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Governing stem cell research in California and the USA: towards a social infrastructure

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Owing to the restrictive human embryonic stem cell (hESC) policies of the US government, the question of whether to pursue human embryonic stem cell experiments has dominated the ethical and political discourse concerning such research. Explicit attention must now turn to problems of implementing the research on a large scale: in the 2004 US elections, California voters approved a state initiative for stem cell research, earmarking $3 billion in direct spending over 10 years. This article explores three ethical and political problem areas emerging out of the California program, the resolution of which will help set the trajectory of hESC research in the US and abroad, and then proposes an institutional approach to help address them: a network of public stem cell banks in the US that feature transparent and shared governance.

Introduction

In the US, human embryonic stem cell (hESC) policy prohibits the use of Federal research money to create new hESC lines and work on all lines created after August 2001 [1]. Opposition to this policy, which rests explicitly on the sanctity of the embryo, reached high pitch during the 2004 US Presidential election. At the national level, Democrats enlisted scientists, patients and celebrities to promote stem cell research as a path to curing terrible diseases and to help prevent 'the theology of a few…to forestall the health and well-being of the many' [2]. In California, voters approved Proposition 71 (Prop. 71), a state initiative for stem cell research and regenerative medicine, earmarking $3 billion in direct state spending during the next 10 years. New Jersey, Connecticut and Maryland have also recently allocated funding for human embryonic stem cell projects, albeit on a smaller scale, and the US Congress has renewed consideration of the issue [3,4].

Up to this point in the USA, the question of whether to pursue human embryonic stem cell experiments has dominated the ethical and political discourse concerning the research. Now, more explicit attention must turn to the ethical and political aspects of its implementation [5]. Although lawsuits challenging the institutional oversight of hESC research in California have delayed the disbursement of Prop. 71 funds for more than a year, policymakers in the state have been hashing out difficult ethical and legal questions surrounding the $3 billion project [6]. Because of the size of the California Stem Cell Initiative and its position at the leading edge of US policy, these ethical and legal issues, and their resolution, carry global significance. In particular, three aspects of implementing hESC research in California have emerged with force and remain controversial: setting funding priorities likely to maximize public health; shaping intellectual property rules for government-funded hESC discoveries; and protecting the interests of the human egg donors needed to generate new hESC lines. This article explores these emergent problems within the US context and then proposes an institutional approach to help address them – a network of public stem cell banks in the USA that feature transparent and shared governance.

Funding priorities

Stem-cell research has been presented in California and elsewhere as a means of bringing health benefits to the public. In California, the text of the *California Stem Cell Research and Cures Bond Act*, passed in 2004, reflects the compromise that research advocates struck with voters, making explicit the central aims of the project, namely 'to realize therapies, protocols, and/or medical procedures that will result in, as speedily as possible, the cure for, and/or mitigation of, major diseases' and also to 'improve California's health care system and reduce the long-term health care cost burden' [7]. However, this new law actually says nothing about how funding priorities should be ordered to accomplish these goals. This problem is not restricted to California: in the USA as a whole there has been little discussion at the state or national level about which hESC research is likely to produce promised health benefits and on what time scale.

A conference held by the newly created California Institute for Regenerative Medicine (CIRM) (http://www.cirm.ca.gov/) in 2005 revealed how scientists themselves disagree on funding priorities: some favor pursuing long-term scientific goals aimed at clarifying the complex problems of stem cell differentiation, whereas others favor the development of therapeutic applications on a shorter timeline. This latter agenda might target existing therapies such as bone marrow transplantation – which relies on the regenerative ability of blood-forming adult stem cells in

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the marrow – that is already used to treat eight diseases but which might be adapted to treat others [8].

Many scientists and policy makers have aired serious concerns that the therapeutic promise of stem cells has been 'hyped,' resulting in a serious risk that public trust in science will be jeopardized when cures fail to materialize in the expected time period. Given taxpayer investment and the public health rhetoric of stem cell research advocates in the USA, it will be essential to publicly deliberate priorities for funding and to lay out reasonable time scales for tangible benefits. This is not merely a task for scientists or technocrats: it is precisely at the level of setting funding priorities that the difficult questions of public values will have to be answered [9,10]. For example, on what basis should disease targets be selected? Will the poor and middle class benefit? And how should public funding be apportioned between basic and applied research or public and private sector? Furthermore, should hESC funding priorities reflect public misgivings about particular types of hESC research such as chimeric experiments [11]?

Priorities can be influenced according to the composition of governing institutions. In California, the $3 billion initiative is governed by the Independent Citizens' Oversight Committee (ICOC), a 29-member body composed of university administrators, industry executives and the advocates of disease groups (http://www.cirm.ca.gov/icoc/). The composition of this group implicitly evinces an interest-group model of how decisions will be made, in which members are expected to advocate for their constituencies. Unlike stem cell funding programs in other states, the California Initiative grants elected officials no influence regarding funding decisions. It remains to be seen how well this body can negotiate the competing claims of particular disease groups, scientists and the private sector. But as funding debates move forward in California and elsewhere, one thing is certain: many US citizens have rested support on assurances that hESC research will lead to therapies, and public debate and accountability in priority-setting will be crucial.

Intellectual property

Intellectual property (IP) on stem cell discoveries is a second controversial issue that has emerged in California. IP policies will help to determine, among other things, the conditions of public access to new therapies, the terms of material-transfer agreements for basic research tools and the quality of returns to government funders. Because of their importance, these rules deserve more public debate and attention.

On an interim basis, California has adopted IP policies consistent with Federal policy under the *Bayh–Dole Act* of 1980 [12], which entitles research institutions to IP rights for any inventions derived from government funding. Intended to stimulate the commercialization of government-funded discoveries, *Bayh–Dole* is widely credited with increasing the patenting activity of universities by tenfold during a twenty year period and generating significant licensing income [13]. Under *Bayh–Dole*, Federal funding agencies do retain a 'march-in' right to compulsory licensing in exceptional circumstances, but the largest biomedical funder in the USA, the National Institutes of Health (NIH; http://www.nih.gov/), has persistently failed to do so. For example, despite public pressure, NIH refused to intervene in the pricing of NORVIR, one of the few successful NIH-funded HIV/AIDS drugs, even after Abbott Pharmaceuticals (http://www.abbott.com/) decided to increase the price fivefold [14].

Public stem-cell funding programs in California and other states should consider alternatives to the *Bayh–Dole* policy for three main reasons. First, if taxpayer-financed initiatives such as Prop.71 aim to generate direct revenue streams back to states, modifications to the basic *Bayh–Dole* policy are required. Second, because stem cell research has been sold as a means of improving the health care system and reducing the total disease burden, IP policies should advance not only innovation but also access to diagnostics, drugs and other treatments. Promotion of private sector patenting by the *Bayh–Dole* policy can lead to monopolistic pricing for many years, spurring private-sector investment but also making drugs less affordable. Further, as the NORVIR example shows, march-in rights by themselves will not ensure the affordability of therapies.

Third, even if society favors speedy innovation more than affordability, using an unadulterated *Bayh–Dole* paradigm might be unwise. Some IP scholars warn that private patent rights in biomedical technologies can actually foster an 'anti-commons' effect, whereby overlapping claims and frequent litigation tie up commercial development [13]. This anti-commons effect, however, is difficult to measure quantitatively, and some recent survey studies have not identified a significant issue [15]. Nevertheless, by some accounts, this problem has already deeply affected the stem cell area: in work funded by Geron (http://www.geron.com/) and NIH, the University of Wisconsin (http://www.wisc.edu/) developed foundational stem cell patents, the licensing fees for which have reportedly slowed the advance of stem cell research [16]. The Wisconsin Alumni Research Foundation (WARF) (http://www.warf.ws/) has recently announced that it will treat CIRM as a commercial entity with respect to licensing its stem cell patents, underscoring the attendant costs of a strong patenting regime in the stem cell area [17,18].

Current indications in California suggest that although policies will be generally consistent with a *Bayh-Dole*-style decentralized IP mechanism, greater efforts will be made to claim a direct public return. In a policy framework adopted by the ICOC on 10 February 2006, CIRM requires universities and non-profit research institutes that receive grants to channel a 25% royalty stream back to state coffers, but only for royalties in excess of $500 000 [19]. The policy also puts certain constraints on the exclusive licensing of CIRM-funded IP by the grantee institution, including requirements that exclusive licensees have plans to provide access to the poor and uninsured in California. However, these rules have not been finalized in the form of regulations nor do they apply to commercial grantees.

How exactly to balance the competing goals of promoting scientific openness and materials sharing, incentivizing commercial research and development, and promoting public access to future biomedical therapies remains

highly controversial in the US stem cell game. In this sense, the IP debates in California are emblematic of ongoing international discussions regarding the patenting and licensing of biotechnology inventions, where new principles and guidelines are emerging. In February 2006, the Council of the Organization for Economic Co-operation and Development (http://www.oecd.org/) agreed on a set of *Guidelines for the Licensing of Genetic Inventions*, which set forth best practices for the broad licensing of biotech research tools and 'widest public access to...products and services based on the inventions' [20]. IP rules for the California stem cell program are an important opportunity to move these emerging norms into practice.

The governance of egg donation

A third key policy area emerging in California and other key cites of implementation is the proper treatment of egg donors for the derivation of new hESC lines [21,22]. Large-scale hESC research programs will probably require the donation of healthy eggs for the creation of new lines. Defining ethical treatment of egg donation for research is more complicated than treatment of embryo donors in the context of IVF or that of sperm and somatic cell donors because egg donors are subjected to greater risks without the prospect of direct benefit [23]. These risks include pain and emotional stress in the short-term and up to a 10% chance of ovarian hyper-stimulation syndrome, which occasionally leads to infertility and even death [24–26].

Current US regulations covering research on human subjects at universities exempt such research from full ethical review by an institutional review board (IRB) if samples or extracted research materials cannot easily be linked back to their donors [27]. Effectively, this means that, under current US law, the extraction of eggs for subsequent hESC research would not be subject to full IRB oversight so long as egg donation had been sufficiently coded [28]. There is broad agreement in the USA that the failure to afford egg donors the status of protected human research subjects represents a serious regulatory lacuna. In April 2005, the US National Academies of Science (NAS; http://www.nationalacademies.org) issued a report recommending that all institutions conducting hESC research have IRB approval for research protocols and also develop additional oversight through specialized ethics oversight committees [29].

Although recent bioethical commentaries and guidelines have focused due attention to filling crucial regulatory gaps [23,29,30], too little attention has been paid to the 'political economy' of egg donation in the hESC context: the patterns of extraction, use and transfer of eggs in relation to markets, power relations, regulation and collective action. Emerging guidelines in the USA with respect to financial compensation to donors deserve deeper scrutiny in light of this political economy of egg donation.

In its recent report, NAS recommended an altruistic regime of egg donation, in which donors are compensated only for direct expenses, in part to be consistent with the *California Stem Cell Research and Cures Bond Act*. This regime would contrast with that of donation in the IVF context, at least in the USA where more of an open market prevails in which women are often paid in excess of $5000 per procedure [31]. Limiting the free market in this context is not an unreasonable approach: inducing egg donors with money would tend to shift, disproportionately, the health burdens of supplying eggs onto poorer women, resulting in possible economic coercion. However, the donation regime proposed by the NAS guidelines – and largely enacted in California – raise three ethical problems that have been inadequately discussed.

First, under the NAS guidelines and the interim California rules, the regime of altruism is deployed asymmetrically with respect to donors and researchers: altruism is required of donors, whereas it is not required of research institutions or corporations that might profit from the donations. Although this asymmetry is not new in biomedical research, it is more troublesome where risk and time-burden of donation is significant.

Second, the NAS guidelines fail to address compensation for donors who are harmed in the process of donation, and proposed rules in California do so insufficiently. Existing Federal research policies do not require compensation for injured research participants, and the NAS guidelines are silent about the issue. However, a compensation system is warranted in large-scale programs of state-sponsored egg donation as a matter of fairness. CIRM has moved part of the way towards closing this gap in a set of proposed research standards, in which funded institutions would have to agree to 'assume the cost of any medical care required as a direct and proximate result of oocyte donation for research' [32]. But because some of the health problems that can be associated with egg retrieval do not show up in the short term, for example, infertility or ovarian diseases, this provision might prove inadequate. Large state-funding programs, such as the one in California, should make sure that research institutions provide insurance to egg donors that covers both the short- and long-term risks associated with egg extraction.

Finally, neither the NAS guidelines nor the proposed California standards would enable donors to exercise any collective power in the governance of the research. The NAS guidelines recommend that local oversight committees include 'representatives of the public', but there is little or no discussion of the collective representation of egg donors in the regime of ethical oversight [29]. However, the contributions of charitable egg donors for public hESC projects arguably give rise to special duties of political accountability to this group of women, which might mean donor representation both on ethics committees and committees setting funding priorities. The significance of the donor group in the hESC research context, the denial of financial compensation and the historic neglect in research of the health issues of women [33] all suggest how a more participatory form of governance might be appropriate, useful and fair.

Public stem cell banks as social infrastructure

In the USA, where Federal initiative is lacking and state stem cell projects rush to fill the void, creative thinking will be required to develop sound policy in the three areas discussed above. To advance those discussions, one proposal for stem cell policy that would generate significant public benefits within these domains remains to be set

forth: the creation of a public stem cell bank in California, to be linked up with national and international networks of similar banks in the future. Nascent efforts to build such facilities have begun in the UK and Wisconsin with some success [34,35]. This idea would not and should not replace the development of binding regulations subjecting human embryonic stem cell research to IRB oversight and other controls. However, in a political climate in which the USA is unlikely to create a new national regulatory architecture for stem cell research, government and charitable funders would achieve better governance for hESC research through an infrastructure of public stem cell banks. If set up properly, such institutions could help expand resources for all research priorities, promote open access and material sharing, and help establish a regime of egg donation that honors the contribution of donors.

In California, and in other state-led research initiatives in the USA, a centralized stem cell bank could be built by requiring that all new hESC lines created with state funds be deposited there. At the repository, staff would have the task of propagating the cell lines, keeping a coded cell line registry and handling distribution to researchers who seek access, thus freeing many scientists from administrative burden. Centralized banking would also expedite standardization, quality control and uniform characterization of cell lines [36], as well as the management of genetic diversity in the archive of therapeutic materials for people with divergent haploypes [37]. Operational costs could be shared by funding agencies and research institutions themselves, which will be saved the expense of developing separate banking and distribution facilities. Eventually, such a public stem cell bank in California could be linked into a larger network of hESC banks in the USA and abroad, including the UK Stem Cell Bank (http://www.ukstemcellbank.org.uk/).

Public stem cell banks could also mitigate some of the challenges discussed previously. First, centralized banking would not solve the basic tension between funding basic as opposed to applied research. However, to the extent that developing an archive of therapeutic-quality lines is a goal to be balanced against basic research, rules could require that even lines used for basic research be banked at therapeutic quality so that their potential use for therapies is guaranteed. Further, stem cell banking would lead to efficiency gains that would free up more funds for basic and applied research. For these reasons, the UK has developed high-quality, centralized banking facilities for therapeutic-quality lines as an early step.

Second, centralized repositories in California and elsewhere could help implement IP policies aimed at lowering the transaction costs of sharing new hESC lines. Even if state funders such as CIRM wish to preserve the right of research institutions to patent new lines, they could make funding contingent on both the deposit of new lines and licensing to non-profit researchers at cost. Commercial licensing could occur among research entities themselves, but would not involve the bank – a model adopted in the UK [38]. Such policies have been implemented by CIRM for non-profit institutions in California already, and would, in fact, be consistent with licensing guidelines enacted by the OECD and by NIH itself [39,20]. If funders choose to pursue a more commons-oriented approach to patents and materials sharing, then stem cell banks could be an efficient and effective way of furthering these goals.

Third, if structured and managed appropriately, the creation of non-profit stem cell banks could generate a better governance regime for egg donation: one that minimizes risks and increases the efficiency and accountability of ethical oversight. As an initial matter, maintaining public hESC repositories would reduce the number of egg donors required to support an expanded program of research. Because the risks of donating are not insignificant, such a policy has distinct ethical advantages compared with maintaining decentralized stem cell banks at each research institution.

Further, the biorepository could also be used to impose a layer of ethical review regarding the derivation and subsequent use of new cell lines, a system with distinct advantages compared with the decentralized oversight proposed under the NAS guidelines and in the preliminary rules of CRIM. In contrast to the UK, the USA lacks a national regulatory authority for the derivation and use of new human embryonic stem cell lines, and existing Federal research rules leave much human stem cell research unregulated. To address these regulatory lacunae, NAS recommended the development of new stem cell ethics committees at each research institution, which would review the research according to specific norms of consent and use, a recommendation that CIRM will probably act on for CIRM-funded research [32]. But in the absence of a national regulatory authority in this area, centralized oversight, organized through a public stem cell bank, might do a better job. Centralized ethical review would be in a better position to impose uniform standards of egg donation on institutions wishing to bank cell lines, and the release of cells could be tied to contractual compliance with the ethics guidelines of the bank. Further, ethical review would be less vulnerable to institutional conflicts of interest, a documented problem of the decentralized IRB system [40]. Finally, having centralized ethical oversight bodies would have an important civic function as a site of research governance accountable for a type of research that is only marginally acceptable to the US public. As hESC and other biotechnologies move forward in the USA and abroad, establishing the trust of the public in research governance will be crucial [41], and establishing visible and nodal institutions for ethical oversight will be particularly important.

Finally, the institutional structure of public stem cell banks could also be used to develop a participatory role for the donor group. In the field of biobanking for population genomics, new norms of participation in research governance by donor communities have emerged [42]. These norms should be applied in the stem cell biobanking context, where the physical and emotional investment of donors, and the privacy risks, are arguably more significant. Important and vexing ethical issues relevant to the donor group will certainly arise, including those surrounding the retention and management of coded identities and the possible recontact of donors in the future. The central banking institution could house an egg-donor group to advise and interact with the central ethics

committee of the bank, empowering donors to participate in deliberations regarding costs and benefits of the hESC research under review. In this way, the duty of the ethics committee to promote beneficence could be brought into line with the altruistic expectations of the donor group. This arrangement would foster more representative governance and a more meaningful dialogue among key partners in the collective endeavor of hESC research.

Conclusion

In the USA the selection of funding priorities, IP policies, a regime of egg donation in California, and other public initiatives will help set the national and international trajectory for hESC research. Considering the high stakes of these policies, more attention should focus on the public obligations of government-funded hESC research and its commitment to an equitable distribution of risks and benefits as policies are implemented. Taking a cue from the UK, centralized stem cell banking in California would bring general gains in efficiency and create a pragmatic opportunity to construct an ethical and legal architecture for long-term public return. This vision of stem cell banks as social infrastructure would provide useful flexibility in the face of a fast-evolving ethical frontier and help build trust between scientific institutions and society.

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