

# Bill C-13 The Assisted Human Reproduction Act: Examining the Arguments Against a Regulatory Approach

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*The temptation to respond to emerging social problems or sensational but atypical events through the vehicle of the generally-applicable criminal law must therefore be resisted, according to this approach [of restraint], and a dispassionate assessment made of the validity of employing the criminal law, as opposed to other, less intrusive or more specialized means.<sup>1</sup>*

*The public tends to demand prohibition of conduct that is universally opposed, but expects issues of moral ambiguity to be regulated.<sup>2</sup>*

## **I. Introduction**

In large part, Bill C-13, *The Assisted Human Reproduction Act*,<sup>3</sup> provides a framework for a reasonable regulatory scheme. It creates the Assisted Human Reproduction Agency of Canada and gives it a broad mandate to “protect and promote the health and safety, and the human dignity and human rights, of Canadians, and to foster the application of ethical principles” in relation to reproductive technologies and to issue licences for a variety of “controlled activities.”<sup>4</sup> As I have argued elsewhere, the adoption of this flexible scheme is an entirely sensible way to regulate reproductive genetics.<sup>5</sup>

However, the bill also prohibits a number of activities, including: reproductive and therapeutic cloning, the creation of embryos for research purposes, germ line alterations, non-

medical sex selection and commercial surrogacy. The continued use of rigid statutory prohibitions has been criticized, to varying degrees, by a variety of commentators, myself included.<sup>6</sup>

In this brief article, I will not revisit the arguments for the adoption of a regulatory approach. Rather, I address three of the main criticisms of the use of a regulatory scheme. The following discussion borrows from and builds on two recently published articles.<sup>7</sup>

## **II. Claim: Statutory Prohibitions are Flexible and Responsive**

A number of commentators have suggested that statutory prohibitions are, in fact, flexible enough to handle this dynamic area, noting that, technically, Parliament can enact and amend laws relatively quickly.<sup>8</sup> Indeed, it has been suggested that Parliament can create a new law or amend an old one in as short as 24 days.<sup>9</sup> The recent terrorism laws illustrate the potential speed of Parliamentary action.<sup>10</sup> But, in reality, Parliament rarely moves so quickly. To cite the most obvious example, the Canadian government has been trying to enact legislation in the area of reproductive technology for almost ten years. There is little reason to believe that Parliament will be inclined to move more quickly in the future. And once the laws are enacted, they may be difficult to alter in response to new scientific developments *or* new social concerns. As noted in the Government of Canada’s *The Criminal Law in Canadian Society*:

The practice of a century in Canada has shown that Parliament can, and has, found it relatively easy to subject conduct to criminal sanctions, in response to specific problems or particular demands. But once an act has been made criminal, it is difficult to remove or lessen criminal penalties, even in response to changes in public attitudes, perceived inconsistencies in application, or emerging experience demonstrating that use of the criminal law might be excessive. . . .<sup>11</sup>

One can argue that this is an area that warrants continued Parliamentary oversight and that, within that context, the Parliamentary process is fast *enough*. Fair enough. Such an argument, however, goes to the issue of democratic accountability,<sup>12</sup> to be covered below, and not to speed of legislative action. Given the pace at which Parliament typically moves to enact or amend legislation, it clearly does not have the flexibility and responsiveness that would characterize a regulatory body. Indeed, the need for flexibility and responsiveness are among the accepted justifications for the very existence of regulatory schemes generally. As noted by Jones and de Villars:

There are a variety of reasons for subordinate legislation, including: . . . c) The power to delegate to an administrator allows greater flexibility in applying statutory provisions to changing circumstances; d) The need for rapid governmental action may require faster administrative response than can be achieved by amending parent legislation; [and] e) Innovation and experimentation in solving social problems may not be possible if parent legislation must be amended.<sup>13</sup>

It should not be forgotten that by creating the Agency the federal government has largely recognized the value of using a regulatory approach in this context. There is not, then, resistance to the regulatory approach *per se*, but to the use of a regulatory approach for the listed prohibited activities. But what is gained by handling these activities through statutory prohibitions instead of placing them in the jurisdiction of the Agency? Why are statutory prohibitions believed to be needed?

### III. Claim: There is a Consensus that Prohibitions are Required

It has been suggested that statutory prohibitions are justified because the prohibited activities are major social concerns and that, therefore, statutory bans are warranted. For example, the Standing Committee on Health stated that: “[t]he use of the statutory ban also signals that these activities are of such concern to Canadians that their status as a prohibited activity may not be altered except with the approval of Parliament.”<sup>14</sup>

*But is there evidence that all of the prohibited activities are a major social concern?*

But is there evidence that all of the prohibited activities are a major social concern? As I have noted in several past publications, other than for reproductive cloning, there is little or no social consensus about the relevant issues.<sup>15</sup> In fact, given available evidence, it seems clear that there is currently no public consensus or agreement within the academic, religious or, even, scientific communities about the risks and benefits of many of the prohibited activities.<sup>16</sup> And for some of the prohibited activities, such as “therapeutic cloning,”<sup>17</sup> the public appears to favour use of the technology. In fact, I am unaware of any data that shows a majority of the Canadian, British or American public to be against therapeutic cloning. Recently, the US President’s Council on Bioethics explicitly noted this lack of consensus stating that, therefore, a ban on all forms of human cloning was not justified and that a moratorium should be imposed to give time “to seek moral consensus”<sup>18</sup> – a surprising result given that a more conservative recommendation was anticipated. For most of the activities that are banned in *Bill C-13*, I am doubtful that the desired “moral consensus” will ever be found.

I highlight this opinion data not to suggest that the government should craft laws based on public surveys (an inherently flawed methodology) or, even, on the hope of building social consensus, but to show that there is no clear evidence that Canadians view many of the relevant activities as grave social concerns worthy of statutory prohibitions (one of the government’s stated justifications for the prohibitions). It is entirely possible to base a law banning a particular technology on strictly moral/ethical arguments – even in the face of a promotive or ambivalent public.<sup>19</sup> For example, it has been suggested that one “test” for whether an

act should be considered a criminal offence is that it must, in some way, “seriously contravene our fundamental values as to be harmful to society.”<sup>20</sup> In this context, it is possible that there may be no consensus about the way and degree to which a given value is implicated, but general agreement about the relevance of the value.<sup>21</sup>

Without a clear and consistent public mandate, it is essential that the relevant “fundamental values” and philosophical foundations for a particular regulatory response be articulated and have an enduring relevance. This is especially true in the regulation of science, where so many of the relevant variables — considerations of safety, the state of the science, and public opinion — are in a state of flux. But in the context of reproductive technologies, there is also little or no agreement about the role or relevance of core values, such as the role of human dignity. In fact, there is still an ongoing debate about whether and how reproductive cloning infringes human dignity or harms the “clone.”<sup>22</sup>

Moreover, the way in which the prohibitions relate to the relevant core values is unclear. For example, the Standing Committee on Health provides a list of “over-arching considerations” – including human dignity, the protection and promotion of health, and non-commodification – but fails to adequately explain why prohibitions are needed in order to protect and further these principles.<sup>23</sup> To cite just one example, the justifications for the ban on therapeutic cloning are that it is “unsafe and commodifies the embryo.”<sup>24</sup>

Though therapeutic cloning could generate a greater demand for embryos, thus creating an environment where commodification is more likely, the *act* of therapeutic cloning does not commodify the embryo. As such, if we agree that commodification is the problem, we could focus the regulatory response on the buying and selling of embryos, not the technology (for example: currently, we ban the buying and selling of kidneys, not kidney transplantation).

Protection of health is the other “core value” invoked by the Standing Committee in relation to therapeutic cloning. However, it is unclear what unique safety concerns are associated with therapeutic cloning (indeed, there is no official documentation regarding the issue) so as to justify a statutory ban. To my knowledge, therapeutic cloning would be no more dangerous than many other experimental treatments (should we use federal statutory bans to address experimental chemotherapy?). In addition, it would be unusual for the government to develop a specific ban for a potentially unsafe medical procedure – regulation, through

the health professions, research ethics policy and Health Canada, is, for better or worse, the norm.

In the end, it is difficult to support the argument that there is a consensus that all of the prohibited activities are grave social concerns worthy of statutory prohibitions. There is no doubt that the public would like to see the area regulated,<sup>25</sup> but there remains little consensus about the severity and nature of the relevant social concerns. This lack of social consensus, the shifting nature of the relevant science and the absence of concrete and coherent ethical counter-arguments, make many of the listed activities, such as therapeutic cloning, wonderful examples of activities that should be closely regulated rather than banned. As argued by Gogarty and Nicol, “The public tends to demand prohibition of conduct that is universally opposed, but expects issues of moral ambiguity to be regulated.”<sup>26</sup> This could be done easily by shifting the control of most of the prohibited activities to the Agency.<sup>27</sup> The Agency will have the flexibility necessary to respond to the diverse and changing social attitudes. And, hopefully, the Agency can serve as a forum for ongoing public dialogue.

#### ***IV. Claim: Regulatory Schemes Lack Sufficient Democratic Accountability***

One can persuasively contend that reproductive genetics is an area of such significance that it demands continued oversight by elected officials and that Parliament is the ideal forum for public debate on this kind of critical social issue. I find this to be the most compelling argument against the use of a regulatory approach.

I have great sympathy for both aspects of this position. Despite the lack of clear justifications for the use of statutory prohibitions, their use ensures Parliamentary involvement in the regulatory process and, as such, any change to the law would likely trigger broad Parliamentary and public debate. Indeed, I believe that, at some level, concern about oversight and accountability lie at the heart of much of the opposition to the use of a regulatory approach. There is an understandable resistance to placing this complex area in the hands of a “bureaucratic entity.”

However, a deep desire for Parliamentary review, on its own, does not stand as a satisfactory justification for the use of criminal legislation. There has to be, of course, a reasoned justification for the use of statutory prohibitions. We do not make something a statutory criminal offence simply to ensure oversight by elected officials. There must

be something about the specific act to warrant the application of the strongest of our regulatory tools. Indeed, as noted elsewhere in this volume,<sup>28</sup> without clear justifications, the long-term legitimacy and, even, the constitutional validity of the legislation may be compromised. To date, these clear justifications have been absent. And given the shifting nature and moral ambiguity of the topic, I believe that clear, generally accepted rationales for many of the suggested statutory bans will always remain elusive.

The challenge, then, is to produce a regulatory framework that can provide the best of both worlds – that is, a flexible regulatory approach that can respond to the rapidly changing science, is respectful of the diverse moral positions, encourages and facilitates ongoing public debate *and* is sufficiently accountable. Though a detailed analysis of the characteristics of the regulatory scheme is beyond the scope of this brief paper, such a body should, at a minimum, have the following elements:

- a multi-disciplinary membership, including experts from the clinical, natural and social sciences;
- a public consultation process;<sup>29</sup>
- an educative and public engagement role (such as the issuance of regular “bulletins” outlining the Agency’s approach to various issues); and
- the use of a negative resolution process.<sup>30</sup>

## V. Other Arguments

Below is a brief review of some of the other arguments relevant to the use of a regulatory scheme.<sup>31</sup>

### **A Regulatory Scheme Will Not Have Symbolic Weight**

Another justification for the use of statutory bans is that they have more symbolic weight than the regulations. As suggested by the Standing Committee: “An outright statutory ban signals more clearly that certain activities are either unsafe or socially unacceptable.”<sup>32</sup> This justification is problematic in that it assumes that the concerns are of such weight as to warrant this type of “signal.” As I note above, the government has not established this fact.

Also, the “symbolic” message of a statutory prohibition is considerably different, at least potentially, from a regulatory approach. The public message of a well-structured regulatory scheme should be that open, vibrant and continued dialogue is encouraged. The message of statutory bans is that public debate is closed.

Finally, there is no reason that a regulatory body could not be set up to be a high-profile, transparent entity that has great symbolic weight.

### **The Technologies Don’t Work**

It has also been suggested that one reason to allow a ban on, for example, therapeutic cloning is that, at the current time, we don’t know if it will work. This is hardly a justification for the enactment of a statutory prohibition. We don’t ban something because it doesn’t work or is currently “impractical.”<sup>33</sup> Obviously, there needs to be another reason for the ban.

### **The Research May Lead to Unsafe and Immoral Practices**

Many of the recommended bans, such as the ban of therapeutic cloning, have been supported on the premise that they could lead to or will facilitate unacceptable procedures. An example argument would be that we should ban therapeutic cloning because it could lead to reproductive cloning. This seems a reasonable argument for regulation but not for a ban. Governments rarely, if ever, ban “precursor” research or technologies. For example, we allow research on highly dangerous chemicals, radioactive materials and infectious agents, all of which, if used improperly, pose a far greater immediate threat to humans than cloning technology.

## VI. Conclusion

The area of reproductive genetics raises a variety of unique and challenging regulatory challenges. It is my hope that the government will be able to create a regulatory framework that retains both the benefits of a flexible and responsive regulatory regime and yet remains sufficiently accountable.

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1. Canada, *The Criminal Law in Canadian Society* (Ottawa: Government of Canada, 1982) at 68.
2. B. Gogarty & D. Nicol, “The UK’s Cloning Laws: A View from the Antipodes” (2002) 9 *Murdoch U. E. L. J.*, online: Murdoch University <[www.murdoch.edu.au/elaw/issues/v9n2/gogarty92\\_text.html](http://www.murdoch.edu.au/elaw/issues/v9n2/gogarty92_text.html)> at para. 32.

3. 2d Sess., 37<sup>th</sup> Parl., 2002 [*Bill C-13*], *Bill C-56, An Act respecting assisted human reproduction*, 1<sup>st</sup> Sess., 37<sup>th</sup> Parl., 2002, was prorogued at the end of the First Session of the Thirty Seventh Parliament last spring. However, it was re-introduced into Parliament as *Bill C-13* pursuant to an Order made October 7, 2002, in the same form as *Bill C-56*.
4. *Ibid.*, s. 22.
5. T. Caulfield, "Clones, Controversy and Criminal Law: A Comment on the Proposal for Legislation Governing Assisted Human Reproduction" (2001) 39 *Alta. L. Rev.* 335 ["Clones, Controversy and Criminal Law"].
6. See California Advisory Committee on Human Cloning, *Report*, online: San Francisco Chronicle <[www.sfgate.com/chronicle/cloningreport](http://www.sfgate.com/chronicle/cloningreport)>; K. Venturatos Lorio, "The Process of Regulating Assisted Reproductive Technologies: What We Can Learn From Our Neighbors – What Translates and What Does Not" (1999) 45 *Loy. L. Rev.* 245; B. Dickens, "Do Not Criminalize New Reproductive Technologies" (1996) 17 *Policy Options* 11; A. Harvison Young & A. Wasunna, "Wrestling with the Limits of Law: Regulating Reproductive Technologies" (1998) 6 *Health L. J.* 239; Canadian Bar Association, "Submission of Draft Legislation on Assisted Human Reproduction" (2002) 10 *Health L. Rev.* 25; E. Parens & L. Knowles, "Reproductive Genetics and Public Policy: Shaping Our Future" *The Hastings Centre* [forthcoming in 2002]; J. Johnston, "Reproduction Bill Could Curb Research More Than Intended" *The Chronicle-Herald (Halifax)* (21 May 2002) B2; L. Knowles, "Science Policy and the Law: Reproductive and Therapeutic Cloning" (2001) 4 *Science Policy and the Law* 13 at 20:
 

[I]t seems clear that rather than using the law to react in an *ad hoc* manner to specific scientific innovations, we should attain a more comprehensive understanding of new developments, and draft laws that reflect that understanding. It is possible to develop a broadly framed legislative mandate and to structure regulatory bodies that are responsive to change.

For a review of relevant policies see M. Herder, "Embryonic Stem Cell Research: No Need to Reinvent the Wheel, Just *Regulate* It" (September 27-28, 2002) Poster: Precedent and Innovation, *Health Law in the 21<sup>st</sup> Century*; G. Annas, L. Andrews & R. Isasi, "Protecting the Endangered Human" (2002) 28 *Am. J. of L. & Med.* 151.
7. T. Caulfield, "Politics, Prohibitions and the Lost Public Perspective: A Comment on *Bill C-56: The Assisted Human Reproduction Act*" (2002) 40 *Alta. L. Rev.* 451 ["Politics, Prohibitions and the Lost Public Perspective"]; and T. Caulfield, "A Rejoinder to Professor Anand" (2002) 40 *Alta. L. Rev.* 507. The sections are reproduced with the express permission of the *Alberta Law Review*. For more complete references, I invite the reader to refer to these articles. See also T. Caulfield, L. Knowles & E. Meslin, "Law and Policy in the Era of Reproductive Genetics" (2002) [submitted for publication].
8. F. Baylis & J. Downie "Ban Cloning: Do you copy?" *The Globe and Mail* (2 July 2002) A13; A. Campbell, "Defining a Policy Rationale for the Criminal Regulation of Reproductive Technologies" in this volume.
9. Baylis & Downie, *ibid.*
10. This reactive use of the criminal prohibitions has also been criticized. "[T]oo often, the response to the emergence of a particular social problem has been an almost routine or automatic invocation of the criminal law, or criminal-like sanctions." *Supra* note 1 at 42.
11. *Supra* note 1 at 46. I recognize that s. 70 compels a review of the legislation in three years. However, such a provision only compels a "review" and not the creation of any new law. It seems unlikely that there will be any greater social consensus three years from today. It makes sense to develop the needed regulatory regime now.
12. For a general review of the limitations of regulatory bodies see D. Mullan, *Administrative Law* (Toronto: Irwin Law, 2001).
13. D. Jones & A. de Villars, *Principles of Administrative Law* (Scarborough: Carswell, 1994) at 82.
14. Standing Committee on Health, *Assisted Human Reproduction: Building Families* (House of Commons, December 2001) at 9. See also Health Canada, "Assisted Human Reproduction: Frequently Asked Questions" (May 2001) online: Health Canada <[www.hc-sc.gc.ca/english/archives/releases/2001](http://www.hc-sc.gc.ca/english/archives/releases/2001)> at question 9: "There is a broad consensus that the activities that would be banned under the proposed legislation are not acceptable in Canada."
15. T. Caulfield, "Politics, Prohibitions and the Lost Public Perspective," *supra* note 7.
16. I reference much of the available data in Caulfield, *ibid.* See also C. Abraham "Stem-Cell Study to Begin Soon in Saudi Arabia" *The Globe and Mail* (13 June 2002) A7, where it is reported that Islamic scholars are drafting "religious rules, or *fatwas*, to guide the world's one billion Muslims through this new frontier in medicine." It is anticipated that the new *fatwas* "will eventually approve the use of so-called therapeutic cloning as a life-saving treatment," and T. Traubman "Leaps of Faith: Dolly the Kosher Camel" *Israel Time* (16 September 2002). See also E. Greenway "Paying Surrogate Mothers OK – Poll" *Edmonton Journal* (17 August 2002) A6, where it was reported that, surprisingly, most Canadian support commercial surrogacy. "The survey found that 54 per cent of respondents agreed that payments to surrogates should be allowed"; J. Johnston, "Sanctifying the Human Genome: Why Prohibit Germline Gene Therapy?" (September 27-29, 2002) Poster: Precedent and Innovation, *Health Law in the 21<sup>st</sup> Century*.
17. The use of somatic cell nuclear transfer for non-reproductive purposes is often referred to as "therapeutic cloning." Though I feel this is an unfortunate term that has contributed to some of the confusion about the application of the technique, the term has made it into common usage and, as such, we will use the term "therapeutic cloning" in this paper. See B. Vogelstein, "When a Clone Is Not a Clone" (2002) 118 *HMS Beagle (BioMedNet)*.



18. The President's Council on Bioethics, *Human Cloning and Human Dignity: An Ethical Inquiry* (July 2002) online: The President's Council on Bioethics <www.bioethics.gov/cloningreport/fullreport.html> at 16. Interestingly, the Council was split. Seven of the members supported a recommendation therapeutic cloning. "Permitting cloning-for-research now, while governing it through a prudent and sensible regulatory regime, is the most appropriate way to allow important research to proceed while insuring that abuses are prevented." *Ibid.* at 17. See also, LA Times, "Cloning Panel Urges Moratorium, Not Ban" *Edmonton Journal* (12 July 2002) A7. See also the published statement by four dissenting members of the President's Council: J. Rowley *et al.*, "Harmful Moratorium on Stem Cell Research" (2002) 297 *Science* 1957.
19. That said, at some level, public opinion must surely be relevant. As noted in the Canadian Government's *The Criminal Law in Canadian Society*, the criminal law should be an instrument of "last resort" and should only be used to respond to "conduct which is culpable, seriously harmful, and generally conceived of as deserving of punishment" *supra* note 1 at 4 [italics added]. The word "consensus" is not used, but the point is clear.
20. Law Commission of Canada, *Our Criminal Law* cited in Government of Canada, *The Criminal Law in Canadian Society*, *supra* note 1 at 44.
21. Indeed, some of the most important legal reforms, such as the human rights movement in the US, faced a degree of public opposition. Moreover, there are many examples of laws being passed without strong public support. See C. Condit, "What is 'public opinion' about genetics?" (2001) 2 *Nature Reviews Genetics* 811.
22. S. Pattinson, "Reproductive Cloning: Can Cloning Harm the Clone?" *Med. L. Rev.* [forthcoming in 2002].
23. Standing Committee, *supra* note 14.
24. *Ibid.* at 10.
25. Indeed, there is some evidence suggesting that the Canadian public views "regulation," rather than specific bans, as the preferred regulatory approach. See Pollara, "Benchmark Survey on Awareness and Knowledge Levels of Assisted Human Reproduction" (Ottawa: Health Canada, 2001), where it was found that in 2001, 59% of the respondents thought research on embryos should be regulated, 26% thought it should be banned and 12% thought it should be neither banned or regulated.
26. *Supra* note 2.
27. In part, this is what has occurred in the UK where they have "two pieces of legislation , one criminalising the use of cloned embryos for the creation of a child (the Cloning Act) and the other regulating the creation of CNR [cell nuclear replacement] embryos through a licensing system (the Human Fertilisation and Embryology Act)," *supra* note 2 at para. 10.
28. See A. Campbell, "Defining a Policy Rationale for the Criminal Regulation of Reproductive Technologies" and B. Billingsley, "A Charter Perspective: Freedom of Expression, Justifiable Limits and the Ban on Therapeutic Cloning" in this volume.
29. The creation of an effective consultation process will be a major challenge. The process will need to be both efficient and reasonably representative. See S. Anand, "Clones, Controversy, Confusion, and Criminal Law: A Reply to Professor Caulfield" (2002) 40 *Alta. L. Rev.* 493.
30. In this approach, the regulations proposed by the Agency would come into effect unless rejected by a negative resolution of the House of Commons. See Canadian Bar Association, *supra* note 6. It is important to note, as highlighted by Herder, "Donate a Definition" in this volume, that the Agency created by *Bill C-13* must have all significant regulations approved by Parliament. This is a less than ideal setup, primarily because it reduces the advantages associated with the use of the regulatory body such as the Agency. A negative resolution process would achieve the same result and would only engage Parliament on controversial issues.
31. I recognize that constitutional issues remain an important issue in this context and may be a primary, yet largely unspoken, justification for the use of criminal prohibitions. However, because the jurisdiction issue is not raised by the government as an explicit policy rationale for the use of criminal laws and I have briefly dealt with the issue elsewhere, I have chosen not to explore it further here. See T. Caulfield, "Clones, Controversy and Criminal Law," *supra* note 5.
32. Standing Committee on Health, *supra* note 14 at 9.
33. The Standing Committee on Health states that we should ban germ line therapy because it is "unsafe and impractical," *supra* note 14 at 11.

