Capitalizing Disease: Biopolitics of Drug Trials in India
Amit Prasad
Theory Culture Society 2009; 26; 1
DOI: 10.1177/0263276409106347

The online version of this article can be found at:
http://tcs.sagepub.com/cgi/content/abstract/26/5/1

Published by:
SAGE
http://www.sagepublications.com

On behalf of:
The TCS Centre, Nottingham Trent University

Additional services and information for Theory, Culture & Society can be found at:

Email Alerts: http://tcs.sagepub.com/cgi/alerts

Subscriptions: http://tcs.sagepub.com/subscriptions

Reprints: http://www.sagepub.com/journalsReprints.nav

Permissions: http://www.sagepub.co.uk/journalsPermissions.nav

Citations http://tcs.sagepub.com/cgi/content/refs/26/5/1
Capitalizing Disease
Biopolitics of Drug Trials in India

Amit Prasad

Abstract
Recent success of Indian engineers, businessmen, as well as other technically qualified professionals has created an obsession with knowledge and creativity. Documents like *India as a Knowledge Superpower* have proliferated and we continually hear the mantra of investing in and harnessing of human capital. There are, however, several strands of human capital in India and not all of them harness knowledge and creativity. People on whom drugs are being tested represent one such human capital, which, even though it is being energetically mobilized to provide India with a strategic advantage in the world market, also highlights the contradictions within India’s shifting imaginary, economy and politics. Drug trials in India, in the context of neoliberal globalization, not only challenge and complicate, but also operate within a constellation of divisions – labor/capital, west/nonwest, colonial/sovereign, national/global and so on. In this article I analyze how the people on whom drug testing is being done in India are being ‘harnessed’ as human capital, which leads to politicization of ‘bare life’ through ‘inclusive-exclusion’.

Key words
biopolitics ■ drug trials ■ governmentality ■ human capital ■ India ■ neoliberalism

Natural resources count, but people count even more. (World Bank, 1997: 1)

*Wealth* in this context is conceived broadly, to include produced assets, natural resources, healthy ecosystems, and human resources. This places the indicator problem squarely in the realm of integrated economic and environmental accounting – loosely dubbed *green national accounting*. (World Bank, 1997: 7)
In a quirky way, the World Bank’s definition and accounting of wealth and sustainable development seem to bring into reality Bruno Latour’s (1993) proposal of the ‘Parliament of Things’ – the boundaries between nature, culture, material artifacts and humans are dissolved and all seem to sit together in the ‘market of things’. Breach of these ‘modernist’ dualisms does not, however, ‘free the multitude’. Instead, as Fernando Coronil argues, ‘by disregarding their differences and subsuming them under the abstract category of “capital”, these resources are treated as equivalent constituents of a “portfolio”’ (2001: 76–7). The people on whom drug trials are being conducted, particularly through ‘outsourcing’, constitute a valuable ‘asset’ in such a ‘portfolio’. Nevertheless, their position presents a paradox, which is evident in the debates over drug trials outsourcing. According to Bindu Dey and Payal Dey from the Department of Biotechnology, Ministry of Science and Technology of the Government of India:

Clinical trials are the buzzword today. In most of the boardrooms promoting ‘Destination India’ by business mediators, ‘Clinical Trials in India’ are being offered as a greater advantage, next only to its well-educated human capital. What is amazing is – how much these promoters understand ‘clinical trials’ and more profoundly the ethics associated with it? The ‘access to lots of patients’, ‘wide gene pool’, ‘meager incentives’ (due to poverty or other economic compulsions) and ‘illiteracy’ sound more like washing dirty linen in public than actual ‘Advantage India’. (Dey and Dey, 2005, emphasis added)

Drug trials in India (as well as other non-western societies), as several scholars have pointed out, are reminiscent of ‘a new colonialism’. They operate much more insidiously, however, and largely through the ‘art of government’ rather than through force or coercion. In particular, they are reflective of a neoliberal governmentality whose lynchpin is human capital. The ‘intellectual instrument’ of this neoliberal governmentality is not political economy but ‘market economy’. The market not only assumes a very different meaning and role, but also operates through a radically different dispositif within neoliberal governmentality.

The market, as Michel Foucault points out, is a crucial element of liberal governmentality too. It represents ‘a mechanism of exchange and a site of veridiction’ (Foucault, 2008: 44). Liberal governmentality, however, has another point of anchorage apart from the market – ‘elaboration of the powers of public authorities and the measure of their interventions by reference to the principle of utility’ (Foucault, 2008: 44). As a result, governmental reason represents a ‘complex interplay between individual and collective interests, between social utility and economic profit, between the equilibrium of the market and the regime of public authorities, between basic rights and the independence of the governed’ (Foucault, 2008: 44).

In contrast, the market within neoliberal governmentality is ‘naturalized’ in terms of formal rules of economic order and subsumes within itself the other anchorage of liberal governmentality – utility. It is no longer, ‘exchange on the side of the market, and utility on the side of the public.
Instead, utility is defined through exchange and that too in relation to the market. Such an orientation of neoliberal governmentality, which is accompanied by a blurring of the labor/capital dualism, has far-reaching consequences in reconfiguring the technology of power, as well as the identity, role and value of people.

The neoliberal actor/worker, for example, becomes a *homo economicus*, who is an entrepreneur of herself or himself. Human capital theory redefines the laborer/worker as an ‘ability-machine’ that produces an earnings stream (Foucault, 2008: 224). Potentiality and possibility for individuals and the population within this ‘rationality of government’, even with regard to issues such as racial or gender discrimination, lies in the capitalization of ‘selves’. In contrast to liberalism, which aimed at ‘the self-limitation of governmental reason’, neoliberalism makes this ‘principle of self-limitation’ superfluous and puts the onus of utility and justice on the individual’s capacity to perform in the market.

The market, therefore, is not just a generator and arbiter of ‘value’ within neoliberal governmentality. Its centrality in ‘regulating’ the population makes it the theater in which concomitant biopolitics takes shape and is enacted. Neoliberal biopolitics does not displace the principle of ‘to make live and to let die’, which as Foucault (1990) shows was an intrinsic element of biopower that emerged in Europe in the 18th century. It circumscribes the principle, however, by making it subservient to capitalization of ‘self’/‘selves’. Biological existence is still reflected in political existence, but both are circumscribed by economic existence.

‘Life’ (or ‘lives’) is, however, differentially and hierarchically mobilized and regulated within neoliberal governmentality. Even though ‘governmental reason’, as Foucault states, does not express division ‘within individuals, men, or subjects, but . . . rather within governmental practice itself’ (Foucault, 2008: 11), in practice governmental reason and division of individuals and the population operate in tandem. The articulation of governmentality as a general principle by ignoring or ‘forgetting’ even while presupposing (sometimes overtly utilizing) differentiations and hierarchies in the population makes it concomitantly and complementarily engaged in dividing agenda/non-agenda as well as individuals and the population. The interventions (in the plural as Foucault argues) of the ‘state’ are, as a result, simultaneously internal (in relation to governmental practice) and external (in relation to different people, social groups and even things), even though they are ostensibly articulated in relation to governmental practice.

The ‘state’ embodies a duality. It is ‘the mobile effect of a regime of multiple governmentalities’ (Foucault, 2008: 77), but it is also engaged in instituting ‘states of exception’. An added consequence of the duality of the state is that it is simultaneously ‘self-aware’ and ‘blind’. It is self-aware in relation to the governmentality (or governmentalities) that it is embedded within; but agendas (and their concomitant impact on people and things) outside governmental reason(s) (particularly the reasons/rationalities that are opposed) become ‘invisible’ to it. The present debate in the United States...
over whether the government should engage only in financial stabilization of the banks and in support of individual enterprise (and spending) through tax cuts or invest in infrastructure development and job creation is a classic, though by no means an exceptional, exemplification of such a characteristic.10

‘States of exception’ are therefore intrinsic to governmentality.11 My concern is not exemplifications of states of exception in the ‘zones’ where the law(s) is (are) suspended. Instead I will show how ‘states of exception’ are constituted in the process of articulating a particular governmental rationality. I will do so by focusing on a threshold case of human capital – the people on whom new and potential drugs are being tested in India (as well as other non-western nations).

These people on whom drugs are being tested represent a human capital which, even though it is being energetically mobilized to provide India with a strategic advantage in the world market, also highlights the contradictions within India’s shifting imaginary, economy and politics. I will show how these people are being ‘harnessed’ as human capital, which leads to the politicization of ‘bare life’ through ‘inclusive-exclusion’.12 This inclusive-exclusion occurs through two intertwined processes/rationalities: ‘capitalization of vitality’ potentially includes these people, yet they largely remain as ‘guinea pigs’ in this process because most of the drugs that are being tested are not for them.13 Moreover, since government-provided healthcare is so poorly funded and mismanaged in India, they have little access even to the medications that are available. ‘Capitalization of humans’ also potentially includes these people, but their ‘value’ (as human capital) is limited because they largely constitute a ‘non-productive asset’ except in the field of drug testing. Capitalization of disease in drug trials outsourcing operates through these governmentalities and exemplifies this double inclusive-exclusion.

Disease as a Marketable Asset

A vast, unwieldy population, a plethora of diseases, and rampant poverty: this was the picture India presented to the outside world till a while ago. But these days the fact that India has the largest pool of patients suffering from cancer, diabetes and other maladies is leading the country to an altogether different destination: the global hub of outsourcing of clinical trials. (Iype, 2004)

Sir Bernard Pellegrin, one of the characters in The Constant Gardener, a fascinating film about drug testing in Africa by multinational companies, during an intriguing dialogue with Justin Quayle, an employee of the British High Commission in Kenya, commented: ‘Do you no good to go poking around under rocks, Justin. Some very nasty things live under rocks, especially in foreign gardens.’ If a section of media is to be believed, only very few nasty things seem to be living under the rocks, as far as drug testing in India is concerned. In fact, drug testing by multinational companies has been hailed as a wonderful business opportunity for India.
Saritha Rai, in an article in the *International Herald Tribune*, emphatically claimed: ‘[t]esting gives India a shot in the arm’ (Rai, 2005). Rai’s opinion is not an exception; it is a commonly expressed view. A variety of statistics have been furnished to bolster this claim. The consulting firm McKinsey [has calculated] . . . that the market in India for outsourced trials will hit $1.5 billion by 2010’ (Kahn, 2006). In 2006, 1 in 100 drug trials were being conducted in India and it is estimated that by 2011 the figure will become 1 in 10. A market report titled *Booming Clinical Trials Market in India*, published in November 2007, declares: ‘[The] Indian clinical trials market is expected to grow at a CAGR [compound annual growth rate] of 36% between 2006 and 2011’ (RNCOS, 2007). Most of the top multinational pharmaceutical companies such as Pfizer, Nova Nordisk, Novartis, Aventis, Astra Zeneca, Glaxo Smith Kline and Eli Lilly are conducting drug trials in India.

There are several reasons why countries such as India have become particularly lucrative for drug trials. Testing a drug in the US and some European countries can cost as much as $150 million and can take from 7 to 12 years. Moreover, recruitment for drug trials has stalled in these countries. Conditions in India are in stark contrast to the situation in these nations. ‘Among India’s notable advantages’, it is being argued, ‘is that its ethnically diverse, largely treatment-naïve populace can be recruited about three times faster than in the United States’ (Borfitz, 2008). Quintiles India,15 which is a subsidiary of a Contract Research Organization (CRO) based in North Carolina in the US, put the advantages for drug testing in India upfront:

India has a vast population. Patient access is fast; fully a third of the population lives in urban areas. Large portions of the population have not been exposed to prior treatment. Tropical diseases and diseases of developed countries are both common in India. Trials opportunities include cardiovascular diseases, diabetes, degenerative neurological diseases, cancers, psychiatric illnesses, and infectious diseases.16

iGate Clinical Research, an Indian CRO, under the label of ‘India Advantage’, lists 10 reasons for conducting clinical trials in India. The first reason on its list is ‘[h]uge patient base with diversity of diseases’. In order to clearly drive home the ‘India advantage’ they list the disease characteristics of the Indian population:

- 40 million asthmatic patients
- 34 million diabetic patients
- 8–10 million people HIV positive
- 8 million epileptic patients
- 3 million cancer patients
- > 2 million cardiac related deaths
- 1.5 million patients with Alzheimer’s disease
15% of population is hypertensive
1% of population suffers from schizophrenia.\(^{17}\)

These characteristics of the Indian population, which were for long consid-
ered hindrances to India’s development and, not to forget, a blot in the
healthcare of citizens, have become ‘assets’. They have come to constitute
a human capital with starkly different characteristics from, say, the software
engineer who has become the iconic Indian human resource. This form of
capital/commodity also reflects a reversal of the Marxist theory of value; it
exists exclusively as exchange value.\(^{18}\)

The ‘competitive advantage’ of India, it is being argued, also lies in
compressing the time taken for drug trials which, along with lower compen-
sation for patients on whom trials are conducted and for the doctors and
other healthcare professionals who conduct the trials, cuts down the cost
considerably.\(^{19}\) Profit is being squeezed not only by providing lower compensation but by squeezing time as well. Quintiles India proudly advertised the
advantage of India in this regard:

These readily accessible patient populations – and our experience in
reaching out to them – result in significant time savings for Quintiles India
customers:

- 30 Parkinson’s patients recruited in just over 2 weeks.
- 50 patients with diabetes recruited in one month.
- 200 patients for a parasitology study recruited in two months.
- 290 patients with mania recruited in eight months.
- 100 patients with breast cancer recruited in ten months.\(^{20}\)

‘In India SIRO CliniPharm recruited 650 patients from five centers in
around 18 months. By comparison in Europe it took 36 months to recruit
85 subjects from 22 centers’ (Balakrishnan and Sharma, 2004). With such
beneficial conditions, obviously India is becoming a major center for drug
trials.

Drug testing in India seems to be an ideal-typical case of continued
capitalist exploitation of people of poorer countries by multinational compa-
nies based in the US or some European nations. It is nevertheless impor-
tant to further analyze the configuration of actors and the topography of
power in order to map the striations and hierarchies of governmentality
within which drug testing is being carried out in India.

It is not only the US- or Europe-based multinational pharmaceutical
companies and CROs who embody the neoliberal rationality in harnessing
human capital in India. Indian CROs and pharmaceutical companies are no
different. In the last few years, several Indian CROs have become key
players in the drug trial market. For example, Bangalore-based Lotus Labs,
whose employee strength grew from 7 in 2001 to 211 in 2005, aims to
capture a big slice of the drug trial market (Rai, 2005).\(^{21}\) Neoliberalization,
as David Harvey rightly argues, ‘has succeeded remarkably well in
restoring, or in some instances ... creating, the power of an economic elite’ (2005: 19).

There is also little to distinguish Indian CROs from the foreign ones in terms of their market-oriented positioning. iGate Clinical Research, another Bangalore-based company, proudly advertises:

iGate Clinical Research has an innovative, client-focused approach to every project... Our services are based on state-of-the-science technologies and best-science-of-the-day processes for complete satisfaction of our clients, project after project.22

Dr Vasudeo Ginde, the Managing Director of iGate, uses the same language as the multinational companies to emphasize India’s advantage in the drug trial business:

It’s not so much that India has a cost arbitrage. It is that India can save significant time to market. You don’t know what is going to be a blockbuster when you launch a drug. But even if you save three months, that might mean $100 million or $50 million in sales – in which case, it is worth it. (O’Connor, 2006)

These Indian business companies and managers are also no longer content with being key local players or comprador elites facilitating imperialist profit extraction; they compete with other multinational companies and, in significant ways, are developing a multinational reach themselves. For example, iGate is a NASDAQ-listed company. Indian pharmaceutical companies have also significantly grown in stature in the last few years. There are more than a dozen Indian pharmaceutical companies at present. Ranbaxy, Dr Reddy’s Laboratories, Cipla and Biocon are the main pharmaceutical companies in India. Though they still focus on the market for generic drugs, they are also directly competing with the big multinational pharmaceutical companies. Biocon displays it upfront on its website: ‘Biocon is a research-driven, global healthcare company ... [that offers] novel therapies on a platform of affordable innovation’.23

Biocon recently bought a 70 percent stake in a German pharmaceutical company, AxiCorp, to expand its reach in Europe (‘Biocon Buys . . .’, 2008). In its efforts at global expansion, Dr Reddy’s Laboratories has been conducting trials of its drug, RUS 3108, to treat atherosclerosis, a major cause of cardiovascular disorders, in Ireland (Special Correspondent, 2005a). Global expansion of neoliberal capitalism, though no longer a one-way street in which companies based in the so-called developed nations buy and control Indian companies and use India only as a drug testing site, is still lopsided.24 Moreover, India remains the main drug testing site for the Indian CROs and pharmaceutical companies too, because, as shown earlier, the competitive advantage of India is too great.

A shift to the non-western or the so-called southern nations clearly highlights the need for retooling the Foucauldian analytics of power. Nicholas Rose, drawing on the concept of governmentality, argues: ‘strategies
for the conduct of conduct increasingly operate in terms of two distinct sectors. For the majority, expertise operated not through social planning, paternalism and bureaucracy, but in terms of logic of choice’ (1999: 88). The other sector, as Rose further argues, consists of the ‘usual suspects’, who constitute the socially problematic marginal groups such as lone parents, drug users, the homeless, etc., who, ‘excluded from the regime of choice . . . are allocated to . . . charities [and] voluntary organizations’ (1999: 88–9). Such a division of the population is an ideal exemplification of the principle of ‘to make live and to let die’. We have to bear in mind, however, that neither this ‘majority’ nor the ‘logic of choice’ are homogeneous categories. More importantly, they are not homogeneous because the general principle of governmentality presupposes and thereby utilizes a hierarchical differentiation of society, even though most often it is not articulated as such.

Human capital theory, not unlike other governmental rationalities, is postulated as a general principle.25 Theodore Shultz was among the first to articulate it in his presidential address at the 73rd annual meeting of the American Economic Association:

*Although it is obvious that people acquire useful skills and knowledge, it is not obvious that these skills and knowledge are a form of capital, that this capital is in substantial part a product of deliberate investment, that it has grown in Western societies at a much faster rate than conventional (nonhuman) capital, and that its growth may well be the most distinctive feature of the economic system.* (Shultz, 1961: 1, emphasis added)

Human capital theory, however, presupposes hierarchical differentiations of population even while it subsumes such differentiations within a general principle. Gary Becker, one of its key proponents, writes:

*Indeed, in a world with constant returns to scale in production, two segregated economies with the same distribution of skills would completely bypass discrimination, and they would have equal wages and equal returns to other resources, regardless of the desire to discriminate against segregated minorities.* (1993: 387–8)

Becker adds: ‘discrimination by the majority in the marketplace is effective because minority members cannot provide various skills in sufficient quantities to companies that would specialize in using these workers’ (Becker, 1993: 388). The general principle of neoliberal governmentality therefore potentially offers the same choice even to the discriminated group. However, since the ideal scenario in relation to which it is articulated does not exist, it sets up different groups (in particular the discriminated ones) for hierarchical mobilization. It should therefore come as no surprise that the people on whom drugs are being tested in India are almost exclusively from the lower classes.
Such a characteristic is not unique to neoliberal governmentality. In fact the logic of choice has most often operated in such a manner and at times even by explicitly highlighting hierarchical differentiation of the population as a part of the general principle of government. Pasquale Pasquino, citing William Petty’s declaration ‘that each young Englishman who dies represented a net loss of £69 sterling’, argues:

The fact that he [William Petty] rated the loss of a young Irishman at £15, the same value as for negroes and slaves, may appear inconsistent. But no matter, science deals only with principles, and the principle was there. Population is wealth, health is value. (Pasquino, 1991: 116, emphasis added)

Petty’s declaration is an exemplification of a principle of government. This principle, however, is also hierarchically striated.

In the case of drug trials in India, members of the Indian CROs and pharmaceutical companies are certainly a part of the ‘majority’ who are overtly wedded to the productive logic of the neoliberal market. However, the people on whom drug testing is done, who are often the marginal, are not ‘excluded’. They have productive value precisely because the dualism of labor–capital is blurred – their ‘non-productive’ characteristic as labor is their greatest asset as capital. They are therefore constituted as human capital through inclusive-exclusion. The status of these people, particularly in the context of hierarchies of class, nation, west/non-west and colonial/imperial, makes their choice in being a part of the market superfluous (ideologically as well as materially). Though it must be added that these people are not directly coerced, they are being lured by the economic ‘advantages’ in being a part of drug trials, particularly since there is hardly any other choice available to them. That is to say, as Couze Venn suggests, ‘[a]t the limit, contemporary governance is consistent with the exclusionary and carceral state, instituting new “dividing practices” that reduce certain categories of people to “bare life”’ (Venn, 2007: 117).

The concept of governmentality is very useful in the analysis/understanding of neoliberalism. It becomes deficient, however, if the operative logic of ‘techniques of government’ or the ‘conduct of conduct’ – the creation of ‘productive’ (through a focus on ‘vitality’, ‘economy’, etc.) citizens/population and the exclusion of non-productive ones – is generalized as a principle without a consideration of its intrinsically hierarchical character. We need to carefully investigate the constitution (analytic and programmatic) and institution (juridical, social and economic) of neoliberal governmentality in order to see how it is inherently striated and hierarchical, even though it is articulated as a general principle.

Law, Ethics and the Drug Trial Market

[T]he modern hunt for bodies leads drugmakers to places almost entirely short of such oversight. Such is the case in India, where one billion body bounty entices industry investigators. (Shah, 2006: 112)
India emerged as a lucrative market for drug trials not just because of the efforts of Indian as well as multinational business. The state brought about crucial legal changes to facilitate the process. The Indian nation-state, very much like many other nation-states, has become a facilitator of transnational neoliberal capitalism (Ong, 1999; Randeria, 2007). In the case of drug trials two legal changes were crucial. First was the acceptance of the World Trade Organization (WTO) agreement on protection of Trade-Related Intellectual Property Rights (TRIPS): this allowed multinational pharmaceutical companies to conduct drug trials in India without fear of Indian companies manufacturing generics of those drugs through reverse engineering. Second, there was a change in the law governing drug testing in India. Indian law, until 2005, allowed drug trials by foreign companies only with a phase lag. In effect, Indian law only allowed replication or extension of already conducted trials, which was hardly profitable to drug companies.

The Amended Drugs and Cosmetics Act of 2005 changed all that. The new law allows conduct of Phase II, Phase III, or Phase IV trials without any phase lag. Phase I requires prior conduct of tests on humans in another country before it is done in India, in the case of non-Indian companies. But by remaining ambiguous on the extent of such tests, the law allows pharmaceutical companies to operate through exception. The change in the Drugs and Cosmetics Act, along with India becoming a signatory to WTO for the protection of patents, provided the legal context for harnessing of human capital in yet another context. These actions of the Indian nation-state, to use Rose’s argument, are ‘not a matter of “freeing” an existing set of market relations from their social shackles, but of organizing all features of one’s national policy to enable a market to exist, and to provide what it needs to function’ (Rose, 1999: 141). Nevertheless, the enactment of these laws in India cannot be separated from the pressures of the so-called developed nations and the pharmaceutical companies based in those nations. In a significant way, the expansion of the ‘pharmaceutical empire’ to India was a direct result of the US designation of ‘intellectual property rights protection as a major security issue’ (Cooper, 2003: 56).

These two changes in the Indian law went a long way in guaranteeing the interests of multinational companies in conducting drug trials (as well as drug development research) in India. Pfizer lauded the Indian parliament’s ratification of the new patent law ‘for abandoning “the utopian concept that every invention should be as free as air or water”’. Aaron Smith, writing for CNN, added a note of caution. In Smith’s (2007) article, ‘India’s Elephant in the Room: Weak Patent Laws’; ‘Les Funtleyder, drug
industry analyst for investment research firm Miller Tobak, said the Indian government’s tweaking of patent laws in 2005 was a step in the right direction, but failed to make any tangible changes. It is relevant to note, as a WHO report pointed out, that the WTO agreement enhanced the existing patent regime even in comparison to the so-called developed nations:

The TRIPS Agreement requires WTO members to provide protection for a minimum term of 20 years from the filing date of a patent application for any invention including for a pharmaceutical product or process. Prior to the TRIPS Agreement, patent duration was significantly shorter in many countries. For example, both developed and developing countries provided for patent terms ranging from 15 to 17 years, whilst in a number of developing countries like India, patents were granted for shorter terms of 5 to 7 years. (WHO, 2005)

The New York Times (2005) in an editorial put it more succinctly:

Heavily tilted by multinational and Indian drug makers eager to sell patented medicines to India’s huge middle class, the decree is so tilted toward the pharmaceutical industry that it does not even take advantage of rights countries enjoy under the W.T.O. to protect public health. (‘India’s Choice’, 2005)

Nevertheless, the technology of power within which drug testing is being conducted in India is not feudal or colonial. Multinational pharmaceutical companies have not had a free ride. In 2007, for example, Madras High Court rejected pharmaceutical company Novartis’ patent application for leukemia drug Gleevec. The court argued that the new drug was not significantly different from its earlier version and hence did not need fresh patent protection.³⁴

The Indian nation-state has not been acting simply as an instrument of the capitalist class, even though these Acts/laws are a result of reconciliation of the interests of various international and national drug companies. What is also happening is, as Foucault suggested, ‘not so much the etatization of society, as the “governmentalisation” of the state’ (1991: 103). More specifically, drug testing in India reflects a governmentalization of the Indian nation-state within a particular logic of ‘growth’ which, however, inherently involves instituting states of exception. Even though such a governmentalization does not ostensibly seek or utilize the division of individuals and the population, in practice, by protecting the interests of a particular set of actors, it allows hierarchical mobilization of different social groups. Hierarchical articulation and regulation of neoliberal governmentality has become possible, however, not just because of the enactment of laws in India, but also because of a reconfiguration of the drug trial process itself, which has occurred in relation to laws and regulations in the US. The role of CROs has been crucial in the reconfiguration of the drug trial process.
Drug trials are increasingly carried out by CROs rather than pharmaceutical companies themselves.

According to the clinical-trials information company Thomson CenterWatch, CROs played a substantial role in 64% of phase 1, 2, and 3 clinical studies in 2003 (for about $7.6 billion in contracts), as compared with 28% in 1993 (for $1.6 billion in contracts). (Shuchman, 2007: 1365; see also Mirowski and Van Horn, 2005)

According to a Tufts study published in 2006:

In 2004, leading CROs managed 23,000 phase I–IV clinical trials worldwide, monitoring more than 150,000 clinical investigators, and enrolled more than 640,000 new subjects.35

Nevertheless, contract research for drug trials is of fairly recent origin. It emerged as an industry in the US in the context of certain legal, scientific, and socio-economic transformations (Petryna, 2007a). Kefauver-Harris Amendments of 1962, which ‘mandated that the FDA [Food and Drug Administration] require drug companies to demonstrate the safety and efficacy of a drug before marketing it’, dramatically changed the drug development process (Mirowski and Van Horn, 2005: 508; see also Petryna, 2007a, 2007b; Piachaud, 2002; Rettig, 2000; Shuchman, 2007). It made development and marketing of a drug more rigorous, but in the process also made it expensive and time-consuming. Contract research emerged as an industry in the 1980s and 1990s, in the aftermath of this juridical change in the US and within a broader transformation in pharma practices:

Since the early 1980s and through the mid-1990s, the pharmaceutical industry . . . experienced a period of . . . mergers, acquisitions, internationalisation, consolidation, downsizing and changing regulatory trends. . . . the impact of these changes upon the pharmaceutical industry has been far reaching. Of noteworthy interest has been the emergence of the ‘niche’ service sector comprising Clinical Research Organizations, otherwise popularly known as CROs. (Piachaud, 2002: 81)

The shift in clinical research practices in the 1990s, however, was a result of a reorganization of pharmaceutical businesses as well as a change in the availability of people for drug trials in the western nations such as the US. In the 1980s when the availability of prisoners became limited by law in the US, ‘pharmaceutical companies lost almost their entire base of human volunteers and shifted a good deal of their research elsewhere’ (Petryna, 2007b: 32). ‘Globalizing clinical research’, as Sonia Shah bluntly argues, solved ‘the pharmaceutical paradox that while the average American brings home more than ten prescriptions a year, just 1 in 350 is willing to play guinea pig for new drug testing’ (2003: 29). CROs’ role in clinical research outsourcing has to be understood within this broader context.
CROs’ ‘Taylorist approach’ in harnessing a ‘specific human capital’, which has resulted in their being called ‘data-production sweatshops’, has been indisputably beneficial to the drug development industry (Azoulay, 2003; Shuchman, 2007). CROs, however, changed the drug development business by reconstructing clinical research (Mirowski and Van Horn, 2005). Perhaps the most crucial impact of CROs in clinical research has been in relation to the ethical evaluation process. CROs use independent Institutional Review Boards (IRB), which was permitted by the FDA in 1981 for ethical evaluation of their clinical work. Independent IRBs, unlike local IRBs, which are regulated by the National Institutes of Health, the Office for the Protection of Research Risks and the FDA, ‘only have to conform to FDA requirements’ (Mirowski and Van Horn, 2005: 515). Moreover, as Sonia Shah argues, ‘many of the FDA’s ponderous regulations stop at the border’ (2003: 31). This makes ethical evaluation of CROs’ clinical work not only faster but also flexible and uncertain. Adriana Petryna puts it aptly:

The new clinical trial environments that CROs help to tailor are adaptable, mobile and to some extent, parasitic. . . . Ethics and method are modified to fit the local context and experimental data required. And this ‘ethical variability’ becomes the core value and a presumed course of action in the global testing of pharmaceuticals. (2007b: 23–4)

CROs therefore operate through a ‘state of exception’, particularly in relation to overseas clinical trials, not as a result of suspension of law(s) but because they can utilize variability and uncertainty in the enactment and execution of laws. They are able to do so by locating themselves in a ‘betwixt and between’ zone. Rachel Behrman, the Director of the Office of Critical Path Programs at the FDA, confirmed the existence of such a situation in relation to the CROs. To quote her: ‘CROs are accountable to the FDA, but “it is not clear whether their accountability is through the sponsor or directly to us”’ (as quoted in Shuchman, 2007: 1366).

It would be too simplistic to argue that CROs deliberately violate ethical guidelines (at least in most cases) or that it is not in their interest to follow such guidelines. Jamila Joseph, in her article titled ‘Entering the Contract Research Industry in India’, predicts:

Companies that expend the effort to develop a strong ethical culture in the CRO marketplace in India will be the ones that endure and mature into the India-headquartered Fortune 500 companies of the future. (Joseph, 2008: 313)

Failures in ethical regulation of drug trials are largely a result of hierarchical structuring of neoliberal governmentality within a particular logic of growth, whereby the value of individuals and the population depends upon their potential for ‘capitalization’ in the market.

The Indian state is simultaneously a mobile effect of and a key actor in this rationality of government. For example, India’s Finance Minister, P. Chidambaram, in his speech before the parliament stated that the
objective of the 2007 budget, which also marked the start of the Eleventh Five-year Plan, was ‘Faster and More Inclusive Growth’ (Chidambaram, 2007). The Economic Survey of India, which accompanies the Indian budget, claimed: ‘Putting more people in productive and sustainable jobs lies at the heart of inclusive growth.’ It exhorts: ‘There cannot be inclusive growth without growth itself.’ The Survey adds:

> It is necessary to make the required adjustments in mindsets, economic behaviour, and policy making. It is important to avoid the misconception that inclusive growth by necessity will have to be low growth. (Ministry of Finance, 2007, emphasis added)

It is obvious that the Indian government wants to operate through the conduct of conduct rather than by coercion and force.

But selective and differential operation of neoliberal governmentality becomes obvious soon thereafter. Apart from elucidating some health and education plans for Indian citizens, the Indian Finance Minister declared: ‘To make India a preferred destination for drug testing, I propose to exempt clinical trial of new drugs from service tax.’ He added:

> This exemption from government of India will attract more clinical trial outsourcing as the pharmaceutical sponsors will heavily benefit from the cash outflows on account of their expenses on CRO fees and other variable pass through expenses. (quoted in Barnes, 2007)

Evidently, support for drug trials outsourcing forms an intrinsic element of the human capital centered neoliberal governmentality in India. However, as I argued earlier, the state’s embeddedness in a particular governmental rationality (or rationalities) makes it not just ‘self-aware’ but also ‘blind’. Hence the Indian government is not similarly enthused to provide protection to some other sectors of the economy, such as farming. In 2008, Finance Minister Chidambaram offered what was called a populist or ‘Aam Admi’ (common people) budget. A key feature of the 2008 budget was debt relief to farmers, whose suicides have captured many news headlines but led to little government intervention. Interestingly, when Chidambaram was asked about the farm loans waiver, he did not at first use the language of growth or ‘vitality’ of population (who are potentially a part of India’s human capital) to justify it. He said: ‘I am simply cleaning up accumulated dust, you may say. It is better to clean up rather than allow the dust to accumulate’ (‘Lobby Behind Every Exemption, Admits FM’, 2008). It is evident that protecting the interest and well-being of sections of the population who cannot capitalize themselves and their products in the market is a ‘non-agenda’ within the Indian government’s rationality of growth.

The Indian government has not been blind towards protection of the rights of patients and the regulation of ethics of drug trials, however. The Indian Council of Medical Research (ICMR) in 2000 published elaborate guidelines for the conduct of drug trials in India. The Drugs and Cosmetics
Act of India makes it mandatory for pharmaceutical companies to follow these guidelines. Nevertheless, juridical implementation of these guidelines remains ambiguous. Vasantha Muthuswamy, who as a Senior Deputy Director General of ICMR played a pivotal role in the formulation of these guidelines, defines the role of ICMR thus: ‘we are not a policing authority and we have no legal authority to take action against anybody’ (quoted in Srinivasan, 2005). ICMR’s recommendation that its ethical guidelines be ratified as a law is pending before the Health Ministry of India.

Muthuswamy is well aware of the imbalance in the protection that is available to those conducting drug trials in comparison to those on whom the trials are being conducted. In 2005 she had admitted: ‘Even on paper, only 40 out of 179 ethical committees that are supposed to approve and monitor trials in medical colleges and research institutes today meet prescribed guidelines’ (quoted in Mudur, 2005). Muthuswamy’s suggestion is that ‘[t]he sponsors should set up monitoring committees to ensure the safety of the person undergoing trial and the implementation of the ICMR guidelines’ (quoted in ‘Monitor Clinical Trials’, 2007). It is relevant to note that Muthuswamy’s suggestion implies a privatization of risk management, whereby those who may be potential violators of ethical guidelines are being asked to take care of its monitoring. The state (as well as its allied agencies), which has been aggressive in enacting laws to protect the benefits and risks of drug companies and CROs, seems to have a different approach when it comes to protection of benefits and risks of the people on whom drugs are being tested. This imbalance makes sense, however, if we realize that the market within neoliberal governmentality has usurped the role of public authorities and is expected to regulate not only exchange but also utility.

In significant ways, clinical trials outsourcing operates differently from the management of security threats, of which ‘war on terror’ is the prime motor. Unlike in the case of security threat management, which seeks to deal with any potential risk (and not just the actual ones), the management of clinical trials outsourcing is marked by the way it ignores and even proliferates risks, particularly for the people on whom drugs are being tested. ‘[P]harmaceutical outsourcing reflects’, as Petryna argues, ‘incomplete contracts’. Incomplete contracts, however, not only are ‘structured in situations of uncertainty, leaving room for contingent or opportunistic behaviors and unresolved liabilities’ (Petryna, 2007b: 33). They also differentially and hierarchically structure uncertainty and risk. That is, incomplete contracts are not just responses to uncertainty; they may also deliberately foster uncertainty by differentially and hierarchically allocating entitlements and risks.

A classic case in this regard, which by no means is an exception, has been the tests conducted by Ru Chih C. Huang, a biology professor at the Johns Hopkins University. Huang ‘tested experimental anti-cancer compounds developed at the Biology Department of Johns Hopkins University . . . on 27 patients at the Regional Cancer Centre (RCC) in Thiruvananthapuram’ (Krishnakumar, 2005). Johns Hopkins later sanctioned...
Huang because she had conducted the tests ‘without the approval of a university review board’ (‘National Briefing . . .’, 2001). A faculty committee also found that the compounds were tested on humans without ‘adequate preliminary tests of the drugs on animals’ (‘National Briefing . . .’, 2001). Media scrutiny of the event eventually led to the information that the research was funded by a Minnesota-based start-up company and that Johns Hopkins held a patent for the drug that was tested. Huang ‘expressed hope that “Hopkins could make a profit if the drug [was] brought to the market in four or five years”’ (Krishnakumar, 2001). When asked about possible harmful effects on the patients, Huang did not take any responsibility and stated: ‘I am not clinically involved with the follow-up of these patients. You would need to direct that question to the appropriate physician’ (Krishnakumar, 2005). ‘The new architecture of global governance characterized by legal plurality and overlapping sovereignties has facilitated’, as Shalini Randeria rightly suggests, ‘the game of “passing the blame”’ (2007: 1). Such a scenario, however, is a direct outcome of states of exception created by selective and differential enactment and regulation of laws, which, as I have argued in this article, occurs because the agenda/non-agenda of this neoliberal governmentality is inseparable from differential and hierarchical division of individuals and the population.

Conclusion: Human Capital, Neoliberal Governmentality and ‘Bare Life’

Mr. Chairman, I represent the state of Florida where we have many lakes and natural reserves. If you visit these areas, you may see a sign that reads, ‘do not feed the alligators.’ We post these signs for several reasons. First, because if left in a natural state, alligators can fend for themselves. They work, gather food and care for their young. Second, we post these warnings because unnatural feeding and artificial care creates dependency. When dependency sets in, these otherwise able-bodied alligators can no longer survive on their own. Now, I know people are not alligators, but I submit to you that with our current handout, non-work welfare system, we have upset the natural order. (Daniel Mica, House of Representatives, United States, 24 March 1995)

Recent success of Indian engineers, businessmen, as well as other technically qualified professionals has created an ‘obsession with knowledge and creativity’ not only in the media but also among policy makers. Documents like *India as a Knowledge Superpower* (Planning Commission, 2001) have proliferated and we continually hear the mantra of investing in and harnessing of human capital. Human capital, it is being argued, is key to India’s growing ability to leapfrog into the ‘developed’ world as a ‘knowledge superpower’. The success of Information Technology (IT) professionals, arguably the iconic figure of India’s human capital, has earned India sobriquets such as the ‘back-office of the world’.

These are not stray expressions of a shifting Indian ‘imaginary’, economy and politics. They are reflections of a neoliberal governmentality whose lynchpin is human capital. We have to be careful in categorizing these
changes simply as yet another extension of a commodification process that can be explained through Marxian analytics such as ‘commodity fetishism’ (Marx, 1977). Human capital no doubt acquires value through its fetishization as a commodity. However, it blurs the labor/capital dualism (which is foundational to the Marxian analytic of commodity fetishism). This becomes particularly stark in the threshold case of human capital – people on whom drugs are being tested. The commodity in this case is not a result of any ‘useful’ or ‘productive’ labor/skill (of the patients/people).

Labor/capital and human/material divisions become muddled also because of neoliberalism’s persistent expansion of the economy (or the economic) into the domain of the social. Such an analytic and programmatic exercise not only breaches the economic/social (or material/human) boundary, it also creates an irresolvable tension between ‘rights’ and ‘value’ of people, both of which become dependent upon the market. Moreover, the shifting of responsibility for risk management to individuals/citizens further complicates the terrain of power and rights of people. This tension becomes more complicated because the value of this new capital – human capital – exists and is regulated in a transnational market in which, even though more powerful nations still continue to dictate terms, Indian business managers and government officials are not comprador elites facilitating colonial exploitation; rather, they are competitors for stakes in the world market.

The role of the sovereign/state, in spite of neoliberalism’s aggressive free market stance, is intrinsic to the institution of states of exception. States of exception, however, are instituted not through a threat of death (at least in democratic societies). Most often, as Foucault pointed out, ‘it is the tactics of government which make possible the continual definition and redefinition of what is within the competence of the state and what is not’ (1991: 103). Nevertheless, the role of the state is critical in the creation of states of exception because neoliberal governmentality simultaneously engages in the division of agenda/non-agenda and individuals and the population, even though it is explicitly expressed in relation to the former.

In the case of drug testing, the ‘concentration camp’ is a fundamental biopolitical paradigm. Ethical and institutional reviews of drug trials all over the world invariably take the ‘concentration camp’ as the point of reference. Recently formulated Ethical Guidelines for Biomedical Research on Human Participants by the ICMR states at the outset:

The shocking details of the post Second World War (1939–45) trial of German medical practitioners accused of conducting experiments on human participants without their consent and exposing them to grave risk of death or permanent impairment of their faculties raised grave concern about subjecting human subjects to medical research. (ICMR, 2006: 2)

ICMR’s document adds: ‘Although consent for participation was recorded in 1900, the Nuremberg Code highlighted the essentiality of voluntariness of this consent’ (2006: 2).
The reference to the ‘concentration camp’ is made, however, with the ostensible purpose of having ethical regulation of drug trials in order to protect the lives of patients/people on whom drugs are tested. Drug testing on people, at one level, also represents, to use Nikolas Rose’s phrase, ‘capitalization of vitality’, in the sense that the experimentation is conducted for the sake of preservation of health and vitality of the ‘population’ or society. Moreover, as Rose further argues, ‘no “sovereign” wills or plans the sickness and death of our fellow citizens’ (2007: 58). However, as I have shown in this article, the state/sovereign can capitalize the sickness of its citizens through juridico-political interventions.

Drugs that are being tested in India (as well as other non-western societies) are rarely for the health and vitality of the people on whom these tests are being conducted. ‘Globally, only 1 percent of the new drugs discovered in the past 25 years have been for tropical diseases’ (Nundy and Gulhati, 2005: 1635; see also Petryna and Kleinman, 2006). The people on whom drugs are being tested know what returns they get from their investments in ‘capitalization of vitality’. For example, Mahesh, who volunteers for drug trials, stated: ‘So far no drug has had an adverse impact on my health. I will continue to do this for the money I get’ (Special Correspondent, 2005b). His friend, who also volunteers for drug trials, added that ‘the 111 dollars he would be paid for testing the drug on himself for 48 hours is more than his monthly takings’ (Special Correspondent, 2005b). In other words, the inducement to be a part of ‘capitalization of vitality’ is largely because of the benefits resulting from their ‘capitalization as humans’ (i.e. as human capital), which, however, is inherently circumscribed because these people do not constitute ‘productive assets’ beyond the arena of drug testing.

I am not arguing that ‘politics of life’ (and ‘capitalization of vitality’) is not central to present-day biopolitics. We have to analyze, however, how the rationalities of government are layered and hierarchically differentiated. We have to be careful in dealing with ‘circuits of exclusion’ so as not to make such exclusions either mere exceptions to a broader governmentality or sacrifices in the name of a greater good. Giorgio Agamben’s cautionary intervention in the debate over politics of life (and death), in an era of biopolitics that is being fruitfully analyzed through concepts such as ‘biosociality’ (Rabinow, 1996), ‘biological citizenship’ (Rose, 2007), ‘experimentality’ (Petryna, 2007a) or ‘cyborg’ (Haraway, 1991), is certainly useful in this regard.

The implications of analyzing states of exception as intrinsic to governmentality are profound, not just for theoretical or academic reasons but also for policy concerns. Ethicality of drug trials cannot be narrowly focused around the issue of informed consent. The problematic of how to make the people on whom drugs are being tested receive juridical, social and economic protection against unethical exploitation has to be seen in a broader context. Informed consent would largely provide legitimacy to the architecture of power that I have analyzed in this article, without disturbing its hierarchical institution and operation. In order for it to be truly
effective, the ethicality of drug trials has to be seen as inseparable from the politization of ‘bare life’ within neoliberal governmentality.

Acknowledgement
I would like to thank Adele Clark, Brian Dolan, Sarah Hodges, Jonathan Xavier Inda, Srirupa Prasad, and the anonymous reviewers for their comments and suggestions.

Notes
1. Latour’s call for freeing the ‘multitude’ or the ‘mass’ (of non-humans as well as humans) has created a lively debate in relation to human/non-human dualism. Paolo Palladino appreciates Latour’s contribution in this regard, but adds: ‘Latour overlooks how the demos already constituted a political order, which excluded women, slaves, and foreigners’ (2003: 330).
2. In a similar vein, David Harvey has argued that ‘[n]eoliberalization has meant, in short, the financialization of everything’ (2005: 33).
3. Drug trials in India as well as in other non-western societies often evoke charges of a new colonialism. See, for example, Nundy and Gulhati (2005); see also Srirupa Prasad quoted in Carney (2005).
5. There is a rich body of studies that analyze the genealogy and impact of neoliberalism; see, for example, Barry et al. (1996), Harvey (2005), Ong (2006), Pieterse (2004), Portes (1997).
6. According to Foucault, ‘one would have to speak of bio-power to designate what brought life and its mechanisms into the realm of explicit calculations and made knowledge-power an agent of transformation of human life’ (1990: 143; see also Rose, 2007). Giorgio Agamben, focusing on what he calls the ‘hidden point of intersection between the juridico-institutional and biopolitical models of power’, argues that threat and decision of death are central to the western polity and metaphysics (Agamben, 1998: 6). Achille Mbembe (2003), instead of using ‘threat of death’ to define the concentration camp as the paradigm of modern politics, develops a broader analytical framework of biopolitics, which he calls necropolitics.
7. According to Foucault, with the emergence of bio-power, ‘[f]or the first time in history . . . biological existence was reflected in political existence’ (1990: 142).
8. This was true even in the mid-18th century. A particular limitation of Foucauldian analysis of biopolitics is that it does not see the emergence of biopolitics in Europe as intertwined with colonial practices outside Europe. Several studies have highlighted how empire/colonialism was intimately tied to the emergence of the nation-state (e.g. Kumar, forthcoming) and in the regulation of individuals and the population in Europe (e.g. Weber, 1976).
9. According to Agamben, ‘The exception is what cannot be included in the whole of which it is a member and cannot be a member of the whole in which it is always included’ (Agamben, 1998: 25, emphasis in the original). Aihwa Ong conceptualizes exception more broadly and analyzes ‘the hinge between neoliberalism as
exception and exception to neoliberalism’ (2006: 5). Mbembe (2003) further expands the states of exception by highlighting ‘necropolitics’ in the cases of slavery, colonialism and even suicide bombing. Caroline Best, in her analysis of new global order, argues that ‘[t]he economy is perhaps the ultimate sovereign exception: it is an exception to the rule of sovereign power itself’ (2007: 101).

10. Most often there would be a range of visibilities and invisibilities (rather than just two opposed poles) in terms of agendas and non-agendas of governmental rationalities.

11. For Agamben the ‘state’ or the ‘law’ are not effects of governmentality (or governmentalities), but rather the nodes that create states of exception. We have to be careful here with regard to Agamben’s analysis of the relation of the state or the law to government, because he also dissolves a dualist separation between inclusion and exclusion and defines the location and the role of the state as that of exclusive-inclusion.

12. Agamben, drawing on Aristotelian distinction between zoe (living) and bios (living proper to an individual or group), argues that ‘the production of a biopolitical body is the original activity of sovereign power’ (1998: 6). As a result, as he further argues, power and bare life are united.

13. This situation itself can be (and often is) attributable to market prospects. For example, Nova Nordisk and Merck are planning to expand their diabetes ‘drug discovery and manufacturing presence in India’ because, according to them, ‘India is one of the world’s largest market for insulin products’ (see http://www.outsourcing-pharma.com/news/ng.asp?n=83321-novo-nordisk-merck-india, consulted February 2008). One way to look at this emerging scenario is that as India becomes a bigger market for drugs, more research will be tuned towards the health of Indians. This surely makes the west/non-west divide more muddled. However, and I think more importantly, this situation continues to point towards the operation of neoliberal capitalism through inclusive-exclusions.

14. Estimates of cost of drug testing vary significantly. One estimate puts the average cost at $802 million (Mirowski and Van Horn, 2005).


16. This quote is from URL (consulted April 2007): www.quintiles.com/Corporate_Info/Regions/south_africa_and_india/India/India.htm. Quintiles has since reorganized its website.


18. In the case of drug testing, unlike prostitutes, boxers, models, etc., it is not the body but the disease that is ‘commodified’. The people on whom drugs are tested are exploited not because they possess unequal ‘capital’, as for example Loïc Wacquant (2001) shows for boxers. Moreover, unlike kidney (or other body parts, blood, semen, etc.) ‘donors’, they do not possess body parts or body products that have any ‘use value’ except in the context of drug testing.

19. This is a common argument. See, for example, Balakrishnan and Sharma (2004).
20. See URL (consulted April 2007): www.quintiles.com/Corporate_Info/Regions/south_africa_and_india/India/India.htm. Quintiles has since reorganized its website and the cited data and web-link is no longer locatable. I have a copy of an earlier web display from where I have cited.


22. See URL (consulted February 2008): http://www.igatecr.com/services/. iGate, which started as DiagnoSearch (a clinical trials management company) in 1997, has now diversified. iGate group now includes iGate Corporation, MASTECH, iGate Clinical Research and RPO worldwide. In 2003, iGate Clinical Research was created after iGate acquired Pittsburgh Clinical Research Network and a majority of DiagnoSearch.


24. From June 2008 Daiichi Sankyo Company Ltd., a Japanese pharmaceutical company, has been the majority stakeholder of Ranbaxy.


26. In a similar vein, though at a slightly different level, Saul Tobias argues: ‘For those detached from the circuits of effective social interactions by virtue of their economic and physical condition . . . the capacity to creatively reshape one’s life may be diminished to the point of inconsequence’ (2005: 82).

27. According to Kaushik Sunder Rajan (2005), the people in Mumbai who are offering themselves for drug trials are most often the ones who have lost their jobs because of the closure of textile mills.

28. Couze Venn argues that pastoral power does not apply in relation to European colonies. He uses the concept of imperial governmentality to analyze power and hegemony in the colonial context (Venn, 2000, 2007). He also argues that recent developments in global corporate capitalism reflect a similar combining of colonial (feudal) power and governmentality (Venn, 2007).

29. Foucault has been criticized by scholars such as Pierre Bourdieu because of his ‘tendency to describe statements only on the basis of their formal characteristics, independently of their content and genesis’ (Callewaert, 2006: 96).

30. According to this amended Act, the procedures for the conduct of clinical trials for ‘New Drug/Investigational New Drug’ are:

(a) human clinical trials (Phase-I) on a new drug shall be made to the Licensing Authority in Form 44 accompanied by a fee of fifty thousand rupees [around $1200] and such information and data as required under Schedule Y; (b) exploratory clinical trials (Phase-II) on a new drug shall be made on the basis of data emerging from Phase-I trial, accompanied by a fee of twenty-five thousand rupees [around $600]; and (c) confirmatory clinical trails (Phase-III) on a new drug shall be made on the basis of the data emerging from Phase-II and where necessary, data emerging from Phase-I also, and shall be accompanied by a fee of twenty-five thousand rupees [around $600].
31. According to Agamben: ‘[o]ne of the paradoxes of the state of exception lies in the fact that in the state of exception, it is impossible to distinguish transgression of the law from execution of the law’ (Agamben, 1998: 57).

32. According to Michael Hardt and Antonio Negri, the present world order represents an empire with ‘no territorial center of power’. Moreover, as they further argue, this empire ‘does not rely on fixed boundaries or barriers’ (2001: xii). Drug trials outsourcing clearly shows that center(s) of power as well as boundaries, even though overlapping at times, are still locatable (see also Cooper, 2008).


34. Novartis ‘warned that the ruling would discourage investments in innovation and would undermine drug companies’ efforts to improve their products’ (Gentelman, 2007).


36. ‘Compared with independent IRBs, local academic IRBs have more lengthy mean approval times: 37 versus 11 days’ (Mirowski and Van Horn, 2005: 515).

37. Melinda Cooper (2008), based on her analysis of handling of AIDS in South Africa, argues that the management of the AIDS epidemic is intimately tied to and intertwined with the management of security threat by the US.

38. For an analysis of the biopolitics of security threat, particularly in the context of management of disease, see Braun (2007) and Cooper (2006, 2008).

39. The theory of incomplete contract has generated a lot of interest among economists. ‘A typical model in that literature [of incomplete contracts] goes as follows. A buyer and seller meet initially. Because the future is hard to anticipate, they write an incomplete contract. As time passes and uncertainty is resolved, the parties can and do renegotiate.’ However, renegotiation leads to unequal sharing of benefits. As a result, ‘each party underinvests ex ante’. ‘The literature studies how the allocation of asset ownership and formal control rights can reduce this under-investment’ (Hart and Moore, 2008: 2).

40. Risk can be differentially distributed also because, as Lisa Adkins points out in her analysis of sexual hierarchies, ‘those who are able to claim self-reflexivity are able to claim their selves as “safe”, while those defined unable adequately to take on technologies of the self are deemed to be “at risk” and “risky”’ (2001: 52).

41. Imbalance in sharing of benefits in the theory of incomplete contracts is seen as a result of renegotiations in the context of changed circumstances and not inherent in making of the contracts. Hart and Moore, however, allude to some such cases. They write: ‘the model may throw light on the role of courts in filling the gaps in incomplete contracts. The idea is that a contractual term provided by the parties may affect entitlements, whereas one provided by an outsider – the courts – may not’ (2008: 19).

42. The Office of Human Research Protection’s review of Dr Huang’s action admits that several other administrators and faculty of Johns Hopkins University either knowing or unknowingly did not act on this matter until reports of mal-conduct by
Dr Huang started to appear in the Indian newspapers. This report is available on the web, URL (consulted May 2009): http://www.dhhs.gov/ohrp/detrm_letrs/YR02/nov02b.pdf

43. According to Nigel Thrift, three developments are redefining what counts as value, one of which is ‘obsession with knowledge and creativity’ (2006: 282).

44. There is a significant change in perspective about India’s population. India, for example, is no longer (at least not merely) referred to or seen as a ticking ‘population bomb’. This stands in contrast to India’s own policies in the past. For example, the National Population Policy of 1976 had succinctly stated: ‘The very increase in population makes economic development slow and more difficult of achievement . . . we have to get out of this vicious circle through a direct assault upon this problem’. A growing population is still considered detrimental to India’s development, but this concern is overshadowed by the celebration of the Indian human capital.

45. The reference to India as the back-office of the world is quite common. See, for example, Outsourcing to India: Crouching Tiger Set to Pounce (Deutsche Bank Research, 2005).

46. According to Coronil: ‘[t]he treatment of people as capital leads to their valorization strictly as a source of wealth’ (2001: 77). Sunder Rajan (2006) shows that the patients on whom drugs are being tested are often the workers who have lost their jobs because of the closure of textile mills. Hence, following Marx, one can argue that ‘division of labor converts the product of labor [though in the case of drug testing it is the product of loss of labor] into a commodity’ (Marx, 1977: 203; see also Sunder Rajan, 2005).

47. According to Marx, ‘use-value . . . has value only because abstract human labor is objectified or materialized in it’ (1977: 129). It can be argued that if we consider skill or knowledge as products of abstract labor and their possessors as ‘guardians’ of these commodities, the labor/capital dualism continues to hold in the case of human capital too. However, we have to be careful because neoliberalism does not simply lead to expansions of capital and commodity, but also to their paradigmatic transformation. American neoliberalism, as Foucault points out, redefines wage as ‘the income allocated to a certain capital’, which has to be called human capital because ‘income cannot be separated from the human individual who is its bearer’ (2008: 226). Also see Becker (1962, 1964), Mincer (1958, 1974), Shultz (1961).

48. Foucault in his commentary on neoliberalism at the University of Chicago has rightly suggested: ‘their consistent expansion of the economic form to apply to the social sphere . . . [elides] any difference between the economy and the social’ (Lemke, 2001: 197; see also Gordon, 1991, esp. 41–4). Gary Becker, arguably the best-known proponent of Chicago School neoliberalism and the concept of human capital, stated explicitly in his Nobel Lecture that he utilized ‘the economic approach to analyze social issues’ (Becker, 1993: 385).

49. The implication of this shift in risk management within neoliberalism is very profound. As Pat O’Malley, following Aharoni, points out:

    . . . risk is by no means to be understood as indicative of an imperfectly governed world. Rather, risk is a source or condition of opportunity, an avenue for enterprise and creation of wealth, and thus an unavoidable and invaluable part of a progressive environment. (1996: 204)
50. According to Agamben: ‘It can even be said that the production of a biopolitical body is the original activity of the sovereign power. In this sense, biopolitics is at least as old as the sovereign exception’ (1998: 6, emphasis in the original).

51. It is quite ironic how the illegal kidney trade in India has occurred against the backdrop of India’s Human Organ Transplantation Act of 1994, which allows organ donation to immediate relatives (father, mother, brother, sister). It also allows organ donation in cases where there is emotional attachment. Lawrence Cohen (2005) has analyzed how the illegal kidney trade in India operates through a state of exception. It is interesting that, in the light of a recent expose of an illegal kidney trade racket in India, the efficacy of the state in operating through exception is being questioned. P. Ravichandran, the director of Madras Institute of Nephrology, for example, states: ‘The choice before us is not between buying and not buying organs. This is happening regardless of the law. The choice is whether transplant operations and the sale of organs will be regulated or not’ (as quoted in Chopra, 2008).

52. Stefan Ecks (2006), following Lemke’s analysis of Foucault’s commentary on neoliberalism, argues that ‘normalization’ may not be useful in analysis/understanding of neoliberalism because neoliberalism operates through differentiation rather than normalization.

53. Rose utilizes Catherine Waldby’s concept of ‘biovalue’, which she used ‘to characterize the ways that the bodies and tissues derived from the dead are redeployed for the preservation and enhancement of the health and vitality of the living’, as an illustration of ‘biovalue as the value to be extracted from the vital properties of living processes’ (Rose, 2007: 32). In Waldby’s study the capitalization of biovalue is occurring by utilizing ‘vital’ properties of the dead for living beings: the dead are a part of the living, to use Agamben’s concept of inclusive-exclusion.

54. As Scott Lash suggests: ‘Foucault’s idea of pouvoir or knowledge-pouvoir describes a shift from an era when such power is basically mechanistic to one in which power is vitalistic’ (2006: 325).

55. To an extent such a scenario exists for people on whom drugs are tested in the West too. For example, in the 1970s prison inmates were prime targets for drug testing in the US (Petryna, 2007b). It is telling that the outsourcing of clinical trials coincided with the banning of clinical trials on prison inmates in the US.

56. According to the World Health Organization: ‘less than 10% of global spending on health research was devoted to 90% of the world’s health problems – a misallocation that has come to be known as the “10/90 gap”; see URL (consulted February 2008): www.who.int/entity/alliance-hpsr/resources/ModuleII_U1_IntroductionV2.pdf

57. In the context of drug testing in low-income countries, Veena Das (1999) criticizes both individualistic and simple communitarian models of bioethics. She instead calls for a reconfiguring of ‘the notion of health as a public good (both global and national)’ so as to shift the focus on questions of equity and justice.

References
Prasad – Biopolitics of Drug Trials in India


Special Correspondent (2005a) ‘Dr Reddy’s Starts Trials for New Drug’, *The Telegraph* (Calcutta, India) 8 February.

Amit Prasad is an Assistant Professor in the Department of Sociology at the University of Missouri-Columbia. His research focuses on transnational, global and postcolonial aspects of science, technology and medicine. [email: prasada@missouri.edu]