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Hegemony in the marketplace of biomedical innovation: Consumer demand and stem cell science

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ABSTRACT

The global political economy of stem cell therapies is characterised by an established biomedical hegemony of expertise, governance and values in collision with an increasingly informed health consumer demand able to define and pursue its own interest. How does the hegemony then deal with the challenge from the consumer market and what does this tell us about its *modus operandi*? In developing a theoretical framework to answer these questions, the paper begins with an analysis of the nature of the hegemony of biomedical innovation in general, its close relationship with the research funding market, the current political modes of consumer incorporation, and the ideological role performed by bioethics as legitimating agency. Secondly, taking the case of stem cell innovation, it explores the hegemonic challenge posed by consumer demand working through the global practice based market of medical innovation, the response of the national and international institutions of science and their reassertion of the values of the orthodox model, and the supporting contribution of bioethics. Finally, the paper addresses the tensions within the hegemonic model of stem cell innovation between the key roles and values of scientist and clinician, the exacerbation of these tensions by the increasingly visible demands of health consumers, and the emergence of political compromise.

1. Introduction

To what extent does the rise of the active health consumer in the globalised knowledge economy of the life sciences challenge the hegemonic model of biomedical innovation propagated by the developed countries of North America, Europe and Japan? Driven by a supply side alliance of science, medicine and industry, that model has assumed that consumer demand will wait passively for the arrival of a supply of new health technologies through the lengthy innovation process of basic research, clinical experimentation, product development, clinical trials, product approval and clinical application. This supply side approach works so long as the authority of science and medicine is able to control the operation of the health care market by convincing consumers that their choice of treatments should be what science and medicine say they should be: the demand side of the market is deemed to be the mirror image of the supply side. Underpinning the orthodox model is an asymmetry of knowledge between science and medicine, on the one hand, and health consumers, on the other. Health consumers do not need their own sources of information because, the logic goes, the supply side is governed to ensure the protection of their interests. Demand side governance through informed consumer choice is therefore unnecessary.

Employing a political economy approach, this paper develops a theoretical framework to analyse the extent to which such a hegemony of innovation values may be challenged when health consumers question that authority, construct and analyse their own knowledge sources and, critically, are able to access a supply of health treatments delivered through an alternative model, or models, of innovation based in the market of medical practice. Under such conditions the demand side may be activated not only in terms of an economic demand for what the orthodox model may judge to be 'illicit' health care products but also a political demand for a redefinition of the innovation model itself, its rules and its values. What constitutes legitimate innovation then becomes problematic.

The political economy of the demand-supply relationship in biomedical innovation and its implications for hegemony are particularly visible in the field of novel stem cell therapies. Here a

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global supply of new therapies from hundreds of clinics offering treatments for a wide range of conditions including spinal-cordinjury, muscular dystrophy, optic nerve hypoplasia (ONH), septo-optic dysplasia (SOD), Lyme Disease, diabetes, ataxia, cerebral palsy and Parkinson's disease connects easily to a global demand from thousands of health consumers (Salter et al., 2014; Sipp, 2011). However, the operation of this market is restricted because the model of stem cell innovation used by such clinics is rooted in the domain of medical practice rather than that of scientific research. Such practice based innovation is condemned as unproven, unsafe and illegitimate by supporters of the orthodox science based model of stem cell innovation – itself able to generate only a very limited supply of new therapies for a restricted range of conditions – and consumers who purchase such stem cell therapy products are dismissed as ill-informed 'stem cell tourists' (Dedmon, 2009; Ryan et al., 2010). International scientific organisations such as the International Society for Stem Cell Research (ISSCR) warn strongly against consumer use of the clinics (Baker, 2008). States with an established tradition of regulation in orthodox biomedical innovation look to tighten their rules to prevent or restrict their operation (Fink, 2010). And bioethicists discuss how better to protect what are assumed to be vulnerable health consumers from exploitation by what are assumed to be mercenary clinicians (Cohen and Cohen, 2010). Yet, despite this, consumer demand for the stem cell therapy clinics continues to increase (Ogbogu et al., 2013), the market for stem cells is projected to rise from $26 billion in 2011 to $119 billion in 2018 (Transparency Market Research, 2013), and the hegemonic structures of the orthodox model are beginning to look less than secure.

The dynamic of the global political economy of stem cell therapies, where an established biomedical hegemony of expertise, governance and values collides with an increasingly informed health consumer demand able to define and pursue its own interest, is thus well established. How does the hegemony then deal with the challenge from the consumer market and what does this tell us about its *modus operandi*? In developing a theoretical framework to answer these questions, the paper begins with an analysis of the major components of the hegemony of biomedical innovation: the scientific paradigm that underpins it, the values that legitimise it, the markets that sustain it and the national and transnational institutions of governance that protect it. Secondly, it examines the hegemonic challenge posed by consumer demand working through the global practice based market of medical innovation, the response of the national and international institutions of science to this emerging counter-hegemony and their reassertion of the values of the orthodox model. Finally, the paper addresses the resulting tensions within the hegemonic model of stem cell innovation between the key roles and values of scientist and clinician, the exacerbation of these tensions by the increasingly visible demands of health consumers, and the political compromises that are beginning to emerge.

2. Hegemony in biomedical innovation

In his essay on how Gramsci's concept of hegemony could be adapted to promote understanding of the problems of world order, Robert Cox argues that the Machiavellian connection in Gramsci's work 'frees the concept of power (and of hegemony as one form of power) from a tie to historically specific social classes and gives it a wider applicability to relations of dominance and subordination, including … .relations of world order' (Cox, 1983: 164). Although in the period since Cox's seminal paper the concept has been applied principally to the global hegemony of the United States and the neo-liberal economy (see eg Beeson and Bell, 2009; Wade, 2002), the applicability of its theoretical thrust to innovation in the knowledge economy of biomedicine, where the dominant innovation model is driven by Western science and Western states, is clear. Throughout the process of biomedical innovation from basic research, through clinical experimentation and clinical trials, to product approval and clinical application can be discerned the operation of the main conceptual elements of Gramsci's analysis.

In this analysis the driving force of hegemony is the *blocco storico*, the historical block and dominant group. More than simply a political alliance between social forces, the *blocco storico* integrates and propagates a set of interests 'bringing about not only a unison of economic and political aims, but also intellectual and moral unity … on a "universal" plane' (Gramsci, 1971: 181–2). This unity is achieved through the maintenance of a cultural hegemony expressed in terms of:

'Consent given by the great masses of the population to the general direction imposed on social life by the dominant fundamental group; this consent is "historically" caused by the prestige (and consequent confidence) which the dominant group enjoys because of its position and function in the world of production.' (Gramsci, 1971: 145).

In biomedical innovation the *blocco storico* is biomedical science: the agency defining, owning and propagating the paradigm governing the production of knowledge in this field from the basic science through to the clinical product. Underpinning the paradigm are the organising values of science: objectivity, the importance of the scientific method, and the discovery and application of generalisable principles of causality. The objective of biomedical science, as with all science, is the advancement of knowledge within the rule systems of the scientific method. This may benefit citizens and society but such benefits are not the primary objective of scientific activity. Hence in its *Guidelines for the clinical translation of stem cells* the ISSCR is at pains to distinguish the activity of clinical research which 'aims to produce generalisable knowledge about new cellular or drug treatments, or new approaches to surgery' from that of medical innovation where 'the main goal of innovative care is to improve an individual patient's condition' (International Society for Stem Cell Research, 2008a: 15). The ISSCR is clear that where there is any conflict between the two objectives, it is the former that should take precedence. Scientific rigour should not be sacrificed on the altar of patient benefit.

Helping to sustain the legitimacy of the paradigm of biomedical science are what Gramsci terms the 'traditional intellectuals' of the hegemony who are 'experts in legitimation' (Gramsci, 1971: 9–10) tasked with 'the function of developing and sustaining the mental images, technologies and organisations which bind together the members of a class and of an historic bloc into a common identity (Cox, 1983: 168). Acting in this role for biomedical innovation are the bioethicists. Their task is to legitimise biomedical innovation through a system of facts and values which, as Berger and Luckman observe, '"explains" the institutional order by ascribing cognitive validity to its objectivated meanings' and 'justifies the institutional order by giving a normative dignity to its natural imperatives' (Berger and Luckman, 1967: 119). It is no coincidence that the rise of bioethics as an intellectual and political force with the capacity to produce, organise and disseminate a moral economy of authoritative governance values directly parallelled the expansion of biomedical research from the 1970s onwards (Evans, 2002: Salter and Salter, 2007). Initially driven by the tenets of American 'principlism', bioethics had as its objective the task, as Albert Jonsen puts it, of creating 'the common coin of moral discourse' in order to help resolve cultural tensions created by medical scientific advance (Jonsen, 1998: 333). Bioethics emerged because it was politically useful and 'met the need of public policy makers for a clear and simple statement of the ethical basis for regulation of research' (Jonsen, 1994, xvi, as quoted by Evans, 2000, 34). Similarly, in her