

# CAN FETAL TISSUE TRANSPLANTATION BE DONE LEGALLY?\*

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## INTRODUCTION

Fetal tissue transplantation therapy is emerging as a promising treatment for several debilitating conditions and diseases in humans. In Australia, fetal tissue has so far been used in the treatment of diabetes. This involves the transplantation of insulin producing cells from the fetal pancreas into insulin-dependent diabetes sufferers. Future application of fetal tissue lies in such areas as brain-related disorders (e.g., Parkinson's disease, Huntington's disease, epilepsy, Alzheimer's disease and paraplegia)<sup>1</sup> and blood disorders (e.g., leukaemia, sickle-cell anaemia and severe combined immunodeficiency (SCID)) which affect the production of blood cells or the functioning of the immune system.

With these prospects, however, fetal tissue transplantation also brings complex issues of, largely, a moral and legal nature. The source of fetal tissue—fetuses—reintroduces the notoriously uncertain and confused area of the legal status of early human life which has been at the centre of the abortion and embryo experimentation controversies. Fetal tissue can be obtained from fetuses that have been aborted (induced or spontaneous)

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<sup>1</sup> Parkinson's disease affects the nervous system and is characterised by a lack of control over movement leading to tremors and/or rigidity. Huntington's disease is a rare genetic disease characterised by chronic involuntary movements and mental deterioration. The onset of the disease usually occurs when victims are in their 30s or 40s and death usually follows within 15 years.

Epilepsy has many forms and results from a disturbance in brain function. It is usually manifested as episodic loss of consciousness and control of movement.

Alzheimer's disease, sometimes known as senile dementia, affects the elderly and is characterised by increasing lapses of memory and control over speech and movement.

or from prematurely born infants who die soon afterwards.<sup>2</sup> The most convenient and abundant source is, however, induced abortions. While abortion is legally available on some specified grounds, the position of fetuses and/or fetal tissue that result is not so clear. The situation is complicated further by speculation on the likely impact of successful fetal transplantation therapy on current abortion practices. It has been suggested, for instance, that women may become pregnant in order to abort and donate tissue to themselves, their children, relatives, friends or other individuals suffering from any of the diseases that fetal tissue could be used to reverse.<sup>3</sup> There are also concerns that current abortion techniques may be tailored to suit the needs of the new therapy rather than the safety of the pregnant woman<sup>4</sup> and that aborted fetuses will be kept alive to ensure that their tissue matures enough for subsequent transplantation.

The excitement about using fetal tissue centres around its capacity for continued growth and its lesser ability to induce rejection. Whereas primarily structural organs, such as the heart and kidney, can be successfully replaced by organ donations from living human beings and cadavers, technical difficulties currently prevent the similar transplantation of regulatory organs, such as the pancreas, the bone-marrow and parts of the brain. In the latter case, fetal tissue is considered superior to donated organs because, after transplantation, the cells retain their capacity for further growth and differentiation, and for establishing the necessary connections with the recipient's cells.

The idea of using the human fetus adds a new dimension to an old problem. In the early 1970s, debate raged in the United States on the issue of fetal experimentation. This resulted in Federal regulations and legislation in some States. Unlike the 1970s debate, however, the issue now concerns not just experimentation but the use of human fetuses as tissue donors. While experimentation could be split into various categories some of which, e.g., therapeutic *in utero*, are for the benefit of the fetus, the use to which fetuses are sought to be put in transplants does not benefit the fetus.

This article will examine legal issues that fetal tissue use gives rise to under Australian law, analyse current regulation in Australia and overseas and put forward a proposal for future legal regulation. In detail, in the next section general legal issues surrounding fetal tissue use will be discussed, while the third part will present current regulation. The

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<sup>2</sup> See, e.g., T. Mandel, "The use of the Immature Pancreas as a source of Tissue for Transplantation in Diabetes" (1985) 5(1) *Bioethics News* 1.

<sup>3</sup> See, e.g., M. Walker, "Fetal Tissue Harvesting: Should Courts be the Final Arbiter?" (1987/88) 23 *Gonzaga L.Rev.* 621.

<sup>4</sup> M. Mahowald, J. Silver and R. Ratcheson, "The Ethical Options in Transplanting Fetal Tissue" (1987) (Feb.) *Hastings Center Report* 9 at pp. 10 and 13.

last main section will contain some suggestions on the future regulation of fetal tissue transplantation therapy.

### FETAL TISSUE USE: EMERGING LEGAL ISSUES

In Australia, use of human tissue depends on donations from persons who are either alive or dead. It is a consensual regime governed by human tissue legislation. The legislation also deals with other issues relating to human tissue, for example, trading in tissue, liability of medical practitioners doing transplant procedures and disclosure of information about the source of tissue. Some of these matters are of relevance to fetal tissue use. Who is to consent to such use? What is the position in respect of sale of fetal tissue? If a recipient of fetal tissue was to contract a disease from the tissue, who would be liable? Such questions cannot be answered at present. The human tissue legislation defines tissue as including "an organ, or part, of a human body or a substance extracted from, or from a part of, the human body".<sup>5</sup> This definition, together with some provisions which specifically exclude fetal tissue from their ambit<sup>6</sup> support the view that this legislation does not apply to fetal tissue. In the absence of any law on these questions the practice has been to rely on professional guidelines which will be discussed below.

However, there are other laws which may have some implications for fetal tissue use. Since the major source of fetal tissue is from induced or elective abortions a starting point could be the law on this subject. Section 65 of the *Crimes Act 1958* (Victoria), for instance provides:

65. Whosoever being a woman with child with intent to procure her own miscarriage unlawfully administers to herself any poison or other noxious thing or unlawfully uses any instrument or other means, and whosoever with intent to procure the miscarriage of any woman whether she is or is not with child unlawfully administers to her or causes to be taken by her any poison or other noxious thing, or unlawfully uses any instrument or other means with the like intent, shall be guilty of an indictable offence . . .

On its face, this provision does not permit abortion in Victoria.<sup>7</sup> However, an interpretation of *unlawfully* now provides the legal basis for abortion in the State. This was done in the landmark ruling of Menhennitt, J. in *R. v. Davidson* that:

For the use of an instrument with intent to procure a miscarriage to be lawful the accused must have honestly believed on reasonable

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<sup>5</sup> See, e.g., *Human Tissue Act 1982* (Victoria) s. 3.

<sup>6</sup> See, e.g., *Human Tissue Act 1982* (Victoria) ss. 5 and 42(2).

<sup>7</sup> In Australia only South Australia and the Northern Territory have statutory provisions comparable to the English *Abortion Act 1967*.

grounds that the act done by him was (a) necessary to preserve the woman from a serious danger to her life or her physical or mental health (not being merely the normal dangers of pregnancy and childbirth) which the continuancy of the pregnancy would entail; and (b) in the circumstances not out of proportion to the danger to be averted.<sup>8</sup>

An abortion within the terms of the ruling thus justifies what would otherwise be a very serious offence (or offences). But the ruling suffers from generality. It does not say how a *lawful* abortion is to be carried out and what is to happen to the fetuses that result from abortion procedures. The practice of abortion results, in most cases in dead fetuses. But can this be justified by the ruling? The ruling is simply silent on this point. In such circumstances a doctor or scientist doing fetal tissue transplantation may think that since the abortion was legal, there is no problem using a fetus that may be alive for a while. But this could be a mistake—one that could be very grave. As will be seen below, even using a fetus that is dead from an abortion is not free from a shadow of criminal responsibility. These reservations arise, for instance, from a consideration of s. 10 of the *Crimes Act 1958* (Victoria) which states:

10(1) Any person who, with intent to destroy the life of a child capable of being born alive, by any wilful act unlawfully causes such child to die before it has an existence independent of its mother shall be guilty of the indictable offence of child destruction . . .

When this section is read together with s. 65, a question that arises is whether a lawful abortion (i.e. a procurement of a miscarriage) covers also the killing of a fetus.

Before going into an interpretation of these provisions, mention should, at this stage, be made of the offence of murder which is associated to the offences of abortion and child destruction. Although murder does not have a statutory definition, it has been authoritatively defined to mean the *unlawful killing of any reasonable creature in being*.<sup>9</sup> It is thought by some that the death of a fetus that survives an abortion is within the purview of this serious offence while others view a lawful abortion as a justification for such death. This difference of opinion may affect any work in the area since the legal situation is not clear. Such a problem was encountered in the United Kingdom where a committee appointed to consider the use of fetuses and fetal tissue in research observed:

The purpose behind the criminal law has always been the protection of the fetus at all stages. However, the law was developed and

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<sup>8</sup> [1969] VR 667 at p. 672.

<sup>9</sup> See the recent article by L. Waller, "Any Reasonable Creature in being" (1987) 13 *Mon. L.Rev.* 37.

expounded before the great changes brought about by the passing of the Abortion Act, with the result that the available authoritative statements of the law do not provide clear guidance in the present situation. Development of the law has also been limited by the rarity of cases in which the activities of the medical profession have given rise to prosecution.<sup>10</sup>

The view that homicide laws are applicable when fetal death is intentionally caused is based on an interpretation of who can be the subject of murder. Queensland, Tasmania, Western Australia, New South Wales and the Australian Capital Territory have provisions on this point.<sup>11</sup> The position in other States is the same but governed by common law. This was expressed, for instance, in *R. v. Hatty* where Barry J. in his direction to the jury stated:

Murder can only be committed on a person who is in being, and legally a person is not in being until he or she is fully born in a living state. A baby is fully and completely born when it is completely delivered from the body of its mother and it has a separate and independent existence in the sense that it does not derive its power of living from its mother . . . That occurs when the child is fully extruded from the mother's body and is living by virtue of the functioning of its own organs.<sup>12</sup>

On the facts of the case, the judge advised the jury to acquit because there was no intention. He was also of the opinion that the proper offence was infanticide and not murder.

The identification of subjects of murder in cases involving procurement of a miscarriage has been particularly problematic. Judicial precedent is not only quite antiquated, as was observed in the Peel Report, but unclear as well. For instance, one authority that is frequently cited is *R. v. West* an English case decided almost 150 years ago. In that case the judge directed the jury that:

if a person intending to procure abortion does an act which causes a child to be born so much earlier than the natural time, that it is born in a state much less capable of living, and afterwards dies in consequence of its exposure to the external world, the person who by her misconduct so brings the child into the world, and puts it thereby in a situation in which it cannot live is guilty of murder.<sup>13</sup>

The effect of such a ruling on modern abortion is not so clear. Some

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<sup>10</sup> *The Use of Fetuses and Fetal Material for Research* Report of the Advisory Group (the Peel Report), Dept of HSS, HMS 1972 p. 4.

<sup>11</sup> See, P. Bates, "Legal Criteria for Distinguishing Between Live and Dead Human Foetuses and Newborn Children" (1983) 6 *U.N.S.W.L.J.* 143, 145.

<sup>12</sup> [1953] *V.L.R.* 338, at p. 339.

<sup>13</sup> (1848) 2 *Cox Crim. Cas.* 500.

would interpret it as prohibiting all abortions that result in a live birth of a fetus however premature,<sup>14</sup> while others argue that lawful abortions are not affected. According to Skegg:

if the issue first came before a court in a case involving the abortion of a pre-viable fetus, and the abortion was performed in a way that was in the best interests of the mother's health, judges would be more likely to take the view that on these facts the doctor was not guilty of murder, even if he knew that the child would not die until after it was removed from its mother's body.<sup>15</sup>

The view that *R. v. West* prohibits all abortions that result in a live fetus could also draw support from *R. v. Castles*<sup>16</sup> where the accused was charged with the manslaughter of a "person capable of being killed" under ss. 224, 292 and 294 Queensland *Criminal Code* 1899. It was alleged that the accused attempted to procure an abortion of a woman who was between 20 and 22 weeks pregnant. Later a child was born alive but died within two hours. The issue was whether the accused had killed a 'child'. Section 292 provided that "a child becomes a person capable of being killed when it has completely proceeded in a living state from the body of its mother, whether it has breathed or not, and whether the navel string is severed or not". For the accused it was argued that s. 292 should be construed as referring to a viable child, namely, one capable of an independent existence from its mother. This argument was rejected by the judge who thought that "the section speaks of a child proceeding in a living state from the body of its mother and that a child who lives, albeit doomed to die, for some period after it has proceeded from the body of its mother, is within the section".<sup>17</sup> The ruling in *R. v. West* was referred to with approval. It is important to note that the charge was later withdrawn and the accused never convicted of manslaughter. This was because the defence argued (and the prosecutor agreed) that the evidence did not establish beyond reasonable doubt that the child was *born alive*. The report states that "it was pointed out that there was no evidence that the child had moved or cried out, and that, whilst there was evidence of the child breathing, it appeared that this was merely a respiratory reflex which had not involved any inflation of the lungs".<sup>18</sup> This requirement may still prove hard to satisfy.

A few observations can be made here on the implications of the

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<sup>14</sup> See, e.g., G. Wright, "The Legality of Abortion by Prostaglandin" [1984] *Crim.L.Rev.* 347.

<sup>15</sup> P. D. G. Skegg, *Law, Ethics and Medicine* (1984) p. 26. See, too, P. Bates *supra* n. 11 at p. 150 where he states (tentatively): "If the child is born alive in a pre-viable state following a *legal* attempt to procure a miscarriage, and then dies, a strong argument could be made that no homicide has been committed. However, it should be stressed that no court has yet ruled on this distinction". (Emphasis original.)

<sup>16</sup> [1969] Q.W.N. 36.

<sup>17</sup> *Ibid.*, at p. 78.

<sup>18</sup> *Ibid.*, at pp. 79-80.

discussion for fetal tissue transplantation. Firstly, the abortion technique used to effect a legal abortion may touch on the issue of liability for murder. Currently there are about four techniques in use in Australian hospitals and clinics offering abortion.<sup>19</sup> Three of them kill the fetus in the uterus while one (which is rarely used) may result in a fetus that is still alive. These techniques are also related to the gestational age of the fetus at abortion. Most abortions (96%) using the fetus-killing techniques are performed in the first trimester (under 14 weeks). The rest (4%) are done in the later stages of pregnancy<sup>20</sup> and will involve techniques that may not necessarily kill the fetus. According to some, this situation is likely to change with the prospect of fetal tissue transplantation. Abortions will be delayed and techniques that avoid or minimise damage to a fetus may be used more often. Assuming this to be accurate, two legal problems will be apparent. Abortion is lawful when performed to protect the life or health of the pregnant woman. If a case were to arise to decide whether an abortion was legal or not the presence of factors such as the preservation of a fetus or its tissue may affect its outcome. It may, however, be hard to prove that an abortion at a late stage using a particular abortion technique is unlawful. The law does not at present say when an abortion should take place. The timing and technique to be used are medical decisions which courts have traditionally been reluctant to question. The same may apply to the seemingly clear-cut case, where a woman conceives and aborts to donate fetal tissue. The problem is, however, still there and doctors are keen to show that they use their position respectably. That is why it has been suggested that there should be a 'Chinese wall' between the physicians performing abortions and those involved in fetal transplantation research and that nominating recipients should be prohibited.<sup>21</sup>

The second problem relates to the use of fetuses that survive an abortion. It has been suggested that the most suitable tissue is obtainable from live fetuses.<sup>22</sup> Thereafter the fetuses are discarded. If this is taken to be true, doctors and others involved in handling such fetuses may, according to some commentators, be committing murder. In the words of one commentator, "if an abortion results in a live foetus in the dish, then it may immediately be the victim of murder or manslaughter, and what was done to it before extrusion may give rise to the most serious criminal responsibility for homicide. It is of no consequence that its life

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<sup>19</sup> In the order of frequency, these are: vacuum aspiration (96.5%), intra-uterine injection (1.7%), dilation and curettage (1.4%) and hysterotomy (0.1%)—South Australia, Eighteenth Annual Report of the Committee Appointed to Examine and Report on Abortions Notified in South Australia for the year 1987, p. 5 Table 7. The figures are believed to represent the situation throughout Australia.

<sup>20</sup> *Ibid.*, p. 5 Table 6A.

<sup>21</sup> See, e.g., M. Danis, "Fetal Tissue Transplants: Restricting Recipient Designation" (1988) 39 *Hastings LJ* 1079.

<sup>22</sup> See, e.g., P. McCullagh, *The foetus as transplant donor* (1987), pp. 105ff.

may end naturally in moments".<sup>23</sup> It has also been suggested that criminal responsibility may extend to doctors performing abortions for the purpose of donating fetuses for transplantation. According to Skegg:

There are circumstances in which a doctor who performed an abortion would have a sufficient fault element for murder. A doctor would have the fault element for murder if he acted with the intention of causing the child to die after it was fully born, or if he was substantially certain that his action would have this consequence. There could therefore be a possibility of a doctor being guilty of murder if he performed the abortion in the hope of providing a living subject for 'fetal' experimentation *ex utero*, or if he performed an abortion by hysterotomy, knowing that the child would not die until after it was removed from its mother's body.<sup>24</sup>

Skegg goes on to distinguish between viable and pre-viable fetuses and suggests that a legal abortion could be a defence against murder in the latter case while it may not be a defence in the former case.<sup>25</sup>

Another problematic area is the use of fetuses that are dead from the abortion. As we have already noted, current law in Australia is not forthright on how abortions should be performed. But is it lawful to perform an abortion in a way that kills a fetus, even though the abortion is a justified one? It has been argued that legal abortion does not necessarily imply fetal death and that there is a duty not to harm a fetus in the course of an abortion so that appropriate care can be rendered for its survival. Putting the question rather bluntly, one writer has asked whether "legalizing a woman's decision to have an abortion necessarily entail(s) legal immunity for killing the foetus".<sup>26</sup> She argues that an abortion technique should not be chosen solely on its effectiveness in killing the fetus and that the law should prohibit it. In examining s. 251 of the Canadian *Criminal Code* 1970 (which is similar in part to s. 65 of the *Crimes Act* (Victoria)) she considers the impact of other offences, for example, homicide, assault and child destruction, and argues that an 'approved' abortion would not be a defence against these other offences. Without pursuing Somerville's thesis any further, the points that are raised exemplify the nature of ambiguity in this area. Although she is largely concerned with the position in Canada, some of the issues are applicable here and are relevant in so far as they reveal areas that need to be streamlined for an effective regime of fetal tissue transplantation. It should be said, however, that current abortion law and practice are far from

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<sup>23</sup> L. Waller, *op. cit.*, p. 52.

<sup>24</sup> P. D. Skegg, *op. cit.*, pp. 24-25.

<sup>25</sup> *Ibid.*, p. 26.

<sup>26</sup> M. Somerville, "Reflections on Canadian Abortion Law: Evacuation and Destruction—Two Separate Issues" (1981) 31 *U. Toronto L.J.* 1.



harmonious. There is, probably, no limit to the speculation as to the possible lawfulness or otherwise, of practices that involve abortion as commonly understood. The law of abortion is almost obscure but doctors are not legal experts, and practise abortion on the basis of what they perceive to be the law, wrong as the perception may be.<sup>27</sup>

Another area to reflect upon is the whole area of fetuses and abortion. This is a highly charged emotive area in many communities arousing moral, legal and political debate. The level that these topics can reach is well illustrated by regulatory developments in the United States. After *Roe v. Wade*<sup>28</sup> legalised abortion in the United States some States sought to regulate fetal research. Some of these attempts clashed with the new constitutional right. For instance, in *Planned Parenthood Association v. The City of Cincinnati*<sup>29</sup> the defendant city adopted a penal ordinance for the disposal of aborted fetuses by hospitals and clinics. The relevant sections of the ordinance required hospitals and clinics where abortion was performed to, among other things, deposit in a vault or tomb, or otherwise dispose of fetuses in a manner approved by the health commissioner, and that disposals should be pursuant to a permit issued by the commissioner. The plaintiffs, providers of abortion services, challenged the ordinance. The court, held among other things, that the ordinance contravened rights guaranteed by the constitution and affirmed in *Roe v. Wade*. It stated (at p. 471):

The City of Cincinnati asserts that it is concerned with the sanitary disposal of fetuses. There is neither a comparable ordinance regarding other human tissue disposal nor any evidence that fetal tissue represents a greater health hazard. In the absence of such evidence it is apparent that this ordinance is intended to interfere with or discourage abortions. No other purpose can be ascertained at this time.

In another case, *Thornburgh v. American College of Obstetricians and Gynecologists*,<sup>30</sup> the US Supreme Court declared invalid certain sections of the Pennsylvania *Abortion Control Act*, 1982 because they had the effect of deterring the free exercise of the right to terminate a pregnancy. The US Court saw its task as one of safeguarding the constitutional principles behind the *Roe v. Wade* decision: "the States are not free, under the guise of protecting maternal health or potential life, to intimidate women into continuing pregnancies" (p.4621). In this instance, one of the challenged sections (s. 3205(a)) required a woman to give her "voluntary and informed consent" to an abortion. While the court had

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<sup>27</sup> See, e.g., K. Mason, "Abortion and the law", in S. McLean, ed., *Legal issues in human reproduction*, (1989), p. 45.

<sup>28</sup> 410 U.S. 113 (1973).

<sup>29</sup> 635 F.Supp. 469 (S.D. Ohio 1986).

<sup>30</sup> (1986) 54 L.W. 4618.

no quarrel with this general principle it objected to details laid down in the statute for obtaining informed consent. These included: the name of the physician to perform the abortion, the possible risks and effects of the abortion, the probable gestational age of the fetus, the fact that medical benefits may be available for prenatal care childbirth and neonatal care and the liability of the father for the support of the child, and availability of printed information listing names of agencies that can help and arrange alternatives to abortion, e.g., adoption. The Court held that these prescriptions were intrusive and exceeded matters relevant to informed consent. Another section (s. 3210(b)) provided in part:

Every person who performs or induces an abortion after an unborn child has been determined to be viable shall exercise that degree of professional skill, care . . . in order to preserve the life and health of any unborn child intended to be born and not aborted and the abortion technique employed shall be that which would provide the best opportunity for the unborn child to be aborted alive unless, in the good faith judgment of the physician, that method or technique would present a significantly greater medical risk to the life or health of the pregnant woman than would another available method or technique and the physician reports the basis for his judgment.

The Court held this provision to be invalid because it involved a "trade-off" between the woman's health and fetal survival which on existing authority was unconstitutional.

### ETHICAL REGULATION OF FETAL TISSUE USE

In considering the regulation of fetal tissue transplantation it may be useful to examine trends in the regulation of fetal tissue use. In Australia, as was stated above, there is no direct legislation on the matter. However the National Health and Medical Research Council (NH & MRC), a national body that oversees medical research, has issued some guidelines on the ethics of research on the human fetus and fetal tissue.<sup>31</sup> The Statement is

intended as a guide on ethical matters for research involving the human fetus or human fetal tissue; included in this research is the possible usefulness of transplantation of fetal tissue for the treatment of disease.

These guidelines cover the fetus *in utero* and the separated pre-viable fetus. The latter is defined as "one that has not attained a gestational age of 20 weeks and does not exceed 400 g in weight". This is to ensure

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<sup>31</sup> *Research Involving the Human Fetus and the use of Human Fetal Tissue*, 1983, Supplementary Note 5 of the NH & MRC Statement on Human Experimentation and Supplementary Notes.

that a viable fetus is given life-sustaining treatment. The applicable conditions are: the fetus should be available as a result of spontaneous or lawful abortion, the fetus should not be dissected while a heart beat or other signs of life are recognisable, those involved in the use of the tissue should be separate from those managing the mother, fetus or determining that the fetus is pre-viable. Other conditions require the conducting of research in institutions with an institutional ethics committee (IEC) to approve the research, and obtaining the consent of the mother and the father if practicable. The guidelines also lay down certain considerations for the guidance of the IEC which include: the fetus should be used as a last resort, no commercial element should be involved in the transfer of the tissue, clinical and research functions should not mix and that the institution should keep a record of all attempts to transplant the tissue. The guidelines were preceded by a background paper by the Medical Research Ethics Committee of the NH & MRC which largely considered existing views on the moral status of the human fetus.<sup>32</sup> The implications of the guidelines for tissue transplants involving the live pre-viable fetus are clear; such fetuses must be dead before transplants can go ahead. Although there is some indication that this may have been dictated by the homicide laws<sup>33</sup> this is not clearly made out. Instead, the paper seems to have, tentatively, regarded fetuses as in some way likely to feel some pain and the test chosen to determine when it is safe to use a fetus is the cessation of heart beat (para. 3.1). The guidelines do not cover research that is done on live viable fetus but it would appear that such research would be prohibited since it is not permitted on live pre-viable fetuses. Moreover, para. 2.17 (of the background paper) states that "a fetus that on separation from its mother is viable is in effect an infant and the research guidelines relevant are those for research on children".

It would appear then that using the fetus as an organ donor may under the NH & MRC guidelines be carried out in limited circumstances. The fetus must be pre-viable, there has to be a cessation of heart beat and approval has to be obtained from an IEC. In practice, the doctor performing an abortion obtains consent from the woman about the use of the fetal tissue. If the tissue cannot be used within a few hours (1-5 hours), it can be frozen.

The major shortcoming of the NH & MRC guidelines is that they are not law. They would not constitute a defence for a clinician who may have such fetuses on his/her hands. Such problems have been

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<sup>32</sup> Ethics in Medical Research Involving the Human Fetus and Human Fetal Tissue, AGPS, Canberra 1983.

<sup>33</sup> Para. 2.15 states: "We believe it is ethically acceptable for tissue to be obtained for research from a pre-viable fetus . . . provided the law is complied with and attention is given to the considerations set out later. A separated pre-viable fetus as defined in paragraph 2.13 shows some signs of life at the time of delivery". (Emphasis added.)

highlighted above, and may include criminal responsibility for the death of "a reasonable creature in being". In addition, it has been argued that the doctor in charge of the abortion may be exposed to liability under both statutory and common law for child neglect.<sup>34</sup> Civil liability in the form of injury to an unborn child that is subsequently born alive could also attach. The guidelines were formulated to cover fetal tissue experimentation and are in need of revision to focus on fetal tissue transplantation.

In the United States, regulation is on both the federal and State levels.<sup>35</sup> Guidelines issued by the US Department of Health and Human Services cover fetal research that is funded by the government (similar to the NH & MRC regime). On the State level some States<sup>36</sup> have enacted laws against fetal experimentation. So far as our examination of fetal tissue transplants is concerned, an example of such a law is the Illinois *Abortion Act*, 1976. Sections 6(3) and 12 provide:

S. 6(3). No person shall use any fetus or premature infant aborted alive for any type of scientific research, laboratory or other kind of experimentation either prior to or subsequent to any abortion procedure except as necessary to protect or preserve the life and health of such premature infant aborted alive.

S. 12. All tissues removed at the time of the abortion shall be submitted for analysis and tissue report to a board eligible . . . There shall be no exploitation of or experimentation with the aborted tissue.

The constitutionality of the above provisions was tested in *Wynn v. Scott*<sup>37</sup> but the challenge failed because the Court found that they did not affect a woman's right to terminate her pregnancy.

In general, experimentation on the live non-viable *ex utero* fetus is prohibited except for therapeutic purposes with the consent of the mother.<sup>38</sup> Mention can also be made of the *Uniform Anatomical Gift Act* (UAGA) which has been adopted in all States. This plays a role similar to the human tissue legislation in Australia. Unlike the latter, however, the UAGA permits gifts of dead fetuses for research or therapeutic purposes and some commentators have read it as permitting fetal tissue transplants.<sup>39</sup>

Britain, like Australia, has no direct law applicable to fetal tissue

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<sup>34</sup> G. Wright, *op. cit.*, p. 348 and Sommerville, *op. cit.*

<sup>35</sup> See, e.g., N. Terry, "Alas! Poor Yorick, I Knew him *ex utero*: The Regulation of Embryo and Fetal Experimentation and Disposal in England and the United States" (1986) 39 *Vanderbilt L.Rev.* 419, 444ff.

<sup>36</sup> The list of States that do and do not have legislation is given by N. Terry, *ibid.*, 446n.

<sup>37</sup> 449 F.Supp. (N.D. Ill. 1978).

<sup>38</sup> N. Terry, *op. cit.*, p. 449.

<sup>39</sup> See, e.g., M. Danis, *op. cit.*, p. 1089. In 1988 the Reagan Administration imposed a moratorium on all publicly funded research on fetal tissue from induced abortions—see, *Washington Post* 1988, April 15, A20, Column 1.

transplants. As early as 1970 the Secretary of State for Social Services appointed a committee to "consider the ethical, medical, social and legal implications of using fetuses and fetal material for research". The committee submitted its report in 1972 recommending a code of practice.<sup>40</sup> With the new advances in fetal tissue transplantation the British Medical Association has issued *Interim Guidelines on the use of Fetal Tissue in Transplantation Therapy*. The guidelines reiterate old principles, e.g., tissue should be obtained only from dead fetuses (fetal death is defined as "an irreversible loss of function of the organism as a whole"), maternal consent should be obtained, abortions should not be influenced by subsequent transplantation, no commerce in fetal tissue, use of nervous tissue and organs and approval by an ethics committee.

Guidelines on the use of fetal tissue in transplantation surgery have also been adopted by the Swedish Medical Society.<sup>41</sup> These describe the projects on Parkinson's disease and insulin cells which use aborted fetuses. They require such projects to be approved by institutional ethics committees and state that abortion should be carried out normally, i.e., that a technique should not be chosen in order to facilitate the researcher's needs of fetal tissue. An exception is made for obtaining nerve cells which require the abortion process to be stopped before the fetus is badly damaged.<sup>42</sup> The Society endorses guidelines passed by the Swedish Physician's Society. These state:

Tissue can be taken from a dead fetus;  
The Transplants Act should be observed and the consent of the mother should be obtained;  
Persons using the fetal tissue should not have any influence in the choice of an abortion technique and there should be no connection between the donor and recipient;  
Tissue from the nervous system should be isolated and fragmented but in other cases parts or whole organs can be transplanted; and  
Each project relating to fetal tissue transplants should be assessed by an ethics committee.

## OPTIONS FOR REGULATION

If fetal tissue transplantation therapy is to develop successfully in Australia there is need for a comprehensive regulatory framework. Currently, dealing in fetal tissue raises serious legal issues of an uncertain nature. Although there are NH & MRC guidelines on the matter these

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<sup>40</sup> See, *supra*, n. 10.

<sup>41</sup> *Transplantation of Tissue from an Aborted Fetus*, 1988. This information is based on an unofficial translation of the guidelines in Swedish supplied to us by the Swedish National Board of Health and Welfare.

<sup>42</sup> The guidelines note that the common abortion method up to the twelfth week is vacuum aspiration which leads to the death of the fetus.

are mostly intended to deal with fetal research and not fetal tissue transplantation. The guidelines have two further problems. They do not resolve the legal uncertainties and reliance on them alone would not guarantee that no offence has been committed. The guidelines are also not binding outside the NH & MRC system and are an insufficient reply to those who would like to see stronger controls.

One option in regulating fetal tissue use would be to enact legislation (whether amending human tissue legislation or independent) that would lay down circumstances for obtaining, storage and use of tissue. It would also remove doubts about the applicability of homicide laws, specify the source of fetuses to be used (e.g., if induced abortions, how they are to be performed), the consents necessary before fetal tissue can be used, relationships between all parties concerned and checks on abuse. Such a step would harmonise transplantation law which currently does not apply to fetuses.

It may be objected that the introduction of legislation to regulate fetal tissue use is unnecessary since the law does not seem to recognise fetuses (for instance, unlike the death of children and adults, the death of a fetus of less than 20 weeks or 400 g is not required to be registered).<sup>43</sup> It may further be argued that legislation by statute will, by implication, grant some status to the fetus which may reverberate in other areas e.g., abortion. Such objections are, however, not tenable. Registration is a procedural matter which does not confer status. Moreover, as was discussed before, the area is legally confused and needs untangling.

An option that could placate some of the fears against a comprehensive statutory approach would be to enact a general statute declaring grounds for abortions and the inapplicability of homicide and other laws to fetuses and fetal tissue. Then a council could be set up to formulate guidelines or a code of practice in accordance with broad principles reached after consultation with the public. The advantage with this approach would be its elasticity in keeping abreast with and directing the course of this branch of medicine. The idea of a council would also ensure that individuals knowledgeable in the various areas affected by fetal tissue will be appointed to the council to contribute towards regulation. This option, however, faces a practical political problem. Abortion is a politically lethal topic that many governments would wish to let lie. In fact it is politically more preferable to maintain the current position where fetal tissue transplants may be carried out even though it may, technically, be in breach of the law.

## CONCLUSION

In this article we have considered legal problems arising from the

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<sup>43</sup> See, e.g., ss. 3 and 12 of the *Registration of Births Deaths and Marriages Act 1959* (Victoria).

use of fetal tissue in transplantation. The area is a grey one that seems to be affected by homicide laws. Ethical regulation was also considered and some options regarding future regulation were suggested. These are, however, modest proposals to get the debate going. Fetal tissue transplantation has great promise and it is crucial that regulatory aspects are handled speedily and properly.