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STRICT LIABILITY AND INFORMED CONSENT: 
"DON'T SAY I DIDN'T TELL YOU SO!"*

Jose E. Maldonado†

INTRODUCTION

As Justice Cardozo stated in the landmark decision of Schloendorff v. Society of New York Hospital:

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.1

Traditionally, courts have applied either tortious battery,² or negligence concepts³ where a physician performs surgery without the informed consent of the patient. Battery liability was rooted in the common law concept of unlawful bodily contact,⁴ while negligence liability is imposed to remedy a physician's breach of duty to inform his patient of material risks inherent in prescribed surgery.⁵ The doctrine of informed consent, as a corollary of negligence law, contemplates the medical consumer having a viable choice of surgical treatment based on the knowledge of material risks.

The application of the existing informed consent doctrine to the day-to-day practice of medicine is fraught with inconsistency.⁶ Legal requirements

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1 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914).
5 186 Kan. at 410, 350 P.2d at 1106-07.
imposed on the physician are ill-defined and diffuse, varying from community to community, and state to state. The result has been a litany of lawsuits by outraged patients, creating uncertainty and confusion within the medical community.

Clearly, the existing doctrine of informed consent must undergo major reconsideration by state legislatures and the legal community if it is to: (1) guarantee a meaningful choice to the medical consumer; (2) lend substance to the medical consumer's heretofore illusory right to self-determination; (3) afford substantial certitude to the medical community; and (4) encourage judicial consistency.

The purpose of this article is the cogent presentation of the arguments favoring application of contemporary strict tort liability concepts to the doctrine of informed consent. While not a panacea, adoption of this proposal would afford the consumer of medical services the requisite protection to make an effective, informed medical choice, while lending consistency and certainty to the physician, long harrassed, both morally and legally, by doubts as to what constitutes an informed consent.

This author will assume, arguendo, for the purpose of this article that all physicians are good-faith, competent practitioners. However, the reader should be forewarned: The existing requirement that medical consumers render an informed consent constitutes a knotty and complex problem, both ethically and legally, for the most conscientious and competent medical practitioner. Entrusting enforcement of the existing informed consent laws to the few physicians who fail to adhere to the high standards promulgated by the medical profession can be likened to "deploying the fox to guard the henhouse."

Likewise, the reader should note that the proposed standard of strict tort liability applies only to the situation in which the physician has failed to adequately advise the patient of the attendant risks of the proposed

treatment, and not to a physician’s liability for treatment where informed consent has been obtained.

**CURRENT STATUS OF INFORMED CONSENT**

The landmark case of *Mohr v. Williams* treated the failure of a physician to obtain an informed consent as a battery. The court’s holding was based in common law, Anglo-American notions of the inviolability of the human body. Traditionally, similar reasoning has been applied where a female patient consented to an operation on her womb and, as a bonus, received a total hysterectomy; where a patient undergoing successful foot surgery was falsely promised by his physician that a small foot bone would not be removed; and where a physician performed surgery during diagnostic anesthesia without consulting the patient, prompting Justice Cardozo’s famous maxim in *Schloendorff*.

It was not until the mid-1950’s that courts began to question the rationality of tortious battery as an appropriate framework. Spurred by a law review article authored by Professor Allan H. McCoid, the courts began to reappraise the battery rationale.

In *Salgo v. Leland Stanford University Board of Trustees*, the Superior Court, in and for the County of San Francisco, undermined 50 years of reliance on battery concepts by upholding a jury instruction that the duty of the physician is to disclose to the patient,...

...all the facts which mutually affect his rights and interests and of the surgical risk, hazard and danger, if any. A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise the physician may not

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7 95 Minn. 261, 104 N.W. 12 (1905).
8 Id at 267, 271, 104 N.W. at 14, 16. The court reasoned:
   [The evidence fairly shows that the operation complained of was skillfully performed and of a generally beneficial nature.
   ...
   [However] the act of defendant amounted at least to a technical assault and battery. If the operation was performed without plaintiff’s consent, and the circumstances were not such as to justify its performance without it, it was wrongful; and if it was wrongful it was unlawful.
9 Id. at 271, 104 N.W. at 16.
10 Pratt v. Davis, 224 Ill. 300, 79 N.E. 562 (1906).
12 Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92 (1914).
minimize the known dangers of a procedure or operation in order to induce his patient's consent.  

On appeal, the trial court's judgment for the plaintiff was reversed due to prejudicial jury instructions regarding the improper application of res ipsa loquitur to the case. However, the trial court's instruction as to the duty of disclosure was permitted to stand.

The abrogation of the battery rationale of the informed consent doctrine continued. In Natanson v. Kline, a 1960 Kansas decision, the tide turned in favor of applying the pure negligence theory. Suit was brought by Irma Natanson for injuries resulting from an allegedly excessive dose of radioactive cobalt during post-mastectomy radiation therapy. Employing a similar line of reasoning as found in Salgo and McCoid, the Natanson court dismissed the malpractice suit because the issues were framed in terms of a battery, and denied rehearing when the plaintiff attempted to create a hybrid cause of action by intermingling battery principles with negligence law. It was abundantly clear that the Natanson court intended to apply the negligence standard to the doctrine of informed consent:

The primary basis of liability in a malpractice action is the deviation from the standard of conduct of a reasonable and prudent medical doctor of the same school or practice as the defendant under similar circumstances.

This standard of care is still the rule in a majority of American jurisdictions.

From the perspective of the injured medical consumer, a glaring weakness of the negligence rationale is the "therapeutic privilege" accorded physicians as a defense to the generally accepted disclosure requirement.

The therapeutic privilege is invoked as a defense for failing to conform to the informed consent requirements generally imposed upon medical practitioners. When allowed by the courts, the privilege exempts a physician from the obligation to inform the patient fully of his condition and of the details of any recommended procedures prior to obtaining the patient's consent to proceed. By definition, the therapeutic privilege allows physicians to withhold some or all information while obtaining consent if the

15 Id. at 578, 317 P.2d at 181.
16 Id. at 579, 317 P.2d at 182.
18 Id. at 394, 350 P.2d at 1095.
19 Id. at 398, 350 P.2d at 1098.
communication itself would cause a patient’s mental or physical condition to deteriorate.... The therapeutic privilege should operate in conjunction with the right to informed consent; although the privilege reduces the information which the patient receives, consent is still required and the choice of medical treatment should still be made by the patient. The privilege does not entitle the physician to substitute his choice for that of the competent adult patient, even if the patient insists upon a course detrimental to his health. The physician should also be precluded from manipulating facts to avoid the need for a patient’s decision, in order to do what is “good for the patient.”

The constrictive influence of therapeutic privilege on the doctrine of informed consent, coupled with the patronizing attitude of many physicians towards the legal rights of medical consumers, guarantees that the “therapeutic privilege” will be, and often is, used in lieu of consent. Since the medical consumer bears the entire risk of injury, and is concerned with his own interest in a way that no one else can be, reason dictates that he be permitted to make the final choice between accepting or rejecting the risks of a contemplated procedure, even if his choice is irrational. Consequently, the “right” to medical self-determination is illusory, and the controlling case law illustrates the predictable outcome when the physician is accorded the right to define the extent to which his privilege shall limit his own duty of disclosure.

THE MEDICAL CONSUMER’S RIGHT TO KNOW VS.
THE PHYSICIANS DUTY TO WARN

The medical consumer’s right to self-determination is no longer a source of dispute in the law. All jurisdictions recognize, in varying degrees, his “right to know” of material risks inherent in a surgical procedure. The right of the medical consumer to “determine what shall be done to his own body” requires disclosure of material risks involved in surgery.

This “right” connotes a “duty” among physicians to disclose all material risks to the competent medical consumer. As an expert, the attending physician takes into account the dangerous propensities of the surgery, as well as the

24 Id. at 504.
26 It is interesting to note that Cardozo, in his often quoted Schloendorff decision, apparently dealing with the problem of apprehensive patients stated only that “[t]here may be cases where a patient ought not to be advised of a contemplated operation until shortly before the appointed hour.” Schloendorff v. Society of New York Hospital, 211 N.Y. at 125 105 N.E. at 92 (1914). The implication is quite strong that Cardozo felt that the patient should be advised under all circumstances, the timing of the disclosure notwithstanding. Shartsis, Informed Consent: Some Problems Revisited, 51 Neb. L.J. 527, at 534-35n. 46 (1972).
27 211 N.Y. 125, 129-30, 105 N.E. 92, 93.
susceptibilities of his patient. The task of the physician is to weigh the benefit of any procedure against its potential danger. The choice he makes is an educated medical judgment, based upon his knowledge of each individual patient and procedure. Likewise, in order to permit an informed and intelligent decision by the medical consumer, the physician is required to warn against material risks, if he has knowledge or should have knowledge of the presence and degree of danger of the material risk, by the application of reasonably developed standards.

Unless a warning is strictly guaranteed, a multitude of variables affect the physician's degree of disclosure. The present trend indicates that the medical consumer's "right to know" is contingent upon (1) the physician's subjective evaluation of his patient's physical and mental state; (2) the predisposition of a particular physician to disclose serious risks to a bedridden patient; (3) the particular physician's assessment of probable symptomatic response to disclosure; (4) the standard degree of disclosure among doctors of similar practice in the area; (5) the law governing disclosure as applied by the courts in the medical consumer's particular jurisdiction; (6) the medical consumer's own tendency to view choice of treatment as a medical decision best left to those skilled in the practice; and, (7) the judicially-

28 Reyes v. Wyeth Laboratories, 498 F.2d 1264, at 1276. (5th Cir. 1974).

29 See RESTATEMENT (SECOND) OF TORTS §402, comment (j), which states:

Directions or warning. In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them. Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger. Likewise in the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required.

But a seller is not required to warn with respect to products, or ingredients in them, which are only dangerous, or potentially so, when consumed in excessive quantity, or over a long period of time, when the danger, or potentiality of danger, is generally known and recognized. Again the dangers of alcoholic beverages are an example, as are also those of foods containing such substances as saturated fats, which may over a period of time have a deleterious effect upon the human heart . . . .

Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous . . . .

spawned "therapeutic privilege" to withhold material risks where disclosure would, in the physician's opinion, worsen the condition of the patient.

In many cases, the variables outweigh the medical consumer's "right" to an informed consent. It blasphemes that right to allow the physician, who owes the duty to inform the medical consumer of all material risks, to determine the extent of disclosure. In a fiduciary relationship, such logic is tantamount to requiring an agent to disclose all "material" facts to his principal, but limiting disclosure to the agent's binding definition of "material." Above all, it must be remembered that, the decision regarding choice of treatment belongs to the medical consumer and not to the physician. Any foreseeable risk is material to the medical consumer's decision, for it is the consumer, and not the physician, who bears the physical (and financial) brunt of the risk.

The judicial confusion regarding informed consent could be easily avoided by the following legal determination: Either the medical consumer is competent to render an informed consent, or he is not. A patient will be competent unless he is a minor, non compos mentis has executed a power of attorney, is subject to a guardianship, or requires emergency care. If the medical consumer, in the absence of these disabilities, can render an informed consent without incurring irreparable harm, then he is competent.

Assuming the patient is competent, he has the right to the disclosure of all material risks. While the patient's reaction to disclosure is viewed as a medical problem, disclosure itself should be viewed as a legal problem. Thus, the medical consumer's choice would no longer be dependent on his physician's willingness to comply with nebulous and unascertainable disclosure requirements.

81 If analogized to the attorney-client relationship, application of "therapeutic privilege-type" reasoning would lead to the curious result of allowing an attorney to settle a case without his client's consent.


83 See Farber v. Olkon, 40 Cal. 2d 503, 254 P.2d 520 (1953); Pratt v. Davis, 224 Ill. 300, 79 N.E. 562 (1906); See also Kelly, supra note 6, at 405, Powell, supra note 6.

84 See generally Barnett v. Bachrach, 34 A.2d 626 (D.C. Mun. App. 1943); Pratt v. Davis, 224 Ill. 300, 79 N.E. 562 (1906); Delahunty v. Finton, 244 Mich. 226, 221 N.W. 168 (1928); Woods v. Brumlop, 71 N.M. 221, 377 P.2d 520 (1962); DiRosse v. Wein, 24 App. Div. 2d 510, 261 N.Y.S.2d 623 (1965); See also Kelly, supra note 6; Levin, supra note 6; McCold, A Reappraisal of Liability for Unauthorized Medical Treatment, 41 Minn. L. Rev. 381 (1957); Plante, supra note 6; Powell, supra note 6; Note, Consent as a Prerequisite to a Surgical Operation, 14 Cinn. L. Rev. 161, 168 (1940); Note 26 Mich. L. Rev. 561, 562 (1928).
NEGligence THEory IS INAPPROPRIATE TO
THE DOCTRINE OF INFORMED CONSENT

Whether the medical consumer's cause of action is characterized as negligence or strict tort liability, the evidence must establish that the defendant acted or failed to act in relationship to the plaintiff in such a manner as to create an unreasonable risk of harm, or as to have created a defective condition unreasonably dangerous to the consumer. However, in a negligence action for damages suffered due to a physician's failure to procure an informed consent, it may be extremely difficult for the plaintiff to prove the particular physician responsible for the failure to warn, or that the failure to warn was negligence, or that the risk was material. Under negligence theory, the possibility exists that the inference of negligence may be negated by an affirmative showing of proper care. As such, the plaintiff must produce evidence to contradict the physician's clear and positive assertion that an informed consent was given by the patient. Often the injured medical consumer is unable to refute evidence of proper care, or to identify the reason for the alleged failure to warn, because he is not as familiar with medical procedure as the physician. In leaving it to the jury to decide whether the inference of negligence has been rebutted, regardless of the evidence against it, the negligence rule approaches the rule of strict liability, and it is needlessly circuitous to make negligence the basis of recovery and impose what is really liability without negligence.

Strict enterprise liability avoids the necessity of proving a failure on the part of the physician to exercise ordinary care.

Imposition of strict tort liability is by no means automatic; the elements tacit or explicit in Restatement (Second) of Torts, Section 402A's mandate must be demonstrated to the trial court's satisfaction, before the burden of the patient's loss will be imposed on the medical supplier. The plaintiff is still faced with an arduous burden of proof. He must prove that: (1) the warning in question was defective; (2) the defect existed at the time the warning left the control of the defendant; (3) that because of the defect the warning was unreasonably dangerous to the consumer (plaintiff); (4) that the consumer was injured or suffered damages; and, (5) that the defect (if proved) was the proximate cause of the injuries. Dean Prosser foresaw this evolution of tort law, heralded by Elmore v. American Motors Corp., which placed
"strict liability on the same footing as negligence, as to all foreseeable injuries." His learned analysis appears to state the better view since, although the medical consumer is deemed individually to have relied upon the warning being free from defects, the public also should be deemed to have relied upon the fact that inadequate warnings generally will not accompany medical services.  

[Liability] should not be based on a technical or artificial distinction between sales and services. Rather, [we] must determine if the policies which support the imposition of strict tort liability would be furthered by its imposition in this case. In the present context, the question is whether it is in the public interest for the consumer/patient or the supplier/hospital to bear the loss incurred by defective, though non-negligent, services.  

Whatever the symptoms, the disease is the same. The typical victim of an uninformed consent, his body and legal rights crippled, takes "pot luck" in the courts. The right of the medical consumer to be warned of inherently dangerous risks in a given surgical procedure is founded on essentially the same over-riding public policy that secures the law of products liability.

APPLICATION OF SECTION 402A  
TO THE DOCTRINE OF INFORMED CONSENT

Restatement (Second) of Torts, Section 402A reads as follows:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and
(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and
(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Strict tort liability resulted from the judicial fusion of tort and commercial law to achieve the basic public policy requirements of our consumer-oriented, mass-production society.

41 Prosser, supra note 4, at 633.
44 Restatement (Second) of Torts §402A.
Its history is that of a movement from a position of no liability at all for the maker who was not in privity of contract with the victim, to a full negligence duty, thence to a liability without "fault," carrying with it the "baggage" of commercial law and the rigidity of its statutory formulation; thence to the major breakthrough, with a rejection not only of privity but of the commercial law disclaimer limitation, and finally, to the creation in the "grand common law tradition" of a new remedy "in tort," designed to be free of the limitations of both commercial law and the statutory mode.⁴⁵

Throughout its brief history, products liability law has been plagued by the semantical predilections of the judiciary. The early rule was that seller's strict liability was limited to users or consumers of the product.⁴⁶ This also was the rule initially embodied in the Restatement (Second) of Torts, Section 402A which speaks of injuries to "ultimate users or consumers."⁴⁷ But, as Dean Prosser noted, the more recent decisions have expanded the class of plaintiffs, limiting the class only by foreseeability.⁴⁸ It is now recognized that neither a change in possession nor an actual sale is required.⁴⁹ Starting with the early cases (phrased in the warranty terminology) of Henningsen v. Bloomfield Motors Inc.,⁵⁰ and Cintrone v. Hertz Truck Leasing & Rental Service,⁵¹ and continuing through the true strict liability cases commencing with Santor v. A & M Karagheusian, Inc.,⁵² and down to the recent case of Realmuto v. Straub Motors Inc.,⁵³ courts have expanded this field in order to fulfill public expectations of vested culpability for goods and services placed in the stream of commerce. As the court stated in Santor:⁵⁴

The obligation... thus becomes what in justice it ought to be—an enterprise liability... which should not depend upon the intricacies of

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⁴⁶ Id. at 351.


⁴⁸ Prosser, supra note 4, at 633.


⁵¹ 45 N.J. 434, 212 A.2d 769 (1965).


⁵⁴ 44 N.J. 52, 207 A.2d 305.
the law of sales. The purpose of such liability is to insure that the cost of injuries or damage... resulting from defective products is borne by... [those]... who put them in the channels of trade, rather than by the injured or damaged persons who ordinarily are powerless to protect themselves.55 (emphasis added)

A product is defined as "that which is produced by nature or made by industry or art."56 Relevant to our examination is the manner in which courts view medical services as a "product" resulting from the medical arts. Traditionally, all types of products have been included in the scope of strict tort liability, ranging from automobiles and airplanes to cinder building blocks, glass doors and paper cups.57 It is enough that the product, if defective, will be recognizably dangerous to the user.

Judicial expansion of the term "product" pours over into "services" where the facts and public policy signal relief for the plaintiff. In Coleman v. Hertz Corporation,58 the court held the defendant automobile rental agency strictly liable for injuries sustained by lessee's employee when a wheel on a leased truck fell off.59 Firestone Tire Company had independently contracted with Hertz to keep the wheels and tires of Hertz's trucks in good repair. First, the transaction between plaintiff and Hertz involved a "lease" and not a "sale."60 Hertz contracted to service, repair, and maintain plaintiff's vehicle. In so doing, Hertz impliedly warranted and represented that the truck would safely perform the function for which it was leased. Because plaintiff used the truck for the purpose and in the manner intended, the lessor was liable for injuries proximately caused by the failure of the truck to perform as warranted.61

The court affixed strict tort liability to lessor's dual breach of duty; first, to provide a safe product (rental truck) and, second, to repair, service and maintain that product.62 The first duty involved a product "per se," while

55 Id. at 65, 207 A.2d at 311-12.
56 WEBSTER'S NEW TWENTIETH CENTURY DICTIONARY OF THE ENGLISH LANGUAGE, UNABRIDGED (2nd ed. 1957).
57 Prosser, The Fall of the Citadel (Strict Liability to the Consumer), 50 MINN. L. REV. 805 (1966).
59 Id. at 945.
60 Id.
61 Id. at 942.
62 Id. at 946. The court reasoned:
We held in Santor the liability of the manufacturer might be expressed in terms of strict liability in tort.... [B]y analogy the same rule should be made applicable to the U-drive-it bailor-bailee relationship. Such a rental must be regarded as accompanied by a representation that the vehicle is fit for operation on the public highways.... Accordingly, we are of the opinion... that the responsibility of Hertz may properly be stated in terms of strict liability in tort.... We adopt, as several other courts have, the reasoning of Cintrone.
the second duty was to "service." The court reasoned that Hertz was strictly liable in tort for its failure to service, repair and maintain the rented vehicle because products liability law "projects a philosophy and spirit broad enough to be consistent with the extension of strict liability to all commercial suppliers, [even] where no sale is involved." 63

In Realmuto v. Straub Motors Co., 64 the Supreme Court of New Jersey held the defendant-used car dealer liable for the defective repair of a used car later sold to plaintiff. 65 Refusing to rule on the broad question of whether a seller of used chattels can be held strictly liable for defects, the court concluded: "...[we] are of the view that a used car dealer ought to be subject to a mishap resulting from any defective work, repairs, or replacements he has done or made on the vehicle before the sale." 66 A used car dealer has the duty of reasonable inspection, testing, and warning of defects. 67 The question being "one of factual causation," 68 the seller was held strictly liable in tort for his defective (negligent) repair.

Strict tort liability was applied to medical malpractice law in the case of Johnson v. Sears Roebuck. 69 The plaintiff, Sharon Johnson, was seriously injured when the wheel of her car fell off. The tire had been installed by defendant, Sears Roebuck & Company. Sears impleaded Columbia Hospital in a third party action, alleging that Columbia Hospital's care of the injured plaintiff was an intervening cause of plaintiff's injuries. The Federal District Court for the Eastern District of Wisconsin prefaced its opinion by stating that the facts invited the application of strict tort liability to "services" 70 and was a case of first impression in Wisconsin. Distinguishing between the hospital's administrative services and the professional medical services rendered by physicians, 71 the court held the sales/service dichotomy untenable. Because strict liability should not be based on a "technical or artificial distinction between sales and service," 72 public policy supports the

63 Id. at 944.
65 Id. at 344, 322 A.2d at 440, where the court stated:
The strict liability in tort rule is, of course, grounded in reasons of public policy. Re-statement, Torts 2d §402A, comment C. It may well be that these policy reasons are not fully applicable to the seller of a used chattel—for example, the buyer cannot be said to expect the same quality and durability in a used car as in a new one and so the used car dealer should not be held to the same strict liability as the seller of new automobiles. (emphasis added)
66 Id. at 344-45, 322 A.2d at 444.
67 Id. at 336-37, 322 A.2d at 440.
68 Id. at 342, 322 A.2d at 443.
70 Id. at 1066.
71 Id. at 1066, 1067.
72 Id. at 1066.
imposition of strict tort liability to shift the risk of loss for defective services to the supplier/hospital, rather than the consumer/patient.\textsuperscript{73}

The overriding public interest demands that "services which hospitals perform for both doctors and patients be performed properly."\textsuperscript{74} Recognizing the serious consequences resulting when a patient receives defective hospital services, the inability of laymen to recognize or control such defective services, and the physician’s need to receive pertinent medical information requisite to a particular course of treatment to be given the patient,\textsuperscript{75} a strict liability cause of action should not be denied simply on a "sales versus service" rationale. The court noted in its opinion:

Medical sciences are not exact. A patient cannot consider a doctor’s treatment to be defective simply because it does not cure his ailment. All that a doctor can be expected to provide is adequate treatment commensurate with the state of medical sciences. In other words, doctors do not contract with patients to provide cures but rather to provide treatment in a non-negligent manner.\textsuperscript{76}

Careful analysis indicates that strict liability should be imposed for a physician’s failure to warn of material risks. There is nothing "inexact" about the duty to warn; it does not involve the slip of a scalpel or the unforeseen risks of surgery. In evaluating the physician’s liability for injuries caused by his inevitably hazardous services, a two-step analysis is required to determine: (a) whether the service is so unsafe that marketing it at all is "unreasonably dangerous per se"; and (b) if not, whether the service has been introduced into the stream of commerce without sufficient safeguards and is thereby "unreasonably dangerous as marketed."\textsuperscript{77} In either case the applicable standard is as follows: In terms of the consumer’s interests, a service is "unreasonably dangerous" only when it is "dangerous to an extent beyond that contemplated by the ordinary consumer."\textsuperscript{78}

Public need favors the continuance of medical services, although "inexact" and unsafe. Therefore, the services are not "unreasonably dangerous per se" merely because the state of medical knowledge in the particular area is unrefined. But the terms "defective condition" and "unreasonably danger-

\textsuperscript{73} Id.
\textsuperscript{74} Id. at 1067.
\textsuperscript{75} Id.
\textsuperscript{76} Id.
\textsuperscript{77} Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1273 (5th Cir. 1974).
\textsuperscript{78} See Boral v. Fibreboard Paper Products Corp., 493 F.2d 1076, 1088 (5th Cir. 1973); Helene Curtis Industries, Inc. v. Pruitt, 385 F.2d 841, 850 (5th Cir. 1967); Wade, Strict Tort Liability of Manufacturers. 19 Sw. L.J. 5, at 15 (1965); See also Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1273-74 (5th Cir. 1974).
ous” are essentially synonymous in products liability law. To the extent that medical services are rendered beyond the realm contemplated by the ordinary patient, the services are unreasonably dangerous “as marketed” unless a warning is given. Thus, the individual patient’s right to know and the public’s interest in securing warnings on a broad scale demand that the doctrine of informed consent coalesce with enterprise liability.

If the physician knows or, by the application of reasonably developed professional skill, and foresight, should have known that an appreciable class of medical consumers undergoing a similar surgical procedure would be subject to an adverse risk, he must give adequate warning to insure the opportunity for intelligent choice as to whether to submit to the surgery or not. Strict liability should be imposed because essentially these are foreseeability cases; the element required to invoke strict liability doctrine is foreseeability.

Strict liability turns not upon the character of the surgery, but upon the misrepresentation of the inherently dangerous nature of the procedure to the medical consumer. The consumer is usually without sufficient knowledge to recognize or control such defective warnings or even to ask questions about the surgery. The doctrine of strict tort liability has been held applicable to a commercial user, and the better view is that benefits of strict liability doctrine extend to “foreseeable plaintiffs” rather than merely to actual users or buyers of goods.

Consider the growing pre-eminence of the centrally-located hospital, which provides its own staff doctors, nurses, laboratories, and administration vis-a-vis the expanding medical needs of modern society. Many medical consumers have no family doctor, and must rely on emergency room treatment. They often have little or no relationship with the physician assigned to their case. If a specialist is required, the doctor-patient relationship grows even more tenuous. Given these factors and the increasing sophistication of medical consumers regarding their legal right to render an informed consent, public policy favors the expansion of strict tort liability to the doctrine of informed consent.

Therefore, medical services that reach the consumer in a defective condition, because they performed without informed consent, should subject the doctor or hospital to strict liability. The physicians and hospitals, as the commercial suppliers of medical services, bear the risk of loss as a cost of

79 See Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1265 (5th Cir. 1974).
81 See Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1278 (5th Cir. 1974).
doing business. Further, where the medical consumer, whose injury the physician should have reasonably foreseen, is injured by surgery without the required warning, a rebuttable presumption should arise that the medical consumer would have reacted reasonably to the physician’s warning, and acted so as to minimize the risk. In the absence of evidence rebutting that presumption, a jury determination that the physician’s failure to warn was the producing cause of the patient’s injury would be sufficient to hold the physician and hospital liable.

STATEMENT OF PROPOSED RULE

Where a physician performs surgery or other remedial treatment without his patient’s informed consent, and that surgery or treatment, if successful, will cause a foreseeable injury to a foreseeable plaintiff, then the physician and hospital will be held strictly liable for damages caused by risks of which the plaintiff was not informed.

POLICY CONSIDERATIONS

The requirement that a medical patient render an informed consent has its basis in law. The crucial question remains: Who shall determine the standard of adequacy for disclosure? This author contends that the standard of adequacy is a legal determination inextricably bound to the legal requirement for informed consent. The mode of treatment, the diagnosis of symptoms, and the prognosis for recovery are medical determinations. But the informed decision to accede to the recommended treatment, based on the knowledge of material risks, is a legal right. As such, it deserves a better remedy.

Physicians and hospitals are engaged in the business of distributing medical services to the public. They are an integral part of an overall production and marketing enterprise that should bear the cost of injuries resulting from defective services. In some cases, the hospital may be the only member of that enterprise reasonably available to the injured plaintiff. In other cases, the physician himself can play a substantial role in insuring that an informed consent is rendered, or may be in a position to exert pressure on the hospital to that end. The physician’s strict liability thus serves as an added incentive to safety. Strict liability on the hospital and physician alike affords maximum protection to the injured medical consumer and works no injustice on the hospital or the physician, for they can adjust the costs of

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83 This definition of materiality is adopted directly from Walts & Scheuneman, *supra* note 25, at 640:

A risk is thus material when a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to undergo the proposed therapy.

such protection between them in the course of their continuing business relationship. 85

The purpose of the rule of strict tort liability is the protection of the average consumer, who is not really in a position to bargain effectively or intelligently. 86 Application of strict tort liability is justified because the public has the right to expect, in the case of services that it needs and for which it is forced to rely upon the medical community, that reputable hospitals and physicians will recognize their legal duty to warn the consumer, and that the medical consumer is entitled to maximum protection at the hands of those who market the services. 87

A duty to warn exists where there is unequal knowledge, actual or constructive, and the defendant, possessed of such knowledge, knows or should know that harm might or could occur if no warning is given. 88 A review of the authorities leaves little question that where a physician has reason to foresee that danger may result from a particular surgical procedure or treatment, he may be required to give adequate warning of the danger. In the absence of adequate warning, liability may arise from use of a surgical procedure not otherwise defective, since failure to warn may itself be the defect which causes injury. 89 Of course, absent evidence that the physician had actual or constructive knowledge of the danger, or where competent waiver of consent is given by the patient, there is no duty placed upon physician to warn.

THE PROPOSED PROCEDURE

Consistent with the aforementioned policies, the following procedure should be instituted by physicians and hospitals to insure that the medical consumer's right to medical self-determination is not abridged, and to protect hospitals from the danger of a lawsuit.

It is recommended that hospitals employ a full-time Information Director to inform consumers of the suggested criteria. The attending physician would complete a few short forms and forward them to the information director. The process is not as burdensome as might seem at first glance. For instance, for ordinary appendectomies on otherwise healthy patients, the risks would be similar. Therefore, when the physician contemplates an ordinary appen-

86 Keystone Aeronautics Corp. v. R.J. Enstrom Corp., 499 F.2d 146 (3rd Cir. 1974).
87 See generally Noel, Products Defective Because of Inadequate Directions or Warnings, 23 Sw. L.J. 256, 296, 297 (1969).
dectomy with no serious complications, the physician would instruct the information director to prepare a "Standard Appendectomy Form," with space for notation of risks peculiar to the particular medical consumer. 60

60 The Ohio Legislature recently adopted a very specific informed consent statute. Ohio Rev. Code §2317.54 (Page 1975) provides:

Written consent to a surgical or medical procedure or course of procedures shall, to the extent that it fulfills either all the requirements in divisions (A), (B), and (C) of this section or the requirements of division (D) of this section, be presumed to be valid and effective, in the absence of proof by a preponderance of the evidence that the person who sought such consent was not acting in good faith, or that the execution of the consent was induced by fraudulent misrepresentation of material facts, or that the person executing the consent was not able to communicate effectively in spoken and written English or any other language in which the consent is written. Except as herein provided, no evidence shall be admissible to impeach, modify, or limit the authorization for performance of the procedure or procedures set forth in such written consent.

(A) The consent sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss of function of any organ or limb, or disfiguring scars associated with such procedure or procedures, with the probability of each such risk if reasonably determinable.

(B) The person making the consent acknowledges that such disclosure of information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner.

(C) The consent is signed by the patient for whom the procedure is to be performed, or, if the patient for any reason including, but not limited to, competence, infancy, or the fact that, at the latest time that the consent is needed, the patient is under the influence of alcohol, hallucinogens, or drugs, lacks legal capacity to consent, by a person who has legal authority to consent on behalf of such patient in such circumstances.

(D) The consent is in ten-point type and is executed in the following form:

CONSENT FOR MEDICAL PROCEDURE AND ACKNOWLEDGEMENT OF RECEIPT OF RISK INFORMATION

State law requires us to obtain your consent to your contemplated surgery or other medical procedure. What you are being asked to sign is simply a confirmation that we have discussed your contemplated operation or medical procedure and that we have given you sufficient information upon which to make a decision whether to have the operation or medical procedure and any choice as to the type of operation or medical procedure of your own free will. We have already discussed with you the common problems of undesired results that sometimes occur. We wish to inform you, not to alarm you. If you wish, however, we can go into more elaborate details of more unlikely problems. If you do not, that is also your privilege. Please read the form carefully and check the appropriate boxes. Ask about anything that you do not understand, we will be pleased to explain it. I hereby authorize and direct ................................, with associate or assistants of his choice to perform the following surgical diagnostic or medical procedure on ................................ as we have agreed upon.

Relationship

I further authorize the doctors to perform any other procedure that in their judgment is advisable for my well being. Details of this operation have been explained to me. Alternative methods of treatment, if any, have also been explained to me as have the advantages and disadvantages of each. I am advised that though good results are expected, the possibility and nature of complications cannot be accurately anticipated.
The Information Director would then apprise the competent medical consumer of the following factors:

(a) the nature of material risks foreseeable during or immediately subsequent to the proposed surgery;
(b) the quantitative possibility (expressed in percentage form) of that particular risk arising during or immediately after the proposed surgery;
(c) the quantitative possibility (expressed in percentage form) of the patient's malady being cured or substantially abated to the extent and that therefore can be no guarantee as expressed or implied either as to the result of surgery or as to cure.

DEGREE AND KIND OF RISKS KNOWN TO BE ASSOCIATED WITH THIS PROCEDURE, INCLUDING ANESTHESIA

EACH MARKED BOX INDICATES SOME RISKS THAT ARE ASSOCIATED WITH THIS PROCEDURE

<table>
<thead>
<tr>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
</tr>
<tr>
<td>Brain Damage</td>
</tr>
<tr>
<td>Quadriplegia (Paralysis of all arms and legs)</td>
</tr>
<tr>
<td>Paraplegia (Paralysis of both legs)</td>
</tr>
<tr>
<td>Loss of Organ</td>
</tr>
<tr>
<td>Loss of an arm or leg</td>
</tr>
<tr>
<td>Loss of function of organ</td>
</tr>
<tr>
<td>Loss of function of an arm or leg</td>
</tr>
<tr>
<td>Disfiguring scars</td>
</tr>
</tbody>
</table>

The doctor has explained to me the most likely complications of undesired results that might occur in this operation or medical procedure and I understand them. The doctor has offered to detail the less likely complications of undesired results which, even if rare, could occur.

I do not wish to have a full description of all the possible complications given to me.

I hereby authorize and direct the above named physician with associates or assistants to provide such additional services as they may deem reasonable and necessary including, but not limited to, the administration of any anesthetic agent, or the services of the X-ray department or laboratories, and I hereby consent thereto.

I hereby state that I have read and understand this consent and that all blanks were filled in prior to my signature.

Date: ........................................................ Time: ................................................ a.m. p.m.
Signature of Patient .........................................................
Signature of Relative (where required) ................................................
Signature of Representative (where required) ........................................

Witness ........................................................

I certify that I have personally completed all blanks in this form and explained them to the patient or his representative before requesting the patient or his representative to sign it.

(Signature of the above named physician)

Any use of the consent form stated in division (D) of this section has no effect on the common law rights and liabilities, including the right of a physician to obtain the oral or implied consent of a patient to a medical procedure, that may exist as between physicians and patients at the time this section is enacted.
that the patient will no longer experience substantial discomfort therefrom following a full recovery;
(d) alternative means of treatment;\(^\text{91}\) and,
(e) the extent, nature, and duration of foreseeable side effects of the proposed surgery.

This procedure would guarantee the medical consumer the proper basis to make an informed legal consent to the surgery. Of course, to be effective, the information given to the medical consumer should be couched in laymen’s terms (e.g. “danger of internal bleeding” and “danger of infection,” etc.).\(^\text{92}\) At this point, the physician would be free to confer with the medical consumer concerning the diagnosis, the nature of his proposed treatment, and his prognosis for recovery. The physician could use this opportunity to elevate the spirits of the medical consumer, while taking into account the consumer’s physical and mental condition.

The delegation of the ministerial duty of warning to a trained Information Director is desirable for several reasons. First, it should mitigate the remonstrations from those physicians who operate under the delusion that the right to render an informed consent is a privilege bestowed upon the medical consumer at the physician’s perogative. Secondly, it will delegate the duty to inform to a readily ascertainable source, who can administer the paper work and ministerial functions involved. The recommended procedure will free the physician so that he may direct his energies toward solving medical (and billable) problems. Further, there will be no question of where responsibility can be found. The proposed procedure, when followed closely, acts as a complete defense to a law suit based on informed consent.

\(^{91}\) For example, a patient is prevented from making a choice if he is unaware of the existence of alternatives to the particular treatment recommended by his physician. See Bang v. Charles T. Miller Hosp., 251 Minn. 427, 88 N.W.2d 186 (1958); Scott v. Wilson, 396 S.W.2d 532 (Tex. Civ. App. 1965).

\(^{92}\) Cobbs v. Grant, 8 Cal. 3rd 244, 245, 104 Cal. Rptr. 514, 515, 502 P.2d 10, 11 (1972).

The court also noted:
The scope of disclosure required of physicians defies simple definition. Some courts have spoken of “full disclosure” ... and others refer to “full and complete” disclosure ... but such facile expressions obscure common practicalities. Two qualifications to a requirement of “full disclosure” need little explication. First, the patient’s interest in information does not extend to a lengthy polysyllabic discourse on all possible complications. A mini-course in medical science is not required; the patient is concerned with the risk of death or bodily harm, and problems of recuperation. Second, there is no physician’s duty to discuss the relatively minor risks inherent in common procedures, when it is common knowledge that such risks inherent in the procedure are of very low incidence. When there is a common procedure a doctor must, of course, make such inquiries as are required to determine if for the particular patient the treatment under consideration is contraindicated—for example, to determine if the patient has had adverse reaction to antibiotics; but no warning beyond such inquiries is required as to the remote possibility of death or serious bodily harm.
CONCLUSION

The general rule of absention from strict tort liability and implied warranty liability for defective medical services is stated in *Perlmutter v. Beth David Hospital*:

>[The daily functions performed by hospitals, have been considered essentially services or have been placed under the heading of professional transactions; thus, such “services” were exempted from strict liability recovery. Two trends away from this simplistic classification are discernable. First, some transactions are regarded as sales, imposing sales liability. Second, courts have begun to look to the reasons for asserting strict liability, without regard to the mechanical tests for sales. The latter policy approach would seem to be the sounder of the two.86]

This author urges legislative adoption of the strict tort liability approach to informed consent. Broad legislative enactment would promote uniformity of law and would establish bold, new guidelines to protect the competent physician from the inconsistencies and vagaries of muddled judicial dictates. Secondly, legislative adoption would protect the competent medical consumer’s rights to self-determination and guarantee that his informed consent be a mandatory pre-requisite to surgery performed on his body. Finally, by requiring the incompetent or unethical medical practitioner to meet definitive legislative guidelines, enactment would stand as the medical consumer’s front-line defense against incompetent medical services.

The proposal is consistent with the policy considerations which underlie the doctrine of strict liability in tort. That policy is not enhanced by court decisions that recognize the physician’s duty to warn, yet refuse to assess liability without proof of negligence. Judicial adoption of this proposal is encouraged. The precedents are clear and the public interest is overriding. The physician and hospital should be held strictly liable because they can more easily spread the risk of loss caused by their failure to warn, and to do so will encourage them to take greater care in obtaining a patient’s informed consent to surgery. The losses should be borne by those who have created the risk and reaped the profits in the stream of commerce.

Our present system is undoubtedly conducive to vexacious litigation. Full disclosure seems a small price, indeed, to both insure the rights of the medical consumer, and to insulate the hospital and physician from litigation. Given these alternatives, must the consumer continue to pay the price?

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86 308 N.Y. 100, 123 N.E.2d 792 (1954).