The Challenge of Regulating Rapidly Changing Science: Stem Cell Legislation in Canada

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Introduction

There is a policy cliche stating that the law lags behind science and is limping a little. There is no doubt that the speed of scientific advances can outpace the often sloth-like tempo of the political and legislative process. In Canada, for example, the reproductive technologies legislation that also governs embryonic stem cell (ESC) research came into force a decade after the publication of the Royal Commission that called for its enactment.

But the law is also often a terribly blunt and clumsy policy tool. It not only lags behind the advances of science but can create unintended hurdles in front of it. Legislation can quickly become an anachronism, no longer reflecting the social mood or scientific realities. If scientific legislation is crafted without careful attention to the underlying science, it may run aground when faced with new scientific realities.

Nowhere are the struggles of law more apparent than in stem cell research an area in which intense soc

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the same time, new approaches to creating stem cell lines have emerged, some to circumvent challenges posed in adopting human ESCs (hESCs). Notable new techniques include interspecies somatic cell nuclear transfer (iSCNT), induced pluripotent stem (iPS) cells, and ESCs derived from parthenogenetic embryos and from embryos generated from isolated blastomeres (Ogbogu and Rugg-Gunn, 2008). Most, if not all, of these techniques were not contemplated during the political debates that led to the current regulatory environment.

This Forum article examines the challenges of drafting legislation in a changing scientific climate by asking how these emerging technologies fit within existing international regulatory regimes. We believe that regulatory uncertainties created by these new techniques demonstrate the limitations placed on stem cell

would normally require licensing, because the outcome of this procedure is de ned as a hybrid and not an embryo, this technique may fall completely outside the established regulatory regime. Therefore, not only does iSCNT creation appear legal, but a researcher may not even need to obtain a license to conduct these studies in Canada.

It is important to note that our view that

a single blastomere from a cleavage-stage embryo and coaxing the isolated cell to develop into a blastocyst, from which stem cells can be derived (Chung et al., 2008). Blastocysts formed from single blastomeres extracted from eight cell mouse or primate embryos cannot complete development even when implanted into a surrogate host (Chan et al., 2000; Rossant, 1976). Since human embryos blastulate at a similar stage to mouse and primate, current scienti c evidence indicates that embryos generated from single human blastomeres are also nonviable.

Our interpretation of Canadian legislation is that both techniques would be treated as creating an embryo for research purposes and would therefore be prohibited. However, this conclusion is not certain, because the term ''embryo'' is loosely de ned in the Act as ''a human organism in the rst 56 days of develop-

emphasizing the technical details of science'' (Nisbet and Mooney, 2007), sticking instead to broad principles and clarity of language that promotes better understanding of the matters at stake.

Second, researchers should highlight the challenges associated with restrictive and inflexible legislation and emphasize the advantages of regulatory guidelines that allow rapid response to scientific advances. Again, whether one advocates a cautious or more permissive approach to regulation, it is important to craft legislative provisions that retain the ability to capture the nuances and unpredictable turns inevitably associated with scientific progress.

Finally, and perhaps most importantly, it is imperative that science policy be founded on clear, transparent principles that will have enduring relevance regardless of where the science takes us. The specific principles must be stated explicitly, such that new developments can be openly considered within that context. Through this process, legislation can comprehensively regulate research while ensuring a clear and fair framework for future scientific advances.

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