LAW AND MEDICAL EXPERIMENTATION: OF EMBRYOS, CHILDREN AND OTHERS WITH LIMITED LEGAL CAPACITY†

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IS THERE A PROBLEM?

Ethical issues relating to "experimentation", or "clinical reasearch", have been debated extensively in the last few decades. The disclosures of the medical experimentations that took place in the Nazi concentration camps led to the Nuremberg Code, followed, some years later, by the World Medical Association adopting the Helsinki Declaration, an ethical code relating to biomedical research involving human subjects[1] and the work of Dr. Beecher in the United States and of Dr. Pappworth in England[2] in highlighting examples of unethical medical research further concentrated the minds of the medical profession on these matters.

Codes and Guidelines, both at national and international level, have been introduced, revised and refined. The United States has been in the forefront of activity: the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was set up in 1974, issued several major reports and recommendations which resulted in the U.S. Congress becoming involved in the ethical regulation of federally funded research.

We seem to be in the midst of considerable activity. In April 1987, the fourth International Bioethics Summit Conference, held in Canada, produced an important document: *Towards an International Ethic for Research involving Human Subjects*. The Australian National Health and Medical Research Council has recently produced a revised *Statement on Human Experimentation*. English developments include the Royal College of

† *Paper delivered at a plenary session of the A.U.L.S.A. conference, Monash University, August 1987.*

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[1] World Medical Association. *Declaration of Helsinki,* Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects. (Adopted, Helsinki, 1964; amended, Tokyo, 1975 and Venice, 1983).

[2] H.K. Beecher, *Experimentation in Man* (1959); H.K. Beecher, *Clinical Investigations – Medical, Ethical and Moral Aspects* (1963); H.K. Beecher, "Ethics and Clinical Research" (1966) 274 *New England Journal of Medicine* 1354; M.H. Pappworth, *Human Guinea Pigs: Experimentation on Man* (London, Routledge & Kegan Paul, 1967).

Physicians' revised *Guidelines on the Practice of Ethics Committees in Medical Research* and also a *Report on Research on Healthy Volunteers*, and in 1986, the British Institute of Medical Ethics completed a study on the ethics of clinical research investigations on children.[3] And many more examples could be given.

As a result of all this activity, most of the ethical issues relating to human experimentation have been clarified and, save perhaps in the area of in vitro fertilisation and embryo research (where the Australian reports, debates and legislation have been followed with great interest around the world), there is a greater ethical consensus than ever before.

What, then, is there left to discuss? Unfortunately, quite a few matters. Codes and procedures have been responsible for improving ethical standards enormously, but examples of unethical research still occur.

Some of these, though publicised recently, have their origins in research work carried out decades ago. For example, *Mink* v. *University of Chicago*,[4] an action litigated into the 1980s, related to research activity between 1950–1952 when pregnant patients at the University of Chicago were, unknowingly, involved in experimental trials of the drug DES (diethystilbestrol). It was only some 20 years later, when their children began to manifest unusually high rates of cancer and other abnormalities, that the issue of unethical and unlawful experimentation was raised. Today, even in the highly regulated American research environment, examples of unethical research still surface. In 1986 Dr. Robert Gale of UCLA (University of California – Los Angeles) was reprimanded by the National Institute of Health for work involving bone marrow transplants because he had not complied with the terms of the approval given by the research ethics committee. In another recent notorious case at UCLA a researcher, whose project had been disapproved by the UCLA research ethics committee on the grounds that more animal studies were necessary, performed bone marrow transplants on uninformed patients in Italy and Israel.

In view of the number of research projects that are being carried out all the time (five hundred clinical research projects involving children are started each year in England and Wales alone) it is perhaps not surprising that questionable procedures can be identified, albiet not in great numbers, in countries around the world. Invasive research procedures do not stop at blood sampling. It has been said that "every orifice of the human body has had instruments inserted during the course of research on children."[5] For example, where there was never any intention to improve their treatment, children with recurrent infections of the urinary tract had catheters passed via the urethra into their bladders which were then inflated with carbon dioxide on several occasions at different speeds to enable various measurements to be made, and also were given general anaesthetics, during which the inside of each child's

[3] R.H. Nicholson (ed.), *Medical Research with Children: Ethics, Law and Practice* (New York, Oxford University Press, 1986).
[4] 460 F. Supp. 713 (1978); affd. 727 F.2d 1112 (1984).
[5] Nicholson, op. cit. p. 19.

bladder was examined with a telescope and a catheter was passed through the abdominal wall into the bladder;[6] a French researcher performed four lumbar punctures each on 57 newborn babies in the first two weeks of life in an unsuccessful attempt to find biochemical support for a rather unlikely scientific theory about brain damage in infants,[7] and so on.

Such examples inevitably raise the question of the legality of medical research and the relationship between law and ethics in this area. This paper will explore some of these matters, particularly as they affect research subjects who do not have the capacity or understanding to consent to such procedures. This will inevitably involve an examination of the distinction between "therapeutic" and "non-therapeutic" research; the legal and practical problems inherent in the notions of informed and proxy consent; the nature of risks that can lawfully be undertaken by research subjects and an examination of the development and effectiveness of research ethics committees.

THERAPEUTIC AND NON-THERAPEUTIC RESEARCH PROCEDURES AND INNOVATIVE THERAPY

Research is often classified broadly as being either therapeutic or non-therapeutic, different ethical and legal considerations being said to turn on that distinction. "Therapeutic research" is research consisting in an activity which has also a therapeutic intention, as well as a research intention, towards the subjects of the research, and "non-therapeutic research" is research activity which does not have that specific therapeutic intention.[8]

It is a distinction which many dislike because it can give rise to harmful misconceptions. Thus, the Canadian Medical Research Council felt that since the dichotomy implies that therapeutic research will have some direct benefit on the patient, "the need for full and careful consent, considered to be so important in non-therapeutic research, is often glossed over because therapeutic research is confounded with treatment or care."[9] A recent illustration of this in England concerned a Medical Research Council prostate cancer trial where the content of the information given to patients was determined by "the surgeons' usual practice". It was alleged that "old men up and down the country are being castrated without their informed consent, for the benefit of a trial, sponsored by the Medical Research Council, that is of little, and possibly no, scientific value."[10] Another example is that of aggressive treatment in neonatal care for infants of birth weight less than 750 grams which,

[6] K.M. Jensen et. al., "Uroflowmetry in Neurologically Normal Children with Voiding Disorders" (1985) 19 *Scandanavian Journal of Urology and Nephrology* 81; Institute of Medical Ethics, *Bulletin No. 6*, September (London, IME Publications Ltd, 1985) pp. 2–3. (hereafter IME)

[7] Nicholson, op. cit. p. 19.

[8] Id. 33.

[9] Medical Research Council (Canada), *Ethical Considerations in Research Involving Human Subjects* (Ottowa, M.R.C., 1978).

[10] IME, *Bull. No. 12*, March, 1986, p. 1; IME, *Bull. No. 13*, April, 1986, p. 10.

it is said, can only be justified as medical research and should be presented to parents in those terms.[11]

The therapeutic, non-therapeutic distinction has also been criticised as being too imprecise. A Louisiana court struck down, as "unconstitutionally vague", a statutory provision that "no person shall experiment on an unborn child or a child born as a result of an abortion, whether the unborn child or child is alive or dead, unless the experimentation is therapeutic to the unborn child or child." The court pointed out that "every medical test that is now 'standard' began as an 'experiment' that became standard through a gradual process of observing the results, confirming the benefits, and often modifying the technique. . . . We have at one end things that are obviously standard tests and [at] the other end things that are complete experimentation. But in the center there is a very broad area where diagnostic procedures. . . overlap with experimentation procedures. . . . Even medical *treatment* can be reasonably described as both a test and an experiment. . . . The whole distinction between experimentation and testing, or between research and practice, is therefore almost meaningless in the medical context."[12] Notwithstanding the force of these criticisms, it is convenient to use this terminology for general analytical purposes.

Another kind of experimental activity, which has already been referred to, must be mentioned specifically, that of "innovative therapy". This describes the performance of a new or non-standard intervention as all or part of a therapeutic activity and not as part of a formal research project. Much innovative, or unorthodox, therapy is surgical in nature, since surgeons often try out modifications to existing surgical procedures and occasionally try out new operations. It can also be highly controversial for many of these modifications or new operations are not undertaken as part of a formal research project and they have not in general been subject to prior peer review or review by a research ethics committee.[13] Even where approval has been given by research ethics committees, innovative surgical procedures can be controversial. A notorious example of this was the Baby Fae case, where a baboon heart was transplanted into a 14 day old infant born with hypoplastic left heart syndrome, a condition that is normally fatal within the first weeks of life. She died 20 days later. The project had been approved by the hospital research ethics committee and parental consent had been obtained. One of the difficulties of this case turned on the classification of the operation: if it was designed as a therapeutic measure, then a case for permitting the operation can be made; if it was not therapeutic, then an operation of this magnitude could in no circumstances be justified. The surgeon clearly believed in the possibility of therapeutic benefit; but if it was an ill-founded belief and

[11] IME, *Bull. No. 18*, September, 1986, p. 4.
[12] *Margaret S.* v. *Edwards*, 794 F.2d 994,999 (1986).
[13] Nicholson, op. cit. pp.36–7. See also E.A. Shinebourne, "Ethics of Innovative Cardiac Surgery" (1984) 52 *British Heart Journal* 597.

it could not realistically be said that there was any therapeutic hope, is it appropriate to allow the category of the operation to be changed?[14]

Similar issues have arisen in England: in 1985 Hollie Roffey became the world's youngest heart transplant patient but survived for only 38 days on an artificial ventilator. There, too, doubts were expressed as to the true nature of the operation and whether such hopeless experiments could ever be justified: "Has adequate experience been gained of heart transplants on children, and of the long-term effects of anti-rejection drugs, to justify their use in neonates? Or may surgeons try anything on infants who are almost certain to die of their heart defect?"[15]

THE LEGALITY OF RESEARCH PROCEDURES

There is little in the way of case or statute law relating to clinical research procedures; and so it is necessary to look at general principles and such limited authorities as there are in various jurisdictions.

1. Research upon Competent Subjects

The legality of clinical research generally is closely related to that of medical treatment. Where there is no element of clinical research involved, the general law is clear: therapeutic procedures performed upon legally competent patients are lawful provided that the patient has consented to such treatment. Of course, the nature of that consent, and how much information the patient should be given about the material risks involved, is a complex matter, and one which has exercised the courts around the common law world. In England, the recent House of Lords decision in *Sidaway* v. *Bethlem Royal Hospital Governors*,[16] appears to have established a test loosely based upon what a reasonable doctor would tell that patient of the risks in the circumstances; full rein is not given to the concept of patient autonomy, and there is considerable scope for a patient's information to be limited, and, indeed, for the doctor in some cases deliberately to withhold information by using his "therapeutic privilege".

Not all intrusive procedures are legitimised by consent. Some acts are inherently unlawful and consenting to them will not change that quality. For example, in England, statute prohibits the tattooing of persons under 18, even though they may have consented[17] and also female circumcision[18] and the common law, as a matter of public policy, will not allow a person to consent to being maimed unless there is some sound justification, such as medical treatment.[19]

[14] R.A. McCormick, "Was There Any Real Hope for Baby Fae?"(Feb. 1985) 15 *Hastings Center Report* 12.
[15] IME, *Bull. No. 15*, June, 1986. p. 14.
[16] [1985] 1 All E.R. 643.
[17] *Tattooing of Minors Act* 1969 (Eng.).
[18] *Prohibition of Female Circumcision Act* 1985 (U.K.).
[19] *Attorney-General's Reference (No. 6 of 1980)* [1981] All E.R. 1057.

Clinical research, within reason and subject to a reasonable risk/benefit ratio, is clearly not against public policy; but, almost certainly, the rights of the research subject will be emphasised as vigorously as, if not more vigorously than, in the case of medical treatment per se. Whilst innovative therapy is basically lawful[20] a doctor may have to justify his decision to depart from the procedures which are usually adopted by members of the medical profession in a given situation.[21] A doctor may not always have to explain to a patient why it is that he prefers one of two or more techniques when different medical personnel employ different methods of dealing with a particular condition; but where he employs a new, experimental therapy in preference to the standard one commonly in use, a legal obligation to inform the patient of this may well arise in order that the patient has the opportunity to decide whether he wishes to consent to this newer therapy: reasonable standards of informed consent to an experimental procedure require disclosure to the patient that the procedure is experimental.[22]

Therapeutic privilege, the right of a doctor to withhold disclosure of some material facts, has no application to cases of non-therapeutic reasearch. This was established in the well-known case of *Halushka* v. *University of Saskatchewan*[23] where a university student volunteered to participate in a research project involving a catheter being inserted in the vein of his arm and being advanced towards his heart and an experimental anaesthetic drug being administered to him. The experiment went wrong and, in spite of the fact that the student had been given some information and had signed a consent form relating to "Heart and Blood Circulation: Response under General Anaesthesia", the court held that his consent was not fully informed and so was ineffective. The "duty imposed upon those engaged in medical research . . . to those who offer themselves as subjects for experimentation . . . is at least as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient. There can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practice. The researcher does not have to balance the probable effect of lack of treatment against the risk involved in the treatment itself. The example of risks being properly hidden from a patient when it is important that he should not worry can have no application in the field of research. The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent."[24]

Indeed, the law may be more demanding, in that a patient is entitled to information about all the facts which may be material to him, even though

[20] For example, doctors and other professionals are not answerable in negligence *only* because they departed from received opinion: *Congenital Disabilities (Civil Liability) Act* 1976 (Eng.) s.1(5).

[21] *Clark* v. *MacLennan* [1983] 1 All E.R. 416.

[22] *Ahern* v. *Veterans Admin.*, 537 F.2d 1098 (1976); *Estrada* v. *Jaques*, 321 S.E.2d 240 (1984).

[23] (1966) 53 D.L.R. (2d) 436.

[24] Ibid. 443-4 per Hall J.A.

they may not be of significance in scientific terms. Thus, in *Hyman* v. *Jewish Chronic Disease Hospital*[25] a group of elderly hospitalised patients "consented" to participation in a research project which involved being injected with a "harmless substance". As the researchers apparently believed that the drug was harmless they thought it counter-productive to mention to the patients that they were cancer cells. This fact, though objectively immaterial from a scientific point of view, would, no doubt, have been highly relevant in influencing patients' decisions whether or not to consent; it was held that the consent was not "informed" as it had been obtained fraudulently. Nothing in the *Sidaway*[26] case is likely to affect the reasoning in these two decisions.

2. Research upon Incompetent Subjects

Consent to medical research must be voluntary consent by a subject with legal capacity to give it. In many cases, however, the research subject may not have that legal capacity: the main example, of course, being children. In other situations the consent given may not be a truly voluntary one because, for example, it may have been obtained by deceit or duress or the research subjects come from particularly vulnerable groups, such as the mentally ill, prisoners, students, hospitalised patients, the elderly etc.

(a) Children: When Do They Have Capacity to Consent?

Many jurisdictions now provide that children have capacity to consent to medical treatment before the age of general legal majority. Typical is the position in England, where legislation provides that:

> "the consent of a minor who has attained the age of sixteen years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his person, shall be as effective as it would be if he were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian."[27]

Two questions are created by such a provision. First, does the capacity to give consent to medical *treatment*, conferred upon a person at 16, extend to consent to medical *research*? The section defines "surgical, medical or dental treatment" as "including any procedure undertaken for the purposes of diagnosis, and . . . applies to any procedure (including, in particular, the administration of an anaesthetic) which is ancillary to any treatment as it applies to that treatment." Nothing is said about experimental procedures, and it is strongly arguable that clinical research, at least for non-therapeutic purposes, is not treatment. Secondly, whatever this provision covers, there is an immediate qualification to the effect that nothing shall be construed "as making ineffective any consent which would have been effective if this

[25] 251 N.Y.S.2d 818 (1964).
[26] Note 16 above.
[27] *Family Law Reform Act* 1969 (U.K.) s.8(1).

section had not been enacted."[28] Thus, the legislation throws us back to the common law position relating to consent to medical treatment.

Clearly, a person who has attained the statutory age of majority, now 18, may consent. Below that age the position was, until recently, obscure. There was some authority, for example in the USA and Canada, that children below the relevant statutory age of majority could, in situations of emergency or "demonstrated emancipation", consent to medical procedures; but beyond that there was no guidance. The question of children's capacity to consent has become a matter of considerable controversy in recent years, however, in connection with the provision of contraceptive advice or assistance, without parental knowledge, to teenage girls. In *Gillick* v. *West Norfolk and Wisbech Area Health Authority*[29] the House of Lords held that the fact that a child was under 16 did not automatically mean that he or she was, in law, unable to give consent to medical treatment. Whether a child was so capable would depend upon the child's maturity and understanding and the nature of the consent required.

But the dicta in that case indicate clearly the considerations that have to be taken into account. For example, Lord Fraser said:

> "It [is] . . . verging on the absurd to suggest that a girl or a boy aged 15 could not effectively consent, for example, to have a medical examination of some trivial injury to his body or even to have a broken arm set . . . Provided the patient, whether a boy or a girl, is capable of understanding what is proposed, and of expressing his or her own wishes, I see no good reason for holding that he or she lacks the capacity to express them validly and effectively and to authorise the medical man to make the examination or give the treatment which he advises. . . . [Nor do I doubt] that any important medical treatment of a child under 16 would normally only be carried out with the parents' approval."[30]

And Lord Templeman stated that the

> "effect of the consent of the infant depends on the nature of the treatment and the age and understanding of the infant. For example, a doctor with the consent of an intelligent boy or girl of 15 could . . . safely remove tonsils or a troublesome appendix."[31]

Paradoxically, Lord Fraser then reverted to the important, although in this kind of situation presumably only ethical, requirement of parental consent: "Nobody doubts . . . that in the overwhelming majority of cases the best judges of a child's welfare are his or her parents."[32] What these dicta emphasise is that age and the seriousness of the procedures are directly related: a child may have legal capacity to consent to a trivial medical procedure at an earlier age than to a more serious procedure. But the judges cannot have it both ways: if the child does have *legal* capacity, then the need to consult

[28] *Family Law Reform Act* 1969 (U.K.) s.8(3).
[29] [1985] 3 All E.R. 402.
[30] Id. 409, 412.
[31] Id. 432.
[32] Id. 412.

the parents is an ethical responsibility alone; if the child does not have *legal* capacity, the need to ascertain the child's views is an important, but extra-legal, matter.

How does this affect the law relating to consent to clinical research? It is clear that a person of 18 or over, who has reached the age of full legal capacity and is not otherwise lacking legal competence, has the capacity to consent to legal research. It is possible that a child between 16 and 18 also has that legal competence in England, if the words "surgical, medical or dental treatment" in section 8 of the *Family Law Reform Act* 1969 are widely construed. But, in any event, at common law any person under the age of 18 has the legal capacity to consent to research procedures if he has sufficient maturity and understanding. Thus, the age and maturity of the child, and the nature of the research procedures, are important considerations in balancing up that equation: the younger a person is, or the more intrusive the nature of the research, the more difficult it would be to persuade a court that the child had the legal capacity to consent. The law will take due account of relevant psychological expertise concerning the intellectual and emotional development of children in general and the onus on the doctor to demonstrate competence would be heavy. Additionally, in circumstances where a court would be prepared to find that a child had the maturity and understanding to consent to medical treatment, it might still refuse to hold that it was insufficient to submit to serious, intrusive research procedures. In practice, of course, it would be unwise to rely only upon the consent of a person under 16 where the research procedure involved any risks to that person.

(b) Children: Proxy Consent

Whether a child has legal capacity to consent to medical research is a matter which affects, at most, a narrow range of children at, or reasonably near, the age of 16. In most cases, of course, children cannot consent. The question therefore arises whether parents or guardians have the power to give proxy consent and, if so, in what circumstances.

The responsibilities of parents ensure that they have the power, and duty, to consent to medical treatment for their children. Presumably this would also cover appropriate therapeutic research and, indeed, innovative therapy. The therapeutic researcher must not be negligent either in the design of the research project or in obtaining proper consent. Thus, in *Burton* v. *Brooklyn Doctors Hospital*,[33] where a premature, but otherwise healthy, infant was permanently blinded as a result of being placed in an experimental treatment pool and given an increased supply of oxygen without either his parents' knowledge or the knowledge of his personal doctor, it was held that there was negligence both in carrying out that particular research activity itself, since its dangers were known to the profession, and, in any event, in not seeking parental consent. It is not clear whether this highly dubious study of retrolental fibroplasia[34] concerned therapeutic or non-therapeutic

[33] 452 N.Y.S.2d 875 (1982).
[34] Nicholson, op. cit. pp. 54–6.

research. If it was the latter, then the scope of the consent which the parents could have given is even more problematical.

There is a widespread agreement that it is ethical, in some circumstances, to carry out non-therapeutic research with children.[35] The fourth International Summit Conference on Bioethics, held in Canada in April 1987, summarised the generally accepted controlling conditions: "The specific project must be approved by a research ethics committee; all needed knowledge must have been obtained through research with adults or animals; there must be no valid alternative to the use of children in the research; a valid proxy consent (by family, guardians, ombudsman, those with power of attorney or others) must have been obtained for each research subject; and to the extent possible, the child should have given assent."[35a] Is this ethical statement, however, reflected in the law?

(c) The "Best Interests" of the Child Approach

For a long time, in England, the advice given to the medical profession was that non-therapeutic research upon young children was unlawful. The Medical Research Council stated that ". . . in the strict view of the law parents and guardians of minors cannot give consent on their behalf to any procedures which are of no particular benefit to them and which may carry some risk of harm."[36] The authority for all this rested on general legal principle, rather than on any specific rule or ruling. Since the general philosophy of the law is that parents and guardians are under a duty to look after a child's interests, it seems to follow that non-therapeutic procedures cannot be justified.

Thus, in the well known case of *Wellesley* v. *Duke of Beaufort*,[37] Lord Eldon, when exercising the Crown's power as *parens patriae*, stated that: "it has always been the principle of this Court not to risk the incurring of damage to children . . . which it cannot repair, but rather to prevent the damage being done."[38] The American Supreme Court, admittedly in a different context, expressed the view that:

> "parents may be free to become martyrs themselves. But it does not follow [that] they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves."[39]

Recent developments in the law relating to sterilisation emphasise the courts' concern to safeguard the "best interests" of incompetent subjects, although

[35] For a deontological argument in favour see R.B. Redmon, "How Children can be Respected as 'Ends' Yet Still be Used as Subjects in Non-Therapeutic Research" (1986) 12 *Journal of Medical Ethics* 77.

[35a] At the time of going to press, the papers had not been published.

[36] Medical Research Council, "Responsibilities in investigations on human subjects" in *Report of the Medical Research Council for the year* 1962–63 (London, HSMO, 1964); G. Godber, "Constraints Upon the Application of Medical Advances" (1974) 67 *Proceedings of Royal Soc. of Med.* 1273, 1311.

[37] (1827) 2 Russ. 1; 38 E.R. 236.

[38] (1827) 2 Russ. 1, 18; 38 E.R. 236, 242.

[39] *Prince* v. *Massachusetts*, 328 U.S. 158, 170; 64 S.Ct. 438, 444 (1944).

the extent to which courts should go in giving effect to those interests has varied in different jurisdictions. Thus, the Supreme Court of Canada refused to sanction a "non-therapeutic" sterilisation of a mentally retarded girl even though it was said to be in her best interests, because it felt that the legislature was better equipped to decide such an important policy matter[40] whereas the House of Lords, scorning the value of the therapeutic/non-therapeutic distinction in this context, took a more robust view of its role and authorised the sterilisation of a 17 year old girl "in her best interests".[41] It would not have acted on a lower criterion than the best interests of the child; and other dicta also emphasise the parental duty to apply this standard.[42]

Thus, there is at least an arguable case in favour of the view that proxy consent cannot be given for non-therapeutic research. But a total ban would be Draconian and certainly out of line with national and international ethical codes. Accordingly, it becomes necessary to look for an alternative view of the law.

3. Alternative Views

(a) Distorting the Concepts of "Therapy"

Some of the views advanced have been unprepossessing. One extreme approach turned on the therapeutic/non-therapeutic distinction. If the concept of "therapeutic" could be widened, then the scope for proxy consent would be increased. For example, the World Health Organisation defines "health" as a state of complete physical, mental and *social* well-being and not merely the absence of disease or infirmity. Accordingly, it could be argued that carefully considered proxy consents for clinical research are exercises in social responsibility which could benefit the future well-being of the volunteered subject since one can reasonably expect a child in later life to identify with the objects of the research. This smacks very much of the "ends justifying the means";[43] and is not attractive as a legal argument. Yet similar semantic arguments have been upheld.

For example, the early kidney transplantations could only be effected between very close relatives and American courts were asked to consider the legality of such transplantations from infant donors to twin donees, in cases where the ages of the sets of twins ranged from 14 to 19. Evidence was advanced that each donor twin and the parents had been fully informed of the nature of the operation and had given voluntary informed consents, and psychiatrists testified that if the operations were not performed and the sick twins were to die, the healthy potential donor twins could suffer "grave emotional impact" for the remainder of their lives. The operations were accord-

[40] *Re Eve* (1987) 31 D.L.R. (4th) 1.
[41] *Re B (a minor)* [1987] 2 All E.R. 206.
[42] *Gillick* v. *West Norfolk and Wisbech Area Health Authority* [1985] 3 All E.R. 432, per Lord Templeman; though dissenting on the main issue in the case.
[43] Although this deontological reasoning is designed to achieve the precise opposite. See Redmon, loc. cit.

ingly adjudged "therapeutic": they were necessary for the continued good health and future well-being of, and conferred benefits upon, the donors as well as upon the donees.[44]

Understandably, there are many who view such artificial attempts to distort descriptive terminology with distaste. For example, one Canadian court which was looking for a "therapeutic" reason for ordering a hysterectomy to be performed on a seriously retarded child, found that reason in the child's alleged phobic aversion to blood which, it was feared, would seriously affect her when her menstrual period began. Accordingly, sterilisation was authorised. The Supreme Court of Canada stated that whilst sterilisation may, on occasion, be necessary as an adjunct to treatment of a serious malady, there was no room for subterfuge and that decision was, at best, dangerously close to the limits of the permissible.[45]

(b) The Concept of "Substituted Judgment"

Another concept which is creeping into American case-law in contrast to the traditional "best interests" approach to proxy consent is that of "substituted judgment". The proxy, or court, does not attempt to decide what is in the "best interests" of the patient, but rather what decision would be made by the individual if he were competent. The court "dons the mental mantle of the incompetent and substitutes itself as nearly as possible for the individual in the decision-making process."[46] It is one of those strange doctrines which was used in England in the early nineteenth century in connection with the administration of the estates of incompetent persons,[47] forgotten, and then rediscovered recently by American courts. It has been raised in cases involving incompetent persons to help establish whether, for example, to consent to the withdrawal of life support systems or to certain unusual or controversial types of medical treatment, such as shock therapy or psychosurgery.[48]

It is a controversial concept, not the least because of the inherent difficulties of attempting to assess what an incompetent patient would have decided were he competent, whether that assessment should be subjective or objective and, if objective, how it can really differ from a "best interests" approach. No court has yet been called upon to authorise its use in connection with clinical research, although it was raised in *Kaimowitz* v. *Michigan Dept. of Mental Health*[49] where it was held, understandably, that no proxy consent could be given for experimental psychosurgery. It is unlikely to be of much help in the current debate.

[44] Such transplantations from infant donors would not be considered ethical today. See also *Strunk* v. *Strunk*, 445 S.W.2d 145 (Ky. 1969).

[45] See *Re K and Public Trustee* (1985) 19 D.L.R. (4th) 255 (Court of Appeal of British Columbia) and *Re Eve* (1987) 31 D.L.R. (4th) 1, 22, 34 (Supreme Court of Canada).

[46] *Superintendent of Belchertown State School* v. *Saikewicz*, 370 N.E.2d 417 (1977).

[47] *Ex parte Whitbread* (1816) 2 MER. 99; 35 E.R. 878.

[48] H.W. Classen, "The Doctrine of Substituted Judgment in its Medicolegal Context" (1985) 31 *Med. Trial Technique Q.* 451.

[49] 42 U.S.L.W. 2063 (1973).

(c) The "Not Against the Interests of the Child" Approach

The most likely approach is to reconsider more carefully the emphasis which the legislature and the courts understandably place upon the need for proxies only to act in the best interest of the child or other incompetent person.

Most of these statements have been made in contexts quite different to those of non-therapeutic clinical research. Although much welfare legislation does stress that the welfare of a child is "paramount", other provisions refer to the welfare of a child being the *first* consideration.[50] "First consideration", of course, suggests that there are other considerations which can be balanced by a parent against the best interests of the child, and indeed override it. And where a court has to carry out these tasks it usually has to act as a "judicial reasonable parent".

The balancing of various interests can best be seen in ward of court cases. For example, in *Re X (a Minor)*[51] the defendants proposed to publish a book describing the depraved behaviour of the deceased father of a 14 year old girl. It was accepted that if she were to read the book or hear about it from others, it would be *psychologically* grossly damaging to her. The Court of Appeal, in exercising its wardship jurisdiction, was not prepared to allow the interests of the child to prevail over the wider interest of freedom of publication. It is not correct to say "that in every case where a minor's interests are involved, those interests are always paramount and must prevail ... The court is required to do a difficult balancing act."[52] Here the court found the scale tipped heavily in favour of publication and against the minor.

Perhaps the most relevant analogy, however, concerns the power to take blood tests from children in paternity actions. Here, the conflict is between the interests of the child and that of doing justice. In 1970 the House of Lords considered a case[53] where an official guardian had objected to a blood test on a child in paternity proceedings on the ground that this intrusive procedure was not for the child's benefit. This argument was not accepted by the court, and statements abound in the judgments that the benefit of the child is not always an adequate criterion. Lord Reid analysed the situation clearly: first, he proclaimed the principle of physical integrity is: "There is no doubt that a person of full age and capacity cannot be ordered to undergo a blood test against his will.... The real reason is that English law goes to great lengths to protect a person of full age and capacity from interference with his personal liberty."[54] Secondly, he struck a blow against one modern theory of children's rights by denying them an absolute right to physical integrity as against their parents: "But the position is very different with regard to young children. It is a legal wrong to use constraint on an adult beyond what is authorised by statute or ancient common law powers connected with crime and the like. But it is not and could not be a legal wrong for a parent

[50] E.g. *Children Act* 1975 (U.K.) ss.3, 59.
[51] [1975] 1 All E.R. 697.
[52] Id. 706 per Roskill L.J.
[53] *S* v. *S* [1970] 3 All E.R. 107.
[54] Id. 111.

or person authorised by him to use constraint to his young child provided it is not cruel or excessive."[55] Thirdly, such a power goes beyond simple domestic situations such as chastisement: "It seems to me to be impossible to deny that a parent can lawfully require that his young child should submit to a blood test. And if a parent can require that, why not the court?"[56] And fourthly, a move away from the "best interests" approach:

> "Surely a reasonable parent would have some regard to the general public interest and would not refuse a blood test unless he thought that would clearly be against the interests of the child?[57] . . . I would hold that the court ought to permit a blood test of a young child to be taken unless satisfied that this would be against the child's interest.[58]"

Thus, there seems to be strong authority for saying that in some cases the "best interests of the child" approach can give way to a rule that a parent should not do anything "clearly against the interests" of the child. This certainly makes sense. In real life, reasonable parents cannot, and should not, always opt for that activity which presents the least physical risk to the child. Children must be allowed to run risks: climbing trees, riding bicycles, playing "rough" sports, where the statistical risks may far outweigh anything involved in properly conducted clinical research. Medical procedures involving slight risks, for example, vaccinations, occur daily where the benefit may be primarily for other children and the community. Thus, a reasonable and socially responsible parent might think that there was merit in taking the social interest into account and contributing to medical research, provided always that the risk to the child was "miminal".

This view of the law accords with the ethical codes and is now being acted upon by the medical profession.[59] Unfortunately, however, the law is not clear beyond all reasonable doubt. A blind development of the "best interests" approach could box the law into an inflexible position. This appears to have happened in South Australia. The *Consent to Medical and Dental Procedures Act* 1985, which was passed presumably to clarify the law relating to teenage girls receiving contraceptive help from doctors, follows the *Gillick* line in providing that a minor under 16 has full capacity to consent to medical procedures if two practitioners are of the opinion first, that the minor is capable of understanding the nature and consequences of the procedure; and secondly, that "the procedure is in the best interests of the health *and* well-being of the minor."[60] It also provides for parental proxy consent, which presumably must be exercised subject to similar restraints. This would seem to authorise a "medical procedure", which is defined as "any procedure carried

[55] Ibid.
[56] Ibid.
[57] Id. 112.
[58] Id. 113. There are now statutory provisions relating to blood testing in these situations e.g. *Family Law Reform Act* 1969 (U.K.) s.21; *Children (Equality of Status) Act* 1976 (N.S.W.) s.19; *Status of Children Act* 1974 (Tas.) s.10; *Community Welfare Act* 1972 (S.A.) s.112.
[59] E.g. "Research on Healthy Volunteers" *Journal of Royal College of Physicians of London*, A Report of the Royal College of Physicians (1986) 20 (Oct.) 243.
[60] Paragraph 6(2)(b). (emphasis added)

out by, or pursuant to directions given by, a medical practitioner".[60a] Only if it complies with the best interests rule; in which case it would be difficult to argue that the scope for non-therapeutic research can be wider. Does that mean that, inadvertently, all clinical research on children under 16 has been ruled out?

There seems to be a strong case for general legislative consideration, and clarification, of the power to give proxy consent for the purposes of research on children.

4. Other Special Groups

Considerable thought has been given to the ethical issue relating to research upon children. Similar concerns are also expressed in connection with adults who are mentally ill or handicapped and with other "vulnerable" populations, although the extent to which they can be identified and "used" is ambivalent.

There seems to be increasing formal protection of the rights of psychiatric patients with regard to medical treatment. Whilst in some circumstances, which are not always easy to be confident about in practice, they have the capacity to consent to their own treatment, in many cases they do not. The English *Mental Health Act* 1983, for example, lays down complex procedures relating to consent and the need to obtain second opinions from non-medical personnel for certain procedures such as psychosurgery or electroconvulsive therapy, as well as establishing a Mental Health Act Commission to further safeguard the interests of patients (although it has been argued by some that such safeguards could operate against the interests of psychiatric patients if applied too rigidly).[61] In these circumstances, the climate relating to research on psychiatric patients is likely to be very restrictive, and it could well be that the courts would be less prepared to see non-therapeutic research volunteered for by proxies than would be the case for children. The Mental Health Act Commission is currently drafting a Code of Practice relating to consent to treatment but such a Code cannot go further than the law is prepared to allow.

Prisoners will usually have the capacity to understand and to consent to medical treatment and also to research procedures. The Royal College of Physicians does not consider it inherently unethical to carry out research on prisoners, stating, for example, that "there might be a reason to believe that a certain hormonal, genetic, psychological or other condition was associated with violence or other pattern of behaviour likely to lead to criminal action". The problem, however, is that in an "inherently coercive situation" there will often be doubt as to whether the consent was influenced by factors which undermine its apparent voluntary nature. The difficulties are further compounded when the subject is a mentally ill prisoner. In *Kaimowitz* v. *Michigan Dept. of Mental Health* it was said that:

> "it is obvious that the most important thing to a large number of involuntarily detained mental patients incarcerated for an unknown length of time,

[60a] Section 4.

[61] A.R. Dyer and S. Bloch, "Informed Consent and the Psychiatric Patient" (1987) 13 *Journal of Medical Ethics* 12.

> is freedom. . . . It is impossible for an involuntarily detained mental patient to be free of ulterior forms of restraint or coercion when his very release from the institution may depend upon his co-operating with the institutional authorities and giving consent to experimental surgery. . . . They are not able to voluntarily give informed consent because of the inherent inequality of their position."[62]

It would seem from this that it would be very difficult to establish that a psychiatrically disturbed patient had the capacity to consent to research procedures, and that a proxy consent would not be legitimate for non-therapeutic research. Prisoners with full mental capacity, however, could consent in law to therapeutic and non-therapeutic research, but it might well be necessary to rebut a presumption that it was not truly voluntary.

Other "vulnerable" populations, such as students, hospitalised patients or the elderly,[63] may not be physically constrained, but nevertheless could be subjected to pressures or temptations which cloud the "voluntary" aspect of consent. It does not follow that financial inducements should destroy the voluntary nature of all responses, yet where students and out of work youths are offered significant sums of money to test new drugs, as happened in London recently, the nature of consents and inducements should be examined very carefully. In defending the use of such volunteers it was argued that there was nothing unethical in paying volunteers to test new drugs so long as they were fully informed of any possible risks; and a further justification was put forward that there was a no-fault compensation scheme in case anything went wrong. This does seem to miss the point: volunteers certainly can give informed consent to properly conducted research procedures, but even informed consent can be involuntary.

THE FIDUCIARY OR TRUST RELATIONSHIP

The present situation is unsatisfactory in that, even when there are no ethical obstacles to seeking the consent of such persons as research subjects, the law is obscure. But the general principles upon which the law should be based are comparable to those which govern fiduciary relationships. These can arise in two ways: first, where there is a special relationship between the parties, such as lawyer/client or doctor/patient, this is presumed; and, secondly, it can be shown to exist in other cases on the particular facts of the case. When there is a presumed fiduciary relationship, equity operates to protect the weaker party. Accordingly in cases of conflicts of interest between the parties, which would occur where the dominant party stood to gain at the expense of the weaker, the law presumes that the benefit was obtained as the result of undue influence and the transaction can be set aside. This applies whether the weaker party is a now wealthy pop-star attempting to challenge a contract with his manager made when he was eager and

[62] 42 U.S.L.W. 2063, 2064 (1973); see also *Freeman* v. *Home Office* [1984] 1 All E.R. 1036.
[63] Schwartz, "Informed Consent to Patricipation in Medical Research Employing Elderly Human Subjects" (1985) 1 *Jo. of Contemp. Health, Law and Policy* 115.

unknown[64] or a family attempting to set aside a patient's will made in favour of her solicitor or doctor. The transaction may not be invalid, but it would have to be shown by that party that there was no undue influence exercised, including at times, the obligation to advise the other party to obtain independent advice. Similar principles could no doubt be applied by courts to "vulnerable", though ostensibly competent, populations who have consented to research procedures. That is not to say that it should not be possible to involve such groups in research projects, but that the principles of fiduciary relationships and undue influence could operate to provide the appropriate additional safeguards for them and ensure that the researchers complied with both their legal and ethical research committee's requirements.

1. The Risk/Benefit Factor

Every ethical assessment of a research project should include a risk/benefit calculation. Ethical codes generally provide that proxy consent may be given for non-therapeutic research on children, for example, for procedures involving "minimal risk". This has been described as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical or psychological examination of healthy children. The United States National Commission, somewhat reluctantly were prepared to allow for rare cases of proxy consent where the risks involved a minor increase over minimal risk (that is, risks of harm or discomfort greater in probability or magnitude than those encountered in the normal life of children but that pose no significant threat to that child's well-being). The Report of the Institute of Medical Ethics was not prepared to go so far. In no case would non-therapeutic research be acceptable where there is a greater than minor increase over minimal. It is likely that courts would be prepared to allow for "minimal risk" situations only.

It is easy to classify, but much more difficult to assess, risks and benefits.[65] Research investigators vary in their perceptions of which procedures come within various categories of risk and it has been recommended that there should be an attempt at arithmetical categorisation. Where the risk goes beyond the relevant category then the proxy consent should have no legal effect. An illustration of a recent research project which had a highly dubious risk/benefit ratio (even as therapeutic research) concerned profoundly deaf children who were surgically fitted with experimental cochlear implants. These consisted of electrodes, inserted into the cochlear to stimulate the auditory nerve, which were connected to a radio receiver under the scalp. The benefit to be gained was no more than a sensation of noise, whilst the risks included at least those concerned with the anaesthetic, damage to the facial nerve, a long term possibility of infections (including meningitis) from implanting a foreign body, and destruction of any remaining functional cochlear.[66]

[64] *O'Sullivan* v. *Management Agency* [1985] 3 All E.R. 351.
[65] For a further classification, see J. Pearn, "A Classification of Clinical Paediatric Research with Analysis of Related Ethical Themes" (1987) 13 *Journal of Medical Ethics* 26.
[66] IME, *Bull. No. 7*, October, 1985, p. 6.

2. Research Ethics Committees

The value of research ethics committees in safeguarding the ethical and legal standards of research projects cannot be too highly emphasised. Their development over the last decade or so has been far more important than the largely theoretical concern of lawyers as to whether research subjects, who rarely if ever go to court over research projects, have given appropriate consent.

In the United States, in particular, federal research funding has been tied to the need to comply strictly to the regulations laid down by ethical research committees. The need to obtain informed consent has had a greater impact in research than in clinical medicine.

> "The crucial difference is this: in clinical medicine physicians have been *exhorted* to solicit consent, by appeal either to medical ethics or legal self-interest; in research, scientists have in many cases been *compelled by regulation* to obtain informed consent."[67]

Whether or not that is an accurate assessment of the position in the United States, it is not necessarily a true reflection of the situation in other countries. It is easy enough to establish such committees, but not so easy to determine whether, whatever good they achieve, they are doing their job well. For example, the case of the prostate cancer trial demonstrates how the backing of the Medical Research Council, albeit to a dubious trial, was sufficient to encourage a local ethics research committee to rubber-stamp the proposal. The structure and functioning of research ethics committees varies considerably in England, and more attention must be given to the number and role of lay persons on such bodies. Whatever their current problems, however, there is no doubt that they are capable not only of ensuring researchers' compliance with the strictly legal requirements, uncertain as they might be in some cases, but they can also superimpose additional ethical requirements which do not yet have the force of law; for example, the increasing recognition of the desirability, in cases of research on children, for the proxy consent of parents to be accompanied by the assent of the children of, say, seven years and over.

THE BALANCE BETWEEN ETHICAL AND LEGAL CONTROL

Whilst there is a need to clarify the present law, a further question is how far the law should be involved in the detailed regulation of matters which at present are predominantly of ethical and professional concern? How best to regulate clinical research, to reassure the public that acceptable ethical bounds will not be broken, is an issue which has parallels in many other areas of activity today.

One of the few examples of a detailed legislative code is that provided by the Californian *Protection of Human Subjects in Medical Experimentation*

[67] R.R. Faden and T.L. Beauchamp, *A History and Theory of Informed Consent* (New York, Oxford University Press, 1986) pp. 222–5.

Act.[68] This contains interesting declarations of principle: that "medical experimentation on human subjects is vital for the benefit of mankind; [but that] such experimentation shall be undertaken with due respect to the preciousness of human life and the right of individuals to determine what is done to their own bodies", followed by a recognition that there is, and will continue to be, a growing need for protection from "unauthorised, needless, hazardous, or negligently performed medical experiments on human beings".[69] There is also an "experimental subject's bill of rights" setting out in legislative form generally accepted ethical principles relating to research and a detailed set of conditions to satisfy the informed consent requirements. Violation of these requirements exposes the offender to civil and criminal penalties.

Attractive as this legislation appears to be, it is necessary to consider whether there are any dangers inherent in a firm and detailed legislative approach. Are legislative prohibitions, backed up by criminal sanctions, an acceptable way of dealing with medical matters?

A WORD, NO MORE, ON HUMAN EMBRYO RESEARCH

This is the kind of difficulty which could be emerging in connection with control over human embryo research and related areas. A recent survey has disclosed that there have been at least 85 committee reports on the new reproductive technologies from more than 25 countries since 1979. Most have come from Australia, led by Victoria, presumably as a result of the pioneering work being done here; followed closely by the U.K. Public opinion, of course, is deeply divided, and the best way forward, scientifically and ethically, is by no means universally settled. Victoria has also led the way with legislation, based upon thoughtful reports of the Waller Committee which, together with the U.K. Warnock Committee Report, have been influential around the world.

The Victorian *Infertility (Medical Procedures) Act* 1984 began well by providing for a Standing Review and Advisory Committee, which, inter alia, is responsible for considering and, if appropriate, approving experimental procedures, in accordance with broadly stated ethical objectives. Thus, there is a legislative framework conferring an ostensibly broad discretion upon the Committee. Researchers who do not submit the research work for approval are liable to criminal penalties. But, the Act also attempted to come down off a precarious fence and legislatively settle some difficult ethical issues by carefully defining, and severely restricting, the type of research which could be carried out on embryos and pre-embryos.[70] Within a very short time scientific advances and a research proposal, acknowledged unanimously by the Committee to be "important and very worthwhile", uncovered ambiguities in the legislation, and even more technical debates as to the meaning

[68] *Cal. Health & Safety Code* (West 1987).
[69] § 24171.
[70] Sub-section 6(3).

of "embryo" and "fertilisation" took place. Even the *Infertility (Medical Procedures) (Amendment) Act* 1987, which attempts to clarify the situation, does not satisfy all the critics, and may not provide a happy solution.

Is this an example, then, of legislation which attempted to do too much, so that now it represents "a major obstacle to significant scientific developments"?[71] Have the lawyers and philosophers let the scientists down?

It must be acknowledged, of course, that embryo research involves quite different issues, or emphases, compared to research generally, or research upon other "subjects" with limited legal capacity. The consent issue, whilst an appropriate one for discussion, is not prominent; instead, it is the acceptability, and limits of, the research itself that is the core question. Also, of course, there is less ethical consensus. Nevertheless, the lessons which can be learned from the Victorian experience is of more general application. First, because legislation tends to be difficult and undesirable to amend quickly, legislative principles are often better than detailed definition and regulations. Secondly, making activities which are still within the area of ethical debate criminal is something that should be done rarely, and with great care; and particularly when such activities are closely related to the work which the doctor or scientist is doing.

CONCLUSIONS

Where, then, does all this lead? First, there does appear to be a need for some legislation – but not too much. Such legislation should do several things: first, it should attempt to provide a legal answer to the doubts which currently exist as to whether any research is permissible on certain classes of non-competent subjects. Secondly, it should indicate clearly when, and in what circumstances, proxy consent can be given. Thirdly, it should ensure that all research projects, therapeutic and non-therapeutic are required to be submitted to appropriately constituted ethics committees. Fourthly, it should provide for a general body to monitor and advise research ethics committees. There may also be some attraction in enacting a code of research subjects' rights, as in the Californian Act. Thereafter, requirements for informed consent, details of the professional and lay composition of research ethics committees, ensuring that they are effective and not simply token rubber-stamping bodies, providing guidelines for innovative therapy and so on should rest with the statutory body.

It is not clear that there is a case for introducing further criminal offences to deter researchers. Professional accountability and the existing civil and criminal law should suffice until a case is made out to the contrary. At the end of the day, the habit of compliance with the established norms for ethical research will be more important than anything else.

[71] For a detailed discussion of the 1984 Act and the 1987 Bill, see C. Corns, "In Vitro Fertilisation: The Problem of Regulation" (1987) 61 L.I.J. 791 and K. Andrews, "Regulating Embryo Experimentation" (1987) 61 L.I.J. 795.