OVERVIEW OF THE LAW OF INFORMED CONSENT

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Almost a century ago, in *Schloendorff v. The Society of the New York Hospital,* 211 N.Y. 125, 129 (1914), Judge Cardozo[2], writing for the unanimous New York Court of Appeals, reaffirmed the principle, fundamental in American jurisprudence, that "[e]very 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. . . . This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained."

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2 Later Chief Judge of the New York Court of Appeals (1927-1932) and then an Associate Justice of the Supreme Court of the United States (1932-1938).

While the immunity from liability for the negligence of its physicians and nurses which charitable institutions such as New York Hospital enjoyed in 1914[3] was abolished in New York in 1957,[4] the doctrine of informed consent, or, put another way, the physician's duty to disclose to the patient (i) the available therapy alternatives, (ii) the goals expected to be achieved, and (iii) the material risks that may follow from the treatment or from no treatment, has survived and is an important part of the contemporary plaintiff's armamentarium and must be so regarded by defense counsel. In many jurisdictions, the common law doctrine has been codified.[5]

"Adequate disclosure and informed consent are . . . two sides of the same coin -- the former a *sine qua non* of the latter."[6] However, the focus is on an *objective* evaluation of the physician's performance of his or her

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[3] The immunity was based on two now rejected theories: (1) implied waiver - "one who accepts the benefit of a charity enters into a relation which exempts one's benefactors from liability for the negligence of his servant's in administering the charity; (2) respondeat superior does not apply to a hospital because "the physician occupies the position, so to speak, of an independent contractor." *Schloendorff,* 211 N.Y. at 129.

[4] *Bing v. Thunig,* 2 N.Y.2d 656, 666 (1957)("It is not alone good morals but sound law that individuals and organizations should be just before they are generous, and there is no reason why that should not apply to charitable hospitals. 'Charity suffereth long and is kind, but in the common law it cannot be careless. When it is, it ceases to be kindness and becomes actionable wrongdoing.")

[5] *E.g., New York Public Health Law,* §2805-d; Ontario, Health Care Consent Act, 1996, S.O. 1996, c.2, Schedule A.

[6] *Canterbury v. Spence,* 464 F.2d 772, 780 n.15 (D.C. Cir. 1972).

obligation to make adequate disclosure, rather than on the patient's subjective understanding of the risks.

The duty to disclose "is more than a call to speak merely on the patient's request, or merely to answer the patient's questions; it is a duty to volunteer, if necessary, the information the patient needs for intelligent decision. The patient may be ignorant, confused, overawed by the physician or frightened by the hospital, or even ashamed to inquire."[7] Moreover, the average patient has little or no understanding of the medicine involved and will not be in a position to identify and then frame the relevant questions in the absence of a prior explanation by the physician.

Of course, a physician is not expected or required to compress the experience gained from four years of medical school, years of post-graduate specialization and a lifetime of experience into a 15 minute or half-hour disquisition. Rather, what is required is a explanation, in non-technical terms, readily understandable by lay persons, of what is at stake -- the material risks and hoped for benefits of the treatment or decision to forego treatment and any available alternatives. If the physician does this, his or her duty will have been discharged, even though the patient, through no fault of the physician, may not fully comprehend the explanation.

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[7] *Canterbury v. Spence, supra,* 464 F.2d at 783, n. 36.

A risk is material, and must be disclosed, "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 forego the proposed therapy."[8] There is no bright line separating the significant from the insignificant. A very small chance of death or serious disability may be significant where the treatment is for a trivial indication. Factors to be considered include the nature of the condition for which treatment is proposed, the dangerousness of the treatment, the incidence of injury and the severity of the potential harm and alternatives.

The duty to disclose, as in any negligence case, calls for conduct that is prudent under all the circumstances. Where nondisclosure of particular risk information is open to debate by reasonable-minded persons, the issue becomes one for the trier of the facts to decide.

A physician is not legally obligated to inform the patient of a risk of which he or she is unaware. However, a question might arise as to whether the physician should have known of the risk and whether not knowing of it constitutes general malpractice.

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[8] *Canterbury v. Spence, supra,* 464 F.2d at 787.

In New York, which has codified the common law rules, there are four statutory defenses to an action for medical, dental or podiatric malpractice based on lack of informed consent:[9]

1. the risk not disclosed is too commonly known to warrant disclosure -- *e.g.,* the risk of infection which is inherent in any operation or period of hospitalization; or

2. the patient has assured the physician that he or she would undergo the treatment or procedure regardless of the risk involved, or has said that he or she did not want to be informed of the risks and alternatives; or

3. consent by or on behalf of the patient was not reasonably obtainable -- *e.g.*, the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent and outweighs any harm threatened by the proposed treatment; or

4. when risk disclosure can reasonably be expected to adversely and substantially affect the patient's condition -- patients may become so ill or emotionally distraught on disclosure as to foreclose a rational decision, or complicate or hinder treatment, or pose psychological damage to the patient.

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[9] In New York, the action sounds in medical malpractice even though the physician is able to demonstrate the necessity of the treatment and that it was performed in accordance with good and accepted standards of medical practice. *N.Y. Public Health Law,* § 2805-d. Characterization of the action as one for malpractice as opposed to the intentional tort of battery may be significant and outcome determinative where different statutes of limitations apply to the two torts.

This last defense must be carefully circumscribed so it does not nullify the duty to disclose. It is not the paternalistic and outmoded notion that the physician may remain silent simply because disclosure might prompt the patient to forego therapy that the physician feels the patient needs.

In *Canterbury v. Spence, supra,* the U.S. Court of Appeals for the District of Columbia Circuit held that expert testimony was not necessary to establish a community standard because "to bind the disclosure obligation to medical usage is to arrogate the decision on revelation to the physician alone. Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves."[10] Instead, the court opted for the general standard set by law for exacting reasonable care under all the circumstances.[11]

In some other U.S. jurisdictions, by judicial decision or legislation, a "reasonable doctor" test is applied to determine the question of whether there has been adequate disclosure of risks. In New York, a statute requires that the cause of action must be supported by expert medical evidence of the alleged qualitative insufficiency of the consent. Where such

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[10] *Canterbury v. Spence, supra,* 464 F.2d at 784.

[11] *Id*. at 785.

evidence is lacking, a defendant's motion for judgment at the end of the plaintiff's case must be granted.[12]

Additionally, in New York, another statute limits a cause of action for medical malpractice based on lack of informed consent to those cases involving "(a) non-emergency treatment, procedure or surgery, or (b) a diagnostic procedure involving invasion or disruption of the integrity of the body."[13] This requirement did not exist at common law.

In *Sidway v. Board of Governors, etc.,* [1985] AC 871, the House of Lords noted that "the proliferation of medical malpractice suits in the U.S.A. has led some courts and some legislatures to curtail or to even reject the operation of the doctrine [of informed consent] in an endeavor to restrict the liability of the doctor and so discourage the practice of 'defensive medicine' -- by which is meant the practice of doctors advising and

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12 *N.Y. C.P.L.R.* § 4401-a. The requirement for expert evidence was added at the insistence of the medical profession and its liability insurers during the "medical malpractice insurance crisis" that existed in New York State during 1974-1975.

13 *N.Y. Public Health Law*, §2805-d(2). Thus, it has been held that there is no liability under a cause of action for lack of informed consent where the physician failed to inform the parents of the risks of giving birth to a deformed child, precluding them from exercising the option of terminating the pregnancy. *Karlsons v. Guerinot,* 394 N.Y.S.2d 933 (App. Div. 4th Dep't 1977); or where a physician failed to advise the decedent of the seriousness of his condition , with the result that affirmative treatment was not sought in a timely manner. *Etkin v. Marcus,* 425 N.Y.S.2d 165 (App. Div. 2d Dep't 1980).

undertaking the treatment which they think is legally safe even though they may believe that it is not the best for their patient."

A plaintiff must also establish that the failure to make adequate disclosure was the proximate cause of the ensuing injury or death. A causal connection exists when disclosure of significant risks incidental to treatment would have resulted in a decision not to undergo it. It must also be established that the undisclosed risk did, in fact, materialize. The treatment must be the proximate cause of the injury, for if the risk does not materialize, there is no liability for failure to secure the consent of the patient.[14]

Courts have recognized that "when causality is explored at a post-injury trial with a professedly uninformed patient, the question whether he actually would have turned down the treatment if he had known of the risks is purely hypothetical . . . And the answer which the patient supplies hardly represents more than a guess, perhaps tinged by the circumstance that the uncommunicated hazard had materialized. . . . It places the physician in jeopardy of the patient's hindsight and bitterness."[15]

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[14] There may still be a cause of action for battery based on the unconsented to touching. *Messina v. Matarasso*, 729 N.Y.S.2d 4 (App. Div. 1st Dep't 2001) (during cosmetic surgery on plaintiff's face, defendant performed an unauthorized procedure on her breasts; the intentional deviation from consent was a battery).

[15] *Canterbury v. Spence*, 464 F.2d at 790.

Accordingly, the issue of causation is to be resolved on an objective basis: what would a prudent person have decided if adequately informed of the material risks of treatment? The patient's testimony might be relevant and probative, but not determinative.[16]

In New York, where medical malpractice cases are generally tried to a jury as the fact finders, the pattern jury instruction explains that:

> It is the doctor's duty to explain, in words that are understandable to the patient, all the facts that would be explained by a reasonable medical practitioner so that when the patient does, in fact, consent, that consent is given with an awareness of
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> (1) the patient's existing physical condition;
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> (2) the purposes and advantages of the operation;
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> (3) the reasonably foreseeable risks to the patient's health or life which the operation, procedure or medication may impose;
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> (4) the risks involved to the patient if there is no operation, procedure or use of medication; and
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> (5) the available alternative and the risks and advantages of those alternatives.[17]

The jury is then asked to answer a series of questions:

(1) Did defendant before obtaining plaintiff's consent to the operation, procedure or use of medication provide appropriate information?

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[16] *Fogal v. Genesee Hosp.*, 344 N.Y.S.2d 552 (App. Div. 4th Dep't 1973).

[17] N.Y. Pattern Jury Instructions, 2:150A.

(2) If "No," would a reasonably prudent person in plaintiff's (or decedent's) position at the time consent was given have given such consent if given appropriate information?

(3) If "No," was the operation, procedure or medication a substantial factor in causing injury to the plaintiff (decedent)?

A physician is entitled to rely on the informed consent given by his or her patient to others and need not again personally interview the patient and obtain the requisite consent a second time. A treating physician or surgeon may rely on the informed consent obtained by a referring or admitting physician. However, such reliance on what another has done carries with it the risk that the physician will be held liable for any deficiency in the information provided to the patient by those to whom the physician's duty of disclosure was delegated.

Under the common law of **Canada,** doctors are required to disclose all material risks to patients before proceeding with treatment. "A material risk is one that a reasonable person in the patient's position would want to know about before deciding whether to proceed with the proposed treatment. Risks that are rare will be material if the consequences of those risks are serious."[18] Failure to do so is negligence.

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[18] *Van Dyke v. Grey Bruce Regional Health Centre* [2005] O.J. No. 2219 at ¶ 63.

A doctor must also advise the patient of all available reasonable alternative treatments. In Canada, just as in the U.S. and the U.K., "the decision whether to proceed with a particular treatment rests with the patient and not the doctor. The doctor must equip the patient with the information necessary to make an informed choice."[19] This means explaining the risks and benefits of each of the medically reasonable alternative treatments.

The concept of informed consent is now defined in considerable detail in Canada's Health Care Consent Act, 1996[20] ("HCC Act") which also covers admission of any person to any public or private hospital or other facility, including a nursing home.

Section 10 of the HCC Act states the general principle that there shall be "No treatment without consent," and imposes on the practitioner the affirmative duty to "take reasonable steps to insure that [the treatment] is not administered unless,"

(a) he or she is of the opinion that the person is "capable with respect to the treatment," *i.e.*, "able to understand the information that is relevant to making a decision about the treatment . . . and able to appreciate the reasonably foreseeable consequences of a decision or lack of decision," [§ 4], and the person has given consent; or

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19 *Id.* at ¶ 67.

20 S.O. 1996, c.2, Schedule A (Ontario).

(b) where the person is thought to be incapable, that the person's substitute decision-maker has given consent on the person's behalf.

Section 11(2) and (3) of the HCC Act provide that a consent to treatment is informed if, before giving it, the person received the information about each of the following matters that is necessary for a reasonable person in the same circumstances to make a decision about treatment:

(1) the nature of the treatment;

(2) the expected benefits of the treatment;

(3) the material risks of the treatment;

(4) the material side effects of the treatment;

(5) alternative courses of action; and

(6) the likely consequences of not having the treatment.

The HCC Act makes an exception that allows for treatment without consent in the case of an emergency, *i.e.,* if the person for whom treatment is proposed is apparently experiencing severe suffering or, in the opinion of the health practitioner proposing the treatment, is at risk, if the treatment is not administered, of sustaining serious bodily harm and communication with the person cannot take place because of a language barrier or otherwise and there is no reason to believe that the person does not want the treatment. § 25(1)

The HCC Act also calls for creation of a Consent and Capacity Review Board to be appointed by the Lieutenant Governor in council [§ 70] to resolve disputed questions of consent and admission to a hospital, psychiatric facility or health facility. The Board's decision, made after a hearing and, if requested, supported by written reasons, may be appealed to the Superior Court of Justice on a question of law or fact or both. § 80.

English law recognizes a duty of a doctor to warn his or her patient of material risk inherent in the proposed treatment, in particular in cases involving surgery and that a failure to warn of such known risks is actionable as a breach of the doctor's duty of care.[21] In *Sidway v. Board of Governors, etc., supra,* the House of Lords, while agreeing on this general principle, was sharply divided over the standard to be applied.

The majority[22] rejected the doctrine of informed consent as set forth in *Canterbury v. Spence, supra,* where it was held that the court (and not accepted good medical practice[23]) determines the scope of the duty and decides whether the doctor has acted in breach of that duty. Lord Bridge of Harwich was of the view that "a decision what degree of disclosure of risks is

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21 *Sidway v. Board of Governors, etc*., [1985] AC 871.

22 Lord Diplock, Lord Keith of Kinkel, Lord Bridge of Harwich and Lord Templeman.

23 This was the test used by the judge in summing up to the jury in *Bolam v. Friern Hospital Mgt Comm.* [1957] 1 W.L.R. 582, subsequently approved by the House of Lords in two cases.

best calculated to assist a particular patient to make a rational choice s to whether or not to undergo a particular treatment must primarily be a matter of clinical judgment. It would follow from this that the issue of whether non-disclosure in a particular case should be condemned as a breach of the doctor's duty of care is an issue to be decided primarily on the basis of expert medical evidence, applying the Bolam test."[24]

Lord Diplock found that the "merit of the Bolam test is that the criterion of the duty of care owed by a doctor to his patient is whether he has acted in accordance with a practice accepted as proper by a body of responsible and skilled medical opinion." In his opinion, the doctor's general duty of care owed to his or her patient "is not subject to dissection into a number of component parts to which different criteria of what satisfy the duty of care apply, such as diagnosis, treatment, advice (including warning of any risks of something going wrong however skillfully the treatment advised is carried out)."

When questioned specifically by a patient of apparently sound mind about risks involved in a particular treatment proposed, "the doctor's

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[24] In *Bolam*, the judge instructed the jury that a doctor is not guilty of negligence if he acts "in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art." quoted by Lord Scarman in *Sidaway v. Board of Governors, etc.*

duty must . . . be to answer both truthfully and as fully as the questioner requires."

Lord Scarman, in *dissent*, would have adopted the objective "prudent patient" standard of *Canterbury v. Spence, supra,* and followed in Canada.[25] If the doctor omits to warn where the risk is such that in the court's view a prudent person in the patient's situation would have regarded it as significant, the doctor is liable, unless, upon a reasonable assessment of the patient's condition the doctor takes the view that a warning would be detrimental to the patient's health.

[25] *Reibl v. Hughes,* 114 D.L.R.(3d) 1 (1980).