Chapter One

TOWARDS A SOCIOLOGICAL UNDERSTANDING OF THE NOTION OF DRUG QUALITY: A REVIEW DISCUSSION

The last two centuries have witnessed the gradual transformation of drugs or pharmaceuticals from products manufactured through the art and expertise of individual practitioners or physicians to objects, which are mass produced in a laboratory and industrial environment, shaped by the complex alliance of the scientific, medical, business and regulatory spheres.¹ Drugs or pharmaceuticals lie at the intersection of different worlds, ranging from the technical or industrial, the commercial, the medical and the legal to the world of their consumers or users. They are constituted by different interests-technical, economic, social and political- and undergo several transformations in their journey from bench to bedside. As ‘chemical’ substances, they have the potential to bring about physiological changes in human bodies, as ‘social’ products and ‘ritual’ symbols, they assist with healing and provide comfort, as ‘commodities’ they shape market interests and as ‘political’ objects, they mould policy and funding concerns at local, national and international levels. Drugs may thus be understood as a social and cultural phenomenon with their own unique biography or life cycle. This life cycle encompasses different stages ranging from their synthesis and development in a laboratory, commercial production, prescription and marketing, consumption and efficacy. Each stage in this life cycle may be

¹ See Gaudillere, 2005.
understood as being characterized by its own context, set of actors, norms and ‘regime of values’.2

The notion of drug quality may be examined in the context of this unique biography or life cycle that drugs undergo, the diverse interests, norms and values that they embody and the complex worlds that they constitute. Notions about drug quality figure prominently in the discourse of firms, regulatory bodies, physicians, health activists and consumers alike, either in the context of research and development strategies, clinical trials, manufacturing related protocols, prescriptions of medical practitioners, marketing strategies and pronouncements of activists and government departments in relation to health policy. The discourse of drug quality, in this sense, may also be understood as being shaped by a multiple set of actors ranging from firms, regulatory bodies, physicians, pharmacists, health activists and consumers3.

However, before embarking on a outlining of the research questions specifically taken up in this study, it would be pertinent at this point to provide an exposition of theoretical perspectives and studies that this research project draws upon in its attempt to problematize and unpack the notion of drug quality in the Indian pharmaceutical industry. In this context, the present study draws upon perspectives and studies, specifically on pharmaceuticals, from sociological and anthropological traditions in addition to certain key concepts from the body of sociological theory, Science, Technology and Society Studies (STSS), Public Health related literature and a few studies from the relatively larger corpus of economic literature on pharmaceuticals4.

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3 ibid.
4 The works of van der Geest et al. 1996 and van der Geest 1984, 2007; Williams et al 2008, involving a monograph of eight sociological studies on diverse themes related to pharmaceuticals; Abraham, 2007, 2008; and Busfield, 2006,
The notion of drug quality, in the sense of articulating the discourse of drug quality deployed by different actors involved in the life cycle of drugs in general, has till date not been a subject of sociological or anthropological investigation. However, in the last two decades, there have been a few attempts by sociologists to examine issues related to the increasing medicalization and pharmaceuticalization in the society, the growing and largely unregulated consumption of drugs and to understand issues related to pharmaceutical innovation, marketing and regulation.

This chapter has been structured into five sections. The first section attempts to sum these above-mentioned few studies of drugs or pharmaceuticals, which fall in this relatively unmapped territory, in the history of sociological and anthropological research. The second section focuses on the body of literature pertaining to the specific histories of pharmaceutical firms, trajectories of contested drugs and studies on the controversial aspects of drug regulation, carried out within the theoretical tradition of Science, Technology and Society Studies (STSS), in the last two decades. This is not to suggest that there has been no overlapping of these theoretical traditions. Drugs constitute ‘boundary’ objects, which overlap heterogeneous worlds, and the therefore, the very nature of the field necessitates and has also witnessed several interdisciplinary investigations. The third section discusses

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5 Within the body of economic literature on pharmaceuticals in India, there have been attempts to understand the notion of drug quality as perceived by the firms. (See Upadhyay et al 2002 and Ray & Bhadhuri 2003). Reference has been made to these studies in the fourth section of the chapter.

6 This chapter clubs together sociological and anthropological studies on pharmaceuticals, partly because such studies have liberally borrowed methodological strategies and theoretical orientations from each other. This is particularly true of the Indian context. The few studies by Indian scholars, mostly related to the sphere of traditional medicine, have also been examined in the first section.


8 Studies combining perspectives from the general body of sociological theory and STSS traditions and similarly those attempting to link the terrain of anthropology of science and technology with the terrain of economic sociology have been mentioned in the sections on anthropological/sociological perspectives on pharmaceuticals and STSS engagements with the terrain respectively.

9 Gaudilliere, 2005.
the body of literature, explicitly dealing with Public Health concerns, both in the international context as well as in the context of the Indian pharmaceutical industry. Studies of the pharmaceutical industry by economists may be categorized as generally falling under the themes of ‘economics of technological change’ and ‘innovation studies.’ In the Indian context, the pharmaceutical industry has typically provided grist for the economist’s and management expert’s mill. Section four attempts to summarize the insights provided by such studies, in terms of their potential to enrich sociological and anthropological understandings of pharmaceuticals in the Indian context. The fifth and last section discusses the central research questions of the thesis and concludes with a brief account of the sequential ordering of the chapters in the thesis.

**Anthropological/ Sociological Engagements with Pharmaceuticals**

Anthropological studies of pharmaceuticals by Western scholars were relatively scarce, till the eighties. These earlier studies were essentially critiques of medicalization and the dumping of medicines by multinationals in the developing countries. (Harden et al. 1991 as cited in Van der Geest et al. 1996: 154). Public health and particularly the World Health Organization’s thrust on ‘essential’ drugs stimulated a resurgence of interest in the policy implications of earlier anthropological studies and initiating of new studies on the use of medicines in these countries. Though these studies were inspired by the ‘exotic’ appeal of the non-Western settings, they were also significant in terms of documenting the every day practices and local realities in which medicines were marketed and consumed, the marketing of drugs through formal and informal channels, the growing trend towards self-medication and the meanings attached to Western biomedicine in these societies. (Sachs, 1989; Nichter, 1980; Sachs and Tomson, 1994; Sacks 1976, as cited in Van der Geest et al 1996: 155).
These studies also triggered a fresh look at Marxian perspectives by examining the transnational flow of pharmaceuticals as commodities, impacted by the dual processes of globalization and localization (Appadurai, 1986; Douglas and Isherwood 1979; Benoist 1989/1990; Lefevre 1991 as cited in Van der Geest et al 1996: 155).

The anthropological emphasis on the biography of drugs in the last two decades owes much to the contribution of Van der Geest et al (1996, Geest 1994, 2007). In their elaborate and detailed review discussion paper, they not only took stock of the nature of prior anthropological engagements with pharmaceuticals but their work also attempted to outline a theoretical and methodological agenda for the examination of the transactions and meanings of pharmaceuticals in terms of the life cycle or multiple stages and transformations-production and marketing, prescription, distribution, use and efficacy - they underwent, the different sets of actors-scientists, firm personnel, health professionals, pharmacists, consumers etc- who engaged with them in each stage, the varied social worlds they inhabited in this process and the different ‘regime of values’ (Appadurai, 1986) they embodied in each stage.10

In the course of identifying research themes dovetailing with each of these biographical life stages, the paper also strung together an interesting conglomeration of ideas. This involved an emphasis on understanding the unique nature of drugs as ‘technical devices and cultural symbols’11; the need to capture the perspective of drug manufacturers in terms of their everyday practices and routines; the scientists’ and firm employees’ attempts to ‘concretize’ their knowledge about pharmaceuticals into industrial activities, social

10 ibid:153
11 Ibid:156
relationships, claims about safety and efficacy of their products and marketing strategies\textsuperscript{12}; the ‘metonymic’ significance of prescriptions as a vehicle of communication, income and control and the interplay of biomedical, social and cultural rationalities in shaping prescription practices of physicians and health professionals\textsuperscript{13}; the “pharmaceuticalization” and “commodification” of health and health care\textsuperscript{14}; the role of self-medication and patient compliance in shaping ‘efficacy’ related notions of drugs\textsuperscript{15}; notions about efficacy and side effects of drugs as a cultural construction with both biological and social dimensions\textsuperscript{16} and the need for a detailed ethnographic examination of the cultures of industrial research and development on pharmaceuticals and ‘reinterpretation’ of drugs in localized settings\textsuperscript{17}.

Anthropological engagements with pharmaceuticals have also focused on the links between medicines and processes of social transformation in terms of the ideology they embody, their latent power and ability to change perceptions of health and construct illness identities, mark social values and relations and simultaneously empower and render dependant their consumers. (Nichter & Vukovic, 1994 as cited in Geest, 2007:303).

In addition to all these dimensions, particularly in recent times, anthropological inquiry into pharmaceuticals has also preoccupied itself with themes such as the dynamics of evidence-based medicine or evidence-based health care, the contribution and potential of anthropological critiques on political economy of health studies and ethical challenges posed by clinical trials on human subjects. Lambert’s (2006) study on the set of practices and techniques for the appraisal and clinical application of research evidence, known in medical

\textsuperscript{12} Ibid: 157. This deficiency has been remedied to a considerable extent by historians and sociologists of science in their engagements with drugs and medical devices in the last two decades. These studies have been mentioned in the second section.
\textsuperscript{13} Ibid: 158-59.
\textsuperscript{17} Ibid: 169-170.
parlance as evidence-based medicine (EBM), is particularly interesting as it highlights how certain notions of evidence in clinical practice are implicit in EBM itself. In particular, it highlights the overweening emphasis on quantitative and particularly epidemiological definition of evidence used in EBM and the neglect of patient narratives and social structural, cultural, political and economic dimensions in descriptions of research evidence as represented within EBM. Her observations on the critical role of anthropological and other qualitative social scientific descriptions in contributing to the evidence base of EBM is, however, tempered with the caveat that such studies need to also re-engage with dicey questions regarding the validity and plausibility of anthropological knowledge claims and ethnographic accounts.

Political economy of health studies has traditionally subsumed three theoretical strands: Marxist approaches, cultural critiques of medicine and dependency theories. Recent anthropological engagements with such studies, while being empirically grounded in the local context, have also strived for a more macro analytical approach, thus laying the foundation for a more ‘critical’ medical anthropology. Clinical trials involving human subjects are an essential ‘rite of passage’ in the life cycle of drugs and pharmaceuticals in general. Anthropological studies on pharmaceuticals and medicine in the last decade have also begun to evince a greater interest in the ethical dilemmas involved in clinical trials, the functioning of institutional ethics committees (IEC) and institutional review boards (IRB) and the methodological challenges that such studies pose for cultural anthropologists. To cite an example: such studies have critiqued the legalistic rendering of informed consent rules by the IECs and IRBs without taking into consideration local and cultural aspects related to nature and context of the research project, communication issues involving

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comprehension of information and the nature of the research by the participants, social positioning of individuals within families, institutions and communities etc (Kaufert and O’Neil, 1990; Kaufert and Putsch, 1992; Marta, 1996; Kuczewski and Marshall, 2001 as cited in Marshall 2003). Moreover, these accounts have also stressed on how attempts by anthropologists to draw out these latent elements through methods such as structured or unstructured interviews, ethnographic participant observation, oral histories or analyses of existing data sets have generally met with resistance by the regulatory authorities19.

A more recent and important anthropological perspective into the world of pharmaceuticals, actually attempts to carry forward Geest’s formulations on the biography or life cycle of drugs.20 In delving into the different stages of this biography, the volume highlights themes as diverse as firms’ easy access to participants for clinical trials in developing countries, the disease mongering strategies deployed by firms such as soliciting of ‘ghost writers’ to pen scientific articles and the sponsoring of scientific symposia and literature collection to create a receptive market in advance for new drugs, the use of audit data by firms as a means of regulating expertise and constituting the market as a domain of practice and the vagaries of self-medication, reinforced through informal channels of pharmaceutical marketing.21

In the context of sociological preoccupations with pharmaceuticals, a very recent and comprehensive review discussion22 observes that sociologists’ engagements with

19 ibid
21 These themes and findings are, however, not exclusive to anthropological perspectives and have also been taken up and highlighted in sociological and public health studies, in addition to studies by historians and sociologists of science. The implication of these findings in terms of the wariness displayed by firms towards ethnographic investigation of their settings is an issue, which would be taken up in the chapter on methodology.
22 Williams et al 2008. These four themes along with the studies included in their monograph and a few other studies have been invoked only for the purpose of providing a structured account of the relevant literature in the first section. Several
pharmaceuticals have primarily devolved around the themes of medicalization and pharmaceuticalization, regulation, consumption and consumerism and expectations and innovation. The term ‘medicalization’ has been traditionally been deployed by sociologists in a value-neutral sense as the transformation of something into a medical matter\textsuperscript{23}. Studies of health and illness, in the seventies pointed to the increasing authority assumed by biomedicine in the social construction of disease and its treatment\textsuperscript{24}, with the role of the pharmaceutical industry receiving marginal attention, save for a sole study by Illich\textsuperscript{25}, which focused on the side effects of drugs but reserved its critique for ‘over reliance’ on drugs and medical practitioners. In the early eighties, Braithwaite came out with a blistering critique of fraudulent practices, including negligence and bribery, of pharmaceutical firms with respect to drug safety testing.\textsuperscript{26} His later work (1993), which highlighted the internationalized nature of corporate crime in the pharmaceutical sector, is extremely relevant in terms of demonstrating how organizational complexity within the firm is more contrived than inherent, the subtle and sophisticated forms of law evasion practiced by firms in terms of dumping of substandard drugs or unapproved drugs in developing countries and well-orchestrated strategies pertaining to clinical testing involving the identification of different and strategic locations for early testing, marketing and final approval. Braithwaite essentially emphasized on a legal-pluralist transnational framework, grounded in consumer and professional activism and stringent regulatory control at local, national and international


\textsuperscript{24} Zola, 1970; Freidson, 1970; Conrad and Schneider, 1980 \textit{ibid}: 814.

\textsuperscript{25} 1975 \textit{ibid}: 814.
levels, in addition to harmonization of regulatory standards on pharmaceuticals to prevent misconduct by pharmaceutical firms.\textsuperscript{27}

Going back to the issue of medicalization, a few studies have highlighted how, in the present context, while the definitional centre of medicalization remains with physicians and health care professionals, the industry constitutes one of its primary drivers (Conrad 2005, 2007, Conrad and Leiter 2004 as cited in Williams et al 2008). Other studies (Moynihan 2002, Moynihan and Henry 2006) have been more stridently critical of the industry and asserted that rather than the notion of ‘medicalization’, notions such as ‘pharmaceuticalization’ and ‘disease mongering’ may be more valid in the present context, given the growing use of pharmaceuticals for diverse purposes which extend beyond the realm of the medical in the society.\textsuperscript{28}

These critiques have highlighted how the industry deploys several strategies which include utilizing physicians, health care professionals, media, academicians, other pressure groups and even consumers to skillfully manufacture new ‘diseases’ instead of drugs and taking recourse to direct-to-consumer advertising to market its products.\textsuperscript{29} In this process, the media, academicians and even consumers have also emerged as key players in shaping both celebratory and critical discourse on drugs depending upon its newsworthiness and in the drive towards medicalization. These studies also point how direct to consumer


\no{\footnote{Many of the law evasion strategies by pharmaceutical firms identified by Braithwaite persist till date and are particularly useful in understanding firm and sector level dynamics in the Indian context. However, subsequent studies by sociologists on the industry have amply demonstrated how misconduct by some pharmaceutical firms have become more subtle and sophisticated, how firms have successfully captured regulatory space and how they attempt to shape regulatory protocols in accordance with their agendas. These have been invoked in the course of the section. Also, the harmonization of regulatory standards on pharmaceuticals to curb misconduct by firms may not as unproblematic as Braithwaite makes it out to be.}}

\no{\footnote{Ibid: 816.}}

\no{\footnote{The example of ‘erectile dysfunction’ disorder is commonly cited by sociologists and public health scholars in allusion to ‘disease mongering’ efforts of pharmaceutical firms. Marcia Angell in her much debated book ‘The truth about the drug industry: What pharmaceuticals firms do and what to do about it’ reveals how the advertisements for drugs for ‘erectile dysfunction’ targeted not only males suffering from impotence but healthy males who had had an occasional spell or even one episode of impotence.}}
advertising has extended the relationship between drug companies, physicians and consumers in ways that are a rehearsal of the early twentieth century period when drug companies had a more direct relationship with consumers.\textsuperscript{30}

In this context, Sismondio (2004), emphasizes on the need for studies of the industry to distinguish between genuine research and commercial promotion and in the process, define a terrain in which medical practitioners, firms and regulators and consumers can clearly distinguish between ethical and unethical practices, in an environment where pharmaceutical firms often present prospective authors with draft versions of their research to ensure favourable reports. The points he raises in this process pertain to the issue of medicalization itself, first, in terms of its examination being confined largely to the politics of the medical profession as it seeks to take control of problems and lives of disempowered patients and to some extent with respect to the economics of the health care sector and secondly the relatively scant attention paid to the processes by which economic interests actually shape medical knowledge and discourse. Another important dimension he highlights pertains to the role of research in the pharmaceutical firm.

Research for pharmaceutical firms is sometimes part of their marketing efforts as firms may carry out research not only to demonstrate, increase or fine tune the effectiveness of their products but also to increase brand recognition. From the point of view of the authors of ghost-written papers, research is also part of marketing in that it contributes to their efforts to market themselves. Among other things, this argument puts a very different light on pharmaceutical companies’ standard argument that they need extra patent protection to cover the extensive costs of drug research.\textsuperscript{31}

Similarly, Fishman’s (2004) study highlights the crucial role of clinical trial researchers as mediators between pharmaceutical companies and patients in the context of

\textsuperscript{30} See 14: 814-16.
\textsuperscript{31} Ibid: 152.
the commodification of female sexual dysfunction (FSD), a medical condition under construction and an open terrain where claims are staked through alliances between researchers, companies and clinicians in the process of the defining of the condition requiring treatment and validation of treatments for that condition. What is interesting about her work is the examination of medicalization as a feminist issue.

Rasmussen’s study (2004), in examining the burgeoning intimacy of firms with academia, highlights how the invoking of science and the utilization of scientific connections by pharmaceutical firms for rhetorical purposes thrived on the internal competition among academicians in research areas which were cutting edge, intellectually exciting and at the same time held tremendous economic promise. Healy’s (2004) expose of ghost writing in the pharmaceutical industry is essentially an insider’s account of pharmaceutical firms’ subtle and often hidden hand in influencing the production of favourable accounts of their drugs, the disconnect between authorship of medical literature and the research that produced them and the gap or moral disconnect between the norms of conventional scientific authorship and the norms governing authorship of commercial medical literature. Biagiolli’s (1999 as cited in Sismondio 2004) critique of ghost writing similarly highlights how the nexus between drug companies and researchers is indicative of the differences between the moral economy of business authorship and that of academic authorship.

For the companies, the papers researched and written on a work-for-hire basis have as their fundamental value an expected payoff in terms of sales, whether that value comes from legitimating drugs or their promotion. Those papers can be freely given to academics for authorship in exchange for increased value from the prestige of authorship. Academic authors serve as celebrity sponsors, though unlike many other celebrity sponsors, their payment is the sponsorship itself. And the only cost to them

32 The author is a psychiatrist and clinical researcher who has authored several historical critiques of the practice of psychiatry in the West.
from publication of a ghost-written paper, at least one that they believe is competent, is the small risk they take that their violation of norms of authorship will be discovered. (ibid: 152).

In a very recent (2009: 171-95) and telling account of ‘ghost writing’, Sismondo demonstrates how the publication of pharmaceutical company-sponsored research in medical journals and its presentation at conferences and meetings is mostly governed by ‘publication plans’ that extract the maximum amount of scientific and commercial value out of data and analyses through carefully constructed and placed papers. Clinical research in this context is mostly performed by contract research organizations, analyzed by company statisticians, authored by independent medical writers, approved and edited by academic researchers who then serve as authors, and the whole process is organized and monitored all the way through to journal publication by publication planners. His work exposes the systematic alliances between marketing departments of pharmaceutical companies, medical journals, publishers and academic authors in catering to their potential audiences and describes a new kind of corporate science, designed to look like traditional academic work, but performed largely to market products.

Greene’s work (2004), a historical account of marketing practices and the evolution of salesmanship in pharmaceutical firms in post-war America, examines the strategies through which, firms succeeded in investing drug salesmanship with the legitimacy of a ‘professional service’, generating widespread acceptance for their presence in clinical spaces and shaping contemporary interaction between physicians and sales representatives. His work is significant in terms of providing insights into corporate and clinical logics and the role played by these early sales representatives in laying the foundation for the systematic process of pharmaceuticals promotion in the contemporary period.
Another work, in a similar vein, centred on the theme of commodification of pharmaceuticals in late capitalism (Tracy 2004: 15-34), observes how the pharmaceutical industry’s logic and practices are crafted carefully in consonance with market dynamics via research and development towards the commodification of its products. In taking a critical and historical vantage point, it examines drug advertising and regulation, particularly in the US context, to demonstrate the ways in which the pharmaceutical industry ensures a wide dissemination of its products to maximize profits through marketing efforts and the creation of diseases as platforms for the expansion of its drug product markets. The study essentially argues that scientific medical practice is closely linked to the economic and technological rationality of market considerations.

With respect to pharmaceuticalization, recent sociological studies have identified several processes at work, including new opportunities for the mediation of pharmaceuticals which bypass the traditional doctor-patient route such as direct to consumer (DTC) sales, the internet and cyber-space culture and the domestication of pharmaceuticals consumption in everyday life, which have forged new links between the corporate world and the private world of citizens in terms of consumer willingness to adopt new medical technologies as solutions to everyday life problems.33

The examination of the different dimensions and processes shaping medicalization and pharmaceuticalization is a common strand underlying all the above-mentioned studies, in addition to a preoccupation with academic integrity and the ethical dilemmas posed by the complex alliance between firms, medical practitioners, clinicians and academicians.

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33 See Fox and Ward, 2008; Miah and Rich as cited by Wiliams et al 2008: 816.
With respect to the body of work on the science and politics of innovation, drug testing and regulation in the pharmaceutical industry, the contributions of John Abraham over the last two decades, both singly and in collaboration with other sociologists, have been a seminal effort in terms of providing a theoretically lucid and methodologically feasible framework to understand the world of pharmaceutical innovation and regulation. Deploying detailed empirical case studies and through international comparisons of drug controversies and corporate bias, these studies have highlighted the inadequacies of existing regulatory practices and procedures, the need for more rigorous policy interventions in the form of independent drugs testing by regulatory authorities, greater public and patient representation on regulatory committees and a more thorough appraisal of regulatory performance at the legislative levels. (Abraham 1993, 1994, 1995, 1997, 2002, 2007, 2008; Abraham and Davis, 2005; Abraham and Lewis, 2002; Abraham and Reed, 2001).

Abraham’s framework (2008), however, essentially posits a realist empirical research programme for the sociological investigation into the complexities of drug development and regulation, a perspective based on:

… a realist conceptualization of interests, in contrast to the notion that interests, objectivity and reality are merely social constructs and that sociological analyses should be confined to the discourse, actor-networks and micro-contextual practices. The objective interests of pharmaceutical companies in profit maximization and of patients/public health in the optimization of drugs’ benefit-risk ratios can be empirically validated. The relationship between those interests and pharmaceutical regulation is best characterized by ‘neo-liberal’ corporate biases at the macro- and meso-levels. How such bias manifests itself at the micro-social level of science based pharmaceutical testing and regulatory decision making is examined using realist sociology of scientific knowledge, which appreciates that assessment of the validity of techno-scientific knowledge claims is essential for their sociological explanation. Commercial interests are shown to have biased science away from the interests of public health, in favour of industry. International comparisons of drug regulation demonstrate that drug injuries are not necessarily an inevitable by-product
of pharmaceutical progress because some countries have fewer drug safety problems than others. Similarly, the lowering of techno-scientific standards for drug safety testing is not an inevitable cost of the faster development of therapeutically valuable medicines but a consequence of the internationalization of neo-liberal corporate bias. (ibid: 869).34

Theoretically, the implication is that objectivist realism provides a philosophically coherent framework for empirical social scientific research on drug regulatory assessments, which can forward public health agendas without being instrumentally technocratic, whereas relativism in contrast is philosophically self-defeating (2002:306). However, Abraham’s formulations pertaining to the theoretical and methodological orientations that ought to be adopted by sociologists in order to understand drug testing and regulatory processes in the industry might perhaps be better understood through a cursory revisiting of his major contributions to the field. His earliest work (1993: 387) on carcinogenic risk assessment of benaxopren in the United Kingdom and the United States attempted to illustrate how commonly agreed technical standards in science could be used to scrutinize the validity of scientific knowledge claims in industry and government and in the identification of similarities between patterns of technical inconsistencies and institutional interests in different international contexts. In addition to arguing how these interest-based biases revealed deficiencies in regulatory policy, the study also proposed some political changes to reduce such biases.

In a separate study on the drug (1994a: 493), Abraham also sought to highlight how scientists and regulators tended to distribute the benefit of doubt about drug safety under conditions of scientific uncertainty. The methodology deployed by him in this related study was similar, involving the scrutiny of the technical coherence of the arguments put forward

34 Abraham’s orientation is interdisciplinary in the sense that he attempts to blend insights from the general body of sociological theory with insights from STSS traditions.
by industrial and government scientists in relation to the safety of the drug. His observations in this context pertained to the willingness of government scientists to award the commercial interests of the pharmaceutical industry an enormous benefit of scientific doubt, which was inconsistent with the best interests of patients. Another interesting insight in this context was how the resultant interpretative flexibility facilitated the distribution of benefit of scientific doubt due to the burden of proof falling on the regulators and their trust in and dependence on industrial scientists. An outcome of this, he concluded, was that the inordinate amount of trust placed in the industry hampered the detection of flaws in manufacturers’ medical data in a timely manner and compromised patient interests.

In a similar vein, his study (1994b:717) on the influence of interests and values on scientists’ safety evaluations of the drug Opren also dealt with the identification of inconsistencies in the technical accounts of both industrial and government scientists and the hazard for public health created by the biased production and interpretation of medical knowledge about the drug. What is relevant here is how his methodology and observations seem to indicate similar processes at work in the case of different contested drugs and the disconnect between the ‘ethos’ of conventional views on science and the norms governing drug testing.

In his studies (1998: 141, 1999:803) documenting the approval and sales of Halcion, a anti-depressant and tranquilizer, in the United States as opposed to its ban in the United Kingdom, despite the seemingly tough stance of the US Food and Administration (FDA) officials in matters related to consumer protection, Abraham demystifies the apparent anomaly by US regulators in terms of micro-sociological processes such as differential regulatory trust, regulators’ socio-technical data selections, medico-scientific disciplinary
influences, organizational and professional interests, conflicts of interests of expert advisors and the growth of the neo-liberal regulatory state rather than merely taking recourse to explanations such as the role of the mass media, the increasing threat of litigation regarding drug injury or deregulatory politics. Another study (2002: 309,329) examines these micro-sociological processes in the context of understanding the culture of regulatory science in the United States. Abraham demonstrates how the practices of regulatory science in the United States are readily contestable and historically contingent, existing within an overarching framework of adversarial political culture and structuring social interests and identifies four key cultural dimensions in the context of these practices: the politics of technology as progress versus hazard, productivity goals, trust and knowledge validation and disciplinary commitments. He posits that contested regulatory practices can better be understood in terms of conflicting positions drawn from these cultural areas of drug regulatory science and that the understanding of regulatory science as culture implies a much more complex framework of values. Abraham also observes that regulatory expectations and paradigms may be regarded as mediating factors between political culture and structural interests, on the one hand, and the outcomes of regulatory science on the other hand.

A key strand in Abraham’s work also pertains to the assessment of risks and benefits of medical drugs. A subsequent study (2002: 19-29) scrutinizes the Halcion case mentioned earlier in the context of interaction between expert risk-benefit assessments of drugs and permissive/precautionary approaches to drug regulation. The study reiterates how the

However, interestingly enough, a later study (Abraham and Davis 2005: 881-92), in carrying out a comparative analysis of drug safety withdrawals in the United Kingdom and the United States in the period from 1971-92, attempts to demonstrate that the fewer drug safety withdrawals in the United States during the period was the outcome of greater stringency by FDA authorities in standards and pre-market review of drugs in comparison to the United Kingdom.
adoption of a precautionary or permissive approach to the risk assessments is not merely a matter to be dealt with by technical experts and science, but a social and political issue with major repercussions for public health. Through the example of Halcion, the author emphasizes how the adoption of a precautionary approach could yield different expert assessments, might require compelling evidence of drug efficacy where good alternative therapies exist, integrate how a drug can be used more safely into evaluation of controlled clinical trial data and put more emphasis on the correlation between disaggregated clinical trial data and spontaneous reports of adverse drug reactions.36

Other important observations (Abraham and Lewis, 1999: 1665-67, 2002:67,87,88) made in the context of public health concerns in Europe pertain to the ‘marketization’ of regulation in the process of harmonization of drug safety standards, the competition between the national regulatory agencies of the European states for application fees from industry by accelerating review and approval times for new drugs and the deficiency in these bodies to accommodate independent scrutiny for robust and informed policy measures. The argument of the authors is that though late modernity has witnessed a pharmaceutical sector in which consumers have become more aware and critically reflexive citizens, the decline in producer power or in medical authority through the fracturing of expertise or related factors has been minimal. They also conclude that, at least in the European context, the sector is highly organized, producer-driven, oligopolous and standardized, rather than disorganized, fragmented and flexible. In the context of harmonization of standards, the authors observe:

In the pharmaceuticals sector, the Europeanized regulatory state is a product of three key factors: the European Commission’s commitment to an ‘efficiency’ regime, which would meet the political objectives of a single European market and the commercial agendas of transnational pharmaceutical companies; the endemic

36 Abraham’s emphatic advocacy of the precautionary method in drug regulation and its implications in terms of benefits to public health is obvious.
corporate bias associated with medicines regulation in the most influential member states; and the considerable success of neo-liberal politics across a number of major member states, including Germany, Sweden and the United Kingdom.

Another related paper (Abraham and Reed, 2001: 113-27) attempts to elaborate on these observations by further exploring the relationships between international harmonization, trade interests in market expansion and the regulatory state. Through a combination of documentary evidence and targeted ‘informant’ interviews, the authors demonstrate the failure of the international harmonization process to increase stringency of standards and how the lowering of standards regarding drug safety was effected by the misrepresentation of societal and political judgments as technical calculations, leading to a resultant lack of public accountability. Similarly, through an examination (2002:337,362) of international standard-setting in the toxicology of pharmaceuticals during the 1990s, involving both the pharmaceutical industry and regulatory agencies in an organization known as the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the authors critique the ICH claims about the implications of ‘technical’ harmonization for the maintenance of drug safety by demonstrating the absence of technoscientific validity for these claims. Further the authors also argue that within the ICH, a discourse of technological innovation and scientific progress has been used by regulatory agencies and the transnational pharmaceutical industry to legitimize the lowering and loosening of toxicological standards for drug testing. The authors also demonstrate how the mobilization and acceptance of this discourse is effected through the argument that these reductions in safety standards would be beneficial in terms of early approval and access to innovative drug products. The authors, in demonstrating the

37 The implications of the international harmonization of pharmaceutical regulatory standards in the Indian context has been discussed in Chapter 7.
implausibility of such claims by the ICH, highlight a problematic aspect in the technical trajectories of regulatory science and observe that the relationships between innovation, regulatory science and ‘progress’ may be more complex and controversial than is commonly assumed.38

A common theme underpinning most of these studies is that the accelerated review times for new drugs, whether through the drive for international harmonization of standards or through regulatory capture by the industry has led to a compromising of drug safety standards and has serious implications for patients’ interests. Another significant strand is Abraham’s emphasis on the tendency of regulatory scientists to interpret social and political issues about the “acceptability” of risk-benefit ratios as reducible to technical calculation (Abraham and Davis, 2007: 424) and regulators’ propensity to generally adopt a technocratic approach to risk-benefit assessment challenges rather than to acknowledge the underlying social values and interests involved. Abraham’s policy related solutions to these challenges includes comparative efficacy testing, conducting of key tests by regulatory agencies involving charging of the costs incurred to industry, greater transparency and accountability of regulators to public scrutiny, elimination of experts’ conflict of interest (Abraham, 2003:135) and incorporation of decisions related to “acceptable” risk-benefit ratios into a political process such as public interest committees comprising elected health officials and consumer/patient representatives who would evaluate “acceptability” in terms of patient and public interest (2007:424).

38 An important but related point made by the authors in this connection also pertains to how regulation and innovation are often investigated separately in science and technology studies, with studies on regulation focusing largely on scientific standards and risk assessment, while the examination of innovation limits itself to the socio-economic dynamics of transforming discoveries and knowledge into marketable products. (ibid, 337).
In the light of the above elaborate discussion, it would also be pertinent to mention the recent Abraham-Busfield (2006, 2007, 2007b) debate which succeeded Busfield’s analysis of scientific fact-making in the clinical trials of drugs and post-approval drugs assessment. Busfield’s article (2006:297-314) essentially sought to explore the ways in which pharmaceutical industry exerted its power to encourage the uncritical and over-extensive use of pills and the relative neglect of the sociological study of the character, ideas and power exerted by the industry in comparison to the medical profession, especially by sociologists of medicine and health care. Her contention was that sociologists of health and illness had carried out some research on pharmaceutical regulation, on the controversies around specific drugs drawing upon insights from sociology of science and a little more enquiry into the dynamics of medical prescribing but that the industry had seldom been mentioned in key textbooks in the field and that this may have been partially due to the field’s origin as sociology of medicine, the preoccupation, especially in Britain with the experience of illness and the general tendency of sociologists to focus on the powerless rather than the powerful.

Also, her analysis, drawing upon Latour’s theoretical and empirical framework, in addition to a more explicit engagement with power, sought to examine the scientific ‘fact-making’ in the pre-approval and post-approval stages of drugs and highlight the industry’s control especially in the pre-approval stage. Her analyses highlighted the industry’s fact-making activities as constituting a form of ideological power, grounded in the industry’s

39 Another important related observation was about pills constituting part of ‘inconspicuous consumption’ and the absence of analysis related to such consumption in sociological accounts of consumption in general and on the use of psychotropic medication in Giddens’ (1991) discussion of anxiety and risk and the ‘reflexive’ power of the self.

40 Ibid: 298.

41 This last observation on sociological preoccupation with the powerless rather than the powerful is not a very original one as Braithwaite(1984) and Van der Geest (1993) had already mentioned it in connection with sociologists’ and anthropologists’ relative neglect of the terrain of pharmaceuticals.

42 Ibid: 297
economic power; companies’ control over research manifested in the search for patentable and expensive drugs with a large market; the anxiety of firms to speed up discovery, testing and approval times and the problematic aspects of cognitive closure of the ‘black box’ of pre-approval regulatory testing, especially as it involves companies’ control of the facts and the selection of the data reviewed by the approval agencies (ibid 302-306).

Abraham’s (2007) response to the article mentioned the reasons for this comparative neglect of the terrain, the reasons according to him being first, industry’s excessive secrecy associated with its discovery and drug testing activities coupled with the limited citizens’ legal rights of access to these activities posing difficulties in terms of in-depth empirical research into the industry, secondly, how sociological explanations of outcomes in the pharmaceutical sector necessitated the acquisition of knowledge about the ‘technical’ science involved in the processes of drug testing and regulation and thirdly, the threat of potential legal action involved in sociological criticism of firms’ activities.43 However, his view was that a substantial amount of research44 had gone into the field in the last two decades and that the assumption of neglect was right only with regard to the terrain of globalization and pharmaceuticals.(ibid 728-29)45 However and most significantly, Abraham’s contention was that the sociological investigation into pharmaceuticals had moved beyond Latour, that ‘Latourian’ analysis could provide descriptive accounts but no methodology for “distinguishing between valid/coherent and invalid/incoherent claims, his theoretical framework eschewing the possibility of such discrimination” and consequently

43 Ibid: 727
44 His own work and theoretical and empirical investigations into the terrain being a case in point.
45 Busfield’s argues that ‘multinationalization’ and ‘Westernization’ are more accurate terms of reference than ‘globalization’
unable to provide adequate explanations of factors such as excessive promotion of prescription drugs, or overuse of drug for example.\textsuperscript{46}

Busfield’s rejoinder (2007b: 738) to Abraham, firstly, while giving due credit to his work, reinforced her argument about the neglect of the unpacking of the science underpinning testing and approval and relatively uncritical acceptance of new drugs\textsuperscript{47} and secondly, emphasized upon the heuristic value of Latour’s work in the context of the current problem. Her contention was that her indication to incorporate notions related to power into her analysis of the pharmaceutical industry was in itself indicative of the inadequacy of the Latourian framework to provide a fuller insight into the science related activities of the industry.\textsuperscript{48}

Coming back to the present review discussion, all these above-mentioned elaborate digressions have been necessary, if only to provide an insight into the variety of theoretical orientations and the methodological dilemmas and challenges that have informed sociological preoccupations with drug testing and regulation in the industry.

With respect to sociological studies of consumption and consumerism, the third theme in the present discussion, preliminary work in this area has focused on ‘social audits’ of the use of prescribed medicines (Dunnell and Cartwright, 1972 as cited in Williams et al 2008). During the subsequent decades, the focus shifted to concerns with the social meanings of medicines and shaping of these meanings’ by the users’ ethnicity and gender\textsuperscript{49}. Recent studies (Fox et al 2007, 2005) have, however, focused on the users of pharmaceuticals as knowledgeable and reflexive actors capable of informed choices in

\textsuperscript{46} These observations are also indicative of the fundamental cleavage between Latourian constructivism and the objectivist realist framework espoused by Abraham.

\textsuperscript{47} Busfield is right to some extent in this assumption.

\textsuperscript{48} Ibid 738-39

\textsuperscript{49} Morgan, 1996; Helman, 1981; Gabe and Phillips, 1982; Cooperstock and Lennard, 1979; Gabe and Thorogood, 1986; and Ettore and Riska, 1995 as cited in ibid: 818.
consultation with professionals.\textsuperscript{50} Recent government policies in certain countries have begun to conceptualize patients as experts and exhort professionals to develop a ‘partnership’ with their patients\textsuperscript{51}. Another study (Stevenson, Leontowitsch and Duggan, 2008), which examined the processes by which consumers of over the counter medicines engage with pharmacists has shown how pharmacist-consumer interactions did not decrease the value of pharmaceutical expertise and how consumers’ acknowledged information asymmetry in relation to pharmacists but treated transactions related to over the counter drugs in a vein similar to other commodities purchased in retail outlets. Other studies have focused on the collective actions of patients and users to represent their interests in self-help groups, patient advocacy groups and health social movements.\textsuperscript{52} In a similar vein, Jones (2008: 929-43) has focused on the processes through which health consumer groups in the United Kingdom disclose and manage links with pharmaceutical companies in the context of their growing involvement in the policy process. Her study examines claims about the industry’s engagements with these groups in an attempt to capture the groups’ policy agenda. Her findings reveal how common interests help to sustain the dialogue between these groups, highlight the coincidence of aims between the two groups and the perception of inevitability of collaboration and tacit support for policy guidelines to manage conflicts of interest.

Another interesting and relevant study (Olesen, 2006: 5-30), in an analysis of the HIV/AIDS medicine access campaign in the period 1998-2001, demonstrates how the campaign played an important role in making the issue resonate in the public spheres of

\textsuperscript{50} The interesting element of these studies is the increasing agency accorded to the consumer as compared to previous notions of consumers as passive recipients of medical technologies.

\textsuperscript{51} Taylor and Bury 2007 as cited in \textit{ibid}: 818.

\textsuperscript{52} Kelleher 2004, Brown et al 2004 as cited in \textit{ibid}: 819.
many countries around the world. The study demonstrates how the campaign activists sought to make the issue of HIV/AIDS medicine access of concern and intelligible to audiences not directly affected by it through emotional and strategic elements in their campaign discourse and how their success was significantly aided by their considerable economic and skill resources and alliances with different states and international institutions.

The sociological research on expectations and innovation is concerned essentially with the claims pertaining to innovative developments and the ‘politicization of all life forms’ in the areas of bioscience, biomedicine and biotechnology, including the “morphing or mutating of biomedicine through molecularization, debates around the vary nature of what it means to be human, the formation of new communities of citizenship and new biosocial identities, the reconfiguration of the boundaries between normality and abnormality, health, illness, treatment and enhancement” (Rose 2007 as cited in Williams et al 2008:819-20). Other studies point out how in the context of the co-production of various utopian and dystopian biofutures, expectations differ between different social groups like scientists, policy makers, industry, consumers etc and how the futures they envisage are ‘contingent’, ‘contested’, ‘imagined’ and based on the ‘retrospecting of prospects’ and the ‘prospects of retrospecting’.

Other areas involving considerable hyperbole and hope include avowedly cutting edge areas like pharmacogenomics and pharmacogenetics and stem cell research. Areas like pharmacogenomics and pharmacogenetics hold out the promise of ‘personalized’ or ‘tailor-made’ medicine in contrast to the ‘one size fits all’ drugs available in the market currently with side effects and adverse drug reactions. However,

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53 The campaign began when 39 of the world’s largest pharmaceutical companies initiated a court case against South Africa for violating the companies’ patent rights. The companies eventually withdrew the case.

54 Brown and Michael 2003, Novas 2001 as cited in ibid: 820-21. The example of venture capital in the pharmaceutical industry may be pertinent here. The discourse of venture capital in the pharmaceutical industry is centred on future prospects and risks. For that matter, the discourse of R&D in the pharmaceutical industry is similar in the context of firm-level investments in research activities.
these medical advancements have generated concerns pertaining to the proliferation of genetic testing and the racial politics of personalized medicine and the actual feasibility of these developments. In this context, a very recent study on expectations within stem cell research, (Wainwright et al 2009: 959-974), discusses the processes through which experts’ persuasive strategies work towards stabilization of emerging models of translational research in this area and argues that these promises serve to advance their interests in the uncertain stem cell field.

**Studies in the Indian Context**

The few sociological/anthropological engagements with pharmaceuticals in the Indian context have by and large focused on the realm of traditional medicine and its encounter with biomedicine. One of the earliest socio-philosophical works in this regard (Nandy and Vishvanathan 1990) attempted to describe three modes of dissent from modern medical philosophy in India, each of which had simultaneously attempted to understand modern medicine and to cope with the typical clinical, social and philosophical problems the attendant mode of healing introduced into the world of applied knowledge. From the irrationality as defiance stance of the theosophists to the culture as resistance of Gandhi to the theory of the exogenous of Sivamurthi, the paper attempted to argue that “these ‘demented’ and ‘other-worldly’ sages had diagnosed the crisis of modern medicine with greater clinical and philosophical perspicacity than did ‘normal’ scientists”. What is important about this work in the context of the present review discussion is the authors’

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55 Brown and Webster as cited in *ibid*: 820

56 Mirroring Western trends, in India, anthropologists and sociologists of medicine have largely been preoccupied with issues related to traditional concerns of medicalization and public health concerns. The present review discussion, in this section, has invoked only those few anthropological/sociological studies with respect to the Indian context, which help to further our understanding of the Indian pharmaceutical industry.
examination of modern medicine as creating a ‘shadow patient’, which involved the "reconstruction of the patient and his suffering into a set of variables and readings as in a laboratory process". The authors’ examination of how modern medicine has led to depersonalization of the patient by giving emphasis to the laboratory reality of the person in preference to his personal and clinical realities is of course a well-established thesis in sociological studies of medicalization in the West.

Other studies (Sujatha and Abraham 2009, Sujatha 2003) have focused on the worrisome aspects of medical pluralism in terms of the dilemmas of incorporating indigenous systems of medicine into a centralized health infrastructure, the expansion of these systems through the pharmaceutical industry for health products, massage centres and spas, the negotiations between the practitioners of different co-existing systems of medicine and the debates on notions of efficacy among these different systems. In this context, Minocha’s study as cited in ibid. 57, though carried out more than two decades earlier in comparison to these above-mentioned works, merits mention since it offers a different view of medical pluralism. Her study attempted to critique the “adaptability of traditional medicine” and highlighted how traditional practitioners were medicating their clients with allopathic formulations, who consumed them like traditional remedies, unaware of their side effects. A related study (Abraham 2009), deploying the framework of medicine as culture and focusing on the indigenous medicine of Ayurveda, deals with the cultural construction of “Kerala Ayurveda” and its reproduction simultaneously as culture and as medicine in cosmopolitan Mumbai.

Naraindas’s work (2006:2658-69), examines the ‘interplay between biomedical and other medical traditions’ in terms of notions about evidence and efficacy and observes how ‘objective tests and measures in biomedicine are accepted as the only legitimate evidence of cure but these do not concur with the premises laid down by these other traditions or with patients’ subjective perceptions of well being’. It argues that a cognitive shift in terms of what constitutes as ‘evidence’ is vital to the practice of these other medical traditions.

In the context of our inquiry into the Indian pharmaceutical industry, Banerjee’s work (2004:89-94) is a significant contribution among these few studies. Her article ‘examines some of the sites of contestation that mark the encounter of Ayurveda with globalization, making it a marginal player in the medical market’. She argues that with the enormous pressure being exerted by the dominant establishment, including the pharmaceuticals industry, ‘alternative medical systems have been confined to marketing alternative products’ and that the real challenge for Ayurveda in the global economy lies in ‘defining the parameters and terms of those parts of knowledge system that are considered adaptable to the market’. She highlights how ‘in the scramble to protect markets and knowledge regimes, it needs to be understood that there is a deeper colonization being played out in the edging out of alternative world views inherent in these medical systems’. In a related and earlier work, (2002: 435-467), she problematizes this encounter between Ayurveda and the market through an analysis of decisions regarding the product profiling, positioning and packaging of Ayurvedic medicines by its leading manufacturer, Dabur. Her analysis views ‘these seemingly mundane decisions as the expressions of a deep operation of power, mediated through culture’. The article attempts to move beyond ‘the simplistic picture of the rise of modern biomedicine at the inevitable and onward march of rationality,
or that of Ayurveda as the helpless victim of modernity’ and argues that the multiple strategies adopted by the Ayurvedic pharmaceutical companies, in response to the changing conditions of the market, can be viewed in larger terms ‘as its response to the changing nature of the field of power. This identifies the ‘moment of confrontation’, the ‘moment of withdrawal’ and the ‘moment of diversion’ as some of the strategic responses.’ Banerjee’s analysis, in demonstrating how these strategies opened up the modern market for Ayurvedic medicines, also dwells on the consequences of these strategies in terms of the reconfiguration of these medicines in the mould of allopathic medicines and their resultant disconnect with the knowledge systems within which they had emerged.

Another important empirical study (Harilal 2009), reflecting on the prolonged history of standardization and professionalization that transformed aspects of the Ayurvedic tradition, examines the challenges faced by the Ayurvedic medicine manufacturing sector. Given that within the tradition, medical ingredients are sourced from herbal, mineral and metal substances that cannot be industrially manufactured, the study underscores the economic relevance of Ayurvedic knowledge and how modern firms have amassed it in a competitive environment.

The relevance of these above-mentioned studies to our understanding of the Indian pharmaceutical industry lies in the fact that the manufacture and marketing of Ayurvedic products also constitutes a part and parcel of the pharmaceutical scenario in India. Though the Ayurvedic manufacturing industry exhibits some differences from the general pharmaceutical industry in India with regard to features such as sources of knowledge, nature and process of drug discovery, scientific applications, fragmentation of markets, consumer categories and pricing, it also exhibits some similarities with the pharmaceutical
sector with regard to aspects such as product innovation, marketing strategies, institutional
development and networking.\textsuperscript{58}

Sundar Rajan’s work (2002)\textsuperscript{59} constitutes an exception to this general sociological
preoccupation with traditional systems of medicine in India and is perhaps the most
significant study in the context of our present discussion. His work attempts to analytically
map the techno-scientific regime of biotechnology in the context of drug development, in a
political economic regime that is marked by the increasing prevalence of such research in
corporate locales, is driven by corporate agendas and practices and therefore has tremendous
implications for the life sciences. Sundar Rajan adopts the methodological strategy of multi-
sited ethnography, involving a range of actors such as academic scientists and industrial
scientists, venture capitalists, entrepreneurs and policy makers, to understand the nature of
such ‘biocapital’ and the negotiations of these actors with these emergent technologies and
political economies. Drawing upon Marxian and Foucauldian perspectives of life, labour and
and value and upon the traditions of STS studies, his thesis “\textit{intervenes in social theoretical
debates not simply around the nature and production of knowledge and value, but also
around the place of larger belief systems – relating to religion, nature and ethics- in such
productive enterprises}”. It also “\textit{simultaneously intervenes in conceptual debates within
cultural anthropology regarding methodological questions that surround the undertaking of
comparative ethnographic projects of powerful sites of knowledge production and value
generation in a globalized world}.”

\textsuperscript{58} Greene 2007 as cited by \textit{ibid}: 45

\textsuperscript{59} Phd dissertation, Science, Technology and Society Program, Massachusetts Institute of Technology, United States.
With respect to marketing of pharmaceutical products, one of the major studies dealing with the Indian situation is that of Kamat and Nichter (1998: 779-94). The empirical study, involving an ethnographic description of pharmacies and pharmaceutical-related behavior behaviour in Mumbai, in highlighting the context in which pharmacy attendants engage in “prescribing medicines” to the public, demonstrates how reciprocal relationships between pharmacy owners, medicine wholesalers, and pharmaceutical sales representatives influenced the actions of pharmacy staff. The study also looks into the role of the medicine marketing and distribution system in fostering prescription practice, pharmacy counter pushing and self medication. In documenting the profit motives of different players located on the drug sales continuum, the authors argue for a closer scrutiny of the economic rationale and symbiotic relations that exist between doctors, medical representatives, medicine wholesalers and retailers by the proponents of “rational drug use”.

Recently, studies conducted under the ‘Tracing Pharmaceuticals in South Asia: Regulation, Distribution and Consumption’ project60, deploying methodological techniques such as anthropological field work with archival and interview-based research, have attempted to examine the conditions that make possible the continuing inappropriate use of medicines in South Asia. The project, based on the premise that phenomena such as pharmaceutical products must be understood as parts of global assemblages which have significant cultural and symbolic meanings, highlights the understanding of the processes that lead to iatrogenic disorders61 and attempts to offer an improved understanding of policy in this field. In this context, a study by Ecks and Basu (2009:46-86), which

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60 A project (2006-09) funded by the Economic and Social Research Commission (ESRC) and DFID, United Kingdom, carried out by researchers in Nepal at Martin Chautari and in India at the Centre for Health and Social Justice, in collaboration with the University of Edinburgh.

61 Those induced unintentionally by a physician’s diagnosis.
emanated from this project, examines the use of antidepressants in India. Drawing upon ethnographic investigations in India and through the example of fluoxetine (Prozac), the authors argue that the spread of anti-depressants in India is ‘unlicensed’ by Euro-American corporations in at least three ways: drug marketing is driven by Indian generic producers, fluoxetine is prescribed by practitioners who have no license to do so and knowledge of fluoxetine is spread through the unlicensed ‘floating’ prescriptions that patients take from one prescriber to another. Another very useful and related study (Bhrlikova et al 2007) primarily outlines the role of regulation and its enforcement in Nepal, with respect to the regulatory requirements pertaining to Good Manufacturing Practices (GMP), the guidelines governing the production, distribution and supply of a drug. The authors’ findings indicate that domestic producers find the increasingly stringent GMP standards a major obstacle in the production of affordable drugs with respect to the domestic market.

Engagements with Pharmaceuticals in Science, Technology and Society Studies (STSS)

The domain of science, technology and society studies has traditionally concerned itself with the decisive role of socio-cultural factors, both internal and external to the world of Science, in determining and moulding the production, application and legitimization of knowledge. Technological processes and artefacts have been construed as being culturally constructed and interpreted through complex contextual and contingent socio-political negotiations (Latour 1987, Mackenzie, D and Wajcman 1999, Collins 1983) within and outside the sphere of Science. Such a premise implies variability, not only in the interpretation of processes and artefacts within and among groups, but also in the final design and content that they assume. The varying norms, interests and world views of different groups, which are embedded in the content of technologies and its processes, have
been invoked by scholars to establish the underlying cognitive, social and cultural bases of these technologies.

Harking back to the immediate context, a principle work, of immediate relevance to understanding the problem at hand\(^62\), constitutes the notion of ‘qualification’ proposed by Michel Callon, a prominent STS scholar. Callon et al. (2002) held that the modern technological economy was an ‘economy of qualities’, involving the qualifying of products and positioning of goods. By ‘qualification’, Callon meant the attribution of some qualities, some characteristics or attributes to a product. Such qualification also included the processes that the product underwent to acquire these attributes. For Callon, such qualification occurred in the context of hybrid forums, involving a heterogeneous group of actors and in a space, which was relatively unstructured. Also, which particular set of actors were involved in this process depended upon the context. Further the attributes of a product thus qualified were not observed but revealed through tests and adherence to particular protocols. These attributes were stabilized over a period of time but were equally subject to change.\(^63\)

Callon’s work essentially attempts to look at the role of technologies in the structuring of economic markets and link the terrain of anthropology of science and technology with markets and the general domain of economic sociology.

Scholarly engagements with pharmaceuticals in the domain of STS, as reiterated earlier, have for the most part been concerned with the specific histories of pharmaceutical firms, trajectories of contested drugs, studies of scientific expertise in an interdisciplinary or international context and studies on the controversial aspects of drug regulation.\(^64\)

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\(^62\) The discourse of drug quality in the Indian pharmaceutical industry.

\(^63\) The relevance of Callon’s work in terms of understanding the qualification of drugs and the discourse of drug quality would be taken up during the discussion on the research questions of the thesis.

\(^64\) A few significant studies have been taken up in this section
With respect to drug regulation and studies of scientific expertise, studies within this terrain have largely attempted to demonstrate how the field is fraught with inherent dilemmas of decision making or ‘risk versus risk’ trade-offs. In this context, Daemmrich and Krucken’s study (2000), examines these dilemmas in the context of the thalidomide case and the responsiveness of German and US regulatory authorities to the medical catastrophe created by the drug. Their study also demonstrates how regulatory systems in these two countries differed with respect to public involvement in regulatory decision making, most notably in the emergence of activist groups and in the politics of clinical trials. A subsequent study by Daemmrich (2002) undertook the examination of the thalidomide controversy in relation to the ‘politics of drug regulatory expertise’. The study demonstrated how scientific and medical evidence could be challenged and expertise discredited in contemporary democracies, regardless of whether such challenges were made in court cases, in regulatory hearings or even within peer-reviewed journals. The study, through a comparison of the controversy in Germany and the United States also highlighted how the sites where these drug related debates played themselves out and the relative ability of expert committees to shield themselves differed significantly between countries. These observations attempt to mark a departure from Foucauldian and Habermasian critiques of expertise, which suggest that expert power and state power are inseparable and hold expert power to be the source of the oppressive, inegalitarian effects of present regimes (Turner 2001).

A related study on thalidomide (Timmermans and Leiter 2000) examined how a standardized drug distribution system contributed to a therapeutic and symbolic makeover of thalidomide, by normalizing the risk of foetal birth defects. The distribution system

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65 In the 1960s, Thalidomide was seen as a horror drug that had caused severe birth defects among over 10,000 babies who were exposed to it in utero.
accomplished this by focusing on the risk associated with female reproductive behaviour and by providing close reproductive surveillance of female patients, leading to a solidifying of social inequalities and professional power relationships.

Another study (Dalgalarrondo and Urfalino 2002) examines the controversy generated by the random selection of AIDS patients for treatments through the process of lot-drawing in France due to the insufficient availability of protease inhibitors. The study highlighted the dynamics of the interaction of media coverage with a specific collective action group and the relations within the network of actors comprising pharmaceutical firms, clinicians, AIDS patient advocacy groups and public agencies and authorities who were involved in getting anti-HIV treatments onto the market in France.

In the context of scientific expertise with respect to drug discovery, till the eighties, historical and social studies of science have by and large unquestioningly accepted the idea, forwarded by pharmaceutical firms, of the traditional model of drug discovery involving a relatively linear and straightforward progression of drugs from bench to bedside, (Pieters, 2004 as cited by Abraham, 2007: 728). As a consequence, these scholars either contented themselves with descriptions of medicine as imaginative biomedical research or confined their attention to issues related to policy and regulatory issues, to the neglect of their scientific and industrial aspects. There were, however, some studies, which were exceptions to the above mentioned trend and which examined the complex alliances between medicine, academic research, industry and the politics of health (Gladdys 1985, Liebanau 1987, Swann 1988 as cited by Abraham, 2007: 728).
However, these studies failed to critically scrutinize the micro-processes of industrial and governmental science and for the most part regarded the content of drug research and development as self-explanatory (ibid: 4-5). Pieters’s work, in attempting to question these unproblematic images of drug research and testing, specifically examined the history of a family of ‘therapeutic proteins’, namely interferons, by providing a detailed historical and sociological account of the events by which the scientific and therapeutic value and use of the interferons unfolded, a process, according to him, “involving conflicts and resistances as well as enrolment and acquiescence”. He highlighted how the process of “naturalizing interferons as part of medical practice” (ibid: 3) involved the establishing of committed links between different individuals and organizations, including laboratory researchers, doctors, drug companies, patients and their families and regulators. His other important contribution in this work includes the review of constructivist preoccupations with medical practice and medical science. Peters mentions (ibid:6-7) how, in the nineties, sociologists, historians and philosophers, including Rein Vos (1991), who examined the discovery of beta blockers and calcium antagonists in relation to the interface between the laboratories and the clinic, Oudshorn (1994), who provided an account of the development of sex hormones and Galambos (1995, 1997), who studied vaccine development, were influenced by constructivist and ethnographic approaches, specifically the concept of ‘actor-network’, in their attempt to understand the complexities of a laboratory oriented medical research, thus providing detailed accounts of the link between the social and cultural commitments of the scientific community to their ideas, methods and procedures. (as cited by ibid 8-9). Other studies on the history of diseases such as cancer, hypertension or depression (Lowy 1996, Healy 2002 as cited by Gaudilliere 2005: 605) have shown how pharmaceutical laboratories
as well as pharmacists have played a very prominent role in shaping the uses of their products. In addition, studies (Lesch 1993, Marks 1992, Sinding 2002 as cited in *ibid* 2005) have demonstrated the channeling back of clinical experience to production plants with the expansion of medico-industrial networks. Recent studies (Tanner 1998, Wimmer 1994 as cited in *ibid*) have begun to focus on the debates around the existence of patents as goods and have argued how the appropriation of knowledge is not limited to its legal dimensions but that controlling the trajectory and uses of new drugs is an issue linked to the circulation or restriction of know-how and tools. A related study on the trajectory of steroids (Gaudilliere and Quirke 2005a) discusses how biologicals were associated with particular forms of standardization, characteristic routes of production and a special legal status as they often crossed the boundary between prescription drugs and freely available consumer goods. In this connection, another article by Gaudilliere (2005: 603-11), also highlights how standardization, a characteristic feature of nineteenth century industrial culture, involving the reduction of variability, monitoring of work practices and homogenization of products, was related to science, both in terms of applying knowledge to standardize the factory and in terms of employing production methods to control nature in the laboratory. Gaudilliere observes how standardization of drugs meant providing identical goods with known properties, regarded as achievable through quality control system and strict production norms. It also implied control of the clinical uses of the drug, standard dosage, routes of administration and indications, the measurement of the pharmacological properties of a drug, with bioassays and controlled animal models being the favoured tool for this task. Such standardization is at once scientific, industrial and clinical. In this context, another paper (Bonah 2005: 696-721) examines the BCG anti-tuberculosis vaccine and discusses the
processes driving the standardization of its safety, stability and medical uses. The study discusses how ‘real-life’ transmission of and protection against the disease were studied in a setting that lay somewhere in between the controlled space of the laboratory and fuzzy experience of medical practice.

Another interesting work (Barry 2005:64-65) attempts to problematize the nature of pharmaceutical R&D in terms of novelty of the entities, the principles underlying their design and in terms of how the development of new drugs involves the multiplication of forms of existence of molecules. Barry’s analysis argues that the molecules produced in the contemporary pharmaceutical laboratory are more or less purified as chemicals but are also enriched in new ways and are part of the increasingly dense, spatially extended and changing informational and material environments formed not just through laboratory syntheses and tests, but through ‘virtual libraries’, computational models and databases and therefore the notion of ‘informed materials’ is a better description of such novel entities.

With respect to the specific histories of pharmaceutical firms, another key strand of inquiry, some of the other important works include Gaudilliere’s study (2005b: 612-43) highlighting the global knowledge management strategy of Schering. This involved the obtaining of patents by the firms and its academic associates on processes of bio-chemical origin. The passing of patent applications, circulation of remarks or comments on technical feasibility and the asking for new examples to justify particular claims led to not only the making of new knowledge but also to the securing of trust within the bio-industrial network. Another study by Quirke (2005:645-74) investigated Glaxo’s strategy and demonstrated how its numerous licensing agreements, which played a critical role in the post-war development of cortico-steroids were not merely evidence of its technical dependency but a
way of ‘internalizing’ emerging competencies in a climate of intense competition, a strategy again resorted to by firms in later decades in the face of competition from start-up biotech firms. Both these studies essentially examine the patent management strategies of firms in a competitive environment.

**Engagements with Pharmaceuticals Dealing with Public Health Concerns**

Public health concerns involving the terrain of pharmaceuticals, in the form of empirical studies, studies carried out from within specific disciplinary vantage points, namely economics, and those with an interdisciplinary orientation, also constitute an important body of literature, especially with the increasing involvement of health activists and patient groups in the regulation of drugs. These concerns have also been articulated in studies mentioned in the two earlier sections, the difference being that the primary orientation and objective of these former studies were to problematize and theorize aspects related to pharmaceuticals within a particular disciplinary framework while the studies in the following section have as their primary objective and agenda, the betterment of public health.

In the international context, the works of Comanor (1986), Melville and Johnson (1982), Norris et al (1980) and Medawar (1984), Angell (2004) and Ashcroft and Pfeffer (2001) have dealt explicitly with issues concerning the activities of the pharmaceutical industry and their implications for public health. Medawar’s celebrated work, as early as in the eighties, outlined how, as many as 70% of the pharmaceuticals in the world market were inessential and undesirable and tended to impair rather than improve health, the unreliable channels of prescription related information for doctors and resultant inappropriate drug use and weak government controls in third world countries. Importantly, he also outlined the
lack of agreement between experts in these countries about the main criteria that could be used to distinguish between more and less acceptable drug products. Norris et al highlighted the dumping of irrational and unwanted medicines in the Third World. Melville and Johnson outlined through detailed case studies the harmful effects of prescription drugs and observed that these problems had compounded due to the preoccupation with the preoccupation with the preoccupation with different groups concerned with drug regulation with its own interests and the undue trust placed on the integrity of firms. Comanor advocated the finding of new and innovative ways to finance pharmaceutical research and development, which did not require a restraint on competition and at the same time, did not lead to higher prices on existing drug products. Ashcroft and Pfeffer challenged the need for secrecy on the part of ethics committees and their decision making, asserting that such a culture went against the norms of transparency and accountability of these bodies to preserve and protect public interest. Angell’s celebrated work on the pharmaceutical industry debunked the popular myth of pharmaceutical firms as “engines of innovation”, asserting that top U.S. drug makers spent nearly 2.5% more on marketing and administration than they did on research, thrived on taxpayer-funded NIH research and spent most of its money discovering me-too drugs for profit. Angell advocated greater transparency in the industry on its activities and independent testing by regulators to ensure greater stringency in drug testing and monitoring standards.

access to medicines and rational use of drugs. They also attempted to critique unethical medical practices and drug pushing strategies of multinational and domestic firms and government policy on pricing and health services. Ramprasad and Dabade’s (1991) commentary critiques the marketing of inappropriate and unethical drugs by multinational firms and outlines the political economy of drug production and distribution in India through explicit and detailed examples. Phadke’s studies (1982) have critiqued the health policy of the government in the seventies with reference to the neglect of the public sector in the production of affordable drugs. Another significant study in 1995 extensively investigated the irrational prescribing habits of medical practitioners in Satara district in Maharashtra and recommended the need for ‘compulsory medical education’ of doctors for rational drug use, governmental efforts to ensure that drug companies printed authentic and balanced information about the drugs they manufactured and circulated, ban on the use of allopathic drugs by non-allopaths, periodic prescription analysis by the government in the private and public health sector and banning of irrational drug combinations. In this connection, Shiva and Rane’s (2004) work on banned and bannable drugs has undertaken a detailed empirical examination of the availability of banned and bannable drugs in the market under different brand names and their use by unsuspecting consumers. In addition, it has also emphatically emphasized the need for the formulation, development and implementation of a rational drug policy based on the concept of “essential drugs” and their “rational” use.

Dasgupta’s (2004) work undertakes a critical review of drugs regulatory policies of the Indian government in the context of the patenting of new drugs. In this regard, Bhaduri and Kumar, in the context of TRIPS and its impact on drug prices and health care in India, point out that TRIPS imposition of grounds of higher R&D costs is unjustified on grounds of
declining R&D productivity and would be detrimental to industrial development and availability of cheap drugs. Ray (2004) provides a descriptive account of the emerging institutional framework of the emerging world order of globalization and India’s reform process in the context of a political economy analysis of medical practice in India. His study indicates that while the emerging international economic order is likely to promote the discovery and introduction of new drugs worldwide and in India, it is unlikely to have any perceptible favorable impact on the health of the Indian population, given the market driven therapeutic focus of new drug discovery research. Further, the study concludes that under the new world order, the price and quality of drugs will move in a direction favoring the rich and discerning patient, while the poor may be deprived of affordable medicines of acceptable quality. Gurbani’s article indicates how isolated educational interventions on the rational use of drugs does not have any far reaching impact and advocates systematic intensive and extensive intervention involving organizations like local medical associations and medical councils.

In the context of access to medicines, Sengupta’s commentary advocates a periodic review of all medicines in the market, their scientific scrutiny, weeding out of irrational drugs, strict norms for licensing of new drugs and implementation of a stringent code of conduct on the promotional practices of drug companies in India. Gehl Sampath’s (2008) recent study, though dealing with access to medicines, approaches the issue from a different angle. Her empirical study attempts to investigate the current legal and economic framework in India and the emerging response of the local pharmaceutical sector since 2005, in order to analyse its implications for access to medicines. Her analysis concluded that strategic government support should be aimed both at encouraging firms to disrupt patterns of global
innovation in the pharmaceutical sector to create products for the poor the world over, making medicines more accessible and to help them focus their efforts on accumulating greater technological capabilities, while maintaining their strength as low-cost innovators of high-value pharmaceutical products. This also involved a revival of the role of the CSIR, a wider range of initiatives for enhanced collaboration between various actors in the pharmaceutical innovation system and enhanced incentives for firms investing in anti-retroviral drugs and drugs for malaria and tuberculosis. Abrol (2004), in the context of examining the post-TRIPS technological behavior of the pharmaceutical industry in India, similarly advocates the intervention of the government to ensure that the domestic industry undertake technological activities that would allow the Indian pharmaceutical sector to upgrade itself for the benefit of development of therapies for the needs of the Indian people in particular and developing countries in general.

Ekbal’s work (1988: 145) outlined the efforts of the Kerala Shastra Sahitya Parishad towards the debunking of a curative oriented, institutionalized, individualized and costly health system and the advocating of a People’s Health Movement and health delivery system biased towards the need of the rural poor through the demystification of pharmaceutical products for the public and the efforts to conscientise medical professionals on health issues. Srinivasan’s (2001) work, while examining governmental interventions in the eighties and nineties, which prevented the spiraling of drug prices and the reactions of different sectors of the pharmaceutical industry to these policies, observed that there existed considerable confusion as to what constituted reasonable prices and policies.
All these works, including commentaries and empirical accounts, give us an insight into the wide spectrum of issues ranging from patents, pricing and policy issues, marketing of ‘irrational’ prescriptions, unethical medical practices, to the need to educate consumers, need to orient and intervene in technological efforts of Indian pharmaceutical firms in harmony with Indian health needs etc that have informed the engagement with pharmaceuticals from a public health perspective.

Engagements with Pharmaceuticals in Economic Literature in the Indian Context

As reiterated earlier, engagements with pharmaceuticals in economic literature has predominantly focused on the innovation efforts of firms and the economics of technological change. More recent efforts have also focused on the implications of new regulatory norms and TRIPS for firms and their research and discovery related efforts.

Some important works on the implications for firms in the changing patent regime include studies by Jha (2007), Ramani and Maria (2005), Chaudhuri (2005), Lalitha (2002), Agarwal and Saibaba (2001). Chaudhuri (2005) outlines the changes in R&D expenditure and structure of R&D activities among Indian pharmaceutical firms after TRIPS. He observes that Indian firms have begun to demonstrate increased ability to produce generics for the developed market as against abilities in the sphere of drug discovery. Jha’s work outlines pharmaceutical firms’ strategies in terms of mergers and consolidations to increase market concentration and tap business opportunities in the value chain in overseas and domestic markets. He observes that, with no Indian firm possessing the expertise to take a potential drug from the investigational stage to the stage of its final market launch, leading firms have been resorting to collaborations with multinational firms, resulting in biases in the choices of therapeutic areas towards lifestyle related diseases. Ramani and Maria’s work
concludes that TRIPS would not have a significant impact on incentives for innovation creation in the biotech segment. In a similar vein, Agarwal and Saibaba call for renegotiation of the TRIPS agreement due its adverse impact on national interests in terms of spiraling prices of new drugs.

In this context, Lalitha’s work outlines the potential strategies for pharmaceutical firms in the new WTO regime such as production of off-patented products, new patented products by acquiring compulsory licensing or cross licensing, collaboration with multinational firms, not only in the sphere of R&D but also in the marketing of new products and improvement in production standards to widen the export market. A related work by her (2002) also outlined how the Drug Policy of 2002 did not adequately address the problems of the firms, whether with regard to price control, MAPE or FDI regulations and would have an adverse impact on the industry. Similarly, Chandran et al (2005) outline the strategies of firms in the new patent regime, including increased R&D efficiencies, development of unique R&D models to significantly decrease R&D costs, establishment of offshore production facilities, collaborations in discovery research and product development, filing of unprecedented number of ANDAs, acquiring the generic shares of global players or niche R&D of startup companies abroad, the greater thrust on clinical research and contract manufacturing for developed countries. A few studies (Visalakshi 2000) have focused on research and development efforts by Indian firms in the context of biotech commercialization and their alliance formation. Lanjouw and Macleod’s work (2005), in the context of outlining the nature of pharmaceutical R&D in India, observe that while there was a surge in the overall investment in R&D, these efforts were considerably less targeted towards the health needs of the developing world.
Other works have focused on issues such as innovation (Mani 2006), internationalization strategies of pharmaceutical firms (Athreye and Godley 2007), highlighted the case of Indian generic drugs in the context of the ‘access to medicines campaign’ (Field 2007) and changing regulatory trends and their implications for pharmaceutical firms (Srivastava 2008). Athreye and Godley’s work finds parallels between the strategies adopted by laggard U.S. firms to gain capabilities in antibiotics during the beginning of the antibiotics revolutions and the leapfrogging strategies of Indian firms, eager to acquire positions in new biotechnology based drugs. They argue that both groups used internationalization strategies to gain technological advantages and build up their firm specific situations.

Mani’s work (2006) undertakes a detailed examination of the Indian pharmaceutical industry from the perspective of a sectoral system of innovation. In consonance with earlier works outlined above, he mentions about the lack of innovative efforts in neglected diseases. Further, he outlines how, though the innovation system possesses the capabilities to develop new chemical entities, the two main components of the innovation system, namely the firms and the government research institutes do not possess all the requisite capabilities to bring new drugs to the markets, an area requiring immediate policy interventions.

Field’s (2006) work outlined how the ‘access to medicines’ campaign, a social movement largely concerned with providing affordable drugs to the poor in developing countries created a discourse that was applied by indigenous Indian pharmaceutical firms to bolster the production of generic drugs and applied R&D. Srivastava’s study outlines the need for regulatory reforms within the drug control administration in India, private sector
medicine distribution in terms of regulation of mark-ups and monitoring systems and the harmonization of regulatory standards pertaining to quality control.

In the context of the present study on drug quality, Upadhyay et al’s empirical work (2002)\textsuperscript{66}, in the context of examining socio-economic aspects of in-house R&D in the Indian pharmaceutical industry, highlighted how in the process of organizational restructuring in the wake of the patent regime, firms had begun to embrace a new conceptualization of drug quality in the Indian pharmaceutical industry, which was multi-dimensional in nature and incorporated a range of parameters such as efficacy, safety, lack of impurities and stability, detailed documentation of the production process and environmental parameters. Ray and Bhadhuri’s\textsuperscript{67} subsequent paper outlined how the relative importance of these diverse parameters in the final quality specification would vary from country to country, depending on the composition of the pharmacopoeia committee and socio-economic priorities of the government and that the increasing stringency in these parameters would act as entry deterrents for firms unable to implement these specifications.

Both these studies are significant in the context of the perspective they offer on the issue of drug quality. However, the mentioned parameters are largely a rendering of the technical features relating to quality outlined by the firms.

The economic literature on pharmaceuticals in India has thus largely been occupied with the strategies of the firms, in the form of research and development, contract manufacturing, technical and marketing collaborations, innovative activities and internationalization efforts and offering a comparative account of these issues in relation to

\textsuperscript{66} The empirical study, sponsored by the Department of Science and Technology, conducted by Upadhyay et al on the socio-economic aspects driving in-house R&D in the Indian pharmaceutical industry. The team members for the project included Dr V. Upadhyay (Principal Investigator), Dr Prajit K. Basu (Co-investigator), Dr Amit Shovan Ray (Co-investigator), Dr Saradindu Bhaduri, Parvathi K. Iyer, Bibhudatta Baral and Tanushree Tripathy. (This researcher was also part of the study team).

\textsuperscript{67} An outcome of this project.
the pre-patent and post patent regime. A few studies have also touched upon the policy environment in which these firms perform their activities and their efforts to cope with the changing regulatory regime. The importance of these studies in contributing to a sociological understanding of the industry is in terms of providing an insight into the issues and debates, which the industry regards as significant to its continuance and well being.

The ‘Construction’ of ‘Drug Quality’: Understanding the Problem in the Context of the Review Discussion

The above discussion provides us with a window into the diverse range of issues explored by different theoretical traditions in their engagements with the terrain of pharmaceuticals, although from the biographical perspective of drugs, one can deduce that gaps exist in terms of ethnographic accounts and analysis of the activities of firms involved in the early stages of drug discovery in the industrial laboratory and perspectives of manufacturers’ in the stages related to commercial production of the drug.

As reiterated earlier, the discourse of drug quality may be examined in the context of the unique biography or life cycle that drugs undergo, the diverse interests, norms and values that they embody and the complex worlds that they constitute. In the context of Van der Geest’s notion of the drug as a social and cultural product and as having a life cycle of its own, one can examine what and how are the ways in which drugs in general are ‘qualified’, during the transformations they undergo in the laboratory, during testing, commercial production, marketing, prescription phase etc and the norms and values that are invoked in each of these stages. Notions about drug quality figure prominently in the discourse of firms, regulatory bodies, physicians, health activists and consumers alike, either in the context of research and development strategies, clinical trials, manufacturing related
protocols, prescriptions of medical practitioners, marketing strategies and pronouncements of activists and government departments in relation to health policy. Such notions cannot be examined in isolation and as being separate from the socio-technical processes, which shape their qualification. Thus, understanding drug quality in the industry is also as much about how drugs are ‘qualified’ by different groups or key ‘actors’ in the industry during the different stages in the life cycle of drugs in general.

The study deploys Callon’s (2002) concept of ‘qualification’ in tandem with Van der Geest’s formulations (1996) on a ‘biographical approach to drugs’ in order to examine how such ‘qualification’ occurs and what are the socio-technical processes shaping such ‘qualification’ in the industry.

In specifically examining how such qualification occurs in the stages of pre-clinical testing and the manufacture of finished formulations at the firm level and how it obtains when the drug enters into a larger theatre of contestations and representation, embodied by the regulatory terrain and the diverse actors that inhabit it, the present study attempts to relate the micro-processes of fact making related to the qualification of drugs in the industrial laboratory to the macro-structural terrain of interests, institutions and regulatory culture.

A final caveat on the use of the term ‘construction’ before embarking on a discussion of the research questions of the thesis. Sismondo (1993:516) outlines the different meanings of the word ‘construction’ thus: 1.) the construction, through the interplay of actors, of institutions, including knowledge, methodologies, fields, habits and regulative ideals; 2) the construction by scientists of theories and accounts, in the sense that these are structures that

68 Articulated in section two of the review discussion.
69 These ideas are elaborated upon in the second chapter, which deals with the methodology deployed in the study.
rest upon bases of data and observations; 3) the construction, through material intervention, of artifacts in the laboratory; and 4) the construction in the neo-Kantian sense, of the objects of thought and representation. In offering these different meanings, he also highlights how meanings (1) and (2) are deployed by constructivists, who are concerned as much with the idea of social interests shaping the sphere of Science as they are with the construction of scientific knowledge in terms of the social nature of knowledge and the idea of the constructed nature of social reality.

The term ‘construction’ has been broadly deployed in terms of the idea that “social reality is not stable and objective; it is recreated in and through human discourse.” (Hegde 2006:34). In this regard, the study also does not attempt to use the term ‘construction’ in the typical ‘Latourian’ sense but only in terms of trying to provide an account of how different actors in the industry may understand and ‘qualify’ drugs in their own particular ways and their negotiations in relation to this. Such qualifications may then be understood as constituting a ‘negotiated order.’

This is also because, while constructionist ideas are useful in the above mentioned ways, they may not provide us with a fuller understanding of how different social and technical factors operate and interrelate beyond the immediate context. (Abraham 2007: 732). In the context of the present study, constructionist ideas may not give us a satisfactory explanation for understanding issues such as why firms work in particular therapeutic areas, why certain drugs fail in the phase of regulation or display adverse reactions etc. Consequently, the interests approach within the Science, Technology and Society (STS) tradition may be more useful in terms of detailing how social interests govern the treatment
of particular claims as facts or scientific knowledge and the discarding of other knowledge claims.

In the context of the present study, the tradition may be useful in helping us to understand the power and influence of the pharmaceutical industry in areas such as preclinical and clinical drug testing and the government regulation of drugs, the disparities between accepted scientific standards for drug testing and how firms actually conduct the tests. In addition, the scientific controversy model within the STS tradition may be useful in terms of understanding the relative power of particular groups within the industry to define certain kinds of knowledge claims about ‘drug quality’ as more acceptable and objective over others’ claims in the context of a drug related controversy.

Central Research Questions
In the light of the above discussion, the study examines the following questions:

1) What are the norms invoked by the firms in relation to the notion of ‘drug quality’ during the different stages in the life cycle of drugs? What are the socio-technical processes driving the qualification of drugs during these stages, specifically during the stage of pre-clinical testing within the industrial laboratory and the commercial production of drugs into finished formulations, within the firm?

2) How is this ‘quality’-related discourse of the firms received and shaped by other agents such as regulatory bodies, health activists, academicians, physicians and pharmacists? What is the extent of agreement and negotiation on these firm-invoked norms? What are the socio-technical processes driving the qualification of drugs in the larger terrain of drug regulation?
3) How does the balance of power operate between these groups with respect to the negotiation over these norms? What is the trade-offs between the different values choices involved here?

Chapterization of the Thesis

The chapters in the dissertation have been sequenced as follows. The present chapter largely attempted to provide an exposition of the diverse range of studies and perspectives on pharmaceuticals carried out within different traditions, in addition to outlining their usefulness for the present study and laying down the central research questions of the study. Chapter 2 provides an account of the methodology deployed in the thesis. Chapter 3 undertakes a brief overview of the Indian pharmaceutical industry in terms of outlining the shifts in regulatory policies, outlining the regulatory guidelines and issues related to patents, data protection, clinical trials and manufacturing activities. Concurrently, it also attempts to provide a snapshot of the activities of the industry. Chapter 4 attempts to elaborate on the micro-processes of ‘fact-making’ or knowledge production and the ‘qualification’ of drugs in a pharmaceutical firm during the stage of pre-clinical testing through an interrogation of the every day practices and routines of the scientists in its discovery research centre. Chapter 5 attempts to understand the socio-technical processes shaping the qualification of drugs during the stage of manufacturing and commercial production. Chapter 6, through the study of a controversial drug, attempts to provide an interesting glimpse into the processes and mechanisms shaping the qualification of drugs outside the realm of the firm. It provides us with an understanding of how, outside the realm of the firm, the drug mediates with other agencies, which then seek to control its therapeutic career. Chapter 7 broadly attempts to examine the contestations between activists, regulators and firms in different spheres of the
contested terrain of drug regulation and their implications for the ways in which drugs are qualified by these groups. Chapter 8 sets forth the principal findings and conclusion of the thesis.