the treatment down if he had known the risks is purely hypothetical: "Viewed from the point at which he had to decide, would the patient have decided differently had he known something he did not know?" And the answer which the patient supplies hardly represents more than a guess, perhaps tinged by the circumstances that the fact that the uncommunicated hazard has in fact materialized.

> In our view, the method of dealing with the issue on [sic] causation comes in second-best. It places the physician in jeopardy of the patient's hindsight and bitterness. It places the factfinder in the position of deciphering whether a speculative answer to a hypothetical question is to be credited. It calls for a subjective determination solely on testimony of a patient-witness shadowed by the occurrence of the undisclosed risk.

\(\text{Id. (quoting Canterbury v. Spence, 464 F.2d 772, 790-91 (D.C. Cir. 1972)).}\)

\(\text{Id. (quoting Cooper v. Roberts, 220 Pa. Super. 260, 286 A.2d 647 (1971)).}\)

\(\text{See 1 S. PEGALIS & H. WACHMAN, supra note 42, at 103-04. In the opinion of the authors, the subjective test is out of step with modern tort concepts by which conduct is generally judged by reference to the reasonable person. Id.}\)

\(\text{65. See Salis v. United States, 522 F. Supp. 989 (M.D. Pa. 1981). In Salis, the patient suffered serious injuries, including loss of a leg, after he}\)
Pennsylvania, however, have not followed the Bowers interpretation of state law on this issue and have not specifically required the patient to show causation as part of his case. For example, in Sauro v. Shea, a dental patient died from a materialized risk of general anesthesia despite the absence of negligence on the part of the dentist. The superior court held that it was reversible error not to charge the jury on the issue of informed consent since the relative risks of general and local anesthesia were not disclosed. The court approved a jury instruction proposed by the plaintiff that allowed them to find the doctor liable without a requirement of causation.

underwent an angiogram and cardiac catheterization. Id. at 991. The court found that there was no negligence on the part of the doctor in the performance of these procedures, but that the risks and alternatives of the procedure had not been properly disclosed. Id. The district court stated that, in Pennsylvania, in order to prove that the consent was not informed, the plaintiff must carry the burden of proving 1) that the practitioner had a responsibility to inform; 2) that the practitioner breached that duty; and 3) that the failure to inform was the causation of the injury. Id. at 998. The court noted that three primary factors must be examined by the trier-of-fact in its determination of whether causation exists: "At the outset, the court must look to the degree of risk actually involved in the relevant procedure. The percentage of peril must be compared to the likelihood of benefit from the therapy and the type of alternatives that present themselves." Id. (citing Dewes v. Indian Health Serv., 504 F. Supp. 203 (D.S.D. 1980); Dessi v. United States, 489 F. Supp. 722 (E.D. Va. 1980)).


68. Id. at 91, 390 A.2d at 260. The patient visited an oral surgeon's office for the purpose of having her remaining 23 teeth extracted. Id. She died as a result of cardio-respiratory arrest, a recognized risk of general anesthesia. 257 Pa. Super. at 91, 390 A.2d at 261.

69. Id. at 92, 390 A.2d at 261. The patient was given her choice between local and general anesthesia. She was not, however, informed of the risks of the surgical procedure or of the comparative risks of the two types of anesthesia. Id. The trial court ruled that because the patient signed a general consent form, there was insufficient evidence, as a matter of law, for the jury to consider the issue of informed consent. Id.

70. Id. It is suggested here that in a case such as Sauro, the addition of a requirement of causation could very possibly lead to a different result since a jury could easily find that a reasonable person about to undergo 23 extractions, after being apprised of all the alternatives and their risks would probably choose to receive general anesthesia.

Since Roberts, juries must decide, in determining whether consent was informed, whether the undisclosed risk was a material one. A "material risk" is one which, if known by a reasonable person in the patient's position might induce him to forego treatment. See Comment, supra note 19, at 1407 n.68. Material risk may also be defined as follows:

The materiality of a risk is a function of the incidence and severity of that risk. Risks which occur frequently but which are not very severe are material, as are risks which are very severe but which do not often occur. The ultimate question of materiality is whether knowledge of the risk before the patient gave his consent would have altered the patient's decision.
C. Refusal to Extend the Informed Consent Doctrine to Prescription Drug Therapy

Treatment with oral medication has posed a particularly difficult problem in the application of the battery theory of liability. In *Malloy v. Shanahan*, an arthritic patient was given a prescription for a drug, the use of which eventually led to her partial blindness. The Superior Court of Pennsylvania considered whether a doctor must disclose material facts, risks, and alternatives associated with a proposed orally administered drug therapy. Refusing to extend the requirement of informed consent to situations in which a doctor prescribes oral medication for his patient, the court stated that informed consent had been required previously only in surgical cases and that it was unwilling to change the law.

In a dissenting opinion, Judge Hoffman theorized that the majority decision was the result of an adherence to the battery theory of liability. In cases in which the operation was obviously necessary, juries can adjust their findings in order to reach a fair result by deciding that the risk which materialized was not material. This materiality requirement, however, does not equal a causation requirement, since a reasonable person might decide to undergo treatment regardless of a material risk. Certainly a "reasonable person" with a life threatening malignancy would consider the risk of an unsightly and painful scar to be material—yet that "reasonable person" would surely choose to have the malignancy removed regardless of the material risk.

The trial court refused to charge the jury on the issue of informed consent. The superior court affirmed, stating that the doctrine of informed consent was inapplicable to the facts of the case. In any event, the court concluded, the patient's independent prolonged use of the drug and the supplying of it by the pharmacies were the proximate cause of the injury.

The majority recognized that informed consent was a requirement in any surgical operation, but it noted that the requirement "has not been extended to therapeutic treatment upon examination of the treating physician, where any change of condition can be diagnosed and controlled." It is suggested here that this reasoning of the majority is specious since it fails to consider the fact that some modern drugs have potentially serious possible side effects which may not be recognizable to the treating physician until the onset of permanent damage. See Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 Rutgers L. Rev. 947, 953 (1964).

Unfortunately, the facts of the *Malloy* case detracted from its attractiveness as a ground-breaking case. Nevertheless, the case pointed out a glaring defect in the battery theory—the inconsistency between the policy of self-determination which is protected by the informed consent doctrine and the requirement that the patient be "touched" before he has a cause of action.
under which no tort could occur without the element of "touching." 74
In his view, the negligence standard should be adopted by Pennsylvania,
since such a change would allow recovery where treatment is therapeutic
as well as surgical in nature. 75 In addition, in Judge Hoffman's opinion,
artificial distinctions necessitated by a battery theory, such as the one
between drugs prescribed for oral administration and those which are
injected, would be eliminated by the use of a negligence framework. 76

Judge Hoffman accused the majority of overlooking the "overwhelming
trend in other jurisdictions toward recognizing the doctrine as being grounded on
negligence rather than battery." Id. (citing Canterbury v. Spence, 464 F.2d
772 (D.C. Cir.) cert. denied, 409 U.S. 1064 (1972); Cobbs v. Grant, 8 Cal. 3d
229, 502 P.2d 1, 104 Cal. Rptr. 305 (1972); Nishi v. Hartwell, 52 Hawaii 188,
475 P.2d 116 (1970); Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093 (1960);
Downer v. Veilleux, 322 A.2d 82 (Me. 1974); Sard v. Hardy, 281 Md. 432,
379 A.2d 1014 (1977); Calabrese v. Trenton State College, 162 N.J. Super.
145, 392 A.2d 600 (1978); Shack v. Holland, 99 Misc. 2d 78, 389 N.Y.S. 2d
988 (N.Y. Sup. Ct. 1976); Wilkinson v. Vesey, 110 R.I. 606, 295 A.2d 676
(1972); Miller v. Kennedy, 11 Wash. App. 272, 522 P.2d 852 (1974); Trogun
v. Fruchtman, 58 Wis. 2d 569, 207 N.W.2d 297 (1973)).

75. In Judge Hoffman's opinion, courts following the trend toward a
negligence standard "have recognized that the failure to obtain a patient's
informed consent does not correspond to the traditional concept of battery
because the doctor's omission rarely results from a willful intent to injure
the patient." Id. at 445, 421 A.2d at 806 (Hoffman, J., dissenting) (citations
omitted). Judge Hoffman recognized also that "[t]he physician customarily
lacks the malicious state of mind associated with intentional torts." Id.

Judge Hoffman clearly advocated exceptions to the requirement of
disclosure:
The standard does not mandate disclosure of every risk involved
in treatment in every situation. Thus, where immediate emergency
treatment is required, the physician may proceed despite the patient's
inability to consent. Similarly, the physician may withhold information
in those rare situations in which the patient's condition is so
delicate that disclosure of risks would be severely detrimental to the
patient or rational decisionmaking would be unfeasible. Additionally,
as in any negligence case, the physician's duty to disclose extends only
to those risks of which he knew or should have known. Finally, the
physician need not engage in a "lengthy polysyllabic discourse on all
possible complications" or a discussion of the "relatively minor risks
inherent in common procedures, where it is common knowledge that
such risks in the procedure are of very low incidence."
Id. at 449, 421 A.2d at 807-08 (Hoffman, J., dissenting) (citations omitted)
(quoting Cobbs v. Grant, 8 Cal. 3d 229, 244, 502 P.2d 1, 11, 104 Cal. Rptr.
505, 515 (1972)).

76. 280 Pa. Super. at 447, 421 A.2d at 806 (Hoffman, J., dissenting).
In the case of prescription drug therapy, courts, looking upon the doctor
as the agent who should receive warnings, have held that manufacturers have
no duty to warn users of the drug directly. See Zaslow, supra note 10, at 22
418, 307 A.2d 449 (1973)). Generally, warnings are placed on labels and in
package inserts, distributed by drug salesmen, and published in the
PHYSICIAN'S DESK REFERENCE. Id. It is the doctor's obligation to convey this
information regarding risks of drug therapy to his patient. See Zaslow, supra,
at 23 (citing Trogun v. Fruchtman, 58 Wis. 2d 569, 207 N.W.2d 297 (1973)).
In Trogun, the patient contracted hepatitis as a result of drug therapy given
IV. The Need for a Negligence Standard

The Supreme Court of Pennsylvania has not spoken on the issue of informed consent since 1966. In the absence of guidance from that tribunal, the superior and federal courts applying Pennsylvania law have, in deciding many informed consent issues, relied on decisions from other jurisdictions. Pennsylvania courts have uniformly, however, declined to abandon the underlying theory of liability utilized by the Gray court, perhaps in a belief that such a fundamental change should emanate from the highest court of the state.

It is suggested here that the time for change in Pennsylvania is long overdue. The battery theory should be retained for use in appropriate

for an inactive tuberculosis condition. 58 Wis. 2d at 572, 207 N.W.2d at 299. The court held that the physician had a duty to disclose recognized risks of drug therapy to the patient. Id. at 593, 207 N.W.2d at 310. However, in Trogun, the court found that the patient had not sustained his burden of proving that the doctor breached his duty to disclose, since there was overwhelming evidence that at the time the drug was prescribed, physicians were unaware of the hepatitis risk. Id. at 604, 207 N.W.2d at 315. See also, Oakes v. Gilday, 351 A.2d 85 (Del. 1976) (failure to inform patient of possible adverse reaction to anti-inflammatory eyedrops which caused glaucoma constituted a valid claim).

It is interesting to note that, even in jurisdictions which use the negligence theory to impose liability for failure to disclose, that theory has rarely been used in drug therapy cases. See Zaslow, supra, at 22. Most actions involving drug therapy have been brought against either the doctor for negligence in prescribing the drug, see, e.g., Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206 (1971), or against the drug manufacturer for failure to provide a warning. See, e.g., Hoffman v. Sterling Drug, 485 F.2d 132 (3d Cir. 1973).

One exception to the rule that the ultimate user need not be warned has been found in mass-immunization programs where administration of the vaccine is performed in an assembly line fashion without the benefit of a treating physician as "learned intermediary." See, e.g., Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974), cert. denied, 419 U.S. 1096 (1974).


79. Malloy was the first case since Gray in which the advisability of changing the theory of liability was squarely considered. There, the majority refused to extend the informed consent doctrine to treatment other than surgery. 280 Pa. Super. at 443, 421 A.2d at 804. In the dissenting judge's opinion, this result flowed from the court's unwillingness to abandon the battery theory. See text accompanying note 74 supra.
situations, such as those in which a doctor operates without consent.\textsuperscript{80} There are compelling reasons, however, for Pennsylvania to join the overwhelming majority of states that recognize the doctrine and treat a breach of the duty to disclose collateral risks of treatment under negligence principles.\textsuperscript{81}

First, the negligence theory of liability more accurately characterizes the tort, since the wrong consists of a failure to fulfill a duty of verbal communication and does not involve touching the patient.\textsuperscript{82} Furthermore, because causation is an indispensable element of a negligence cause of action, the patient must show that the doctor's breach of his duty of disclosure led directly to the injury.\textsuperscript{83} The imposition of this requirement would correct a patent unfairness in Pennsylvania's present formulation of the informed consent doctrine, since it would prevent recovery where the patient would have undergone treatment even if he had been fully informed.\textsuperscript{84}

\textsuperscript{80} See, e.g., Cobbs v. Grant, 8 Cal. 3d 229, 240, 502 P.2d 1, 8, 104 Cal. Rptr. 505, 512 (1972). The court in Cobbs would limit the battery theory as follows:

The battery theory should be reserved for those circumstances when a doctor performs an operation to which the patient has not consented. When the patient gives permission to perform one type of treatment and the doctor performs another, the requisite element of deliberate intent to deviate from the consent given is present. However, when the patient consents to certain treatment and the doctor performs that treatment but an undisclosed inherent complication with a low probability occurs, no intentional deviation from the consent given appears; rather, the doctor in obtaining consent may have failed to meet his due care duty to disclose pertinent information. In that situation the action should be pleaded in negligence. \textit{Id.} See also Plante, supra note 1, at 650.

\textsuperscript{81} For a list of states which recognize the cause of action for lack of informed consent as one which sounds in negligence, see note 74 supra. The need for the adoption of the negligence standard was recognized as early as 1957. See McCoid, supra note 19, at 434.

\textsuperscript{82} For a discussion of the rationale used by courts that have adopted the negligence standard, see note 26 supra.

\textsuperscript{83} See 2 D. LOUISELL & H. WILLIAMS, \textit{supra} note 2, at \$ 22.01; Waltz & Scheuneman, \textit{Informed Consent to Therapy}, 64 Nw. L. Rev. 628 (1970). "[T]his basic principal of tort law [causal connection] has been alluded to more frequently by commentators than courts in the medical malpractice area." \textit{Id.} at 646 n.69. Prior to \textit{Canterbury}, courts gave little attention to causation in informed consent cases. Meisel, \textit{The Expansion of Liability}, \textit{supra} note 1, at 108. In his opinion, "[i]t should not be surprising that the courts have paid scant attention to the necessity for a causal connection between the failure to disclose and the injury since this requirement is such a well-established principle of negligence law." \textit{Id.} at n.160.

\textsuperscript{84} See 1 S. PEGALIS & H. WACHMAN, \textit{supra} note 42, at 102-03. The authors note, It is universally accepted that the plaintiff cannot recover, in the absence of proof by a preponderance of the evidence, that the patient would have withheld consent to the course of treatment or procedure in the face of the required and adequate disclosure of the risks and
Finally, utilization of a negligence framework would extend the patient’s right to know the material facts regarding treatment to situations in which oral medication is prescribed. Since courts require drug companies to warn only the doctor of risks associated with prescription drugs, the only way a patient can learn of material risks of drug therapy is if the information is relayed to him by his doctor. Accordingly, it is not unreasonable to hold a doctor responsible for disclosure of material facts, risks, and alternatives associated with prescription drug therapy.

V. CONCLUSION

Since Gray, Pennsylvania courts have vigorously protected the patient’s right to self-determination. They have measured the standard of disclosure, not by what doctors as a group usually disclose, but by what the reasonable patient in the plaintiff’s situation would want to know in making his decision. The adoption of this lay standard has enabled the patient to prove his case without the need for the testimony of an expert witness to establish the professional standard. In addition, the Pennsylvania courts have mandated that, in every case, the question of whether a consent was an “informed” one must be decided by the jury.

85. See note 88 infra.

86. See note 76 supra. See also Restatement (Second) of Torts § 402A comment k (1965). If labeling is proper, a drug is not considered inherently dangerous and a manufacturer cannot be held liable under strict liability concepts. The plaintiff can prevail only by showing that the labeling was misleading or false. See Zaslow, supra note 10, at 23 (citing McEwen v. Ortho Pharmaceutical Corp., 528 P.2d 522 (Or. 1974); Hoffman v. Sterling Drug, Inc., 485 F.2d 132 (3d Cir. 1973)).

87. For a discussion of the infrequently litigated duty of the doctor to warn of risks of drug therapy, see note 76 supra.

88. In Malloy v. Shanahan, Judge Hoffman noted in dissent: “Where a physician prescribes a drug without properly informing the patient of risks involved, he invades the patient’s bodily integrity and violates the patient’s concomitant right to know just as if he had performed a surgical operation without first obtaining the patient’s informed consent.” 280 Pa. Super. at 447, 421 A.2d at 806 (Hoffman, J., dissenting).

89. See Meisel, The Expansion of Liability, supra note 1, at 94 and n.119. Cooper v. Roberts was among the first decisions to adopt the “lay standard” of disclosure.

90. Expert testimony is not necessary to establish the lay standard. See note 52 and accompanying text supra.

91. The question of whether the consent was informed is always a question for the jury in Pennsylvania. In both Roberts, where the risk of correctable perforation was 0.0004%, and Gray, where the risk of paralysis or death was
But the doctrine of informed consent is still relatively new to the courts and will of necessity continue to evolve. Hopefully, in further shaping the doctrine, the next step that will be taken by the Pennsylvania courts will be an adoption of the negligence theory of liability. This would ensure that the patient's right to self-determination will be recognized regardless of the modality of treatment. In addition, this change would be fairer to health care practitioners because the harshness of the battery theory would be mitigated by a causation requirement. Certainly such a change is imperative if the courts of the Commonwealth are to ensure fairness to all parties as well as logical consistency in the law of informed consent.

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15 to 20%, the court determined that a jury question existed as to whether the risk should have been disclosed. See notes 39 and 47 supra.

92. See J. Ludlam, supra note 4, at 40. Ludlam notes that there is a significant trend toward codification of informed consent law. Id. In his opinion, this will slow if not stop, the evolution of law in this area since courts will be more concerned with statutory interpretation than with the desirability of physician-patient communications. Id. For a discussion of the codification of informed consent in Pennsylvania, see note 55 supra.

93. There is no requirement that the doctor touch the patient under a negligence theory of liability. Therefore, adoption of that standard will assure that a requirement of risk disclosure will be enforced when the doctor prescribes oral medication.

94. See Plante, supra note 1, at 666. Since the essence of the wrong in a battery case is the unauthorized touching, once the touching is shown, the cause of action is complete. Id. In a negligence action, a cause-in-fact relationship between the plaintiff's ignorance of the risk and his willingness to undergo the procedure must be shown. Id. Conversely, if the patient knew the risk, the failure of the doctor to disclose it would not be causally connected with the injury. Id.