THE CARHART CASE AND LATE-TERM ABORTIONS – WHAT’S NEXT IN AUSTRALIA?

A recent case in the United States Supreme Court has indicated a change in course on the issue of abortion rights. In Gonzales v Carhart 127 S Ct 1610 (2007), the Supreme Court, in April 2007, upheld federal legislation banning a particular late-term abortion procedure with no exceptions (even to preserve the mother’s life). This column examines the case in the context of recent Australian cases involving abortion issues. It extrapolates from Carhart to consider the potential for the Australian High Court to disrupt access to safe, medically supervised and performed abortion.

INTRODUCTION

This column seeks to critically review the law in Australia on late-term abortions in relation to the recent, controversial and no doubt influential decision of the United States Supreme Court in Gonzales v Carhart 127 S Ct 1610 (2007). In that case legislation was upheld which prohibited a specific late-term abortion procedure that contained no exception where it is to protect the health of the mother.

LATE-TERM ABORTION: THE AMERICAN EXPERIENCE

President George W Bush signed the Partial Birth Abortion Ban Act 2003 18 USC § 1531 (the Partial Birth Act) into law in 2003 with strong Christian1 support. The Act bans second-trimester abortions using the intact D&E procedure (where the maternal cervix is dilated and the fetus is extracted whole, the skull being iatrogenically collapsed in order to fit through the cervix) without any exception to protect the health of the mother. Strict anatomical measures circumscribe the boundary at which a doctor performs an illegal D&E procedure and faces severe sanction (including up to two years imprisonment). The term “partial-birth abortion” was coined by the United States “right-to-life movement” to bring (unfavourable) attention to the procedure and distance it from more clinical terminology.

The Partial Birth Act was challenged through a series of federal appeal courts and was found to be unconstitutional as it did not provide a “health exception” for pregnant women who faced a medical emergency2 and because the Act covered “not merely intact D&E but also certain other D&Es”, therefore placing an undue burden on a woman’s ability to choose a second-trimester abortion.3 As the Court of Appeals indicated in overturning the Partial Birth Act, “when a lack of consensus exists in the medical community, the Constitution requires legislatures to err on the side of protecting women’s health by including a health exception”.4

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2 Sometimes denoted “evangelical” or “right wing”, though these are loose and inaccurate characterisations.

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Overturning the previous rulings, on 18 April 2007 the United States Supreme Court, in *Gonzales v Carhart* 127 S Ct 1610 (2007), upheld a federal law that banned intact D&E, a specific late-term abortion procedure.

The court rejected the two main arguments that the Partial Birth Act should be declared unconstitutional:

• that it created an undue burden on women as it was not clear if the ban was restricted to intact D&E procedures, or potentially covered all D&E procedures; and
• that the prohibition on intact D&E lacked a “health exception” where the life or health of the mother was at risk.

On the first argument, the majority found that the Act was not void due to vagueness; nor did it impose an undue burden as it was explicitly restricted to intact D&E procedures (at 1625-1639). The majority found three specific criteria in the Act that limited its scope to intact D&Es:

• a physician must “vaginally deliver a living fetus” (emphasis added);
• the fetus must be delivered beyond an anatomical marker (any point past the fetal navel); and
• the physician must have “deliberately and intentionally” delivered the fetus to one of the anatomical landmarks for the purpose of killing it (this excludes a physician from liability if he or she “delivers” beyond the anatomical limit by accident during another D&E procedure) (at 1626-1628).

In relation to the second “health of the mother” argument over the constitutionality of the Partial Birth Act, the majority (as discussed below) seemed partial from the outset in its consideration of the opposing views. Substantial evidence was presented to the court from medical experts (including the American College of Obstetricians and Gynecologists) on the benefits and increased safety of intact D&E for women with certain conditions and in general (eg, decreased risk of cervical laceration) (at 1631-1633). Yet the majority was influenced by evidence from other physicians that intact D&E offered no more safety advantages than other second-trimester abortion procedures. Therefore the majority concluded that “[this] medical uncertainty over whether the Act’s prohibition creates significant health risks provides a sufficient basis to conclude …. that the Act does not impose an undue burden” (at 1637). In the majority’s opinion (at 1636), “the law need not give abortion doctors unfettered choice in the course of their medical practice, nor should it elevate their status above other physicians in the medical community”.

This was the first time in six years that the United States Supreme Court had heard a major abortion case, and it followed new appointments to the Bench. The court was sharply divided, with the decision split five to four. President Bush had appointed two new male conservative justices, Samuel Alito and John Roberts (replacing Justice Sandra Day O’Connor, a leading abortion rights supporter on the Bench, and the late Chief Justice Rehnquist). With this case it became clear that there has been a decided ideological shift in the balance of the court. The two new justices provided the solid conservative majority needed to allow the federal partial-birth abortion ban to go into effect. The decision to uphold the ban could prove historic as it possibly signals a new willingness, under Roberts CJ, to revisit the basic right to abortion guaranteed under the influential case of *Roe v Wade* 410 US 113; 93 S Ct 705 (1973).

**Critique of the majority opinion**

Kennedy J delivered the opinion of the court in what can only be described as impassioned and partial language. The majority commenced its judgment with detailed description of the intact D&E procedure. They used the emotional account of a nurse who was present at one such abortion and compared it to the clinical account given by the doctor as evidence of a callous and inhumane procedure which must be stopped (at 1622-1633). They neglected to mention that this procedure was considered “necessary and proper by the American College of Obstetricians and Gynecologists (ACOG)” (at 1641, Ginsburg J dissenting). Instead, the majority relied upon the evidence selectively

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5 Kennedy J delivered the opinion of the court, Roberts CJ and Scalia, Thomas and Alito JJ joined. Thomas J filed a concurring opinion in which Scalia J also joined.
brought before Congressmen during the Partial Birth Act’s passage through Congress. They quoted with approval that “Congress found, among other things that ‘[a] moral, medical, and ethical consensus exists that the practice of performing partial-birth abortion … is a gruesome and inhumane procedure that is never medically necessary and should be prohibited.’” (at 1614). However, as Ginsburg J indicated in her scathing dissent (at 1643):

[N]one of the six physicians who testified before Congress had ever performed an intact D&E. Several did not perform abortion services at all; and one was not even an obgyn [sic] … [the] oral testimony before Congress was not only unbalanced, but intentionally polemical.

The majority opinion relied heavily on the fact that the state had a significant role to play in protecting the fundamental value and dignity of human life “from the very inception of pregnancy” (at 1633). They found that the Act was essential to “[draw] a bright line that clearly distinguishes abortion from infanticide” (at 1634). They indicated that the court’s precedents after Roe v Wade had “undervalue[d] the state’s interest in potential life” (at 1626). Yet this commitment to the value and dignity of life that the Act purports to have distinctly excludes the same respect for human life of the woman who may be seeking a late-term abortion. The Act does not provide an exception to its “partial-birth abortion” prohibition on the grounds that the health or life of the mother may be at risk. The majority failed to consider that the vast majority of these late-term abortions are done due to serious health problems faced by the mother (such as cancer, high blood pressure, risk of stroke, blood loss, damage to vital organs, and loss of fertility) and the fetus (serious fetal abnormality). Implicit in the majority judgment is the belief that second-trimester abortions are used by women as another means of contraception. Such a non-evidence-based belief can be seen in the following passage of the majority opinion (at 1634):

[I]t seems unexceptionable to conclude that some women come to regret their choice to abort the infant life they once created and sustained … [A] necessary effect of the regulation [prohibiting intact D&E] and the knowledge it conveys will be to encourage some women to carry the infant full term, thus reducing the absolute number of late term abortions.

The majority then indicated that maternal love was the height of respect for human life, and the Act recognises this reality (at 1634). Yet, as Ginsburg J deftly pointed out (at 1649), while there may be such a loving maternal bond, “not all pregnancies, [as] this Court has recognized, are wanted, or even the product of consensual activity”.

The conservative pro-life tone of the majority continued throughout the judgment, but reached its high point with the following statement (at 1617, emphasis added):

The government may use its voice and its regulatory authority to show its profound respect for the life within the woman.

More concerning still was that, as Ginsburg J emphasised in her dissent, this reasoning by the majority explicitly stated that they were willing to reconsider Roe v Wade. In Roe the court identified that the critical consideration for determining a woman’s freedom to choose to terminate her pregnancy was the point at which the fetus is viable outside the womb. In Planned Parenthood of Southeastern Pennsylvania v Casey 505 US 833; 112 S Ct 2791 (1992) the Supreme Court affirmed that any State legislative restriction of abortion services must protect, even after viability, the health of the woman (at 1640). The decision in Carhart, in Ginsburg J’s opinion (at 1650), has blurred the line that was drawn by the court previously by maintaining (at 1627) that “[t]he Act [legitimately] appl[ies] both previability and postviability because … a fetus is a living organism while within the womb, whether or not it is viable outside the womb”. Now, it seems to Ginsburg J, the difference between abortion and infanticide is based on an anatomical location of a fetus when a procedure is performed.

Ginsburg J in her dissent made the following, oft-quoted, observations (at 1641 and 1653):

Today’s decision is alarming … It tolerates, indeed applauds, federal intervention to ban nationwide a procedure found necessary in proper cases by the American College of Obstetricians and Gynaecologists (ACOG). It blurs the line, firmly drawn in Casey between previability and postviability

abortions. And, for the first time since Roe, the Court blesses a prohibition with no exception safeguarding a woman’s health … In candor, the Court, and the Court’s defense of it, cannot be understood as anything other than an effort to chip away at a right declared again and again by this Court – and with increasing comprehension of its centrality to women’s lives.

The United States Partial Birth Act itself does not save a single fetus from destruction. It merely targets a medically safe method of performing an abortion. It signals to each pro-life State legislature that the United States Supreme Court is ready to reconsider one of its most important and controversial pro-liberty decisions. To Ginsburg J this represents the ultimate betrayal of judicial authority (at 1652):

[T]o overrule under fire in the absence of the most compelling reason to re-examine a watershed decision would subvert the Court’s legitimacy beyond any serious question.

FIRST-TRIMESTER ABORTION IN AUSTRALIA: THE THIN VEIL OF LIBERALITY

While our Constitutions and jurisprudence are vastly different in terms of their explicit support for basic rights, there can be little argument that legal trends in United States and Australian law frequently intersect where fundamental human liberties are concerned. It would be a remarkable coincidence if similar principles of justice and human rights did not percolate through the different legal strata in each nation to influence pivotal decisions such as Roe v Wade 410 US 113 (1973) in the United States and R v Wald (1971) 3 DCR (NSW) 25 and R v Davidson [1969] VR 667 in Australia. Therefore when the United States Supreme Court, as it has in Carhart, makes a dramatic shift on its previous findings in relation to legislation seeking to prohibit abortions, it would be naïve to disregard its potential to affect the course of Australia’s abortion laws.

In Australia a woman’s ability to terminate her pregnancy should not be critically dependent on which jurisdiction she lives in, or alternatively what resources she has to travel to more accommodating jurisdictions. Much of the criticism of Australia’s abortion laws is focused on the confusing nature of the differing judicial interpretations of what may be termed “unlawful” under the relevant Crimes Acts, which permit abortions only on maternal health grounds to be determined by doctors who act as “gatekeepers” to the procedure. Further legal uncertainty arises in connection with late-term or second-trimester pregnancies involving severe fetal abnormalities or danger to maternal life, particularly in those jurisdictions which have child destruction laws.

Despite the fact that crimes legislation in most Australian jurisdictions maintains the illegality of abortion (with health exceptions), the majority of Australians appear to support equity of access for safe (medically supervised) abortions. Most Australians for the last two decades have supported the basic liberty of a woman’s right to choose and not be forced by the government to give birth to an unwanted child. Ultimately, the majority of Australians support a woman’s right to have access to safe and legal abortions. Despite this public acceptance of abortion, the procedure continues to take place in Australia without legal certainty, for either the woman seeking the termination or for the doctor performing it, that they will avoid criminal liability.

There has been much recent criticism of Australia’s abortion laws due to the confusing web of criminal law and disparate judicial interpretation of what is “unlawful” in each jurisdiction. Given the politically “hot” nature of the abortion debate, there has been little legislative action by politicians to help clarify abortion law in Australia.

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8 Victoria, Queensland, South Australia and the Northern Territory have child destruction laws.
10 Kelley and Evans, n 9.
11 de Crespigny and Savulescu, n 7 at 202.
What is clear is that women do not have a constitutional or firm common law right to abortion on demand in Australia. Kirby J noted in CES v Superclinics (Australia) Pty Ltd (1995) 38 NSWLR 47 at 61 that it was common knowledge that first-trimester abortions were available on demand in New South Wales and the legislature’s reluctance to intervene must signify some degree of acquiescence in the status quo. Despite this apparent freedom of choice, a woman’s right to have an abortion is not guaranteed and is constantly under attack in Australia.

In the Australian Capital Territory abortion is now more difficult to characterise as a criminal offence. In Western Australia abortion is legal if the woman consents and it is prior to 20 weeks gestation. In the other States and the Northern Territory, abortion is still an unlawful criminal offence with judicial interpretations of “unlawful” based on subjective maternal health grounds. Prior to fetal viability, the test remains: “is the abortion necessary to preserve the mother’s health from serious danger to her life, or physical or mental health, outside the normal dangers of pregnancy?” Kirby J (obiter) in CES v Superclinics (Australia) Pty Ltd (1995) 38 NSWLR 47 at 63 indicated that the test may be even more subjective, allowing for an “honest belief on reasonable grounds” that the “danger to the woman’s health may be constituted by economic, social or medical grounds which need not arise only during the course of pregnancy”.

Despite this veil of liberal availability, in all jurisdictions women seeking abortions face legal confusion as to the legality of the difficult choice facing them. The fragility of liberal abortion laws was exposed in an appeal to the High Court in Superclinics Australia Pty Ltd v CES (unreported, S141/1996). The Australian Episcopal Conference and the Australian Catholic Health Care Association sought leave to appear as amici curiae (friends of the court) in this appeal. The High Court was evenly split (three to three) on whether to allow the church organisations standing. Brennan CJ, a devout Catholic, used his decisive vote to allow both parties standing. Ultimately, an out-of-court settlement was reached and the appeal did not proceed. The transcript records this response from McHugh J (p 9):

But Mr McCarthy, Wald’s Case has stood in NSW for 25 years … The Crimes Act of NSW has been changed year after year, and the legislature has not altered the decision in Wald … You are asking us in Civil Proceedings to make a ruling on the lawfulness or otherwise of abortion.

Given the High Court’s willingness to allow leave for pro-life church organisations to have standing, it seems plausible that if a similar test case came before the High Court a majority may take it as an opportunity, on ideological religious grounds, to reconsider the well-established compromise between women’s rights and protection of the vulnerable achieved for abortion law (particularly in relation to early-term procedures) in Australia by R v Wald (1971) 3 DCR (NSW) 25 and R v Davidson [1969] VR 667. Given the absence of any relevant constitutional rights, this would then throw women’s privacy and autonomy concerns into the unpredictable maelstrom of a policy debate excessively influenced by religious concerns about which a democratic society will never agree.

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13 The case of CES v Superclinics (Australia) Pty Ltd (1995) 38 NSWLR 47 was appealed to the High Court and many conservatives (both on and off the Bench) called for a reconsideration of R v Wald (1971) 3 DCR (NSW) 25 and R v Davidson [1969] VR 667. As a result, the High Court came close to challenging the legality of abortions in the first trimester (the court is currently quite pro-life) but the case was settled out of court before the trial concluded.
14 Health Act 1911 (WA), s 334(2). See also Skene, n 12, p 366.
15 Crimes Act 1900 (NSW), ss 82, 83, 84; Criminal Code (Qld), ss 224, 225, 226; Criminal Law Consolidation Act 1935 (SA), ss 81(1), 81(2), 82, 82(2); Criminal Code (Tas), ss 134(1), 134(2), 164; Crimes Act 1958 (Vic), ss 65, 66; Criminal Code (NT), ss 172, 173, 174.
17 de Crespigny and Savulescu, n 7 at 202.
LATE-TERM ABORTION: A DARK CLOUD GATHERS

The legal uncertainties surrounding abortion in Australia are compounded in the case of late-term abortions where they may overlap with the crime of child destruction. Thus there may be two differing laws on abortion that may apply in a particular case. There has never been a prosecution for child destruction in Australia despite laws in Victoria, Queensland, South Australia and the Northern Territory against child destruction. Even so, the uncertainty remains. In Australia there have been two cases relating to late-term abortions, one in New South Wales and the other in Victoria.

New South Wales: The Sood case

The case of R v Sood [2006] NSWSC 1141 saw Dr Suman Sood convicted of the crime of illegally procuring a miscarriage on a woman who was 22-24 weeks pregnant. Sood’s conviction arose primarily because she had failed to make the proper inquiries that could have satisfied her about the necessity of the abortion. What was of particular importance from the Sood case was Simpson J’s formulation of what is considered a “lawful” abortion (at [17]):

Unlawfulness is thus established if the Crown proves, beyond reasonable doubt, one or more of the following:

(i) that the accused person did not honestly and genuinely hold the requisite belief (ie that termination of pregnancy was necessary in order to protect the mother from serious danger to her life or health, whether physical or mental); or
(ii) that, if and to the extent that, such a belief were held, it was not based upon reasonable grounds; or
(iii) that a reasonable person in the position of the accused would have considered that the risk of termination was out of proportion to the risk to the mother of the continuation of the pregnancy.

This test differs significantly from the formulation in Wald and Davidson, where the test of proportionality was considered to be subjective to the doctor’s assessment, rather than a requirement that a reasonable person consider the balance of risks in favour of the abortion.

Victoria: The Royal Women’s Hospital case

The case of Royal Women’s Hospital v Medical Practitioners Board (Vic) [2006] VSCA 85 is a particularly disturbing case as it involved a legal late-term abortion which became the target of an anti-abortion lobbyist, devout Catholic and Australian Senator by the name of Julian McGauran.

In 2000 Mrs X, a 40-year-old woman, was referred to the Royal Women’s Hospital after her 31-week-old fetus had been diagnosed with skeletal dysplasia (dwarfism). She arrived at the emergency department distressed, becoming “hysterical and suicidal, demanding that her pregnancy be terminated” (at [1]). After further tests were carried out, the diagnosis was confirmed and Mrs X was referred to a psychiatrist for counselling and assessment. The psychiatrist recommended that the termination take place to “preserve the health and life of Mrs X” (at [1]). Several medical practitioners were consulted within the hospital and they concurred. A “fetal reduction” procedure took place and Mrs X delivered a female stillborn (at [1]). Mrs X wanted to let the matter rest in order to get on with her life.

In 2001 Australian Senator Julian McGauran reported the case to the Medical Practitioners Board of Victoria, alleging the abortion was illegal and that there had been a misdiagnosis and requesting an investigation. Senator McGauran then requested details of the case from the coroner, which the Chief Coroner forwarded to the Senator (without the patient’s consent) rather than returning them to the hospital. In Gerber’s opinion, the coroner’s “action in releasing this information was not only...
injudicious and beyond the coroner’s authority, but was in breach of Victoria’s privacy legislation.”

Upon receiving the patient’s file, the Senator forwarded it to the Medical Practitioners Board of Victoria in support of his claims.

On 16 September 2006, the Medical Practitioners Board cleared the doctors of unprofessional conduct. The Board stressed that it was not its role to determine whether a specific clinical decision was appropriate, but to determine whether the conduct of the doctor(s) in making that decision had been professional. *Royal Women’s Hospital v Medical Practitioners Board (Vic) [2006] VSCA 85* is a further reminder that a woman’s right to an abortion is a basic liberty constantly under attack, the privacy of which should never be taken for granted.

**CONCLUSION: WOMEN’S REPRODUCTIVE RIGHTS, PATIENT AUTONOMY AND THE CONSERVATIVE JUDICIARY**

The “gate-keeping” decision on whether an Australian woman can terminate her pregnancy is likely to be increasingly taken out of the doctor-patient relationship and placed in the courtroom. This is more alarming given the composition of the judiciary: mainly older men selected (by a non-transparent process) increasingly for their political and religious views as well as their legal accomplishments. Their views on abortion are most likely not necessarily going to be a reflection of what the broader Australian view is on the topic of access to abortion.

In the current political and judicial climate, the result in *Gonzales v Carhart* 127 S Ct 1610 (2007) sets a worrying precedent for women’s reproductive rights and patient autonomy not just in the United States but in Australia. Given the current state of our abortion laws, and the lack of individual human rights under our constitution, there are no guarantees that the abortion issue will not come before the High Court of Australia in the near future. If it does then that test case may create the another argument for replacing the fiction of common law rights protected by the judiciary with the certainty of constitutional rights applied by a new generation of jurists more in touch with international trends. Ultimately, in Australia, there needs to be a strong legislative response that corresponds with the public’s perceptions, and acceptance, of a woman’s right to have an abortion. Given the volatility and power of the pro-life movement, political impetus to make the necessary changes will always be restricted.

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**RECENT DEVELOPMENTS**

**R v Sutton**

In April 2001, Matthew Sutton’s life was taken by his mother and father in an act to prevent their son losing all quality of life. Matthew Sutton was a 29-year-old male born with a genetic abnormality called Patau Syndrome (Trisomy 13) who suffered from significant physical and mental disabilities. These included a cleft lip and palate, no eyes, deafness (completely deaf in his right ear and only 30-40% hearing in his left) and profound mental retardation. He required full-time care and, over his life, needed innumerable medical and surgical interventions. All of this had a significant impact upon

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24 It should be noted that Senator McGauran forwarded Mrs X’s name in material he sent to *The Age* newspaper in 2005 (despite a suppression order by Master Wheeler of the Victorian Supreme Court). This persuaded the Victorian Health Services Commissioner to refer Senator McGauran to the Privacy Commissioner, where the issue is still current: see Gerber, n 23 at 359, 361.


26 de Crespigny and Savulescu, n 7 at 202.
his parents’ health, including illnesses such as depression and anxiety. Finally, Matthew was diagnosed with a diseased bone in his head just behind his left ear (mastoid process) that required surgical intervention. The risks of this surgery included deafness for at least three months with the potential of 70% recovery of his already diminished hearing, paralysis to the left side of his face and loss of speech and taste. Matthew’s parents did not believe this was in the best interests of their son and on the night of 22 April 2001, Matthew was given his normal medications plus a sedation drug. Afterwards, by means unknown, Mr Sutton took the life of his son. Raymond and Margaret Sutton were charged with murder by the police and pleaded guilty to manslaughter.

In *R v Sutton* [2007] NSWSC 295 Barr J accepted the guilty plead to manslaughter, stating (at [38]): “It seems to me that nothing the Court can do by way of sentence can add to the offenders’ suffering. The need for further punishment is spent.” Raymond and Margaret were ordered to serve a five-year good behaviour bond with ongoing psychiatric treatment.

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**PRIVATE HEALTH INSURANCE ACT 2007 (CTh)**

The *Private Health Insurance Act 2007* (Cth) and seven related Acts were introduced to Parliament as a package on 7 December 2006 and came into effect on 1 April 2007. They were announced by Health Minister Abbott as providing a legislative framework for important reforms to private health insurance described by the government on 26 April 2006 to “enhance choice, certainty and the value of private health care” and “to make private health insurance more competitive and attractive to consumers”.

This package of legislation was introduced by the government in order to further the policy objective of making the otherwise inefficient private health insurance a viable industry in Australia through government subsidisation. The current raft of changes ensures that:

- those who purchase private health insurance have 30% of their premium subsidised by the Australian Government, with rebates of up to 40% for older Australians;
- Australians are encouraged (through penalties) to take out private health insurance when they are younger (as under the Lifetime Health Cover arrangements a loading is added to the cost of a premium where a person takes out cover from the age of 32);
- a reduction in patients’ out-of-pocket expenses, and better information about prospective out-of-pocket expenses under the No Gap/Known Gap schemes;
- consumers can be assisted more by the Private Health Insurance Ombudsman when there are disputes about benefits payable for services; and
- more patients will be able to benefit from hospital services delivered in their own homes.

The Explanatory Memorandum to the Bill indicated that these changes do not detract in any way from people’s entitlements under Medicare, and will not result in a two-tier health care system.

TAF and SJ

**INFERTILITY TREATMENT AMENDMENT BILL 2007 (Vic)**

The Victorian Parliament, on 3 May 2007, passed legislation allowing the therapeutic cloning of stem cells. The Bill, an amendment to the *Infertility Treatment Act*, passed the Victorian Upper House in a historic 23 to 16 conscience vote. Victoria has become the first State to pass such laws, which mirror existing federal laws on therapeutic cloning.

The offence of creating a human embryo clone has been removed permitting embryonic cloning, but such embryos would have to be licensed, destroyed within 14 days and not implanted into a woman. The changes now allow excess human embryos from IVF treatment to be used to create stems cells for medical research.

Somatic cloning (the creation of an embryo other than by human sperm and egg) will only be permitted under licence and only for a period of up to 14 days. The creation of chimeric
(animal-human hybrid) embryos is banned unless authorised by a strict licence. The only chimeric embryo licences that may be issued are the ones giving effect to recommendations 17 (allowed only up to the first cell division) and 24 (the restricted use of animal oocytes) of the Lockhart Committee. Cloned embryos, by any method, are still never to be implanted into a woman. Victorian Health Minister Bronwyn Pike indicated that, despite these changes, the licensing provisions remain very stringent and that there needs to be strong ethical boundaries on this type of research.

**NATIONAL HEALTH AMENDMENT (PHARMACEUTICAL BENEFITS SCHEME) ACT 2007 (Cth)**

The *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007* (Cth) was introduced into the House of Representatives on 24 May 2007, one week after the first exposure draft was produced. It was passed by the Senate within a month. The Senate Community Affairs Committee was convened within a week, heard submissions on a Friday, reported on the next Monday and the legislation was passed on the Wednesday. Such precipitant haste over changes to one of the most significant components of Australia’s public health infrastructure is completely unjustifiable and highlights the need for minor political parties to again hold the balance of power in the Senate.

The Bill’s amendments (new ss 85AB, 85AC) to the *National Health Act 1953* (Cth) fracture the unitary PBS formulary into two: F1 chiefly for single-brand (or patented) medicines that are not in a therapeutic group and F2 for generic medicines. Specific and standardised price cuts and disclosures will be imposed only on F2 generic medicines (new Div 3A of Pt VII). Policy announcements made with the legislation state that reference pricing will be limited to six existing F1 therapeutic groups, or to where comparators in new such groups have met the imprecise standard that they are “interchangeable on an individual patient” basis (proposed ss 84AG and 101(3BA)).

These amendments to the *National Health Act 1953* (Cth) contradict assurances given to a Senate Select Committee by Australia’s chief negotiator to the Australia-United States Free Trade Agreement (AUSFTA), and subsequently by the Federal Government, that the fundamental mechanisms of the PBS would not be altered thereby. They also appear to highlight the problems with allowing an AUSFTA Medicines Working Group, comprising high-level health policy officials from the United States and Australia, to meet in secret (no detailed minutes are released to the public) and discuss changes to medicines policy in our country. The F1-F2 scheme, with its plan for ultra low-cost generics delinked from expensive innovator products, may not be best suited for the small-volume Australian market. It is also unlikely to promote a value-added Australian generics industry that attracts our best science and chemistry graduates to diversify into biosimilars, nanomedicines and pharmacogenomics. The creation of a special F1 category for new medicines on the basis that their “innovative” claims are related to their single “brand” status in relation to competitors, represents a fundamental shift of Australian medicines policy away from valuing pharmaceutical innovation against traditional PBS evidence-based criteria of “objectively demonstrated therapeutic significance” toward valuing it through nominally “competitive markets” (the United States position under Annex 2C.1 of the AUSFTA). It is to be hoped that subsequent amendments to this legislation will clarify that the process of cost-minimisation for a new patented medicine unable to scientifically prove health innovation against a comparator (even if in F2) will be unaffected, that the definition of “interchangeable on an individual patient basis” will be made evidence-based and that the new pseudo policy-making working group between Medicines Australia (the pharmaceutical manufacturers lobby group) and the Department of Health and Ageing over F1 medicines, is abolished. The related policy move to full-cost recovery from industry for the Pharmaceutical Benefits Advisory Committee (PBAC) should also be overturned as creating a conflict of interest that does not facilitate national benefit.

**Medical law reporter**