

# *Regulatory design strategies and enforcement approaches for research involving human embryos and cloning in Australia and the United Kingdom – time for a change*

Sonia Allan\*

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## *Abstract*

This paper examines regulatory design strategies and enforcement approaches in the context of the UK and Australia's regulation of research involving human embryos and cloning. The aim is to discuss current regulation in view of the impending review of the *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition of Human Reproductive Cloning Act 2002* (Cth). It is argued that the type of regulation used in relation to those who are licensed to research in Australia is unsuitable due to an over-emphasis on deterrence and the authoritarian approach taken by regulatory bureaucracies. The cost and efficiency of the current system is also questioned. The central thesis is that a co-regulatory system that combines the existing framework legislation with self-regulation should be adopted for licence holders. Such regulation of licence holders should include responsive regulatory strategies. 'Command and control' design strategies and deterrence approaches present in the current regulatory systems for breaches of legislation by non-licence holders and serious breaches by licence holders should be maintained.

## **I Introduction**

Subsequent to the first legislative review of the *Prohibition of Human Cloning Act 2002* (Cth) ('PHC Act') and the *Research Involving Human Embryos Act 2002* (Cth) ('RIHE Act'),<sup>1</sup> the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth) received Royal Assent on 12 December 2006. The resulting amendments to the RIHE Act and the PHC Act (now titled the *Prohibition of Human Cloning for Reproduction Act 2002* ('PHCR Act')) shifted previous boundaries about acceptable research involving human embryos by altering definitions and broadening the scope of activities permitted under the Acts. It is time for another review.<sup>2</sup> While the

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\* Senior Lecturer, School of Law, Deakin University; Senior Fellow, University of Melbourne. This article is based upon the author's PhD thesis. Thank you to all those who have read and commented on drafts. Particular thanks to my supervisors Professor Loane Skene and Associate Professor Christine Parker, the anonymous referees, and former colleagues at the School of Law, University of Adelaide who kindly read final drafts.

<sup>1</sup> PHC Act s 25(3) and s 47(3) of the RIHE Act required the review of the Acts after three years of their being enacted.

<sup>2</sup> *RIHE Act* s 47A; *PHC Act* s 25A.

focus of the original legislation and the last review was what to permit and/or prohibit in relation to the contentious ethical, moral and scientific issues of research involving human embryos and cloning, this paper argues that the next review should also focus upon the model of regulation adopted and how it can be improved.

This paper analyses the UK and Australian approaches to the regulation of research involving human embryos and cloning. The UK is discussed, as in 2002 Australia adopted a similar regulatory system to that which had been in place in the UK since 1990. The UK system has recently been subject to extensive review, which emphasised the need for better regulatory design strategies and enforcement approaches. It is helpful therefore to contrast the UK and Australia to evaluate whether the UK has made significant improvements to the older regulatory system, and whether Australia should follow suit. In conducting the examination, three different regulatory design strategies that may be adopted to regulate research involving human embryos and cloning—‘command and control’; ‘self regulation’; and ‘co-regulation’—are considered. In addition, the regulatory systems are evaluated in the context of Ayres and Braithwaite’s model for ‘responsive regulation’,<sup>3</sup> which is ‘a leading approach to describing and prescribing how regulatory enforcement action best promotes compliance’.<sup>4</sup> The paper argues that co-regulatory strategies that incorporate responsive regulation should be adopted in both the UK and Australia in relation to the regulation of licence holders.

Part II examines the regulatory systems in place in the UK and Australia and critiques the approaches the respective jurisdictions have taken. It highlights that both systems have lacked a satisfactory level of cooperative, persuasive and educative approaches, have been costly and overly bureaucratic, and that better regulation could be achieved.

Part III considers the recent shift in the UK to better regulatory design strategies and enforcement approaches. It highlights that while the ‘command and control’ model has been maintained, moves toward co-regulation and inclusion of many features of the Ayres and Braithwaite responsive regulation model have been made.<sup>5</sup> The aim is to reduce bureaucracy, increase efficiency and reduce costs.

Part IV argues that Australia should also modify its regulatory approach. It considers the shortfalls of the current system and the costs of regulation in relation to the small number of research institutes that are currently engaging in research involving human embryos in Australia. The central thesis is that a co-regulatory system should be adopted in relation to licensing and oversight which utilises cooperative, educative and persuasive enforcement approaches for regulating licensed research activities.

Part V contains recommendations for the use of a self-regulatory body in conjunction with the current legislative framework. In the alternative, how the current regulatory body could be modified better to reflect co-regulation is examined. The recommended system would differ from a purely responsive regulatory approach in that the top level ‘command and control’ design strategies and deterrence approaches present in the current regulatory

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<sup>3</sup> Ian Ayres and John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford University Press, 1992); John Braithwaite, *Restorative Justice and Responsive Regulation* (Oxford University Press, 2002).

<sup>4</sup> Vibeke Lehmann Nielsen and Christine Parker, ‘Testing Responsive Regulation in Regulatory Enforcement’ (2009) 3 *Regulation and Governance* 376.

<sup>5</sup> Ayres and Braithwaite, above n 3.

systems would be maintained for breaches of legislation by non-licence holders. Regulatory responses to serious breaches by licence holders would also not necessarily occur in a stepwise fashion.

It is concluded that the UK and Australia need to reduce the regulatory burden placed upon compliant licence holders and address the issue of how to reduce the costs of the regulatory systems that govern research involving human embryos and cloning. While the UK is achieving this, Australia still has some way to go.

## **II Regulatory design strategies and enforcement approaches adopted in the UK and Australia**

### **A *Background to the regulatory systems in the UK and Australia***

#### **1 *United Kingdom***

In 1982, the UK Government set up the Committee of Inquiry into human fertilisation and Embryology, under the chair of philosopher, Dame Mary Warnock ('Warnock Committee'). The committee's terms of reference were:

To consider recent and potential developments in medicine and science related to human fertilization and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications of their developments; and to make recommendations.<sup>6</sup>

The Warnock Committee published its report ('Warnock Report') in July 1984.<sup>7</sup> It recommended new legislation setting out legal limits on assisted reproduction and research involving human embryos and the setting up of a licensing authority.

The majority of the Warnock Committee took the view that although a human embryo had a special status entitling it to 'some protection in the law', it might still be used at its very earliest stages of development as a means to an end that was good for other humans.<sup>8</sup> There was strong support from the majority for the use of unused human embryos from IVF in research, and a slim majority favoured the generation of embryos for research purposes in extraordinary circumstances. However, this was coupled with a cautiousness that demanded research involving human embryos was conducted with oversight. The Warnock Committee recommended the establishment of a government licensing authority to oversee both clinical IVF and research involving human embryos. The objectives of a stricter regulatory regime were not to prevent research involving human embryos, but rather to allow it within certain parameters including those that satisfied the call for some level of 'respect'.

In March 1985, the Medical Research Council and Royal College of Obstetricians and Gynaecologists founded the Voluntary Licensing Authority for Human In Vitro Fertilisation

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<sup>6</sup> Ibid 4.

<sup>7</sup> Ibid.

<sup>8</sup> Ibid.

and Embryology (VLA)—an interim body established as a result of the view that the setting up of a statutory body would take some time.<sup>9</sup> The VLA carried out the licence inspections and issued licences to centres based on written applications to the VLA describing the particulars of the treatment services or research on embryos that such centres wished to undertake or were already providing. Six years after the Warnock report, virtually all of the Warnock Committee's recommendations were translated into the *Human Fertilisation and Embryology Act 1990* (UK) ('HFE Act'). The Bill received Royal Assent on 1 November 1990, and the Human Fertilisation and Embryology Authority (HFEA) was established.<sup>10</sup>

From 1991 to the present, official licensing authorities have reviewed all research proposals involving human embryos in the United Kingdom. They have also kept detailed records on the number of embryos used in research and published annual reports on approved projects.<sup>11</sup> While there have been a number of revisions and legal challenges to the HFE Act since its inception, the approach taken in the UK has been permissive and facilitative, allowing researchers to use human embryos subject to licensing conditions.

## 2 Australia

Prior to 2002, some states had legislation regulating assisted reproductive technology (ART) and associated research,<sup>12</sup> however other states and territories were regulated only by National Health and Medical Research Council (NHMRC) guidelines,<sup>13</sup> adherence to which might affect funding for projects, but was not required by law. Although there had been a number of reports and inquiries since the 1980s in relation to human cloning and research involving excess ART embryos<sup>14</sup>, there was no uniform regulation governing either. Following significant parliamentary debate and public consultation,<sup>15</sup> the RIHE Act and the PHC Act received Royal Assent on 22 December 2003, with a majority of provisions coming into force on 16 January 2003.<sup>16</sup> States and territories enacted empowering or mirror legislation in order to give full effect to the Commonwealth legislation countrywide.<sup>17</sup> The

<sup>9</sup> Science and Technology Select Committee, *Fifth Report*, House of Commons Paper No 7, Session 2004–05 (2005).

<sup>10</sup> HFEA took up its full statutory responsibilities in August 1991. *Human Fertilisation and Embryology Act 1990* (UK) s 5.

<sup>11</sup> See for example, Human Fertilisation and Embryology Authority, 'Research we have approved', (December 2010), <<http://www.hfea.gov.uk/166.html>> and Human Fertilisation and Embryology Authority, 'Publications on embryo research & new technologies' (December 2010), <<http://www.hfea.gov.uk/153.html>>.

<sup>12</sup> See the then *Reproductive Technology (Clinical Practices) Act 1988* (SA); *Infertility Treatment Act 1995* (Vic); *Human Reproductive Technology Act 1991* (WA).

<sup>13</sup> See the then National Health and Medical Research Council, *Statement on Human Embryo Experimentation* (1982); National Health and Medical Research Council, *Ethics in Medical Research Involving the Human Foetus and Human Foetal Tissue* (1983).

<sup>14</sup> See, e.g., Senate Select Committee on the Human Embryo Experimentation Bill 1985, Parliament of Australia, *Human Embryo Experimentation in Australia* (1986); Committee to Consider the Social Ethical and Legal Issues Arising from In Vitro Fertilisation, Parliament of Victoria, *Report on the Disposition of Embryos Produced by In Vitro Fertilization* (1984); Special Committee, Queensland Government, *Report of the Special Committee by the Appointed Queensland Government to Inquire into the Laws Relating to Artificial Insemination, In Vitro Fertilization and Other Related Matters* (1984).

<sup>15</sup> See, e.g., Senate Community Affairs Legislation Committee, Parliament of Australia, *Provisions of the Research Involving Human Embryos and Prohibition of Human Cloning Bill 2002* (2002).

<sup>16</sup> RIHE Act (Cth) s 2; PHC Act (Cth) s 2.

<sup>17</sup> *Human Embryo (Research) Act 2004* (ACT); *Human Cloning (Prohibition) Act 2004* (ACT); *Research Involving Human Embryos (New South Wales) Act 2003* (NSW); *Human Cloning for Reproduction and other Prohibited Practices Act 2003* (NSW); *Research Involving Human Embryos and Prohibition of Human*

Commonwealth Acts are discussed here, keeping in mind that the initial provisions of the state and territory acts mirrored such legislation. Problems to which this complex system may give rise are discussed below.

In terms of deciding *what* to regulate and *where* to draw the line, the RIHE Act (2002) was introduced to govern the use of ‘excess’ ART embryos by both publicly and privately funded researchers. An embryo was considered to be ‘excess’ if the embryo was created by ART, for use in the ART treatment of a woman and was excess to the needs of the woman for whom it was created and her spouse (if any) at the time the embryo was created.<sup>18</sup> Once an embryo was declared to be excess,<sup>19</sup> the RIHE Act allowed research on excess human embryos only by those people who were licensed unless a particular use fell under one of the exceptions in the legislation.<sup>20</sup>

The object of the PHC Act was to ‘address concerns, including ethical concerns, about scientific developments in relation to human reproduction and the utilisation of human embryos by prohibiting certain practices.’<sup>21</sup> In particular, the PHC Act expressly prohibited the creation of a human embryo clone for any purpose.<sup>22</sup> Other practices that were strictly prohibited are also set out in the Act.<sup>23</sup>

The implementation of such legislative prohibitions via the PHC Act therefore served to draw the line for permissible and prohibited research. While the PHC Act prohibited activities that were considered unacceptable for moral, ethical, or the level of risk reasons, the RIHE Act permitted activities provided certain criteria were met—including licensing.

## B *Regulatory design strategy*

Both the UK and Australia adopted a ‘command and control’ approach in regulating research involving human embryos and cloning. In both jurisdictions, influence is exercised by imposing standards backed by criminal sanctions. The force of the law is used to prohibit certain activities, to demand some sort of positive action, and to prescribe conditions for entry into conducting research involving human embryos via a licensing system. In both jurisdictions, regulatory bureaucracies—the UK HFEA, and the Australian NHMRC Licensing Committee—have been established to enforce the command and control

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*Cloning Act 2003* (Qld); *Research Involving Human Embryos Act 2003* (SA); *Prohibition of Human Cloning Act 2003* (SA); *Human Embryonic Research Regulation Act 2003* (Tas); *Human Cloning and Other Prohibited Practices Act 2003* (Tas); *Health Legislation (Research Involving Human Embryos and Prohibition of Human Cloning) Act 2003* (Vic); *Human Reproductive Technology Amendment Act 2004* (WA). The Northern Territory government follows South Australian legislation.

<sup>18</sup> RIHE Act s 9.

<sup>19</sup> Pursuant to consent provisions in the Act: See *Research Involving Human Embryos Act 2002* (Cth) s 24 (1)(a)–(b).

<sup>20</sup> RIHE Act s 10(1)(b), (2) (which lists the exceptions).

<sup>21</sup> PHC Act s 3.

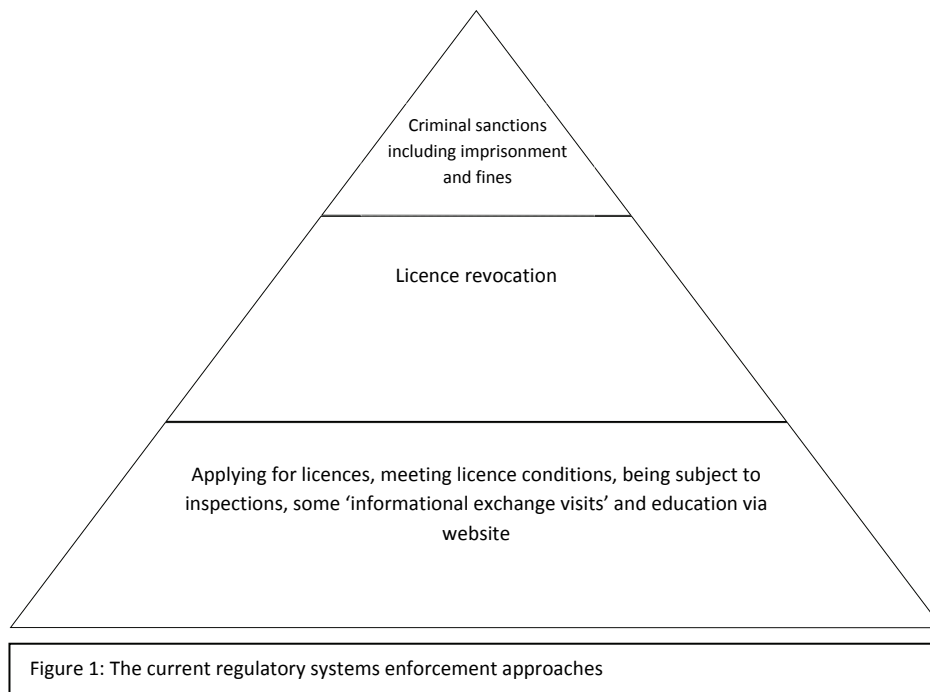
<sup>22</sup> *Ibid* s 9.

<sup>23</sup> These include creating a human embryo other than by fertilisation, or developing such an embryo; creating a human embryo for a purpose other than achieving pregnancy in a woman; creating or developing a human embryo containing genetic material provided by more than two persons; developing a human embryo outside the body of a woman for more than 14 days; using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo; heritable alterations to genome; collecting a viable human embryo from the body of a woman; and creating a chimeric or hybrid embryo: *ibid* ss 13–20.

approach.<sup>24</sup> The licensing process operates to screen entry into certain activities, and also to set out such things as expected standards, the manner of conducting the activity (for example, in making decisions about how many embryos may be used), and to oversee and carry out inspections of the licensed facilities. The UK HFEA is also granted some rule/decision making power via its publication of a code of practice.

### C *Enforcement approach adopted*

Both the UK and Australia's enforcement approaches emphasise the detection of breaches, by way of regular inspections, oversight of licence holders, and penalising offenders. The significance of penalties of up to 10–15 years imprisonment for either licence holders or others who breach the Acts may also *theoretically* place the rational actor in a position in which she or he would decide against the commission of an offence due to costs outweighing benefits. If the enforcement approaches of both jurisdictions are conceptualised in a pyramid, a hierarchy of penalties and regulatory requirements becomes evident. This is illustrated in Figure 1:



At the tip of the pyramid, criminal sanctions are found in relation to prohibited activities or operating without a licence in both jurisdictions. For those who are licensed there are also

<sup>24</sup> HFEA took up its full statutory responsibilities in August 1991. *Human Fertilisation and Embryology Act 1990* (UK) c 37, s 5; RIHE Act s 13 (see also s 16 for the details of the persons who make up the NHMRC Licensing Committee).

other options. Nonetheless, even for licence holders, it is a narrow pyramid lacking lower level enforcement approaches that would reflect a more responsive regulatory model.<sup>25</sup> Cooperative, responsive and educative approaches are largely missing or represented only to a small degree—with respect to the licensing and monitoring regimes—at the base of the pyramid.

Although the Australian Lockhart Committee Report said that ‘the monitoring and compliance framework used by the inspectors is based on a model of “cooperative compliance”, which encourages licence holders and others affected by the legislation to cooperate with the NHMRC to comply with the legislation’,<sup>26</sup> Australia’s greater emphasis on deterrence can be seen when considering its monitoring system closely. There are few instances in which the monitoring/inspection system seems to engage in a ‘dialogue’ (that is, a two-way exchange) with those being regulated. The first is to arrange an inspection (although noting that the inspectorate might decide to conduct an inspection unannounced—a threat and deterrent against wrongful behaviour at any time). The second is that before or during an inspection, ‘licence holders may request advice from the inspectors’.<sup>27</sup> The inspectors may also under the direction of the Chair of the Licensing Committee, provide formal verbal or written advice to bring issues or breaches to the attention of the licence holder. However, this is not dialogue. Similarly the Licensing Committee releases information on compliance and the operation of the regulatory system on the NHMRC website such as information kits, and reports. Such tools do serve a communicative and educative purpose, which in turn do at least *theoretically* assist with compliance. But again, this is not dialogue or cooperation. Rather it is one-way communication.

The most cooperative aspect of the NHMRC Licensing Committee oversight is that it engages in ‘information exchange visits’ ‘in order to strengthen cooperative compliance of organisations and persons affected by the legislation through an increased awareness of legislative requirements.’<sup>28</sup> They also prefer to conduct such visits to unlicensed premises rather than formal inspections, and ‘through these visits, NHMRC inspectors gain valuable information regarding relevant activities undertaken by organisations.’<sup>29</sup> In addition, ‘inspectors provide information to assist organisations in the establishment of appropriate protocols that ensure compliance with the legislation’.<sup>30</sup> Still, the level of two-way communication seems minimal.

In the UK some cooperative, persuasive and/or educative activities also occur at the base of the pyramid. The licensing and monitoring system is implemented in much the same way as that in Australia. The HFEA, however, has additional powers in relation to its publication of a Code of Practice, which contains, amongst other relevant things, guidelines that provide further information concerning the manner in which licensable activities are to be carried out and the functions and responsibilities of licensees. They have also, since 2004, employed a ‘horizon scanning panel’ which serves as an early warning system to identify

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<sup>25</sup> Ayres and Braithwaite, above n 3, 39.

<sup>26</sup> Legislation Review Committee, Parliament of Australia, *Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002*, (2005) 111.

<sup>27</sup> Ibid.

<sup>28</sup> National Health and Medical Research Council, *NHMRC Embryo Research Licensing Committee Report to the Parliament of Australia: For the Period 1 April to 30 September 2004* (2004) 11

<sup>29</sup> National Health and Medical Research Council, *NHMRC Licensing Committee Report to the Parliament of Australia: For the Period 1 October 2003 to 31 March 2004* (2004) 15.

<sup>30</sup> Ibid.

new developments that may impact on the field of ART or embryo research.<sup>31</sup> The HFEA draws from issues identified in journal articles, conferences and/or suggestions and advice from international experts in the field of ART and embryo research via internet communication, questionnaires and a meeting once a year.<sup>32</sup> The Horizon Scanning activities therefore involve greater use of two-way communication than found in Australia.

### D *Evaluating the UK and Australia's systems in the context of responsive regulation*

Looking at each of the regulatory systems and enforcement approaches adopted, it is apparent that neither approach fits Ayres and Braithwaite's model of 'responsive regulation'.<sup>33</sup> In relation to sanctions, both systems contain deterrence and incapacitation mechanisms that, in addition to restorative justice, Braithwaite contends should all be included in a responsive regulatory scheme.<sup>34</sup> To some extent these mechanisms are ordered hierarchically in the respective regimes. The broadest form of mechanisms and interactions (licensing and monitoring) between the regulators and regulatees occur at the base of the regulation pyramid. Sanctions which would incapacitate are at the top. However, deterrence approaches to prevent researchers from committing offences by way of the threat of imprisonment; pecuniary penalties; and/or licence revocation, are employed extensively. The regulatory system lacks proven options for securing compliance such as base level responsive enforcement mechanisms, as set out in Ayres' and Braithwaite's ideal pyramid.<sup>35</sup>

The regulatory regimes also do not provide for a system in which one would move up the pyramid always starting at the base. While to some extent more cooperative strategies are deployed at the base of the pyramid and progressively more punitive approaches may be utilised, neither jurisdiction's regulatory system encapsulates the notion that regulators should start with the presumption of being cooperative '*however serious the crime*'.<sup>36</sup>

However, in some instances, such as where strict prohibitions exist, or where people are operating outside of the licensing system, having a dynamic model would not work. Some breaches *should* be dealt with immediately at the top of the pyramid—for example, attempting human reproductive cloning. In recognising that neither the UK's nor Australia's regulatory system fits Braithwaite's model of 'responsive regulation' perfectly, it is not suggested that the strict prohibitions that have been decided upon through extensive consultation and review processes be ignored or removed. Even Braithwaite recognises that, when there are 'compelling reasons to do so', it might be appropriate to abandon the presumption of starting at the base of the pyramid.<sup>37</sup>

The problem with the systems in the UK and Australia is not that they have oversight bodies or impose criminal sanctions, rather it lies in relation to those who willingly subject themselves to the licensing system and who wish to work within the regulatory framework

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<sup>31</sup> Human Fertilisation and Embryology Authority, 'Horizon Scanning Panel', (10 April 2009) <<http://www.hfea.gov.uk/1132.html>>.

<sup>32</sup> Ibid.

<sup>33</sup> Ayres and Braithwaite, above n 3.

<sup>34</sup> Braithwaite, above n 3.

<sup>35</sup> Ayres and Braithwaite, above n 3.

<sup>36</sup> Braithwaite, above n 3, 30 (emphasis added).

<sup>37</sup> Ibid 30.



to conduct research involving human embryos and cloning. In particular, the regulatory design strategies and enforcement approaches may have a big impact on their acceptance of the regulatory system, and subsequently on compliance. It is to a consideration of the regulatory systems and how they could be improved in relation to *licensing and monitoring activities* that the discussion now turns.

### III The UK: a shift in regulatory approach but not design strategy

#### A *Better regulation: improving efficiency, cutting bureaucracy*

In 2004, the UK Department of Health undertook a review of its ‘arm’s length bodies’ (‘the Arm’s Length Review’) in an effort to improve efficiency and cut bureaucracy.<sup>38</sup> In addition to the Arm’s Length Review, a review of the 1990 HFE Act in early 2004, extensive public consultation in 2005, the publication of a White Paper in December 2006,<sup>39</sup> and a Joint Committee of both Houses established to consider the Human Tissue and Embryos (Draft) Bill 2007 (UK), led to the recognition of ‘the lack of research undertaken as to the workings of the current regulatory structure, and improvements that could be made’.<sup>40</sup> ‘[G]reater savings, consistency, efficiency and co-operation ... within and between’ the HFEA and the Human Tissue Authority (HTA) was called for, as was support for a ‘lighter touch’ approach to regulation.<sup>41</sup>

Policy proposals from the 2006 White Paper<sup>42</sup> were given form in the *Human Fertilisation and Embryology Act 2008* (UK) c 22.<sup>43</sup> The purpose of this Act was to ‘amend the law relating to [ART] and embryo research’.<sup>44</sup> The UK government supported the move towards lighter touch regulation. Section 8ZA of the revised HFE Act requires the HFEA to carry out its functions effectively, efficiently and economically and with regard to the principles of best regulatory practice.<sup>45</sup> This is also underpinned by the UK Government’s ‘Better Regulation’ agenda, which builds on the recommendations of two major policy reviews—the Hampton Review of regulation and inspection<sup>46</sup> and the Better Regulation Taskforce report *Less is More*.<sup>47</sup> The Hampton Review set out a vision of regulatory systems

<sup>38</sup> Department of Health (UK), *Reconfiguring the Department of Health's Arm's Length Bodies*, (2004).

<sup>39</sup> Department of Health (UK), *Review of the Human Fertilisation and Embryology Act: Proposals for Revised Legislation (Including Establishment of the Regulatory Authority for Tissue and Embryos)*, (2006).

<sup>40</sup> House of Lords and House of Commons, *Joint Committee on the Human Tissue and Embryos (Draft) Bill*, House of Lords Paper No 169, House of Commons Paper No 630, Session 2006–2007, (2007) 77.

<sup>41</sup> *Ibid* 33.

<sup>42</sup> As updated following the pre-legislative scrutiny by the Joint Committee and the government’s response to this scrutiny Department of Health (UK). See *Government Response to the Report from the Joint Committee on the Human Tissue and Embryos (Draft) Bill* (2007) 5.

<sup>43</sup> The new legislation received Royal Assent on 13 November 2008.

<sup>44</sup> *Human Fertilisation and Embryology Act 2008* (UK) c 22, Part 1.

<sup>45</sup> *Human Fertilisation and Embryology Act 1990* (UK) s 8ZA(1).

<sup>46</sup> Philip Hampton, Treasury, *Reducing Administrative Burdens: Effective Inspection and Enforcement* (2005).

<sup>47</sup> Better Regulation Task Force, *Regulation—Less is More: Reducing Burdens Improving Outcomes: A BRTF Report to the Prime Minister* (2005).

based around risk and proportionality.<sup>48</sup> The *Less is More* report concluded that the regulatory burden on business could be considerably reduced by decreasing administrative costs, prioritising new regulations, and simplifying and removing existing regulations.<sup>49</sup>

While the main features of the command and control regulatory model were retained by continuing with framework legislation and a regulatory body, additional provisions were implemented which reflected an increased emphasis on a cooperative, persuasive and educative approach. The amendments to the HFE Act also required the HFEA to ‘have regard to the principles of best regulatory practice including that regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed’.<sup>50</sup> Such provisions moved away from over-regulation and created opportunities to reduce costs.

The changes in regulating research involving human embryos and cloning were reinforced by two other extraneous requirements: the *Regulators’ Compliance Code* and the *Regulatory Enforcement and Sanctions Act 2008* (UK) c 13 (‘the better regulation requirements’). These created statutory requirements regarding how regulators in the UK must regulate, and therefore impacted upon the regulation of research involving human embryos and cloning.

### 1 *The Regulators’ Compliance Code*

Since 6 April 2008, UK regulators, including the HFEA, must have regard to the provisions of the *Regulators’ Compliance Code* (‘the Code’)—a statutory code of practice intended to encourage regulators to achieve their objectives in a way that minimises the burdens on business.<sup>51</sup> The Code applies when regulators determine their general policies or principles about how they exercise their regulatory functions, set standards or give general guidance. It does *not* apply at the regulatory decision-making level including individual enforcement decisions. The Code is based on the seven principles of inspection and enforcement identified in the Hampton Report.<sup>52</sup>

1. comprehensive risk assessment should be the foundation of all regulators’ enforcement programs;
2. there should be no inspections without a reason, and data requirements for less risky businesses should be lower than for riskier businesses;
3. resources released from unnecessary inspections should be redirected towards advice to improve compliance;
4. there should be fewer, simpler forms;
5. data requirements, including the design of forms, should be coordinated across regulators;
6. when new regulations are being devised, departments should plan to ensure enforcement can be as efficient as possible; and
7. 31 national regulators should be reduced to seven more thematic bodies.<sup>53</sup>

<sup>48</sup> Ayres and Braithwaite, above n 3.

<sup>49</sup> Better Regulation Task Force, above n 47, 3.

<sup>50</sup> *Human Fertilisation and Embryology Act 1990* (UK) s 8ZA(2).

<sup>51</sup> Department for Business Enterprise and Regulatory Reform, *Regulators’ Compliance Code: Statutory Code of Practice for Regulators* (2007) 7.

<sup>52</sup> Hampton, above n 46.

<sup>53</sup> *Ibid* 2.

The purpose of the Code is to embed a risk-based, proportionate, targeted and flexible approach to regulatory inspection and enforcement among the regulators to which it applies. It does not dismantle the ‘command and control’ structure, but is aimed at ensuring that ‘regulators are efficient and effective in their work, without imposing unnecessary burdens on the parties they regulate’<sup>54</sup> within that structure.

## 2 *The Regulatory Enforcement and Sanctions Act 2008 (UK)*

The *Regulatory Enforcement and Sanctions Act 2008 (UK)* c 13 (‘RES Act’) governs the operation of a large number of government regulators, including the HFEA. Guidelines to the RES Act state it was introduced as a result of regular complaints from businesses, frontline public and third sector workers ‘about the time they spend on regulation and the many ways in which they find rules frustrating’.<sup>55</sup> To address these concerns, the UK government stated it was ‘committed to pursuing a programme of ambitious and wide-ranging regulatory reform’.<sup>56</sup> ‘Key to this is regulating only when necessary and doing so in a light-touch way that is proportionate to the risk; setting exacting targets for reducing the cost of administering regulation; rationalising inspection and enforcement arrangements; and supporting compliance including tackling businesses that deliberately or consistently flout their regulatory responsibilities’.<sup>57</sup>

Part Three of the RES Act provides a framework of administrative sanctions that will allow regulators to tackle non-compliance in ways that are transparent, flexible, and proportionate to the offence.<sup>58</sup> Part Four of the RES Act places a duty on specified regulators to review the burdens they impose, reduce any that are unnecessary and unjustifiable, and report on their progress annually.

### B *Better regulation: the HFEA response*

In 2008, the HFEA announced a comprehensive review of its organisational functions in a program of work called ‘Programme 2010’.<sup>59</sup> They recognised that the changes to the HFE Act gave rise to the need to implement changes to their functioning and their obligation to respond to better regulation initiatives. Programme 2010 involved consultation with clinics and other stakeholders to ensure the organisation’s future ways of working were as efficient and effective as possible.<sup>60</sup> In undertaking their review, the HFEA stated the main points of focus for regulatory improvements were the publication of the eighth edition of the HFEA Code of Practice and related improvements to their inspection, licensing and processes.<sup>61</sup>

<sup>54</sup> The code refers to ‘regulated entities’ which includes businesses, public sector bodies, charities and voluntary sector organisations that are subject to regulation.

<sup>55</sup> Better Regulation Executive, *Regulatory Enforcement and Sanctions Act 2008: Guidance to the Act* (2008) 5.

<sup>56</sup> Ibid.

<sup>57</sup> Ibid.

<sup>58</sup> Noting that pts 1 and 2 of the *Regulatory Enforcement and Sanctions Act 2008 (UK)* c 13 relate to local authorities and do not concern HFEA, pt 3 gives regulators listed in sch 5 to the Act (including the HFEA) an ‘extended tool kit of alternative civil sanctions as a more proportionate and flexible response to cases of regulatory non-compliance normally dealt with in the criminal courts.’

<sup>59</sup> Human Fertilisation and Embryology Authority, *Annual Report and Accounts 2007/08*, (2008) 9.

<sup>60</sup> Human Fertilisation and Embryology Authority, *The HFEA Improvement Programme*, <<http://www.hfea.gov.uk>> 12 April 2009.

<sup>61</sup> Ibid.

### C *The eighth edition of the HFEA Code of Practice*

The HFEA's objective in drafting their eighth edition of the HFEA Code of Practice was 'to improve the effectiveness and usability of the Code of Practice ... to comply with the new requirements of Human Fertilisation and Embryology legislation'.<sup>62</sup> They identified the key to the new regulatory approach was helping and encouraging licensed centres to understand and meet regulatory requirements more easily; better differentiating between requirements and guidance; removing unnecessary guidance and reducing complexity; and introducing greater consistency and alignment to the inspection process.<sup>63</sup>

### D *'Decreasing the Burden' of licensing and inspection processes*

In their 2007/08 Annual Report, the HFEA stated there had been 'further streamlining of the licensing process for research and treatment through the introduction of risk-based inspection, using a revised risk assessment tool'.<sup>64</sup> This equates to a move toward a regulatory approach that responds to risks associated with research and practice in an appropriate manner. This move was confirmed in a speech given by the Interim Chief Executive of the HFEA, Alan Doran, who outlined 'where the HFEA were heading' in relation to inspection.<sup>65</sup> He stated the HFEA 'should inspect to the degree and at the frequency indicated by three factors: hard edged risk assessment, statistical analysis or serious adverse incidents, and licensing requirements'.<sup>66</sup> Most importantly, he emphasised 'a shift towards self-assessment and a presumption that centres wish to show compliance rather than that it is the HFEA's role to find failure'.<sup>67</sup> This reflects the recommendations made in the Hampton Report and the subsequent 'better regulation requirements'.<sup>68</sup> It also accords with the arguments presented here that a cooperative, persuasive and educative approach in the first instance would be better than one in which the HFEA adopts strict authoritarian and 'deterrent' approaches from the beginning and goes looking for 'baddies'. The 2008/2009 Annual Report affirms that all of this work continued into that business year.<sup>69</sup>

The Hampton Report drew upon Ayres' and Braithwaite's theories,<sup>70</sup> recognising that 'regulatory compliance was best secured by persuasion in the first instance, with inspection, enforcement notices and penalties being used for more risky businesses further up the pyramid'.<sup>71</sup> Subsequently, in the UK, any large-scale random inspections of the past have been replaced by more targeted intervention.<sup>72</sup> With these developments 'has come a general

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<sup>62</sup> Ibid.

<sup>63</sup> Ibid.

<sup>64</sup> Human Fertilisation and Embryology Authority, *Annual Report and Accounts 2007/08* (2008) 10–11.

<sup>65</sup> Alan Doran, 'Inspections—Where are we Heading?' (Speech delivered at BFS Summer College, Liverpool, 2–5 September 2008).

<sup>66</sup> Ibid.

<sup>67</sup> Ibid.

<sup>68</sup> Department for Business Enterprise and Regulatory Reform (UK), *Regulators Compliance Code: Statutory Code of Practice for Regulators* (2007) 7; *Regulatory Enforcement and Sanctions Act 2008* (UK) c 13.

<sup>69</sup> Human Fertilisation and Embryology Authority, *Annual Report and Accounts 2008/09* (2009).

<sup>70</sup> Ayres and Braithwaite, above n 3, 39; in Hampton, above n 46, 27.

<sup>71</sup> Hampton, above n 46, 27.

<sup>72</sup> Ibid.

acceptance among business and regulators that inspections are an inefficient enforcement mechanism in lower-risk or high-performing businesses, and that risk assessments should inform the work programmes of inspectorates.<sup>73</sup>

### E *Improving the use of Regulatory Sanctions*

Integral to adopting a ‘responsive regulatory approach’ and increasing cooperative, persuasive and educative approaches are the type of sanctions used in relation to enforcement. The HFEA indicated that preparatory work had begun relating to the potential future increase in regulatory powers arising from the RES Act and further work planned for 2010–11.<sup>74</sup> In doing this the HFEA was responding to the UK Government’s position that ‘regulators should have access to effective sanctions that are flexible and proportionate and that ensure the protection of workers, consumers and the environment when tackling non-compliance by businesses.’<sup>75</sup> This position is based upon the acceptance in full of recommendations made in the 2006 Macrory Report,<sup>76</sup> which looked at the effectiveness of existing sanctioning regimes.<sup>77</sup> The Macrory Report, undertaken following the Hampton Report’s findings that regulators’ penalty regimes were cumbersome and ineffective, set out a blueprint for transforming the regulatory sanctioning regime in the UK. It also extensively referred to Braithwaite’s responsive regulatory theory.

Macrory found that many regulatory sanctioning regimes were over-reliant on criminal prosecution and lacking in flexibility.<sup>78</sup> He made a number of recommendations to ensure regulators have access to a flexible set of sanctioning tools that are consistent with the risk-based approach to enforcement outlined in the Hampton Review.<sup>79</sup> This included proposing an alternative system of civil sanctions in order to set up a modern and targeted sanctioning regime that would enable regulators to match the sanctions to the circumstances of different cases.<sup>80</sup>

The RES Act, in adopting these principles, allows a Minister, by order, to give a regulator access to four new civil sanctions:

1. Fixed monetary penalty notices<sup>81</sup>—regulators may impose a monetary penalty of a fixed amount;
2. Discretionary requirements<sup>82</sup>—regulators may impose, by notice, one or more of the following:
  - a variable monetary penalty determined by the regulator;
  - a requirement to take specified steps within a stated period to

<sup>73</sup> Ibid.

<sup>74</sup> Human Fertilisation and Embryology Authority, *Annual Report and Accounts 2008/09* (2009) 14.

<sup>75</sup> Better Regulation Executive, above n 55, 27.

<sup>76</sup> Ibid 27–8.

<sup>77</sup> Richard B Macrory, *Regulatory Justice: Making Sanctions Effective* (2006).

<sup>78</sup> Ibid 7.

<sup>79</sup> Ibid, see especially Chapter 6.

<sup>80</sup> Ibid.

<sup>81</sup> *Regulatory Enforcement and Sanctions Act 2008* (UK) c 13, ss 39–41.

<sup>82</sup> Ibid ss 42–45.

- i. secure that an offence does not continue or happen again (compliance notice); or
  - ii. secure that the position is restored, so far as possible, to what it would have been if no offence had been committed (restoration notice);
3. Stop notices<sup>83</sup>—to prevent a business from carrying on an activity described in the notice until it has taken steps to come back into compliance; and
  4. Enforcement undertakings<sup>84</sup>—which will enable a business, which a regulator reasonably suspects of having committed an offence, to give an undertaking to a regulator to take one or more corrective actions set out in the undertaking.

The new powers are an alternative to criminal prosecution and it will be for the regulator to determine the appropriate response to a particular instance of regulatory noncompliance.

On 17 December 2008 the HFEA Committee recommended the HFEA apply for three of these powers: Discretionary Requirements, Stop Notices and Enforcement Undertakings.<sup>85</sup> Such powers would give the HFEA more power to use coercive force than it currently has, noting that such powers may only be applied to criminal offences.<sup>86</sup>

### **F *Ongoing public consultation, policy review and cost reduction***

As most researchers and practitioners in the UK are unlikely to engage in behaviour contrary to the HFE Act, emphasis on adequate communication, cooperation, persuasion and education at the base of the regulatory pyramid is most important for the better operation of the regulatory system. The HFEA has continued to engage in ongoing policy review and development, widespread public dialogue and consultation as issues arise, and reports on the horizon scanning issues identified, prioritised and considered. In accordance with the government's 'Better Regulation' agenda it has developed a model process for conducting impact assessments and for costing the implications of simplification plans. Such increasing dialogue can only serve to improve the operation of the HFEA. It has also continued to work toward the requirement that the Authority 'carry out its functions effectively, efficiently and economically'.<sup>87</sup>

### **G *What the future holds***

On 26 July 2010 the UK Department of Health released its latest 'Report of the Arm's Length Bodies Review'.<sup>88</sup> It announced that the intention is eventually to transfer the HFEA's functions between a new research regulator, the Care Quality Commission ('CQC'), and the Health and Social Care Information Centre. In considering how the CQC will function, the UK Department of Health has asked the Academy of Medical Sciences to

<sup>83</sup> Ibid ss 46–49.

<sup>84</sup> Ibid s 50.

<sup>85</sup> Trish Davies and Kristen Veblen, *Regulatory Enforcement and Sanctions Act, 2008* (HFEA Authority Paper for Decision No 477, 2008).

<sup>86</sup> See *Human Fertilisation and Embryology Act 2008* (UK) c 37, s 41.

<sup>87</sup> *Human Fertilisation and Embryology Act 1990* (UK) c 37, s 8ZA(1).

<sup>88</sup> Department of Health (UK), *Liberating the NHS: Report of the Arm's Length Bodies Review* (2010).

conduct an independent review of the regulation and governance of medical research which is expected in late 2010. Currently a number of different arm's-length bodies have responsibility for different aspects of research regulation, including giving permissions. The UK Department of Health states:

There is a strong argument for rationalising this and creating greater strategic coherence around research by placing responsibility for these different aspects of medical research regulation within one arm's-length body that would perform a stand-alone technical function as a research regulator. This would streamline the process of gaining permission to undertake medical research, making it more attractive to universities and health institutions. Moreover, there is potential for a single research regulator to have wider cross-government reach.<sup>89</sup>

For the moment, the HFEA will be retained with the aim of transferring its functions by the end of the current Parliament. In the meantime, the Department of Health will examine the practicalities and legal implications of how to divide the HFEA's functions between the Care Quality Commission with respect to regulating research, and the Health and Social Care Information Centre with respect to regulating ART clinics. The aim continues to be to reduce bureaucracy and improve efficiency by abolishing arm's-length bodies that do not need to exist, streamlining the functions of those that do and transferring functions that can be better delivered by other organisations.<sup>90</sup>

#### **IV Australia: one step forward, two steps behind?**

Australia took a great step forward in choosing to adopt a national regulatory framework approach to govern research involving human embryos and cloning rather than imposing a complete ban or leaving the law in its previously inconsistent state. Nonetheless, Australia's regulatory design and enforcement approaches lag behind those of the UK. In answering the question of how to regulate, Australia has implemented the very system that has been extensively reviewed in the UK.

##### ***A Problems with review process and ability to respond to change***

There is a stark contrast between the Australian review system and the continuous review process and policy development that occurs in the UK given the quite different powers of the HFEA to those of the NHMRC Licensing Committee. The HFEA conducts regular policy reviews and public consultations on relevant issues. This contrasts with Australia's policy review and public consultation phase which involves the setting up of a special parliamentary committee to review the legislation periodically. The Australian review of the 2002 legislation took place in late 2005, and amendments to legislation did not come into force until 2007. The next review is due this year. As such, any significant form of public consultation and review is occurring about once every five years in Australia. Legislative changes then follow, thus taking up to seven years to complete the entire review process.

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<sup>89</sup> Ibid 18.

<sup>90</sup> Ibid 4.

Legislative review and subsequent legislative amendment is the only avenue to address what is permitted or prohibited.

### B *Problems with costs of running such a system*

Better regulation also means a cost-effective regime. The estimated or budgeted cost of the Australian licensing system in relation to whom and what it regulates appears completely out of proportion to the number of regulatees in Australia and the risk of wrongdoing. There is also no opportunity for cost recovery.

While the Director of Licensing for the NHMRC has indicated there are ‘no documents on the public record’ that provide information about the exact costs of the NHMRC Licensing Committee,<sup>91</sup> the 2005 Lockhart Committee Report has stated that ‘the costs of supporting the Licensing Committee and the national compliance system are significant.’<sup>92</sup> The Lockhart Committee reported that the Australian Government Portfolio Budget Statement for the financial year 2003–04 indicated a total commitment of \$3.3 million per year.<sup>93</sup> Due to lack of information on the public record it is difficult to discern whether the \$3.3 million dollars is in fact spent by the NHMRC Licensing Committee. Nonetheless, such an amount seems disproportionate to the NHMRC Licensing Committee’s functions. Such functions are to refuse or grant licences; maintain a publicly available database containing information about licences issued; monitor activities and ensure compliance with the legislation and take necessary enforcement action if non-compliance is identified; and report to the Australian Parliament at six-monthly intervals on the operation of the RIHE Act and the licences issued under the Act.<sup>94</sup>

Since the NHMRC Licensing Committee’s inception, this translates in practice into the NHMRC Licensing Committee and its inspectorate being in charge of granting licences to, monitoring and reporting on less than a handful of research institutes. For example, there were *four* research institutes that held licences in 2006. As at March 2010, although there were 10 current licences granted by the NHMRC Licensing Committee, those 10 licences were held by only *two* institutes: Sydney IVF held eight of these licences; Melbourne IVF held two.

The NHMRC Licensing Committee reports that it conducted 48 information exchange visits during six of the 14 reporting periods.<sup>95</sup> Licensing Committee Meetings are

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<sup>91</sup> Email from Melissa Crampton, Director of Licensing NHMRC Licensing Committee to author, 18 March 2009. The author also conducted extensive searches of the Australian Government Department of Health and Ageing, Health and Ageing Portfolio Budget Statements, from the 2002–03 financial year to the 2008–09 financial year; NHMRC Annual Reports; NHMRC Licensing Committee Reports; and general web searches trying to find information concerning what the NHMRC Licensing Committee actually costs.

<sup>92</sup> Legislation Review Committee, Parliament of Australia, above n 26, 99.

<sup>93</sup> One could assume that this figure would have risen each year, but as the actual figure is unknown, \$3.3 million is used for this discussion.

<sup>94</sup> RIHE Act Part 2 (Divisions 4 and 5).

<sup>95</sup> National Health and Medical Research Council, *NHMRC Licensing Committee Report to the Parliament of Australia for the Period 1 April 2009 to 30 August 2009* (2009); *1 October 2008 to 31 March 2009* (2009); *1 April 2008 to 30 September 2008* (2008); *1 October 2007 to 31 March 2008* (2008); *1 April 2007 to 30 September 2007*(2007); *1 October 2006 to 31 March 2007* (2007); *1 April 2006 to 30 September 2006* (2006); *1 October 2005 to 31 March 2006* (2006); *1 April 2005 to 30 September 2005* (2005); *1 October 2004 to 31 March 2005* (2005); *1 April 2004 to 30 September 2004* (2004); *1 October 2003 to 31 March 2004* (2004); *1 April 2003 to 30 September 2003* (2003); and *19 December 2002 to 31 March 2003* (2003).



reported to occur on average two to three times bi-annually, with an approximate total of 26 meetings since the committee was formed.<sup>96</sup> Many of these meetings appear to occur over two days.<sup>97</sup> There also has been at least one instance of international travel by the Chair of the NHMRC Licensing Committee,<sup>98</sup> although this does not appear to be a regular occurrence. Costs associated with information exchange visits, as well as Committee meetings (which may include accommodation and travel expenses, as well as payment of committee members), maintaining a database, reporting bi-annually to the Minister, running a website and any international travel and associated costs need to be established. It is doubtful that large sums could be justified given that in fact the NHMRC licensing committee is currently governing *two* research institutes. The majority of these activities depict a bureaucracy at work.

Significant costs were also incurred in 2007 when a decision by the NHMRC Licensing Committee to reject an application for a variation of licence was challenged by Sydney IVF in the Administrative Appeals Tribunal. The Chair of the NHMRC Licensing Committee reported that '[m]embers agreed the cost and time of the process was significant however members also agreed the exercise was extremely valuable as an investment for the future'.<sup>99</sup> A more cooperative regulatory system would serve to avoid such costs other than where criminal activity has occurred. While the focus here is on costs, it is also noted that allowing such matters to reach courts or tribunals again illustrates the adversarial approach inherent in the current regime.

The Lockhart Review highlighted that to date no cost recovery mechanism has been applied to the costs of the NHMRC Licensing Committee.<sup>100</sup> In fact, there is *no opportunity* for cost recovery. Recovering any significant cost of the regulatory system in Australia from the licensed institutes would be impractical and not possible—there are simply too few institutes. The Lockhart Committee stated that 'considering the small number of licence applications received, it is unlikely that introducing cost recovery would be cost-effective or efficient'.<sup>101</sup> They also recognised 'organisations are already meeting the costs of compliance with the national regulatory scheme and, in relation to compliance with licensing requirements, these costs may be significant'.<sup>102</sup> This indicates the current system places significant financial burdens on those being regulated, another potential reason for regulatee dissatisfaction.

The call therefore is to consider whether Australia could move to a more flexible, and potentially less costly, system.

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<sup>96</sup> Ibid.

<sup>97</sup> Ibid.

<sup>98</sup> In June 2005 the Chair of the Embryo Research Licensing Committee, Professor Jock Findlay, and Dr Harry Rothenfluh of the NHMRC, visited the HFEA to 'discuss topics of mutual interest, including processes for assessing and taking decisions on licence applications, monitoring and compliance strategies': National Health and Medical Research Council, *Annual Report 2005* (2005).

<sup>99</sup> National Health and Medical Research Council, *Report of the 168<sup>th</sup> Session of the National Health and Medical Research Council* (2007) 8.

<sup>100</sup> Legislation Review Committee, Parliament of Australia, above n 26, 99.

<sup>101</sup> Ibid 100.

<sup>102</sup> Ibid.

### C *Lockhart Committee Review*

While the Lockhart Committee acknowledged that ‘prescriptive legislation has a number of disadvantages because it is difficult to anticipate advances in knowledge and potential new uses of the technologies’,<sup>103</sup> it stopped short of considering the *type* of regulatory system in place. Rather, it suggested the NHMRC Licensing Committee be given powers to make ‘binding rulings ... on its interpretation of the legislation’<sup>104</sup> which could be subject to parliamentary scrutiny by ‘a legislative requirement that the Licensing Committee must report immediately on its rulings to the NHMRC and to parliament and that the rulings must be tabled in parliament for its consideration.’<sup>105</sup> They suggested that ‘this may also avoid the need for further reviews of the legislation outside the usual parliamentary process of amendment.’<sup>106</sup>

Giving the NHMRC Licensing Committee powers to make binding rulings on its interpretation of the legislation reflects the view that the NHMRC Committee is in the best position to make such rulings. The Lockhart Committee may have presumed the NHMRC Licensing Committee would consult with research scientists, practitioners and the community when making such rulings, but it is not inherent in what they say. This does not accord with the principles concerning the best modes of regulation and enforcement. It certainly does not recognise or consider principles of co-regulation and how they may serve to enable rule making to be a process in which regulatees and stakeholders, including the public, have a greater role in the overall functioning and implementation of the system.

Notably, changes to give the NHMRC more powers pursuant to the Lockhart recommendation were not made in the 2007 amendments to the RIHE Act or the PHRC Act.

## V **Changing the Australian regulatory system to suit the Australian context**

The legislature should not ignore the extensive research into better regulation conducted in the UK that has led to direct revision of the regulatory system upon which the Australian system is modelled. Nor should one ignore that licensed researchers continue to indicate their desire for a less onerous scheme of licensing and compliance, while simultaneously demonstrating nothing but compliance since the inception of the RIHE and PHRC Acts and corresponding regulatory regime.

While the Australian regulatory system should not remove the heavy penalties at the top of the pyramid in Figure 1, it should address the fact that cooperative, educative and persuasive approaches are largely missing or represented to only a small degree at the base. Introducing a co-regulatory approach at the base of the pyramid to govern *licensed* research activities would complete the system. It would allow for the continued presence of strict prohibitions and enforcement approaches for those that might commit offences outside of

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<sup>103</sup> Ibid 158.

<sup>104</sup> Ibid.

<sup>105</sup> Ibid.

<sup>106</sup> Ibid.

the licensing system, or licence holders who engage in severe breaches of the regulatory system, while allowing for responsive regulation of licensed activities.

It is proposed that the most appropriate regulatory system for the Australian context is one in which researchers continue to be governed by the RIHE Act and PHRC Act. Given the small scale of operation in Australia, however, a different approach to the licensing and monitoring of such activities could be taken. Like the UK, this could involve transferring the functions of the current regulatory body elsewhere. However, it is unlikely that a central legislative body that regulates all research in Australia is likely to be set up in the near future. In the meantime, Australia could better recognise the value of calling upon self-regulatory bodies already in place to take over the ‘bottom level’ of regulation. It is suggested here that the Reproductive Technology Accreditation Committee (‘RTAC’) could take over the operation of the NHMRC Licensing Committee with regards to licensing, monitoring and overseeing research activity. The NHMRC could maintain a modified role to complement RTAC functions and provide higher level enforcement if necessary.

### A *Why RTAC?*

RTAC was established in 1987 by the Fertility Society of Australia.<sup>107</sup> Its primary responsibility is accreditation of ART Clinics against a code of practice developed by the industry, *The Code of Practice for Assisted Reproductive Technology Units* (‘RTAC Code’).<sup>108</sup> The current edition of the RTAC Code states that its purpose is to ‘promote continuous improvement in the quality of care offered to people accessing fertility treatment; provide a framework and set criteria for the auditing process that leads to accreditation of organisations that deliver fertility services; and to ensure the auditing process is carried out in an independent, non-adversarial and constructive manner’.<sup>109</sup> The RTAC Code dictates critical criteria for ART organisations that are audited annually by RTAC in accordance with their ‘RTAC Certification Scheme’<sup>110</sup> and ‘Good Practice Criteria’ which are audited every three years.

As an industry regulatory body, RTAC already provides an example of self-regulation in some states<sup>111</sup> and co-regulation in others<sup>112</sup> in the context of ART.

Self-regulatory states opt to follow federal guidelines published by the NHMRC which describe a range of prohibited or unacceptable practices in conjunction with extensive self-made and self-administered rules of RTAC. The Queensland government has stated:

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<sup>107</sup> The Fertility Society of Australia is the peak body representing scientists, doctors, researchers, nurses, consumers and counsellors in reproductive medicine in Australia and New Zealand. See <<http://www.fertilitysociety.com.au/home/about/>>.

<sup>108</sup> Fertility Society of Australia and Reproductive Technology Accreditation Committee, *The Code of Practice for Assisted Reproductive Technology Units*, revised May 2008.

<sup>109</sup> *Ibid* 4.

<sup>110</sup> Fertility Society of Australia, *Reproductive Technology Accreditation Committee Certification Scheme (RTAC Scheme)* (2008). In 2007, the FSA decided to introduce independent (third-party) certification of ART units as the basis for considering the RTAC licence, and asked the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) to assist in the development and delivery of an RTAC Scheme. The RTAC Scheme consists of a detailed Management Manual developed by RTAC and the RTAC Code of Practice and was developed by the RTAC Technical Committee and JAS-ANZ.

<sup>111</sup> New South Wales, Queensland, Tasmania and the Australian Capital Territory.

<sup>112</sup> Western Australia, South Australia and Victoria.

RTAC accreditation and requirements to comply with the NHMRC Ethical Guidelines provide a rigorous framework to ensure excellence in the provision of ART services. ... There is no evidence to suggest that such accreditation and ethical oversight has been lacking or has enabled ART practitioners to engage in inappropriate practices.<sup>113</sup>

Similarly, community groups have expressed satisfaction with a self-regulatory approach in the ART context, particularly in relationship to its flexibility and ability to respond to emerging scientific advances:

Despite the initial scepticism of the government, RTAC has demonstrated that self-regulation can work ... Benefits of self regulation include its flexibility as it is more able to respond to emerging scientific advances, reflect developing social expectations and allow for a greater degree of autonomy for consumers in the decision making process. Importantly RTAC is not restricted to rigid legislation but using the Code of Practice requirements as a minimum standard, seeks to continually improve practice. This is crucial to improving the quality of care as needs are identified.<sup>114</sup>

However, concerns about the negative aspects of self-regulation have also been expressed. The Committee of the St Thomas More Society in their submission to the Lockhart Committee did not support a self-regulatory approach particularly because of their concern that legislation would 'ensure the industry operates in accordance with established ethical standards, including transparency and full disclosure of risk'.<sup>115</sup>

As research involving human embryos and cloning raises such public concern and potential risks, *some* government oversight is necessary. Consequently, what is suggested here is a co-regulatory system. An example of this strategy is seen in the Australian states that have chosen to govern ART by utilising both legislation and RTAC oversight. For example, Western Australia mandates RTAC accreditation under their ART legislation.<sup>116</sup> Similarly, the Victorian Assisted Reproduction Treatment Authority (VARTA)<sup>117</sup> works closely with RTAC in regulating Assisted Reproduction Clinics.

The benefits of utilising such a system are illustrated by the following statements. Ms Louise Johnson, CEO of the then ITA:

I think one of the important processes is not only is there a checking that various requirements are met in all areas of ART practice and the legislation...but as well as quality assurance, quality improvement is also looked at. And there is quite a strong team that is put together by RTAC that visits various licensed places and clinics.<sup>118</sup>

Similarly, Professor Jock Findlay, also of the ITA:

<sup>113</sup> Legislation Review Committee, Parliament of Australia, above n 26, 125, quoting Queensland Government, Submission No LRC930.

<sup>114</sup> Ibid quoting ACCESS (Australia's National Infertility Network), Submission No LRC899.

<sup>115</sup> Ibid quoting St Thomas More Society, Submission No LRC397.

<sup>116</sup> *Human Reproductive Technology Act 1991* (WA) s 29(5)(aa)(i).

<sup>117</sup> Established under the *Assisted Reproductive Treatment Act 2008* (Vic). The previous body was known as the Infertility Treatment Authority (ITA).

<sup>118</sup> Legislation Review Committee, Parliament of Australia, above n 26, 124, quoting Louise Johnson (Victorian ITA).

[W]e rely absolutely on the expertise of RTAC to give accreditation for the clinical practices of the units that we license... we're very satisfied with the RTAC process as we see it in Victoria. We think it's very thorough, very professional and we certainly rely on it for their part of it.<sup>119</sup>

The essential element of a co-regulatory approach highlighted by these examples is that cooperation between the government (and its agencies) and those subject to the regulation is possible and reportedly works very well in an area which has raised significant moral and ethical concerns.

It is noted that RTAC not only emphasises but *requires* adherence to ethical modes of conduct, guidelines and HREC requirements as well as ensuring safety and standards are met. RTAC also uses *independent* auditors to carry out inspections of regulated facilities which provide an added layer of protection against concerns about disclosure of non-compliance where self-regulatory bodies are used.

Given that RTAC already functions to oversee all ART, it would also be the appropriate body to oversee research involving human embryos. This more closely mirrors the role of the HFEA than the current NHMRC licensing system. That the HFEA functions are eventually to be transferred to a new research oversight body does not diminish this argument. The HFEA's future is not being determined by a conflict between regulating ART and research involving human embryos, but rather by a nationwide effort to reduce bureaucracy. The likelihood of Australia establishing a similar nationwide system in the near future is low. It can, however, move to reduce the bureaucracy and costs associated with having a separate licensing committee for research involving human embryos particularly as the number of institutes currently holding licences is *two*.

RTAC could serve to reduce authoritative enforcement approaches, incorporate a form of self-regulation but with more stringent oversight, and streamline the number of inspections that are currently conducted by the NHMRC Licensing Committee Inspectors. This is justified given the small number of licensed research institutes in Australia; that inspections carried out by the NHMRC Licensing Committee Inspectors rely on data contained in the research facility's files anyway; and the result of all inspections since the NHMRC Licensing Committee's inception has been to find licence holders compliant and that there have been no breaches of the legislation.<sup>120</sup> Finally, using RTAC could also address the cost recovery issue relating to the current NHMRC Licensing Committee noting that RTAC collects fees from the ART Clinics it governs.

## B *Making it happen*

The regulatory strategy suggested could be inserted into the RIHE Act and PHRC Act as it has been in state legislation regarding ART. Of course, if RTAC were to assume responsibility for the licensing and oversight of research involving human embryos some modifications may be necessary. For example, their current committee may need to be expanded. This would serve the purpose of assuaging public concern regarding utilising a self-regulatory body, but more importantly because for the purposes of such licensing and

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<sup>119</sup> Ibid, quoting Jock Findlay (Victorian ITA).

<sup>120</sup> Ibid.

oversight there is consensus about the need to utilise other expertise, for example an ethicist, and a legal expert. Some of these requirements will already be fulfilled by the current professional and layperson membership of the RTAC Committee, while other positions would have to be appointed according to need.

In implementing RTAC licensing and oversight functions a self-report system could be implemented except where there is concern about non-compliance. This would work as the current system relies on inspection of files held by researchers, a defacto form of self-regulation in that it relies on researchers to keep accurate records and report honestly.

Such a system should incorporate Parker's meta-regulatory style in which the 'role of legal and regulatory strategies is to add the "triple loop" that forces [regulatees] to evaluate and report on their own self-regulation strategies so that regulatory agencies can determine whether the ultimate substantive objectives of regulation are being met'.<sup>121</sup> In this way co-regulation combines the elements of legislation, especially its predictable and binding nature, with the more flexible regime of a form of self-regulation. This model not only requires internal monitoring and evaluation of compliance, effects and outcomes, but reporting to regulatory authorities which allows them to evaluate and revise the licensee's operations, and assess whether the substantive objectives of regulation are being met.<sup>122</sup> RTAC's role therefore would be to monitor compliance and evaluate and revise licensee's operations where necessary. RTAC could also play a role in addressing the bureaucratic redundancy of particular procedures concerning licence variations.

### C *A role for the NHMRC*

The NHMRC could still play an important role in the overall regulation of research involving human embryos and cloning. For example, RTAC might work with the NHMRC in achieving compliance and/or where there are issues of non-compliance. The two bodies could work together to achieve cooperative compliance by delivering education, seminars and maintenance of website information. The NHMRC could continue to provide a location (the NHMRC website) at which reports on licensing, and information about research and compliance are published, and communication with the public occurs. The NHMRC 'Information Exchange Visits' could form the basis for further educative programs to be run by RTAC.

The NHMRC might also deliver enforcement strategies that a self-regulatory body cannot. For example if there were non-compliance, it might be RTAC's initial function to issue warning letters, vary licences and/or to place tighter control on a research institute's performance. However, if non-compliance continued, RTAC's role might be limited and the NHMRC role increased for issuing directions to comply with the relevant legislation. This moves into the 'command and control with discretionary enforcement approaches' level of the pyramid as depicted in Figure 2 below. If non-compliance persisted, then further penalties such as loss of licence, injunctions and/or criminal sanctions might be pursued by way of an enforcement officer or by direct notification to the relevant authorities and prosecution in the courts.

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<sup>121</sup> Christine Parker, *The Open Corporation: Effective Self-Regulation and Democracy* (Cambridge University Press, 2002) 245.

<sup>122</sup> *Ibid.*

Finally, through communication, cooperation, and consultation, the bodies could work together with researchers and the community to provide a more flexible and responsive approach to regulation. Rather than giving the NHMRC power to make rulings, such dialogue and communication might be fed back into the Parliament where necessary amendments could be made on an ongoing basis rather than having major reviews of the legislation every three years—again a costly and inadequate process.

#### D *Can RTAC meet this role?*

One possible issue regarding the above suggestion is that RTAC would need to work within the complex system of regulation that already exists in Australia. Unlike the single national system that exists in the UK, the Commonwealth laws of Australia must operate in tandem with the laws of the states and territories that originally enacted mirrored legislation. The fact that changes to federal legislation have not resulted in identical changes in each of the state jurisdictions has led to a system which is made more complex due to variations between jurisdictions.

For example, while some states and territories passed corresponding legislation after the RIHE and PHRC Acts were amended in 2007,<sup>123</sup> Western Australia (WA) did not follow suit.<sup>124</sup> The legal position in WA therefore differs from the federal legislation in that creation of embryos using somatic cell nuclear transfer for research purposes is prohibited, while it is permitted by the Commonwealth Acts. Here the dilemma is whether RTAC is equipped to deal with the differences that might arise should someone apply for a licence to do research in WA. The WA legislation is capable of operating concurrently with the RIHE Act,<sup>125</sup> but because of the Commonwealth powers to legislate on matters concerning the importation and exportation of human material, patenting, trade and commerce, corporations and external affairs,<sup>126</sup> corporations may arguably apply for licences under the Commonwealth Acts to do research not permitted under the state Act, which governs individuals.

However, in asking the NHMRC Licensing Committee about their view regarding the WA position, the author received the following response:

The Licensing Committee does not have an ‘official view’ on the relationship between the Commonwealth Act and WA following the defeat of the legislation in WA. There

<sup>123</sup> *Human Cloning and Embryo Research Amendment Act 2008* (ACT); *Human Cloning and Other Prohibited Practices Amendment Act 2007* (NSW); *Research Involving Human Embryos and Prohibition of Human Cloning Amendment Act 2007* (Qld); *Human Cloning and Other Prohibited Practices Amendment Bill 2007* (Tas); *Infertility Treatment Amendment Act 2007* (Vic); *Assisted Reproductive Treatment Act 2008* (Vic).

<sup>124</sup> The rejection of corresponding legislation by Western Australia occurred after a team led by Shinya Yamanaka at Kyoto University published a paper reporting that differentiated human skin cells could be reprogrammed to an embryo-like state: see Kazutoshi Takahashi et al, ‘Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors’ (2007) 131 *Cell* 861. The resulting cells are referred to as ‘induced pluripotent stem’ (iPS) cells. The success of a similar approach was reported by a University of Wisconsin team led by James Thomson and Junying Yu: see Junying Yu et al, ‘Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells’ (2007) 318 *Science* 1917. Both the Japanese and US research called into doubt the need for human embryonic stem cell research and, as such, the need for permitting the use (and inevitable destruction) of embryos created using cloning technologies or excess to ART for the purposes of obtaining stem cells.

<sup>125</sup> *Research Involving Human Embryos Act 2002* (Cth) s 42 provides that the Act is not intended to exclude the operation of any law of a state, to the extent that the law is capable of operating concurrently with the RIHE Act.

<sup>126</sup> *Commonwealth Constitution* s 51(i), (xviii), (xx), (xxix).

are currently no licences issued to organisations in WA so there is no immediate need to address the issue. If a licence application is submitted by an organisation from WA, the Licensing Committee will consider it on its merits and will take legal advice at that time about the interaction between the two sets of legislation in relation to the specific licence application. It is the Committee's understanding that the main issue will be the status of the organisation in relation to paragraph 51 of the Constitution and that this will determine which legislation applies. Furthermore, the committee considers it likely that most organisations applying for a licence will be constitutional corporations. However, the Committee will be guided by advice from the experts in constitutional law at the Australian government Solicitor's Office which will be obtained if/when the situation arises.<sup>127</sup>

Such a response suggests that the NHMRC Licensing Committee is not necessarily in a better position than RTAC would be regarding what to do in such a situation. That is, RTAC could similarly obtain legal advice should such a situation arise. In addition, RTAC already works within a complicated framework regarding ART in which some states legislate and others do not. It is clearly adept at managing differences among jurisdictions.

### E *The alternative*

The alternative to the above suggestion may be to continue to use the NHMRC Licensing Committee albeit in a significantly modified form. This is not the preferred model due to the arguments presented above concerning better regulatory practice. However, given the potential of this model as an alternative, it is necessary to address how the current regulatory system can move toward incorporating responsive regulation within the NHMRC licensing regime.

Under this model the NHMRC Licensing Committee's functions, operation and enforcement approaches still need to be reviewed, costs and bureaucracy reduced, and the sharing of responsibilities between public and private partners enabled. 'Low risk' (in terms of compliance) licensees may for example, undertake a self-report/assessment regime in relation to their compliance with licence conditions, which would reduce the need for frequent inspections. In developing the details of such self-report/assessment the NHMRC Licensing Committee could cooperate with those subject to the regulation in the process of creating the new rules.<sup>128</sup> This would enable moving away from the apparent view that the NHMRC Licensing Committee is in the best position to decide upon rules and regulations recognising the legislature has set the essential legal framework. The NHMRC Licensing Committee's role should be to monitor the outcome, but only intervene where necessary. Again, this is a mode of 'meta-regulation' in which the 'role of legal and regulatory strategies is to add the "triple loop" that forces [regulatees] to evaluate and report on their own self-regulation strategies so that regulatory agencies can determine that the ultimate substantive objectives of regulation are being met'.<sup>129</sup>

All other suggestions made above in relation to using RTAC would equally apply under this model. That is, regard should be had to the provision for a framework of

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<sup>127</sup> Email from Melissa Crampton, Director of Licensing NHMRC Licensing Committee, to the author, 27 August 2008.

<sup>128</sup> Linda Senden, 'Soft Law, Self-Regulation and Co-Regulation in European Law: Where do they Meet?' (2005) 9(1) *Electronic Journal of Comparative Law*, <<http://www.ejcl.org/91/art91-3.html>>.

<sup>129</sup> Parker, above n 123.



administrative sanctions that will allow regulators to tackle non-compliance in ways that are transparent, flexible, and proportionate to the offence,<sup>130</sup> and place a duty on specified regulators to review the burdens they impose, reduce any that are unnecessary and unjustifiable, and report on their progress annually.

Recognising that the current set of enforcement options available to the NHMRC Licensing Committee is limited to informal actions, direct action in respect of a licence or referral to the police, it would be beneficial to have more flexible powers to enable proportionate enforcement. However, it must be stressed that most regulatory functions do not relate to such things but rather to regulating compliant licence holders. *The focus should not be predominantly on enforcement or non-compliance as there has not been any wrongdoing in Australia.* Caution should therefore be exercised in giving further regulatory powers to the NHMRC Licensing Committee which may result in increasing the costs of the regulatory system rather than addressing issues of better regulation and the need to decrease regulatory burdens. While incorporating RTAC into the regulatory regime may provide for at least some cost recovery, modifying and utilising the NHMRC Licensing Committee alone does not provide the same opportunity. There is a need to recognise the licensed researchers and practitioners undertaking research involving human embryos are ‘good apples’, and focus upon implementing increased cooperative, persuasive and educative approaches.

Figure 2 depicts these proposed model(s):

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<sup>130</sup> Noting that Parts 1 and 2 of the *Regulatory Enforcement and Sanctions Act 2008* (UK) c 13 relate to local authorities and do not concern HFEA, Part 3 gives regulators listed in Schedule 5 to the Act (including the HFEA) an ‘extended tool kit of alternative civil sanctions as a more proportionate and flexible response to cases of regulatory non-compliance normally dealt with in the criminal courts’: Better Regulation Executive, above n 55, 7.

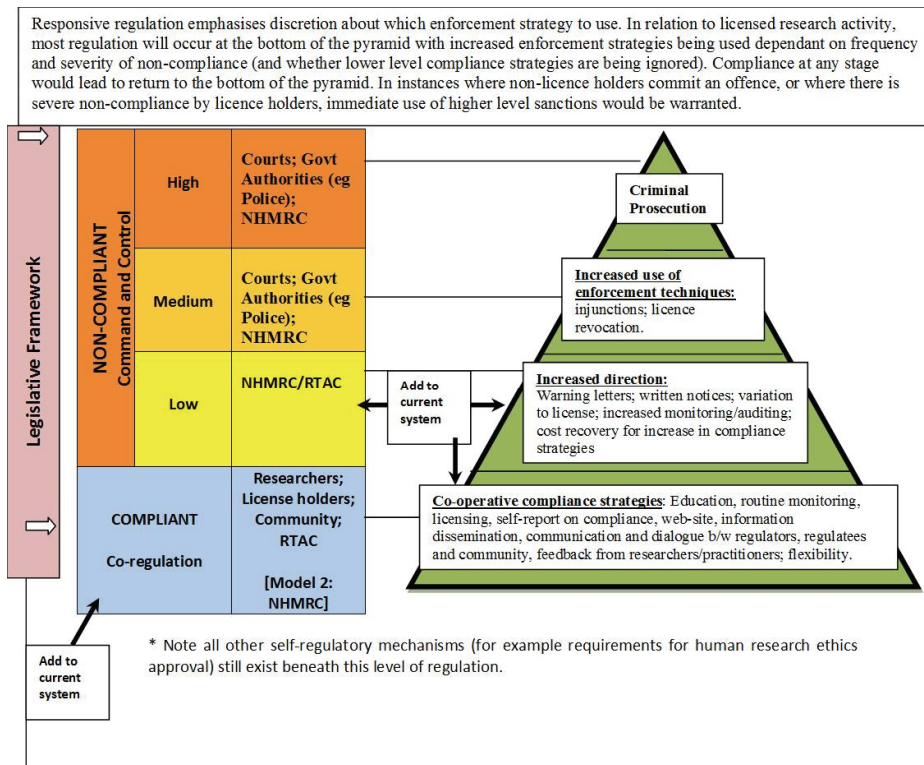


Figure 2: Proposed model for Australia

## VI Conclusion

The above discussion shows that both the UK and Australia need to reduce the regulatory burden placed upon compliant licence holders and address the issue of how to reduce the costs of the regulatory systems that govern research involving human embryos and cloning. While a cautious approach was warranted with the advent of the Acts in order to determine what to permit and/or prohibit, it is apparent that reducing the regulatory burden upon compliant licence holders, and moving toward better regulation generally, is warranted. The UK is in fact working towards this goal, while Australia has yet to revise the choice of regulatory model.

The current Australian regime may be depicted by a pyramid in which the licensing and oversight at the bottom of the pyramid is a way of 'policing' research activities while severe penalties for breaching the law are at the top. The proposed model (see Figure 2) instead recognises the different levels of compliance/non-compliance with which a regulatory system that incorporates co-regulation and responsive regulatory approaches might deal. It adds the co-regulatory base levels of the pyramid in which licensed researchers and practitioners who will comply in any event [self-regulation] may be governed within the legislative framework using cooperative approaches. The second level

of the pyramid allows for governance of researchers and practitioners who have engaged in 'low-level' non-compliance by including the ability for regulators to choose to use appropriate persuasion/educative strategies and therefore adding to the current system a range of further enforcement options. The top levels of the pyramid continue to provide strategies for dealing with egregious non-compliers, including those who are conducting research without an appropriate licence or licence holders who engage in serious offences. It maintains strict prohibitions and the ability to pursue heavy sections and/or criminal penalties for such behaviour.

The entire pyramid reflects the ability to utilise both punishment and persuasion. The focus should not unnecessarily be on the risk of wrongdoing, but rather it should be on the fact that instances of wrongdoing will be the exception rather than the rule. That is why the bottom of the pyramid is broad and the tip narrow. It represents that most researchers will operate at the base of the regulatory system and are not in need of punitive or deterrent enforcement approaches. It is again noted that of all the inspections conducted by the NHMRC Licensing Committee to date, there has never been a finding of non-compliance.

Of course the suggested model does not intend to do away with notions of precaution or recognition of the perceived risks involved in conducting research involving human embryos and cloning.<sup>131</sup> Recognition of public perception of risk and concerns about the treatment of human embryos continues to be of fundamental relevance when discussing rationales for regulation and has played an important role in both the UK and Australia when making decisions about *what* to regulate and *where* to draw the line in relation to such research. However, when choosing *how* to regulate, we need to be mindful of research that suggests that people see risk subjectively.<sup>132</sup> Decisions about risks are made based upon the information people are given, and people generally see most risks in society as being unacceptably high.<sup>133</sup> On the other hand, the greater perceived benefit the greater the tolerance for risk, and vice versa.<sup>134</sup> The suggested model in this paper takes into account research literature and the practice of risk communication which, rather than treating all subjective deviations from expert estimates as products of ignorance or stupidity, has seen a move to approaches which promote risk communication as a two-way process in which both 'expert' and 'lay' perspectives should inform each other'.<sup>135</sup> Dialogue is fundamental to the model suggested here.

The model also accommodates the notion that despite the current risks identified in relation to research involving human embryos or cloning and/or the fear of researchers behaving criminally or unethically, the wider community does not want to stop *all* research. They have in fact shown they are happy for research to proceed within the parameters set by the legislation. Similarly, researchers and practitioners have shown that they are 'amenable

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<sup>131</sup> See Roger Brownsword and Han Somsen, 'Law, Innovation and Technology: Before we Fast Forward—A Forum for Debate' (2009) 1 *Law, Innovation and Technology* 1 for a general discussion and call for consideration of the role regulation may play in relation to 'emerging technologies'.

<sup>132</sup> Simon P Thomas and Steve E Hrudey, *Risk of Death in Canada: What We Know and How We Know It* (Earthscan Publications, 1997).

<sup>133</sup> Paul Slovic (ed), *The Perception of Risk* (University of Alberta Press, 2000).

<sup>134</sup> Ibid.

<sup>135</sup> Department of Health and Aging (Cth), *Environmental Health Risk Assessment Guidelines for Assessing Human Health Risks from Environmental Hazards*, <<http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-ehra-2004.htm~ohp-ehra-2004-framework.htm~ohp-ehra-2004-framework-3.htm>> (September 2004).

to some form of regulation within this context'.<sup>136</sup> Scientists and practitioners 'want to work within what the general public sees as acceptable and are happy to take responsibility for themselves within these parameters'.<sup>137</sup> What the proposed model aims to address is the danger of promulgating bad regulation where undue attention is placed on things that are unlikely to occur, or regulation is addressed towards heightened risk perception or risk aversion alone.<sup>138</sup> Such attention or emphasis may result in slipping 'into a cycle of increased regulation to meet the demands of increased risk aversion'<sup>139</sup> and adopting regulatory design strategies and enforcements approaches that emphasise fear rather than providing a balanced, responsive approach to regulation. This in turn is unnecessarily costly and bureaucratic. Ultimately a system that utilises industry knowledge and expertise, and treats those regulated with respect while also setting clear legislative boundaries will undoubtedly result in a better regulatory regime.

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<sup>136</sup> SM Allan, *The Regulation of Research Involving Human Embryos and Cloning in the United Kingdom and Australia* (PhD Thesis, The University of Melbourne, 2009).

<sup>137</sup> *Ibid* 243.

<sup>138</sup> Department of Health and Aging (Cth), above n 137.

<sup>139</sup> Better Regulation Commission, *Risk, Responsibility and Regulation: Whose Risk is it Anyway?* (2006) 5.