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**THE REGULATION OF DECEASED ORGAN DONATION IN
NEW ZEALAND**

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Abstract

This paper analyses the regulatory framework governing deceased organ donation in New Zealand. In particular, it provides an overview of the reform process that led to the Human Tissue Act 2008. By examining the complex issues that arise in the organ donation context, it seeks to demonstrate that the reform process failed adequately to address the central issue of informed consent. It is argued that this prevented a meaningful reform of the law in this area. The paper draws on select aspects of regulatory theory and analogous legal regimes to lend support to the views expressed herein, and to offer comment on how the reform process could be structured more effectively in the future. In particular, it is argued that increased public participation will be a necessary factor in resolving the informed consent issue. Finally, the paper briefly considers the Financial Assistance for Live Organ Donors Bill that is currently before Parliament. It argues that, while the Bill is meritorious, it is unlikely to have a significant impact on donation rates and that a more constructive course of action would be to address the issues discussed herein.

Key words: regulation; deceased organ donation; informed consent; Human Tissue Act.

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I Introduction

New Zealand has, for some time, had one of the lowest rates of organ donation in the Western World. In 2013, New Zealand's rate of donors "per million population" was placed at 8.1. By contrast, Australia was placed at 16.9, and Spain, the world leaders in organ donor numbers, at 35.1.¹

According to Organ Donation New Zealand, the official donor agency:²

More than 550 New Zealanders are waiting for an organ transplant and approximately 450 of these are waiting for a kidney transplant. People waiting for a heart, lungs or liver may die without a successful transplant while those waiting for a kidney transplant lead lives restricted by long-term dialysis treatment... Many more people are waiting for tissue transplants, including corneas, heart valves and skin.

By way of contrast, there were just 46 deceased organ donors in New Zealand in 2014. This was the highest number achieved in the previous decade.³

In 2005, just prior to winning the largest number of seats in that year's general election, the Labour party announced its health policy. As part of that policy, the party made a commitment to raising the rate of organ donation in New Zealand.

Annette King MP, speaking on behalf of the party, stated:⁴

The issue of consent has stimulated considerable debate, and the Organ Donation Register [a proposed central register for donors in New Zealand] will ensure that there is an effective, informed consent process, so that people who have indicated they want to be organ donors have their wishes respected.

At that stage, the law regarding organ donation was still governed by the Human Tissue Act 1964, an outdated piece of legislation. A review undertaken by the Ministry of Health in 2004 had identified substantial shortcomings in the regulation of organ donation, and proposed that a new regulatory framework be implemented in the form of a new Human Tissue Act.⁵

¹ Organ Donation New Zealand "International donor rates" (2015) Organ Donation New Zealand website <<http://www.donor.co.nz>>.

² Organ Donation New Zealand "Waiting list" (2015) Organ Donation New Zealand website <www.donor.co.nz>.

³ Organ Donation New Zealand "Number of deceased organ donors in New Zealand" (2015) Organ Donation New Zealand website <<http://www.donor.co.nz>>.

⁴ New Zealand Labour Party "Organ Donor Register to be established" (press release, 1 September 2005).

⁵ Ministry of Health *Review of the Regulation of Human Tissue and Tissue-based Therapies: Discussion document* (2004) at 100.

In 2006, the Human Tissue Bill was introduced into Parliament. Pete Hodgson MP, Minister of Health at the time, stated:⁶

The decisions surrounding organ donation are among the most difficult that individuals and their families will face. It became clear during the Human Tissue Review that gaps in [the] current law were making it difficult for families to work through organ donation decisions. The result has often been a default position of not to donate....

For example, the Current Driver Licensing Register is only an indication of a person's wishes, not legal consent for donation. This has often left grieving families unsure about what to do...

It is hoped that the creation of a new Register that provides legal consent and the work of Organ Donation New Zealand to improve awareness will lead to an increase of informed choices to donate.

The system for recording one's wishes on a driver licence was inadequate. In no way could it be said to amount to informed consent, yet it was the only readily accessible means of recording one's wishes regarding donation. At the outset, a major focus of the regulatory reform was improving that consent process, thereby boosting donation rates.

However, as the Bill made its way through Parliament, it became clear that overhauling the regulatory framework would not be a straightforward process. The Bill faced strenuous opposition by the Māori Party, who argued that a system of individual consent regarding the disposition of a deceased's body was inconsistent with tikanga Māori. This opposition captured a central tension in the proposed framework: whose wishes ought to be accorded primacy in the donation setting? The individual or the family? This tension caused a division of opinion during the debate of the Bill.

The Bill also faced opposition by the intensive care physicians ("intensivists") who worked at the coalface of organ donation. Deceased organ donation in New Zealand can usually only proceed when whole brain death has been declared but circulatory function remains. This almost exclusively occurs in the intensive care setting.⁷ The intensivists claimed that the donor register would make little practical difference in increasing donation rates. Furthermore, they

⁶ Human Tissue Bill 2006 (82-1); New Zealand Labour Party "Human Tissue Bill introduced in Parliament" (press release, 7 November 2006).

⁷ Very occasionally it occurs in the emergency department as well. See: Australian and New Zealand Intensive Care Society (ANZICS) *The Anzics Statement on Death and Organ Donation* (3rd ed, 2008) at 20.

made it clear that any system that required the wishes of the individual to be enforced against the surviving family was contrary to accepted practice, and would be ignored by them.⁸

As a result, the regulatory reform devolved into a process whereby competing considerations took hold and pulled in different directions. The minority views of the Māori party clashed with those of the National party, who argued that individual consent must take precedence and that any informed consent process would be stripped of its efficacy without a central register. The Bill was steadily modified in an attempt to strike a balance between these competing considerations.

Consequently, the initial regulatory objective of increasing donation rates by improving the consent process was displaced by competing objectives. This created an internally conflicted framework that rolled on, unresolved, into the eventual Human Tissue Act 2008, an Act that did little more than reinstate the position that existed prior to the reforms.

This paper provides an overview of the reform and investigates the unique regulatory context of organ donation in order to examine the issues that ought to have been explicitly addressed and balanced. In addition, it borrows from regulatory theory and comparative fields to substantiate the claim that the reform process lost sight of the initial regulatory objective and fell short of achieving any meaningful reform.

Finally, the paper briefly considers the Financial Assistance for Live Organ Donors Bill that is currently before Parliament. It will argue that this Bill, while meritorious, is unlikely to have a significant impact on donation rates and that a better course of action would be to address the issues discussed herein.

⁸ See Part IV below.

II Background

First, it is necessary to set out a brief background to the reform. By looking at past legislation and the factors that informed the initial stages of the Human Tissue Bill's passage through Parliament, the initial purpose of the reform can be contrasted with the eventual form of the legislation. As will become apparent, the focus of the reforms shifted with increasing input from the interested parties involved in organ donation.

A Donation

It has been said that one organ donor represents “up to seven lives saved”, given the sum of organs potentially available for transplantation.⁹

In 2006, over one million New Zealanders had elected to be a donor on their driver licence, yet in the previous year only 29 people had become donors after their death.¹⁰ One reason for this disparity was that the election to be a donor on a New Zealand driver licence had no legal force. It might have been indicative of the wishes of the deceased, but it fell well short of the informed consent required by the medical profession. As such, it would never be relied upon in practice. However, the extent to which the public was aware of this was unclear. Barbara Stewart MP stated that:¹¹

[M]any people believe in recording their wishes through the driver's licence system, yet there is actually no link between Land Transport New Zealand and any health database. We must wonder why that process has been followed, when any decision actually made and recorded on a driver's licence cannot be accessed in any way. That process [really] does not mean anything at all.

During the third reading of the Bill, Judy Turner MP put the matter rather more strongly:¹²

[The] fact that we have this silly donor provision on our driver's licence is a complete nonsense. When we sign up for a driver's licence we want a driver's licence; we are not

⁹ Specifically, two lungs and kidneys and one heart, liver and pancreas. See: Thomas May, Mark P. Aulisio and Michael A. DeVita “Patients, Families, and Organ Donation: Who Should Decide?” (2000) 78(2) *Millbank Quarterly* 323 at 324. For the sake of completeness, it should be noted that pancreas-only transplants generally do not proceed in New Zealand because the side-effects from the post-transplant immunosuppressant drugs required are considered to outweigh the therapeutic benefits of transplantation. Pancreas transplants are usually performed with simultaneous kidney transplants for conditions which result in a non-functioning pancreas, such as Type 1 Diabetes. See: National Ethics Advisory Committee *Ethical Issues Relating to Access to Organ Transplantation: NEAC Report to the Associate Minister of Health* (20 January 2015) at 3.

¹⁰ (14 November 2006) 635 NZPD 6471.

¹¹ (14 November 2006) 635 NZPD 6470.

¹² (8 April 2008) 646 NZPD 15439.

thinking about donations. When the question is put to us at that point we make a kind of snap and fairly thoughtless decision one way or another. It is a bit of a blunt instrument and it means nothing.

Even among donors who did satisfy the informed consent requirements, donation would not always proceed. Sue Kedgley MP noted that in 2005, there was a pool of 104 potential donors, but the possibility of donation was not even raised with the family in 35 instances.¹³

B Human Tissue Act 1964

Prior to the reforms, the use and collection of human tissue from deceased persons in New Zealand was regulated by the Human Tissue Act 1964 (the “1964 Act”). When the 1964 Act was drafted, the only available transplants were corneas and heart valves.¹⁴ By the 21st Century, it was argued that the Act was failing to keep pace with technological developments in organ donation medicine.¹⁵

Section 3 of the 1964 Act regulated the removal of human tissue for “therapeutic purposes”.¹⁶ Section 3(1) set out the relevant consent requirement. The wording of the provision is curious. If a person had *requested* that their body or a specified part of their body be donated, the person lawfully in possession of the body (“PLIPOB”) could authorise the removal of body parts in accordance with the request.¹⁷ Such a request could have been made in writing “at any time”, but an oral request was only legally enforceable if made in the presence of two witnesses “during [the potential donor’s] last illness”.¹⁸ The PLIPOB was entitled to rely on the deceased’s request unless there was reason to believe that it had subsequently been withdrawn. The following persons were deemed to be a PLIPOB for the purposes of the Act:¹⁹

- (a) The person for the time being in charge of any hospital care institution within the meaning of [the relevant defining Act], in respect of any body lying in that institution:

¹³ (14 November 2006) 635 NZPD 6471.

¹⁴ Alison Douglass “The new Human Tissue Act” (2008) NZLJ 377 at 377.

¹⁵ Douglass, above n 14, at 377.

¹⁶ Therapeutic purposes was not defined in the Act, but must have included organ donation.

¹⁷ “PLIPOB” is an abbreviation borrowed from Professor PDG Skegg’s “The Removal and Retention of Cadaveric Body Parts: Does the Law Require Parental Consent?” (2003) 10(3) OLR 425 at 429.

¹⁸ Section 3(1).

¹⁹ Human Tissue Act 1964, s 2(2)(a)-(c). Out of interest, it should be noted that the provision gave authority to the person in charge of a hospital within the meaning of the Mental Health (Compulsory Assessment and Treatment) Act 1992 over any body lying in that institution that was the body of a patient. Similarly, s 2(c) gave authority to the prison manager over any body lying in the prison that was the body of a prisoner. The person in charge of any hospital care institution within the meaning of s 58(4) of the Health and Disability Services (Safety) Act 2001 was given authority over “any body lying in that institution”, not only those of patients.

- (b) The person for the time being in charge of any hospital within the meaning of the Mental Health (Compulsory Assessment and Treatment) Act 1992, in respect of any body lying in the hospital, being the body of a patient:
- (c) The prison manager of any prison, in respect of any body lying in the prison that is the body of a prisoner.

Section 3(1A) was inserted in 1989 by amendment,²⁰ and provided that the PLIPOB was entitled to rely on a written request by the potential donor where that request was held on a “health computer system”. This amendment enabled a central register of potential donors to be created. At that time it was hoped that this would increase rates of deceased organ donation. However, the register did not have the desired effect.²¹

In addition, s 3(2) allowed a PLIPOB to authorise the collection of human tissue so long as, having made such reasonable enquiry as was practicable in the circumstances, there was no reason to believe that the deceased had objected to the collection of their tissue, or that any partner or surviving relative of the deceased did not so object.²² Therefore, if the PLIPOB wished unilaterally to authorise collection, they had to enquire as to consent. However, that enquiry was sensitive to circumstance, such as the difficulty in locating a surviving relative of the deceased, or the pressure to utilise viable organs before they deteriorated.

Section 3(4) provided that no removal of human tissue could be effected “except by a medical practitioner”. The provision stated that such a practitioner must be satisfied, by personal examination of the body, “that life is extinct”. This was the extent of the 1964 Act’s reference to what constituted death for the purposes of organ donation.²³

Several points may be noted here. First, while the PLIPOB (usually, but not always, a medical practitioner) was entitled to rely upon the request of the deceased unless there was reason to believe the request had been withdrawn, there was no positive obligation on the practitioner to make any enquiry as to whether the request had been withdrawn.

²⁰ Human Tissue Amendment Act 1989, s 3.

²¹ Susan Watson “Gifts to strangers: organ donation in New Zealand” (2002) NZLJ 291 at 291.

²² Section 3(2)(a)-(b).

²³ The current Act is no clearer in this regard, see Human Tissue Act 2008, s 50(2): “A qualified person must not collect human tissue [unless] the qualified person is satisfied, by personal examination of the body, that the individual concerned is dead.”

Secondly, if the PLIPOB wished to authorise the collection of organs in accordance with s 3(1) of the Act, the wishes of the family were irrelevant. In theory at least, this would have allowed a practitioner to collect the organs of an older child against the wishes of the parents.²⁴

Thirdly, any authorisation given under s 3(2) contained no requirement of consent on the part of the surviving family. All that was required of the PLIPOB was that he or she make “such reasonable enquiry as [may have been] practicable” and obtain the consent of the coroner if necessary.²⁵ It should be noted that in a Code of Practice for Transplantation of Cadaveric Organs released by the Department of Health, it was advised that:²⁶

In most instances it [would] be sufficient to discuss the matter with any one relative who [had] been in close contact with the deceased, asking him his own views, the views of the deceased and also if he [had] any reason to believe that any other relative would be likely to object.

C Human Tissue Review

1 Code of health and disability services consumers' rights

Between the 1964 Act and the reforms, the medical profession underwent substantial changes in respect of patients' rights. In 1996, the Code of Health and Disability Services Consumers' Rights (the “Code”) came into force as a regulation under the Health and Disability Commissioner Act 1994.²⁷ The Code set up a series of rights for consumers of Health and Disability services, and corresponding obligations imposed on medical professionals providing those services.

This followed the 1988 Cartwright Inquiry,²⁸ and established a patient-centred medical approach that shook the profession free from its former paternalistic attitudes.²⁹ It placed patient rights at the forefront, with particular emphasis on the right to give informed consent. Under Right 7 of the Code every patient has the right “to make an informed choice and give informed consent”.³⁰ This right distils the patient's related rights to be treated with dignity, to

²⁴ See Skegg, above n 17, at 431.

²⁵ See s 3(5).

²⁶ Department of Health *A Code of Practice for Transplantation of Cadaveric Organs* (1987) at 4.3(d).

²⁷ Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, s 1.

²⁸ Silvia Cartwright *The Report of the Cervical Cancer Inquiry* (Government Printing Office, 1988).

²⁹ Ron Paterson “The Cartwright Legacy: shifting the focus of attention from the doctor to the patient” (2010) 123 NZMJ 6.

³⁰ Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, s 2.

be given all relevant information concerning their condition and treatment options and to be protected from the vulnerability inherent in the doctor-patient relationship.³¹ Fundamentally, the right to make an informed choice regarding treatment options substantiates the patient's autonomy.

2 *Human tissue review*

In March 2004, the Ministry of Health published a review of the existing regulation of human tissue.³² A new Human Tissue Act was proposed from the outset and informed consent was a key focus.

The Ministry stated that “[t]he rights and expectations of the public [had] become more sophisticated since legislation such as the Human Tissue Act 1964 was passed.”³³ Presumably, what the Ministry meant by this was that more sophisticated procedures had become available, and that new public expectations had developed in response. The document's explicit focus was on “the regulatory environment” governing the use of human tissue.³⁴ One goal of the review was:³⁵

To develop a new regulatory framework...that appropriately [promoted] the cultural and spiritual needs of New Zealanders and the public good associated with the use of human tissue for therapeutic and non-therapeutic purposes.

The Ministry stressed that in practice, organ donation in New Zealand would not proceed without the consent of the family. Even at that stage, it was accepted that any refusal by the surviving family would override the express wish of the deceased to be a donor. It was noted that this was a “contentious” notion for some.³⁶ Apart from being contentious, it was also argued to be at odds with the legislative intent.³⁷

³¹ Ron Paterson, above n 29, at 7.

³² Ministry of Health *Review of the Regulation of Human Tissue and Tissue-based Therapies: Discussion document* (2004).

³³ Ministry of Health, above n 32, at 1.

³⁴ Ministry of Health, above n 32, at 1.

³⁵ Ministry of Health, above n 32, at 1.

³⁶ Ministry of Health, above n 32, at 64.

³⁷ See Chen, Palmer and Partners *Organ Donation: A comparative legal analysis and options for change in New Zealand* (2003) Unpublished paper prepared for the Nana Sue Project, Quality Shoe Marketing, Wellington. By contrast, s 8(g) of the Coroners Act 1988 required a coroner, in deciding whether or not to authorise a post-mortem examination, to have regard to “[t]he desire of any member of the immediate family of the person concerned that a post-mortem examination should be performed.” This created a positive obligation on the part of the coroner to ascertain the views of the surviving family that, as mentioned above, was not incumbent on a PLIPOB seeking to authorise collection of the deceased's organs under s 3(2) of the Human Tissue Act 1964. It is arguable that analogous language could have been introduced into the Human Tissue Act, either at the time of drafting or

The Ministry noted a number of problems with the existing law.³⁸ First, despite the 1989 amendment that allowed for the creation of a centralised donor registry, organ donation rates in New Zealand were still very low.

Secondly, there was no obligation on a medical practitioner to carry out a donor's request.

Thirdly, the practice among medical practitioners was always to seek the family's consent before collecting organs, which was said to be contrary to the intent of the legislation.

Fourthly, it was noted that the driver licence registration system for donors (practically speaking, the most common way people would be likely to record their wishes) was not binding under the Human Tissue Act.

The Ministry also referred to the main regulatory issue in saying that “[p]ublic debate about the legislation in New Zealand centres on the ability for the family to override the wishes of the deceased person...”³⁹ The Ministry framed the essential question as how to resolve two competing principles: maximisation of health benefits through increased transplantation (pro-collection) and according respect to the wishes of the deceased's family (pro-family/whanau consent).⁴⁰ It was pointed out that if primacy was accorded to the former, any system that eroded the need for consent (such as a “presumed consent” model) would gain legitimacy.⁴¹

3 *Initial focus: improving consent*

The net result of the Ministry's consultation was a recommendation that the system be improved to uphold the wishes of the individual donor. This would have been consistent with the principle of informed consent. However, as will be seen, this objective was not pursued to the end. It will be argued below that inherent issues in the way the regulatory reform proceeded caused the law to founder before it could properly address the issues it set out to.

through the Human Tissue Amendment Act 1989, if Parliament had desired authorisation of the collection of organs to be contingent upon the consent of the surviving family.

³⁸ At 64-65.

³⁹ At 65.

⁴⁰ At 66.

⁴¹ At 65.

III Human Tissue Bill

Consistent with the original direction of the reform, the draft Human Tissue Bill contained the following clause:⁴²

45 Authority to act on appropriate consent

- (1) Appropriate consent (as defined in section 7) given other than under section 33 or 34 may be acted on with no further authority than this subsection.
- (2) In particular, appropriate consent (as so defined) given by an individual, nominee, or nominees, in accordance with section 28(a) or (b), is valid, and may be acted on, even if it is disagreed with by the responsible person, or all or any members of that individual's immediate family, or both.
- (3) Appropriate consent (as so defined) given under section 33 or 34 may be acted on with no further authority than this subsection only if the following requirements (if applicable) have been satisfied:
 - (a) the requirement to comply with section 46 before acting on consent given under section 33 on behalf of the immediate family:
 - (b) the requirement to comply with section 47 before acting on consent given under section 34 by a senior available next of kin.

It is clear, and it was accepted by the Health Committee, that this clause gave primacy to the wishes of the deceased donor.⁴³

A First Reading

During the Bill's first reading, Ruth Dyson MP referred to the issues raised by the Ministry of Health's review, noting that the Bill aimed to:⁴⁴

[A]ddress concerns raised during public consultation, including a lack of clarity around the informed consent requirements for the collection and retention of tissue; the role of family members in giving consent for the collection and use of tissue from a person who has died, and the lack of individual autonomy in the area; a lack of clarity in relation to the donor status on the national register of drivers' licences – many people think the register records consent, when it records only an indication of wishes – and New Zealand's organ donation rates, which are low compared with other OECD countries.

⁴² Human Tissue Bill 2006 (82-2).

⁴³ Human Tissue Bill 2006 (82-2) (select committee report) at 3.

⁴⁴ (14 November 2006) 635 NZPD 6467.

Ms Dyson further commented that the objectives of the Bill were to:⁴⁵

Ensure that the autonomy and dignity of the individual from whom tissue is collected is recognised and respected, and that the cultural and spiritual needs of New Zealanders are recognised and respected. Further objectives are to ensure there is clarity for clinicians and the public around the consent process, clear mechanisms for the use and management of human tissue for non-therapeutic purposes, and consistency with regulations in other related areas.

Ms Dyson noted that informed consent was “the fundamental principle underpinning the lawful collection and use of human tissue from deceased people.”⁴⁶ Ms Dyson further commented that there was “considerable support from a broad range of people” for the wishes of the deceased to take primacy, and that the “existence of appropriate consent would be sufficient for [donation] to be lawful.”⁴⁷ However, she also stated that “*in practice*, there may be a number of reasons why [donation] should not proceed.”⁴⁸ For example, the bereaved may be “distressed” by the decision to collect the organs of the deceased. This indicates that even at the early stage of the Bill, there was a rift between the formal legal possibility of the legislation and how it might be applied in practice.

Interestingly, it was noted that the Bill made provision for situations where, owing to existence of appropriate safeguards, the requirement for informed consent could be dispensed with in the public interest. Research approved by an ethics committee was cited as an example.⁴⁹ Reference was also made to tissue collected by the coroner, and for “criminal justice purposes”.⁵⁰

The final point raised by Ms Dyson was that the Bill aimed to strike “a balance between respect for the wishes of the deceased person and the cultural and spiritual needs of his or her family”.⁵¹

B Select Committee

Both the National Party and the Māori Party expressed contrasting minority views at the Select Committee stage. The Māori Party had tabled amendments that allowed the surviving family to submit an overriding objection that would prohibit the collection or use of organs from a

⁴⁵ At 6467.

⁴⁶ At 6468.

⁴⁷ At 6468.

⁴⁸ At 6468 (emphasis added).

⁴⁹ At 6468.

⁵⁰ At 6468.

⁵¹ At 6469.

consenting donor.⁵² These amendments were rejected by the Health Committee and defeated when later tabled as a Supplementary Order Paper.⁵³

The National Party had expressed the view that they “fully [supported] the fundamental premise of the bill that the informed consent of the individual has primacy”.⁵⁴ The Party further supported the inclusion of a national register, expressing their concern that without a means to record the informed consent of prospective donors, the effect of any public campaign to increase donor rates would be “diluted”.⁵⁵

However, the Committee stated that they “[understood] the difficulty of enforcing the wishes of the deceased individual if those wishes conflict with the wishes of the individual’s family.”⁵⁶ Accordingly, they recommended that the Bill provide for the authority not to act on informed consent. The Committee reported:⁵⁷

The proposed consent framework in the bill gives primacy to any informed consent given or objection raised by the individual whose tissue might be collected or used. However, we understand the difficulty of enforcing the wishes of the deceased individual if those wishes conflict with the wishes of the individual’s family. Most of us consider it necessary that anyone proposing to collect or use human tissue, such as organ donation co-ordinators or transplant surgeons, be able to decide not to proceed with collection or use of tissue where families strongly oppose it. We consider that the bill should provide informed consent requirements that must be met before tissue collection or use [proceeds]; it should not require that collection or use must happen if these informed consent requirements are met. We therefore recommend making it explicit that nothing in the bill requires that—

- collection or use of human tissue proceed
- informed consent for the collection or use of tissue be acted on.

⁵² In submission to the Health Committee, later formalised in Supplementary Order Paper 2007 (156) Human Tissue Bill 2006 (82-1) (proposed amendments) at 1.

⁵³ (13 November 2007) 643 NZPD at 13059.

⁵⁴ Human Tissue Bill 2006 (82-2) (select committee report) at 8.

⁵⁵ At 8.

⁵⁶ At 3.

⁵⁷ At 3.

When the Bill was reported by the Committee, Clause 45, mentioned above, had been deleted by unanimous agreement, and the following clause inserted in its place:

10C Person justified in deciding not to collect or use tissue

A person who proposes to collect or use human tissue is justified in deciding not to do so if satisfied, based on all information available to the person in the circumstances, that any informed consent for the collection or use of that tissue should for any reason not be acted on.

This clause found its way unaltered into the eventual Act.⁵⁸

C In Committee / Third Reading

By the time the Bill was debated, issues began to arise regarding the scope and thoroughness of the reform. Jonathan Coleman MP foreshadowed the Bill's limitations when he stated:⁵⁹

[A]t the end of the day, I do not think we will get anywhere fast or come to any substantial destination on this whole issue of human tissue donation, and on the rights of people to determine what happens to their tissue, unless we hold that concept of the primacy of informed consent at the very heart of the debate.

To Dr Coleman, this underpinned the National Party's minority stance. He was concerned that the technical debate surrounding the Bill risked losing sight of that core principle.

Judy Turner MP, speaking on behalf of United Future, stated:⁶⁰

[T]he obvious point, or crux of the matter, is the hearts and minds of family members at what is a very traumatic time in that family's life. They are the people who decide, and even if they know that their family member was keen to be a donor, the pressures and emotional turmoil they are facing at that time can cloud the issue. This is a stone that I believe has not been fully turned over and explored yet.

One option proposed by Ms Turner was to have blood donation staff undertake the organ donation conversation with potential donors. Apart from hypotheticals, Ms Turner's driving point was that she believed "[The Government] had not thoroughly examined every opportunity" at the time of the Bill's third reading.

⁵⁸ Human Tissue Act 2008, s 17.

⁵⁹ (13 November 2007) 643 NZPD 13053.

⁶⁰ (8 April 2008) 646 NZPD 15439.

However, Lesley Soper MP commented on her experience at the Select Committee stage, stating that the Health Committee had “heard during the hearing of submissions many, many heartfelt submissions for and against individual or family decisions on these matters.”⁶¹ She considered the Bill to strike “a good balance” in that respect.⁶²

The legislation arguably did not strike a balance at all. By providing legislative sanction for the decision not to proceed, the status quo of requiring the family’s consent was reinforced, which in fact undercut the informed consent principle.

Nevertheless, the view that the Bill represented a balance of the difficult competing positions prevailed and the resulting Act was in accordance with the recommendations of the Health Committee.

⁶¹ At 13055.

⁶² At 13055.

IV Regulatory Context

In this section, the unique context of deceased organ donation will be explored. In particular, it will be argued that as a regulatory system, it suffered from myriad conflicts that created significant complications.

By highlighting the factors peculiar to organ donation, it will argue that the reform process failed adequately to hold the essential question of informed consent in its sights, and that this caused the process to break down.

Following this, aspects of regulatory theory will be employed to illustrate the importance of clearly defining the regulatory “targets”, discussed below. The regulatory context of organ donation involves a variety of “instruments”. It will be argued that the failure adequately to frame the regulatory targets blocked any discussion of whether one instrument ought to have been emphasised over another.

This situation will be contrasted with a brief overview of the theory of “smart regulation” to demonstrate how viewing the reforms through a regulatory lens confirms that the reform process stalled before it could arrive at a meaningful conclusion on the relevant issues.

A Regulatory Targets

The Human Tissue Act 2008 was intended to provide a comprehensive framework regulating the collection and use of human tissue from deceased persons in New Zealand.⁶³

Given its aims, the regulatory system has certain distinct but related regulatory “targets”. On the one hand, the regulatory target is the policy initiative that the law seeks to secure. This can otherwise be understood as the regulatory “objective”. On the other hand, the regulatory target is the actor whose behaviour is regulated. This can otherwise be understood as the “subject” of the regulation. Both give rise to issues in this context.

1 Regulatory objectives

As mentioned above, the impetus for change can be traced back to the Labour party’s election promise to establish an organ donor register and boost organ donation rates.⁶⁴ As such, the

⁶³ It was not intended to cover reproductive tissue or cells, which are instead governed by the Human Assisted Reproductive Technology Act 2004.

⁶⁴ And to the credit of Andy Tookey, who lodged a petition with the Government to review the organ donation laws that prompted an earlier Ministry of Health review. See: Petition 2002/25 of Andy Tookey and 1,169 others (26 November 2003) (as reported by the Health Committee).

regulatory objective could fairly be framed as raising organ donation rates. Indeed, during the debate of the Bill, frequent references were made to New Zealand's poor rate of donation and the pressing need to improve it. Indeed, Jonathan Coleman MP argued that the "real impetus" for the Human Tissue Bill was addressing this issue.⁶⁵

A further objective closely related to raising the donation rate is the need to realise the therapeutic potential of available organs. Given the organ shortage, if circumstances allow for collection, the regulatory system must enable available organs to be collected.

The debate surrounding the passage of the Bill also made it clear that another regulatory objective existed in the need to ensure that the cultural and spiritual needs of the immediate family of the deceased were respected.

A fourth regulatory objective also existed by virtue of the central role of informed consent in the legislation. By placing consent at the centre of the regulatory framework, the principle of autonomy is accordingly upheld. If it is accepted that the ability to exert control over one's body is an expression of autonomy, an appropriate objective of such a framework should be to give proper recognition to the wishes of the deceased.

These regulatory objectives found legislative expression in the purpose provision of the Human Tissue Act.⁶⁶

3 Purpose of this Act

The purpose of this Act is to help to ensure that collection or use of human tissue-

- (a) occurs only with proper recognition of, and respect for, --
 - (i) the autonomy and dignity of the individual whose tissue is, before or after his or her death, collected or used; and
 - (ii) the cultural and spiritual needs, values, and beliefs of the immediate family of that individual; and
 - (iii) the cultural, ethical, and spiritual implications of the collection or use of human tissue; and
 - (iv) the public good associated with collection or use of human tissue (whether for health practitioner education, the investigation of offences, research, transplantation or other therapeutic purposes, or for other lawful purposes); and
- (b) does not endanger the health and safety of members of the public; and

⁶⁵ (13 November 2007) 643 NZPD 13054.

⁶⁶ Human Tissue Act 2008, s 3.

- (c) generally does not involve the requirement or acceptance, or the offering or provision, of financial or other consideration for the tissue.

2 *Regulated subjects*

First, the Act provides that only a “qualified person” may collect tissue.⁶⁷ This is obviously intended to restrict collection to medical professionals and trainees.⁶⁸ Contravention of the consent requirements by any medical professional will be met with penalties, provided by the Act.⁶⁹ By providing a system of rules and sanctions governing the behaviour of the medical professionals involved in the organ donation context, those medical professionals are regulated subjects.⁷⁰

Secondly, by spelling out the requirements for informed consent and by providing a legislative hierarchy for who is entitled to give informed consent or raise an objection on behalf of the deceased,⁷¹ the legislation also regulates the prospective donors and their surviving family by defining their rights.

Thirdly, the legislation also has the effect of regulating the supply of deceased organs in New Zealand. Therefore, the potential pool of recipients on the waiting list for those organs are also regulated subjects.

B *Conflict of Interests*

One issue with the regulatory framework is that the regulatory objectives mentioned above conflict. A related issue is that the interests held by the various participants in the regulatory system also conflict.

Upholding the autonomy of the individual and according due respect to the cultural and spiritual needs of the family are, in some instances, squarely at odds with one another. The most obvious case of this is where the wishes of the deceased are contrary to the cultural and spiritual beliefs of the surviving family, who may not agree with organ donation.

⁶⁷ Section 50.

⁶⁸ See the criteria in s 50(3).

⁶⁹ Section 22.

⁷⁰ The normal procedure in situations of proposed organ donation is for the intensivists caring for the patient to consult a donor coordinator to discuss the option of donation prior to broaching the topic with the surviving family. The donor coordinator will stand by, ready to liaise with the organ removal team and associated support staff should it be decided that collection is to proceed. See: Australian and New Zealand Intensive Care Society (ANZICS) *The Anzics Statement on Death and Organ Donation* (3rd ed, 2008) at 24.

⁷¹ See Human Tissue Act 2008, Subparts 1 and 3.

However, it is also the case when an individual has consented to donation, but out of sensitivity to the family's grief, the conversation is avoided.

When such deadlock situations are possible, the regulatory reform should weigh the competing interests and reach a principled decision on which will have primacy. It will be argued that this did not occur in the reform process, and as a result, the wishes of the family were given default primacy without any principled justification.

Respecting the cultural and spiritual needs of the family also has the potential to conflict with the objectives of raising organ donation rates and realising the therapeutic potential of available organs. Under the current system, the donation conversation takes place in the context of end-of-life care. It is a time when the surviving family are forced to cope with the death of a loved one, and are potentially experiencing significant emotional distress.

An objective of raising donation rates will dictate that collection of the deceased's organs must be pursued, whereas an objective of respecting the needs of the family will dictate that they should be given space to deal with their bereavement. The organ donation conversation is a rational one, but it occurs at a time when people are not necessarily thinking rationally.

Similarly, the interests of the surviving family also conflict with the interest of patients on the waiting list who stand to benefit from organ donation. Any decision that foregoes collection out of respect for the surviving family deprives the waiting list patients of a life-saving procedure. This was not ignored in the debate of the Bill. For example, Jo Goodhew MP stated that "[New Zealanders] whose future health may depend on aspects of this legislation are also stakeholders."⁷² However, it will be argued that, ultimately, the significance of this point was not properly addressed in the reform process.

C Conflict of Roles

One of the most problematic conflicts in the current system of organ donation lies with the role of the intensivists.

During the second reading of the Human Tissue Bill, Judy Turner MP reported on her experience on the Health Committee. She spoke of the submissions received by the Committee as far back as 2002 from intensivists and relayed their submission that:⁷³

⁷² (23 October 2007) 643 NZPD 12625.

⁷³ (23 October 2007) 643 NZPD 12619.

[The Government] could regulate as much as [it] wanted regarding having a register, and making it mandatory, and closing the door for families to object once somebody had made up his or her mind - [The Government] could pass any law [it] liked – but they, as caring health professionals working with families and loved ones, were [never] going to insist that organs were harvested from a body against the wishes of a family.

During the first reading of the Human Tissue Bill, Jackie Blue MP commented on the submissions received on her own member's bill, the Human Tissue (Organ Donation) Amendment Bill. The Bill sought primarily to establish a nationwide register for organ donors. Dr Blue noted:⁷⁴

Interestingly, the main objections to a voluntary opt-on register [were] from intensive care doctors and some transplant surgeons, who [felt] that a register would be overly bureaucratic and expensive, and that it would not increase the number of donors. The doctors also [considered] that families, when asked about donation, do not object in the vast majority of situations, *and do not support the donor's wishes being paramount*.

As will be discussed below, the intensivists consider support of the family to be inextricable from end-of-life care. As such, “closing the door” on the family is seen as contrary to their whole professional approach.

D Māori Cultural Objection

Any system of regulation that seeks to secure legitimacy must reflect the wider cultural beliefs of New Zealanders, and take account of tikanga Māori.⁷⁵ In this context, cultural beliefs have been defined as “those beliefs relevant to organ donation that derive from the broader culture inherent in one's ethnic group membership”.⁷⁶

During the first reading of the Human Tissue Bill 2006, Tariana Turia MP stressed that there was an important distinction between living and deceased organ donation as far as Māori were concerned. Fundamental Māori views concerning the “circle of life” required that all bodies be returned to the earth intact.⁷⁷ According to Ms Turia, the legislation governing deceased organ donation was fundamentally flawed vis-à-vis Māori because the “sacred value of whakapapa” precluded acceptance of the basic premise that organ donation between the dead and the living

⁷⁴ (14 November 2006) 635 NZPD 6469 (emphasis added).

⁷⁵ Law Commission *The Legal Framework for Burial and Cremation in New Zealand: A First Principles Review* (October 2013) at 16.4.

⁷⁶ Carmen M. Radecki and James Jaccard “Psychological Aspects of Organ Donation: A Critical Review and Synthesis of Individual and Next-of-Kin Donation Decisions.” (1997) 16(2) *Health Psychology* 183 at 184.

⁷⁷ (14 November 2006) 635 NZPD 6473.

was appropriate. As such, she said the Bill “would not even get to first base” in addressing the “cultural, spiritual, and ethical implications of the collection and use of human tissue”.⁷⁸

In commenting on the proposal that an individual’s wishes be able to override the wishes of the surviving family, Ms Turia said:⁷⁹

That does not sit well with [the Māori Party]. No individual stands alone. Our kaupapa, our tikanga as tangata whenua, describe an individual person or body not as merely his or her own but as a connected and vibrant manifestation of whakapapa, the ancestral line. The link, the chain of whakapapa, is therefore of significance to the whanau as a whole, and decisions to sever such a link have implications for the well-being of the whanau, past, present, and future.

During the debate of the Bill, Te Ururoa Flavell referred to the Māori perspective vis-à-vis the legislation as a “clash of ideology – or philosophy, if you like – in respect of how we view death, how we view body parts and so on.”⁸⁰ Mr Flavell referred to the Supplementary Order Paper that the Māori Party had tabled allowing the family a statutory right of veto over the wishes of the deceased, and made the following remarks:⁸¹

Although the Māori Party holds the expectation that all legislation should recognise tikanga Māori, as was anticipated in the signing of the Treaty of Waitangi, this is especially so with any legislation concerning whakapapa material. I suppose it is an entirely reasonable expectation that in Aotearoa New Zealand any laws concerning human remains could acknowledge the world view of tangata whenua, thereby giving recognition to the rights of the collective alongside Western World views that give precedence to the rights of the individual. The purpose of our Supplementary Order Paper is to open the bill’s consent framework to both world views and create a truly bicultural law. Given the presence of both our nation’s and other culture’s world views that esteem the collective, there is also the opportunity to create a multicultural law.

However, Ms Turia also noted that there could reasonably be a divergence of views on the issue within discrete Māori communities. She accepted that:⁸²

⁷⁸ At 6473.

⁷⁹ At 6474.

⁸⁰ (13 November 2007) 643 NZPD 13057.

⁸¹ At 13058.

⁸² At 6474.

[It was] not inconceivable that [a whanau or hapu] may well weigh up all the determining factors and conclude they may indeed derive some benefit from the donation of human tissue and, as such, it should be up to them to decide.

Indeed, Steve Chadwick MP confirmed this when she spoke about her involvement with the Ministry of Health during its consultation period as part of the Human Tissue Review. While corroborating the view that Ms Turia expressed, Ms Chadwick said “but, oddly, there is always another side.”⁸³ She reported meeting with a number of families whose sentiments she paraphrased as follows:⁸⁴

If we are involved primarily with our general practitioner and our primary health organisation, and we understand how they take our organs when we are declared brain-dead, what those organs are used for, and that procedure, kei te pai, we do not feel quite so frightened about this.

The issue is also complicated significantly for Māori by the fact that the Māori population is overrepresented in dialysis statistics.⁸⁵ Mr Flavell highlighted the internal tension this has the potential to create when he stated:⁸⁶

Until one is in [the donation situation], one will never really understand how important [the issues] are... I noted that not a lot of Māori were on the register, and it would be fair to say, of course, that many Māori would be the ones...screaming out for some of the organs...we are talking about.

This broad ideological objection to the organ donation legislation is addressed further below.

E Donor Register Question

The question of whether a central donor register ought to be set up consumed a lot of the debate around both the Human Tissue Bill and the Human Tissue (Organ Donation) Amendment Bill. The register was a central feature of the latter Bill.

It should be recalled that an attempt at a donor register had already been attempted by an amendment to the Human Tissue Act 1964.⁸⁷ In a 1991 review of that register, the Department

⁸³ At 6475.

⁸⁴ At 6475.

⁸⁵ Bridget Faire and Ian Dittmer “Improving equity of access to deceased donor kidneys in New Zealand” (2008) 18(1) *Progress in Transplantation* 10 at 10.

⁸⁶ (13 November 2007) 643 NZPD 13057.

⁸⁷ See the discussion of the Human Tissue Act 1964 in Part II above.

of Health noted that the most frequently cited issues that medical staff faced in retrieving organs were.⁸⁸

[A] lack of intensive care resources, a lack of national coordination, patients not being put on ventilators, difficulties in asking for consent, lack of awareness of donation by provincial hospital staff, and public confusion over the concept of brain death.

The report of the Select Committee stated that the evidence did not indicate that a register would have a meaningful impact on organ donation rates.⁸⁹ The Committee considered the two bills contemporaneously and considered the “consent framework for the collection and use of human tissue” proposed by the Human Tissue Bill to be adequate. Essentially, the Committee considered the creation of a register to be “unnecessary”.⁹⁰

However, an option was retained in the legislation allowing for the Governor-General, by Order in Council, to make regulations establishing a central register at a later date, should it become desirable to do so.⁹¹

This accorded with the submissions of the intensivists on the Bills, and it is submitted that this is correct. However, it is argued that the reason a central register would not have had a meaningful impact on donation rates is that the conflicts inherent in the organ donation context present a more significant obstacle than the ability easily to record one’s wishes regarding donation.

Without first addressing the substantial issues inherent in the regulatory system, it is unlikely that the creation of a centralised register would have had any meaningful impact. The weight of discussion during the passage of the Bill focussed on whether there was sufficient evidence to warrant creation of a register, rather than on whether there were more systemic problems that precluded its effectiveness that ought to have been addressed. In this sense, it is argued that the donor register issue was something of a distraction from the real issues standing in the way of New Zealand’s donor shortage problem.

⁸⁸ Department of Health *Donating Organs in New Zealand: A review of the National Register* (1991).

⁸⁹ Human Tissue (Organ Donation) Amendment Bill 2006 (33-1) (select committee report) at 2.

⁹⁰ At 2.

⁹¹ Human Tissue Act 2008, s 78.

V *Guidance from Regulatory Theory*

A *Regulatory instruments*

Morgan and Yeung have attempted to classify regulatory instruments according to their underlying modality, but stressed that such classifications are not “watertight”. However, what they do offer is a “vantage point from which to begin [the] exploration of the mechanics of regulatory control”.⁹² The utility of this vantage point is that it in turn allows questions of the validity of a particular choice of regulatory instrument to be raised.⁹³

The following section provides a brief description of regulatory instruments and their application to the organ donation context. In doing so, it seeks to demonstrate that the regulatory framework draws on a number of instruments, each of which gives rise to possible issues.

1 *Command*

Command as an instrument of regulation can be understood as the “State promulgation of legal rules prohibiting specified conduct, underpinned by coercive sanctions [if] the prohibition is violated”.⁹⁴ This is known as “imperium”. However, Daintith has argued that the concept of command is wider than simply rule-based coercion, and can encompass the “employment of the wealth of government” in pursuit of policy objectives.⁹⁵ This is known as “dominium”. The legal rules surrounding consent in the Human Tissue Act are a basic form of imperium. The proposed Financial Assistance for Live Donors Bill, discussed below, is a basic form of dominium.

The medical professionals in the organ donation context will always necessarily be a conduit through which the Act is applied in practice. Therefore, the coercive sanctions aimed at medical professionals in the Act serve not only to guide their behaviour, but also whether or not the wishes of the surviving family or the deceased will be carried out. In this way, the legal rules governing consent, and thereby regulating donors and the surviving family, are given legal force.

⁹² Bronwan Morgan and Karen Yeung *An Introduction to Law and Regulation: Text and Materials* (Cambridge University Press, Cambridge, 2007) at 79.

⁹³ Morgan and Yeung, above n 92, at 79.

⁹⁴ Morgan and Yeung, above n 92, at 81.

⁹⁵ T Daintith “The techniques of government” in Morgan and Yeung (eds), above n 92, at 81.

Daintith has argued that the notion of experimentation in deploying policies of either imperium or dominium responds to the problem of uncertainty:⁹⁶

To operate efficient policies which seek to change people's behaviour, government needs adequate information about how they should behave – that is, what standard or target it should set; secondly, about how they are behaving now, and why; and thirdly, about what sanctions or incentives will align their behaviour with the desired standard or target. None of this information is easy to come by, but getting any of these answers wrong is liable to vitiate the policy.

Daintith further argued that information requirements are useful in explaining government choices regarding which regulatory instruments to employ in pursuit of policy objectives.⁹⁷ Therefore, not only does information inform the particular choice of regulatory instrument, but logically it should inform the way in which that instrument is deployed, i.e. the precise form of any legal rule or incentive.

2 *Consensus*

Consensus-based instruments rely upon co-operation as the operative means of regulating behaviour. The distinguishing characteristic of this class of regulatory instrument, then, is that the underlying modality is the *consent* of its participants.⁹⁸

The usual form of consensus-based regulation is self-regulation, a concept that carries a great deal of baggage in the literature. Morgan and Yeung describe the self-regulatory arrangements as “informal in nature, deriving their force from social norms and consensus, rather than from legally enforceable agreement.”⁹⁹

The sanctioning response in situations of self-regulation is a threat of social disapproval and ostracism, rather than a legally coercive sanction. Therefore, the role of the law in such a situation would be to intervene if the threat of social disapproval or ostracism were to prove inadequate in protecting the public from harm.¹⁰⁰

Intensivists can be conceived as partly self-regulated. The oft-cited fear of intensivists that they would be “perceived as ghouls” for collecting organs against the wishes of the surviving family reflects the threat of social disapproval and ostracism mentioned above and delivers the

⁹⁶ T Daintith in Morgan and Yeung (eds), above n 92, at 85.

⁹⁷ At 85.

⁹⁸ Morgan and Yeung, above n 92, at 92.

⁹⁹ At 95.

¹⁰⁰ At 96.

coercive force that shapes the behaviour of intensivists in the real world, far and above the specific legal rule.¹⁰¹ The passages from intensivists quoted above are demonstrative in this regard.

Therefore, whatever the parameters of the law surrounding the collection of organs from deceased persons, any system of regulation cannot ignore this self-regulatory aspect governing the behaviour of the intensivists and the consequent practice of organ collection.

3 *Communication*

Communication-based tools of regulation also depend upon consensus. Under a communication-based model, enhancing the information available to the public seeks to exert indirect influence that will cause people to change their behaviour in a way that helps to secure the regulatory objective.¹⁰² This system of regulation is largely absent in the New Zealand context. However, if implemented it would fall largely to Organ Donation New Zealand, who is “adamant that its role is about education and raising the community’s awareness.”¹⁰³

Under this approach, a public education campaign would be required to bring attention to the donor shortage, and also to the fact that the family has the last say on the matter. By enhancing the information surrounding donation processes, it would be hoped that prospective donors would formally document their intention to be a deceased donor, but also to communicate this desire to their families, and ensure that the family will agree to uphold the donor’s wishes in the event of their death.

There are a number of issues with this approach. First, it places an onerous requirement on the prospective donor to ensure their wishes have the best chance of being upheld. Expecting all donors to go to such lengths to express their wishes seems unrealistic. Furthermore, it has been argued that:¹⁰⁴

[Measures that seek to] exhort the public to act in pro-social ways that are consistent with government policy objectives [rest on the] rather optimistic [assumption] that individuals are receptive to, learn from and act upon, the information communicated.

¹⁰¹ See, for example, Eike-Henner Kluge “Decisions about organ donation should rest with potential donors, not next of kin” (1997) 157(2) *Can Med Assoc J* 160 at 161.

¹⁰² Morgan and Yeung, above n 92, at 96.

¹⁰³ (8 April 2008) 646 NZPD 15443, per Steve Chadwick MP.

¹⁰⁴ Karen Yeung “Government by publicity management: Sunlight or spin” in Morgan and Yeung (eds), above n 92, at 99.

Secondly, even if a donor could secure their family's agreement to consent to donation in the hypothetical, the situation is altogether different at a time when the family is highly distressed at the loss of a loved one.

Therefore, whatever the measures put in place by the donor, there remains no way for him or her to be sure that those wishes will be carried out. To highlight the significance of this final point, attention must be drawn again to the fact that donated organs equal lives saved, and the decision to donate might be one of the last significant decisions that an individual is able to make during his or her life.

The notion that the deceased's body can proceed to do good after death might be underscored by powerful and genuinely held altruistic and normative beliefs.¹⁰⁵ However, no matter how strongly the prospective donor feels on the matter, those wishes must be submitted to the uncertainties of a potentially distraught surviving family and a highly cautious team of medical staff.

¹⁰⁵ Radecki and Jaccard, above n 76, at 185.

VI *Burial Law*

A *Law Commission Review*

In October 2013, the Law Commission released an Issues Paper that sought to investigate burial and cremation law in New Zealand.¹⁰⁶ A particular focus of the Law Commission's work was investigating how New Zealanders approached death and the dealings with human remains.

The Commission noted that burial and cremation regulation was a field that many people would be unfamiliar with until they were forced to confront it.¹⁰⁷ The same could be said for organ donation. Therefore, any attitudes that the Law Commission was able to glean regarding how New Zealanders approach the issue of death and, particularly, the wishes of the deceased are likely to be of value in the discussion of organ donation legislation.

In Part Four of the Law Commission's review, they addressed decision-making and disagreement regarding posthumous arrangements. While the Law Commission noted that the instinct of most people tasked with making such arrangements was to "do the right thing" by the deceased, precisely what that entailed was shaped by those persons' particular beliefs.¹⁰⁸ For some, the wishes of the deceased gave rise to a moral duty on the part of the bereaved to see to those wishes being effected, even when they conflicted with the beliefs of the person responsible for making the arrangements. For others, death was said to "[engage] much wider family and community interests and obligations than simply enacting the wishes of the deceased ... [the] dead must accommodate the needs of the living".¹⁰⁹

The Commission narrowed the issue down to the question: whatever the decision-making model adopted, ought the view of the deceased to be given more legal force? The tension created by this question was well encapsulated by the Commission when they stated:¹¹⁰

[A]s individuals we may feel we have a strong interest in being able to direct what happens to our bodies after death, but as members of bereaved families we may see merit in a more nuanced and collective approach to such decision making.

The default position in the context of burial disputes in New Zealand is that the executor of the deceased's estate has the right to determine the final arrangements. This common law "executor

¹⁰⁶ Law Commission, above n 75. This was the second Issues Paper in the Commission's review.

¹⁰⁷ At 5.

¹⁰⁸ At 1.53.

¹⁰⁹ At 16.

¹¹⁰ At 1.61.

rule” was affirmed by a majority of the New Zealand Supreme Court in *Takamore v Clarke*.¹¹¹ The executor is required to take into account the “customary, cultural and religious practices” of the deceased and their family, but there is no obligation of consultation.¹¹² The Law Commission noted that the executor rule is inconsistent with the tenets of tikanga Māori, which see arrangements concerning the deceased’s body as a community matter that requires robust discussion in a collective forum.¹¹³

An important element of the executor rule that the Law Commission highlighted is that the executor, in making the final decisions regarding arrangements, was required to take into consideration the wishes of the deceased, but was not legally bound to carry them out.¹¹⁴ This had been the case since the executor rule was established by the 1882 English decision of *Williams v Williams*.¹¹⁵

By contrast with the executor rule, the United States generally gives paramountcy to the wishes of the deceased, pursuant to a common law right of the deceased to have his or her testamentary wishes govern disposition of the body.¹¹⁶

The Commission noted that the deceased’s wishes do not have legally binding effect in New Zealand, and made a convincing case for statutory reform of New Zealand’s burial and cremation laws.¹¹⁷ In doing so, they distilled the central issue in these matters down to a relatively simple question: should the individual have control over the manner in which his or her body is treated following death? The Commission set out the arguments for and against such a proposition, which are of general relevance to the present organ donation discussion.

1 For paramountcy of deceased’s wishes

The case for individual paramountcy is that the right to control what becomes of one’s own body is an expression of the individual’s autonomy, a right widely recognised among the living in New Zealand’s legal system.¹¹⁸ It was argued that this was a modern attitude on death and

¹¹¹ *Takamore v Clarke* [2012] NZSC 116.

¹¹² At [156].

¹¹³ At 14.12.

¹¹⁴ At 14.33.

¹¹⁵ *Williams v Williams* [1882] 20 Ch D 629; Law Commission, above n 75, at 14.75.

¹¹⁶ Law Commission, above n 75, at 14.59-14.60.

¹¹⁷ At 15.26-15.28.

¹¹⁸ See Rosalind Atherton “Who owns your body?” (2003) 77 ALJ 178 at 184 as cited in Law Commission, above n 75, at 16.10.

dying that moved away from the traditional family focus. Interestingly, its application to burial law was said to have derived from principles surrounding donation of one's body.¹¹⁹

Upholding the autonomy of the individual required giving effect to his or her expressed wishes regarding disposition of their body. The ability to make autonomous posthumous choices regarding organ donation was said to lend weight to the notion that burial choices should likewise be honoured.¹²⁰ As we have seen, this is not the case for organ donation in New Zealand.¹²¹ However, the conceptual link drawn between organ donation wishes and burial and cremation choices confirms that fundamental issues of autonomy and interest underlie both contexts.

A link was also drawn to succession law. The Law Commission cited Daniel Sperling, who argued in *Posthumous Interests: Legal and Ethical Perspectives*:¹²²

If by enforcing a will what we care deeply about is respecting the decedent's wishes and autonomy, then it is not clear why this principle should be defeated in situations where the decedent's wishes are concerned with the disposal of her own body. On the contrary, it seems unambiguous that a person's body is one of the most precious things about which she cares, certainly more than her real property.

It was also noted that upholding the autonomy of the individual might be considered very important where the individual's religious or cultural beliefs conflict with those of their family.¹²³

The Law Commission also noted the discussion in *Takamore* that the European Convention on Human Rights protected the right to respect for private and family life and the right to freedom of thought, conscience and religion, which might lend some protection to the particular beliefs of the deceased.¹²⁴

Finally, the Law Commission pointed out that for some people, autonomy ought to end at death, and those people will be fine with delegating the decision surrounding arrangements to their

¹¹⁹ At 16.12.

¹²⁰ Law Commission, above n 75, at 16.12.

¹²¹ It should be noted that the Law Commission had proceeded on the basis that choices surrounding organ donation were legally binding in New Zealand. See Law Commission, above n 75, at 183, n 543. While the deceased's choices may be determinative in a dispute regarding the formal state of consent, they are stripped of any legal force by the practice of intensivists and the s 17 authority not to act provision discussed above.

¹²² Daniel Sperling *Posthumous Interests: Legal and Ethical Perspectives* (Cambridge University Press, New York, 2008) as cited in Law Commission, above n 75, at 16.13.

¹²³ At 16.14.

¹²⁴ At 16.15.

surviving family. This might well be the case in some instances. However, a positive decision to express one's wishes surrounding burial arrangements, or organ donation, would offer compelling evidence that that individual did not feel that way.

2 *For paramountcy of bereaved's wishes*

The interests that the surviving family have in determining the arrangements regarding the deceased were said to address the grief that the family experiences, provide closure, and help the bereaved readjust following their loss.¹²⁵ These arguably relate more intuitively to funereal or burial arrangements, which are per se a means for addressing the loss of the deceased. Therefore, it is unclear how applicable the points raised by the Law Commission are in the context of organ donation.

However, one point raised in the review which is of persuasive value was that family members who were compelled to uphold burial arrangements with which they were opposed might feel "inhibited in their grief" and have difficulty in finding closure.¹²⁶ Intuitively, this situation would also apply in the context of organ donation. It is certainly arguable that upholding the wishes of a donor against the wishes of the surviving family would negatively impact or exacerbate the grief the family is already experiencing at their loss.

3 *Statutory reform: the right to decide?*

The Law Commission considered whether the appropriate course was to adopt a statutory right of decision that would amount to an enforceable legal interest.¹²⁷

In a passage that can be analogised with the organ donation context, the Law Commission suggested that, given current practice, a statutory right of decision might be artificial. It was pointed out that, more often than not, families reached decisions regarding burial arrangements among themselves with little reference to the executor.¹²⁸ However, they did argue that, insofar as practice represented community values, any statutory reform ought reasonably to reflect that practice.

¹²⁵ See 16.17-16.21.

¹²⁶ At 16.21.

¹²⁷ At 16.27-16.40.

¹²⁸ At 16.30.

VII *Assessing the Conflicts*

A *The Ethics of Informed Consent*

The tension between the wishes of the deceased and the wishes of the surviving family is not endemic to New Zealand. In 1997, ethicist Eike-Henner Kluge published a short article on the state of organ donation laws in Canada.¹²⁹

Transplant societies had suggested that Canada reform their transplant laws to bring them in line with the French model of presumed consent. However, Kluge noted that “there [was] already a supply of organs available that [did] not require the establishment of a registry or a change in existing laws”.¹³⁰ Namely, those patients who had explicitly consented to donation. While the relevant organ donation legislation provided that consent gave full legal authority for the retrieval of organs, Kluge noted that “almost without exception [consent] of the donor’s next of kin [was] required”.¹³¹ He cited guidelines prepared by an organ retrieval program in Ontario that stated “[i]f the next of kin refuse consent for organ and/or tissue donation *their wishes must be respected*.”¹³² Kluge’s findings were not unusual. In fact, this approach appears to be standard in most jurisdictions where individual consent provides legal authority for the removal of organs.¹³³

Kluge took exception to the protocols. Not only did he consider them a waste of precious resources and a flouting of the organ donation laws, but he also argued that they “[raised] serious ethical issues”.¹³⁴ The transplant societies had argued that if they contravened the wishes of the family to collect organs, “they would be perceived as ghouls”.¹³⁵ In response, Kluge reiterated the issue and asked: “Is it the potential donor who has the right to decide what shall happen to her/his body, or is it someone else? Does informed consent count, or doesn’t it?”¹³⁶ He took a hard ethical line on the issue by concluding that “the [organ] shortage would not be as bad as it is if donated organs were in fact retrieved, if the wishes of potential donors were followed and if the ethics of informed consent were taken seriously.”¹³⁷

¹²⁹ Kluge, above n 101.

¹³⁰ At 160.

¹³¹ At 161.

¹³² At 161 (emphasis in original).

¹³³ See, for example, Radecki and Jaccard, above n 76, at 187.

¹³⁴ At 161.

¹³⁵ At 161.

¹³⁶ At 161.

¹³⁷ At 161.

While Kluge's analysis represents a firm view on the issue, his position can fairly be criticised as being rather unsympathetic to the medical specialists tasked with organ retrieval, if not out of touch with the reality of the situation. However, his argument is persuasive academically, and it will be argued that the questions he raised were not adequately addressed during New Zealand's reform process.

B The Reality of End-of-life Care

By way of contrast, in 2004, Stephen Streat, an intensivist in the critical care department at Auckland Hospital, presented a clinical review of the "moral assumptions" that underpinned organ donation within the ICU setting.¹³⁸ In the review, Dr Streat argued that a utilitarian rational moral perspective pervaded the existing literature. Within such a perspective, he argued that the assumption was that increasing organ donation rates was the goal and gaining the consent of the surviving family was to be regarded as a "success".

In short, he suggested that the posture of the organ donation system was pro-collection, deriving from a sense that society is morally obligated to increase donation and that prospective recipients have some form of entitlement to donated organs. This perspective in turn lent the foundation for arguments asserting a higher "moral authority" in the wishes of the deceased donor, as compared with the surviving family.

Streat challenged that assumption on the grounds that it was out of touch with the "interpersonal reality of the situation in which organ donation occurs".¹³⁹ He argued that it mistakenly places the focus on "the benefits that accrue to recipients of transplant organs", when it should be on the conversation that occurs between the recently bereaved and a health professional.¹⁴⁰

As mentioned above, intensivists see care of the family as inextricably linked to the care of the patient. Therefore, to Streat, a "morally neutral" stance that allows the focus to shift from maximising the donation rate to "facilitating an informed family decision about organ donation, based on a robust understanding of all the relevant issues", is how the process ought to be structured.¹⁴¹

Interestingly, Streat argued that benefits would accrue to the transplant community under his approach. He contended that, through an acceptance that donation occurred in a non-coercive

¹³⁸ Stephen Streat "Clinical review: Moral assumptions and the process of organ donation in the intensive care unit." (2004) 8(5) *Critical Care* 382.

¹³⁹ At 384.

¹⁴⁰ At 384.

¹⁴¹ At 386.

environment, donation rates would “accurately reflect” the level of societal support for the process. Although he acknowledged that a more coercive or “aggressively defended” system of honouring the wishes of the deceased might lead to higher rates of donation (by removing the decision and “sense of obligation” from the family), he argued that empirical data was needed to support any such theory.¹⁴²

Streat’s argument appears to take it for granted that the family’s wishes over the treatment of the deceased’s body should have primacy, or at least be on an equal footing. Doubtless, sympathy must be had for the situation that intensivists are put in when broaching the topic and managing an emotionally fraught situation. However, simply asserting that it is also the role of the intensivist to care for the family of the deceased fails to provide a convincing justification for subrogating the express wishes of a donor when they are known.

Streat argued that by approaching the discussion as “offering the option”, the intensivist was free to act as an “honest broker”. Accordingly, they could pursue “the integrity [and] excellence of process, neutral to the donation outcome and respecting the legitimacy of the family decision.”¹⁴³

It was seen above that during the reform of the Human Tissue Act, the provision according paramouncy to the wishes of the deceased was removed, and the provision that established an authority not to collect inserted, mainly in response to the intensivists’ clinical practice. Therefore, the informal agreement, or agreed practice, was validated by the legislature, even if not converted into a binding legal rule.

C Where Does That Leave Informed Consent?

While an individual is alive, they have a right of control over their body. This basic right has a range of expressions, many of which will attract the protection of the law.¹⁴⁴ That right will usually only be curtailed in exceptional circumstances. For present purposes, the most relevant expression is found in the concept of informed consent.

The patient’s informed consent is paramount while they are alive. As was discussed above, this concept was central to the Cartwright Inquiry and the resulting Code of Health and Disability Services Consumers’ Rights. The medical profession, and the law, are both to hand to assist in upholding informed consent. In the medical context, the protection afforded to the autonomy

¹⁴² At 386.

¹⁴³ At 386.

¹⁴⁴ The torts of assault, battery and false imprisonment are trite examples.

of the patient requires not only that services *not* be performed on patients without their informed consent, but also that such consent is sufficient to allow those services *to be* performed.

The distinction is important. In the regulation of organ donation, it illustrates how the principle of informed consent broke down before the logical end point. While the Human Tissue Act purported to place informed consent at the centre of the regulatory regime, it was heavily curtailed by the legislative endorsement of the intensivists' practice. The result is that the individual's consent is protected to the extent that an express wish not to donate will be upheld, but an express wish to donate will not.

If the regulatory objective was to enhance end of life care, understood as including the family of the deceased, a potential justification for contravening the informed consent of the donor arises. However, that debate simply was not had during the reform. As noted above, there were several competing regulatory objectives, and again it is asserted that failing to balance them obscured the essential issue of how informed consent should operate in the donation context.

D The Māori Cultural Objection

It is possible that the Māori Party's ideological objection was based on a misconception of the way the law would work in practice. Without the knowledge that the intensivists' practice would continue to demand family consent, upholding informed consent at the heart of the legislation might have appeared to threaten the collective interest the party spoke of.

Nevertheless, their view suffers from a more fundamental flaw. It assumes that upholding the individual's wishes is incompatible with tikanga Māori. However, it is not entirely clear that that follows. Even if individual consent was strictly upheld, it would only operate to the exclusion of the collective interest where the individual had made a positive decision for that to be so. In that respect, the individual rejects the collective interest, not the legislation.

While it is true that the legislation allows this, it is no different than the way informed consent is upheld while the individual is alive. If a Māori individual has an appendectomy, for example, the collective interest may feel that the appendix ought to be committed to the earth as whakapapa material. However, that decision rests with the individual. They are free to honour

tikanga practice, or to reject it. In that respect, the legislation is culturally neutral, and good practice dictates that the individual simply be given the opportunity to make that decision.¹⁴⁵

Accordingly, it is argued that the legislation is compatible with tikanga Māori, but only where the individual so decides, either formally (by entrusting the decision to his or her family), or informally (by expressing no wishes on the matter and thereby triggering the legislative decision-making hierarchy for the next-of-kin). The position sought by the Māori Party would not have restored an equality that was lacking. Rather, it would have formally elevated the collective interest above that of the individual.

Then Minister of Health, David Cunliffe MP, echoed these criticisms when he stated that he did not consider the Bill to be contrary to the Treaty of Waitangi. Mr Cunliffe continued:¹⁴⁶

The bill is, in my view, a permissive bill which establishes at a minimum the rights and responsibilities of the individual in respect of human tissue, but does not preclude the role of whānui in forming a collective decision that may influence the individual should that be appropriate.

Pete Hodgson had earlier argued along similar lines when he said he considered that the Bill did not “preclude” the tikanga that the Māori Party MPs had spoken of.¹⁴⁷

Clearly, the issue is of great significance to Māori, and there is no easy answer. However, that ought not logically to preclude upholding informed consent. It is up to Māori communities to determine the role of tikanga in donation practice. But it ought to be up to the individual to decide whether those views are shared.

E Decision-making Process

In 1997, Radecki and Jaccard published a review of the psychological aspects surrounding decisions to donate.¹⁴⁸ Significantly, the review examined “consent” decisions; viz. the decision of the family whether or not to consent to the collection of the deceased next of kin’s organs. This category of consent decisions was subdivided into those situations where the deceased’s attitude toward donation was known and those where it was not.

¹⁴⁵ See, for example, Canterbury District Health Board *Clinical Manual: Return of tissue/body parts to patients* (2011) at 6.

¹⁴⁶ At 13059.

¹⁴⁷ (14 November 2006) 635 NZPD 6476.

¹⁴⁸ Radecki and Jaccard, above n 76.

The research indicated that in the former, the decision of the family generally followed the wishes of the deceased.¹⁴⁹ However, it was noted that although individuals typically considered it important to discuss their views on organ donation with their families, it was a relatively rare occurrence in practice.¹⁵⁰

When the wishes of the deceased were not known, it was found that the consent decision depended on a complex interaction of variables, including the family's own views toward donation, their ability to cope with stress, their views toward the medical profession and, crucially, the perceived sensitivity of medical specialists.¹⁵¹ The authors noted that “[f]amilies need to sense that their feelings have been acknowledged, and that they have received all pertinent medical information in a simple and sensitive matter, and that they will be assured private time with the deceased.”¹⁵² The “[p]erceived support of medical staff” was seen as “pivotal” to the decision to consent. When placed within the emotionally charged context produced by death, this highly contingent situation lends support to the intuition that intensivists and other medical staff seeking to broach the topic of collecting organs from the deceased are faced with an extremely delicate task.

Alongside their own religious and cultural views, families were found to employ “attributional beliefs”, whereby the families used existing information such as the religious or altruistic beliefs of the deceased and his or her tendency to make provision for events that occurred after death, in order to determine the deceased's likely attitude toward donation.¹⁵³

The research illustrated the importance of undertaking family discussions. While 93% of respondents to a survey reported that they would follow the express wishes of a deceased next of kin, the number that would consent to organ collection dropped to less than 50% when the wishes of the deceased were not known.¹⁵⁴

F Taking Away the Decision

Very briefly, this section considers legislation where it has been deemed necessary, in the public interest, to make provision for the collection of human tissue without recourse to the

¹⁴⁹ At 187.

¹⁵⁰ At 189.

¹⁵¹ At 187-188.

¹⁵² At 188.

¹⁵³ At 187-188.

¹⁵⁴ At 189.

wishes of the surviving family. It is intended that this provide a contrast to the organ donation context in order to provoke consideration of two points.

The first is that there does not appear to be any principled distinction between the following legal regimes and organ donation that justifies a different approach. The second is that it is arguable whether the public interest in the following situations is greater than the therapeutic benefit of increasing available organs. It is submitted that, consistent with the above arguments regarding informed consent, this latter point is a fortiori when the individual has consented to donation.

1 Coroner's post-mortem

Under s 31 Coroners Act 2006, the coroner may direct that a post-mortem examination be performed for the reasons specified therein, having regard to the criteria set out in s 32. Under s 33, there is a right on the part of the surviving family “in some cases to object” to a post-mortem directed under s 31. This right to object only accrues in circumstances where the coroner is, after having made all reasonable enquiry, satisfied that the death does not appear to have been the result of a crime and that no international or domestic legal obligations require the post-mortem to be performed.¹⁵⁵

Furthermore, the right does not accrue at all if the coroner decides that the particular facts of the case warrant urgent examination of the body.¹⁵⁶ After the objection has been raised, the coroner may nevertheless direct that the post-mortem go ahead.¹⁵⁷ The decision nevertheless to proceed can be challenged in the High Court within 48 hours by originating application.¹⁵⁸ Given that the right to object does not accrue in cases of urgency, it follows that in such circumstances, a High Court review of the decision would not be available at all.

2 Criminal justice procedure

Section 20 of the Human Tissue Act provides that informed consent is not required for the collection of human tissue in a range of situations.¹⁵⁹ These include when the tissue is collected for criminal justice purposes;¹⁶⁰ in order to implement an order of the Court;¹⁶¹ for the

¹⁵⁵ Coroners Act 2006, s 33(2)-(3).

¹⁵⁶ Section 33(1).

¹⁵⁷ Section 34(2).

¹⁵⁸ Section 34(3)-(5), s 35.

¹⁵⁹ See also the Criminal Investigations (Bodily Samples) Act 1995 and the Criminal Investigations (Bodily Samples) Amendment Act 2003.

¹⁶⁰ Section 20(a).

¹⁶¹ Section 20(b).

performance of a post-mortem;¹⁶² for purposes of research approved by an ethics committee;¹⁶³ or for reasons of public health and safety.¹⁶⁴

VIII *Smarter Regulation*

A *The Essential Elements*

In the context of environmental regulation, Neil Gunningham and Peter Grabosky have attempted to synthesise key theoretical and pragmatic concepts in regulation in order to investigate how to arrive at an “optimal” mix of policy instruments.¹⁶⁵ The authors stressed that the focus should be on the interrelationship of different regulatory approaches, and how different combinations of instruments affect the pursuit of regulatory objectives in various contexts.¹⁶⁶

They pointed out that regulatory solutions have often evolved in response to specific problems, rather than as part of a coherent, integrated system. As such, there was a tendency on the part of “policymakers [to fall] into the trap of simply adding a new instrument to their arsenal of weapons without giving sufficient thought to how this will impact on their overall regulatory strategy.”¹⁶⁷

The authors argued that, as well as the tendency to develop regulation in an “ad-hoc” manner, policymakers often viewed regulatory instruments as alternatives to one another.¹⁶⁸ They argued that:¹⁶⁹

[A] better strategy [would] seek to harness the strengths of individual mechanisms while compensating for their weaknesses by the use of additional and complementary instruments...In the large majority of circumstances (though certainly not all), a mix of instruments is required, tailored to specific policy goals.

In the context of environmental regulation, it was said that:

¹⁶² Section 20(d).

¹⁶³ Section 20(e). It should be noted that this provision explicitly states that such collection may proceed “even though the ethics committee knew that informed consent had not been, and would not be, obtained for the research.”

¹⁶⁴ Section 20(g).

¹⁶⁵ N Gunningham and P Grabosky “Smart Regulation” in Morgan and Yeung (eds), above n 92, at 124.

¹⁶⁶ At 125.

¹⁶⁷ At 126.

¹⁶⁸ At 126.

¹⁶⁹ At 126.

What is needed...is not simply the introduction of a broad range of policy instruments, but the matching of instruments with the imperatives of [the issue] being addressed, with the availability of different regulatory actors, and with the intrinsic qualities of each other.

Gunningham and Grabosky set out three components that they believed were essential to smarter regulatory design. First, they introduced “regulatory design processes”, whereby policymakers are required to identify the regulatory objectives, characterise the “problem”, canvass the available options, and deal with issues of participation and consultation.¹⁷⁰

Secondly, they identified a set of regulatory principles that must underpin successful regulatory design. The most relevant of these for present purposes were favouring complementary mechanisms over “single instrument approaches”, reducing interventionist measures, empowering “surrogate regulators” to allow redeployment of government resources and maximising the “opportunities for win-win outcomes”.¹⁷¹

Thirdly, the authors encouraged emphasis on addressing how the available regulatory instruments will work in combination with one another.

B Smarter Organ Donation Regulation

As was argued above, the reform involved a range of competing regulatory objectives. In terms of Gunningham and Grabosky’s “smarter design processes”, there were several deficiencies. First, as already discussed, the failure to acknowledge that the regulatory targets conflicted obstructed any meaningful discussion regarding how the objectives ought to be ranked or how to deal with the conflicting interests in the system. This meant it was unclear what the legislation was supposed to achieve. The regulatory “problem” was poorly characterised.

Early in the reform, the problem appeared to be that the individual’s wishes could be overridden, which was inconsistent with the principle of informed consent. This was seen to coincide with the problem of New Zealand’s poor rate of donation. However, by the end of the reform process, the regulatory problem was difficult to ascertain. It is submitted that this resulted from the failure to keep informed consent at the centre of the debate, as was urged by Jonathan Coleman MP during the Bill’s third reading.¹⁷²

If the regulatory problem was poorly characterised, arriving at the necessary response was always going to be problematic. This was confirmed by the modification of the legislation that

¹⁷⁰ At 127-128.

¹⁷¹ At 128.

¹⁷² See Section III above.

attempted to accommodate the competing positions. Quite apart from striking a balance, it simply reinstated the pre-reform position. Ironically, the Māori party's Supplementary Order Paper formally prioritising the rights of the surviving family was voted down 10 votes to 109, only for that position to be established de facto by the operation of the eventual Act.¹⁷³

Had the Government kept their sights on the informed consent issue, it would have forced a discussion of a range of issues. For example, the attitude of the intensivists would have come under greater scrutiny. Their approach rests on the assumption that society would disapprove of enforcing the wishes of the deceased against the wishes of the family. This may not be correct. If it was demonstrated not to be correct, the reform process would likely have taken a considerably different course. Given the inherent conflict in the intensivist's role, the obvious solution would have been to take the problematic organ donation conversation away from them in favour of a medical professional who was prepared to assert the interests of the donor. With the endorsement of the public, this might have been an acceptable solution.

The characterisation of the regulatory instruments in the donation setting also demonstrates the difficulty in arriving at the optimal regulatory solution. As was seen above, deceased organ donation engages a number of diverse instruments. If the discussion of informed consent allowed a line to be drawn in the sand, it would have dictated what weight ought to be accorded to each instrument, based on its appropriateness in securing the regulatory objective. In addition, the benefits and shortcomings of each instrument would have been able to be balanced in a cooperative way to further the regulatory objective.

Instead, the various instruments all met somewhere in the middle. For example, the command provisions that provided sanctions against the medical staff converged with the legislative endorsement of the intensivists' consensus practice in a manner that logically led to a more defensive position. The legislation threatened to punish them for getting it wrong, but expressly said they were justified in not proceeding at all.

C Participation and Awareness

An appropriate first step for addressing the informed consent issue would have been through increasing public participation. At times during the passage of the Bill, it appeared that a lack of clarity surrounding the expectations of the public paralysed the debate over whose wishes ought to be prioritised in the donation setting.

¹⁷³ (13 November 2007) 643 NZPD at 13059.

Public participation in a regulatory process secures legitimacy. It flows from the wider democratic concept that those who are affected by a decision-making process ought to be afforded the opportunity to participate in it.¹⁷⁴

In addition to assisting the resolution of the informed consent issue, Mark Bennett and Joel Colón-Ríos have argued that increased public participation secures more general benefits. These include: increasing accountability and assessing the regulator's decisions; providing educational benefits for the public and the regulators; increasing the quality of the outcomes; and upholding democratic justifications.¹⁷⁵

The educational benefits that derive from increased participation are especially relevant to the organ donation context. Issues of awareness are related to issues of participation. The fact that people were generally unaware of the ineffectiveness of the driver's licence system was an awareness issue. The fact that people might be unaware that their informed consent may be overridden by their surviving family is also an awareness issue. Bennett and Colón-Ríos argued that educational benefits have the effect of producing a more informed citizenry, who are better versed in their rights.¹⁷⁶ They also argued that:¹⁷⁷

If more people are allowed to participate in a decision-making process and if, by participating, they gain a “sophisticated technical and social understanding” of the relevant issues and of the ways different solutions might impact their own communities or different sectors of society, it is likely that the quality of the substantive outcomes will be improved.

Furthermore, they noted that:¹⁷⁸

By being exposed to the views of interested citizens and groups, it becomes easier for [the regulatory decision-makers] to explain the reasons behind policies which might at first sight appear unpopular to the electorate.

It is submitted that an increased emphasis on public participation might have helped to orientate the reform process. Part of the problem during the debate of the Bill was that the minority views of the Māori party and the National party were diametrically opposed. Public opinion pointing

¹⁷⁴ Mark Bennett and Joel Colón-Ríos “Public Participation and Regulation” in Susy Frankel (ed) *Learning from the Past Adapting to the Future: Regulatory Reform in New Zealand* (LexisNexis, 2011) 21 at 25.

¹⁷⁵ Bennett and Colón-Ríos, above n 174, at 28-37.

¹⁷⁶ Bennett and Colón-Ríos, above n 174, at 30.

¹⁷⁷ At 31.

¹⁷⁸ At 31.

one way or another might have shaken the debate free from this ideological stalemate and enabled the Government to take a definitive stance on the issue.

In keeping with the arguments above, it is submitted that this would have had positive flow on effects in the form of the legislation. Whether the legislation would have been vastly different is unclear. In principle, there seems to be no reason why informed consent should cease to operate at death. However, at the very least, forcing the issue into the spotlight and drawing on public participation would have ensured that whatever the eventual legislation, it would have resulted from a contested and representative value judgement, rather than a poorly executed reform process.

IX Looking Forward

A Statistics

As can be seen from the following table, the Human Tissue Act has not had a significant effect on the deceased donation rate:¹⁷⁹

Number of deceased organ donors in New Zealand

Year	Donors
2014	46
2013	36
2012	38
2011	38
2010	41
2009	43
2008	31
2007	38
2006	25
2005	29
2004	40
2003	40

Furthermore, a recent audit of deaths in the ICU in New Zealand identified issues in the relationship between deaths in the ICU and organ donation.¹⁸⁰ Between 2008 and 2012, the number of patients who died with severe brain damage while ventilated in ICU was 1,745. Of those deaths, organ donation was formally discussed in only 381 instances (20%).¹⁸¹

According to Dr James Judson, the data demonstrated that “[there was] unexplained variance [among ICUs] in mention of donation, discussion of donation, discussion with ODNZ [and] brain death testing.”¹⁸² Furthermore, the data also showed that “[there] must be missed opportunities for organ donation [within the population of ICU deaths]”.¹⁸³

¹⁷⁹ Organ Donation New Zealand “Number of deceased organ donors in New Zealand” (2015) Organ Donation New Zealand website <<http://www.donor.co.nz>>. It should be noted that decreases in serious road collisions and advances in management of critical care patients have likely reduced the pool of potential donors. Nevertheless, the statistics indicate that a substantial increase in donation rate has not been effected by the Human Tissue Act 2008.

¹⁸⁰ Organ Donation New Zealand *The ICU Death Audit* (25 November 2014).

¹⁸¹ Organ Donation New Zealand, above n 180, at 9.

¹⁸² Organ Donation New Zealand, above n 180, at 15.

¹⁸³ Organ Donation New Zealand, above n 180, at 15.

B NEAC Report

Earlier this year, the National Ethics Advisory Committee published a review of ethical issues surrounding the access to organ transplantation for waiting list patients.¹⁸⁴ Considering the significant impact that a donated organ has for a patient who requires one, and the severe shortage of organs for transplantation, the NEAC considered it “important to review the processes for determining who receives an organ and assess whether they were fair, transparent and robust.”¹⁸⁵

The NEAC’s report identified issues with “equity of access to living and deceased donor transplantation”, the “application of ethical principles to the processes for listing patients and allocating deceased donor organs”, and “deceased donor list numbers for kidney transplants”.¹⁸⁶

Specifically, the equity of access issue revealed that Māori and Pacific Island patients were less likely to receive a transplant than New Zealand European patients. It should be noted that the equity of access issue for ethnic minorities is not restricted to the New Zealand context.¹⁸⁷

Regarding the application of ethical principles to transplant decisions, the Committee stated that the key principles that ought to guide clinical decisions allocating scarce organs were the likely outcome, need and urgency, and equity.¹⁸⁸ However, issues were identified regarding how these principles were being applied in transplant decisions, and how they were balanced.¹⁸⁹ For example, it was unclear how a patient ought to be ranked if there was a good prospect of survival but the patient had not been on the waiting list for very long.¹⁹⁰ The Committee argued that “allocation decisions need to be ethically defensible, as deceased donor (and non-directed living donor) organs are a community-held resource.”¹⁹¹

Finally, the report identified a narrow ethical issue concerning the management of deceased donor list numbers.¹⁹² As at January 2015, there were 600 people on the waiting list for a kidney transplant. The Committee noted that around 170 patients were added to this list each year,

¹⁸⁴ National Ethics Advisory Committee *Ethical Issues Relating to Access to Organ Transplantation: NEAC Report to the Associate Minister of Health* (20 January 2015).

¹⁸⁵ At 2.

¹⁸⁶ At 3.

¹⁸⁷ See, for example, Dean M. Harris *Healthcare Law and Ethics* (3rd ed, Health Administration Press, Chicago, 2008) at 230.

¹⁸⁸ At 5.

¹⁸⁹ At 7-8.

¹⁹⁰ At 8.

¹⁹¹ At 8.

¹⁹² At 9-10.

whereas only 110 transplants were performed. By contrast, other countries such as Australia demonstrated a transplant rate that exceeded waiting list additions. The Committee noted that some patients on the waiting list in fact had a very poor prospect of receiving an organ, but would not be aware of this. Accordingly, it was suggested that the “false hope” given to such patients was a potential ethical issue.

The significance of the NEAC report is that it demonstrates that the shortage issue may be even more severe than it first appeared. If New Zealand’s regulation of deceased organ donation results in a system with sub-optimal collection rates, the need for transplantation processes to be ethically and clinically sound is even stronger.

C Financial Assistance for Live Donors Bill

In 2015, a bill was drawn from the ballot that purported to bolster the financial assistance given to live altruistic organ donors. The Bill was claimed to be a partial means of addressing New Zealand’s low rate of organ donation.¹⁹³

The Bill seeks to establish an ACC-style compensation scheme for live donors that will partially compensate foregone income during the donor’s convalescence. The Bill explicitly noted it was:

[N]ot intended that the support provided to donors be material enough such that ambivalent or financially straightened citizens might be motivated to donate when otherwise they would not... [Rather,] it eases the financial stress on those who will do so solely for altruistic reasons.

Therefore, it avoids the ethical minefield of providing financial consideration for donated organs.

Intuitively, an ACC-style system of compensation seems a reasonable way to counteract one hurdle that prospective donors face. As noted at the outset of this paper, the vast majority of patients on the waiting list for organs are in need of a kidney. The statistics of transplant operations in New Zealand also demonstrate that roughly the same number of kidneys proceed from live donors as deceased donors each year:

¹⁹³ In the Bill’s explanatory note it states “New Zealand has one of the lowest rates of organ donation in the Western World. There are a number of reasons for this, but one of them is the financial barrier to live donation. This Bill addresses that barrier.”

Number of transplant operations in New Zealand

Organs transplanted	2010	2011	2012	2013	2014
Hearts	11	11	12	9	17
Lungs	9	10	12	19	17
Livers (deceased donors)	35	36	29	31	38
Livers (living donors)	6	8	3	3	5
Pancreas	3	3	2	1	2
Kidneys (deceased donors)	50	61	54	55	67
Kidneys (living donors)	60	57	54	58	72

The policy initiative is obviously a valuable one, provided of course that it actually has the effect of boosting donation rates. However, research has called into question the efficacy of financial incentives in influencing individuals' decision to donate.¹⁹⁴ Given the explicit goal of raising donation rates, the merits of the proposed compensation scheme are almost entirely contingent on demonstrating that the financial hardship imposed on live donors is a significant reason for electing not to donate.

By contrast, as was argued forcefully by Kluge, there is already a potential pool of donors whose consent is obtained or obtainable, yet collection is being blocked through the way the system is structured.

The Government will need to be careful to avoid falling into the trap, warned against by Gunningham and Grabosky above, of simply bringing new regulatory tools into the mix without consideration of the bigger picture. The subsequent inclusion of a financial assistance regime for live donors runs the risk of being an addition of an ad-hoc instrument aimed at addressing a specific problem, without consideration of its impact on the overall regulatory strategy, save for an assumption that it will help.¹⁹⁵

Furthermore, setting up an ACC-style compensation scheme for live donors will require a significant financial investment from the State, and the question of whether those funds would be better employed in addressing the inherent issues in the regulation of deceased organ donation should certainly form part of the debate surrounding the proposed Bill.

¹⁹⁴ Radecki and Jaccard, above n 76, at 185.

¹⁹⁵ Above n 193.

X Conclusion

The Act made some useful improvements on the pre-2008 law. Cleaning up the consent provisions regarding who could consent on behalf of the deceased was a necessary step. It was noted that this was an extremely technical legislative task, and the resulting legislative hierarchy is fairly sound in that regard.¹⁹⁶ Furthermore, the driver licence registration system was in dire need of phasing out. It did not amount to informed consent, and the public was generally unaware of this, yet it was the generally accepted means of recording one's wishes. It was counterproductive.

However, what was lacking in the reform was a meaningful discussion of informed consent and its operation in the donation setting. It was taken for granted that the family had at least an equal interest in the disposition of the deceased's remains. That view did not rest on any real public participation justification. Rather, it resulted from a compromise reached by accommodating the professional views of intensivists and the clash of views represented most strongly by the National Party and the Māori Party.

The failure adequately to frame the regulatory objectives was related to this deficiency in the reform. Without clearly framing those targets, it was unclear which of the various regulatory instruments was most appropriate. As a result, several instruments were deployed, with little explicit consideration of what the consequences of their cooperation would be.

If public participation had made it clear that the expectation was for individual wishes to be upheld, a command-based reform regulating the intensivists was inappropriate. As was seen, they were adamant that their clinical practice would be unaffected by legislative direction.

With public sanction, it might have been considered appropriate to put in place a "grim reaper" of organs who was prepared to assert the interests of the deceased. If medical professionals are prepared to assert the authority of the coroner in the public interest, why not also for organ donation? Such an approach would at least be consistent with the principle of informed consent. Alternatively, a "softer" approach might have been called for.¹⁹⁷

¹⁹⁶ (13 November 2007) 643 NZPD 13053.

¹⁹⁷ In 2010, Jurgen De Wispelaere and Lindsay Stirton proposed an excellent alternative to the status quo for deceased organ donation. They did not attempt to divorce the view of the deceased's surviving family from the equation, but rather focussed on improving the process of engaging in the "consent" discussion. Their solution was to allow the donor to appoint a "designated second consentor" (DSC) who formally agrees to uphold the donor's decision after the donor's death. Under this system, the DSC, usually familiar to the surviving family, represents the interests of the donor. Not only does this provide a more constructive "deliberative space", but it

Similarly, if the interests of the potential donees had been elevated, a different course would have been appropriate. As was seen above, other legislation, and the Human Tissue Act itself, had made it clear that certain public interests could justify dispensing with the requirement for informed consent. A question that was not debated at all during the reform was whether the therapeutic benefit of increased organ collection was one of those public interests. The case for this argument could only have been a fortiori when the donor had consented as well. Again, public endorsement of such a view would have allowed the legislature to act boldly and put in place a law that actually broke new ground.

Instead, New Zealand was left with a compromise position that sidesteps the issue. It provides legislative endorsement of the intensivists practice to ascribe de facto paramountcy to the wishes of the surviving family. However, this is simply a reinstatement of the default position *not* to donate, which was flagged early on in the reform as a key issue. The wishes of the individual are thrown to the uncertainties of grief and the tact of the medical staff.

Without a convincing and principled justification, this is an unsatisfactory situation. If the Government wishes to make any real improvement on New Zealand's poor rate of donation, it must first ascertain whether a system that is postured against collection actually finds favour with the public. Aside from this, a decision that has the effect of subrogating the express wishes of the donor, wishes that might represent the last significant decision they were able to make in their life, must at least have a principled justification.

Lastly, it should be noted that these issues are only likely to become more pressing as the population and prevalence of end-stage renal and liver diseases continue to rise.

also relieves the medical professionals from their conflicted role. See: Jurgen De Wispelaere and Lindsay Stirton "Advance commitment: an alternative approach to the family veto problem in organ procurement" (2010) 36 J Med Ethics 180.

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