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Catholic Identity and Health Care

This is an edited record of the address given by Sir James Gobbo to the Centre's Annual General Meeting on 13 October 2010.

The topic of Catholic Identity is a timely one. It is fair to say that Christianity, particularly Catholicism, has had to contend with an increasingly secular and materialistic society. In our own lifetimes there has been an enormous change in that regard. Advocates of an anti-religious secularism have always existed: there's nothing new about that. But they have gone beyond what used to be a kind of a mannered debate between intellectuals, with good manners despite opposing views. The new advocates now of a totally secular or atheist position often relentlessly attack religion. One of these, Richard Dawkins, when asked whether religion had an enriching benefit for people, especially in great religious paintings, described the painters as simply doing it for money. Well, that's a really foolish reply. Does it apply to great artists like Fra Angelico who painted those wonderful Annunciations? Besides, he was a Dominican monk and on no view was he painting for money. Religion works on all different levels, for all sorts of different people. Some are very intellectual about their religion; some need aids to pray; some need the rosary; some welcome images of saints. It has always been so. But now the New Atheists use these practices to say that the Church is exploiting the ignorance of people and mock as superstitious those who believe in God.

'Some reduction in Catholic Identity … is self-imposed.'

Christianity and in particular Catholicism is suffering from an additional attack, namely the scandals of sexual abuse of some who were entrusted into the care of Catholic and Christian organisations. It is likely that there were cases where authorities were too slow about acting in relation to those who were suspected of such abuse. It is greatly to the credit of His Grace Archbishop Hart, who made a public statement about this recently, that he acknowledged what had happened and explained the steps taken by the Archdiocese of Melbourne to provide justice to the victims of past sexual abuse and to work to prevent future abuse. Many of the cases under discussion were 20 or more years ago and were not recent.[1]

There has been a significant decline in attendances in most Christian Churches including Catholic Churches. Many young people brought up as Catholics do not go to church any more except perhaps at Christmas or Easter. Regular churchgoing has become less common except for the new groups from Asia and Africa. They are bringing a new vitality. There has also been a significant decline in vocations, and some religious congregations have totally disappeared. I am not referring to the great ones like the Sisters of Charity or the Sisters of Mercy and like Congregations. But there are some small congregations that have just wound themselves up and have disappeared. One of the consequences of all this is that there has been a general loss of confidence, and in a sense the laity relies upon the clergy and religious to be their front window - too much so, probably. There has been a reduced Catholic presence. Added to this is the likelihood that the occasional damaging publicity about the lamentable past cases of abuse shuts out the enormous contribution that Catholic religious and laity are making through Catholic organisations in the field of health welfare and education.

Identifying as Catholic

Some reduction in Catholic Identity is due to the tide of aggressive secularism and some to adverse publicity about the abuse issues. But some is self-imposed.

There are projects or bodies referred to in public advertisements where there is no word at all in the description of the project that it is in fact sponsored by a Catholic organisation. Sometimes you might think that

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that is not necessary. Sometimes, there is a single word that should suffice such as the words Cabrini or Sisters of Mercy or Sisters of Charity or St Vincent's. Now it might be said, with justice I think, that those are such iconic institutions, that everybody knows they stand for Gospel values and that they are strong Catholic institutions. But it may well be that there is a whole new generation who do not know that they are Catholic Institutions.

I have an example (I won't identify the hospital) where the person in charge would not permit holy water blessings to be given to Catholics upon request, such request to be secured after asking those who were Catholic patients if they wished to have the blessing. It was refused on the grounds that "it might give them false hopes". Now that was in a Catholic Hospital in Melbourne.

'Another issue is the offer of relevant pastoral services to patients or inmates. In order to do this, the hospital or service must ascertain upon entry or referral, the religion, if any, of the patient in question. But some facilities do not complete the relevant box.'

The Professional Supplements in the weekend newspapers are full of advertisements for positions in schools, welfare organisations, hospitals and so on. Every single private school - whatever the denomination - states its denomination. Be it a Wesleyan, Catholic, Anglican, whichever school, they all identify their religions. But Healthcare and Welfare bodies which are in fact Catholic frequently do not identify themselves as religious facilities much less identify which religion.

Sometimes there is a mention underneath that "*this is sponsored by the MacKillop Organisation; a partnership of various bodies*;" and sometimes there is no mention at all. Now if we are concerned about diminishing Catholic identity, we have to ask ourselves, "Why is this happening?"

Difficult issues can arise where there is a merger between a secular and a Catholic religious organisation to conduct a service. At the very least, the merged entity should identify the partners who auspice/sponsor that entity. This is illustrated in the case of Eastern Palliative Care (EPC), an entity in which there are three partners. There are the Sisters of Charity through St Vincent's Hospital, the Order of Malta in Victoria through Order of Malta Hospice Home Care (Vic) Inc., and Outer East Palliative Care Service, a community organisation in the Outer Ranges at Healesville. There is only limited reference to the three partners in EPC material and this material does not refer to the religious character or history of the two religious bodies. These two, namely Sisters of Charity and the Order of Malta, are both Catholic religious bodies with a rich history in hospice care. It was a Sister of Charity, namely Mary Aikenhead, who was the founder of modern hospice care in Dublin. In 1902, the Sisters of Charity established the first modern hospice in London known as St Joseph's Hospice. The Order of Malta included the care of the dying in its first hospital in Jerusalem in 1098. Thereafter, the Hospitallers of St John as they were then known, always built and conducted hospitals in their long stay in Rhodes and Malta.

Other issues arise with other service providers, when management and even staff may know that a particular entity was a Catholic one but patients and the general public are unaware of this.

Another related issue not confined to Catholic facilities is the offer of relevant pastoral services to patients or inmates. In order to do this, the hospital or service must ascertain upon entry or referral, the religion, if any, of the patient in question. It is the patient's prerogative to decline to answer or to decline any service. But there are cases where some facilities do not complete the relevant box. How can one be sensitive to the faith of a patient if it is not known what is that faith? By analogy, in the wider area of cross-cultural services, how can there be sensitivity to the culture of a client or patient if one does not know – much less even enquire – what is the culture of the client?

There is reluctance for Catholics to identify themselves. Can I give an illustration, a practical one, from my own experience as Governor? I went to a volunteering celebration - I think it was then held at Wesley Uniting Church in the city - and many religions were represented. After I made a speech about volunteering, people came forward and spoke about the work they were doing as volunteers; it was very moving. The only odd thing was that none of the Catholics said that doing this work was a living-out of their faith (I knew a lot of these volunteers because I had been in that sector for years). Some of the Evangelicals did, but none of the Catholics did. Yet I knew that their commitment was fantastic and that they were strong Catholics. Now, why is that? Perhaps they felt that they would be showing off to say that "*I do this because I see this as a living out of what I believe in - my Gospel values*?" Whatever the reason they didn't say it, and they probably never say it, and yet at a public forum like that what a great opportunity to do so. So there's a kind of blandness, almost a sense of apology, perhaps a sense of "*I mustn't say anything to make myself different.*" One wouldn't think that 63% of Australians in the last Census said they were Christians.

Invigorating Catholic Identity

An identity should not only state the values you stand for, but it should invigorate those who share this identity. It must also respect the traditions that you follow. It is important to acknowledge and to be fair to the people who went before you. Indeed this is an issue of justice, not merely fairness. May I offer an example? How many of you know that there was a religious basis for the Epworth Hospital? It is certainly not a religious hospital now. It was the creation of the Methodist Church – it was an entirely Methodist Hospital. For years and years, it operated as a Methodist Hospital. If you walk into the

Epworth now, you will find it difficult to see any reference to it once being a religious hospital at all. What would the good Methodists, who laboured hard to build that place, and to keep it going, what would they be saying to us if they came back today? Where is there anywhere, an acknowledgement of the sort of people that came together in faith to put together this hospital? How many of you know that near the Treasury Gardens in Melbourne there was for many years a Presbyterian hospital called St Andrew's? It became Peter MacCallum. Even when I was the Chairman of the Board at Mercy Private, we were having meetings together with the Epworth and St Andrews, both Private Hospitals. We were talking to one another as faith-based hospitals. We felt we had something special that we were bringing to people.

'Religious schools and institutions enjoy exemptions from some legislative provisions. If Catholic and other religious organizations adopt a bland face so that Catholic identity appears not to matter, there is a danger that Government may say: Why should you continue to enjoy an exemption?'

There is a further reason for urgently addressing the issue of Catholic identity. There is a body of legislation in Victoria usually described as Equal Opportunity Acts which limit the right of employers to exclude persons on the grounds of their unsuitability because of the religious values of the employing institution. Religious schools and institutions enjoy exemptions from some legislative provisions. These exemptions are important and in part depend for their continued existence on the argument that religious organizations conducting schools or hospitals depend on the maintenance of their uniform values in order to meet the aspirations of the faith involved. If Catholic and other religious organizations adopt a bland face so that Catholic identity appears not to matter, there is a danger that Government may say: Why should you continue to enjoy an exemption when you place so little public emphasis on your Catholic values and Catholic Identity?

Caroline Chisholm

That takes me to Caroline Chisholm after whom this Health Ethics organisation is named. More than two years ago I gave the annual Mannix Lecture, arranged by the Newman College Students' Club. This lecture was about Leadership and I included a detailed discussion about Caroline Chisholm. In the course of preparation I looked at the website of a number of organisations using the name Caroline Chisholm including of course your own admirable Ethics organisation. Now I am sure all of you know that Caroline Chisholm was a strongly committed Catholic from the time she became a convert to Catholicism upon her marriage to Captain Chisholm, himself a Catholic.

I was disappointed to find that on its website the Caroline Chisholm Society described Caroline Chisholm as an Anglican without noting that she was an active Catholic during her long public life. I wrote to the Society asking for a change in description but as of yesterday – two years on – no change had yet been made. (I'm pleased to say that since this talk was given, the biography on the Caroline Chisholm Society has been changed. It now indicates both Mrs Chisholm's conversion to Catholicism and the place of religious faith in her life and mission).

Almost everyone knows of her heroic role befriending immigrant groups especially women. But surprisingly many present day Australians do not know she was an ardent Catholic. She did her great work expressly as a living out of her faith. She was an extraordinary woman. She was in the 1840s the first woman in Australian history to take a public stand on any issue. Her personal sanctity and career were such as to make her a possible candidate to follow our first Australian Saint – St Mary of the Cross MacKillop. In 1843 she stood up and spoke up for the under-privileged and the deprived, especially the single women that were brought out to Australia then found themselves in terrible strife. She made it her apostolate to look after them. She secured an old barracks building and turned it into a dormitory but first she slept there for two nights with rats crawling all over her.

If there is any doubt as to her public profile in her life time, let us see how she was described by Reverend John Dunmore Lang who labelled her 'an artful female Jesuit'. In 1847 in a pamphlet 'entitled' *Popery in Australia and how to check it effectually* he wrote:

> *Mrs Chisholm is a Roman Catholic, of no common caste, a perfect devotee of the Papacy. In all her efforts on behalf of emigration she is completely identified with the Romish priesthood of New South Wales ... her whole and sole object is to Romanise that Great Colony and by means of a second and, if possible, still greater land-flood of Irish Popery under the guise of a great scheme of National Emigration, to present it in one time to God, the Virgin Mary and the Pope, purified, or at least in the fair way of speedily becoming so, from the foul and pestilential heresy of Protestantism!*[2]

It is a sad reflection on Catholicism in our time if, as seems likely, there are many Australians, including many Catholics, who do not know, let alone celebrate, the life of this heroic woman.

After I had prepared this address I found a message by the Catholic Archbishop of Melbourne Denis Hart to a 2009 Catholic Social Agencies' Seminar, describing the value of spelling out the good news and spelling out what Catholic agencies have to offer. He said this: "*We must dismiss two extremes. One is to see ourselves as a Catholic ghetto, whereby we do not want to cooperate in*

any government instrumentality in any way, retiring from the world and setting up a Catholic club. That is not what we do as Catholics... In the other extreme we can see ourselves as no different from any government instrumentality. Of course, we are Christians, but we keep this to ourselves. We make the faith private and personal. By doing so we dumb down the Catholic identity, we become politically correct, we do not offend anybody, we cease to proclaim Christ visually or vocally in our workplace."[3]

In conclusion I commend the Archbishop's message and I hope you agree that there are many valid reasons why Catholics should be taking stock on the issues of Catholic identity – as a matter of being true to one's faith, as a matter of being a witness to Gospel Values and as a matter of justice to those who have gone before us. It is a principle that is equally valid for all other Christians.

ENDNOTES

[1] Archbishop Denis Hart, *A Pastoral Letter on Sexual Abuse*, Catholic Archdiocese of Melbourne, http://www.cam.org.au/sexual-abuse/a-pastoral-letter-on-sexual-abuse.html

[2] Margaret Kiddle, *Caroline Chisholm* (Melbourne: Melbourne University Press, 1950), 88.

[3] Archbishop Denis Hart, *Address at the Strengthening Catholic Identity seminar*, Catholic Archdiocese of Melbourne, http://www.cam.org.au/archbishops-homilies-2009/address-at-the-strengthening-catholic-identity-seminar.html

All on-line resources accessed 25 March 2011

Sir James Gobbo ✠

Sir James Gobbo was born to Italian parents who emigrated to Australia. He attended Xavier College before studying law at the University of Melbourne. He was awarded a Rhodes Scholarship in 1951.

After many years of service as a barrister and then as a Queen's Counsel, Sir James was appointed a judge of the Supreme Court of Victoria – a role he fulfilled from July 1978 until his retirement from the bench in February 1994.

After a period as Lieutenant-Governor of Victoria, Sir James was appointed the twenty-fifth Governor of Victoria in 1997. He was the first Australian state governor of Italian descent. He served in this role from 24 April 1997 to 31 December 2000.

Over the years, he has served on many boards and councils. He is a long-time friend and supporter of St Vincent's Health and Mercy Health. The Boardroom at Mercy Private Hospital is the Sir James Gobbo Board Room.

Sir James was made Knight Bachelor in 1981, and became a Companion of the Order of Australia (AC) in 1993.

His autobiography ***Something to Declare*** was published in 2010 by Melbourne University Press.

Australia's National Protocol for Organ Donation after Cardiac Death

This article explores how some of the ethical issues raised by Donation after Cardiac Death are addressed in Australia's new National Protocol. It endorses much of what has been established for the management of professional conflicts of interest, the management of conflicts between the wishes of donor and family, the use of ante mortem interventions, and the determination of death. However, it calls for a 5 minute observation time before the declaration of death, and a stronger statement about conscientious objection.

During the development of organ transplantation in the 1960s and early 1970s, organs came from donors who had died according to the standard cardiopulmonary criterion of irreversible cessation of circulation of blood within the body of the donor. As the concept of brain death became generally accepted, from that time until recently, almost all organs have come from donors who died according to the neurological criterion of irreversible cessation of all functions of the brain. Over the last decade, however, organ donor programmes around the world have sought to enable both Donation after Brain Death (DBD) and Donation after Cardiac Death (DCD). There are at least three reasons for this. Firstly, when people have stated that they wish to be organ donors if this is possible, this approach allows more people to donate, and therefore respects and facilitates their wishes. Secondly, the altruistic act of organ donation which often saves other people's lives, also brings comfort and consolation to the family of the donor. Thirdly, enabling both DBD and DCD increases the number of organs for transplantation, which allows programmes to save or significantly improve many more lives.[1]

Countries with well-developed DCD programmes include the United States, Canada, Australia, New Zealand, Japan, the United Kingdom, the Netherlands, Spain, Belgium, France, Latvia, Switzerland, and Austria. World-wide, most DCD is controlled. In these cases, the potential donor is in the Intensive Care Unit; agreement has been reached that further treatment is futile; and there is then a planned withdrawal of cardio-respiratory support (WCRS).

Australia, New Zealand, the United States, Canada, and the United Kingdom focus almost exclusively on controlled DCD. On the other hand, other countries – particularly Spain, France and Japan – focus primarily on uncontrolled DCD. This means that discussions about organ donation begin only after the potential donor has already died. Most uncontrolled DCD donors are either dead on arrival at hospital, or dead after an unsuccessful attempt at cardio-pulmonary resuscitation (CPR). [2]

'When people have stated that they wish to be organ donors if this is possible, Donation after Cardiac Death allows more people to donate, and therefore respects and facilitates their wishes.'

In Council of Europe countries, there were 2,729 DCD donors between 2000 and 2008. They contributed a total of 5,004 transplanted organs (4,261 kidneys, 505 livers, 157 lungs, and 81 pancreases).[3] There were no more than 4 DCD donors in Australia in any year between 1989 and 2004. Since then, there has been a significant increase with 9 in 2005, 8 in 2006, 19 in 2007, 23 in 2008, 42 in 2009, and 69 in 2010. In 2010, these 69 donors were 22% of the total of 309 donors. These 69 DCD donors contributed 272 organs or tissues (including 117 kidneys, 12 livers, 27 lungs, 75 corneas, and 26 heart valves).[4]

There is considerable variation in DCD protocols around the world.[5] As DCD develops in Australia, the Australian Government commissioned the *National Protocol for Donation after Cardiac Death* to provide consistent standards and practices around Australia.[6] This article will briefly review both the process whereby the *National Protocol* was prepared, and its main contents. It will then consider how the *National Protocol* addresses some of the ethical issues associated with DCD.

Process of Preparation

In July 2008, a National Summit on Organ Donation called for the development of an Australian national DCD protocol. This proposal was progressed by the Australian Health Ministers Advisory Council (AHMAC), who decided that the *National Protocol* would be developed under the oversight of the National Health and Medical Research Council (NHMRC), and primarily informed by three Australian documents - the NHMRC's *Organ and Tissue Donation After Death, for Transplantation*, the Australian and New Zealand Intensive Care Society (ANZICS)'s *Statement on Death and Organ Donation*, and NSW Health's *Organ Donation after Cardiac Death: NSW Guidelines* - as well as other significant national and international documents.[7]

A Working Party was established. Working in consultation with other stakeholders and under the oversight of the NHMRC, it prepared a draft protocol.[8] There was both targeted and public consultation about this draft mid-2009. The Caroline Chisholm Centre for Health Ethics contributed one of 42 submissions to the public consultation. While we thought that the draft was very good on clinical processes, we also thought that it needed more development on the involvement and care of the donor's family. In my opinion, almost all of our concerns are addressed by the final version of the *National Protocol*.

Several more drafts and further consultation with specific groups followed. A plain language statement was also developed.[9] The NHMRC formally approved the *National Protocol* on 2 July 2010. At the same time, the Australian Organ and Tissue Donation and Transplantation Authority (AOTDTA) assumed responsibility for the national implementation of the *National Protocol*.[10]

Main Contents

The *National Protocol* is 50 pages in length. It contains a Foreword written by the Chair of the Working Party Dr Gerry O'Callaghan, and a three-page Introduction. Section One (pp. 8-9) identifies ethical principles which should inform the DCD process, and prerequisites which must be present if DCD is to proceed.

Section Two (pp. 10-14) is the Protocol. It identifies twelve stages in the DCD process. These are:

1. Assessing medical suitability for DCD
2. Determining the patient's wishes
3. Formal consents and authorisation
4. Planning and preparation
5. Ante mortem interventions
6. Withdrawal of cardio-respiratory support
7. Management after withdrawal of cardio-respiratory support
8. Determination of death
9. Management after determination of death
10. Post mortem procedures
11. Retrieval surgery
12. Case review

The Protocol lists the various steps in each stage. It identifies the ethical, legal and logistical considerations relevant to each step. It also assigns responsibility for each step (for example, to the Intensivist, the ICU Team, the AOTDTA Organ Donor Coordinator, or the Surgical Retrieval Team). Section Three (pp. 15-24) covers each of these stages in more detail.

The *National Protocol* also contains six Appendices. Appendix A contains a DCD flowchart and checklist. Appendix B summarises the legislative requirements in each Australian State and Territory. At 12 pages, it is by far the longest of the Appendices. Appendix C considers key ethical issues. Appendix D details the process of developing the Protocol. Appendices E and F are respectively a list of abbreviations and a glossary. Finally, the *National Protocol* concludes with a Reference List.

Let us now consider how the *National Protocol* addresses some of the ethical issues raised by DCD:

Managing Professional Conflicts of Interest

If a health professional had full responsibility for both the care of a patient in ICU and the facilitation of possible organ donation by them, they would be rightly concerned that their interest in organ donation might compromise their care of the patient. Further, even if care was not actually compromised, the patient's family would also be rightly concerned about the potential in this situation for compromise. This would undermine their trust in the health professional. Indeed, if there were many situations like this, it could also undermine public confidence in organ donation.

'DCD may only be considered after an independent decision has been taken to withdraw cardio-respiratory support.'

I believe that our best guarantee against compromise is the integrity of health professionals. The *National Protocol* also identifies at least three strategies to manage both the reality and the appearance of professional conflicts of interest. Firstly, it states as an overarching principle that "the needs of the potential donor and the family should take precedence over the interests of organ retrieval." (p. 8) Secondly, it requires a clear distinction between the treating team, and the organ retrieval and transplantation teams. Thus, for example, "the person responsible for withdrawal of cardio-respiratory support must act independently of the retrieval and transplantation teams (pp. 13, 21), and "death must not be determined or certified by a member of the retrieval or transplantation team." (pp. 13, 22) Thirdly, the *National Protocol* mandates that "DCD may only be considered after an independent decision has been taken to withdraw cardio-respiratory support." (p. 9) This may not forbid brief mention of the possibility of organ donation beforehand (cf p. 17), but it certainly requires that serious discussion and consideration of this possibility should take place only after there is agreement that cardio-respiratory support will be withdrawn.

Managing Conflicts between the Wishes of Patient and Family

In most cases, their family will respect a patient's decision for organ donation, particularly if the patient has discussed this decision with them beforehand. Indeed, even if the family were not aware of this decision, it is still rare for them to go against it. In those rare circumstances when they do, health professionals should seek to understand the family's concerns and also to correct any misapprehensions. However, if these concerns cannot be resolved, "it may be justifiable to override the patient's decision to donate… on the grounds that the patient may have withdrawn consent if they had understood the distress that this would cause to his or her family." (p. 41)

Ante Mortem Interventions

After a decision for DCD, there are some changes which either should or might be made in the patient's care. The withdrawal of cardio-respiratory support (WCRS) might be delayed so preparations can be made for organ retrieval and transplantation. WCRS might also occur not in the ICU but in or near the operating room. Blood and other tests should be conducted to determine both donor suitability and suitable organ recipients. To improve organ viability, the patient might be given the anticoagulant heparin (to prevent thrombotic obstruction of blood vessels), the vasodilator phentolamine (to increase organ blood flow), and/or the thrombolytic agent streptokinase (to dissolve clots which might interfere with organ blood flow). In some countries, there might be femoral cannulation so organ-preserving solutions can be infused rapidly after death.

The *National Protocol* rightly states that ante mortem interventions may be considered "only if it is anticipated that they will not harm the patient and will not hasten or cause the death of or compromise the continuing care of the patient." (p. 12) While they do no harm, some interventions will not benefit the physical health of the patient. Instead, they are intended to improve organ viability, and therefore they ultimately benefit the organ recipient. The *National Protocol* again rightly states that the ethical justification for these interventions "must be grounded in a broad understanding of the patient's interests:"

> [S]uch patients have an interest in having their recorded or expressed choices executed. It is reasonable to assume that… this includes performing the donation in a way that will maximise its likely success, consistent with not harming the patient. (p. 42)

'Ante mortem interventions may be considered "only if it is anticipated that they will not harm the patient and will not hasten or cause the death of or compromise the continuing care of the patient."'

The administration of these interventions "requires a careful case-by-case assessment of each intervention and each patient." As most potential donors have not consented specifically to these interventions, consent must be sought from the patient's family or substitute decision makers.[11] However, while this is possible in every other state and territory, it is not possible in New South Wales. New South Wales law does not permit substitute decision makers to authorise non-therapeutic interventions, so, apart from blood tests and changes to the timing and site of WCRS, ante mortem interventions are rarely permitted in New South Wales.[12]

The *National Protocol* adds that "there is no medical indication or current support for [ante mortem] interventions such as femoral cannulation or the administration of medications such as phentolamine, and these are not practiced in Australia." (p. 20)[13]

Determination of Death

In DCD, death occurs through irreversible cessation of circulation. The *National Protocol* requires that after the withdrawal of cardio-respiratory support, death should be determined based on the standard clinical signs of immobility, apnoea (cessation of breathing), absent skin perfusion, and absence of circulation. To ensure that death is properly determined, the *National Protocol* also suggests that the usual clinical examination for the absence of circulation should "ideally" be "supplemented with intra-arterial pressure monitoring if available." (p. 13)

After cessation of circulation, how long should the observation period be before death is declared? The observation period must be long enough to ensure that death has indeed occurred. On the other hand, it should also be as short as possible to minimise damage to the organs. Some European countries understand death only as the irreversible cessation of all brain functions. Because the entire brain takes some time to die after circulation ceases, Austria, the Czech Republic, and Switzerland require an observation time of 10 minutes; Latvia requires 15 minutes; and Italy requires 20 minutes.[14] However, the observation time in most countries and most protocols is instead intended only to ensure that the absence of circulation has become irreversible.

In 2001, the Society of Critical Care Medicine distinguished between a stronger meaning of irreversibility and a weaker meaning. The stronger meaning of irreversibility requires that "the heart cannot be restarted *no matter what intervention is done*." In other words, it would require us to consider what might be possible through CPR even in cases in which CPR will not be attempted. On the other hand, the weaker meaning of irreversibility requires only that "circulation cannot be restored without… those means refused by the patient."[15] In DCD cases, it has already been determined that ongoing treatment is futile. CPR will therefore not be attempted in these cases. It is thus surely reasonable to use the weaker meaning of irreversibility when we consider the observation period for DCD cases.

In DCD, then, the observation period must simply be sufficient to exclude the spontaneous recovery of heartbeat and circulation which is called auto-resuscitation. Now, the first systematic review of auto-resuscitation took place only in 2010. From a search of all material written in English, French, German and Spanish within the international medical data base, the review ultimately found only 27 articles, which together reported 32 cases of auto-resuscitation. All of these were either case reports or letters to the editor, and thus medical evidence of lesser weight. Significantly, however, all these cases of auto-resuscitation followed attempts at CPR. In the absence of cardiopulmonary resuscitation, auto-resuscitation has never been reported. The authors, however, recommend caution in using their findings: because of the small number of cases, their findings are not really sufficient to define the limits of auto-resuscitation.[16]

'The observation period must simply be sufficient to exclude the spontaneous recovery of heartbeat and circulation which is called auto-resuscitation.'

From limited evidence, then, the 1993 Pittsburgh Protocol required an observation time of 2 minutes. In 1997, the US Institute of Medicine recommended 5 minutes. They noted that this was "on the conservative side of the current range," but argued that it is important to ensure that death has occurred, to reassure the public of this, and to prevent the appearance of haste. In 2001, the Society of Critical Care Medicine (SCCM) concluded that "no less than 2 minutes is acceptable, and no more than 5 minutes is necessary." The 2005 US national consensus conference endorsed the SCCM position.[17] Consistent with all this, Australia's *National Protocol* recommends an observation time of "not less than 2 minutes and not more than 5 minutes." (pp. 13, 22)

World-wide, 5 minutes is the most common observation time.[18] The United States is one of very few countries which permit a 2 minute observation period, but even there the most common period is 5 minutes.[19] The Canadian standard requires 5 minutes.[20] For different reasons based on their concept of brain-stem death, the UK standard also requires 5 minutes.[21] While others may disagree, in my opinion it would be prudent for Australian DCD programmes to allow 5 minutes observation time, especially while DCD is still becoming established in Australia.

Conscientious Objection

Rightly or wrongly, some people within our society have ethical concerns about Donation after Brain Death and/or Donation after Cardiac Death. When health professionals are in this situation, we show our respect for them and for their conscience and professional integrity by recognising and explicitly stating their right to conscientious objection. Thus, for example, the NHMRC has stated:

> While an individual health professional must not be required to participate in an activity that the person believes to be wrong, the exercise of conscientious objection should never put a patient receiving care at risk of harm or abandonment, or undermine confidence in others who have chosen to participate in a widely accepted professional activity such as organ donation.[22]

The *National Protocol* is less explicit about conscientious objection. It does state that health professionals who do not have "commitment to organ donation related activities" have "an obligation to inform their colleagues and facilitate the involvement of other appropriate health professionals." (p. 15) However, the *National Protocol* lacks an explicit and clear statement about conscientious objection – which is, in my opinion, a significant defect. When the *National Protocol* is reviewed and revised (as it must be before July 2015), I hope that this defect is remedied.

ENDNOTES

[1] J. L. Bernat et al, "Report of a National Conference on Donation after Cardiac Death," *American Journal of Transplantation* 6, no. 2 (February 2006): 281-291 at 287; cf National Health and Medical Research Council and Australian Organ and Tissue Donation and Transplantation Authority, *National Protocol for Donation after Cardiac Death*, 5, DonateLife, http://www.donatelife.gov.au/The-Authority/National-Protocol-for-Donation-after-Cardiac-Death.html

[2] Sam D. Shemie et al, "National Recommendations for Donation after Cardiocirculatory Death in Canada, *Canadian Medical Association Journal* 175, no. 8 (10 October 2006): S1 – S24 at S5. DCD donors are also divided into Maastricht Category I (dead on arrival), Category II (unsuccessful resuscitation), Category III (controlled), Category IV (cardiac arrest after brain death), and Category V (cardiac arrest in a hospital patient). These categories were first developed at an international conference on DCD held in Maastricht in The Netherlands in 1995, with Category V being added in 2003.

[3] Beatriz Domíniguez-Gil et al, "Current Situation of Donation after Circulatory Death in European Countries," *Transplant International* 24 (2011): 676-686 at 679.

[4] Australia and New Zealand Organ Donation Registry, *2011 Report*, 1, 14 and 15, ANZOD Registry, http://www.anzdata.org.au/anzod/ANZODReport/2011/ANZOD2011.pdf

[5] Domíniguez-Gil et al, 679; Sonny Dhanani et al, "Variability in the Determination of Death After Cardiac Arrest: A Review of Guidelines and Statements," *Journal of Intensive Care Medicine* published online 12 August 2011, Sage, http://jic.sagepub.com/content/early/2011/08/09/0885066610396993

[6] *National Protocol*, 4.

[7] National Health and Medical Research Council*, Organ and Tissue Donation after Death, for Transplantation*, NHMRC, http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e75.pdf. Both the ANZICS *Statement* and the NSW Health *Guidelines* have since been slightly revised. The current versions are Australian and New Zealand Intensive Care Society (ANZICS), *The ANZICS Statement on Death and Organ Donation* Edition 3.1, ANZICS, http://www.anzics.com.au/publications-a-resources; and NSW Health, *Organ Donation after Cardiac Death: NSW Guidelines* (14 April 2011), NSW Health, http://www.health.nsw.gov.au/policies/gl/2011/pdf/GL2011_005.pdf. The other documents reviewed included guidelines from four Victorian hospitals, and the then-current standards for Canada, New Zealand and the United Kingdom.

[8] Australian Organ and Tissue Donation and Transplantation Authority and National Health and Medical Research Council, *Draft National Protocol for Donation after Cardiac Death*, NHMRC, http://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/consult/consultations/Draft_National_Protocol_for_DCD.pdf

[9] Australian Organ and Tissue Donation and Transplantation Authority, *DCD Plain Language Statement*, DonateLife, http://www.donatelife.gov.au/Media/docs/DCD%20plain%20english_September%202010-39dd1180-ca2c-4bf0-acc9-89e66f8f88f4-0.pdf

[10] For more on its development, see *National Protocol*, 5, 43-45.

[11] For more on ante mortem interventions, see Bernadette Richards and Wendy A. Rogers, "Organ Donation after Cardiac Death: Legal and Ethical Justifications for Antemortem Interventions," *Medical Journal of Australia* 187, no. 3 (6 August 2007): 168-170; Bernadette Tobin, "Donation after Cardiac Death: Ethical Challenges in a 'New' Pathway to Donation," *Bioethics Outlook* 19, no. 1 (March 2008): 5-9 at 8.

[12] NSW Health, 3, 9.

[13] Similarly, the current UK standard notes Scottish advice that "use of vasodilator therapy (eg phentolamine) is not common practice and is not recommended." Or again, the current Canadian standard notes that in the United States "phentolamine use is less common and the use of streptokinase is not well established. Many, but not all, European countries have followed the Maastricht policy precluding the use of medication that is not beneficial to the patient until after death." For this, see British Transplantation Society and Intensive Care Society, *BTS/ICS Consensus Guidelines on Organ Donation after Circulatory Death* (14 December 2010), 21, BTS, http://www.bts.org.uk/transplantation/standards-and-guidelines/; and Shemie et al, S13.

[14] Domíniguez-Gil et al, 679.

[15] Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine (SCCM), "Recommendations for Nonheartbeating Organ Donation: A Position Paper," *Critical Care Medicine* 29, no. 9 (September 2001): 1826-1831 at 1827.

[16] K. Hornby, L. Hornby, and S. D. Shemie, "A systematic review of autoresuscitation after cardiac arrest," *Critical Care Medicine* 38, no. 5 (2010): 1246-1253; cf James L. Bernat, "How autoresuscitation impacts death determination in organ donors," *Critical Care Medicine* 38, no. 5 (2010): 1377-1378.

[17] University of Pittsburgh Medical Center Policy and Procedure Manual: Management of Terminally Ill Patients Who May Become Organ Donors After Death," *Kennedy Institute of Ethics Journal* 3 (1993): A1-A15 at A6; Institute of Medicine (IOM), *Non-heart-beating Organ Transplantation: Medical and Ethical Issues in Procurement* (Washington, D.C.: National Academy Press, 1997), 5f; SCCM, 1828; J. L. Bernat et al, 282.

[18] Dhanani et al, 4.

[19] Shemie et al, S8.

[20] Ibid., S6.

[21] *BTS/ICS Consensus Guidelines*, 8, 13.

[22] National Health and Medical Research Council, *Organ and Tissue Donation by Living Donors*, 29, NHMRC, http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e71.pdf; cf *Organ and Tissue Donation after Death, for Transplantation*, 19-20.

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Kevin McGovern ✠

Gene Patents

A patent provides the exclusive legal right to a person or company to regulate the distribution, manufacture or use of their invention. This paper examines some of the issues surrounding Gene Patents. Although there is a drive to abolish Gene Patents, we argue that refined and clearly defined regulation would continue to support medical research, avoid exploitation, and be of benefit to public health.

The first patent was granted in England in 1449 for a form of stained glass.[1] Patents were granted by the Crown. James I (1603-1625) abused his royal authority by granting monopolies based on his own personal preferences. This provided him with influence over the access and pricing of goods. The "*Statute of Monopolies*" passed by English Parliament in 1623, consequently barred most royal monopolies and sought to protect new inventions for up to fourteen years.[2] This law still influences Patent Law today.

Federation in 1901 gave the Australian Government the authority to create laws regarding patents and intellectual property. The enactment of the *Patents Act 1903* formalised this authority. The current basis for patent law in Australia is the *1990 Patents Act.*[3] Although it was considered, the Senate Committee on Industry, Science and Technology did not support the exclusion of Gene Patents in 1990.[4] Over time, this *Act* has been influenced by two international agreements: the 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS),[5] and the Australia-United States Free Trade Agreement of 2004.[6]

Patents

For something to be patented under the *1990 Australian Patent Act* it needs to fulfil the following criteria: it is a 'manner of manufacture,' novel, involves an inventive step and will be useful to society. Invention details must also be "well disclosed or described."[7] A patent permits the patent holder "exclusive rights to exploit their patented invention," for the term of the patent. This exclusivity prevents non-authorised parties from gaining a benefit through use or exploitation of the invention.[8] Numerous Australian inventions are global successes. The safeguards provided by the patent system, encourage research and the development of novel products. Patents can also promote the transfer of technology at a global and national level, encouraging trading partners to provide similar rights. This provides protection for Australian exports in global markets.[9]

In 2004, it was observed that the *Australian Patent Act 1990* does not have a "research exemption" clause. A research exemption clause would cover those whose activities utilise patented material for a non-commercial/experimental purpose.[10]

Genes

A gene is a unit of hereditary material with its own unique location (locus) on a chromosome. Chromosomes are composed of deoxyribose nucleic acid (DNA) and are found in the nucleus of human cells. DNA is made up of two chains of nucleotides.[11] The approximately 3 billion DNA nucleotide base pairs of the human genome, code for between 20,000-25,000 human genes. These genes are located on 23 chromosome pairs present in almost every single cell in the human body. This genetic code is present at conception. Thus, genes can be considered a naturally occurring substance within nature.[12]

The order of the nucleotides (DNA sequence) found within genes provide the human body with the code for determining the synthesis of particular proteins within each cell.[13] Proteins are an integral part of the human body. They can be structural (tissue), carry out chemical reactions (enzymatic), act as messengers (hormonal), and regulate gene expression.

Genes affect the inherited characteristics of an individual. A mutation is when the number or order of the nucleotide bases is altered in a gene. This can occur through DNA copying mistakes during cell division, or as the result of environmental factors or genetic engineering. The mutation may have no effect, or may result in a disease or disorder or an altered characteristic.[14] Many genetic tests have been developed to detect these mutations.

Gene Patents

Over the last 20 years, the knowledge of gene functions within the discipline of biotechnology has developed rapidly. This has resulted in biotechnologies becoming the focus of the patent system.[15] Gene Patents include genetic technologies and products, i.e. proteins, DNA sequences, vaccines, kits utilising a portion of a DNA sequence, natural and isolated genetic materials. In Australia the *1990 Patent Act*, allows "an isolated or purified genetic sequence for which a use has been identified," to be patented.[16] It is regarded under the *Act* as an invention.

Areas of health care that can be influenced by Gene Patents are: diagnostic testing where sequences can form the basis of a test; the development and manufacture of medicines which could involve a particular protein coded for by a DNA sequence; Gene Therapy, where a faulty DNA sequence for a particular gene can be replaced by the healthy DNA sequence; and vaccine production which can involve DNA sequences for specific proteins.[17]

What are the concerns regarding Patents on Genes?

Those who oppose Gene Patents, believe that they hinder and deter research into new medicines, treatments and diagnostic testing. Higher costs, the inhibition of free exchange of materials, exploitation of information and occasional legal battles are often cited reasons. Most

importantly, genes are a naturally occurring part of us. Existing at conception, they are not invented, but instead, simply discovered. This is the most crucial point in the argument put forward by many who desire the abolition of Gene Patents.[18]

'Those who believe Gene Patents are necessary suggest that patents offer protection and motivation for investment in the medical field. … A fall in investment could translate into less innovation in medical research.'

Those who believe Gene Patents are necessary suggest that patents offer protection and motivation for investment in the medical field.[19] It is through the protection of a patent that the innovators of a particular field of research will gain funding (via investors) to further develop early research into a novel diagnostic tool or test, a device, vaccine or medicine. A fall in investment could translate into less innovation in medical research. Patent details are placed in the public domain for others to access. However, the information can be utilised for further developments but within the confines of the patent restrictions.[20]

Overall the concerns from both sides regarding Gene Patents fall into two broad categories:

1. The Law or practice of patenting genetic materials and technologies.
2. The manner in which gene patents are exploited in the market place.[21]

The case of Chakrabarty in 1980[22] where the US Supreme Court stated it was possible to patent "anything under the sun that is made by man," became the verdict that began the avalanche in the issuance of patents.[23] However, recent court cases in the United States of America and the European Council of Justice and court challenges in Australia are disputing the validity of Gene Patents. A number of the monopolies that have been created by these patents have become a major source of friction. However, an equilibrium needs to be established between benefits to the public health interest, the scientist, and business investor.

BRCA1 and BRCA2 - breast cancer genes 1 and 2 - are genes linked to a predisposition to familial breast or ovarian cancer. In 2002-3 and 2008, Genetic Technologies (Australia), attempted to compel laboratory testing sites to abide by its patent rights for these genes.[24] In 2008, after withdrawing its directive the company announced that, "the new Board has duly completed this review and resolved to immediately revert to its original decision to allow other laboratories in Australia to freely perform BRCA testing."[25] Motives for the reversal of the directive were not given to a Senate inquiry. However, amongst the reasons suggested, one possibility was that their decision may have been based on its original reversal in 2003 when the company stated that the BRCA genes "are our gift to the Australian people."[26]

The controversy arising from the patent rights over the BRCA1 and BRCA2 was the impetus for a Senate inquiry. In November 2010 the Senate Community Affairs Committee published a report on Gene Patents.[27] Sixteen recommendations were the outcome of the inquiry, including suggestions for several amendments to the *Patent Act 1990.* The recommendations included a research exemption clause, and the establishment of a transparency register, requiring companies to disclose their patents in specific areas.[28] Further, it should be made more difficult to claim a gene patent by an increase in the requirements for the inventive step due to advances in technology for gene isolation. The usefulness criteria ought to assure the patent has a "specific, substantial and credible use," to reduce the broadness of patents.[29] Also sought was a clarification of the "circumstances in which the Crown use provisions may be employed; and that the government develop clear policies for the use of the Crown use provisions."[30] Crown use provisions under the *Act* are available "to ensure that governments in Australia can balance the grant of exclusive patent and design rights to Intellectual Property owners, with the needs of the Australian public."[31]

Recent developments in Australia

On November 26th 2010, the day the Senate Report on Gene Patents was released, a Private Member's Bill, *the Patent Amendment (Human Genes and Biological Materials) Bill 2010,* was introduced by Senator Bill Heffernan into the Australian Senate.[32] In late February 2011, a Private Member's Bill was introduced into the House of Representatives, by Peter Dutton, mirroring the Bill in the Senate. While the Senate report recommends regulation of Gene Patents, both Bills support the abolition of patents on genes, which will include DNA, RNA, proteins and cells.

The Bill has been referred to the Legal and Constitutional Affairs Legislation Committee for inquiry and a report is due by 16 June 2011.

'The debate should not have been about genes and biological materials patents but on the regulation of these patents and how their right is exercised.'

Discussion

This paper is a brief overview of some of the issues that have led to the introduction of the Private Member's Bill - *the Patent Amendment (Human Genes and Biological Materials) Bill 2010*, that is now before the Australian Parliament. Opponents of the Bill have suggested that the debate should not have been about genes and biological materials patents but on the regulation of these patents and how their right is exercised.[33] AusBiotech[34] agree that existing legislation in particular how a patent right is exercised requires reviewing, but states there is no

convincing reason to ban patents on biological materials.[35] The recommendations by the Senate inquiry stand to address these issues of regulation and use of patents.

'We require a patent system for gene technologies that does not restrict access for research, recognises potential problems, and seeks to address these problems in a fair and equitable manner.'

A brief review of Annual Reports from many of Australia's Medical Research Institutes provides information on the number of grants they are dependent upon to bring an innovation from the bench to the public. Some receive less than half of their income from government grants. The concern of Dr Julian Clark from Walter and Eliza Hall Institute, is that "patents are vital to attracting investment in discovering and developing new therapies and vaccines due to the extremely high cost of development."[36] Further, Dr Clark is concerned that capital could be channelled elsewhere to globally encouraging environments. This could also impact on the personnel who are behind the innovations: if the capital goes, so may they. As Dr Clark points out, failure of innovations is high (90-99%) for both diagnostics and therapeutics, thus investment in this area is risky.[37]

Gardisal Vaccine, is a vaccine which provides immunity against some of the human papilloma viruses known to cause cervical cancer. It was supported from bench to vaccine by CSL, a biotechnology company in Australia. Gardisal vaccine was the outcome of years of research from Dr. Ian Frazer and colleagues. Intellectual property consultant from CSL, Jon Cox, states that CSL wanted to support Dr Frazer's discovery in 1991. Yes, there were battles over patents and who discovered the virus and the link to cancer first, but without monetary support from CSL and several other multinational pharmaceutical companies we would not have the vaccine available today.[38] Although developed with the support of private biotechnology companies, the Australian government provides Gardisal free of charge on the national immunisation schedule to those who are eligible.[39]

Conclusion

Catholic Social Teaching teaches that capitalism in a system that is within a strong judicial framework is acceptable.[40] Gene Patents are related to our health, thus they become an emotional issue as they can and have limited access to services and products. Patenting of genetic technologies may not necessarily be the optimal method to promote medical research and develop new therapies, but abolishing Gene Patents will not provide us with a perfect system either. We require a patent system for gene technologies that does not restrict access for research, recognises potential problems, and seeks to address these problems in a fair and equitable manner. An effective regulatory regime may well be a better outcome than the banning of Gene Patents.

ENDNOTES

[1] State Library of Victoria, "Patents," State Library of Victoria, http://guides.siv.vic.gov.au/patents
[2] Luigi Palombi, *Gene Cartels* (Cheltenham: Edward Elgar Publishing, 2009), ix-x.
[3] Australian Law Reform Commission, *Genes and Ingenuity Report, Gene Patenting and Human Health (*Canberra: SOS Printing Group (Australia), 2004), 54.
[4] Ibid., 170.
[5] TRIPS is an international agreement administered by the World Trade Organization (WTO) for its members. Amendments (patent term extended from 16 years to 20 years, compulsory licensing and Crown use provisions) were required so the Australian *Patent Act 1990* would be consistent with the TRIPS Agreement. Australian Law Reform Commission, 89-90.
[6] Matthew Rimmer, *Intellectual Property and Biotechnology* (Cheltenham: Edward Elgar Publishing, 2008), 12.
[7] Community Affairs Reference Committee, "Gene Patents", Commonwealth of Australia, http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents_43/report/report.pdf 10
[8] Ibid., 6.
[9] Australian Government IP Australia, "Patents," Commonwealth of Australia, http://www.ipaustralia.gov.au/patents/index.shtml
[10] Australian Law Reform Commission, 318.
[11] Nucelotides consists of four chemical bases adenine (A), cystosine (C), guanine (G) and thymine (T).
[12] National Human Genome Research Institute, "A Brief Guide to Genomics," genome.gov, http://www.genome.gov/18016863
[13] Triplets of nucleotides code for a particular amino acid (building block of proteins). Enzymes and messenger molecules assist with the synthesis of proteins. Located in the cell nucleus is messenger ribonucleic acid (mRNA). mRNA is the enzyme that is responsible for copying the information found in a particular gene's DNA. The mRNA moves out of the nucleus to the ribosome in the cell cytoplasm. The ribosome reads the code on the mRNA and translates it into proteins by linking together amino acids in a specific order depending on the original genetic code (gene expression). National Health and Medical Research Council, "Medical Genetic Testing Information for Health Professionals," NHMRC, http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/e99.pdf 1, National Genome Human Research Institute.
[14] Ibid.
[15] Australian Law Reform Commission, 61.
[16] Community Affairs Reference Committee, 70.
[17] Nuffield Council on Bioethics, "The ethics of discussing DNA, A Discussion Paper," Nuffield Council on Bioethics, http://www.nuffieldbioethics.org/sites/default/files/The%20ethics%20of%20patenting%20DNA%20a%20discussion%20paper.pdf 70, 24, 62-3; Community Affairs Reference Committee, 73; Jill O'Donnell , "Gene Patents: Crucial to Academic Cancer Vaccine Research," Paradigm Shift, http://blog.cancerresearch.org/jill/2009/07/gene-patents-crucial-to-academic-cancer-vaccine-research.html
[18] Community Affairs Reference Committee, 76; Nuffield Council on Bioethics, pg 5-6.
[19] Nuffield Council on Bioethics, 6.
[20] AusBiotech, "AusBiotech makes submission to gene patent inquiry," Ausbiotech, http://www.ausbiotech.org/data/downloads/AusBiotech%20Submission%20on%20Patent%20Amendment%20Bill.pdf Appendix 1, 1.
[21] Australian Law Reform Commission, 67.
[22] Chakrabarty applied to patent a bacterium that had plasmids (non-nuclear portions of DNA) inserted into it, making the

bacterium capable of degrading different hydrocarbons.
[23] Douglas Robinson and Nina Medlock, "Diamond v. Chakrabarty: a Retrospective on 25 Years of Biotech Patents," *Intellectual Property & Technology Law Journal* 17, no 10 (2005): 12-15 at 12-13.
[24] Community Affairs Reference Committee, xi.
[25] Genetic Technologies, "New Position re BRCA Testing" Genetic Technologies," Genetic Technologies, http://www.gtglabs.com.au/announcements/new-position-re-brca-testing
[26] Community Affairs Reference Committee, 6,7.
[27] Ibid.
[28] Ibid., xix, 66-7.
[29] Ibid., 144-5.
[30] Ibid., 146-7.
[31] Ibid., 120.
[32] Parliament of Australia, Senate, "Completed Inquiries," 33 Parliament of Australia, http://www.aph.gov.au/senate/committee/clac_ctte/completed_inquiries/index.htm; Parliament of Australia, Senate, "*Patent Amendment* (*Human Genes and Biological Materials) Bill 2010* Information about the Inquiry," Parliament of Australia, http://www.aph.gov.au/Senate/committee/legcon_ctte/patent_amendment/info.htm. The Explanatory Memorandum for the Bill states that the amendments proposed in the Bill will: "advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials...that are identical to such materials as they exist in nature." The purpose of the Bill as stated by Senator Heffernan during its introduction is "to amend the *Patents Act 1990* to prevent the patenting of human genes and biological materials existing in nature." In particular, the Bill will amend section 18 of the *Act* to add a further definition of what is not a patentable invention: "biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature." A definition of biological materials as including DNA, RNA, proteins, cells and fluids will also be added. Fiona Pringle, "Australian Patents Act - proposed amendments to prevent gene patenting," Bladwins, http://www.baldwins.com/australian-patents-act-proposed-amendments-to-prevent-gene-patenting/
[33] Davies Collison Cave, "Bill to ban gene patents introduced to Lower house," Davies Collison Cave, http://www.davies.com.au/pub/detail/397/bill-to-ban-gene-patents-introduced-to-lower-house
[34] AusBiotech is Australia's biotechnology industry organisation, which represents over 3,000 members, covering the human health, agricultural, medical device, bioinformatics, environmental and industrial sectors in biotechnology. AusBiotech, "About Us," AusBiotech http://www.ausbiotech.org/content.asp?pageid=2
[35] Davies Collinson Cave, AusBiotech.
[36] Walter and Eliza Hall, "Gene patent bill threatens research, does not tackle community concerns," Walter and Eliza Hall, http://www.wehi.edu.au/uploads/media_releases/gene_patenting_final.pdf
[37] Ibid.
[38] Ruth Beran, "Ian Frazer's patent problem", Australian Life Scientist, http://www.lifescientist.com.au/article/print/161373/ian_frazer_patent_problem
[39] Several commentators have expressed concerns regarding the Gardisal vaccine. See, for example, Family Life International NZ "Gardisal A guide for parents and caregivers," Family Life International NZ, http://www.fli.org.nz/Default.aspx; Jane Mair, "The Gardisal Vaccine – Is it Safe and Effective?" *The Nathaniel Report 28 (2009): 9-12.*
[40] Pontifical Council for Justice and Peace, *Compendium of the Social Doctrine of the Church* (Vatican City: Liberia Editrice Vaticana, 2004), 190-191.

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