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Seminar report

Government strategies and commercial models: interdisciplinary perspectives on innovation in stem cell science,

Royal Society of Medicine,

London, Friday, September 21, 2007.

Attendees: Professor Derek Burke (Chair); Professor Steven Wainwright (CBAS, KCL); Professor Mike Michael (Sociology, Goldsmith's); Dr. Margaret Sleeboom-Faulkner (Anthropology, Sussex); Dr. Barbara Prainsack (CBAS, KCL); Dr. Kathryn Ehrich (CBAS, KCL); Shawn Harmon (Innogen, Edinburgh)

Speakers: Professor Brian Salter; Dr. Olivia Harvey; Dr. Melinda Cooper; Amanda Dickins (CBAS, KCL)

Introduction and background:

Our intention with this seminar was to facilitate theoretical debate about the relationship between government strategies, commercial models and the global economy of stem cell science. This one-day seminar examined different aspects of the national economies of stem cell science in China, India and the US from the interdisciplinary perspectives of the Global Biopolitics Research Group.

The aim was to enhance our theoretical understanding of how governments around the world influence and engage in the potentially lucrative markets emerging from developments in stem cell science in order to develop and maintain national advantage. In enhancing their global position, governments may introduce a range of policies that support and develop stem cell science. Examples include: substantial investment in stem cell science, the strategic coordination of stem cell science, the establishment of public-private partnerships, regulation of stem cell science and the introduction of robust property-rights regimes aimed at facilitating private investment.

Significantly, the way that stem cell science can be supported by individual states is also substantially affected by political, social and cultural factors. The value attached to the embryo in different cultural locations, the supply of materials to research, the development of international agreements, the public support for science and international competition for stakes in the knowledge economy all impact on the global development of the stem cell industries. How innovation systems respond to these factors will have substantial implications for the stem cell economy.

The seminar drew together academic participants with an interest in the social studies of stem cell science, innovation, biotechnology, political science, and the global bioeconomy.

Summary:

Professor Derek Burke, former Vice-Chancellor of the University of East Anglia, chaired the meeting. Derek opened the meeting by offering a tribute to his friend and colleague, Anne McLaren, who died in a car accident earlier this year. Derek told us that Anne was a model scientist, politician and regulator keenly interested in developing biomedical science and the associated issues. Anne served on the original Warnock Commission in the late 70s and early 80s and many others since then. You can read more about Anne's life in an obituary in *Nature*. Derek also reminded us of the main research question of the day: how can the Global Biopolitics Research Group move their analysis forward in an interdisciplinary area where there are no established models?

Professor Brian Salter was the first speaker with a paper on 'States, strategies and stem cell science: the global politics of speculative futures'. Brian argued that the key aspects of how states determine a response to stem cell science is their understanding of the future value of stem cell science and their speculation about the global political value of developing a national response to stem cell science. Brian then went on to outline two different approaches in the global political dynamic represented by the developing states of China, India and Singapore for example, on the one hand, and the competition states of the UK, US and Europe on the other hand. A question Brian asked at this point was: is there even such a dynamic; and, if so, what are states doing about it?

Brian argued that the important point about state responses to stem cell science is the 'economic imagination' that drives state decisions. That is, do states anticipate some kind of national advantage from enhancing or facilitating their local stem cell industries? Or, alternatively, do states see investment in stem cell research as a negative aspect? The point here is that the future of the stem cell industries is determined *politically*, with the empirical or economic data used to support either agenda. Overall, the kind of strategy a state adopts serves a particular view of itself in the global future.

Competition states operate to enhance the conditions of innovation and to maintain hegemony. Policy

considerations might include: enhancing the cultural acceptability of science, attracting and maintaining a scientific labour force, enhancing investment and the organisation of science, deciding on ownership of bodily material and intellectual property, and developing guidelines on human subject testing, good clinical practice and good manufacturing practice.

By contrast, development states want to challenge the superiority of competition states and gain economic advantage at the same time. Development states use a variety of strategies: such as attracting their overseas trained scientists back to their country of origin and developing alternative models of funding of and collaboration in scientific research than exist in traditional economies. In effect, developing states make a range of choices or trade-offs about where or when they enter into the stem cell innovation process.

Some of the questions and comments raised by the seminar participants at this point included the comment that attracting and retaining the interest of pharmaceutical companies are major factors in state strategies; the strengthening of global ethical and manufacturing standards will affect the tension between competition and development states because developing states will want to be seen as legitimate players in the global stem cell economy; there are clear parallels between the development of the global stem cell economy and GM or environmental politics; and the influence of market access is a major factor in determining state strategies. Steve Wainwright asked how much the commercial implications of stem cell science affect the development of state strategies and how much of that comes down to rhetoric about cell transplant, despite or because of the admission that the cell transplant model is not the best one to work with in developing stem cell science.

Brian responded to these comments by recognising that the development state is admittedly a problematic concept; that states *always* respond politically to the developing situation and scientists have to respond and engage with the political agenda that determines funding. A further discussion focused on the difficulties of dealing with the uncertainty of the stem cell economy and the experimental nature of doing stem cell science.

Olivia Harvey then presented the next paper: 'The social studies of stem cell science and human embryonic stem cell science in the United States'. Olivia outlined how the components of innovation discussed by Brian are operating in the US. The key points raised by Olivia were that the US is scientifically strong but organisationally weak, that intellectual property in the US is the strongest in the world yet is also problematic for developing local industries, and that there is actually very little human embryonic research being conducted in the US, despite the high profile nature of the debate. Another significant factor about the stem cell industries in the US is that investment is high, public interest groups have a big influence on developing research agendas and that human embryonic stem cell science is irrevocably tied to the anti-abortion movement.

Olivia pointed out that human embryonic stem cell science in the US is underpinned by a regenerative medicine model for both private and public research that is unlikely to be the most viable from a commercialisation point of view, given the current lack of clinical evidence. However, if the current clinical trials underway should prove to be successful, then the regenerative medicine model will generate renewed enthusiasm from investors, regulators, clinicians and patients. Olivia argued that there is a distinct possibility of market failure in the US stem cell industries, and that from a social studies of stem cell science perspective, regulatory uncertainty, gaps in sociological knowledge about stem cell research in the US, a lack of sufficient legal safeguards and a high degree of public involvement in the debate renders the human embryonic stem cell enterprise in the US highly unstable.

Comments made by the audience included: that there is no funding to conduct sociological research in the US in the same way that has been conducted in the UK; that the reasons for such disparity in interest in

the social studies of stem cell science are worth investigating; that different public and political reaction to human embryonic stem cell science across different states has much to do with the inherited legal traditions of particular states; and that the relationship between patients, clinical trials, clinicians, scientists and the market are very complicated. Derek also pointed out that the US is an extremely diverse place and that this diversity is reflected in the development of the stem cell industries.

After lunch Melinda Cooper presented a talk on the nature of clinical trials, with some specific examples from China and India in particular. Melinda began by outlining the inherently problematic nature of clinical trials as a model of efficacy. Following the work of Hans Jorg-Rheinberger Melinda argued that scientific invention is partially dependent on unpredictable outcomes; a point that renders the whole concept of the clinical trial as incontrovertible evidence that a medicine is safe and effective difficult to justify on the basis of clinical trials alone. In short, the clinical trial is both an experiment and a testing device; it operates as both a proof of acceptable standards and also as a means for determining what will happen. In terms of using clinical trials in stem cell research though, Melinda asked: are stem cells even a standardizable product?

Regardless of the difficulties associated with the use of clinical trials, they are standard practice for the development of therapeutic products. Melinda pointed out that there is currently a stand-off between science and pharma over clinical trials. Clinical trials are expensive to run, yet the progress of stem cell science as a therapy depends on proving clinical success. Off-shoring of clinical trials is an attempted solution to the problem of what is euphemistically described as 'more traditional locations'. China and India are two favoured locations due to the availability of skilled labour, the potentially large pool of treatment-naive patients and cheaper administration costs in general. Melinda also pointed out that the history of the double-blind clinical trial using volunteers as a gold star standard is relatively short, and that there are significant political issues created by the global stem cell economy and the off-shoring of clinical trials. For example, how are citizens in off-shore locations pressured into supplying clinical labour to the clinical trial? In conclusion, Melinda asked: to what extent does the experimental nature of clinical trials undo global standards? And how does this relate to the question of human labour?

Melinda's example of clinical trials conducted in China raised a host of questions from the audience. Derek questioned the ethical provenance of trials conducted in non-standard ways. An interesting discussion between participants focused on the validity of the work done by a company called Beike, who cite substantial evidence of clinical success along with government support on their web-site. Melinda argued that this example demonstrates the difficulty of globalising standards, whereas Amanda argued it is unclear whether Beike are actually conducting clinical trials. At this point Steve Wainwright pointed out that scientists tend to self-regulate on clinical trials as they risk ostracism from the scientific community if their results are considered questionable. Derek also noted that there is a difference between the risks of a clinical trial and the potential for unpredictability – unpredictability is no reason not to do clinical trials.

The discussion then moved on to the point raised by Melinda that clinical trials depend on clinical labour. This idea of clinical labour is part of larger work on the bioeconomy by Melinda and Cathy Waldby about the political consequences of developments in biomedicine. Melinda pointed out that the kinds of people who are seduced into clinical trials are at the margins of citizenship and that clinical trials therefore raise issues about equity. As Barbara Prainsack mentioned, this has been happening widely in Western Europe. In developing her ideas about clinical labour Melinda has been using the work of Aiwaha Ong on 'spaces of export zone' and would like to extend this to thinking of the clinic as an export zone too. Brian pointed out here that it is important to recognise that stem cell science is not the only policy arena where these issues are occurring and that like other arenas stem cell science forms part of wider global political processes.

Overall, Melinda argued that pharmaceutical companies want to reduce their labour costs and participation in clinical trials is the biggest labour cost they have. Brian suggested that this is just one of the drivers in the overall stem cell economy and that the standardisation of clinical trials has knock on effects onto many other aspects of industry development and state strategies.

Amanda Dickins then presented her paper on 'China: Venture capital, commercial models and stem cell research'. Amanda argued that in terms of China and venture capital, it is helpful to think about what states are actually doing within the international political economy. Amanda suggested that China is clearly in stem cell research for the money that it could potentially generate for the country. Amanda referred to two funding programs that indicate China's investment in science: 863 and 971. 863 was a program established in the 1980s to enhance translational research. 971 started in the late 1990s after the market crash in 1996 to fund basic research. Amanda then asked what she calls 'the 500 billion dollar question': does investment in infrastructure really translate into market share?

Amanda pointed out that there is a significant funding gap between basic research and product development in the stem cell industries. The question is: how can this funding gap be covered? In China, Amanda told us, there are many start ups that used a mixed model approach in their business plan. Although these companies have some success, Amanda argued that without a strong VC sector in China, there is still a significant funding gap. The Chinese government has made a significant effort to try and develop their local VC industry, yet in terms of market-share, biomedical products are still a very small part of overall investment. Another important point about VC in China is that much of it is government controlled and is therefore very susceptible to the prevailing political climate. There has however been a huge market growth in foreign direct investment in the last 5-6 years due to the collapse of the Silicon Valley dot.com boom. This left many investors with nothing to invest in locally so they started looking off-shore for alternatives. However, foreign direct investment, while growing, is still not enough to cover the funding gap. Amanda finished by asking two questions: how will the funding gap be covered in the long-term? And, is it possible that the Chinese government's massive investment in stem cell science could result in its global dominance of the stem cell economy?

Questions and comments raised by the audience focused on the sheer complexity of developing effective commercial models in China. Foreign VC models don't work, despite attempts to implement US style VC in China. The political nature of funding stem cell research in China means that scientists are under enormous pressure to generate results and get funding, which is further complicated by the nature of the relationships that exist between governments, universities, and companies in China. Amanda said that the stem cell industry is also hampered by the complexity of the stock market in China and the nature of tradeable versus untradeable shares, which is currently in flux as the rules are changing. A lack of experience in growing companies also poses problems for the stem cell industries in China.

Conclusions:

In his concluding remarks Brian began by observing that the interdisciplinary nature of the work of the Global Biopolitics Research Group makes the analytical task both more challenging and more complicated. Nevertheless, there are two polarising points running through the issues discussed at the seminar: how globalisation impacts on the developing global stem cell economy and how states respond to this. Brian recognised that the concept of 'commercial models' that we have been using to mediate these two poles has needs to be refined in the light of the seminar. Nevertheless, we have learnt that the North American nationalist, market-based model that we have been using has a number of implications for thinking through how states engage with one angle of the stem cell economy. The lessons learnt from the seminar include: that at different points in the development of the stem cell industries states have a differential ability to handle costs; that reactions to the global stem cell economy depends on local political and ethical cultures, which raises the question of the significance of cultural embeddedness in general. Furthermore, the notion of culture that tends to underpin discussions about stem cells needs to be

expanded from thinking simply about sensitive ethical issues to include cultural issues about commercial success or political context. Overall though, Brian maintained that the question of political imagination is the most important driver of the global stem cell economy, that different states have very different relationships to this political imagination and that ultimately this determines how they engage in the global stem cell economy.

Dr. Olivia Harvey
Professor Brian Salter