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Experimental Labour—Offshoring Clinical Trials to China

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Abstract The State Food and Drug Administration of China has reported a dramatic increase in multicentre, multinational clinical trials over the past several years. This is in keeping with a growing trend towards the off-shore outsourcing of clinical trials from North America and Western Europe to 'nontraditional locations' such as Eastern Europe, China, and India. Within China, the post-socialist reform of health care, internal divisions of labour and the politicization of the healthcare system have all created the conditions under which contract clinical trial work is becoming an imperative both for hospitals and the growing number of working uninsured. The paper brings together a critical insight into current theories of bioeconomic innovation with new political economies of informal labour and offshoring. It argues that the clinical trial phase in the production of bioeconomic value is routinely overlooked in scholarly accounts but is key to understanding the speculative overinvestment and translational difficulties of the pharmaceutical industries today. As a way of reformulating the problem, the paper suggests that human subject experimentation would be more fruitfully reconfigured as a form of labour—experimental or clinical labour. The research hospital clinic therefore emerges as an export labour zone in 'experimental body work.'

Keywords Clinical trials · China · Clinical labour · Contract research organization · Neoliberalism

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The State Food and Drug Administration of China has reported a dramatic increase in multicentre, multinational clinical trials over the past several years.[1] This is in keeping with a growing trend towards the outsourcing of clinical trials from North America and Western Europe to 'non-traditional locations' such as China and India. Clinical trials are an increasingly globalized affair, mediated by internationally mobile contract research organizations (CROs) who specialize in navigating the complexity of national regulations and health care systems in order to find the most cost-effective location for conducting trials. Over the last decade, the failing states of Eastern Europe and more recently the rising bioeconomies of China and India have become favoured destinations for conducting multi-site clinical trials.[2]

The clinical trial is a graduated, progressively scaled up experiment designed to measure the safety and efficacy of biopharmaceutical compounds. Although drug testing is an increasingly distributed, globally dispersed enterprise, the standard clinical trial protocol continues to be dictated by the US Food and Drug Administration (FDA). Since 1962, the FDA has required three phases in the testing of new biopharmaceuticals in humans. After pre-clinical testing on animals, phase I trials are conducted on a small number of healthy volunteers (20–100) and are primarily designed to ascertain the safety of the drug in humans. Phase II trials involve larger numbers of patients (often several hundred, both healthy and ill) and may last from a few months to several years. Phase II studies are designed to further test safety but also to determine if the compound has any therapeutic efficacy. In a phase III study, testing is further scaled-up to include several hundred or several thousand patients over several years. This large-scale testing provides a more refined, quantitative estimation of the drug's effectiveness and possible adverse reactions in patients suffering from the ailment the drug is designed to target. Once it is successfully completed, the pharmaceutical company can apply for FDA approval for the drug. Most Phase II and III trials are conducted as double-blinded randomized trials with one portion of the patient group receiving a standard treatment or placebo. Although academic research centres provide a disproportionate number of the lead molecules in drug development, pharmaceutical companies, often acting on license to the smaller academic research centres or private–public research ventures, sponsor most clinical trials. Over recent years, the large pharmaceutical companies have themselves increasingly turned to contract research organizations to oversee the actual logistics of large-scale multi-site clinical trials. Contract research organizations are particularly active in mediating between institutions (commercial, academic, small and large-scale), locations (on and offshore, local, regional and national authorities) and regulatory guidelines. In order to participate in the expanding market in biomedical R&D, emerging economies such as China and India are more or less obliged to streamline their existing regulations (if these exist) to conform to the standards set by the FDA. Over the past few decades, the Chinese government has actively promoted this process of international harmonization, introducing not only mandatory clinical trial phases but also good clinical practice

[1]The Chinese State Food and Drug Administration (SFDA) is responsible for the evaluation and inspection of clinical trials of new drugs. According to SFDA's data, the number of multicentre clinical trial applications in the first half of 2003 was almost as large as the combined total in 2001 and 2002. http://eng.sfda.gov.cn/eng/.

[2]On clinical trials in Eastern Europe, see Petryna (2006, 2007) and in India, see Sunder Rajan (2007).

(GCP) guidelines and ethical procedures in line with international standards. The results of clinical trials conducted in China are now accepted by the FDA, which means that Chinese medical institutions (and their patients) now have an immediate stake in the global drug development process.

The global restructuring of pharmaceutical R&D and testing lends itself to a number of interpretations. The major pharmaceutical companies express a frank interest in the cost effectiveness and efficiency gains to be made by outsourcing clinical trials to contract research organizations and offshoring at least some of their stages to the less costly environments of the 'developing world.' Yet clearly, the move towards the outsourcing of clinical and biomedical innovation is not unidirectional. The current reconfiguration of R&D involves a complex interplay of competitive strategies on the part of both the advanced economies and the emerging economies of India and China, who both aspire to participate as high-tech contenders in the emerging biomedical economy. The rise of China and India as innovation states complicates the dynamics of global R&D, for while multinational companies are interested in the immediate cost savings to be gained from off-shoring, China and India are taking advantage of relocation to develop their own R&D capacities in pharmaceutical and biomedical innovation (Salter et al. 2006, 2007). Moreover, while the USA and Europe have an obvious interest in penetrating the vast patient markets of China and India, the traffic is not all one way, with many Chinese and Indian research teams attempting to pass approval by the US and European regulatory authorities. In this context of rapidly evolving competition, the Chinese state is taking on a prominent role in financing, fostering and encouraging processes deemed to be advantageous to its domestic industries—encouraging FDI, investing in science education, adopting incentives for private investment, encouraging overseas-trained scientists to return home and harmonizing regulation in accordance with international standards.

Alongside these innovation strategies, the institutional reorganization of clinical trials in both China and North America is closely related to the market liberalization of health care and growing inequalities in the access to health insurance. Within China, the post-socialist reform of health care, internal divisions of labour and the politicization of the health-care system, have all created the conditions under which contract clinical trial work is becoming an imperative both for hospitals and the growing number of working uninsured. Market reform has gone hand in hand with an extreme increase in poverty and internal migration on the part of the rural poor, most of whom have been simultaneously divested of public health insurance and affordable medical care. In the Chinese context, it is the 'floating population' of transient workers, with their limited rights to urban residency, who are most actively engaged in the lower echelons of the emerging post-socialist economy. Here as elsewhere, the reconfiguration of the clinical trial industry is in keeping with wider shifts in the global political economy of labour, migration and citizenship.[3] It

[3]For detailed discussions of migration and the informalization of service labour in the global political economy, see Sassen (2003); and for a particular focus on the role of the 'floating populations' in fuelling post-socialist China's economic growth, see Ong (2007) and Dutton (2004). With particular reference to the clinical trial industry, both Petryna (2006) and Sunder Rajan (2006) have noted that the intensification of clinical trial work in Eastern Europe and India has been facilitated by the absence or demolition of public health care and the existence of 'surplus populations' at the limits of citizenship.

therefore needs to be addressed as such, as a form of highly precarious service labour, and placed within the context of other modes of informalized, contract labour in the post-socialist Chinese economy.

Experimental (or clinical) labour is a term I have coined with Catherine Waldby in order to account for some of the groundwork through which value is created in the emerging biomedical economies (Waldby and Cooper 2008). I use the term experimental labour, for example, to refer to the services provided by a patient recruited into a clinical trial or a woman or man who provides tissues for use in biomedical research. An essential component of clinical trial participation is what is referred to as 'risk' in technical terms but which might be better rendered by the more suggestive term 'exposure'. Human subject experimentation in drug testing can be described as a form of transformative exposure, where the patient is called upon to both *experience* the sometimes unpredictable metabolic effects of pharmaceutical compounds and *perform* a number of second-order tasks such as adhering to a strict regime of diet and drug administration, self-monitoring and recording of information. This is a depiction of labour that places it somewhere between passive and active participation, experience and self-experiment. Labour would then be defined as the experience of self-transformation—commodified. If we were to redefine labour in this way, the contribution of the clinical trial participant or tissue donor to the production of bioeconomic value would become more readily comprehensible. The clinical labourer is the person who 'consents' to their own self-transformation for a certain return (although this return can be direct or indirect, monetary or in kind). What the investor receives in exchange is a surplus of experimental information, or a literal surplus of biological potentiality (the stem cell line for example) that can then be transformed into the surplus value accruing from bio-innovation.

The category of labour cannot account for all the reasons that motivate patients to participate in clinical trials. In some cases, access to an experimental drug is a last-resort treatment and source of hope for patients in the later stages of a terminal illness. The methods of clinical labour also differ according to the kind of biopharmaceutical compound to be tested (molecule or biological) and the phase of testing—while Phase I trials present the most immediate dangers of adverse reactions, Phase II and III trials potentially involve the problems of coercive recruitment (the fact that sick patients might participate in a trial due to lack of access to medicine), the discontinuation of life-saving medicines and the use of placebos.

To formulate human subject experimentation as a form of labour is at once an observation and a provocation. The briefest review of the industry literature makes it clear that pharmaceutical companies do indeed count the costs of clinical trial testing as something akin to a labour cost—to be amortized wherever possible. Moreover, in the USA, the market liberalization of health care and insufficiencies of health insurance have meant that clinical trial participation is beginning to be organized along the lines of other more familiar forms of casualized service labour—as distinct not only from the 'gift relation' idealized in bioethical discourse, but also from the incarceral forms of experiment which were common in the USA up until the 1970s. A similar process is discernible in China, where the contracting of clinical trials to public hospitals has gone together with a rapid demolition of collective health care. In common with other kinds

of bodily service, human subject experimentation, even when remunerated, is not often recognized as labour. Human rights discourse in bioethics has trouble distinguishing this kind of service from a 'gift', while liberal bioethics confines its analysis to the absence or presence of the informed consent contract. Both discourses obscure the extent to which the 'clinical service' contributes to the production of biomedical innovation and the monetary value accruing from it. Perhaps 'labour' is always a critical concept and one that emerges from a point of view of non-compliance or contestation. By reformulating human subject experimentation as labour, I am therefore hoping to open up the scope of political critique to include a consideration of this liminal, but essential moment in the production of biomedical value.

In what follows, I will first consider the current productivity crisis of the pharmaceutical industry as one of the key factors motivating the push towards the offshore outsourcing of clinical trials. I suggest that the political costs of human subject experimentation play an important role in this crisis, but are routinely overlooked by the contemporary literature on pharmaceutical innovation. I will then consider the institutional reorganization of clinical trials within the USA over the past three decades, before tracing a similar process in China. In parallel with the marketization of health care provision in both contexts, I argue, human subject experimentation has moved from an incarceral model of labour (exemplified in the literal conduct of clinical trials in US state prisons up until the 1970s) to a more distributed, but no less coercive form of clinic-based 'work for health care'.

The Impasses of the Pharmaceutical Industry—Between Speculation and Experiment

Despite rising profits, the 1980s and 1990s were a time of declining R&D productivity in the pharmaceutical industry (Dosi and Mazzucato 2006). With few prospects for marketable pharmaceutical compounds on the horizon, the rising profits of the pharma industry have been sustained by me-too drugs, IP strategies and market expansion. The division of labour between mass pharmaceutical production and innovative new biotechnologies has been one response to this crisis, since the current business models of pharma are premised on the idea that at some point it will acquire and develop the new product lines emanating from the biotech industry. While the high-risk, early stage development of experimental new therapies is outsourced to small biotech companies, often in association with academic labs, the pharmaceutical companies hope to benefit from the fruits of this research through exclusive licensing agreements and joint ventures. As yet, however, few of the hoped-for new therapies have come to fruition in a way that would be economically viable for the pharma industry. The result is an impasse between speculative promise and experimental realization. Up until now, the promise of future product lines from new technological innovations has been fuelled by an accumulation of speculative innovation value—notably on intangibles such as patent rights—a model that can only sustain itself for as long as investor faith is maintained. Accordingly, the prospective business interests of the pharmaceutical industries have been supported by heavy lobbying around issues of patent protection, trade secrets and the imposition of a globally valid intellectual property rights regime.

This problem, which is generally categorized as a failure of 'translational research', has been analysed in detail by innovation theorists such as Gambardella (1995), Dosi and Mazzucato (2006), Nightingale and Mahdi (2006) and Pisano (2006). Yet these theorists tend to ascribe the current innovation crisis to failures of speed, efficiency and data-processing, as if the current process only needed to be accelerated and streamlined for the pharma industry to regain its former high rates of productivity.[4] This literature has strikingly little to say about the labour costs of professional scientific and clinician work and nothing to say about the clinical trial process itself. Thus Ashish and Gambardella have coined the term 'innovative labour' as a way of accounting for the contribution of lab-based scientific work to the creation of biomedical innovation (Gambardella 1995; Ashish and Gambardella 1994), but when it comes to the clinical trial phase of product development, they talk of the *application* of scientific knowledge rather than innovation and value-creation through labour. Such accounts underestimate the important generative role of clinical trials in the creation of new biomedical entities. Human subject experimentation is the sine qua non of biomedical invention. There is no medical efficacy, no patentable biomedical innovation, and thus no innovation value without the participation of living bodies in clinical trials. Yet this essential moment in the creation of biomedical value rarely disrupts the standard accounts of the 'translational research' process. Perhaps the problem lies in the very concept of 'translation', which suggests that the passage from laboratory to human experiment is simply a question of mass reproducing and refining results that have already been produced in vitro. As a result, the complexity of drug metabolism appears as nothing more than a hurdle on the road to drug discovery and biomedical innovation—unavoidable but uninteresting in and of itself. The clinical trial is meant to function as a simple testing device, a means of replicating results that have been hypothesized in the lab, yet arguably surprise, and thus invention, happens at this stage too.[5] It might even be argued that the complexities of clinical trial participation represent a crucial, not incidental factor in the current productivity crisis of biomedical innovation. After all, biomedical innovation value necessarily remains speculative until it is realized in the form of workable bodily experiment, with all its potential for surprise and danger. The

[4]Gambardella (1995), Dosi and Mazzucato (2006), Nightingale and Mahdi (2006) seem to share the conviction of the pharmaceutical industry that the industrialization and rationalization of drug R&D should translate, at some point, into increasing rates of productivity. They cite rational drug design, high-throughput screening and genomics as key developments in this regard. In contrast, Pisano (2006) offers a more sceptical appraisal of such technological solutions, arguing that the drug R&D process is inherently uncertain, notably because of the complexity of human-drug interactions. The argument I am developing here is close to that of Pisano, although the latter fails to extend his discussion of drug metabolism to include the political risks of human subject experimentation.

[5]It should be noted that the late twentieth century model of biomedical science tends to conceive of the clinical trial as a reproducible test rather than an experiment—with its potential for surprise. The institutional division between scientific laboratory and clinic therefore tends to be conflated with the difference between experimental innovation and simple application. On the distinction between the test and the experiment, see Rheinberger (1997), who argues that true scientific experiment involves the production of surprise. With reference to large-scale non-biomedical technologies, Krohn and Weyer (1994) have identified a similar division between the field test and the 'real-world' experiment, noting that scientific protocol is unwilling to consider the productive and experimental value of applied science performed outside the lab. My suggestion that biomedical innovation often takes place de facto in the clinical testing stage is indebted to Krohn and Weyer (1994).

problem for the pharmaceutical industry lies in the rising political costs of experimental surprise. Where a high level of experimental error—experiment early and often, fail early and often—might be acceptable as a commercial risk in scientific lab work, it becomes a whole different problem when the experiment is a Phase I clinical trial that takes place in vivo.

I would therefore argue that the political costs of biomedical risk (costs that go beyond medical liability and regulatory oversight to include loss of reputation) are one of the factors motivating the push towards the outsourcing and offshoring of clinical trials. The process of outsourcing has intensified even within the USA over the past decade, as drug testing is increasingly contracted out either to private medical practitioners or to specialized contract research organizations (CROs).[6] CROs, who sell themselves on the speed of their results and pay lower wages than their competitors, have progressively taken over much of the work formerly performed in-house or by academia. The considerable rise in CRO activity has thus allowed the major pharmaceutical companies to cut back on their professional labour costs—and arguably, to sideline some of the pressures from federal regulators (Shuchman 2007). At the same time, the contractual outsourcing of clinical trials is responsive to a wider shift in the very organization of human subject experimentation in the USA. In the next section, I outline the shift from a culture of state prison-based clinical trials to a model of contractual outsourcing that shares much in common with other, more familiar forms of service labour in the post-fordist economy. This in turn suggests that the off-shore outsourcing of clinical trials is not so much, or not only, a simple delocalisation of 'first-world' labour to the 'developing world' as a process of labour transformation occurring simultaneously across borders.

Experimental Labour—The Prison, the University and the Clinic

It is not commonly known that prison-based clinical trials were once the norm in North American pharmaceutical research. During the 1960s, an era of intense inventiveness and sales' growth, pharmaceutical companies in North America were conducting the greatest part of clinical trials amongst prison populations, even going so far as to build state-of-the-art clinical trial laboratories on prison grounds.[7] Their concern was not only to recruit prisoners as human subjects but also to train prison inmates as clinicians, capable of carrying out tests at a fraction of the cost outside

[6]Thomson CenterWatch, the professional information site on clinical trials, estimates that CROs played a substantial role in 64% of phase 1, 2 and 3 clinical studies in 2003 as compared to 28% in 2003 (Thomson CenterWatch 2007).

[7]The widespread use of prisoners incarcerated in the US's state prison systems began in earnest during World War II. As so often, it was a state of war that justified the use of uncommon means to initiate scientific progress. With large numbers of troops suffering from infectious diseases on the war front, prisoners were called upon to participate in large-scale drug trials and blood transplant experiments in order to accelerate the development of new cures. The actual conduct of clinical trials, it seems, was envisaged as a practice of total war, pitting the allies against their microbial enemies. The practice, however, was not suspended after World War II and continued to grow steadily throughout the following decades. See on this point Hornblum (1998: 83).

prison walls. The commercial benefits of this move were starkly highlighted in the testimonial of a group of prisoners who brought a lawsuit against the corrections department in 1968, claiming that the companies had obtained hundreds of thousands of dollars of labour for free (Hornblum 1998: 103). The penal–medical alliance was at least partly motivated by changes to the FDA requirement for clinical trials. In 1962, the FDA responded to the thalidomide scandal by requiring three phases of human clinical trials, including Phase I trials on healthy subjects, before a drug could be marketed. This meant that the small number of hospital patients that had hitherto been required for clinical trials was suddenly insufficient. And as Hornblum points out, state-controlled prisons seemed to offer the perfect conditions for both industrial-scale labour and the requirements of standardized clinical experiment—highly regimented, isolated, living conditions and a workforce that was 'cheap, available and confined,' not to mention already highly stratified along class and race lines (Hornblum 1998: 108). While the use of prisoners as drug trial participants came under increasing scrutiny throughout the seventies, it is only very recently, in 1981, that the FDA officially outlawed the practice.[8]

During the 1980s, most clinical research was conducted by Academic Health Centres (ACHs) or in-house by the research institutions of pharmaceutical companies. More recently, both of these institutional settings have been superseded by the rise of the contract research organization or CRO. While these entities offered a limited range of contractual services in the early 1980s, they now aspire to cover all aspects of the drug development and clinical trial process, including drug discovery, pre-clinical testing, marketing and 'bioethical services'. Most importantly perhaps, given the pharmaceutical industry's interest in expanding markets and labour offshoring, the CROs offer specialized services in 'regulatory arbitrage', services designed to locate the most favourable political environment for every aspect of the drug production process. Drawing on various sources of statistical data, Mirowski and van Horn argue that CROs have significantly displaced the institutional role of ACHs over the last few decades, now accounting for around 90% of outsourced clinical research (Mirowski and van Horn 2005: 506). How are we to interpret this shift in the institutional housing and conduct of pharmaceutical R&D and clinical trials? Much of the R&D and clinical labour contracted out to CROs is of a more standardized and fungible nature (Phase II and III rather than Phase I trials, for example), which means that professional labour costs tend to be lower. But the immediate cost-cutting benefits of lower labor costs are not the only incentives of outsourcing. Mirowski and van Horn, for example, argue that as a recent institutional innovation, CROs benefit from the relative lag in regulatory oversight which renders their data even more 'reliably proprietary' than that of the large pharmaceutical corporations (Mirowski and van Horn 2005: 513).[9]

In the meantime, the decline of both the prison-medical clinic and the academic health centre has had important effects on the profile of the clinical trial participant

[8]Code of Federal Regulations 21, part 50, 44, 'Restrictions on Clinical Investigations Involving Prisoners.'
[9]This relative freedom of movement extends to the standard bioethical procedures such as IRBs (institutional review boards). While academic and in-house research centres are generally obliged to refer to small, institutionally located IRBs for bioethics approval, legislation passed in 1981 made it possible for CROs to consult independent IRBs that are not subject to the same regulatory oversights (Mirowski and van Horn 2005: 514–515).

and his or her engagement in the larger process of health care reform. This is a system in which the greater part of clinical trials are administered either by private medical practitioners or contract research organizations, both on contract to a larger pharmaceutical company. While drug trials no longer take place within the walls of a state prison, the circumstances that drive a patient to volunteer in a clinical trial and a medical practitioner to undertake contract pharmaceutical work may be no less coercive. Indeed it would seem that the very process of health care liberalization has led to the decline of a state-based health complex—liberating the experiment from the confines of the state institution, whether punitive or welfarist—only in order to re-establish its new methods of control in the open, unconfined space of the 'free market'. Jill A. Fisher comments that the current practice of private-clinic based contract research, in which an individual medical practitioner will take on trial contracts on behalf of the pharmaceutical industry, is directly motivated by the effects of neo-liberal reform on the health care system as a whole (Fisher 2007). As medical practitioners face diminishing revenues, contract work becomes an alternative form of income, while for under- or uninsured patients, clinical trial participation may represent one form of casualized, high-risk labour amongst many others and perhaps the only means of access to health care. Not surprisingly, the profile of patient recruitment that seems to be emerging from this labour regime is one that overlaps with the lower echelons of the US economy.[10] The situation is not without problems of its own, even from the point of view of the pharmaceutical industry, which routinely complains about the costs of US-based contract work, the length of time required for recruiting suitable patients, their unreliability, high drop-out rates, non-compliance and lack of clinical readability. In other words, at the very moment that neo-liberalism vaunts the flexibilities of decentralization, subcontracting and the de-collectivization of labour and its risks, it finds itself confronted with the problem of excessive flexibility—and how to re-confine it. Even while the pharmaceutical industry intensifies its outsourcing contracts within the USA, the drive to push the clinical trial process offshore represents one way of resolving this problem—at least in the short term.

Offshoring the Experiment—The Clinic as Export Labour Zone

During the 1980s, the pharmaceutical consortiums were heavily involved in lobbying for the enforcement of global IPR (intellectual property right) laws. More recently they have shifted rhetorical tactics, attributing their losses to the longueurs of the clinical trial process. The arguments are more or less explicit in their nostalgia for the old, incarceral methods of medical experiment. There have been open calls for a return to prison-based clinical trials. There have also been moves to 'flexibilize' the golden standard of clinical trial design—the randomized, controlled trial—in

[10]On this point in general see Fisher (2007). A recent media report details the case of a North American-based CRO that has hired out a disused hotel as a clinical testing center where it employs largely Mexican immigrants. See Shuchman (2007).

order to make it more responsive to incoming results.[11] But by far the most popular recommendation in recent years has been the offshore outsourcing of clinical trials to destinations such as China, India and Eastern Europe (Petryna 2006). Off-shore outsourcing affects two areas of biomedical R&D—that of scientific and clinic-based professional labour, and that of tissue sourcing, clinical trials and product development. Multinational companies have an obvious interest in the pool of high skilled science graduates located in China and India, including an increasing number of Western-trained returnees who are able to perform R&D at much lower costs than their North American counterparts. An even more compelling draw-card, though one not often stated out loud, are the vast numbers of Chinese and Indian health-care patients who are liable to participate in clinical trials, again at much lower (political and economic) costs than their Western counterparts. The standard insider arguments reassure investors that off-shoring will open up access to vast pools of patients, many of whom are relatively treatment naïve, often because of a lack of access to health care; that recruitment and insurance costs for these patients are much lower than comparable prices in North America; and that lack of access to health care will make them compliant in adhering to clinical trial protocols (Kearney 2006). In short, it would seem that off-shoring represents one way for the pharmaceutical industry to re-establish some of the conditions of mass, standardized, low cost trial it no longer finds in the US.

In 2005, half of the 1,200 clinical trials conducted by twelve of the largest US pharmaceutical companies were conducted offshore, in the UK, Russia, India and China (Bailey et al. 2007). It is predicted that EU and US-based multinational pharma companies will double their clinical research activities in developing nations between 2006 and 2009, with China and India now expected to be the major destinations (Kearney 2006).[12] Up until recently, most foreign drug company investment in China was restricted to marketing, sales and manufacturing. Changes to domestic regulation in 2003 made it legal to include China in multinational drug trials, and since then multinational pharmas have begun to seriously invest in China as an R&D centre (Humphries et al. 2006). Prior to 2003, new drugs could only be approved in China if they had already been approved for marketing in Europe and in the US. They also needed to be subject to a phase III trial in China before receiving approval for consumption in the Chinese market. The novelty of legislation introduced in 2003 is that it allows for the simultaneous testing of new drugs in China, the US and Europe, even when these drugs have not received approval by the FDA. As a result, clinical trial data collected in China is now being used not only for the domestic approval of drugs already accepted in the US but also as a platform for developing new drugs for the international market.[13] The response to these

[11]Flexible or adaptive clinical trial design, which allows clinicians to change the variables of the testing protocol as results come in, have been heavily promoted by pharmaceutical companies, with the regulatory support of the FDA (Vastag 2006; Thomas Scott and Baker 2007).

[12]In 2007, China was placed first in a Country Attractiveness Index for clinical trials released by the business consulting company A. T. Kearney (Bailey et al. 2007). This index was calculated on the basis of data relating to patient pool, cost efficiency, regulatory conditions, relevant expertise and infrastructure.

[13]For a full list of multinational pharmaceutical investment in China, see Vaidya et al. (2007: 20–22) and on the internationalisation of Chinese clinical data, see Vaidya et al. (2007: 27).

regulatory changes has been a marked increase in investment on the part of international pharmaceutical companies. China now has the highest annual growth rate of all clinical trial markets, emerging and established (Thiers et al. 2008: 2). Most of the larger multinational pharma companies have now invested in research ventures in China or are planning to do so within the next two years, with small to medium biotech companies following in their wake (Goodall et al. 2006). Amongst the more prominent pharmaceutical companies, AstraZeneca established an in-house clinical trial centre in 2002 and Pfizer opened its Asia-Pacific Data Management Centre in 2005, both in Shanghai. There has also been a rapid proliferation of domestic and foreign contract research organizations (CROs) mediating between the interests of large pharmaceutical companies, clinical trial centres in hospitals and the SFDA.[14] While most of the clinical trials are in phase III, there has also been a marked increase in phase I trials, often considered to be the most 'high-risk' because of the relatively untested nature of the drug and the fact that testing is carried out on healthy patients (Humphries et al. 2006: 358–359).

Despite an initial lag then, the pharmaceutical/biomed complex seems to be following in the path of manufacturing, software and ITCs, relocating its R&D to environments where the costs and conditions of clinical research labour and human subject recruitment are less onerous. China in particular—much more so than its rival, India—offers the institutional remnants of a once highly organized public health tradition, although the latter, as I will show in the following section, is undergoing its own process of internal reform.

Post-Socialist China as Experimental Economy

In some respects, the rhetoric of Maoist public health has persisted even into the market-reform era.[15] However, it has also been profoundly undermined by one of the most accelerated processes of health-care demolition the world has seen. In the wake of the market-oriented reforms of 1978, the Chinese government proceeded to overhaul its health care system by cutting the state's share in total health expenditure and shifting responsibility onto provincial and local authorities, with their variable capacities for raising tax revenue. The immediate effect of this reform was a growing disparity between poor, rural areas and industrialized, coastal regions, as the latter had much greater opportunities for revenue raising. At the same time, as Blumenthal and Hsiao recount, the health care system underwent a process of de facto

[14]Jim Morioka (2006) provides a list of 100 clinical research organizations currently operating in China. See also Vaidya et al. (2007: 27–29) for further detail on CRO activity in China.

[15]This is perhaps most visible in the area of reproductive health, where a general ethos of *yousheng* prevails (*yousheng* literally means healthy birth, but is often translated by the English term 'eugenics'). Indeed, according to Greenalgh and Winkler (2005), the transition to a market economy has ushered in an even stricter form of eugenic population control in China, with the introduction of a family planning policy designed to control both the quantity and quality (*renkhou zuzhi*) of newborn children. Moreover, the rhetoric of Maoist public health has remained highly visible in the PRC's propaganda campaigns in response to emerging infectious disease outbreaks—as evidenced by the quasi-militaristic propaganda campaign launched after the outbreak of SARS (Sharma 2004).

privatization, to which the central government turned a blind eye (Blumenthal and Hsiao 2005: 1166–1167). With the sharp reduction in public financing, hospitals were forced to generate their own sources of private income. This shift was in fact facilitated by the government's decision to introduce a system of price regulation, whose intended purpose was to insure a basic level of health care provision. As a consequence of this reform, it was now legal for hospitals to earn extra profits from non-basic health care services such as new drugs, diagnostic tests and high-cost technologies. At the same time, the standardized salary regime for hospital doctors was supplemented by a bonus system calculated on the basis of the doctor's revenue-raising activities. The more new drugs or high-price services a doctor was able to sell, the higher the bonus. Doctors and hospitals thus find themselves in a position where they have much to gain from delivering for-profit health care. As a growing number of hospitals in the major cities of China receive SFDA accreditation to run clinical trials, the recruitment of patients into drug testing protocols now represents one of these emerging sources of income.

In all respects, China seems to have pursued the process of neo-liberal health care reform with all the enthusiasm of the USA, and with equally catastrophic results. 'China's newly privatized health care delivery system suffers from all the problems of its distant US cousin, but more so. Only 29% of Chinese people have health insurance, which they now need in order to cover the costs of care. Out-of-pocket expenses accounted for 58% of health care spending in China in 2002, as compared with 20% in 1978. In a 2001 survey of residents in three representative Chinese provinces, half of the respondents said that they had foregone health care in the previous 12 months because of its cost' (Blumenthal and Hsiao 2005: 1167). The risks generated by the reform-era demolition of health have been borne disproportionately by the rural poor, who no longer have access to the collective health care offered by the agricultural communes.

It is only against the background of these reforms that we can understand the growing importance of clinical trial participation as a form of labour in the new Chinese economy. As in the US under Reagan, the Chinese government has shifted its priorities from ensuring a collective redistribution of public health to investing in and promoting high-return biomedical services, which will only be available to the wealthiest, insured sectors of the population. This shift is in keeping with reform-era China's vision of its future role in the global economy. China is no longer content to play host to off-shored industrial production. It now aspires to compete with the USA and EU as an innovation economy and biomedical research is one of the key foci of its high-tech programs (Salter et al. 2006). Thus, at the same time as it has withdrawn from universal health coverage, China has made considerable investments in such experimental areas as stem cell science, genetics and biochips. But this is only one side of China's unique approach to global competition. For it seems that while it is seeking to promote its domestic science laboratories as centres of high-tech innovation and contenders in the world IP market, it is also targeting its poorer populations as potential clinical trial participants and tissue sources—both for domestic and foreign interests. The government is playing an active role in encouraging foreign companies to conduct clinical trials in China (Bailey et al. 2007: 58). Over recent years, it has established drug approval and good clinical practice

regulations conforming to global standards;[16] created specialized training centres for clinicians, special technology zones for contract research organizations; and pursued a high-profile corruption case against the former head of the SFDA (he has since been sentenced and executed). At the same time, the large urban hospitals that have received government accreditation for conducting clinical trials have made major investments in infrastructure and staff training. Along with the introduction of personalized bonuses for clinicians, the revenue-raising imperative that now weighs on hospitals means that clinical trials are becoming an essential source of income for the Chinese biomedical enterprise as a whole–in short, a form of export labour like any other. And as is already the case in the USA, the patients who are most likely to volunteer for clinical trials are those who have been left uninsured in the wake of health care reforms—often the same rural migrants who engage in seasonal, low-wage work in the urban centres; the floating population whose high-risk circulation across borders of all kinds is proving so productive for the emerging Chinese economy. For China's growing number of uninsured, enrolling in a clinical trial is often the only way of gaining access to expensive medical treatment, at least for as long as the trial lasts (Berton 2006; Vaidya et al. 2007: 23; Xu et al. 2006: 371).

Multiple models are emerging for the institutional housing of clinical trials. Most clinical trials take place in the large hospitals of major cities, where recruitment posters are prominently displayed in the waiting rooms.[17] A small number of contract research organizations have also been authorized to set up independent centres of their own.[18] An alternative model is offered by the illegal, but reportedly still flourishing trade in blood products, which operates in much the same way as a make-shift, mobile clinic, travelling around the country-side in search of its contract workers (Anagnost 2006). In none of these models can the conditions of experiment be characterized as incarceral as such. Rather, the off-shored clinical trial takes place in the space of 'free movement' opened up by market reform, where the clinic plays the role of traffic filtering gate, separating patient flows according to their health coverage and revenue-raising potential, and performing multiple functions for different classes of patient. This process of institutional transformation of the clinic is by no means smooth, as attested to by the frequency of physical assaults on hospital staff.[19] Nevertheless, there is a clear expectation on the part of foreign investors that relocation to China will compensate for the excessive fluidity and

[16]Multinational multicentre clinical trials are a new phenomenon to China but have been increasing rapidly. Since the late 90s, only hospital centres and clinics accredited by the Chinese SFDA (State Food and Drug Administration) and compliant with international Good Clinical Practice (GCP) regulations are authorized to conduct clinical trials. According to Morioka (2006), approximately 145 clinical trial centres and 165 medical institutions have obtained SFDA licenses for conducting clinical trials. For a detailed analysis of the development of Human Subjects Protection in China and current shortcomings, see (Xu et al. 2006).

[17]The majority of patients are recruited into trials on the invitation of their medical practitioners, although some Contract Research Organizations report direct advertising in newspapers (Anderson 2007).

[18]See Jia (2005).

[19]See Watts (2007). In 2007, the Chinese government made the decision to deploy police in hospital wards and clinics in order to protect medical staff from patients who had been refused or couldn't afford treatment. According to this article, citing the *China Daily*, 5,500 medical workers were injured by protesting patients in 2006.

'non-compliance' of the North American volunteer. In its report on pharma off-shoring, investment consultant firm Ernst & Young cites China's extensive health infrastructure and large public hospitals as a key argument in its favour, clearly calculating that the remnants of its mass healthcare system will reintroduce an element of predictability, if not coercion, into the clinical trial business (Ernst and Young 2006). With the relocation of clinical trial service providers to China, it seems that the reform-era clinic is set to play much the same role as an export processing zone, one which seeks to capitalize on the experimental body labour of the poor and uninsured as a means of inserting itself into a global economy of for-profit medical care.[20]

Whether Chinese patients will be as compliant as expected is an open question—in their studies of the offshored high-tech work site, both Andrew Ross and Aihwa Ong point out that foreign companies are coming up against the problem of extreme labour mobility, as the floating class exercises one of its last remaining freedoms, that of fleeing from one work site to the next (Ross 2006; Ong 2007). Neo-liberalism here confronts one of its characteristic problems: How to incarcerate a form of labour that is constitutively in-movement? How to re-introduce an element of coercion into the flow of traffic? Given the growing importance of offshored biomedical and pharmaceutical experiment, it is highly likely that the same kind of problems will be encountered in the effort to valorize the bodily labour of the clinical trial participant.

In what follows, I will consider one case in which the participants in a clinical trial did lodge an official complaint with the Chinese and North American authorities. This case, I suggest, is indicative of larger problems in the current political economy of health care and clinical trials in China.

HIV/AIDS and the Price of Exposure

In January 2003, four HIV-positive farmers from Henan province, representing a further 15, sent a letter of complaint to the US National Institutes of Health and the Chinese Ministry of Health claiming that they had been mistreated in the course of a clinical trial based at Ditan hospital in Beijing. The patients were all in the later stages of HIV/AIDS and had participated in a trial for VGV-1, an experimental compound designed to increase the efficacy of anti-retroviral drugs. The website of the company that developed the drug, the California-based biotech company Viral Genetics, describes the China trial as a 34-patient open label, pilot study of treatment naïve subjects in stage three of the HIV/AIDS illness.[21] Pilot studies are small

[20]Of particular interest here is Aihwa Ong's discussion of zoning technologies in reform-era China and East Asia in general (2007). Ong suggests that the creation of special economic zones is what allows the state to open up a space of neo-liberal experimentation within its own borders, without otherwise questioning the state's authoritarianism. The idea of the special economic zone as an *experimental* site is a particularly apt description of the reform-era hospital.

[21]http://www.viralgenetics.com/ See in particular the following pages—http://www.viralgenetics.com/Ctrials.html and http://www.viralgenetics.com/inv_fsheet.html. *Viral Genetics* has since conducted a large Phase III clinical trial on the VGV-1 drug in South Africa.

feasibility trials conducted prior to full-scale investigations, while open-label designates a study in which both the health providers and the patients are aware of the drug being administered (as opposed to the double-blind method). A previous pilot study involving ten patients in Mexico had suggested that VGV-1 could restore the effectiveness of other AIDS drugs when used in conjunction with existing anti-retroviral therapies. In the Chinese study, the patients recruited into the trial were not taking ARVs and were thus treatment naïve. This, however, was not the focus of the formal complaint made by the trial participants, who pointed instead to deficiencies in the informed consent procedures and unexpected side effects. Several participants developed severe reactions and were forced to pay for additional medication to treat them. The patients complained that the risks had either not been explained at all or had been mis-represented (some of them were under the impression that the drugs would cure them). In several cases, informed consent procedures were neglected; others had to pay for copies of the informed consent form. The patients' expenses were not covered as agreed and participants were not informed of the results of the trial. When these complaints were referred to the Institutional Review Board (IRB) of the National Center for AIDS/STD Prevention and Control, it recommended that in future doctors should make better efforts to explain trials to patients and ruled that participants should be paid expenses at the rate of 10 yuan per day. Their conclusion, however, was that there were no 'serious problems' with the trial.

In the international scientific media, commentators on the VGV-1 trial have focused on the shortcomings of bioethical procedure, noting in particular that while Viral Genetics had obtained approval from the hospital IRB they had failed to submit an ethics application to the SFDA, as was required of them (Cyranowski 2005; Chigwedere 2006). Responses such as these tend to limit the scope of debate to the presence or absence of the informed consent contract, institutional review boards and proper regulatory oversights. Here I follow Kaushik Sunder Rajan in suggesting that the very vocabulary of bioethical discourse serves to obscure the political–economic dimension of contemporary drug testing, deciding in advance that human subject experimentation can be considered *as anything but labour*. Kaushik Sunder Rajan has pointed out that the problems inherent in the informed consent contract are identical to those identified by Marx in the liberal work contract, suggesting that in some respects bioethics has emerged as today's rhetoric of choice for liberal individualism. The liberal contract presumes the formal equality of contracting parties. As the worker's right to the labour of his own body was guaranteed by liberal contract theory, the assumption was that the worker was 'free' to enter into the labour contract. But as Marx insisted, since the labourer typically owned nothing except the labour of his own body this was at best a 'freedom under duress.' Thus concludes Sunder Rajan 'the concerns raised over ethical variability in global clinical trials are often premised on the notion that ethical enforcement is likely to be looser in the Third World than the First. My attempt here has been to show, on the contrary, it is precisely the global harmonization of ethical standards that provides the conditions of possibility for the experimental subjection of the 'merely risked' Third World subject; and further, that this harmonization of ethics goes hand-in-hand with the global harmonization of property regimes' (Sunder Rajan 2007: 83).

It is surely not an incidental detail of this case that the patients participating in the trial were recruited from amongst the same rural poor who had been infected through

unsafe commercial blood transfusion practices during the 1990s (Anagnost 2006). The fact that these patients did not have access to health insurance or antiretroviral drugs was a crucial element in determining their clinical value as treatment naïve subjects. It was also a key element in their decision to participate in the trial, according to several of the participants, since the VGV-1 drug would represent their only access to late-stage therapeutic treatment (Cyranowski 2005). These circumstances point to the uncomfortable conclusion that even if the liberal contract of informed consent had been implemented, it could only serve to facilitate a labour relation in which the labourer has 'nothing left to sell but exposure itself'. Given that HIV/AIDS drugs are considered one of the most promising areas of investment for overseas drug company investment in China, the VGV-1 trial points to some of the structural problems inherent in the current reconfiguration of the clinical trial industry. At issue here is not the value of clinical trials as such (whose necessity is unquestionable) but the political economy of 'surplus health' (Dumit 2006, unpublished data), risk exposure and its distributions. The politics of inclusion in clinical trials is a complex one—as demonstrated by the demand for higher-risk experiments formulated by AIDS activists in the 1980s and 1990s, and more recently by reforms aiming at a more expansive inclusion of women and ethnic minorities in the collection of pharmaceutical data (Epstein 2007). While keeping this complexity in mind, it is important to recognize that the expansive inclusion of new populations into the clinical trial contract can also serve to open up new reserves of high-risk labour. Indeed the VGV-1 case suggests that the frontiers separating high-risk forms of 'clinical labour' are quite porous—the farmers who had been infected by HIV/AIDS when selling their blood subsequently sold their services as HIV-positive clinical trial participants—and continuous with other circuits of labour mobility in contemporary China (in this case the seasonal migration of the rural poor).[22] When inclusion responds to the imperative of minimal health care and a derisory wage and when it is otherwise divested of all forms of risk-protection (health care, medical insurance, continuity in medication and minimal access to existing therapies), it demands to be considered a form of labour, *one in which risk exposure itself is the service to be valorized*. I would suggest that the politics of exposure evidenced in the VGV-1 trial is not specific to this particular case but represents one of the principle motivating factors behind the current process of clinical trial off-shoring. The countries which are of particular interest for contract research organizations—China and India—are characterized by vast social inequalities, with highly stratified levels of access to health-care. If CROs are to realize their promised cost-reductions in these countries, it is only logical that clinical trial recruitment will target those sectors of the population who would not otherwise have access to medical treatment. At the same time, plans for the expansion of pharmaceutical markets into China and India are also highly selective: it is expected, for example, that the pharmaceutical companies will target at most 10% of domestic markets, in other words, the percentage of the population covered by health insurance and with adequate funds to purchase patented drugs (Ernst and Young 2006). If current trends are to continue, the picture that emerges here is of a biomedical economy in which the 'surplus' populations of China are engaged in the high-risk production of biomedical consumption-value, from which they in particular will be excluded. In the context of overall cutbacks in public health expenditure in China, due in great part to the

effects of neo-liberal oriented market-reform, it seems probable that the globalization of pharmaceutical R&D will exacerbate current divisions of labour in the production of health 'surplus' and its risks.

Toward a Political Economy of Experiment?

The current restructuring of pharmaceutical production raises larger theoretical questions about the place of 'experiment' itself within post-Fordist economies. The sociologist Nigel Thrift is not alone in suggesting that post-Fordism, unlike the Taylorist/Fordist industrial economies that preceded it, works through prospective innovation-value rather than the accumulation of time-past. Post-Fordist economies are experimental in the sense that they aim to provoke the emergence of the unpredictable 'transformation-event'. The mode of value-accumulation thereby shifts from one based on economies of scale to one geared towards economies of transversal connection in space and speculative pre-emption in time (the evocation and capture of the new or emergent). In the words of Nigel Thrift, the post-fordist mode of accumulation attempts to 'squeeze every last drop of value of the system by increasing the rate of innovation and invention through the acceleration of connective mutation' (2006, 281). Here 'the intention is to read and exploit signs of invention by regarding the body as a mine of potentiality and to generate and harness unpredictable interactions as a source of value' (2006, 286). Thrift's arguments rest heavily on the work of neo-Schumpeterian innovation theorists who argue, for example, that experimentation has become the principle site of value-creation in post-fordist economies and that the latter is to be defined by its ability to provoke the unforeseeable error. In the words of one group of theorists who have written extensively on both IT and pharmaceutical innovation:

> 'The new information provided by trial and error experiment to an experimenter are those aspects of the outcome that he or she did not (was not able to) know or foresee or predict in advance—the 'error'' (Thomke et al. 1998, 316)

The neo-Schumpeterian school has been particularly active in analysing the dynamics of such innovation-based sectors as ICTs and the pharmaceutical, biomedical and biotech industries, with their need for intensive, accelerated experiment. Indeed the topos of experimentation is so suggestive and so close to the technological innovations of contemporary biomedicine (with its interest in recombination, transformation events and the de-standardized reproduction of life) that one contemporary theoretical biologist has suggested we refigure evolution itself in terms of 'natural experiment' rather than 'natural selection' (Reid 2007). Thus Robert Reid proposes that evolution is driven by emergent novelties and innovative variation, which are hindered rather than promoted by the process of natural selection. Theoretical biology and Schumpeterian-inspired innovation theory here come to confirm each other while preventing any critical insight into the actual political economy of clinical experiment.

My purpose here is not so much to challenge the descriptive insights offered by contemporary innovation theories, which undoubtedly point to important historical shifts in the organization of value-creation, but rather to reintroduce the question of

power and its asymmetries into the analysis of experimental economies. What would it mean to include the labour of the clinical trial participant in this economy of innovation through experiment? Such a move would open up the deceptively simple question of why the productivity of the experiment is assumed to stop at the doors of the laboratory. When does an experiment cease being a productive, innovation-generating event and turn into a reproducible test? Why is the clinic excluded from the production of experimental and innovation value? And why is the contribution of the clinical trial participant reduced to the simple alternative between compliance and non-compliance? Rethinking the demarcations between lab scientist, clinician and human subject as divisions of labour would illuminate the politico-economic imperatives that currently structure the post-Fordist will to experiment. At the same time, it would require that we rethink the category of labour itself in line with the demands of post-Fordist innovation economies. In these conditions, labour is no longer reducible to the measurable expenditure of force (Marx) or the standardized time-motion capacities of the assembly-line worker (Taylor), but must be conceived of as a form of experiment—indeed in this case as a form of organized *self-experiment* in which the 'worker' is required to risk the sometimes unpredictable effects of metabolic compounds on his or her body.[22] The participation in clinical trials is doubtless one of the most extreme forms of contemporary experimental labour, simply because it invalidates any distinction between labour power and the body of the labourer. Yet it is this very extremity which demands attention and points to the current shortcomings of standard and critical accounts of innovation economics. Unless we look in detail at the 'lower ends' of the innovation-value chain, where experiment is inseparable from the messiness and 'non-compliance' of bodily metabolism, we too risk repeating the fantasmatic accounts of standard innovation theories, which in their relentless separation of spheres, deliver experiment to a realm of immaterial, virtual self-sufficiency.

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[22]I am not the first to conceive of labour as invention. Lazzarato (2002) is one theorist who has very seriously considered labour in these terms, although he too tends to privilege the cognitive forms of innovative labour over the bodily. For an extensive discussion of Lazzarato's theory of labour as invention, see Cooper and Waldby (2008).

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