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# 1

## Globalization, Stem Cell Markets and National Interests

Throughout the developed and developing world, states are investing public funds in basic ESC science and devising regulatory frameworks to facilitate research. In the neoliberal climate that has dominated, or at least influenced, most national administrations in the Organisation for Economic Co-operation and Development (OECD) since the 1980s, the provision of large-scale public funding for biomedical research is startling when set against stagnant or declining health budgets, the steady marketization of health services and the growing pressures on universities to find corporate research funding. Moreover, it suggests that, contrary to much of the globalization literature that emphasizes an overall decline of state power in the face of transnational communications and global markets (Ohmae, 1995; Bauman, 1998; Starnge, 2000), nation states are in fact significant actors in the biotechnology sector, particularly in the stem cell sector. This involvement, however, does not imply the existence of a nationally or locally based bioeconomy. Stem cell research and development (R&D), regenerative medicine and the bioeconomy in general are intensively globalized, through multiple levels of transnational commercial, policy and research networks. McMeekin and Green, in their introduction to a special issue of *New Genetics and Society*, which focused on the UK biotechnology industries, observe: ‘The [contemporary] biotechnology sector is the first science-intensive set of industrial activities which has been truly globalized “from birth”’ (2002, p. 101).

In this chapter we will investigate the role played by state institutions in the fostering of hESC research, and the life sciences more generally. Politicians and policymakers tend to foreground humanitarian rationales for supporting such research, pointing to the potential for real and significant clinical effects and applications for the ageing, the disabled and those waiting for organ and tissue transplants. Although such

therapeutic aims are laudable, and dearly held by many clinicians, policymakers, patient support groups, patients and caregivers, they do not fully explain the active interest of the advanced industrial states in stem cell research. We must also consider the kind of economic productivity represented by stem cell research and the ways in which the reformulation of state-market-civil society relations in the wake of post-Fordism and globalization gives nation states strong incentives to foster nodes of the global stem cell economy within their national borders.

In what follows, we examine the kinds of pressures and constraints placed on contemporary nation states by the move to knowledge-based economies, the innovation and commercial structure of biotechnology R&D, the global marketization of health services and the ageing of populations. State interest in stem cell research is, we argue, economically driven in a broad sense, with population health benefits and clinical applications assigned a secondary consideration. As erstwhile Keynesian and corporatist welfare states such as the United Kingdom, Canada, Australia and Western Europe move closer to the status of competition states, the biotechnology area assumes more importance in economic policy. HESC research has the potential also to deliver health benefits to national populations. This potential makes hESC doubly attractive for nation states that face loss of popular support and political legitimacy, as the health and welfare of their populations become a lower priority than the fostering of global economic competitiveness. While competition states seek to roll back public welfare provision and provide residual 'workfare' benefits and services (Jessop, 2002), hESC research receives state support, we argue, because it has the potential to promote national health and relieve some of the growing pressure on aged and disability pensions through the promotion of biomedical innovation.

## Biotechnology knowledge economies

ESC research and regenerative medicine are among the most recent innovations in what the OECD (1989) has described as the third wave of biotechnology development. The first two waves comprise:

*Classical Biotechnology* ... the cumulative trial-and-error developments in the production of beer, cheese and bread, etc. as well as traditional animal and plant breeding and *Modern biotechnology* ... the science-based developments from the late 19th century that led to the modern pharmaceutical and food processing industries.

(McMeekin and Green, 2002, p. 102)

Third-wave biotechnology is characterized by the re-engineering of microbiological processes and the multiplication of industrial/medical applications in diagnostics, industrial processing, pharmaceuticals and agriculture. This third wave began to build in the 1970s. Corporations, universities and state administrations started to respond to the restructuring of the global economy in the wake of the dramatic decline in profitability of the OECD nations' Fordist industrial base, centred on mass manufacture, Keynesian economic policy and state insulation of national economies from the fluctuations of global finance. Saturated domestic markets, growth in wages and decreasing profit from mass-manufacture techniques prompted nationally based Fordist firms to expand into foreign markets and use stateless finance capital as credit, undermining the ability of the nation state to regulate or profit from their activity (Jessop, 2002). Declining profits prompted companies to look beyond the Fordist models of mass production and consumption regulated within the space of the nation state. Companies searched for new material bases of profitability in technological innovation and more flexible forms of production. They turned to the basic scientific research carried out in universities during the 1950s and 1960s in biology, communications engineering and information sciences and began to explore the commercial applications of this research. Since the 1970s, each of these areas has been developed into generic 'technology platforms' (McMeekin and Green, 2002), which 'underpin a wide range of industrial sectors without being unique to any one' (Etzkowitz and Webster, 1995, p. 495), and form the competitive basis for a growing number of sectors.

This commercial exploitation of basic science underpins the OECD nations' transition from industrial mass-manufacture economies to knowledge economies, dependent on a highly educated workforce; technical research and innovation; and extensive cooperation among university, industrial and government sectors to pursue promising research directions and strategic advantages (Etzkowitz, 2003). In this context, state agencies increasingly play a coordinating role, for example, promoting and linking national and international research networks, and shaping research directions through public-private partnerships (Cooke, 2002).

The development of these knowledge-driven sectors of the economy has a strong speculative dimension, however, in both the scientific and fiscal sense. In 1980, the US legislature passed the Bayh-Dole Act, designed to encourage commercial enterprises to invest venture capital directly in university-based biotechnology research, via IP regimes and

public–private partnership research funding. Since then, many nations within the OECD have introduced similar legislation to encourage innovation-based commercial enterprise through university–private sector links, and changes in IP regimes (Mowery and Sampat, 2004). These changes have facilitated collaboration between university basic biology laboratories and biotechnology and biomedical firms interested in commercial applications.

However, many lines of basic biology research fail to deliver usable applications or sustainable profitability. The dot.com boom and bust of the late 1990s reveals the risks and difficulties associated with developing new R&D-driven industries. This uncertainty is particularly marked in the biotechnology area, where high levels of expensive expertise are required and where development pipelines tend to be long and unpredictable. As we noted in the introduction, 20 years of genetically oriented biomedical research has failed to produce safe gene therapy applications, for example. Currently, many nations in the OECD are making substantial public investments in large population biobanks, research facilities designed to facilitate pharmacogenetic drug discovery and design, but this methodology might also prove unproductive. As Rabinow and Rose (2006) observe of genomic medicine, the translation of laboratory-based biotechnical innovation into therapeutic applications is a highly uncertain process.

[I]t is still not clear whether the new forms of molecular and genomic knowledge are actually capable of generating the kinds of diagnostic and therapeutic tools that its advocates hope for. The stakes here are high, economically, medically and ethically. They lie in the presumed capacity of genomics to form a new ‘know how’ that will enable medicine to transform its basic logic from one based upon restoring the organic normativity lost in illness to one engaged in the molecular re-engineering of life itself.

(Rabinow and Rose, 2006, p. 212)

Despite these difficulties and setbacks, the OECD (2004, 2006) regards the biotechnology sector as relatively immature and open to much more innovation and industrial development. Biotechnology offers the best hope for a new long wave of economic growth, the OECD argues, because it has the capacity not only to develop new specific products and processes but also to change the material base of significant sectors of the economy. A bioeconomy is a sort of regenerative economy,<sup>1</sup> replacing non-renewable resources such as fossil fuels and

environmentally toxic chemical processes with the self-regenerating and environmentally friendly capacities of living process. The OECD explains it in the following terms.

The bioeconomy [is] the aggregate set of economic operations in a society that use the latent value incumbent in biological products and processes to capture new growth and welfare benefits for citizens and nations. These benefits are manifest in product markets through productivity gains (agriculture, health), enhancement effects (health, nutrition) and substitution effects (environmental and industrial uses as well as energy); additional benefits derive from more eco-efficient and sustainable use of natural resources to provide goods and services to an ever growing global population. The bioeconomy is made possible by the recent and continuing surge in the scientific knowledge and technical competences that can be directed to harness biological processes for practical applications. Looking to the future, new techniques in biotechnology, genomics, genetics, and proteomics will continue to converge with other technologies resulting in potentially large-scale changes to global economies in the next thirty years.

(OECD, 2006, p. 1)

As Cooper (2006) observes, regenerative medicine, including stem cell research, is a clinical analogue of this idea of a regenerative economy, promising to produce self-regenerating bodies in place of the 'spare parts' bodies of the industrial era, dependent on allogenic tissue economies that circulate surplus tissues from donor to recipient (Waldby and Mitchell, 2006). However, these clinical and industrial regenerative biotechnologies are still at the level of basic science and speculative imagination. Biotechnology research in general, and stem cell research in particular, involves a search for new biovaluable technologies (Waldby, 2002) – optimum points of microbiological leverage and productivity – that could form the basis for a whole suite of clinical applications, in the same way that the microprocessor in information and communication technologies (ICTs) has formed the basis for a wholesale transformation in communications. In part, the interest in basic stem cell science is driven by the hope that understanding the basic biology of embryology, ontogenesis and tissue generation will eventually act as a motive force<sup>2</sup> within the biomedical sectors, a major innovation that will enable the regeneration of parts of the human body and so transform significant aspects of clinical medicine.

## **Biotechnology research and the competition state**

Human ESC research is still at an early stage, focused on an understanding and technical mastery of the basic biology. There is currently no hESC technology in phase-one clinical trial, at least not in North America, Europe or Australia. We cannot rule out the possibility of hESC clinical trials being currently run in China or India. HESC technologies are regarded as a risky commercial proposition compared with haematopoietic and mesenchymal stem cells because of their basic research status and the social controversies that surround them. The commercial stem cell landscape reflects this assessment. In 2006, the Biophoenix stem cell report identified 106 stem cell companies around the world, but only 11 were focused primarily on hESCs. The report estimated the worth of the whole global stem cell market to be \$24.6 billion in 2005, growing to \$68.9 billion in 2010, but it did not expect any hESC therapies to emerge during this period. Rather, the majority of stem cell commercialization will revolve around drug screening, cord blood banking and expansion, bone/cartilage and skin regeneration, and stem cell mobilization agents. Faced with long and highly uncertain outcomes, and a perception that hESC research is controversial, venture capital and stock market investment have been slow to enter the field. Only \$50 million of venture capital was invested in stem cell R&D worldwide in 2004, and pharmaceutical companies are investing in the area very selectively (Biophoenix, 2006).

In this uncertain scientific, political and commercial climate, many OECD nation states, including most of the G8 nations<sup>3</sup> have proved willing to make substantial public investments in hESC research and to develop sympathetic regulatory systems. Of all investment in stem cell research worldwide in 2004, 75 per cent was from government sources (Biophoenix, 2006). Although much of the critical literature around biotechnology emphasizes the commodification of living processes attendant on the influx of venture capital and development of start-up biotechnology companies in the 1980s and 1990s (Gold, 1996; Andrews and Nelkin, 2001; Scheper-Hughes, 2002), public investment in stem cell research is not as anomalous as it might appear. Löfgren and Benner (2005) point out that unlike the highly competitive, design-based ICT industries, the most mature sector of the new knowledge economies, biotechnology development as a national economic activity since the 1970s has required substantial state involvement and support. They situate this observation within a broader critique of the globalization literature. Following Cerny (1997) and Jessop (2002), they observe that

the reductions in government spending and state activity anticipated in much of the globalization literature have not in fact taken place. They point to a transformation in the form and orientation of the state in the wake of post-Fordism and globalization, rather than to a simple, quantitative reduction in its powers. In particular, they point towards a state deeply involved in the selective promotion and support of global industry, and often of other processes of globalization as well. Cerny (1997) describes the rapid transition from the post-war Keynesian state, whose political legitimacy derived from its ability to insulate key areas of the national economy from market forces, to what he terms the *competition state*, which encourages marketization and promotes the globalization of industries within its national borders.

Rather than attempt to take certain economic activities *out* of the market, to 'decommodify' them as the welfare state was organized to do, the competition state has pursued *increased* marketization in order to make economic activities located within the national territory, or which otherwise contribute to national wealth, more competitive in international and transnational terms.

(Cerny, 1997, p. 259; emphasis in original)

While post-war economic development in the OECD focused on national self-sufficiency across a range of industries and basic economic activities (e.g., banking and steel manufacture), the competition state selectively and intensively fosters the competitive advantage of some of its industries in the global economy. Contrary to neoliberal doctrine, Cerny argues, this transition has not involved a reduction of state activity. Instead, it has shifted state intervention from decommodifying bureaucracies to marketizing ones. In many ways, it involves the *expansion* of state activity, targeting intervention and support to particular economic sectors.

By targeting particular sectors, supporting the development of both more flexible manufacturing systems and transnationally viable economies of scale, and assuming certain costs of adjustment, governments can alter some of the conditions which determine competitive advantage ... promoting research and development; encouraging private investment and venture capital ... often through joint public/private ventures; developing new forms of infrastructure ... removing barriers to [labour] mobility, and the like.

(Cerny, 1997, p. 264)

Löfgren and Benner (2005) identify extensive state involvement with the biotechnology industries across the OECD, with states focusing support and intervention on universities and the R&D system, configuring the IP climate, making public/private research funding available, creating systems to encourage the commercialization of basic research and fostering knowledge sharing. They note a pragmatic mix of neoliberal and coordinated approaches, with an emphasis on entrepreneurship and venture capital sitting alongside state–industry partnerships, market regulation and ethical restrictions on scientific procedures.

In the case of hESC research, we can see multiple levels of competition–state support. As a potential new core technology, stem cell R&D enjoys complex kinds of strategic and institutional support, in addition to straightforward research funding, as states attempt to secure competitive advantages in future commercial developments. One prominent form of support is state funding and guidance of a series of globally oriented stem cell research networks designed to bring together regional, national and transnational expertise. In the United Kingdom, the Medical Research Council, the peak medical research body, supports and helps organize the International Stem Cell Forum, a network that includes medical research organizations from 14 states that fund stem cell research and aims to promote global good practice and encourage bilateral collaboration and knowledge sharing.<sup>4</sup> The Canadian government funds a Canadian Stem Cell Network that brings together scientists, policymakers and bioethicists from across Canada to ‘create a critical mass of knowledge’, to be ‘a catalyst for the development of new therapies’, to ‘promote informed debate’ and to ‘facilitate the transfer of technologies to the marketplace’ (Canadian Stem Cell Network, 2005).

In Australia, the Victorian state government has committed funds to create a secretariat for an ‘International consortium of stem cell networks’, which will involve the participation of nationally or regionally based networks in Canada, Scotland, North Rhine, Norway and Israel, as well as the US National Institutes of Health and the International Society for Stem Cell Research.

In this proliferation of state-supported, globally oriented research networks, we can see the new ‘governance’ role played by competition states, wherein states shape policy formation within an economic or social sector, not through top-down command and control mechanisms but through the coordination of negotiations among key institutions in relatively flat, transnational networks of interest (Coleman and Perl, 1999). We can also see a quest to find the best level of scale for optimum knowledge sharing and synergies. Stem cell networks range from those

focused on regional economies (such as the New South Wales stem cell network focused around Sydney, Australia, or the East-of-England stem cell network, focused around Cambridge), through the national scale (such as the Canadian example), to the transnational networks centred in various major innovation hubs like London. In a highly globalized industry like stem cell R&D, no particular level of scale has clear primacy, and research centres are likely to be involved in several networks at once, as different innovation bases compete to become primary anchor points for research sharing and coordination.

State funding and coordination initiatives are also used to encourage research partnerships between commercial firms and academic stem cell researchers working on the basic science. These initiatives are generally designed to encourage communication and collaboration between basic science biologists and biotechnology companies, collaboration that Jessop (2002) notes is encouraged even in neoliberal economies.

It is recognised that many high-growth [new technology] sectors are so knowledge and capital intensive that their development demands extensive collaboration (especially at pre-competitive stages) among diverse interests (firms, higher education, public and private research laboratories, venture capital, public finance etc.).

(Jessop, 2002, p. 127)

The UK Stem Cell Initiative, for example, based in the Department of Health, is an advisory group that brings university and private-sector stem cell researchers together to develop a 10-year vision for UK stem cell research. Its goal is 'to make the UK the most scientifically and commercially productive location for this activity over the coming decade, and which commands the support of public and private research funders, practitioners and commercial partners' (UK Stem Cell Initiative, 2005c). The UK Stem Cell Bank has also been set up in part to facilitate research cooperation and sharing between public and private researchers, both in the UK and internationally. The Singaporean government's largess in pouring public funding into Biopolis and the Biomedical Sciences Initiative is intended to recruit both academic and commercial scientific expertise to the island state and facilitate cooperation and technology transfer (Van Epps, 2006). In Australia, the National Stem Cell Centre has received substantial government funding to conduct research into four platform technologies – ESCs, adult stem cells, tissue repair technology and immune system modulation technology – and 'undertake world-class stem cell research to a stage where it can attract

strong commercial interest' (Australian Stem Cell Centre, 2005). The US state-based initiatives use a similar model. The Wisconsin research program includes a coordinated suite of funding and policies designed to spread the research effort across a number of sites and biomedical disciplines and to link up medical and biology research training, basic biological research, clinical research, commercial biotechnology R&D and venture capital.<sup>5</sup> In each case, we can see direct state involvement in the production and diffusion of stem cell-related knowledge, and in configuring the relationship between a knowledge commons around basic stem cell research in which researchers can collaborate without commercial restraint and the commodification of stem cell knowledge in IP regimes (discussed in detail in Chapter 2).

### **The post-welfare state and the promotion of medical innovation**

ESC technology, despite its controversial status, offers competition states other potential benefits beyond those provided by successful international economic performance. Cerny notes that a major political problem for competition states is the establishment of popular legitimacy in the wake of the deprioritization of public welfare. Broadly speaking, the social policy transformations associated with the public fiscal crises of the 1970s, the shift to post-Fordist economies and the dissemination of neoliberal 'solutions' have involved

a shift in the focal point of party and governmental politics away from the general maximization of welfare within a nation (full employment, redistributive transfer payments and social service provision) to the promotion of enterprise, innovation and profitability in both private and public sectors.

(Cerny, 1997, p. 260)

Innovation and successful international competition become surrogates for national welfare, a substitution that is neither stable nor fully accepted by populations, Cerny argues. The focus on competing in the global economy 'hinders the capacity of state institutions to embody the kind of communal solidarity or *Gemeinschaft* which gave the modern nation-state its deeper legitimacy, institutionalized power and social embeddedness' (1997, p. 251).

In the health area, the post-war welfare state derived a degree of its legitimacy from the provision of comprehensive health care and

its general collective management of the populations' health risks through public expenditure. Since the late 1970s, such national health systems have been restructured. States have generally not retrenched national health or public health insurance systems, but they have nevertheless found ways to expose public systems to various forms of marketization and reduced eligibility for publicly funded treatments. This restructuring has involved the selective privatization of profitable sectors; subsidization of parallel private hospital systems; means-testing and co-payment systems for treatments; and the exercise of tight fiscal controls and rigorous forms of cost-benefit analysis and evidence-based evaluation on surgical procedures, therapies and pharmaceuticals (Saltman, 2003).

Nevertheless the share of health expenditure as a proportion of GDP has steadily grown over the last two decades in the OECD, and health-care expenditure is under continuing upward pressure from high-technology medicine and the demand for long-term care for a steadily ageing population (Jacobzone, 2003). Simultaneously, as we discussed in the introduction, decreased fertility and the demographic shift towards an ageing population is believed to depress economic growth through increased demand on welfare and health-care provision and reduction of taxation revenues (Martins et al., 2005). One response to these pressures has been the gradual demutualization and devolution of many aspects of health care from state responsibility to individual responsibility for self-care and self-provision, through private forms of health consumption (Novas and Rose 2000; Ericson et al., 2000) and participation in global markets for private health services.

Given this configuration of tensions between the deprioritization of welfare (including health), the drive to secure globally competitive industries and the emergence of global as well as national markets for therapeutic applications, states have a strong set of incentives to invest in hESC research and regenerative medicine. If the basic science of hESC technology can be mastered and therapeutic applications commercially developed, nation states stand to reap the economic benefits associated with hosting leading-edge regenerative medicine commerce, in demand throughout global markets. It is estimated that at least 300 million people in the United States, the EU, and Japan alone could potentially benefit from stem cell therapy of some kind (Biophoenix, 2006).

Over and above this, however, states may gain certain benefits of legitimacy. As Sheila Jasanoff argues, biotechnology is increasingly caught up in the political legitimacy of nation states and their abilities to deliver care and health to their citizens.

If collective defense and welfare goals remain intransigent problems, as the 'war on terror' clearly demonstrates, then the mood of the moment seems all the more hospitable to state-supported advances in the life sciences, which promise citizens fulfillment on an intimate, personal scale, through longer, healthier, more liberated lives for themselves and, in time, their genetically tailored children. ... Advances in biological knowledge seemed to add point and meaning to the modernist project of rational, science-based problem solving at a moment when doubts about the goals and instruments of modernity were increasingly in evidence. Biological science and technology projected a confident ability to take much that is mysterious, elusive, particular, and problematic in the human condition and bring it within the realms of order, prediction, uniformity, and control. The life sciences in short presented themselves as ideal instruments to states in late-modern crises of legitimation.

(2005b, pp. 36–7)

HESC research also presents possibilities and hopes for health and welfare budget containment, an attractive prospect to states concerned with balancing budgets. As we noted in the introduction, regenerative medicine has the potential to reduce disabilities associated with ageing populations and extend working life. An OECD workshop into healthy ageing identifies leading-edge biotechnological innovation as the best means to improve aged health, not only increasing longevity but also disability-free years.

Biotechnologies are revolutionising the ageing experience by offering earlier diagnoses, new treatments such as regenerative and genetic interventions and ultimately disease prevention.... Techniques to prevent or replace lost functions are borrowing from the body's own development processes, for example, the use of pluripotent cells for cell transplants and organ regeneration, or the use of hormone therapies for lost bone and muscle mass.... In a 20-year time horizon, it may even be possible to address the fundamental causes of the ageing process and prevent or delay the onset of its most important diseases.

(OECD, 2003, p. 12)

Furthermore, as the rapporteur's scientific summary of the workshop notes, medical biotechnology both addresses social aspirations and reduces public health expenditure, particularly when delivered through public-private partnerships. 'Technology applied to geriatric medicine

not only responds to the aspirations of the elderly by providing the best hope for preventing or reversing the diseases and disabilities of ageing, it will also reduce health-care costs' (Weksler, 2003, p. 18). The workshop also noted the keen interest of large pharmaceutical companies in the area of geriatric medicine and health delivery services.

## Conclusions

It is evident then that hESC technologies represent a possible solution to a complex set of economic and welfare problems for contemporary states. Success in hESC research would give the sponsoring state a leading edge in the fostering of a new industry with a huge potential global market – the market for regenerative therapies. It would attract significant investment from the pharmaceutical and medical device sectors, and be a source of national scientific prestige and economic dynamism. At the same time, it would contribute in a highly visible way to the welfare of the population, without a concomitant expansion in public service delivery. The reduction of disease burden in the elderly and disabled would help to contain health-care costs and extend active life. In the final analysis, public investment in hESC research is so attractive for states because it expresses both concern for the well-being of populations and the drive for global economic competitiveness, without any apparent contradiction between the two aims. It can, in theory, deliver health improvement not through the Keynesian mechanisms of comprehensive provision but rather 'as a positive [externality] of enterprise, innovation and profitability' (Hay, 2004, p. 40).

Of course, it remains to be seen if stem cell research can fulfil such a promise, and the path to the delivery of clinical therapies is likely to be more circuitous than the political 'big picture' acknowledges, as considerations of clinical risk, treatment costs, intellectual property restrictions and large-scale tissue procurement come into play. In the next chapter we take up these last two points in more detail, as we consider some of the *material constraints* on hESC research, the problems presented by the scarcity and uneven distribution of the stem cell lines themselves. In many jurisdictions, laboratory researchers have very little access to viable, well-characterized stem cell lines. The availability of hESC lines is shaped by a number of factors, including rates of ethical procurement of precursor tissues (embryos and oocytes), local regulatory regimes and intellectual property configurations. In what follows, we consider the ways these factors shape the global tissue economy of hESC research, their modes of circulation, availability and scarcity.

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