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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.

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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-cord injury, 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 paralleled 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

study of science in the United Kingdom, United States, and Germany, Jasanoff notes the dawning recognition in all three political systems of the risks and promises engendered by the multifaceted advances in genetics and biotechnology and shows how ‘bioethics offered the promise of bringing order and principle to domains previously governed by irrational, emotive and unanalysed reactions.’ (2005: 171).

As the traditional intellectuals of biomedical science, bioethicists act to further its ideological interests (Callahan, 2006; Koch, 2006). Through the enunciation and application of a set of principles, standardised rules are established that enable the translation of different moral positions to a common metric capable of facilitating, usually on a cost-benefit basis, choices and decisions. For the principles to operate efficiently, they must combine to produce a system capable of commensuration (the discarding of information), predictability and calculability: the characteristics of a currency (Evans, 2000). In this sense bioethical debate can be seen as a supporting forum for trading-off of values to facilitate and legitimise the operation of the research funding market of science, which we will discuss shortly. The two markets work in tandem with the goal of maintaining the hegemony of biomedical innovation. Whilst bioethics legitimises the values of the hegemony, institutions act to safeguard and enforce its rule systems. As with Cox’s portrayal of the neo-liberal hegemony, biomedicine works through a world hegemony which is ‘expressed in universal norms, institutions and mechanisms which lay down general rules of behaviour for states and for those forces of civil society that act across national boundaries – rules which support the dominant mode of production’ (Cox, 1983: 172). Transnational scientific organisations and national regulatory bodies provide the institutional vehicles for the dissemination of the Western model of biomedical innovation, drawing on the ‘objective’ qualities of the scientific method as their main source of legitimation. In parallel with the operation of the neo-liberal hegemony, international institutions perform an ideological role in helping to ‘define policy guidelines for states and to legitimate certain institutions and practices at the national level’ (Cox, 1983, 173). In stem cell innovation, that role takes the form of guidance on the governance of the basic and pre-clinical stages of stem cell innovation driven by the work of the UK Stem Cell Bank, the International Stem Cell Forum (ISCF) and the ISSCR. Through their links with national research funding agencies, these organisations have constructed an international infrastructure for the governance of the basic stem cell science dealing with both technical and ethical issues of standardisation (Eriksson and Webster, 2008; Waldby and Salter, 2008).

A major task of the transnational governance of science by science is to ensure that, in its support for biomedical innovation, the funding market of basic life sciences research works within the hegemonic assumptions of the biosciences community. This market operates quite independently of the health care market through which health consumer demands and preferences for the innovation products may be subsequently expressed. Policy initiatives to develop a new area of medicine or treatment regime for a particular disease work through public and private research funding agencies dependent, through the peer review system, on scientific expertise for judgements regarding the allocation of research resources. Although this market is obliged to respond to the stated priorities of government, it does so within an epistemic framework driven by the imperatives of a value system dedicated to the systematic advancement of scientific discovery, not to the interests of the state and its citizens. Much has been made of the alleged changes in the practice of science in response to pressures from these interests, seeing the changes as indicative of a fundamental shift from autonomy to public responsiveness (Buchbinder, 1993; Gibbons et al., 1994). However, others are more sceptical, suspecting that science

may be simply adapting the cosmetic portrayal of its activities to the new ideological climate of accountability whilst retaining the substance and control of its direction (Pestre, 2000; Shinn, 2002).

From the Gramscian perspective, it is to be expected that the hegemony of biomedical innovation will to an extent adapt in response to such pressures for change. This is what Gramsci terms *trasformismo* – a ‘strategy of assimilating and domesticating potentially dangerous ideas by adjusting them to the policies of the dominant coalition’ (Cox, 1983: 166–7). Successful hegemonies are those capable of recognising, responding to and, if necessary, accommodating the challenge from rising power groups (Germain and Kenny, 1998). Part of the contribution of nation states to the maintenance of the global hegemony may be in enabling hegemonic adaptation through negotiation and arbitration whilst retaining its essential character and power relationships. The adaptive capacity of a hegemony is a measure of its sophistication and its durability.

Trasformismo of the hegemony has proved to be more necessary as the innovation process moves from the realm of basic research to its application in the clinical setting. In the case of UK biosciences, the longstanding tension between state and science has most recently found political expression in the debate surrounding the ‘translation’ of laboratory based research into health products through efficient commercialisation. Most notably, the Cooksey Report *A review of UK research funding* concluded ‘that the UK is at risk of failing to reap the full economic, health and social benefits that the UK’s public investment in health research should generate’ (the state interest) as a result of two key gaps. These are ‘translating ideas from basic and clinical research into the development of new products and approaches to treatment of disease and illness; and implementing those new products and approaches into clinical practice’ (Cooksey, 2006: 3). Policies to address the gaps were subsequently implemented through the new institutional vehicles of Biomedical Research Centres, the Academic Health Sciences Centres, the Medical Research Council’s (MRC) translational funding programmes (including one on translational stem cell research), the joint MRC/Technology Strategy Board (TSB) Biomedical Catalyst initiative and the TSB Catapult Programme (Dzau et al., 2010; MRC, 2014; TSB, 2014).

Although these kinds of state interventions employ the research funding market as an instrument for reforming the nature of biomedical innovation to render it more responsive to the state’s economic and social priorities, they do not, nor are they intended to, challenge the power structures of the biomedical science hegemony. Rather, *trasformismo* requires a mode of adaptation that works with the weave of those institutions to achieve a sensible compromise between the interests of science and those of the state in the pursuit of hegemony maintenance.

The hegemony’s capacity for *trasformismo* is also evident in its conception of the role of health consumers in the creation and application of medical knowledge. Traditionally that role has been seen as essentially passive with consumers accepting that their role, and some would say duty, is to contribute to life sciences research through participation in clinical experimentation and trials and, when the research cycle is complete, receive the clinical benefits thus generated (Harris, 2005). Certainly the hegemonic model does not expect them to engage in the agenda setting of medical research nor to question either the scientific logic that governs the sequence of basic research, clinical experimentation, product development, clinical trial and product approval or the lengthy timescale (10–15 years) required to complete it. That is regarded as the task of those who exercise power in the orthodox model of biomedical innovation: the scientific community, funding agencies, government and industry who contribute to the several stages of the innovation process.

However, some hegemonic flexibility in the clinical domain of biomedical innovation, again driven by the state, is apparent in the incorporation of health consumers into the institutions of medical science through what has been termed 'sponsored consumerism'. This is a policy with a long and chequered history in the UK National Health Service (NHS) where health consumers are given various types of consultative and advisory roles but no real power (Salter, 2003). Closely allied to this process of institutional inclusion has been the creation of an apparatus of sponsored public participation by states aware that public trust in science can no longer be assumed but that the legitimacy of science has to be politically constructed to support its hegemonic position. Much of the debate over how best to do this and so resolve the tensions between science, the state and health consumers has understood these tensions as matters of disputed facts, requiring either education of a (deficient) public to equip them with the correct, scientific, understanding of the issues, or engagement of an (informed) public to achieve consensus through dialogue. Examples of the latter are initiatives such as consensus conferences, citizens' juries, and public debates such as the 'GM Nation?' debate (Irwin and Wynne, 1996; Rowe and Frewer, 2005). In the case of UK health research, the creation of the Health Research Authority (HRA) in December 2011 'to promote and protect the interests of patients in health research and to streamline the regulation of research' (HRA, 2014), working through a detailed public involvement strategy, brings these elements together and establishes an institutional platform for health consumer sponsorship with statutory backing from the Care Act 2014.

Such techniques of institutional inclusion in the clinical research domain of biomedical innovation allow health consumers to be absorbed into the governing apparatus of the life sciences funding market and obliged to work within the agreed hegemonic agenda of science and state. The hegemony assumes the absence of any interaction between health consumer demand and competition in the research funding market. Instead, the 'demand' for the products of innovation is seen to originate in the systems of reimbursement, primarily state and insurance funds, in which health consumers are embedded. State and insurance organisations make choices on behalf of health consumers. In the absence of any direct market power in this domain, health consumers can only turn to the resources of patient organisations – at best a weak form of political power – to offset the established institutional dominance of science and state (Baggott and Forster, 2008; Wood, 2000). Given this situation, it would seem that the capacity of health consumers to establish an effective counter-hegemony in biomedical innovation is bound to be limited.

3. Consumer demand and the emerging counter-hegemony

Gramsci and Cox assume that for hegemony to be challenged there must exist a counter-hegemony armed with the institutions, intellectuals and the capacity to wage a 'war of position' to 'undermine the legitimacy of the dominant ideology' (Lipsitz, 1988: 146). It is argued here that a global challenge to the hegemony of biomedical innovation has indeed emerged in the case of stem cell innovation but as much through the individualised mechanism of the market as a vehicle for consumer choice as through the formal interplay of institutions and ideas. Health consumers have begun to question the hegemonic model economically, through the market choice of health care products unapproved by the hegemony (Deloitte Centre for Health Solutions, 2011; Bookman and Bookman, 2007); politically, through organised political challenge of the hegemonic model, such as in the case of AIDS patients (Epstein, 1996); and, to a lesser extent, ideologically, through the propagation of alternative narratives about the process of

innovation (Woods and McCormack, 2013).

The origins of the challenge to the hegemony of biomedical innovation lie partly in the nature of the research funding market itself. Competition between the domains of science for limited funding resources leads to an inflation of claims regarding what investment in a particular domain will achieve. With states now insisting that life sciences funding be linked to the productivity of the field and its economic and social benefits (see eg Department for Business, Innovation and Skills, 2011), science domains have an incentive to argue that theirs can deliver faster and more efficiently than others. These statements then impact on health consumer demand by creating expectations about the early availability of the new treatment. A form of what has been termed 'promissory politics' is thus created characterised by an inflationary spiral of 'hype and hope' with clinicians caught between the twin forces of competitive science and expectant health consumers, in stem cell science as elsewhere (Morrison, 2012; Murdoch and Scott, 2010).

The expression of this demand forms part of an expanding global health care market for both established and new treatments (Connell, 2011; Cortez, 2008; Kangas, 2010). As with other markets, it has benefitted from the liberalising effects of the free movement of goods and services promoted under the auspices of the World Trade Organization and its General Agreement on Trade in Services (Smith, 2004; Smith et al., 2009). Supported by an enabling infrastructure of affordable travel, facilitating agencies, internet based advertising and information and investment by governments keen to access foreign revenue, the global market for orthodox health care has expanded rapidly with new suppliers particularly in emerging economies such as India, China and Singapore (Deloitte, 2009). Established treatments span the full range of medical services but most commonly include dental care, cosmetic surgery, elective surgery, and fertility treatment (Lunt et al., 2011). Estimates of the value of the global health consumer market range from approximately 8 million cross-border patients generating a market value of USD 24–40 billion per year (Patients Beyond Borders, 2013) to a market size of USD 60 billion (2007) and upwards (Herrick, 2007; Deloitte, 2009).

The global market for established health care treatments constitutes a model and infrastructure of service delivery readily applicable to the provision of novel therapies. As such it has the potential to act as a vehicle for counter-hegemonic development in biomedical innovation in terms both process and legitimating values. At the centre of the model is the informed health consumer who assumes she/he has the right to make their own choices to buy treatment in a health care market which is another form of mass consumption. In so doing, they reflect on information about their condition and appropriate treatment drawn from a wide range of sources which include not only the formally approved outlets of science and state but also the burgeoning information banks of the internet (Sulik and Eich-Krohm, 2008). The latter has proved to be particularly important to consumers of stem cell therapies given that the advice of the national and transnational hegemonic institutions of biomedicine is hostile towards the stem cell therapy clinics consumers often want to access (see eg ISSCR, 2008a; Australian Stem Cell Centre, 2009). In their search for information, such consumers regularly engage with the numerous interactive facets of the Web 2.0 architecture (social networking sites, blogs, wikis, folksonomies, video sharing sites, hosted services, Web applications and mashups) as do the supplying clinics (Chen and Gottweis, 2013; Levine, 2010; Petersen et al., 2013). Their demand is fuelled by the characteristics of a particular disease condition, the proximity of pain and/or death, and the limits of local treatment which generates a calculation of risks and benefits with its own internalist rationality and values. Such a subjective rationality may be at odds with the rationality of the external observer,

be they scientist, bioethicist or policy maker, and generate a robust demand with limited responsiveness to negative information about stem cell therapies and a high tolerance of health risk (Miller and Joffe, 2009; Slevin et al., 1988). It cannot be assumed that such a consumer demand will behave in a manner consistent with the values and rationality of the hegemonic model of biomedical innovation. The demand may display its own logic, dynamic and direction. Supported by the internet's facilitation of the demand-supply engagement, the demand acts to create a dynamic stem cell therapy cybermarket operating separately and in parallel to the world of orthodox medicine with its fixed information sources, rigid regulatory apparatuses, and static power groups.

The ability of health consumer demand for stem cell therapies to find and activate new sources of information and supply in the absence of an adequate supply of new therapies from orthodox stem cell science poses an economic challenge to the hegemonic order of biomedical stem cell innovation. It does so through a preparedness to accept the products of the practice-based model of *medical innovation* employed by the stem cell clinic providers, a model roundly denounced by supporters of the hegemonic model of *scientific innovation*. The two models are informed by the contrasting values of medicine and science. Hence, whereas for the former the goal is the benefit of the individual patient, for the latter the goal is scientifically generalisable results achieved through the application of the scientific method (Lindvall and Hyun, 2009; ISSCR, 2008b: 15). Embedded in practice, then, 'Medical innovation in cellular therapy may be viewed as the ethical and legitimate use of non-approved cell therapy by qualified health care professionals in their practice of medicine' (Gunter, 2010: 966). The treatment should be scientifically based and safe, but its efficacy does not have to be proven. For example, in the case of the innovative use of stem cells in heart repair, Mathur and Martin argue that 'When potential clinical benefit has been shown, safety is the primary consideration that should determine further trials. An understanding of the mechanism of benefit is highly desirable yet not necessary.' (Mathur and Martin, 2004: 188).

Such an approach offends the fundamental scientific value that causality should be understood in order that generalisable knowledge may be produced and applied, a central feature of the hegemonic model. Given this value position, it is unsurprising that the national and transnational institutions of stem cell science take the view that, whilst 'Historically, many medical innovations have been introduced into clinical practice without a formal clinical trials process', it should nonetheless only be used 'in some very limited cases', 'only in exceptional circumstances ... primarily for seriously ill patients who lack good medical alternatives' and as a 'one off' (ISSCR, 2008b: 15; Australian Stem Cell Centre, 2009). In addition, the ISSCR is clear that there is a distinction between 'responsible clinician-scientists' providing this limited medical innovation and medical innovation provided through 'the commercial purveyance of unproven stem cell interventions' which it condemns (ISSCR, 2008b: 5). In other words, the use of the market to supply medical innovations in response to consumer demand is unacceptable. For health consumers to assert that their demand should form part of the process of innovation, rather than simply exist as a given once the process is complete, is a therefore a perspective that has to be rejected.

It is, nonetheless, a perspective that is gaining political as well as economic traction. By activating medical innovation through the registering of their demand in the market of medical practice, stem cell health consumers have stepped outside the economic limits of the hegemony (the research funding market and the customary systems of reimbursement) and used their economic power to begin to legitimise the clinician values (the primacy of care for the patient) of those supplying the innovative therapies. With the

impetus established outside the geographical and ideological territory of the hegemony, consumers whose ability to access stem cell therapies within that territory has been frustrated by the rules of the orthodox model have then begun to question its legitimacy – as, for example, happened recently in Italy (Margottini, 2013). A counter-hegemony is beginning to take shape as a market-based consumer-oriented challenge has been matched by political challenge in the form of health consumers' assertion of their right to help determine the nature of biomedical innovation. In taking this path, stem cell consumers are joining the broader journey of health activism which, following the example of HIV/AIDS activism (Epstein, 1996; Levine, 1988), has challenged the lengthy and exclusive nature of the orthodox model arguing for greater health consumer choice and involvement throughout the innovation process. Consumer groups such as women, disability groups, and those with neuromuscular disease have questioned, and in some cases rejected, the accepted right of medical science to be the sole arbiter of the patient contribution to innovations in their own treatment (Rodwin, 1994; Ruzek, 2007; Woods and McCormack, 2013). In France, parents of children with neuromuscular dystrophy took the initiative to create and set the innovation agenda of a research infrastructure capable of addressing their children's therapeutic needs (Rabeharisoa, 2003). So although the hegemonic model by which new health therapies are researched and developed remains politically intact, numerous precedents have been established for its underlying values and legitimacy to be challenged, changes proposed and a counter-hegemony established (Rabeharisoa and Callon, 2002).

It is inevitable that the emergence of a counter-hegemony should engage the interest of the hegemony's traditional intellectuals, the bioethicists. For the most part, bioethicists have responded by protecting the hegemonic paradigm of stem cell innovation using a strategy of ethical exclusion rather than positive engagement with counter-hegemony values. They have propagated ostensibly neutral arguments which focus on the issues confronting the hegemonic model in stem cell science within its own domain whilst neglecting the ethical issues associated with market based medical innovation (Lysaght and Campbell, 2013). As a result, much of the bioethical stem cell debate has centred on the moral issues raised by the creation and destruction of human embryos in the generation of human embryonic stem cells (hESCs) and the type of governance arrangements that would deal with the issues whilst allowing the science to advance (see eg Brown, 2013; Walters, 2004). The impact of this highly selective debate, often translated through national bioethics committees into policy advice, is apparent in the global emergence of standardised national policies for dealing with the hESC issue with some adaptation to local cultures (Salter and Salter, 2007).

This discursive marginalisation of medical innovation is justified in terms of the importance of the full implementation of the scientific method (medical innovation is unacceptable because it includes unknowns in the causality chain) coupled with a view of the negative effects of the market mechanism in stem cell innovation. As Paolo Blanco, a leading stem cell scientist puts it in an article in *Nature*: 'Claiming the right to market products ahead of *proof of efficacy* can only bring ineffective products to market, degrade medicine and impoverish all except, perhaps, the fortunate sellers.' (Blanco, 2013, our emphasis) In common with the global health care market in general where 'medical tourism' is frequently seen by bioethicists as ethically problematic (Johnston, 2010; Snyder et al., 2010), stem cell consumers are assumed to be subject to the naturally exploitative character of the market and incapable of making their own informed choices. As Mason puts it: 'Stem cell tourism is undoubtedly a growing menace to vulnerable patients and their care-givers, potentially inflicting physical, psychological

and major financial damage at a most difficult time of their lives' (Mason, 2010: 684). And on the supply side, stem cell clinicians are portrayed as 'predators disguised as life-saving physicians' driven by profit alone (Mason, 2010: 683; see also Cohen and Cohen, 2010). The remedy proposed is more supply side regulation of the stem cell therapy market in order to protect the consumer, eliminate the 'rogue' clinician provider and maintain the ascendancy of the hegemonic model of stem cell innovation.

4. Hegemonic tensions and political compromise

The initial response of the hegemonic model of stem cell scientific innovation to the economic challenge posed by the operation of consumer choice in the global stem cell therapy market has been the reassertion of scientific values and the exclusion of medical innovation from the agenda and the debate. The objective has been the retention of the control of innovation within the research funding market of the scientific community, supported by the ideological dominance delivered by the moral economy of bioethics, with the market of medical practice as a source of innovation thus isolated and marginalised. Despite the initial success of this strategy, there are tensions within the institutions of the hegemonic order which threaten its long term stability and suggest that political compromise, more *trasformismo*, is required.

An illustration of this tension comes from Patrick Taylor, a member of the ISSCR Task Force on the Clinical Translation of Stem Cells, who suggests a counter-narrative to that of the scientific hegemony:

'That innovative therapy can be, and continues to be, so positively transformative in the right circumstances, ought to make us cautious, I think, about treating it as a presumptively flawed and inferior activity that requires the corrective guidance of the research paradigm. Each is legitimate in a certain sphere; each has different goals; and, as I shall argue, each has distinct oversight needs.' (Taylor, 2010: 286).

This sentiment is echoed by the International Society for Cellular Therapy (ISCT) which maintains that medical innovation has an equal status with science led innovation and that 'There is a place for both [medical and scientific] paradigms in the cell therapy global community' (Gunter, 2010: 966). Taking a broader view of biomedical innovation, one that is inclusive of the demand side of the stem cell therapy market, the ISCT argues that patients and their families or partners 'should have the right to seek treatment for their diseases. No entity should withhold this fundamental right unless there is a high probability of harm to the patient' (Gunter, 2010: 966). Here, for the first time, we see the primacy of the health consumer in the formulation of stem cell innovation governance expressed in terms of both citizen rights and consumer access. Its ideological significance for the hegemony is considerable: once consumer demand is accepted as an important value in the debate, it leads to an analysis of the supply side where scientific innovation and medical innovation are given equal weight and assessed in terms of not only their scientific integrity but also their ability to respond to health consumer demand. This, in turn, presents problems for key components of the hegemony: firstly, the relationship between the innovation roles of scientist and clinician and, secondly, how each relates to the changing role of the health consumer.

Within the hegemonic model of biomedical innovation there have always been tensions between the values and working assumptions of scientist and clinician, between the competing objectives of the advancement of knowledge, on the one hand, and care for the patient, on the other. In their exploration of these two cultures using interviews with stem cell scientists and clinicians, Cribb et al. note that 'the normative structures produced by the

institutions and organisations of the scientific and the clinical construct different ethical spaces and role positions' reinforced by the institutional accountabilities to their respective, and quite distinct, professional communities. Scientists are accountable to the peer review mechanisms and hierarchies of science, clinicians to the regulatory bodies of medical practice (2007: 353). Their capacity to work harmoniously together or to negotiate the resolution of differences in their common pursuit of biomedical innovation is therefore constrained by their separate professional responsibilities (Wainwright et al, 2006). For the health consumer, the implication of these tensions between two key roles in the hegemonic model is that their own role relationship with the innovation process may be framed as 'researcher-subject', 'clinician-patient', or, sometimes, both (Easter et al., 2006: 697). The significance of the clinician's medical values in the applied stages of stem cell innovation is that this part of the hegemonic innovation process is more likely to be responsive to the demands of health consumers than if scientific values regarding the disinterested pursuit of knowledge dominate the domain. It means there is a tension between the public hegemonic narrative of scientific innovation propagated by the professional and funding bodies of science and the private reality of how translational research actually takes place once the stages of clinical experimentation and clinical trials with patients are reached.

With clinicians within the hegemony already culturally inclined to be more sympathetic to the health consumer perspective, states increasingly aware that global markets provide their citizens with options that render the timescale of the orthodox model unconvincing, and health consumer activism in biomedical innovation a growing political force, the pressures for change in the hegemonic model of stem cell innovation are mounting. Resistance to change comes primarily from the science, its infrastructure of research funding, and its traditional intellectuals, the bioethicists. In this situation it is inevitably the state which is the prime mover in the search for hegemonic adaptation. As that search progresses, the initial ideological shift has proved to be a move away from the scientific requirement that a new therapy be judged safe and of proven efficacy and towards the requirement that it be safe and has the *possibility* of efficacy. Clearly this means a diminution in the status and significance of the scientific criterion that an understanding of the process of causality is a necessary condition of any biomedical innovation.

Thus far states have approached the task of hegemony adaptation by amendments to the national regulatory frameworks of biomedical innovation, universally based on the orthodox scientific model, with the goal of creating greater flexibility in the responsiveness to health consumer demand through the earlier creation of a supply of new therapies. For example, energised by its large investment in regenerative medicine of which stem cell science forms a significant part, Japan has revised its Pharmaceutical Affairs Law to enable the conditional approval of potential therapies after initial safety tests in order to deliver therapies that are deemed safe, but perhaps ineffective, as quickly as possible to patients who do not otherwise have access to treatment (METI, 2014). In the UK, the Early Access to Medicines Scheme launched in April 2014 will provide access to designated products several years before licencing for health consumers with life threatening or seriously debilitating conditions without adequate treatment options. Products will be assessed on the basis of Phase I and/or Phase II data (ie efficacy will not be proven) (Medicines and Healthcare Products Regulatory Agency, 2014). And in the US, the Investigational New Drugs procedures allow the use of 'an investigational drug outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition who has no comparable or satisfactory alternative treatment options' (US Food and Drug

Administration, 2014). Such products do not have to be licenced or to have reached the point in their development where efficacy is proven.

The very recent introduction of these reforms means that it is too early to say how successful they will prove to be as a political compromise between the hegemonic power of science in stem cell innovation and the economic, political and ideological challenge from the growing counter-hegemony of health consumers. Working as they do through the existing policy apparatus of the orthodox hegemonic model of scientific innovation, such reforms are still institutionally incongruent with two important governance domains which reside outside it yet form part of the market dynamic of stem cell therapies supplied through medical innovation: medical practice and consumer demand. The former is governed through the normal regulation of the professional standards of medical practice by licencing bodies and medical malpractice laws; the latter through the availability of comprehensive data regarding the quality of the product to enable informed consumer choice. Neither has been addressed by the reforms thus far, constrained as these are by the policy borders of the hegemonic territory, though the reforms proposed by Lord Satchi's Medical Innovation Bill currently making its way through the UK Parliament suggest that change may be imminent (UK Parliament, 2014).

5. Conclusions

Health consumers are able to challenge the hegemony of the science-based paradigm of stem cell innovation through the exercise of their demand in a global market of practice-based medical innovation. Despite the global reach of biomedical science, its ideological cadre of bioethicists acting as its traditional intellectuals, its total dominance of the research funding market, its extensive political network of transnational scientific institutions and its established alliance with agencies of the state, in the case of stem cell innovation the hegemony has proved fallible. A counter-hegemony has begun to emerge in an economic territory over which the hegemony has little control, where consumers are geographically mobile, and where the demand-supply relationship is engineered through an elusive system of internet-driven information. As the counter-hegemony gains strength, so the collision in biomedical innovation between the logic of consumer choice and the logic of orthodox science becomes ever more apparent. Even within its own territory the hegemony has suffered reverses as states, impatient with the implacable adherence of science to its values without apparent regard for those of medicine, have begun to make regulatory changes to enable greater responsiveness to health consumer need and so draw their citizens back within the hegemonic boundaries.

In many ways, the biomedical innovation hegemony is static, embedded in the fortress of professional and state institutions that constitute its means of dominance, unable effectively to counter, or perhaps perceive, the nature of the hegemonic challenge. Meanwhile, its traditional intellectuals, the bioethicists, have yet to offer either a convincing analysis of the problem or a strategy to deal with it. Medical innovation, though a common part of clinical practice, is not regarded as a legitimate area of possible compromise by the hegemony but rather as a territory whose procedures offend the causality principles of the scientific method so central to the hegemonic identity. On their side, stem cell health consumers are pursuing their interests through an engagement with a global market that exploits the information possibilities of the Web 2.0 architecture to the full and bypasses the hegemonic messages of the institutions of stem cell science. As they do so, what might be termed 'political consumerism' is emerging: a hybrid form of politics characterised by a combination of the institutionalised health

activism of patient groups and the novel, spontaneous, internet-based networks of health consumers, their relatives and friends.

In the face of these hegemonic tensions, a key political role in any re-negotiation of the hegemony of stem cell innovation is that of the clinician: an embedded feature of the hegemonic structure of scientific biomedical innovation yet ideologically committed to the interests of the health consumer. If the global market for stem cell therapies supplied through practice based medical innovation continues to expand, states sensitive to the loss of domestic markets this represents may take the view that the hegemony should address the governance needs of the clinician's territory of medical innovation, rather than continuing to exclude this territory on the grounds that it is ideologically unacceptable to the rigorous tenets of science. Such a course will be difficult but necessary if the hegemony is not to be outflanked by a counter-hegemony where the innovative capacities of the market respond to the increasingly informed demand of the health consumer.

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