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 'non-traditional 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 health-care system, have all created the conditions under which participation in contract clinical trials is becoming an imperative both for hospitals and the growing number of working uninsured.

This paper considers the relocation of clinical trials to China as a key site for examining the evolving fortunes of Chinese and North-American neo-liberalism. Beginning with the premise that neo-liberalism as a mode of capitalism oscillates between the imperatives of labour fluidity and incarceration, it considers the history of clinical trials, imprisonment and regulation in the US as the necessary context for understanding the recent rush to off-shoring. It then turns to the shifting position of China's floating population in the emergence of a post-socialist economy. What can we deduce about the trends towards social and economic reform in China, where the legacy of a strikingly state-planned approach to public health is being displaced by a dramatic restructuring of the health system, every bit as radical as that pursued by Reagan and his successors in the United States? Drawing on the work of science philosopher Hans-Jörg Rheinberger and recent reconsiderations of the informal services sector, the paper suggests that human subject experimentation should be

considered as a form of labour - experimental or clinical labour. The research hospital clinic therefore emerges as an export labour zone in 'experimental body work.'

Experimental Life

In his study of experimental complexity in biology, the philosopher of science Hans-Jörg Rheinberger distinguishes between the testing device, which produces standards or replicas and legitimates prediction, and the experimental system, which is creative only inasmuch as it periodically disrupts the regularities of the test and generates events of an entirely unanticipated nature. The unanticipated event is not the result of subjective error but is on the contrary entirely objective, real, indeed realer than real, since it confirms the resistance of the experimental object (1997: S245-S246). It eludes simple prediction and yet this doesn't mean that it descends from nowhere, as if *ex nihilo*. The experimental event can only be generated from within a matrix of provisionally stable connective relations, the established norms, protocols and materials of the experimental system, whose very repetition is what gives rise to occasional instabilities. In Rheinberger's words, the experimental event is the result of epistemic and material *conjunctures*; modes of connection that are productive because they destabilize and deterritorialize the normative systems they have brought together.

Rheinberger is interested in the biological sciences in general. Nevertheless, I want to suggest that there is something unique to the bio*medical* experiment, something that further complicates its relation to the unanticipated event. The testing of a new pharmacological compound, a biological device or tissue, cannot only occur in vitro – it must also be experienced in vivo. It needs to be ingested, metabolized and lived-with, in order to prove its eventfulness. In this way, biomedical experiment is always a self-

experiment, even when carried out en masse: a transformation of body and mind whose effects remain a little bit incalculable, whatever the precautions taken. There is thus an interesting tension between the imperatives of standardization and safety that allow a drug to become marketable and the incalculable edge of the experiment—where the event comes into being. Without a doubt we owe much of our present-day pharmacopoeia to the willingness of scientists and other experimenters to ingest the results of their own curiosity, sometimes with fatal consequences.[i] There is a long and fascinating history of scientific self-experimentation, but it exists in an uneasy relationship with the present-day norms of clinical practice. The randomized clinical trial, a testing device designed to measure the likelihood of the unexpected, is one way the modern, post World War II pharmaceutical industry has been able to forge a certain scientific and industrial respectability (Marks 1997). The use of suitably compliant testing populations—detainees in the American state prison system—has been another, less respectable way of standardizing the procedures of clinical trial, while perhaps allowing for a certain margin of 'creativity' in the protocols of experiment. Is this space of unconfined experiment the dirty secret of pharmacological invention? And what happens when it becomes too public and controversial, and therefore too costly, for the pharmaceutical industry? At least one commentator and insider of the pharmaceutical industry has suggested that the ethical regulation of clinical trials should be held partly responsible for the dramatic decrease in real pharmacological invention over the last few decades (this comes from a commentator who is extremely critical of the politics of the drug industry) (Pignarre 2003).

The tension between incarceral and voluntary experience, objective and subjective science, self-experiment and rationalized torture, is recurrent in the history of science. But it is particularly salient one today, when the pharmaceutical industry is

faced with declining rates of drug innovation, expiring patents and the chronic 'non-compliance' of its clinical trial participants.[ii] In the era of contract-based, casualized participation in clinical trials, how do you channel the will to experiment into a form of compliant service? And how do you transform a culture of experimental drug consumption into marketable form?[iii] From the point of view of the pharmaceutical industry, these problems have only been compounded by the increasingly intense regulation of the clinical trial, drug approval and drug classification process (legal or illegal status of the compound, use and misuse in its consumption) over the same period. In response to their perceived financial difficulties, the pharmaceutical industries are currently engaged in an intensive restructuring of the clinical trial process itself, both as a scientific method and a clinical practice. There are on-going efforts to replace the golden standard of randomized controlled clinical trials (RCTs) with a more 'flexible', indeed experimental, protocol, one which would allow the clinician to modify research questions in response to incoming results. The institutional context for clinical trials has also undergone several important shifts over the past few decades, from a situation in which prison-based trials were once the norm to the current rise in contract research organizations (CROs) responsible for outsourcing and off-shoring trials to cheaper locations and subject populations.

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. Moreover in the United States, 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 United States up until the seventies. 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. I therefore propose to reconceive of clinical trial participation as a form of *clinical* or *experimental* labour and situate it at the very heart of contemporary processes of value creation. Perhaps 'labour' is always a critical concept and one that emerges from a point of view of non-compliance or non-readability, to adopt the vocabulary of the pharmaceutical industry. Therefore, by reformulating human subject experimentation as labour, I am 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.

Experimental (or clinical) labour is a term I have coined with Catherine Waldby in order to account for the creation of surplus value in the emerging biomedical economies (2008). We conceive of clinical trial participation and tissue provision as a form of labour in which consumption and production of bodily effects blur together in the experience of self-transformation (Waldby and Cooper 2008).[iv] 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 to *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, subjective and objective science. Labour would then be defined as the experience of self-transformation – commodified. The process of self-transformation can be creative of new relations and stabilities, productive of the unexpected and the useful, without being positive, pleasurable or even survivable. 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 his or her 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.

Experimental labour is self-transformation – commodified. But self-transformation, even of the biomedical kind, is not reducible to the commodification process, even when it is difficult to separate these processes historically. Taking my cue from Rheinberger, I therefore want to propose a general theory of experimental self-transformation, not as an end in itself, but as a way of formulating a proper critique of the political abuses of the biomedical experiment in contemporary neoliberal forms of capitalism. The biomedical experiment works through the materialization of conjuncture across multiple levels. Most immediately, it involves the complex interaction of molecules, medical device or tissue transplant with the patient's body, mind and nervous system. Taking a much larger perspective, the process of biomedical experiment might be widened to include the whole question of disease emergence, mutation and resistance. Recent philosophies of science suggest that evolution itself,

particularly when considered at the level of the micro-organism, should be conceived of as a process of *natural experiment* rather than natural selection, one in which the transversal circulation and recombination of mobile genetics elements plays a key role (Reid 2007). Of course, the properly biological aspects of any disease (emergence, evolution, modes of infection, creation of resistances) are engendered within, and inseparable from, a whole context of more or less stable social relations, desires and practices. Limiting ourselves to the case of an infectious disease such as HIV/AIDS, on the rise in China, this context incorporates everything from the susceptibilities of particular bodies to infection (gender, sexual practices, immune suppression, previous history of medication), the social, cultural and economic risk factors (gender, age, sexual practice, drug use, economic status, work), the medical/public health infrastructure (access to insurance, drugs, public health provision), seasonal migration, sexual violence and desire. Recent epidemiological accounts of China suggest that the highly unstable, experimental nature of post-socialist economic reform has played an important role in the ecologies of emerging, mutating diseases such as SARS and HIV/AIDS.

In this paper, I will be interested in the contemporary politics of clinical trials as it is being played out on a global level. In particular, I will be investigating the stakes at play in the recent trend towards the offshore outsourcing of clinical research and testing from North America to China. What is motivating this push on the part of the multinational pharmaceutical industry? How are the politics of clinical trials connected to the market liberalization of health care in both contexts? The will to experiment, I would suggest, is intrinsic to neo-liberal modes of accumulation. Neoliberalism can thus be provisionally characterized as that form of capitalism which most immediately profits from the experimental destabilization of social norms, the seasonal mobilization

of ‘free’ labour and the circulation of non-familial forms of desire -- not to mention the emergence of new ecologies of disease. And yet it constantly comes up against the problem of how to confine, render compliant and valorize the fluidities of social, bodily and epidemiological experiment. In a very concrete way, this tension is visible in the recent history of clinical trial research in the US, where the widespread use of prisoners as clinical labourers has been progressively replaced by a highly flexible, all too non-compliant work force of casualized human subjects. I would suggest that the push towards offshore outsourcing of clinical trial research to China is at least partly motivated by the desire to re-discover some of the labour compliance and clinical readability once offered by the US prison-pharma complex. In the meantime however, China itself is undergoing an intense experiment in neo-liberal market reform, which is producing uncertainties of its own. The economic success of reform-era China is crucially dependent on the labour of its floating populations—who also happen to be intensively engaged in the production of new gender, sexual and social relations. The development of a Chinese labour market in clinical research is no exception to these trends. It too draws on the circulation of bodies and desires associated with seasonal migration, rural exodus, communal disintegration, sex work and IV drug consumption. It too, in other words, is interested in capturing some kind of surplus from the experimental destabilization of social connections.

In her recent study on post-socialist China, Lisa Rofel (2007) has argued that the experience of desire has been pushed to the forefront of the neo-liberal transformation in China, inflecting even the language of everyday political discussion, where the idiom of hearts (*xinli, xintai*) and feelings (*ganjue*) has replaced that of consciousness. The on-going Chinese experiment in political and economic liberalization, she notes, is widely understood to imply an opening up of desire to the

new experience. In this way, 'desire in China has been assigned the weight of throwing off historical constraints and of creating a new cosmopolitan human nature in the contingent context of postsocialist experiments and post-Cold War global politics' (2007: 198). As politics itself is reconfigured in experiential and experimental terms, she argues that new hierarchies are being built around the distinction between legitimate and illegitimate desire, which more often than not collapses into the difference between non-commodified and transactional desire. With the influx of rural migrants into the cities and the rise in transactional sex work for both men and women, new ideas about social class are emerging, which turn on the difference between those who freely experiment in desire and those who are merely experimented upon. The difficulty of separating the two, I would suggest, is itself revealing about the neoliberal mode of capitalism in China and is of particular relevance to the politics of drug trials.

The Prison 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.[v] 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 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, it seems, 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 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 guinea pigs came under increasing scrutiny throughout the seventies, it is only very recently, in 1981, that the FDA officially outlawed the practice.[vi]

In the meantime, the conduct of clinical trials in the US has shifted to a 'voluntary' system, which is not without its own forms of control. This is a system in which the greatest part of clinical trials are administered either by private medical practitioners or contract research organizations, both on contract to a larger pharmaceutical company. 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 prison, 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). 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 the prison-based biomedical complex—liberating the experiment from the confines of the state institution—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 industries, is directly motivated by the effects of neo-liberal reform (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.[vii] 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 US, the drive to push the clinical trial process offshore represents one way of resolving this problem—at least in the short term.

Off-shoring the Experiment—The Clinic as Export Labour Zone

Throughout the ’80s, the pharmaceutical consortiums were heavily involved in lobbying for the enforcement of global IPR (intellectual property right) laws. More recently, there has been a change in rhetorical tactics. It would seem that the threat to profits no longer lies in unenforced IP but rather in 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 make the clinical trial process more ‘flexible’—as flexible, in other words, as the standard North American clinical trial participant (Vastag 2006), (Thomas-Scott and Baker 2007). 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. Off-shoring affects two areas of biomedical R&D--that of scientific and clinical labour, as the costs of employing comparably trained scientists in East Asian countries is significantly lower than in the

UK, US and Europe; and that of tissue sourcing, clinical trials and product development (Petryna 2006). 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, is the vast number of Chinese and Indian health-care patients who are liable to participate in clinical trials, again at much lower costs than their Western counterparts. The standard insider arguments are quite explicit about their desire for a more compliant patient: 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; recruitment and insurance costs for these patients are much lower than comparable prices in North America; and lack of access to health care will motivate patients to adhere 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 U.S. pharmaceutical companies were conducted offshore, in the UK, Russia, India and China (Bailey, Cruickshank and Sharma 2007). The prediction is that EU and US-based multinational pharma companies will double their clinical research activities in developing nations over the next three years, with China and India now expected to be the major destinations (Kearney 2006). In 2007, China was placed first in a Country Attractiveness Index for clinical trials released by the business consulting company A. T. Kearney (Bailey, Cruickshank and Sharma 2007).[viii] In the wake of market reform, there was a rapid growth in foreign drug company investment in China, although most of this was originally 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, Niese and Dai 2006). 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 drugs for the international market.[ix] Most 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) operating in China.[x] 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.

In some respects, the contemporary Chinese health system continues to bear the imprint of the Maoist era, when massive prevention, immunization and sanitation campaigns were launched to curb the extremely high rates of infectious disease and infant mortality. With the introduction of near total access to basic health care, the Mao era public health system had virtually eradicated smallpox, plague and cholera by 1960. This was by no means a history of linear progress, since considerable setbacks occurred during the Great Leap Forward and the Cultural Revolution. Nevertheless, life expectancy jumped from 35 to 68 years between 1952 and 1982, while infant mortality rates fell from 250 to 40 deaths per 1,000 live births. In many ways, the Maoist approach to public health did not depart significantly from the bio-political methods favoured by European states over the same period—disease control was thus envisaged as a method of total war, engaging the entire population in a rigorous effort of collective discipline and surveillance, and aiming in the long run for the final elimination of the microbial foe. Moreover, Maoist public health included an intense surveillance over cultural and personal norms of conduct. Illegal drug-use and prostitution were targeted as practices to be eliminated. Indeed, it seems that along with the circulation of microbial vectors, human traffic of all kinds—by which I mean China's floating population, the circulation of vagrants, orphans and unaccompanied women—was subject to intense campaigns of re-confinement. By the early 1960s, the PRC claimed to have wiped out prostitution from main land China (it had at least wiped out the most visible, public forms of the practice), a victory it celebrated by closing

down all of its research institutes into venereal disease.[xi]

The legacy of a Maoist-inspired public health philosophy 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, it would seem that political decentralization 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.[xii] In the area of reproductive health, it seems, the transition to a market economy in China has not displaced but rather intensified the selective deployment of a state eugenics. 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).

However, this rhetoric 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 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 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 thus find themselves in a position where they have much to gain from delivering non-basic health care.

In all respects, China seems to have pursued the process of neo-liberal health care reform with all the enthusiasm of the US, and with equally catastrophic results. "China's newly privatized health care delivery system suffers from all the problems of its distant U.S. cousin, but more so. Only 29 percent 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 percent of health care spending in China in 2002, as compared with 20 percent 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 general level 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 US and EU as an innovation economy and biomedical research is one of the key foci of its high-tech programs (Salter, Cooper and Dickins 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, Cruickshank and Sharma 2007: 58). Over recent years, it has established drug approval and good clinical practice regulations conforming to global standards[xiii]; 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). 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 US, 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, Liapi and Kermani 2007: 23; Xu, Li, Ma, Liu and Cong 2006: 371).[xiv]

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.[xv] Multiple models are emerging for the institutional housing of clinical trials—while most take place in suitably authorized hospitals, some contract research organizations are seeking approval to set up independent centres of their own.[xvi] Moreover, 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 countryside 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.[xvii] Nevertheless, there is a clear expectation on the part of foreign investors that relocation to China will compensate for the excessive

fluidity and '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 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).

Whether or not 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.

Traffic and its Discontents

The constitution of this experimental, floating labouring class, and the challenge it poses to a Leninist eugenic public health, is reflected in the shifting politics of the PRC on such practices as commercial sex work, drug taking and HIV/AIDS.[xviii] The Communist Party first adopted measures against prostitution after conquering Shijiazhung in 1949, when it summarily shut down all local brothels and sent prostitutes to re-education camps. In other cities, prohibition was less spectacular but no less effective, with the introduction of various legal restrictions leading to a gradual

phasing out (Henriot 1995). Although prostitutes were considered victims of labour exploitation rather than criminals, official prohibition meant that many of them were interned in re-education camps and forcibly returned to their families or farm collectives to engage in "productive" work. Interestingly, it seems that the effort to regulate prostitution was conceived of as part of a larger project of control over China's floating populations in general – vagrants, beggars, homeless children, drug addicts and unattached women – who threatened to undermine state control over both productive and reproductive labour (Henriot 1995: 473). Within the Maoist project of collective nationalism, the unregulated movement of people, their exodus from rural to urban centres and from family to street-life, could only be seen as a drain on the productive energies of the nation.

Herein lies a key difference with the politics of post-reform China--since in often unacknowledged ways, the latter's economic success is intimately dependent on the seasonal mobility of the floating poor. The Mao-era restrictions on migration were officially relaxed in the 1990s in implicit recognition of this fact, although rural migrants are in principle required to return to their villages when not employed. In this way, the post-reform era has established something like a controlled traffic flow between rural and urban regions. China can no longer afford to re-discipline its floating poor into the stable structures of agricultural collectives.[xix] And yet the social and cultural deterritorialization generated by market reform also presents enormous problems in terms of the destabilization of social relations. Market liberalization has not only transformed the relationship between rural and urban China; it is also generating extreme reconfigurations in the realm of ethnic, sexual and gender politics.[xx]

Along with this upsurge in human traffic of all kinds, there is a common

assumption that market reform has once again opened the gates to prostitution, bringing with it the old drug problems, venereal diseases and now HIV/AIDS. In its response to this revival, the reform-era PRC has vacillated between the old punitive methods and a more accommodating, indeed enabling, approach. The Ministry of Public Security has launched periodic crackdowns since the late 90s, rounding up the poorer and most visible of sex workers – those working on the street – before making loud public announcements about progress made in the on-going task of eliminating prostitution. And in terms of public health responses, Maoist methods of quarantine, surveillance and re-education coexist in seeming contradiction with local campaigns for HIV prevention and condom distribution (Hyde 2007: 202; Beyrer, 1998: 115). But given the growing importance of prostitution for China's regional economies, it is arguable that the old punitive measures can only go so far. In 2000, the 'new left' economist Yang Fen estimated that the Chinese sex industry contributes up to 12% of GDP. When the State Council issued its "Regulation on the Management of Places of Entertainment" in 1999, he argues, the Chinese GDP dropped by one percent (Zhong Wei 2000). Sex work, along with drug trafficking, also forms a major impetus behind the economic success of such border-regions as the Mekong river. The plans to convert this area into a tourist-driven development zone, linked up with northern Thailand, Burma, western Laos and Yunnan by a series of cross-border trade routes, has received support from The Asian Development Bank and ASEAN states (Beyrer 1998: 108). Indeed, it appears that in some of the more impoverished areas of China we are seeing a return to the regional financing strategies of the Republican Era, where provinces such as Yunnan gained up to half of their revenues from taxes on prostitution (Remick 2004; Hyde 2007: 201-202). As I suggested above, the introduction of clinical trials into China is parasitic on these developments, since the patients who are most likely to be

recruited into clinical trials are also those that are over-represented amongst China's floating populations. As a part of the informal economy, clinical trial work should therefore be placed alongside prostitution, drug trafficking and consumption, blood sale and various forms of service labour (domestic or in the tourist industries) as absolutely pivotal to the success of China's special economic zones. These are all forms of labour that generate value from the transversal circulation of desires, affect, body fluids and pharmacological substances; and labouring bodies whose surplus exposure to biomedical risk (from unprotected sex, needle sharing, unsafe blood donation or simple lack of health care) is precisely what makes them valuable from a clinical point of view. Epidemiological studies suggest that there is considerable overlap between HIV risk, rural-urban migration, seasonal work such as mining and sex work, injection drug use and participation in high-risk forms of biomedical labour. The most publicised example of the latter in recent years has been the illegal trade in blood products, where many of the rural poor who donated blood for income were infected with HIV and other diseases due to unsafe blood transfusion procedures.[xxi] The frontiers separating these different forms of experimental labour are quite porous – a recent scandal revealed that migrant rural workers who had been infected by HIV/AIDS through such blood transfusion practices were subsequently recruited into clinical trials for the experimental ARV drug VGV-1.[xxii] Here it becomes clear how the exposure to risk – in this case, a mortal risk to the blood donor – can be recycled and capitalized as a form of experimental labour, without any comparable risk to the investor. This is a regime of capital formation in which the exposure to biomedical risk has become an actual motor of accumulation, since it can be expected both to ensure the 'compliance' of the trial recruits and the 'readability' of the clinical information that can be extracted from them. With its active investment in the biomedical innovation sector, the Chinese state is no longer in a

position to simply clamp down on formerly illegal practices such as drug taking and prostitution or to pursue an excessively punitive line in public health.[xxiii] On the contrary, it needs, at least a certain extent, to facilitate the continual emergence of new biomedical risks; to channel rather than prohibit the circulation of the floating poor and their sicknesses.

This raises the question of whether or not we are likely to see the rise of new kinds of political action at this level—in other words, a contestation of the very *experience* of neo-liberalism, which for many is at minimum an experience of extreme exposure. It is in the destabilizing conjuncture--the production of new social and epidemiological relations--that reform-era China finds its most promising source of surplus value, the experimental something that needs to be valorized and contained. It is here too that it is likely to encounter the strongest experimental 'resistance' on the part of those who are called upon to live the process of transition in vivo (Rheinberger S246). The extreme disparities that divide contemporary China are nowhere more apparent than in the embattled clinic, where security forces now oversee relations between patients and hospital staff (Watts 2007). There has been at least one instance of a formal complaint against the clinical trial process, where participants in the VGV-1 trial (mentioned above) reported abuses of trust to both the US NIH and Chinese Ministry of Health (Cyranoski 2005). But this is perhaps only the most obvious form of protest. The experimental transformation of post-reform China has had immense consequences in terms of familial, sexual and gender relations and places the politics of desire at the very centre of labour concerns. China has already seen the rise of new kinds of sex and gender politics around prostitution and sexual minorities, with the inevitable challenge that these minorities pose to official doctrines of public health. Insofar as such movements are capable of sustaining the *desire* for experiment while challenging the

brute *imperative* to experiment embodied in the clinical labour contract, they promise to formulate a powerful riposte to the emerging labour relations of the biomedical and pharmaceutical economy.

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[i][1]See Altman (1998).

[ii][2] I'm here thinking of Joseph Dumit's notion of surplus health (2006).

[iii][3] See again Kane Race (2005) for an insight into this tension in contemporary drug production and consumption.

[iv][4] Recent work on the biotech economy has attempted to re-deploy the concept of reproductive labour as a way of thinking through the role of bodily (often female) or biological labour (the work performed by cells and other life forms) in the creation of value. See on this point Waldby and Cooper (2008) and Franklin and Lock (2003: 3-22). In this article, I have chosen to deploy 'experimental labour' as an alternative term because of the limitations inherent in the concept of reproductive labour. In response to the seemingly endless innovations of the productive and financial economy, there is a tendency in this literature to want to re-anchor value in the realm of reproductive labour. The claim is that something has been forgotten, some essential input into the production of value systems, which we as critical theorists need to recognize and re-valorize. The claim that reproductive labour represents the ultimate source of all wealth is thus proposed as an alternative to Marx's labour theory of value, without questioning the difficulties already inherent in this theory. Already in Marx's analysis, the reproductive labour of woman is defined, logically enough, as that which *reproduces*, *repeats* and *conserves* the already existing relations of production, in both the cultural and biological realms. While production is charged with the endlessly heroic revolution of social norms, reproductive labour gets credited with the menial task of repetition. An obvious difficulty with this conception of things is that it tends to push any counter-political impulse into a highly reactionary mode—the return to the reproductive feminine, the earth, the familial and subsistence economy become the only way of registering one's complaint against capitalism. This is a particular danger when one makes the attempt to extend Marx's labour theory of value to include sex, race, ecological and genealogical relations and is apparent in the work of feminist and anti-imperialist theorists such as Maria Mies (1998) and Vandana Shiva (1997). An entirely different set of practical possibilities is opened up if we make the decision to

conceive of the productive underworld as already in a state of constant self-experimentation, already testing and destabilizing its boundaries and predictabilities, in much the same way as Rheinberger's experimental system. The question then becomes: how to contest the capitalization of these modes of self-experiment without opting for an anti-experimental, neo-fundamentalist politics?

[v]5 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).

[vi]6 Code of Federal Regulations 21, part 50, 44, 'Restrictions on Clinical Investigations Involving Prisoners.'

[vii]7 On this point in general see Jill A. Fisher (2008). 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 Schuchman (2007).

[viii]8 This index was calculated on the basis of data relating to patient pool, cost efficiency, regulatory conditions, relevant expertise and infrastructure.

[ix]9 For a full list of multinational pharmaceutical investment in China, see Vaidya, Liapi and Kermani (2007: 20-22) and on the internationalisation of Chinese clinical data, see Vaidya, Liapi and Kermani (2007: 27).

[x]10 Jim Morioka (2006) provides a list of 100 clinical research organizations currently operating in China. See also Vaidya, Liapi and Kermani (2007: 27-29) for further detail on CRO activity in China.

[xi]11 On these points, see Hsieh (2007).

[xii]12 The burdens of this policy, according to Greenalgh and Winkler, have been disproportionately borne by women, and in particular by rural women, who are deemed to reproduce in 'higher quantity and lower quality' than their urban counterparts. In the birth planning campaigns of the 80s and early 90s, medical teams were deployed to villages to carry out en-masse sterilizations in rural villages. In their scale, standardization and incarceral methods, it seems that these punitive

interventions into the bodies of the rural poor were carried out along the lines of agricultural mass production. In the words of Greenalgh and Winkler, '…most sterilizations were performed during rushed campaigns, when outside medical teams spent short periods in local areas conducting surgeries en masse, often without adequate facilities, sanitary equipment, or anaesthetic'; 'in some times and places, the spaying of pigs was no mere metaphor. Rural women were taken by force, placed in cages, and transported to quasi-public operating areas, where one after another they had their tubes tied or IUDs inserted without anaesthetic' (Greenalgh and Winkler 2006: 251 and 252).

[xiii][13] 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, Li, Ma, Liu and Cong 2006).

[xiv][14] 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 health access. It is highly probable that clinical trial recruitment in these countries will target those sectors of the population who wouldn't 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). In the context of overall cutbacks in public health expenditure, 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 inequalities.

[xv][15] 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.

[xvi]16 See Heping Jhia (2005).

[xvii]17 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*, 5500 medical workers were injured by protesting patients in 2006.

[xviii]18 I use the term "sex work" deliberately here, since long before the term came into use by Western prostitutes campaigning for workers' rights, the Chinese Communist Party had already categorized prostitution as a labour practice, a class phenomenon more than a question of cultural, moral or gender politics (Henriot 1995).

[xix]19 On this point, I am inspired by Michael Dutton's subtle analysis of governmental and police responses to the floating population. Comparing the relaxation of China's household registration laws to Marx's analysis of the enclosure movement and the creation of a "free" or surplus force of labour, he writes: "Two moves of government, two responses, two sets of regulation form the 'double pincer movement' through which the drama is played out. Peasants are offered to the market as 'free' labour (what Marx describes as the wage slave) and simultaneously disciplined into the language of the market by the harshness of the alternative (strict laws against vagrancy, prostitution, itinerant suspects etc.). This double move is a compact signed under two names: one signs 'freedom' (the freedom of movement to places of work, the freedom to buy and sell one's labour power, not to mention the freedom to trade), the other signs 'restriction' (restrictions upon those who can and cannot remain in the cities, restrictions upon acceptable and unacceptable forms of work: women can work as char-ladies – the so-called baomu – but not as sex workers)" (Dutton 1999: 10).

[xx]20 For an excellent insight into some of these processes, see Sandra Theresa Hyde (2007).

[xxi][21] On all these points, see Quian, Vermund, Wang (2005); and on the blood market and its political economy Anagnost (2006).

[xxii][22] VGV-1, a combination ARV drug developed b y the California-based biotech Viral Genetics, was tested in Ditan hospital Beijing (Cyranoski 2005). Participants in the trial were recruited from amongst the same rural poor who had been infected through unsafe commercial blood donation during the 1990s and who were led to believe that the experimental drug would cure HIV/AIDS. In 2003, three HIV-positive farmers from Henan province, representing a further fifteen patients, made a complaint to the US National Institutes of Health and the Chinese Ministry of Health, claiming not to have been properly informed of the risks. Several of the patients suffered severe side effects as a result of taking the drug. Their subsequent medical expenses were not taken in charge by the hospital.

[xxiii][23] This point was brought home in an academic conference on HIV/AIDS vaccines in China, where participants discussed the incompatibility between a regime of biomedical experiment dependent on the participation of sex workers and the punitive reeducation programs of the Chinese government (Watanabe 2000: 5).