

IN STEM CELL RESEARCH WE TRUST?

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INTRODUCTION

In law, a “trust fund” is commonly understood to refer to some form of property held in trust for the benefit of another. “Trustees” are those who are charged with holding this property in trust, carrying out other specific duties, and/or given powers affecting the disposition of the property, all for the benefit of another.

Various governments have recently committed sizeable sums of tax dollars and established organizations to support stem cell research, which, although not described as such, meet these definitions – they are, in the final analysis, intended to benefit the public. We focus upon two such funds (one in California, the other in Canada), their putative trustees (the “California Institute for Regenerative Medicine” (CIRM) and the “Stem Cell Network” (SCN)), and their corresponding beneficiaries (the citizens of each jurisdiction).

While there are differences between these two government-funded initiatives, their constituting frameworks, mandates and responsibilities, they are essentially the same in one crucial respect: the public’s interest in seeing that these funds are used wisely and that the trustees perform their functions responsibly, is tremendous. And it is in this respect that each of these initiatives is, in our view, problematic at present.

Our purpose is to identify the special concerns that these initiatives pose and call attention to the types of reforms that are needed to better ensure that these investments ultimately benefit their respective publics.

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Conception and Funding: On November 2, 2004, by a 59 to 41 percent majority, Californians voted in favour of “Proposition 71”, the California Stem Cell Research and Cures Initiative. Proposition 71 constitutionalized the right to conduct stem cell research (including the use of somatic cell nuclear transfer or “SCNT”), and established a \$3 B ten year fund (\$295 M per year) from tax-free state bonds for the new state research funding agency, CIRM, to distribute.

Mission: The purpose of Proposition 71 was to establish “an institute which will issue bonds to support stem cell research, emphasizing pluripotent stem cell and progenitor cell research and other vital medical technologies, for the development of life-saving regenerative medical treatments and cures” (<http://www.cirm.ca.gov>).

Structure and Governance: The CIRM is governed by an “Independent Citizens’ Oversight Committee” (ICOC), made up of 29 individuals including the primary author of Proposition 71 as the ICOC chair, a vice chair person, a variety individuals affiliated with California institutions or entities engaged in stem cell research, as well as several “patient advocates”. The CIRM is also composed of Working Groups responsible for reviewing grant proposals and making funding recommendations.

Priorities: Proposition 71 requires the CIRM to prioritize research involving human embryonic stem cells and/or SCNT technology, and to develop intellectual property (IP) agreements as part of any grants that are awarded in order to allow the “State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials” without unduly hindering those engaged in the same.

CANADIAN STEM CELL NETWORK

Conception and Funding: The SCN was established by the federal government’s flagship science and technology program, the Networks of Centres of Excellence program, funded by Canada’s three research funding councils in partnership with Industry Canada. The SCN was created in 2001 with an initial \$21.1 M grant over four years, which has recently been renewed through March 2006, with an additional \$5.3 M commitment.

Mission: The mission of the SCN “is to be a catalyst for realizing the full potential of stem cell research for Canadians.”

Structure and governance: The SCN is a non-profit corporation governed by a Board of Directors drawn from those in business, health charities, academia and government. The Executive and Scientific Directors manage the SCN’s day-to-day operations, working with the leaders of four research themes. Over 70 scientists, clinicians, engineers and ethicists and nearly 160 trainees located in 23 institutions across Canada are members of the SCN.

Priorities: The SCN made a decision to prioritize commercialization, and have created a private company called “Aggregate Therapeutics” (AT). Thus far, 8 key research institutions have agreed to pool their IP under the umbrella of AT (SCN Annual Report, 2004–2005), and if a significant proportion of the total IP held by Canadian scientists and institutions – approximately 158 patent families relating to stem cell research have been identified – are pooled, then a great deal of publicly funded assets and resources will be conjoined by the corporation (ReSearch Money, 2004; Herder & Brian, under review).

COMMON CONCERNS

Both CIRM and SCN function as state-sponsored research funding agencies. Though the SCN’s activities have been ongoing for some time, the operations of its commercialization pilot project, AT, have yet to begin in earnest. Similarly, lawsuits challenging the constitutionality of the legislative scheme underpinning the CIRM, initiated by both pro-life groups and taxpayers concerned about the fiscal responsibility of the plan, have prevented any funds from actually being distributed to date, and a constitutional amendment introduced to “redefine CIRM” and its governing rules may result in further delays (Cohen, 2005). This period of pause provides a critical opportunity to address the following concerns surrounding transparency, conflicts of interest, and IP arrangements, which we believe are common to the CIRM and the SCN (particularly in relation to AT).

Transparency: The process preceding the vote on Proposition 71 was open but deeply misinformed regarding the therapeutic promise of stem cell research as well as the feasibility of the proposed financing of the CIRM (Center for Genetics and Society, 2006). SCN’s confidential consultations with Canadian scientists, research institutions, technology transfer officials and industry stakeholders leading to the incorporation of AT contrast in form only. Now that each initiative is in place, decision-making processes must be more transparent in order to mitigate conflicts of interest and respond to benefit-sharing obligations tied to IP.

Conflicts of Interest: Both CIRM and SCN are rife with built-in, institutional conflicts of interest. All members of CIRM’s ICOC are tied to some institution or constituency vying to benefit from the allocated public funds. Though “a constitutional amendment that would tighten the CIRM’s conflict-of-interest rules, and force [the ICOC] to hold all of its meetings in public” has been put forth, its fate remains unclear as the CIRM has taken active steps to discourage it (Aldhous, 2005; Center for Genetics and Society, 2006). Many of those involved in the SCN in a decision-making capacity have direct ties to the very research institutions that are in competition for funding. The incorporation of AT potentially exacerbates this problem by increasing the ability of the SCN’s scientific members to personally profit from advances in stem cell science.

IP Arrangements: Proposition 71 specifically requires CIRM to develop IP agreements with the entities it funds to allow the State of California to share in any financial benefits that accrue; one proposal preserves a 10% research royalty for the State (Silfen, 2005). However, the prospect that CIRM will endorse any such mechanism is now in serious jeopardy because it may be illegal for the State to retain any royalties while financing CIRM by way of tax-free bonds (Center for Genetics and Society, 2006). The outlook for such a benefit-sharing mechanism is equally bleak in Canada. The SCN has dismissed any suggestion that AT should allocate 1–3% of its revenues to the federal government or some charitable organization. IP also figures critically with respect to the eventual development of accessible, affordable clinical applications. However, CIRM has gone so far as to hire private lobbyists to resist incorporating such criteria into its policy considerations (Center for Genetics and Society, 2006), while AT, as a private company, is obligated by law to serve the interests of its shareholders, not Canadians in general, which could well include selling stem cell-based therapies at exorbitant prices back to the consumers who financed them in the first place.

CONCLUSION

In their one-year review of CIRM, the Center for Genetics and Society criticized the CIRM most harshly for their failures to work towards maximizing health equity, minimizing conflicts of interest, cooperating with the state legislature, and providing responsible leadership. In the mid-term review, the SCN was criticized for its failure to integrate normative analysis into the scientific projects, as well as a failure to address broader social and ethical issues. These criticisms cannot be taken lightly – the evaluation of science is no longer limited to an evaluation of potential risks and benefits; values and societal goals will and should influence how science is conducted and supported (Leshner, 2005).

Meaningful commitments to transparent decision-making, rigorous conflicts of interest policies, and benefit-sharing are all needed. We remain skeptical, however, that those reforms will be adopted given the records of these funding agencies to date and the powerful interests that stand to benefit from the current state of affairs. What is fundamentally required in our view, then, is a recognition on the part of these scientific communities that their long term interests are ultimately inseparable from those of their respective publics. If the public perceives a breach of its trust, its financial support is likely to be quickly withdrawn. In their current configurations, the California Institute for Regenerative Medicine and the Stem Cell Network’s Aggregate Therapeutics increase the likelihood of that eventuality. Scientists and research institutions engaged in stem cell research ought to understand that the level of trust placed in these initiatives demands more, and oblige the CIRM and the SCN to take appropriate action.

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