

# Canada's Stem Cell Corporation: Aggregate Concerns and the Question of Public Trust

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**ABSTRACT.** This paper examines one nascent entrepreneurial endeavour intended by Canada's Stem Cell Network to catalyze the commercialization of stem cell research: the creation of a company called "Aggregate Therapeutics". We argue that this initiative, in its current configuration, is likely to result in a breach of public trust owing to three inter-related concerns: conflicts of interest; corporate influence on the university research agenda; and the failure to provide some form of direct return for the public's substantial tax dollar investment. These concerns are common to many efforts to commercialize academic science but are rendered particularly acute in this case given the therapeutic promise of stem cell research and the considerable number of resources related to stem cell research in Canada, which Aggregate Therapeutics is expected to pool. We do, however, believe that the company can be altered to guard against a violation of the public's trust, and so we present concrete modifications to its structure, which we contend should be given immediate consideration.

**KEY WORDS:** biotechnology, Canada, commercialization, governance, intellectual property, patent, public trust, stem cell

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In November 1998, three seminal scientific experiments in stem cell research were reported.<sup>1</sup> While loud debates quickly ensued over the moral aspects of human embryonic stem cell research, a number of more quiet steps were taken toward developing this emerging field of research into an enterprise. Following intense periods of national debate, leading countries in science and technology (the U.S., the U.K., Singapore, as well as several others) have opted to permit stem cell research under varying conditions. In public conversation, the enormous medical and health benefits expected for each nation's citizens provided governments with an overwhelming rationale to support stem cell research, and in particular, human embryonic stem cell research. However, the project of commercializing stem cell research – whether through patenting stem cell discoveries or through new researcher–university–industry 'partnerships' – has not been at the forefront of public engagement in any country to date.

In this paper, we aim to focus the conversation on the broad topic of commercialization by exploring one specific government-sponsored initiative, a biotech company called "Aggregate Therapeutics",<sup>2</sup> recently created by the Canadian Stem Cell Network (SCN), a member of the federal Networks of Centres of Excellence programme.<sup>3</sup> The SCN is a federally funded research consortium established to facilitate Canadian efforts, expertise, and excellence in stem cell research. One of its primary activities over the past several years has been to establish a commercialization strategy for stem cell research in Canada, resulting in the recent creation of Aggregate Therapeutics. While we focus specifically on this particular company, the concerns we identify are not different in kind from those related to the

commercialization of university research in general, whether in Canada, the U.S., or elsewhere.

At the same time, rather than provide a systematic summary of the already-rich literature exploring the nature and effects of academic entrepreneurship, including concerns surrounding trade secrecy, intellectual property, conflicts of interest, the erosion of public trust in multivested science, and the loss of public-interest science (Krimsky, 2003) we focus on this particular exemplar of academic entrepreneurship with regard to which these concerns are especially acute. Two factors account for why we believe the risks typically associated with commercialization are more acute with regard to Aggregate Therapeutics: (1) the great therapeutic potential of human stem cell research, which Canadian citizens (or key *stakeholders* in Aggregate Therapeutics) have been promised;<sup>4</sup> (2) the considerable resources devoted to stem cell research in Canada, which the SCN envisions the company will pool together (and hold in the interests of its *shareholders*).<sup>5</sup>

In short, Aggregate Therapeutics does nothing to address the situations in which the interests of the stakeholders and shareholders fail to coincide.<sup>6</sup> In that instance, corporate obligations to deliver dividends legally trump broader social responsibilities. However, while the question of whether Aggregate Therapeutics will actually undermine the Canadian public's stake in stem cell research is difficult to answer, our central claim is that the company's current design and pride of place within the SCN make a violation of the public's trust foreseeable.<sup>7</sup> And if and when such a violation results, governmental support (in the form of grant money and infrastructure) for Canadian stem cell science may quickly vanish. In that eventuality, stakeholders and shareholders alike – the public, the researchers, and the institutions – stand to lose.

We develop this claim in the following three sections. First, we place Aggregate Therapeutics in context, briefly explaining the cultural shift in the university research setting, the notion of technology transfer and industry partnership that commercialization is premised upon, and the relatively recent proliferation of stem cell start-up businesses. Second, against this background, we define our specific concerns with Aggregate Therapeutics. These include conflicts of interest, corporate influence on the

university research agenda, and lack of returns on public investment. These concerns outweigh the potential gains to be made by the creation of Aggregate Therapeutics as presently engineered. Third, we outline concrete ways in which the company can be modified to better protect the public trust and manage the risk to the interests of everyone involved: the risk to the public in not seeing the promised health benefits, and the risk to scientists, research institutions and the SCN itself if the formation of Aggregate Therapeutics somehow precipitates a decrease in public support for stem cell research.

### **Aggregate Therapeutics in context**

Working in a laboratory in the newly created Ontario Cancer Institute in the early 1960s, Ernest McCulloch and James Till demonstrated the existence of stem cells (Becker et al., 1963; McCulloch and Till, 1960, 1962; Till and McCulloch, 1961). Patenting their work was not even discussed – they regarded it as basic biological research outside the parameters of patent protection – though novel procedures with direct clinical application for humans, had they been devised, might have proven to be a different story.<sup>8</sup> In that era, patenting basic scientific discoveries was simply considered inconsistent with the mission of public institutions (Nelkin and Nelson, 1987; Weiner, 1987).

However, this position has essentially been reversed due to a series of events originating in the U.S. in the 1960s, '70s and '80s, including: a significant increase in governmental research funding; the birth of commercial biotechnology following the discovery of recombinant DNA technology; a ruling by the U.S. Supreme Court opening the door for patenting life forms;<sup>9</sup> and the enactment of legislation<sup>10</sup> by Congress encouraging universities to patent discoveries realized with public funds and license them to industry for conversion into marketable products (i.e. technology transfer) (Mowery et al., 2001). Although Canada has not enacted parallel legislative reforms, a “multitude of mutually reinforcing policy instruments” has been equally effective in institutionalizing commercialization goals (Atkinson-Grosjean, 2002; Fisher et al., 2001, p. 307).<sup>11</sup> A cultural change has occurred, dubbed

“the second enclosure movement” (Boyle, 2003), which supports a general trend in favor of patenting research outcomes, even basic scientific discoveries with no immediate clinical use, as a matter of general practice in the life sciences. Today, the Ontario Cancer Institute, where McCulloch and Till conducted their groundbreaking work, is amongst the leading holders of intellectual property relating to stem cells in Canada.<sup>12</sup>

While institutions like MIT and Stanford in the U.S. have long embraced entrepreneurialism as a legitimate part of the university mission (Etzkowitz, 2003), changes in the university research setting – changes that resulted from a pressure to endorse commercialization objectives – are much more evident over the last quarter century (Stein, 2004). On average, American universities as a whole received fewer than 250 patents per year prior to 1980 whereas more than 3600 were obtained in 2004.<sup>13</sup> The number of U.S. patent applications filed by Canadian Universities jumped from 66 in 1991 to 1265 in 2004.<sup>14</sup> Every major research institution in North America now has a technology transfer office to secure, maximize and exploit its intellectual property holdings (Fisher and Atkinson-Grosjean, 2002).<sup>15</sup> Individual university scientists seem to exhibit a growing sense of entitlement to profit from ‘their’ inventions, making the creation of start-up companies relatively commonplace. Commercialization is explicitly entrenched in the mandates of research funding agencies such as the Canadian Institutes of Health Research, Genome Canada and the SCN.<sup>16</sup> At the same time, there is increasing critical commentary about the consequences of this cultural change, for instance, for the direction of the research agenda, the character of publicly funded research institutions and the scientists they employ (Downie, 2003; Lewis et al., 2001; Rai and Eisenberg, 2003). Some posit that the dramatic rise in academic-industry liaisons reprograms the ethical norms of basic scientific research: “secrecy replaces openness, knowledge is privatized, scientific discoveries become commodities, and conflicts of interest are ever prevalent” (Krimsky, 2003). Science may never have fully conformed to Mertonian ideals of “universalism”, “communalism”, “disinterestedness”, and “organized skepticism”, and differences between sub-disciplines surely exist (Shorett et al., 2003, p. 124). Nevertheless, many believe the

“scientific commons” to be under unprecedented threat (Nelson, 2004).

Within this context of commercialization and attendant controversy, a sub-sector of biotech companies focusing on stem cell research has emerged. Several companies had already invested in cell-based therapies such as bone marrow transplants, but the announcements of November 1998, especially the work of James Thomson demonstrating the derivation of stem cell lines from human embryos, caused an immediate “gold-rush” towards the field (Marshall, 2000, p. 1419). Existing companies such as Geron Corporation oriented their business plans toward applications with human embryonic stem cells, and new corporations formed in pursuit of other promising avenues of stem cell research (Brower, 1999; Marshall, 2000; Vogel, 2003). The excitement dissipated, however, as stem cell research became mired in political controversy and the lengthy lag in transition between basic stem cell discovery and commercial end-product became clearer. As a result, venture capitalists have not provided the investment needed for many of these companies to survive; even those like Geron with sizeable intellectual property assets in hand have had to adopt more conservative business measures, laying off scientists, delaying more costly research, and rethinking business models premised upon personalized medicine (Giebel, 2005; Vogel, 2003). Reflective of this trend, in Canada there are very few biotech companies focusing on stem cell technologies.<sup>17</sup> In fact, the biotech sector in Canada has in general struggled to sustain itself.<sup>18</sup>

The outlook for private stem cell enterprises, whether in Canada, the U.S. or elsewhere, may therefore seem bleak at the moment. As one commentator has noted, “[s]tem cell research needs to be incubated in academia much longer before it is ready to graduate into a business that can commercialize the technology and deliver real products” (Giebel, 2005, p. 800). Under the university–industry technology transfer paradigm, the lack of venture capital means that most advances in the field made in the near future will be attributable to sources of public funding. Indeed, some state governments in the U.S. have begun to take steps to ensure that ample funding is in place. With the acceptance of Proposition 71 by Californian voters in 2004, a sum of three billion U.S. dollars was committed to stem cell

research and the creation of the “California Institute for Regenerative Medicine”; similar multi-million or billion dollar public funding proposals have been put forth or passed in Connecticut, New Jersey, Pennsylvania, Delaware, and Illinois, with other states such as Massachusetts and New York financing initiatives using combinations of public and private money (Herrera, 2005).

Though not on the same scale, the Canadian government has also made a significant public tax dollar contribution in support of stem cell research, relative to the size of the research community.<sup>19</sup> The SCN plays a central role in deciding how to allocate these funds and, as we noted above, it has crafted Aggregate Therapeutics as its vehicle of choice for capitalizing on Canadian stem cell science. Originally, this corporation was intended to be “groundbreaking” in design, attempting to bring all Canadian stem cell researchers and their host institutions under one virtual roof.<sup>20</sup> A complex capital share structure was to allow participating teams of researchers or institutions to share in whatever economic gains resulted from the scientific contributions of other teams while receiving greater rewards when their work was responsible for those gains. A mechanism to automatically transfer intellectual property (specifically, patented stem cell technologies) generated by participating researchers and institutions formed part of the original proposal, as well. However, after three years of planning and repeated rounds of confidential consultations with prospective participants (scientific researchers, university technology transfer officials, and venture capitalists), Aggregate Therapeutics now appears structurally indistinguishable from any traditional biotech start-up company: instead of a standardized licensing agreement, interested scientists and research institutions will transfer patent rights to the company on a case-by-case basis in exchange for company shares.<sup>21</sup>

The SCN believes that the failings of stem cell businesses in the U.S. and those of Canadian biotech companies in general can be overcome. The SCN expects that Aggregate Therapeutics will be attractive to Canadian researchers and institutions because its high quality management team will be able to give sound advice for adapting stem cell technologies to the clinic while meeting applicable regulatory requirements, which will, in turn, motivate the

researchers and institutions to license patented stem cell technologies to the company and subsequently engender considerable investor interest.<sup>21</sup> According to the Executive Director of the SCN, although the legal structure is traditional in many respects, “the Aggregate business model/approach is highly innovative in its focus on early stage translational development, and its collaborative approach to working with a diverse group of investigators in partnership with their technology transfer offices.”<sup>21</sup> Aggregate Therapeutics will, in the SCN’s opinion, produce more revenue and funding for stem cell research, enable capacity-building by creating longer term employment opportunities for Canadian stem cell scientists, and hopefully improve the likelihood that Canadians will ultimately see the health benefits of stem cell research that they have been promised.<sup>22</sup>

Conversely, we contend that, in its present configuration, Aggregate Therapeutics presents several serious concerns. Taken together, these concerns increase the risk that this unique company will be perceived as responsible for any failure to realize the potential health benefits of stem cell research, whether that connection is real or only apparent. If the general Canadian public deems its trust to have been violated in this way, very little support, economic or political, for those scientists engaged in this critical area of research may remain.

### **Concerns about Aggregate Therapeutics**

The SCN’s move to create Aggregate Therapeutics is not particularly surprising: though subject to frequent attack, the prevailing assumption is still that the development of biotechnology inventions through public–private technology transfer produces a net benefit to society and its taxpaying citizens. Regardless, we think there is heightened potential for a violation of the public trust in this instance. On the one hand, the public is in general far more skeptical of scientists and their chosen endeavours than they were historically: “Scientists are no longer perceived exclusively as guardians of objective truth but as smart promoters of their own interests” (Haerlin and Parr, 1999, p. 499). On the other hand, the expectations generated in relation to stem cell research, even when stripped of rhetoric and hype, are exceedingly high. While these expectations seem

to outweigh this skepticism at this time, the general public will be quick to judge the actions of stem cell scientists if the therapeutic promises are not realized. The three concerns that follow – conflicts of interest, influence on the university research agenda, and the failure to build in real returns on investment – explain why we believe that Aggregate Therapeutics may make a negative judgment inevitable.

### *Conflicts of interest*

All research universities have technology transfer offices designed to maximize royalty revenues from patented inventions; career benchmarks for researchers in the life sciences are now more tied to patents held, rewarding those who patent first and publish later. As universities become willing partners, if not sometimes market leaders, in the business of science, conflicts of interest become a much more prevalent problem (Bekelman et al., 2003; Lexchin et al., 2003; Morin et al., 2002). A conflict of interest<sup>23</sup> should alert society to “proceed with caution in the face of some actual or potential wrongdoing, primarily among people who hold positions of public trust” (Krimsky, 2003, p. 125). The powerful nature of this commercial presence and participation is not to be underestimated (Bok, 2003; Capron and Schapiro, 2001); in well-known cases such as the death of Jesse Gelsinger during a gene transfer trial, actual conflicts of interest have resulted in tragic outcomes for human research participants (Waring and Lemmens, 2004); in others, where monetary profits have been made, the integrity of universities and individual researchers has been the subject of repeated public attack (Weiner, 1987).

It is in this latter sense that scientists' involvement with Aggregate Therapeutics could prove immediately troublesome. Assuming that a significant percentage of Canadian-owned intellectual property pertaining to stem cells is licensed to the company – assuming, that is, a sizeable proportion of the 158 patent families originally intended to be pooled<sup>24</sup> – high levels of venture capital investment should in principle follow. And with the current business structure, any such benefits or future profits from stem cell research products that accrue to Aggregate Therapeutics will flow only to company shareholders, i.e. participating researchers, institutions, and

private investors. There is a huge potential for profit *for the shareholders*, if stem cell research lives up to only a fraction of its promised success. For this reason, notwithstanding their incredulity toward any suggestion that financial interest would affect the way they conduct their research, scientists who fail to take seriously the disconnect between their perception of their own research and the public's perception of the scientists' research risk a serious crisis of confidence (Capron and Schapiro, 2001). Discerning whether an actual conflict of interest exists, or has failed to be appropriately addressed, is difficult given the blurred boundaries between public research institutions and aggressive for-profit vehicles (Krimsky, 2003). In the case of Aggregate Therapeutics, the distinction between the two may simply seem irrelevant given the concrete legal partnership between the SCN and Canadian universities and research hospitals in the company and the potential for large financial gain. Moreover, the resulting loss of public confidence in scientists may escalate to a complete loss of trust, depending on the influence of Aggregate Therapeutics on the direction of the research agenda.

### *Corporate influence on the research agenda*

Intimately linked to this concern about conflicts of interest, whether perceived or real, is the hypothesis that Aggregate Therapeutics will not only support but also shape what kinds of stem cell research are performed in Canada. Again, this is bound up in the broader issue of the commercialization of university environments, which has resulted in a decline in “public interest science” (Krimsky, 2003, pp. 181–182). Scientists in the life sciences are increasingly apt to see themselves as no longer having a commitment to investigate major societal problems if there exists the financial incentive to focus on a different research agenda. In other words, choices in research agenda are becoming more and more dictated by commercial priorities as opposed to social – or even scientific – priorities.

The SCN's corporate initiative renders this problem particularly acute and the frustration of the public trust more likely, given the social promise of stem cell research. In Canada, the vast majority of citizens depend predominantly, if not solely, upon

medical services provided under the publicly funded healthcare system. However, avenues of research that ultimately prove more amenable to the constraints of that kind of healthcare system are less likely to be traveled in the context of a commercially driven vehicle for research, which aims to spark quick venture capital investment and recoup high operating costs, for example, by promising advances in personalized medicine.<sup>25</sup>

### *Returns from capital investments*

Our underlying idea in the foregoing is that private profit from public investment can translate into perceived conflicts of interest or undesirable research outcomes, and that either one is capable of breaching public trust. There is a final concern posed by Aggregate Therapeutics that builds further on this underlying idea, which we think is critical to develop in detail but can be summarized as follows: there is nothing built into the corporation's structure to provide a return on the public's substantial capital investment in stem cell research and its commercialization.

Considerable federal government funds have subsidized the very proposal of Aggregate Therapeutics, and the efforts expended to get participating research institutions, researchers, and technology transfer offices, on board. Additionally, the public has funded much of the research that generated bundles of intellectual property held by Canadian institutions<sup>26</sup> now expected to be transferred to the company. This brings into play a specific feature of commercialization and technology transfer: the double-payment problem. A careful examination of the current plan for biotechnology development reveals that the taxpayer essentially pays twice for the each product: "once through taxes to support the research that yielded the invention, and then again through higher monopoly prices and restricted supply when the invention reaches the market" (Eisenberg, 1996, p. 1666) and is purchased either by the government or health care consumers directly, depending on the nature of the healthcare system.

Opinions diverge as to whether this double-payment problem is in fact detrimental from the public's point of view. Some suggest that because the public "absorbed the risk that nothing would come

of its investment" by the time an invention is patented by academic researchers, "perhaps the public would benefit more fully from the inventions it has paid for by putting them in the public domain, and thereby reducing the price that consumers pay for products based on the inventions in competitive markets" (Eisenberg, 1996, pp. 1668–1669). Conversely, proponents of commercialization typically argue that commercial development necessitates substantial follow-on investment in order to conduct clinical trials, ensure safety and efficacy, and manufacture and market products. Intellectual property attracts investment to cover these costs; therefore inventions that are in the public domain are unlikely, in their opinion, to ever enter the commercial development pipeline (Eisenberg, 1996, p. 1669). The double-payment problem has been a stock criticism of biotechnology development almost from the start, but one that has not succeeded in evoking any lasting policy reform. It is not that these products ought to be free because the public has made a down payment; however, stronger provision for the public to obtain a return on its investment ought to be made.

From a public trust perspective, this double payment problem may become enormously damaging. To reiterate, by virtue of its design and the public's substantial investment in Aggregate Therapeutics' intellectual property holdings and stem cell technologies – technologies deemed to hold the potential for revolutionary health benefits – Aggregate Therapeutics will have placed itself in an unparalleled position of public trust to deliver on the promises of stem cell research in a socially responsible manner. And this trust will be frustrated if the public is one day forced to pay exorbitant prices for clinical applications developed by the company, or worse, if a foreign corporation buys out Aggregate Therapeutics,<sup>27</sup> and its products are later resold to Canadians at exorbitant prices. Indeed, those behind the company readily concede that buy-out by a larger foreign corporation is not only foreseeable but, in their view, perhaps even a necessary outcome in terms of the long-term sustainability of stem cell research through a for-profit vehicle.<sup>28</sup> The specter of monopoly abuse – raised, for example, when Myriad Genetics Inc., the U.S. company attempted to charge Canadians thousands of dollars for tests screening for genes linked to cancer – and the

ensuing outrage,<sup>29</sup> looms far larger for a company made possible with huge sums of Canadian tax dollars.

Yet there is a powerful incentive to do these things (e.g., sell or license assets to a foreign entity) if this is in the best interests of Aggregate Therapeutics' shareholders, among whom members of the Canadian general public are not to be counted. Any exercise of corporate social responsibility is fundamentally limited by the nature of a private corporation. The theory of corporate obligations has recently progressed to at least include the notion that, as a matter of ethics, corporations *should* take into account the interests of its stakeholders (groups or individuals who can affect, or are affected by, a corporation in the execution of its mission), as opposed to considering only the interests of its shareholders (those owning an actual equity interest in the company).<sup>30</sup> But, as a matter of law, Aggregate Therapeutics *must* act in the best interests of its shareholders, rather than in the interests of the greater community, i.e. the Canadian public (Bakan, 2004; VanDuzer, 2003). Therefore, while the Canadian government and its taxpayers undeniably meet the definition of a stakeholder, there exists no binding legal precedent on Aggregate Therapeutics to require it to respect those wider ethical obligations. In our view, then, the sheer potential profitability of the company because of its massive (publicly funded) pooled resources, and the profound possible impact of stem cell science on human health, renders its for-profit incorporation an ominous prospect.

Considered together with the concerns surrounding potential conflicts of interest and direction of the university research agenda, without any mechanism to protect some form of return for the public's investment or even a requirement to consider those interests at all, Aggregate Therapeutics may be perilously close to negative appraisal in the court of public opinion.

### **Suggested structural modifications**

It is possible, however, to curb this cumulative risk by taking steps to ensure that Canadian citizens share in whatever benefits Aggregate Therapeutics produces. A series of modifications to the company are possible, which we consider in turn.

First, the legal nature of Aggregate Therapeutics could be modified to reflect its importance to the

Canadian public. Rather than a typical private, for-profit entity, the company could be incorporated as a "public-purpose corporation" (Bakan, 2004, p. 160) with an explicit mission to further the project of delivering affordable, widely beneficial stem cell technologies to Canadians. In addition, Aggregate Therapeutics could copy other longstanding enterprises created to manage income from patented inventions, such as the "Research Corporation", created by University of California researcher F.G. Cottrell in the early 20th century (Weiner, 1987), and be amended into a not-for-profit entity. At the very least, these two modifications should make the interests of the broader stakeholder community a legitimate consideration in all Aggregate Therapeutics' business decision-making processes. It should also undermine the perception that those involved are motivated primarily by individual financial gain, and perhaps motivate company management and scientists to set research priorities that do not lose sight of the constraints of Canada's publicly funded healthcare system.

Second, two types of mechanism that allow the public to have a direct return from its investment should be put in place. The federal government should (a) establish a charitable organization or foundation in order that it be made a shareholder in the company on behalf of all Canadians;<sup>31</sup> and, (b) require that a defined percentage of company revenues be allocated to that charitable organization to support other valuable research, perhaps even stem cell research projects not of interest to scientists participating in the company.<sup>32</sup> Precisely this suggestion has been made recently in the U.S. context in relation to *all* "companies that make use of publicly funded research" (Kesselheim and Avorn, 2005, p. 853). And while "the true return [from tax dollar investment] is the promotion of the social well-being through the increased production of the public good," (Brody, 1996, p. 9) providing this kind of return on investment will make Aggregate Therapeutics more accountable to Canadians.

These two types of modifications cannot preclude the troublesome scenarios described above, such as buy-out by a foreign corporation. Moreover, they may result in lower levels of initial private venture capital investment. But the expected intellectual property holdings and collective expertise of

Aggregate Therapeutics' and its researchers should nevertheless work to attract a tremendous total investment from private companies and investors as well as other sources such as philanthropic organizations. Additionally, by reorienting the company in the public's name and interest, these modifications undermine the possibility that Aggregate Therapeutics will be seen as perpetrating a violation of public trust. Adopting these modifications is therefore crucial for scientists hoping to spend their careers exploiting the value of stem cells for human health.

Despite overarching changes in patterns of university research, we remain optimistic that a significant number of Canadian scientists will agree these modifications are necessary to serve the public good. In so doing, they would be choosing to follow scientists such as F.G. Banting and C.H. Best, whose decision to patent a method for producing synthetic insulin to ensure its safe production while making certain that it was widely available to the public later resulted in the creation of the "Banting Research Foundation", which has served as a significant source of research funding since 1925.<sup>33</sup>

## Conclusion

As we disclose at the outset of this paper, our skepticism of the merits of the commercialization of academic science informs much of our analysis of Aggregate Therapeutics. That broader debate has yet to be resolved and "catalyzing commercialization" remains one of the Stem Cell Network's primary objectives within the Networks of Centres of Excellence program. Putting aside this difference in worldview for the time being, let us seek some common ground. An important starting point is the growing recognition amongst scientists that they need public support to move forward, and that their concerns have to stretch beyond technical health and safety issues to societal and ethical implications of their research (Capron and Schapiro, 2001). Scientists are more frequently urging one another to take a more active role in public education, open honest dialogue, and long-range thinking (Singer, 2001). The scientific community is, in other words, becoming cognizant that the control scientists are able to exert over how the risks (to the public trust, to research participants, in pursuing one scientific

endeavour over another, etc.) are to be defined and controlled depends on how the public perceives the scientific research and emerging technologies, and how much the public trusts the scientists (Capron and Schapiro, 2001). We are certain the SCN is already well aware of these challenges.

With this awareness in mind, it is possible to see that the concerns we raise about Aggregate Therapeutics may be less about the commercialization of research and technology transfer *per se*, and more about the need to establish a connection between the way in which research is supported, what the societal outcomes are, and how those outcomes can be improved (Guston and Sarewitz, 2002). When science is controlled by private interests, whether a profitable product can be produced is more likely to be the focus than whether the research has social benefits or will be distributed equitably (Atkinson-Grosjean, 2006; Krinsky, 2003). Apart from vague projections of capacity building, job creation and improvements in other economic indicators, we are left merely to *assume* that the commercialization process and partnerships between university researchers and biotech companies produce positive social outcomes. With a lack of financial accountability to its most vulnerable stakeholders, the case of Aggregate Therapeutics is no different. The consultation process that led to company's creation was enshrouded in secrecy; all meetings were held behind closed doors and to date little information is available in the public domain.

The public trust vested in stem cell research in Canada demands better than vague promises given the concerns we highlight. The onus rests on the Stem Cell Network, the Canadian government, stem cell scientists, and research institutions to redesign Aggregate Therapeutics. The process must be transparent and all parties must meaningfully commit themselves to one common goal, upon which each of their individual interests depends: protecting the public trust in stem cell research. This is the only prospect for responsibly advancing stem cell science in Canada.

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## Notes

<sup>1</sup> See Thomson et al. (1998), Shablott et al. (1998) and Wade (1998).

<sup>2</sup> There is very little publicly available information about this company. The website simply reads “Aggregate Therapeutics Inc. is a biotechnology company founded by leading Canadian stem cell scientists and major research institutions,” online: <http://www.aggregate-tex.com/> (accessed: 30 November 2005). In addition, informational sessions about the commercial initiative at the SCN’s general meetings have been closed.

<sup>3</sup> For an historical account of this program, see e.g., Fisher et al. (2001).

<sup>4</sup> Numerous authorities have issued statements championing the tremendous potential of stem cell research, including the National Institutes of Health, ‘Stem Cells: Scientific Progress and Future Research Directions’, online: <http://stemcells.nih.gov/info/scireport/> (accessed: 30 November 2005). Perhaps most dramatically, one commentator referred to stem cell research as the “great biomedical promise of our time” in the prestigious *New England Journal of Medicine* (see Sandel, 2004).

<sup>5</sup> Personal communication with Drew Lyall, Executive Director of the SCN; see also ‘Stem cell technology transfer strategy could create new model for successful commercialization of university research’, *ReSearch Money* 18 (16 July 2004), 6.

<sup>6</sup> As explained further below, a stakeholder is a group or individual who can affect, or may be affected by, a corporation in the execution of its mission purposes, while a shareholder owns an actual equity interest in the company.

<sup>7</sup> For our purposes, it is important to draw a distinction between the public *interest* and the public *trust* in stem cell research. In our view, the public interest in stem cell research lies in the development of widely beneficial and affordable clinical applications; the public trust lies in the perception or belief that that interest is being pursued or protected. The relationship between the two is not necessarily one-to-one; for example, the public may perceive a violation of its trust when, in fact, its interest is actually being protected.

<sup>8</sup> Personal Communication with James Till.

<sup>9</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>10</sup> Two statutes were enacted in order to enable and provide incentives for universities to transfer inventions produced with public funds to private entities: see the Bayh-Dole Act of 1980. Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-28 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (1994)); and the Stevenson-Wydler Technology Innovation Act of 1980. Pub. L. No. 96-480, § 2, 94 Stat. 2311-2320 (1980) (codified as amended at 15 U.S.C. §§ 3701-3714 (2000)).

<sup>11</sup> Other jurisdictions have also sought to broadly model themselves after the U.S. approach as well: see Howard (2004) and Siepmann (2004)

<sup>12</sup> See Science-Metrix & MSNBC, ‘Potential for Stem Cells Science and Technology in Canada: Great Promises and Challenges’, prepared for the Canadian Biotechnology Secretariat, online: [http://www.science-metrix.com/pdf/Stem\\_Cells\\_Metrix.pdf](http://www.science-metrix.com/pdf/Stem_Cells_Metrix.pdf) (accessed: 30 November 2005).

<sup>13</sup> Association of University Technology Managers (AUTM), Licensing Survey, Fiscal Year 2004 Survey Summary, online: <http://www.autm.net/news/dsp.news-Details.cfm?nid=69> (accessed: 30 November 2005).

<sup>14</sup> These figures are derived from data provided by the Association of University and Technology Managers (as summarized in Atkinson-Grosjean, 2002, p. 107) and Statistics Canada: see ‘2004 Survey of Intellectual Property Commercialization in the Higher Education Sector’ (27 January 2006), online: [www.statcan.ca/english/sdds/4222.htm](http://www.statcan.ca/english/sdds/4222.htm) (accessed: 28 April 2006).

<sup>15</sup> In Canada, these offices are typically referred to as “industry liaison offices” (see Fisher and Atkinson-Grosjean, 2002).

<sup>16</sup> See, respectively, mission statements and objectives listed on each of these organization’s websites, online <http://www.cih-irsc.gc.ca/e/29529.html>; <http://www.genome-canada.ca/>; and <http://www.stemcellnetwork.ca/aboutus/index.php> (accessed: 30 November 2005).

<sup>17</sup> “Stem Cell Technologies” may in fact be the only Canadian-based company devoted primarily to stem cell research, however, its business model is geared towards providing technologies that enable this form of research to be conducted rather than developing stem cell-based applications *per se*, online: <http://www.stemcell.com> (accessed: 30 November 2005).

<sup>18</sup> See, for example, ‘BIOTECCanada presentation to Standing Committee on Finance Pre-Budget Hearings, Nov. 3, 2005, online: [www.biotech.ca/PDFs/BIOTECCanadaFINANCECMTE-en.pdf](http://www.biotech.ca/PDFs/BIOTECCanadaFINANCECMTE-en.pdf) (accessed: 30 November 2005).

<sup>19</sup> See *ReSearch Money*, *supra* at 2: In the first 18 months of the project, “\$500,000 in cash and in-

kind have been expended on the project and an additional \$3–4 million is being sought to enhance the viability of private financing.” Also, the National Science and Engineering Research Council (NSERC) awarded \$400,000 towards this initiative. To date, approximately \$5 million in “pre-seed funding” for Aggregate Therapeutics has been secured (Stem Cell Network, Newsletter, June 2006, online: <http://www.stemcellnetwork.ca/news/newsletters/newsletter9en.pdf> (accessed: 11 August 2006).

<sup>20</sup> See *Research Money*, supra.

<sup>21</sup> Personal communication with Drew Lyall, Executive Director, Stem Cell Network.

<sup>22</sup> Stem Cell Network, Catalyzing: Commercialization, online: <http://www.stemcellnetwork.ca/success/commercial.php> (accessed: 26 October 2005).

<sup>23</sup> A conflict of interest is broadly describes any situation in which one’s official position is used to derive some form of personal benefit, whether financial or non-financial. As Waring and Lemmens note, conflicts of interest give rise to both short (e.g. the protection of research participants) and long term concerns (e.g. the integrity of the research process and the independence of medical science). It is worth noting that Waring and Lemmens specifically identify the SCN’s creation of Aggregate Therapeutics as a potential example of the latter (2004, p. 274).

<sup>24</sup> See *Research Money*, supra.

<sup>25</sup> The promise of personalized medicine is a clear risk in the context of human embryonic stem cell research (see Baylis, 2005). More generally, see Callahan (1999).

<sup>26</sup> It is important to keep in mind that this is a sizeable asset. According to the study performed by Science-Metrix, supra, Canada ranks with first (tying with the U.S.) in terms of technological output amongst G7 countries, which is determined by the number of inventions and the average number of citations per patent relative to country and research community size.

<sup>27</sup> Canada’s biotech companies have certainly been bought out in the past. For example, Allelix Biopharmaceuticals Inc., Canada’s first biotech, was sold to a U.S. corporation. Allelix’s former president/CEO, Dr. Graham Strachan, has, incidentally, worked with the SCN regarding Aggregate Therapeutics.

<sup>28</sup> See Moseley (2005).

<sup>29</sup> Myriad Genetics Inc. holds U.S. patents for two genes, BRCA-1 and BRCA-2, used to perform cancer screening tests. Mutations of the BRCA-1 and BRCA-2 genes increase a woman’s predisposition to breast and ovarian cancers. In the US, in exchange for very high royalties of approximately \$2500US, Myriad has licensed the rights to perform these tests to about a dozen laboratories. Ontario’s Genetic Diagnostic Laboratories has a comparable genetic

test, which costs \$1150CDN. However, Myriad is currently trying to enforce patents on the BRCA-1 and BRCA-2 genes in Canada. For a discussion of this and the attendant problems (see Gold et al., 2002)

<sup>30</sup> In 1962, the economist Milton Friedman argued that corporations are economic institutions that have no “social obligation other than to make as much money for their stockholders as possible”(see Friedman, 1962). Twenty years later, R. Edward Freeman stepped away from the classical perspective espoused by Friedman, and developed a framework that accounted for the demands of special interest groups. Beyond the traditional groups of management, employees, and stockholders, corporate stakeholders could now make explicit and implicit claims on corporations. This framework, in contrast to that envisaged by Friedman, paints corporations as both economic and social institutions (see Freeman, 1984).

<sup>31</sup> Creating such an organization is preferable to making the government itself a shareholder for at least two reasons. First, if the government were a shareholder it would inevitably be in a position of conflict in its dual capacity of regulator of research and a financial benefactor thereof. Second, given recent political developments in Canada, the public is not likely to place a great deal of trust in the government.

<sup>32</sup> This revenue could also be earmarked for so-called ‘orphaned’ areas of research, completely unrelated to stem cell research.

<sup>33</sup> Online: <http://www.utoronto.ca/bantresf/> (accessed: 30 November 2005).

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