Prospective application of a five-step regulatory assessment model to a proposed federal sperm donor registry in Australia: Is it in the public interest?

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It has been proposed that a nationally mandated donor registry be established in Australia to provide data for estimating the possible number of inadvertent half-sibling matings resulting from the multiple use of anonymous donors in donor insemination and to assist identity-release donors and their donor-inseminated children to establish contact. A five-step regulatory assessment model, as described by Johnson and Petersen in 2008, was applied prospectively to the proposed donor registry to identify public interest issues. The resultant issues concern the public ethical interest in child welfare; the public health interest in avoiding genetic abnormalities/disease; public socio-political and legal interests in avoiding inadvertent consanguineous relationships; public ethical and health interests in avoiding identity issues in the donor-inseminated child; and public socio-ethical interests in providing nationally mandated, comprehensive records of donor insemination outcomes. These results provide a basis for further discussion in regard to donor insemination legislation at the federal level.

INTRODUCTION

Many countries, either through legislation or guidelines, limit the number of offspring each anonymous sperm donor can father so as to reduce the risk of inadvertent half-sibling mating. There is also a need to consider limiting the multiple use of identity-release sperm donors[1] because, in the last few years, donor anonymity has been revoked in a number of European countries as well as some States in Australia and it is becoming increasingly important to investigate and control for the psychosocial impact of multiple family connections within the donor insemination family network. This is a new form of familial relationship and it is not known how donors and their offspring will manage contact with potentially high numbers of "extended family members" within the donor insemination community.[2]

There is now, therefore, not only the necessity to control for the risk of inadvertent half-sibling mating but an obligation to control for potential risks associated with multiple interfamily contact within the donor insemination community and to put in place management strategies to assist in the process of connecting and supporting family members while investigating the epidemiological impact

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[1] An "anonymous" donor can refer to either donors who are granted anonymity or are anonymous by default because their donor-inseminated children are unaware of their donor origins. An "identity-release" donor, on the other hand, is one about whom identifying information may be released when their donor child reaches maturity.

[2] Janssens MW, "Colouring the Different Phases in Gamete and Embryo Donation" (2009) 24 *Human Reproduction* 502; Scheib JE and Ruby A, "Contact Among Families Who Share the Same Sperm Donor" (2008) 90 *Fertility and Sterility* 33.

of these extended donor insemination family relationships.[3] To assist in the establishment of sperm donor limits, it has been suggested that a nationally mandated donor registry be established in Australia to monitor and track donor insemination outcomes.[4] Further to this, it is important to define and address the broader public interest issues implicated in the establishment of a national registry and to determine what form – guidelines or legislation – the regulation of donor insemination should take.[5]

The purpose of this article is first, to discuss the fact that, on the world stage, Australia is unique in how it supervises donor insemination. Like the United Kingdom and some other European countries, the Australian State of Victoria implements strict laws regarding the use of donated gametes. There is, however, no federal legislation in Australia regarding the supervision of donor insemination or the documentation and tracking of donor insemination outcomes. Specifically, there is no federal legislation regarding limits on the use of donor sperm[6] and this has created confusion and uncertainty for some within the Australian donor insemination community.[7] The author has suggested[8] that a nationally mandated donor registry would assist in addressing the difficulties in monitoring and tracking donor insemination outcomes that are caused by each State independently imposing their own guidelines and/or regulations regarding donor insemination. Secondly, the article describes how limits on both anonymous and identity-release donor sperm will reduce the risk of inadvertent half-sibling mating and the possible negative psychosocial impact of multiple families interacting within the donor insemination network. The article then outlines the public interest issues implicated in a federal registry of donors and prospectively applies a five-step regulatory assessment model – as described by Johnson and Petersen in 2008 – to the proposed federally mandated donor registry.[9]

REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGIES IN AUSTRALIA

Unlike some countries in Europe, the Australia Federal Government has not been an active participant in the regulation of assisted reproductive technologies (ART). Until recently, it administered ART solely through the Reproductive Technology Accreditation Committee (RTAC) Code of Practice and the ethical guidelines of the National Health and Medical Research Council (NHMRC),[10] but then federal legislation became necessary, to address concerns regarding gene technology, human embryo

[3] Sawyer N, "Reply of the Authors: Beyond Consanguinity Risk: Developing Donor Birth Limits that Consider Psychosocial Risk Factors" (2009) 91 *Fertility and Sterility* e13; Scheib JE and Ruby A, "Beyond Consanguinity Risk: Developing Donor Birth Limits that Consider Psychosocial Risk Factors" (2009) 91 *Fertility and Sterility* e12.

[4] Sawyer N, "Removing the 'Relative' Uncertainty Within the Australian Donor Insemination Network" (2009) 17 JLM 270.

[5] Johnson and Petersen, in using the expression "public interest", acknowledge that the definition of "public interest" is hard to determine and its meaning is "vague and contested": Johnson M and Petersen K, "Public Interest or Public Meddling? Towards an Objective Framework for the Regulation of Assisted Reproduction Technologies" (2008) 23 *Human Reproduction* 716. Hence, for the purposes of this article, the term "pubic interest" is used to describe "considerations affecting the good order and functioning of the community and government affairs, for the well-being of citizens": seeNew South Wales Ombudsman, *Fact Sheet 16 – Public Interest* (New South Wales State Government), http://www.ombo.nsw.gov.au/show.asp?id=371 viewed 20 April 2009.

[6] Petersen K, Baker HW, Pitts M and Thorpe R, "Assisted Reproductive Technologies: Professional and Legal Restrictions in Australian Clinics" (2005) 12 JLM 373.

[7] Donor Conception Support Group (DCSG Australia), http://members.optusnet.com.au/dcsg/header/press.html viewed 28 June 2009.

[8] Sawyer, n 4.

[9] Johnson and Petersen, n 5.

[10] Bell K, "An Overview of Assisted Reproduction in Australia and Directions for Social Research" (2006) 4 *Australian Journal of Emerging Technologies and Society* 15; Petersen, Baker, Pitts and Thorpe, n 6; Petersen K and Johnson M, "SmARTest Regulation? Comparing the Regulatory Structures for ART in the UK and Australia" (2007) 15 *Reproductive BioMedicine Online* 236.

research and cloning technology.[11] There are now Commonwealth statutes directly relating to these new areas of research and technology.

General supervision of ART in Australia, however, is still an extensive regulatory construction consisting of statutes, professional self-regulatory standards and processes, and ethics committees[12] and there is an ongoing lack of federal legislation regarding ART despite the federal and State governments indicating, at the 2003 meeting of the Council of Australian Governments (COAG), that they intended to work towards uniform legislation across Australia and to standardise the regulation of ART.[13] Victoria is the only State in Australia that follows the United Kingdom model and has criminal laws dictating how ART is to be supervised. South Australia, Western Australia and New South Wales do have ART statutes but they are administered by statutory councils and health officials and are not subject to criminal law as they are in Victoria.[14] In these four States, the federally sanctioned ART profession's self-regulatory structures still define clinical and scientific standards through guidelines administered by the RTAC Code of Practice and the NHMRC, but statutes have precedence over both the RTAC Code of Practice and NHMRC guidelines[15]. Thus, ART legislation in Australia is unique in that it follows the United Kingdom model at the Victorian State level – but is more akin to the United States model at the federal level.

Furthermore, there is no federal mandate limiting the multiple use of sperm donors in Australia. There are, however, legislated limits in three of its States and because States can independently impose their own guidelines and/or regulations regarding donor insemination and donor limits, considerable variation has emerged: the *Assisted Reproductive Technology ACT 2007* (NSW) stipulates five families per donor, the *Assisted Reproductive Treatment Act 2008* (Vic) specifies 10 families per donor, while the *Human Reproductive Technology Act 1991* (WA) and *Human Reproductive Technology Amendment Act 1996* (WA) limit each donor to five families. These limits, however, do not appear to be evidence-based. The RTAC, although it is in charge of clinic accreditation, does not stipulate that a donor be required to report if and where they have previously donated or that providers keep track of the number of children generated by any given donor. Furthermore, it does not monitor the recommended limit of 10 families per donor[16] and there is no mandate requiring that records be kept regarding donor insemination or its outcomes.[17] There is, therefore, a pressing need for the establishment of a nationally based donor registry so that all donor insemination outcomes across Australia can be tracked. This is so that the risk of inadvertent half-sibling mating can be reduced and the psychosocial impact of multiple families interacting within the donor insemination network can be investigated and managed.[18]

[11] Karpin I and B. Bennett, "Genetic Technologies and the Regulation of Reproductive Decision-making in Australia" (2006) 14 JLM 127.

[12] Szoke H, "The Nanny State or Responsible Government?" (2002) 9 JLM 470.

[13] Bell, n 10.

[14] Johnson M, "The Art of Regulation and the Regulation of ART: The Impact of Regulation on Research and Clinical Practice" (2002) 9 JLM 399.

[15] Smith M, "Revisiting Old Ground in Light of New Dilemmas: The Need for Queensland to Reconsider the Regulation of Assisted Reproductive Technologies" (2007) 7 QUTLJJ 425.

[16] Petersen, Baker, Pitts and Thorpe, n 6.

[17] Smith M, "Reviewing Regulation of Assisted Reproductive Technology in New South Wales: The Assisted Reproduction Technology Act 2007 (NSW)" (2008) 16 JLM 120.

[18] Sawyer N, "Who's Keeping Count? The Need for Regulation is a Relative Matter" (2009) 92 *Fertility and Sterility* 1811

LIMITING THE USE OF DONOR SPERM

Risk of inadvertent half-sibling mating

To control for the risk of inadvertent half-sibling mating, The Netherlands and Taiwan have both adapted a model developed by Curie-Cohen[19] to establish limits on the multiple use of sperm donors in their countries. To investigate the probability of half-sibling mating due to the multiple use of sperm donors in Australia, the author has endeavoured to apply Curie-Cohen's model using Australian data to estimate variable values. It was impossible, however, to use the Curie-Cohen model for Australia because inadequate records are kept regarding relevant donor insemination-related data from which to compute variables.[20] The Australian Institute of Health and Welfare (AIHW) National Perinatal Statistics Unit (NPSU) collects data from fertility clinics' regarding ART cycles and births but it was found to have limited information regarding donor insemination.[21] Most significantly, it does not collect data regarding the number of sperm donors used per year and this makes it impossible to estimate the average number of offspring per donor. To develop and implement a predictive model and assist policy-makers with the setting of donor limits based on empirical evidence,[22] a centrally based, national record of donors and their offspring is essential.

Risks associated with complex donor insemination and family relationships

Further to the above, donor insemination providers in Victoria, the United Kingdom and other European countries are no longer permitted to recruit or use anonymous donors. A nationally based donor registry is therefore essential, not only to assist in the matching of sperm donors and their donor-inseminated offspring but ultimately to inform the placing of evidence-based limits on the use of identity-release sperm. Since early 2006 there has been an ongoing campaign in Victoria encouraging parents to disclose donor origins to their donor-inseminated children and providing support for them in this endeavour.[23] Both donors and donor-inseminated offspring are now able to request contact after provisions under the *Infertility (Medical Procedures) Act 1984* (Vic) (enacted 1988) came into force in July 2006. Additionally, the *Infertility Treatment Act 1995* (Vic) legislated that only identity-release donors could be used for donor insemination conception after 1 January 1998. In Western Australia, mature donor offspring will be permitted access to identifying information about their donors in 2022, when amendments to the *Human Reproductive Technology Act 1991* (WA) come into force[24] and in New South Wales the *Assisted Reproductive Technology Act 2007* (NSW) has secured the right of donor-conceived children to be informed of their genetic origins when those born from sperm donation, after January 1, 2010, reach 18 years of age. It is important to place interim limits on the use of identity-release sperm while tracking and investigating the experiences of those donor-inseminated offspring and donors who have established contact. This is a new form of family relationship[25] and it is not known how those within the donor insemination family

[19] Curie-Cohen M, "The Frequency of Consanguineous Matings Due to Multiple Use of Donors in Artificial Insemination" (1980) 32 *American Journal of Human Genetics* 589; deBoer A, Oosterwijk JC and Rigters-Aris CAE, "Determination of a Maximum Number of Artificial Inseminations by Donor Children per Sperm Donor" (1995) 63 *Fertility and Sterility* 419; Wang C, Tsai M, Lee M, Huang S, Kao C, Ho H and Hsiao CK, "Maximum Number of Live Births per Donor in Artificial Insemination" (2007) 22 *Human Reproduction* 1363.

[20] Sawyer, n 18.

[21] Wang Y, Dean J, Badgery-Parker T and Sullivan E, *Assisted Reproduction Technology in Australia and New Zealand 2006*, *Assisted Reproduction Technology Series No 12* (AIHW Cat No PER 43, Sydney, 2008).

[22] Sawyer N and McDonald J, "A Review of Mathematical Models Used to Determine Sperm Donor Limits for Infertility Treatment" (2008) 90 *Fertility and Sterility* 265.

[23] Infertility Treatment Authority Newsletter, *Voluntary Donor Registers* (Victorian State Government, August 2008), http://www.ita.org.au/www/257/1001127/displayarticle/newsletters--1001385.html viewed October 2008.

[24] Godman KM, Sanders K, Rosenberg M and Burton P, "Potential Sperm Donors', Recipients' and Their Partners' Opinions Towards the Release of Identifying Information in Western Australia" (2006) 21 *Human Reproduction* 3022.

[25] Freeman T, Jadva V, Kramer W and Golombok S, "Gamete Donation: Parents' Experiences of Searching for Their Child's Donor Siblings and Donor" (2009) 24 *Human Reproduction* 505.

network will manage contact with high numbers of extended family members with whom they have no shared familial history or genetic heritage.[26]

The implementation of a federally mandated donor registry in Australia would also enable further research into the wider epidemiological effects of donor insemination. The vast array of regulations and legislation across Australia makes it very difficult to track donor insemination outcomes and control for the risks involved in the multiple use of sperm donors. Further to this, anecdotal evidence suggests that it is also proving extremely confusing and disruptive to the ongoing wellbeing of donor-inseminated children as they come of age[27] as it depends on which State they were conceived in and when they were conceived as to whether they are eligible to request information about their donor.

This lack of federal legislation regarding limits to donor use and donor insemination in general also constitutes a threat to the public interest because, apart from the reasons delineated above, the set of rules and regulations which are currently in place are based on guidelines, not statutes, and are thus not subject to the same level of checks, balances and formal review as legislation.

PUBLIC INTEREST IN LEGISLATION

Donor insemination can be viewed in one of two ways: as either a purely medical procedure or as a procedure with complex interpersonal and public implications, socially, psychologically and ethically.[28] If we accept the latter position, it is essential for the public to be involved in setting up a regulatory framework in Australia that balances the requirements of all stakeholders. Currently, clinical and scientific standards – to protect the interests of both ART patients and the ART profession in general – are established and monitored through the RTAC Code of Practice and NHMRC guidelines. Statutory regulation, however, would have a more extensive role – as it does overseas – by providing a way to protect the public interest through facilitating the process of public debate, the identification of what *actually* constitutes the public interest in this instance, and ultimately, what is needed for public acceptance.[29]

Johnson and Petersen[30] identified four main classes of potential public interest in ART regulation:

- public health interest;
- public financial interest;
- public ethico-legal interest; and
- public socio-political interest.

Public health and public financial interests both view the patient as a consumer whereas public ethico-legal and public socio-political interests view the patient as a citizen. Johnson and Petersen concluded that there was a need for some special regulations but that it is often difficult to precisely determine regulation objectives and how they are justified. To address this problem they proposed a five-step model for developing and reviewing ART regulatory policy and practice.[31] Table I outlines how this could be applied to the assessment of the proposed national donor registry for donor insemination in Australia.

[26] Scheib and Ruby, n 2.

[27] Victoria, Infertility Treatment Authority, "Parents Want to Tell Children about Donor Conception ... and Children Want to Know", *News Release* (Victorian State Government), http://www.ita.org.au/ viewed 25 November 2008.

[28] Szoke, n 12.

[29] Szoke, n 12.

[30] Johnson and Petersen, n 5.

[31] Johnson and Petersen, n 5.

Table 1 Application of the five-step regulatory assessment model prospectively to a proposed national donor registry

Regulatory step	**Implementing a national donor registry**
1. Identification of public interest objective(s) that underpin regulatory policy	Explicit *public ethical interest* in child welfare by avoidance of the genetic abnormalities associated with consanguineous relationships. Implicit *public health interest* in avoidance of genetic abnormalities by facilitating the sharing of health and genetic information. Implicit *public health interest* in avoidance of genetic disease by enabling ART programs to share donor information. Implicit *public socio-political and legal interests* in avoidance of inadvertent consanguineous relationships. *Public ethical and health interest* by encouragement of, and support for, parents in telling children about genetic origins. *Public ethical and health interest* by avoiding identity issues in the donor-inseminated child. *Public socio-ethical interests* by responding to public fears and doubts about adequate supervision of relatively recent reproductive clinical procedures. *Public health interests* by protecting "genetic solidarity" in regulating for uncontrolled selection of specific social traits associated with the multiple use of a single donor.
2. Relative priority and weight of each objective	Interests of potential children may have priority over parental autonomy and donor privacy. May conflict with donor right to privacy. May conflict with right of parents to a private family life.
3. Possible regulatory instrument for implementing regulation	Statutory requirement on all donor insemination practitioners/clinics to record and then report all donors and donations and resulting live offspring to a central registry.
4. Possible monitoring processes(s) in place to determine whether instrument achieves objective	Inspection and audit by the RTAC. Feedback from clinics. Anecdotal evidence form donors, recipient parents and donor-inseminated offspring.
5. Corrective possibilities available in case regulatory instrument fails: 5(i) Adjust regulatory instrument to more efficiently align objective and outcome 5(ii) Apply existing instruments more strictly 5(iii) Review whether objective is achievable and /or desirable	5. Instrument will fail if clinics do not report donors/donations/live births, if donors fail to disclose previous donations or if parents don't report births. 5(i) RTAC can adjust requirements as need arises. 5(ii) RTAC can revoke or place conditions on a practitioner/clinic's licence with statutory breaches an indictable offence. 5(iii) Would require statutory review.

Adapted from Johnson and Petersen, n 5.

Step 1 should be a clear statement of what the legislation is trying to achieve and why. In this case, a nationally mandated donor registry would be used to provide data that could:

- enable the development of a predictive model to assess and control for the risk of half-sibling mating;
- assist in the matching of donors and their donor-inseminated offspring;
- provide information for an investigation into and assessment of psycho-social issues and support programs in donor insemination; and
- inform the setting of donor limits.

The public interest issues include:

(i) Explicit *public ethical interest* in child welfare through the avoidance of the genetic abnormalities that are more likely to affect offspring resulting from close consanguineous mating, which, in this case would be the offspring resulting from the inadvertent mating of half-siblings born from the same sperm donor;

(ii) Explicit *public health interest* in avoidance of latent genetic abnormalities in donor-inseminated offspring by enabling the sharing of information between clinics regarding up-to-date donor medical history, the tracking of the health outcomes of the donor's natural and donor-inseminated offspring and limiting donor use;

(iii) Implicit *public health interest* in avoiding the spread of genetic disease by enabling donor insemination programs to share donor information regarding sperm use, health and location of donor-inseminated and natural offspring;

(iv) Implicit *public socio-political and legal interests* in avoidance of inadvertent consanguineous relationships between donor-inseminated half-siblings by tracking and limiting the use of anonymous donor sperm;

(v) Implicit *public ethical and health interest* by encouragement of, and support for, parents in telling children about their genetic origins so the offspring can be aware of the possibility of half-sibling mating;

(vi) Explicit *public ethical and health interest* by avoiding identity issues in the donor-inseminated child by enabling either identifiable or non-identifiable genetic information to be available to donor-inseminated children to whom parents have disclosed donor origins;

(vii) *Public socio-ethical interests* by responding to public fears and doubts in regard to the regulation of relatively recent reproductive clinical procedures by providing national legislation mandating comprehensive records in relation to donor insemination outcomes; and

(viii) *Public health interests* by protecting "genetic solidarity"[32] and in regulating for uncontrolled selection of social traits such as specific talents and abilities, height, and other physical characteristics associated with the multiple use of a single donor.

Step 2 should be a clear statement about the relative priority of each of the objectives in Step 1. In this case, the objectives will possibly give precedence to the wellbeing and best interests of potential children over and above those concerning parental autonomy and donor privacy – as is currently the case in Victoria (Australia) and the United Kingdom.[33]

[32] "Genetic solidarity" refers to the "genetic fitness of the population as a whole" where, in the case of over-use of one individual donor's sperm, there could be an increase in the occurrence of certain late-onset genetic disorders that can then affect the whole population if not detected: see Johnson and Petersen, n 5.

[33] Baker GHW, "Problems with the Regulation of Assisted Reproductive Technology: A Clinician's Perspective" (2002) 9 JLM 457; Johnson M, "Escaping the Tyranny of the Embryo? A New Approach to ART Regulation Based on UK and Australian Experiences" (2006) 21 *Human Reproduction* 2756.

Although this may be seen to conflict with the donor's right to privacy in Victoria, donors are aware that provisions under the *Infertility (Medical Procedures) Act 1984* (Vic) (enacted in 1988) allow their donor-inseminated offspring, at age 18, to request identifying information about their donor and to initiate contact. Under this legislation, donors are not compelled to be identified or make contact but it remains to be seen if donor-inseminated children will pursue contact regardless, and thus invade donors' privacy. All donors registered in Victoria after 1998, under the *Infertility Treatment Act 1995* (Vic), are identifiable and should be aware that their donor-inseminated offspring or recipient parents may request identifying information.

Furthermore, it may conflict with the right of parents to a "private family life", as outlined in Art 12 of the *Universal Declaration of Human Rights*, in that parents may feel pressured to disclose donor origins to their children, either by clinics or reproductive agencies such as the Victorian Infertility Treatment Authority (ITA) where, in Victoria, post-1988 donors can request contact.

Step 3 outlines the possible regulatory instrument or instruments for implementing regulation.[34]

In this case the regulatory instrument would take the form of a statutory requirement that all those who practise donor insemination – private practitioners, hospitals or clinics – record and report all donors, donations and resulting live offspring to a central donor registry. Additionally, information concerning donor medical histories would be recorded and available for access by donor insemination providers.

Step 4 describes a possible system of monitoring the process or processes in place to determine whether the instrument – in this instance, the statutory requirement for providers to report all donors and donor-inseminated births to a central registry – merits the costs it incurs and is achieving its objectives.

In this case, inspection by the RTAC could determine if the clinics were collecting and recording the required information; audit by the RTAC could determine administrative and other costs; feedback from clinics could indicate any difficulties experienced either with accessing or processing information regarding donors and/or recipient parents and donor-inseminated offspring; and anecdotal evidence from donors, recipient parents and donor-inseminated offspring as to their experiences and perceptions regarding the process could be used to inform decisions as to the efficacy of the statutory requirements.

Step 5 relates to the corrective options available if costs are too high or objectives are not being met. In this case the instrument will fail if any of the three stakeholders – donors, recipient parents or donor insemination providers – withhold or fail to record reportable information. This would occur if donors fail to disclose important information such as the date/s and location/s of previous donations and accurate family medical history, if recipient parents fail to report donor-inseminated births, or the donor insemination providers are not diligent in their recording of donor details and donor-inseminated births.

Corrective option **5(i)** suggests adjustment of regulatory instrument or instruments so as to more efficiently align objectives and outcomes. In this case the RTAC can adjust the instrument as the need arises. For instance, if the information necessary for the matching of donors and their offspring is not detailed enough, perhaps more frequent updating of donor information, such as place of residence, will be required.

Corrective option **5(ii)** suggests applying the existing instruments more strictly and in this case the RTAC can revoke or place conditions on a practitioner/clinic's licence with statutory breaches enforced as an indictable offence. If necessary, the withholding of reportable medical information or donation history by the donor could be addressed in a similar manner.

[34] This point is considered in more detail in Johnson M and Petersen K , "Instruments for ART regulation: what are the most appropriate mechanisms for achieving smart regulation of ART?" In: Jackson E, Day Sclater S, Ebtehaj F, Richards M (eds), *Individual Freedom, Autonomy and the State.* (Oxford, UK and Portland, USA: Hart Publishing, 2008).

Corrective option **5(iii)** suggests reviewing whether the objectives are, in fact, achievable and/or desirable and this would require statutory review. This could only be assessed after the full impact of the legislation has been realised and outcomes are being manifest.

DISCUSSION

The supervision of donor insemination in Australia needs to be federalised. To achieve this, thorough and comprehensive records need to be kept at the federal level, the State level and by the service providers themselves so that the location and number of both anonymous and identity-release donors and their donor-inseminated offspring can be documented and tracked across the whole country.[35] To this end, it has been suggested that a nationally mandated donor registry be established.[36]

Currently in Australia, issues that relate to health come under State jurisdiction unless, for some reason, they are referred to the Commonwealth.[37] The only federal law regarding ART is legislation responding to concerns about the use of embryos in research and human cloning.[38] There is no national mandate about keeping records regarding donor insemination[39] and this is a problem if there is a need to keep track of donors so as be able to provide information to donor-inseminated offspring or make estimates of the likelihood of half-sibling mating due to the multiple use of sperm donors. There are indications that the federal and State governments intend working towards uniform legislation across Australia to standardise the regulation of ART.[40] This would, of course, include donor insemination. If sperm donor limits could be seen as a pubic interest issue and in the context of children's rights and wellbeing, policies could then be regarded as a federal responsibility.

CONCLUSIONS AND RECOMMENDATIONS

The public interest would be best served if a centrally based, national record of donors and their offspring were established in Australia, as it is in the United Kingdom and some other European countries. It is recommended that the results from the application of Johnson and Petersen's[41] five-step regulatory assessment model to the proposed national donor registry be considered as a starting point for further discussion regarding the public interest issues involved in establishing the national donor registry and limiting the use of donor sperm.

[35] Sawyer, n 18.

[36] Sawyer, n 3.

[37] Petersen and Johnson, n 10.

[38] Karpin and Bennett, n 11.

[39] Petersen, Baker, Pitts and Thorpe, n 6.

[40] Bell, n 10.

[41] Johnson and Petersen, n 5.

