

Pharmaceuticals, State and Local Communities: A Study of Health Inequalities in Hyderabad

A Thesis Submitted to the University of Hyderabad

in Partial Fulfillment of the Requirements for the Award of

DOCTOR OF PHILOSOPHY

IN

DEPARTMENT OF SOCIOLOGY

BY

SHILPA KRISHNA

12SSPH08



हैदराबाद विश्वविद्यालय
University of Hyderabad



प्रतिष्ठित संस्थान
INSTITUTION OF EMINENCE
राष्ट्रीय अपेक्षाएँ, वैश्विक मानक
National Needs, Global Standards

**DEPARTMENT OF SOCIOLOGY, SCHOOL OF SOCIAL SCIENCES,
UNIVERSITY OF HYDERABAD, HYDERABAD-500046, TELANGANA, INDIA.**

2023



DECLARATION

I, **Shilpa Krishna**, hereby declare that this thesis entitled “**Pharmaceuticals, State and Local Communities: A Study of Health Inequalities in Hyderabad**”, submitted by me under the guidance and supervision of Prof. N Purendra Prasad, is a bonafide research work for the award of Doctor of Philosophy in Department of Sociology from the University of Hyderabad. I also declare that it has not been submitted previously in part or in full to this University or any other University or Institution for the award of any degree or diploma. I hereby agree that my thesis can be deposited in Shodhganga/INFLIBNET.

A report on plagiarism statistics from the University Library (IGML) is enclosed.

Shilpa Krishna,
Reg. No: 12SSPH08.

Prof. N Purendra Prasad,
Supervisor,
Department of Sociology,
University of Hyderabad.



CERTIFICATE

This is to certify that the thesis entitled “**Pharmaceuticals, State and Local Communities: A Study of Health Inequalities in Hyderabad**”, submitted by **Ms. Shilpa Krishna**, bearing Reg. No. **12SSPH08**, in partial fulfillment of the requirements for the award of Doctor of Philosophy in Sociology, is a bonafide work carried out by him under my supervision and guidance, which is a plagiarism-free thesis.

The thesis has not been submitted previously in part or in full to this or any other University or Institution for the award of any degree or diploma. Further, the student has the following publication(s) before submission of the thesis/monograph for adjudication and has produced evidence for the same in the form of acceptance letter or the reprint in the relevant area of his research:

A. Publications in Academic Journals:

1. Krishna, S., & Prasad, N. P. (2014). Ethical issues in recruitment of “healthy volunteers”: study of a clinical research organisation in Hyderabad. *Indian J Med Ethics*, 11, 228-32.
2. Reddy, C., Joshua, G., Pradhan, I., Touthang, J., Das, L. K., Chakraborty, M., ... & Krishna, S. (2019). ‘Research Scholars’ Epistemological Predicament. *Economic & Political Weekly*, 54(23), 35-42.
3. Krishna, S (2016). ‘Issues of Accessibility and Affordability to Medicines in India’, in Purendra Prasad (ed.) *Sociology of Health*. New Delhi: Epathashala, University Grants Commission-Ministry of Human Resource Development, Government of India.

4. Krishna, S (2016). 'Drugs and Patents', in Purendra Prasad (ed.) *Sociology of Health*. New Delhi: Epathashala, University Grants Commission-Ministry of Human Resource Development, Government of India.
5. Krishna, S (2016). 'Irrational Use of Drugs and Unethical Practices', in Purendra Prasad (ed.) *Sociology of Health*. New Delhi: Epathashala, University Grants Commission-Ministry of Human Resource Development, Government of India.
6. Krishna, S (2016). 'Medicalisation and Pharmaceuticalization', in Purendra Prasad (ed.) *Sociology of Health*. New Delhi: Epathashala, University Grants Commission-Ministry of Human Resource Development, Government of India.
7. Krishna, S (2016). 'Clinical Trails and Ethical Issues in India', in Purendra Prasad (ed.) *Sociology of Health*. New Delhi: Epathashala, University Grants Commission-Ministry of Human Resource Development, Government of India.
8. [Book Review] 2020. Claudia Lang, *Depression in Kerala: Ayurveda and mental health care in 21st century India*. Routledge (2018), in *Contemporary South Asia*, Vol (28) Issue 3: 422-423.
9. [Book Review] 2020. Mark McCormack, Eric Anderson, Kimberly Jamie, Matthew David, *Discovering Sociology*. Red Globe Press (2018), in *Magazine of the British Sociological Association*, Spring 2020: p.27

B. Presentations in Research Conferences:

1. Presented a Paper titled 'Ground Realities in Clinical Trials' in the course on Ethical and Legal Issues in 'New Frontiers' in Bio-Medical Research organised by Sama Resource Group for Women and Health on July 13-15, 2018 at Hotel Baseraa, Secunderabad.
2. Presented a Paper titled 'Pollution and its Impact: A Case Study in Hyderabad' in the International Conference on Health and Air Pollution: Effects and Management (ICOHAP-EM-2018), organised by the International Development Centre Foundation (IDC), held at India International Centre, New Delhi on 7-8 September 2018.
3. Presented a Paper titled 'Pharmaceutical Industry and Health Hazards: A study in Hyderabad' in 14th World Congress and 7th National Conference on Bioethics on the theme of Health for All in an Unequal World: Obligations of Global Bioethics, organised by Forum for Medical Ethics Society, Sama Resource Group for Women and Health, St.

John's National Academy of health sciences and Society for Community Health Awareness, Research and Action (SOCHARA), held at St. John's National Academy of Health Sciences Bengaluru, India on 5th and 7th December 2018.

Further, the student has passed the following courses towards fulfilment of coursework requirement for Ph.D. was exempted from doing coursework (recommended by the Doctoral Research Committee) on the basis of the following courses passed during her M.Phil. program and the M.Phil. degree was awarded:

Sl. No.	Course Code	Course Title	Credits	Results/Grade
1	SS600	Advanced Sociological Theory	4	PASS/B+
2	SS601	Advanced Research Methods	4	PASS/B+
3	SS602	Dissertation- Topic Related Course	4	PASS/B+
4	SS780	Regulating the Social Body: A Study of Clinical Trials in Hyderabad	12	PASS

Prof. N Purendra Prasad,
Supervisor.

Head,
Department of Sociology,
University of Hyderabad,
Hyderabad- 500 046.

Dean,
School of Social Sciences,
University of Hyderabad,
Hyderabad- 500 046.

Acknowledgment:

Embarking on a journey into the intricate and highly safeguarded terrain of the pharmaceutical industry was a formidable task, and the successful completion of this research owes its existence to the unwavering support and contributions of a multitude of individuals. I extend my sincere gratitude to the following:

First and foremost, my deepest appreciation goes to my research supervisor, Prof. N Purendra Prasad. His timely interventions, insightful suggestions, and unwavering confidence in me have been pivotal to the fruition of this thesis. He has been a constant support during the emotional ebbs and flows of this period, and I am profoundly grateful for his efforts in making my PhD experience both productive and stimulating. From my MA days, he instilled confidence in me, providing continuous support at both personal and academic levels. His encouragement and freedom allowed me to explore diverse themes discussed in the thesis, and his role as a supervisor, well-wisher, and constant support has been immeasurable. I am forever thankful to him, and words fall short to express my deep indebtedness.

Special thanks are extended to the doctoral committee members, Prof. Sasheej Hegde and Prof. Prajith Basu, for their valuable contributions.

I express my immense gratitude to the Department of Sociology, where kindness abounded. Prof. Chandrashekar Bhat, Prof. Vinod Jairath, Prof. Lakshmi Narayan, Prof. Sasheej, Prof. Aparna Rayaprol, Dr. Janardhan, Prof. Nagaraju, Prof. Raghav Reddy, and Dr. Asima.

The members of our research group, under the mentorship of Prof. N Purendra Prasad (Satish, Lalhmangaihi Priyam, Debapriya, Chandra Shekar, Bhupathi, Lalatendu, Rajesh, Abhijit, Jagdeep, Chinna, Rehaman, Naresh, Ravi, and Minu), deserve special mention for their unwavering support, insightful comments, and assistance throughout this journey. I extend my sincere gratitude, particularly to Satish, Ravi, and Minu, for shouldering the challenging tasks associated with my thesis. My appreciation extends to the office staff of the Department of Sociology – Tirupathaiah, Madhusudhan, Chandrakanth, Sreedharan, and a special acknowledgment to Geetha Patil for her unwavering support. This research would not have been complete without the invaluable contributions of my respondents. I extend my sincere thanks to activists, advocates, victims, bureaucrats, journalists, officials, and industry representatives, each playing a pivotal role in this study. Lastly, and most importantly, I extend heartfelt thanks to my family for their unwavering support throughout this journey. This collaborative effort and support from all mentioned above have been the bedrock of this research, and I am profoundly grateful for their significant contributions.

DECLARATION & CERTIFICATE

ACKNOWLEDGEMENTS

List of Contents	i
List of Tables, Maps, and Figures	iv
Abbreviations	v

List of Contents

Chapter No	Sl. No	Particulars	Page No.
Chapter One	1	Introduction	1 to 22
		Research Problem	6
		Research Questions	7
		Research Objectives	7
		Field	8
		Methodology	15
		Access and Challenges	16
		Methodological Tools	18
		Respondents	19
		Researcher's Reflections	21
		Thesis Limitations	22
		Chapterization	22
Chapter Two	2	Paths of Power: Mapping Accumulation, Regulation and Health Inequality in the Pharmaceutical Landscape	23 to 63
	Section I	The Tangible Power of Medicines: Efficacy and Usage	24
		Pharmaceutical Nexus	30
	Section II	Pharmaceuticalization	34
		Pharmaceuticals and Commercialisation	37
		The Indian Context	41
	Section III	State and Regulation	43
		Pharmaceutical Scandals: Issues and Regulatory Lapses	45
		State and Health	50
	Section IV	Health and Inequality	53
		Power	57
		A Discussion on the Political Economy of Pharmaceuticals	62

Chapter Three	3	From Policy to Hype: The State as an Architect of Pharma Vision	64 to 111
		Pharma Industry: Technical Insights	65
Section I		Pre-Independence	67
		1947-1970	69
		Industry Policy Resolution (IPR)-1948	69
		Pharmaceutical Industry	70
		The First Five-Year Plan (1951-1956)	70
		Industrial Policy Resolution-1956	71
		Licensing Policy	71
		State and the Drug Industry till the 1970s	72
		Drugs and Pharmaceutical Industry in the early 1970s	73
		The Development of Different Acts and Legal Provisions	75
Section II		Intellectual Property Rights (IPRs)	76
		Pre-1972 -Product Patents Period	77
		The Process Patent ERA- 1972-2005	78
		Hathi Committee Report (HCR)	79
		Indian Patents Act 2005 onwards	83
		2017- Pharmaceutical Policy	86
		Draft National Pharmaceutical Policy 2023	87
Section III		Health Policies	89
		Health for All?	93
		Regulations	97
		Regulatory capture	101
Section IV		Discussion	106
 Chapter Four	 4	 Pharma's Dark Curtain: The Unseen Costs of Medical Advancements	 112 to 162
Section I		Bulk drug capital- Hyderabad	115
Section II		Examining Highly Polluting Industries and Treatment Plants	123
Section III		Toxic Shadows- Villages Battling the Environmental Fallout of Industries	134
		Technologies of Power: Court Directives- Contradictions Exposed	142
Section IV		Concerns of residents in Industrial Zones	151
Section V		Discussion	157

Chapter Five	5	Pathopolitics and Social Suffering	163 to 186
	Section I	Invisibilization of Suffering and Invisible Suffering	165
		Smell	166
		‘Normalizing’ Suffering	170
	Section II	Structural Violence/Suffering	172
		Narratives	176
		Double Body Burden	180
		Changing Dynamics	182
	Section III	Discussion	184
 Chapter Six	 6	 Conclusion: Reflections on Pharmaceuticals, State, and Health Inequalities	 187 to 201
		In Hindsight: Recapitulating Essential Elements	188
		Pharmaceutical Industry and State	190
		Bulk Drug Capital and Regulatory Capture	191
		Health Inequalities	193
		Social Suffering	195
		Changing Dynamics	197
		Prospect or Uncertainty?	200
 References			 202-241

List of Tables, Maps and Figures

Sl. No	Particulars	Page No
Table 1.1.	Profile of the Respondents	19
Table 1.2.	Landless Respondents–Educational Qualification	20
Table 1.3.	Landholders Profile	21
Map 1.4.	Non-Attainment cities in Telangana	14
Map 4.1.	Pollution Affected Villages	135
Figure 4.1.	Present condition of IDPL	117
Figure 4.2.	Nakkavagu Sub-Basin	120
Figure 4.3.	Effluents released from Ramky Hazardous Waste Plant	133
Figure 4.4.	Cattle death	136
Figure 4.5.	Effluents released directly into water streams	138
Figure 4.6.	Contaminated ground water	139
Figure 5.1.	Loss of crop	181
Figure 5.2.	Real Estate- Gated community villas in the study area	184

List of Annexures

Sl. No	Particulars	Page No
Annexure I	Images of polluted sites during senior advocate MC Mehta’s visit to the study area	i to viii
Annexure II	Images indicating non-compliance of NGT directives	ix to xii
Annexure III	Images indicating continuity of non-compliance of NGT directives in 2022	xiii to xix
Annexure IV	Images of polluted sites collected from secondary sources	xx to xxv
Annexure V	Letters to Regulatory Authorities by Captain Rama Rao and Save Our Urban Lakes (SOUL)	xxvi to xxix

Abbreviations

ADHD	Attention Deficit Hyperactivity Disorder
AMR	Anti-Microbial Resistance
API	Active Pharmaceutical Ingredient
APIIC	Andhra Pradesh Industrial Infrastructure Corporation
CAD	Coronary Artery Disease
CAG	Comptroller and Auditor General of India
CAP	Citizens Against Pollution
CDRI	Central Drug Research Institute
CDSCO	Central Drugs Standard Control Organization
CETP	Common Effluent Treatment Plant
CIPLA	Chemical, Industrial and Pharmaceutical Laboratories Ltd
COB	Carry-on-Business
CPCB	Central Pollution Control Board
DCGI	Drug Controller General of India
DGTD	Directorate General of Technical Development
DPCRC	Drug Price Control Review Committee
DPEA	Drug Prices Equalization Account
DPT	Diphtheria Pertussis Tetanus
DRL	Dr. Reddy's Laboratories
EMA	European Medicines Agency
EPA	Environmental Protection Act
EU	European Union
FERA	Foreign Exchange Regulation Act
GMP	Good Manufacturing Practice
GPN	Global Production Networks
HAL	Hindustan Antibiotics Limited
HCR	Hathi Committee Report

HPV	Gardasil Human Papillomavirus
IDMA	Indian Drug Manufacturers Association
IDPL	Indian Drug and Pharmaceuticals Limited
IDR	Industries Development and Regulation Act
IMD	International Institute for Management Development
IPCA	The Indian Pharmaceutical Combine Association
IPR	Industrial Policy Resolution
IPRs	Intellectual Property Rights
JAP	Joint Action Plan
KSMs	Key Starting Materials
MAPE	Maximum Allowable Post-manufacturing Expenses
MAT	Moving Annual Total
MDR	Multidrug-Resistant
MNCs	Multinational Corporations
MoC&F	Ministry of Chemicals & Fertilizers
MoHFW	Ministry of Health and Family Welfare
NCE	New Chemical Entities
NGT	National Green Tribunal
NITI Ayog	National Institution for Transforming India
NPPA	National Pharmaceutical Pricing Authority
NPP	National Pharmaceuticals Policy
NPVP	National Pharmacovigilance Programme
OECD	Organisation for Economic Co-operation and Development
OPPI	Organisation of Pharmaceutical Producers of India
OTC	Over-the-Counter
PETL	Pattancheru Enviro Tech Limited
PLI	Production-Linked Incentive
PPEPCI	Pharmexcil Pharmaceuticals Export Promotion Council of India
PRDC	Pharmaceutical Research and Development Committee

PSCI	Pharmaceutical Supply Chain Initiative
PTUAS	Pharmaceutical Technology Upgradation Assistance Scheme
PvPI	Pharmacovigilance Programme for India
R&D	Research and Development
SDG	Sustainable Development Goal
SOL	Standard Organics Limited
TNCs	Transnational Companies
TRIPS	Trade Related Aspects of Intellectual Property Rights
TSDFs	Toxic Substances Disposal Facilities
TSIIC	Telangana State Industrial Infrastructure Corporation
TSPCB	Telangana State Pollution Control Board
UNGP	United Nations Guiding Principles on Business and Human Rights
UNICEF	United Nations International Children's Emergency Fund
UN	United Nations
WDCR	World Digital Competitiveness Ranking
WTO	World Trade Organization

CHAPTER: 1

INTRODUCTION

Of all the forms of inequality, injustice in health is the most shocking and inhumane.

— Martin Luther King Jr (March 25, 1966)

The thesis is an outcome of a time, when global attention has heavily focused on health due to the COVID-19 pandemic, highlighting a fundamental aspect of human well-being. The pandemic has not only deepened our understanding of the complex relationship between the state and capital (Freudenberg, 2021) particularly within the pharmaceutical industry but has also spurred this thesis to explore the nuanced interplay, refine existing questions and introduce new dimensions, as the crisis prompts a critical reevaluation of how state interventions shape the industry and impact global health outcomes. The uncertain origins of COVID-19, resembling the 2003 SARS outbreaks, are associated with the repercussions of aggressive capitalist production. The surge in pandemics has been linked to environmental degradation driven by capitalism since 1940, resulting in the emergence of pathogens, including HIV, Ebola, and Zika, primarily originating from wildlife (Attard, 2020). In the current global context, exacerbated by the pandemic, this study, thus, critically analyzes the prevailing perception of pharmaceutical companies as quasi-deities and saviors during health crises.

Health, as understood here, transcends the mere absence of disease, encompassing physical, mental, and social well-being. It represents a dynamic equilibrium where individuals can actualize their potential, navigate life's challenges, contribute productively, and engage meaningfully within their communities (WHO, 1978). Key stakeholders in the realm of health are broadly categorized into those who 'pay, provide, and produce'. The financial dimension involves those Who Pay, including governments, private insurers, and individuals, whose funding decisions influence healthcare accessibility, affordability, and quality. Those Who Provide, comprising healthcare practitioners and facilities, significantly impact the quality of healthcare through competence, availability, and ethical standards. Disparities in

their distribution contribute to regional differences in healthcare access. Lastly, Those Who Produce, encompassing pharmaceutical companies, medical device manufacturers, and research institutions, play a pivotal role in advancing medical science and improving healthcare outcomes (Burns, 2014). This thesis centers its focus on, Pharmaceuticals ‘who produce’, delving into the dynamics and implications within the broader healthcare landscape.

The global ramifications of the pandemic, emphasize challenges in countries lacking robust public health systems, grappling with unequal resource access, social inequality, democratic governance issues, and institutional shortcomings. While influenza, tuberculosis, malaria, and HIV/AIDS persistently claim millions of lives annually, COVID-19 worsened health inequalities and created uncertain futures, notably in developing countries, particularly countries like India. The Indian government has been actively implementing hegemonic market-oriented policies while simultaneously expressing community health narratives in response to grassroots pressures. The lack of adequate attention, robust mechanisms, and discourse on state interventions for marginalized lives in India, influenced by structural inequities in class, caste, gender, and space, exacerbates the confluence of inequalities, particularly health inequalities, further amplified by the state of the healthcare system. Health inequalities are increasingly recognized as the result of social, material, and cultural disparities rooted in societal inequalities, stemming from variations in power, wealth, income, social status, connections, and knowledge. The emphasis lies in comprehending the political economy of health inequalities and the associated politics of distribution and access. It is crucial to explore how power imbalances are portrayed and reinforced in healthcare. Addressing unequal health outcomes, as highlighted by Paul Farmer (2001), does not equate to eliminating the foundational forces of inequality (Prasad, 2018, 2022).

At the global level, efforts to reduce health inequality are increasingly tied to the accessibility, affordability, and availability of pharmaceuticals; nevertheless, the pharmaceutical industry consistently maintains a high ranking in terms of profitability. Contrary to the perception that profits arise from therapeutic advances, only about 1.3 percent of the industry's post-tax expenditures contribute to basic research crucial for new medication development. Additionally, a significant portion of new medicines introduced by pharmaceutical corporations provide limited therapeutic benefits, where a majority were

deemed ‘nothing new,’ and a substantial number posed serious safety concerns without evident benefits (Lexchin, 2018). The following paragraphs will elucidate the various issues, concerns, and challenges prevalent within the industry.

In John Le Carré's (2001) film *The Constant Gardener*, the pharmaceutical industry is portrayed as akin to the malevolent empire of the Soviet Union in Cold War novels, revealing a narrative of testing hazardous drugs on impoverished Africans, suppressing information about lethal side effects, and silencing whistleblowers. Le Carré's complex tale is characterized as a profound exploration of the dark side of unbridled capitalism. This depiction of the pharmaceutical industry, though seemingly preposterous, characterizes pharmaceuticals as a ruthless and corrupt form of capitalist enterprise, as echoed by critics (Angell, 2004; Moynihan & Cassells, 2005). The industry's reputation has suffered due to major scandals, including litigation against manufacturers of certain medications. The backlash against big pharma is fueled partly by the over-promotion and overuse of a small number of drugs, leading to a shift in the balance of benefits and risks.

Critics argue that rather than developing innovative products, major drug companies focus on protectionist strategies, contributing to a slowing influx of useful new drugs into the market. Despite claiming entrepreneurial flair, big pharma is revealed to be highly reliant on state patronage. The pharmaceutical industry's intimate connections with political processes and regulatory agencies have compromised the efficacy of regulatory oversight. Contrary to perspectives depicting big pharma as purely malevolent or altruistic, the industry is portrayed as a cautious and conservative entity, heavily dependent on a few blockbuster drugs, employing restrictive practices, and enjoying state subsidies, while capitalizing on the growing medicalization¹ of society (Fitzpatrick, 2006). This medicalization occurs through influential lobbying efforts aimed at shaping state policies.

Over the past four decades, the pharmaceutical industry has actively lobbied for stronger Intellectual Property Rights (IPRs), a campaign spearheaded by Pfizer CEO Edmund Pratt. Their efforts led to the establishment of the World Trade Organization (WTO) in 1995 and the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

¹ Medicalization is the process by which non-medical problems become defined and treated as medical problems often requiring medical treatment. (Conrad & Bergey, 2015)

TRIPS mandated global patent standards, imposing a twenty-year product patent duration for pharmaceuticals. The pharmaceutical industry aimed to standardize IPRs globally, disregarding countries' developmental levels. By 2000, developing nations faced soaring drug prices due to strengthened IPRs, especially in HIV triple therapy. In response to these activities by the industry, developing nations such as South Africa enacted measures to allow generic substitution and importation of non-counterfeit patented medicines without permission. The United States (U.S) and European Union (EU), treating TRIPS as a baseline, sought to enhance IPR strength in subsequent trade deals, limiting access to essential medicines. In 2006, Thailand issued a compulsory license for HIV treatment, facing negative responses from the EU Trade Commissioner and drug manufacturer Abbott. The experience of Thailand illustrates how governments and the industry leverage IPRs to pressure developing countries.

Compulsory licenses, a legal provision under TRIPS, are criticized by brand-name corporations like Bayer, whose CEO referred to it as 'essential theft.' Bayer's profit-centric focus on global health concerns is evident in their admission that the highly effective drug sofosbuvir (Sovaldi) was developed for Western patients who could afford it. In addition, pharmaceutical corporations, driven by financial interests, control knowledge about drugs, influencing all stages of pre-market clinical trials. Pro-corporate bias is introduced through selective reporting, misleading presentation of data, and ghostwriting. Companies like Merck and GlaxoSmithKline have been implicated in these practices. The use of 'Key opinion leaders'(KOLs)² is another strategy employed by companies to maintain credibility, but deviation from corporate messages jeopardizes the value of KOLs, illustrating the industry's focus on profit over ethical and global health considerations (Lexchin,2018).

Sociologically, issues related to negligence, fraud, and bribery in drug safety testing by the Pharmaceutical industry were focused on by Braithwaite (1984). By the early 1990s, sociologists in this field recognized that the industry's influence on drug testing and approval

² Corporations acknowledge the credibility gap inherent in directly presenting evidence about their products to physicians. To address this challenge, they enlist doctors and researchers referred to as "key opinion leaders" (KOLs). Corporations must maintain the façade that KOLs are independent sources of information to uphold the trust of doctors exposed to their presentations. However, when KOLs exhibit independent behavior and diverge from the corporate messages, their value to the corporations becomes questionable (Sismondo, 2013). An example is noted when a KOL authored case reports on a medication from a company he frequently represented, portraying the product less favorably than a competitor's drug. Upon the public disclosure of these case reports, his speaking invitations plummeted from four to six times per month to virtually none (Norton, 2000, p. 508).

extended beyond overt misconduct to more subtle forms of shaping and influencing. While the power and influence of the pharmaceutical industry were apparent to sociologists since Braithwaite's time, the 1990s saw the development of systematic sociological methodologies. These aimed to identify and explain the mechanisms of industry influence within the science-based processes of drug testing and government regulation, including laboratory testing and the creation of scientific papers. The sociological challenge was to systematically connect the micro-social processes of knowledge production in drug testing to the macro-structural landscape of institutions, interests, and political culture in society (Abraham, 1995). This effort involved understanding drug testing and regulation as processes that generate scientific knowledge claims, with scientists forming networks to achieve their goals, as conceptualized by Latour's 'fact-making' (1979). This framework emphasized conflicting interests, namely the pharmaceutical industry's commercial interests versus the health interests of patients and the wider public. Central to the sociological methodology was the identification of technical inconsistencies in claims made within drug testing and regulation. This involved mapping these inconsistencies onto interests and other macro-structural phenomena. Technical inconsistencies could be observed, for instance, between accepted scientific standards in a subfield of drug testing (clinical trials) and a pharmaceutical company's actual testing practices or between the interpretative standards applied by the same scientist to the results of different studies (Abraham, 1993).

Amidst the prevailing challenges and perceptions surrounding the pharmaceutical industry, Abraham and Davis (2007) assert that this sector stands apart from others, exhibiting distinctive characteristics and complexities unlike any other industry or commodity, inherently tied to improving people's health and distinguishing it from mere commodity production. Unlike industries with primary goals of employment and profitability, the pharmaceutical sector's *raison d'être* lies in contributing to medicine and therapy for patients. While acknowledging the socio-economic objectives of employment and profitability, these are secondary to the fundamental purpose of pharmaceuticals. The logical position that pharmaceuticals should aim for is to enhance health. Social science and policy research often describe how pharmaceutical innovation and marketing occur, detailing the actions and perspectives of involved agents. However, the significance lies in assessing these activities against the core purpose of pharmaceutical production producing drugs that genuinely enhance health (Abraham & Davis, 2007).

The pharmaceutical industry plays a crucial role in the provision of healthcare services globally. However, the industry's activities are often shaped by political and economic factors, including state policies and regulations, that can create and perpetuate health inequalities among different social groups. This thesis aims to investigate the political economy of the pharmaceutical industry, the state, and health inequalities.

Research Problem:

Pharmaceuticals are expected to play a crucial role in providing healthcare services, mitigating human suffering, and saving lives. However, they are not without controversy, as seen in the case of the bulk drug manufacturing industry in Hyderabad in 1980s and 1990s, one of India's most polluted industrial areas with a high antimicrobial resistance rate. Despite these concerns, the Telangana government proposed the establishment of India's largest integrated pharmaceutical city³ in Hyderabad in 2015, spanning over 19,000 acres (The Hindu, 2018). The pharmaceutical industry in Hyderabad has faced criticism, notably from the Comptroller and Auditor General of India (CAGI), for non-compliance with pollution control norms and failure to adhere to Good Manufacturing Practices guidelines. This non-compliance has led to the contamination of water bodies, soil, and crops, resulting in severe health issues for the surrounding communities (Nordea Report, 2016). The unaccounted costs of these hazards reveal loopholes in pharmaceutical regulation. India holds a significant position in the global generic API merchant market, with generic drugs constituting 70% of the country's pharmaceutical sector revenue. Despite reports of Hyderabad being one of the most polluted industrial areas, there is an on-going expansion in the pharmaceutical industry. Keeping this as an overview, this study seeks to critically examine the complexities of the pharmaceutical industry in Hyderabad by scrutinizing the roles of various stakeholders, including the industry, state regulations, and affected communities. The overarching goal of the thesis is to investigate the political economy of the pharmaceutical sector, state dynamics, and health disparities in India's bulk drug capital. It aims to delve into the power dynamics and operational mechanisms within the industry, unraveling the historical context and the broader relationship between regulators and the pharmaceutical sector. Notably, the research

³ Hyderabad Pharma City is an initiative of the former IT and Industries Minister, Government of Telangana, K. T. Rama Rao. Hyderabad, the capital of Telangana State and has been an industrial capital and major economic hub. Pharmaceuticals is one of the major industries in and around Hyderabad in addition to Information Technology. Contributing to more than 40% of the bulk drug production in the country. Hyderabad has been named as the “Bulk Drug Capital of India” and the “Vaccine Capital of the World”. In December 2019, the Government of India granted it the National Investment Manufacturing Zone (NIMZ) status and recognized that the Pharma City Project is of national importance. (Telangana Today, 2020)

is not confined to environmental pollution but aims to reveal the industry's historical evolution and its inherent nature.

Research Questions

1. What is the logic through which pharmaceutical industries continue to reproduce their power over the state and people?
2. What are the technologies of power adopted by the industry to produce health inequalities?
3. How do we understand the social suffering of the affected communities?

Objectives:

- To trace the historical processes involved in the growth and development of Hyderabad as the bulk drug capital of India.
- To examine the role of the State in Pharmaceuticals and their impact on health and well-being.
- To delineate the dynamics of Pharma industries regulation and its consequences for the local communities.
- To analyze the politics of reproducing pathologies and social suffering as well as countervailing forces.

Field

In the pharmaceutical industry's relationship with the state, the term 'field,'⁴ as per Pierre Bourdieu's (1992) conceptualization, represents a structured network of objective relations. Positions, defined by power or capital, determine profits for pharmaceutical companies. This framework shows the interconnected positions within the industry's social space, especially evident in its interaction with the state. Power dynamics and determinations highlight how pharmaceutical companies influence regulatory bodies, policies, and the broader population. Conceptually, analyzing the pharmaceutical industry as a field provides nuanced insights into its objective relations and power dynamics with the state, impacting regulatory decisions, resource access, and public well-being.

In this milieu, the selected site to study the pharmaceutical industry, particularly the bulk drug industrial zones, is Hyderabad, the capital of Telangana state in India (see Map 1.1). Situated amidst the undulating terrain of the Deccan Plateau in the Indian subcontinent, Hyderabad city and its surroundings are endowed with several natural and artificial water bodies, locally referred to as Cheruvus (lakes), Kuntas (ponds), etc. These bodies served as reservoirs for irrigation, drinking water, and groundwater replenishment, constituting an integral element of the city's urban ecology. Five pharmaceutical industrial estates (see Map 1.2) were established in Hyderabad, namely Patancheru, Bollaram, Jeedimetla, Kukatpally, and Sanathnagar. Among these five estates, Patancheru (earlier, in Medak district, Andhra Pradesh) is positioned along the lake shores, leading to a continuous discharge of untreated industrial effluents into these water bodies, transforming them into virtually lifeless 'toxic ponds' (Rao, 2001)).

Notably, several rivers and streams, such as Isakavagu, Nakkavagu, and Manjeera (upstream of Nakkavagu confluence), have been polluted by these industrial effluents. Some significant polluted lakes/cheruvu include Kazipalli cheruvu, Gandigudem cheruvu, Nagula cheruvu, Kistareddypet cheruvu, Muktakanta cheruvu, Aminpur cheruvu, Bollaram cheruvu, Saki

⁴ The term 'field,' as conceptualized by Pierre Bourdieu, denotes a network or configuration of objective relations between positions. These positions are defined objectively by their present and potential situation (situs) in the power or capital distribution structure. The possession of such power or capital determines the access individuals have to specific profits within the field. Additionally, positions are characterized by their objective relationships to other positions, involving dynamics like domination, subordination, homology, and more. This understanding of a field, articulated by Bourdieu and Wacquant in 'An Invitation to Reflexive Sociology' (1992), underscores the interconnectedness of positions within a social space. Viewing fields as structured networks provides valuable insights into the determinations imposed upon individuals, agents, or institutions based on their placement within these configurations.

cheruvu, Muthangi cheruvu, Isnapur cheruvu, Chitkul cheruvu, Lakadaram cheruvu, Pedda cheruvu, Yerdanur cheruvu, Gummadidala tank, Bonthapalli tank, Jinnaram cheruvu, Kalateleal cheruvu, and Digwal cheruvu, among others. The incessant seepage and infiltration from these contaminated water bodies, drains, and other waste disposal sites have resulted in the extensive pollution of the groundwater and drinking water sources in the region (Rao, 2001; Ramachandraiah, 2007).

The industrial expansion in Patancheru since the 1980s led to escalating air and water pollution, impacting farmers' livelihoods due to the absence of effluent treatment plants. Over 300 pharmaceutical and chemical industries, lacking environmental impact assessments, contributed significantly to global generic drug exports, yet environmental consequences were disregarded. In 1987, the state government closed 22 polluting industries, but bureaucratic non-compliance in erstwhile United Andhra Pradesh, now Telangana, denied justice and compensation to the affected populace (Sahu, 2007; Reddy, 2022). The people of Medak protested industrial pollution for over two decades, initiating a legal battle with a Writ Petition in 1990 in the Supreme Court. Despite numerous orders directing compensation from polluting industries, the legal process is progressing slowly. Pollution-affected people (PAP⁵), supported by citizens against pollution (CAP⁶), closed 22 industries in 1987. Twenty villages were 'identified' as highly polluted in Patancheru industrial estates, and mentioned in the court orders namely -Arutla, Baithole, Chidruppa, Chitkul, Gandigudem, Inole, Ismailkhanpet, Isnapur, Kandi, Kalabgoor, Kistareddypet, Khazipalli, Lakdaram, Muthanghi, Patancheru, Peddakanjarla, Pocharam, Ramchandrapuam, Rudraram, and Sulthanpur (details in Chapter 4). However, bureaucratic and local state's indifference have allowed pollution to be continued.

PAP organized relay hunger strikes, protests, and legislative assembly submissions for industry closures. Advocate M C Mehta and the Supreme Court played key roles, issuing orders for a cleaner environment and ecosystem restoration. State-level bureaucratic non-compliance in Andhra Pradesh denied justice and compensation. Despite Supreme Court orders and the National Green Tribunal's judgments, Patancheru's environmental situation has not improved. The Vidhi Centre's (2020) study highlighted an 'unequal fight' between

⁵ PAP, which stands for Pollution Affected People, is the generic term used in legal documents, by activists, advocates, and journalists to describe residents living in manufacturing vicinities affected by pollution.

⁶ An environmental action group based in Hydera-bad

local petitioners and industrialists, with the 'polluter pays principle' not adhered to and the prevalence of inadequate healthcare, hazardous waste dumping, rising health expenditures, and forced land sales by farmers. The NGT's 2017 judgment directed entitlements for Pollution Affected People, but the industrial lobby impedes implementation (Sahu, 2007; Green Peace, 2004; Reddy, 2022).

The present study selected Patancheru for in-depth analysis due to its extensively documented environmental pollution issues, and legal battles in the court. This location has been a focal point of reports, struggles, resistance, and arguments. Despite facing challenges and opposition, the industry has persistently reproduced itself. Patancheru is known for its high pollution levels, acknowledged not only by the scientific community and experts but also by state regulatory bodies, as indicated in Maps 3 and 4 taken from the Telangana State Pollution Control Board (2019). Patancheru in the Medak District has been recognized as one of the 24 critically polluted areas in India by the Central Pollution Control Board in 2009-2010. Patancheru industrial zone hosts the majority of the bulk drug industries compared to other pharmaceutical industrial estates. The official number of total bulk drug industries in the entire district was challenging to track due to ambiguous names and a lack of proper cooperation from state officials. Nevertheless, an attempt is made to compile a list of bulk drugs (API) in the chosen field site. This information was obtained from district officials after multiple visits and requests, resulting in a comprehensive list from which APIs were extracted for further analysis. The villages and industries selected for the study were identified from legal documents recognizing these places as highly polluting and polluted. Despite on-going legal proceedings, the pollution caused by these industries is well-documented in documentaries and by activists. By leveraging documentary evidence, this research study showcases that public discourse and official reports openly acknowledge criticisms concerning pharmaceutical drug production practices aimed at generating a surplus.

The well-documented pollution issue aligns with the insights of Joseph Dumit (2012), who emphasized that mere exposure is insufficient for critique; it is imperative to illustrate how the system perpetuates detrimental tendencies despite being aware of them. Expanding on the narrative of the industry's persistent pollution, the objective is to elucidate how these adverse practices in surplus generation have become ingrained and accepted within the existing

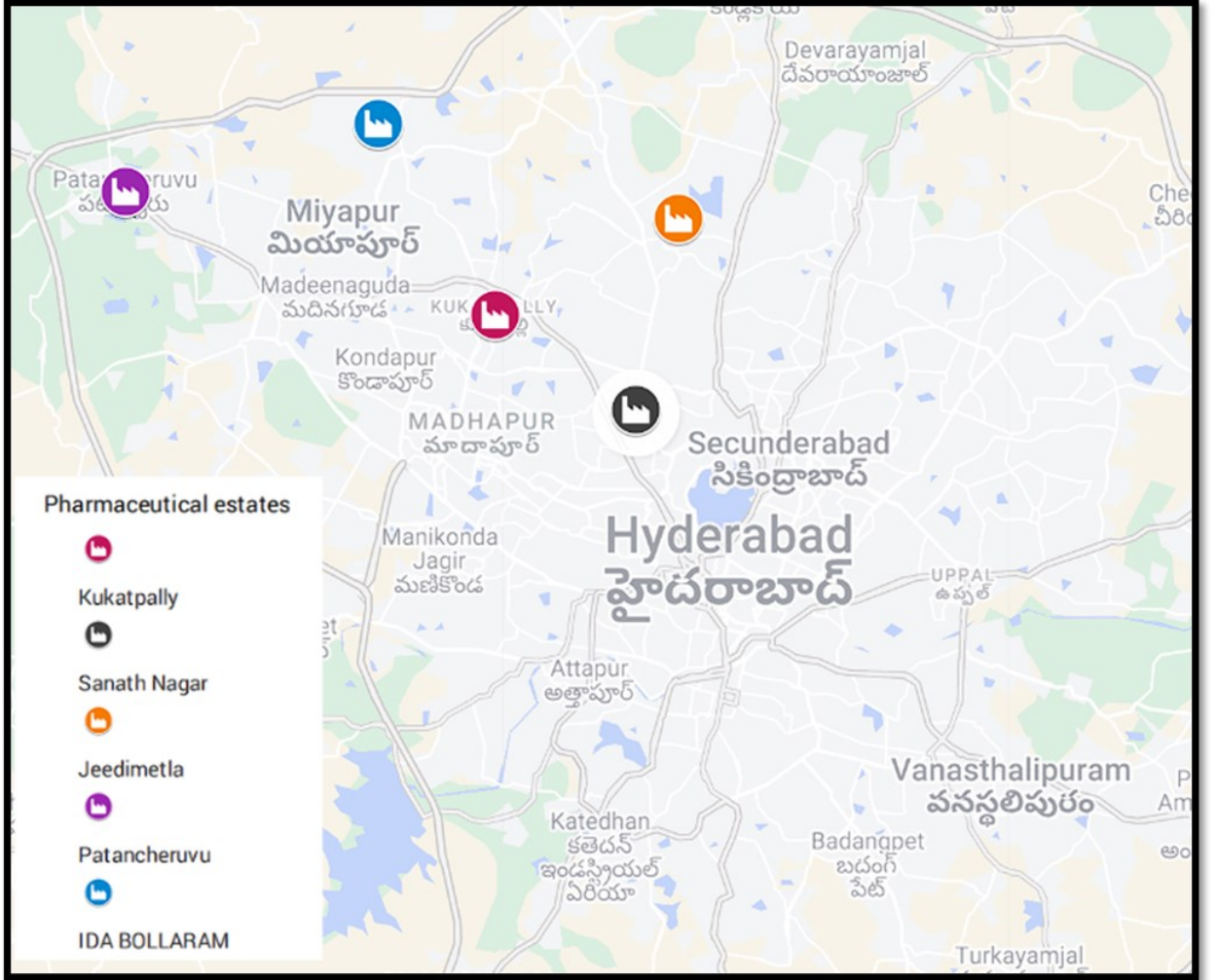
system. It emphasizes why such normalization demands a higher degree of scrutiny and a more urgent call for change than conventional arguments may suggest (Dumit, 2012).

Map 1.1: Telangana State in India



Source: https://commons.wikimedia.org/wiki/File:Telangana_districts.svg#/media/File:Telangana_districts.svg

Map 1.2: Industrial Estates in Hyderabad



Source- Google Maps.

Map 1.3: Polluted Industrial Areas in Telangana



Source-Telangana State Pollution Control Board. (2019)

Map 1.4: Non-Attainment cities in Telangana⁷



Source-Telangana State Pollution Control Board 2019

⁷ Non-Attainment Cities: (NAC)- Cities are declared non-attainment if, over 5 years, they consistently do not meet the National Ambient Air Quality Standards (NAAQS) for PM 10 (Particulate matter that is 10 microns or less in diameter) or NO₂ (Nitrogen Dioxide).

Methodology

The thesis adopts the Marxian political economy approach to capture the intricate interactions between the industry, the state, and the local populace. This approach aids in comprehending and elucidating the dynamics of capitalism, including the origins of social and economic disparities and the various ways these inequalities are reproduced in advanced capitalist societies (Fine & Filho, 2016). The purpose of applying this analytical approach to study the pharmaceutical industry is that it reveals insights into its historical development, societal impact, and material foundations, exposing the nature of the industry's, power dynamics, the root causes of healthcare inequalities, and how capitalism shapes and reproduces these inequities, all within the evolving mechanisms of industrialized capitalist societies. There is a paucity of studies that examine the production process and the industry's practices for surplus accumulation. Existing research predominantly concentrates on drugs, their life cycle, and associated processes, highlighting surplus generation from conception to consumption. In contrast, this study explores the production process, emphasizing surplus generation not only through the manufactured drug but also via the intricacies of the manufacturing process itself. Research in the pharmaceutical field presents unique challenges, requiring researchers to navigate negotiations with gatekeepers and intricate structures of hierarchy and power. Methodological challenges compel a re-evaluation of established academic notions surrounding the field, 'fieldwork' and 'research ethics'. Emphasizing the significance of addressing the intricacies of accessing pharmaceuticals, particularly given the confidentiality and scientific concerns, this section addresses the challenges and methods used to collect data and the ethical strategies deployed for maneuvering around restrictions at the industry, state, and community levels, particularly during the initial stages of entry and rapport building.

The commencement of this research coincided with external factors, notably the peak of the Telangana separation movement,⁸ leading to difficulties in accessing government departments and officials. The field visits commenced before the state division when Telangana was still part of undivided Andhra Pradesh. Data collection faced obstacles during the Telangana separation, with many government reports being unavailable or inaccessible. The field site was bustling with movement during this period, limiting my activities. The thesis is the culmination of research spanning and continuing since 2013.

⁸ The separate state of Telangana was established in 2014, following movements advocating for its formation.

Access and Challenges

A pilot visit was undertaken in January 2013 to areas affected by the pharmaceutical industry to prepare for field immersion. Eager to explore the polluted sites, I relied on Google Maps for directions and entered the industrial zone. My first encounter, far from the manufacturing units, was an overpowering and nauseating smell, signaling an unexpected challenge. The immediate concern was how one could conduct research in such an environment, and this reflection emphasized the realization of the crucial need to investigate this area. It emphasized the importance of studying this place because people are not just living in this pervasive smell but are also living with it. The unpleasant smell prompted me to incorporate the perspective of suffering into the study, emphasizing health inequalities not only through major illnesses but also in the basic necessity of breathable air and the very existence of life being affected.

Upon entering the manufacturing zones, I was stopped and questioned extensively. Mere entry into the zone was monitored by gatekeepers, who would inform the unit supervisors about outsiders entering this zone. Industry officials approached me to inquire with several questions, ranging from personal to professional, such as who sent me, from where I have come from, verifying my identity cards, and why I was observing/gazing at their industry. They even checked to see if I had taken any pictures. However, in 2013, I was using only a basic model phone and not a smartphone with a camera. Access to pharmaceutical manufacturing zones proved elusive, with gatekeepers hindering even mere viewing, let alone access to their units. Given the reputation of the place for pollution, industries were cautious about researchers and journalists visiting and reporting on them, obstructing such visits. I learnt the importance of not venturing alone into unknown places and decided to visit with locals.

Visiting nearby villages and interacting with the locals revealed a negative perception of the researchers in the region. Previous researchers had made false promises, taken away documents, and left the community disillusioned. The initial challenge was difficulty in obtaining respondents in the Pattancheru area due to frequent exposure to researchers throughout the year. People expressed skepticism, saying, *‘What would I gain by telling you my problems? You come today, ask, and leave, but my situation will remain the same. You*

people take away our documents for your work, and later, you don't return. How should we trust you?'

This initial pilot study raised concerns about how to build trust, considering the negative impact left by researchers before me from various institutions and universities. To address this challenge, I considered gaining access through insiders or individuals known and trusted by the community. The chosen approach was to contact those working for the people, mainly activists, and to my surprise, even they were skeptical about researchers, and reception from them was also not welcome.

Activists also had negative experiences with researchers, adding another hurdle to the study. Navigating this challenge required building trust through collaboration with activists and engaging with their work. Access to affected areas necessitated leveraging connections through insiders, facilitated by activists. However, the initial approach indicated that activists sought researchers or academics committed to activism and genuinely helping people rather than merely providing opportunities for research purposes which they considered unethical. Access to the field was through activists and hence activism became a key factor, and I gradually became involved in their activities. While this delayed the work, it provided nuanced details that wouldn't have been accessible through interviews alone. Many of the activists actively engaged in the field were elderly, and my participation involved assisting them and taking over their roles in polluted areas, providing a firsthand experience that wouldn't have occurred if I hadn't become part of their group. Consequently, locals who were initially disinterested in participating in the study began to perceive me as one among them. Access to activists underscored the significance of being perceived as an insider within the activist group. This not only facilitated collaboration but also enabled access to areas that only insiders or informants associated with activists could reveal. Informants included executives working in the industry, those who were working for the industry, and government officials, all of whom were willing to share information, under the condition of anonymity due to concerns about the potential repercussions from their employers or the industry itself.

Methodological tools:

This research adopted a qualitative approach and employed a combination of primary and secondary data collection methods. Respondents were identified using purposive and snowballing sampling techniques. In pursuing the research questions and objectives, In-depth and unstructured interviews, Focused group discussions (FGDs) as well as participant observation, were used. FGDs were organized with PAP and these sessions provided a platform for participants to share their lived experiences, concerns, and coping mechanisms collectively. Group dynamics allowed for the exploration of shared narratives and the identification of common themes related to health impacts, community responses, and advocacy efforts. Purposive sampling was employed to select the affected villages and industries based on judicial documents. By attending meetings, seminars, business conventions, and conferences organized by state bodies and bulk drug manufacturing institutes, I was able to gain insights into the activities of industries.

Secondary data was collected from the reports on pollution control boards (both at the state level as well as central), letters and complaints to state authorities, government websites, regulatory periodicals, and reports primarily related to pharmaceuticals and industries. Additionally, online periodicals, publications from international organizations, and reports from central and state governments were consulted. Newspaper documents, websites, and various other sources of information were also referred to as part of the secondary data collection process.

Table 1.1: Profile of the Respondents

Sl. No.	Respondents	Number
1.	Bulk Drug Manufacturing Association (BDMA)	5
2.	Federation of Indian Chambers of Commerce and Industry (FICCI), APIIC-TSIIC	3
3.	IDPL- Ex-Employees	7
4.	Pollution Control Board	8
5.	Political Representatives	12
6.	Environmentalists/Activists/Journalists	25
7.	Advocates	4
8.	Doctors	12
9.	Registered Medical Practitioners	6
10.	Patients-Migrants	80 Men
11.	PAP-Petitioners/Appellants -Land Holders	200 (Men-187; Women-13)
12.	PAP- Landless	200(155 women- 45-Men)
13.	School Children	50 boys
	TOTAL	612

Respondents

Respondents in serial numbers 7 to 13 belonged to the 20 polluted villages in Patancheru industrial estates, as mentioned in the court orders - Arutla, Baithole, Chidruppa, Chitkul, Gandigudem, Inole, Ismailkhanpet, Isnapur, Kandi, Kalabgoor, Kistareddypet, Khazipalli, Lakdaram, Muthanghi, Patancheru, Peddakanjarla, Pocharam, Ramchandrapuam, Rudraram, and Sulthanpur.

Enrolling and attending the BioAsia⁹ convention conducted annually helped gain access to Bulk Drug Manufacturing Association (BDMA) members, State Representatives, the Federation of Indian Chambers of Commerce and Industry (FICCI), and the Telangana Industrial Infrastructure Corporation (TSIIC).

⁹ BioAsia is an international business convention promoted by the Government of Telangana in partnership with the Government of India and Federation of Asian Biotech Associations [FABA]. Over the years, the event has witnessed the participation of more than 1500 global leaders from over 50 countries every year. The convention hosts an array of activities including business partnering, exhibition, technology conferences with talks from some global thought leaders, interactive sessions, CEO Conclave, start-up showcase, bio park visits, networking dinners and more.

Access to Indian Drugs and Pharmaceuticals Limited (IDPL)-Ex. Employees were interviewed sourcing through contacts from people's health organization called Jana Vignana Vedika¹⁰.

Patients-Migrants include 80 respondents (Men) in the age group of 14 to 24 years, who migrated for work in industries. They were impacted by health-related issues and their work conditions.

Petitioners/Appellants - Land Holders include 200 respondents (Men-187; Women-13): age group between 50 to 85years. Appellants in cases filed against industries for the compensation of loss of their livelihoods as their land became unfit for cultivation due to industrial pollution.

Non-petitioners - Landless- 200 respondents (Women-155; Men-45): age group between 18 to 60 years. 89 women worked in housekeeping jobs; 30 of them would go do domestic work in a nearby gated community.

School Children - 50 respondents (Boys): a new residential welfare school was established in one of the polluted villages and school, and the children who were not used to pollution earlier could not cope with the problem and showed immediate signs of ill-health.

Table-1.2: Landless Respondents–Educational Qualification

S No	Stages of School	Men	Women
1	No schooling	15	34
2	Primary School	5	36
3	Middle School	8	20
4	High School	12	45
5	Graduates	5	20
	Total	45	155

¹⁰ The Jana Vignana Vedika (JVV) is a science organization working for the popularization of science.

Table-1.3: Landholders Profile

S No	Land size (acres)	Men	Women
1	Less than 5acres	43	4
2	5 -10 acres	67	4
3	10-15acres	51	-
4	15-20 acres	19	-
5	20-25 acres	7	-
	Total	187	13

Researchers' Reflections

Initially, my own gender presented a hindrance in the research process, but over time, perceptions changed. Individuals, both men and women who initially made inappropriate comments later became key respondents. I also recognized the importance of avoiding preconceived opinions and acknowledged the inclination of individuals to engage in pranks or light-hearted interactions with strangers, not necessarily with malicious intent. Despite being perceived as an insider after overcoming initial hurdles, I acknowledge that I remained an outsider. I realize that I could not fully assimilate into their struggles and the challenges associated with the pollution issues they endure.

Even though I became an insider and was recognized as an activist, I could not position myself among them. Activists are stalwarts in my perception (relentlessly fighting since 1986 without any self-interest and some of them are in their 80's), and the work they have done to help people surpasses my contributions. I prefer to see myself as someone there to assist them, acknowledging the level of their commitment and impact.

Researching the polluted sites was challenging and emotionally draining, often leaving me with a sense of gloom and sadness. I am mindful of my positionality, biases, and potential influences on the research process.

Thesis Limitations

Entry inside the manufacturing units remained elusive due to the industry's lobbying efforts. The drugs manufactured in these units were not within the scope of the study. Being associated with the activist group provided advantages but also labeled me as an activist in the eyes of the industry. Access to manufacturing units was not possible. By grounding the research in judicial documents, limitations were established, focusing specifically on instances outlined in these legal records. Despite the prevalence of malpractices and issues within the industry observed in various industrial estates, these instances are not addressed here. This decision is driven by the extensive nature of the challenges at hand and the imperative to maintain focus, avoiding unnecessary diversions in the thesis. Consequently, only industries explicitly mentioned in the legal documents, reports, and locations already identified as polluted were considered. This deliberate selection aimed not only to streamline the research but also to mitigate potential legal complications.

Chapterization

The thesis is organized into six chapters, each with a specific role in addressing research questions. Chapter 1 introduces the research problem, providing a field description, key questions, objectives, and employed methods. In Chapter 2, paths of power are explored, mapping accumulation, regulation, and health inequality in the pharmaceutical landscape to comprehend its political economy. The third chapter traces the historical growth of the pharmaceutical industry, emphasizing the state's role in creating its value, contributing to regulatory capture. Chapter 4 investigates the impact of industry growth in Hyderabad, addressing practices, regulatory capture, and sociological frameworks examining health inequalities. Chapter 5 focuses on the social suffering of people living near pharmaceutical facilities, exploring their stratifications, and coping mechanisms. Finally, Chapter 6 serves as a conclusion, summarizing key findings and synthesizing intricate relationships between the pharmaceutical industry, the state, and the people.

Chapter: 2

Paths of Power: Mapping Accumulation, Regulation and Health Inequality in the Pharmaceutical Landscape

This chapter establishes the foundational framework for the study, guiding the research questions in subsequent chapters. In the previous chapter, the field description unveils the regulatory violations of pharmaceutical industries since the 1980s. This revelation emphasizes the discernible influence these activities wield over governmental bodies. The industry's triumph transcends national borders, reaching a global scale. The thesis aims to comprehend the industry's power dynamics and unveil the apparatus it employs, outlining these aspects for further exploration. This chapter probes into the operational mechanisms of the pharmaceutical sector, scrutinizing the power apparatuses it employs to fortify its influence. This is primarily through the efficacy of the medicines produced, the processes of medicalization and pharmaceuticalisation, and the regulatory capture as integral contributors to this power. These intricate dynamics collectively shape and amplify the industry's power over society.

The chapter is organized into four sections, each dedicated to a focused exploration of key themes. The first section provides a nuanced understanding of medicines and pharmaceuticals, analyzing their dynamics through the lens of anthropology and sociology. The second section illuminates inherent commercial interests, investigating the nexus between medicalization and pharmaceuticalization. The third section delves into the intricate relationship between the state and pharmaceuticals, emphasizing regulatory aspects and addressing issues of regulatory capture and corporate bias. This bias manifest when the industry's commercial interests take precedence over public health considerations. The fourth section examines health inequality, applying a health-centered perspective grounded in commercial determinants and understanding it through the power framework. This section underscores the industry's pivotal role in shaping the political economy dynamics of the pharmaceutical landscape. Each section systematically navigates through these thematic explorations, mapping their intricate influence within the pharmaceutical realm.

Apart from the initial exploration of how pharmaceuticals were perceived in early anthropological and sociological studies, this chapter specifically delves into the profit-oriented aspects of the pharmaceutical industry.

SECTION I

The Tangible Power of Medicines: Efficacy and Usage

Globally, the perception of well-being and health is progressively linked to the availability of pharmaceuticals (Petryna, Lakoff, & Kleinman, 2006), as exemplified during the COVID-19 pandemic. The society demands more from the pharmaceutical sector than mere profit generation for its shareholders (Mulinari, Davis, & Ozieranski, 2020); it necessitates the development of products that contribute to health improvements. Medicines, defined as substances capable of altering the condition of living organisms, hold significance in alleviating ill-health and are primarily valued for their curative efficacy. The epitome of medicines is the *materia medica*, which alleviates illness, and for most individuals, their value lies in their healing efficacy (Tan, 1994). Although the industry claims that higher sales indicate the successful delivery of valuable innovations for patients and governments, especially in the past four to five decades, it is important to recognize the need to examine commercial motives. Regulatory bodies are expected to evaluate claims about pharmaceutical products before granting market approval, recognizing the potential conflict between industry interests and public health. Paradoxically, during the neoliberal era, there has been a simultaneous introduction and maintenance of state regulation, acknowledging the divergence of interests, alongside a trend of deregulatory reforms ostensibly designed to promote pharmaceutical innovation in the interests of the industry (Mulinari, Davis, & Ozieranski, 2020).

The pharmaceutical industry is predominantly involved in manufacturing therapeutic drugs, and in some instances, it also produces vaccines, contraceptives, nutraceuticals, and other medical technologies. This sector operates within the private commercial domain in various countries, especially in major research-based pharmaceutical-producing nations such as the United States, United Kingdom, Switzerland, Sweden, Netherlands, Japan, Italy, Germany, France, and Belgium. Even within these nations, commercial pharmaceutical companies may collaborate with public entities in developing or disseminating specific products (Balance,

Pogany, and Forstner, 1992). The development of new drug¹¹ products referred to as new chemical entities (NCEs) or new active substances (NASs), relies on extensive research and development (R&D). These substantial R&D expenditures necessitate the participation of major commercial enterprises, leading to the industry's dominance by large transnational companies. The pharmaceutical sector has witnessed increasing oligopoly trends, evident in notable mergers since the 1990s. The dynamics of the market and competition are influenced by intellectual property laws. Research-based companies can protect their NCE discoveries through patents, granting exclusivity for a limited period, usually 15-20 years. Following this period, generic pharmaceutical companies may produce generic drugs. Consequently, manufacturers have a vested interest in swiftly developing, testing, and gaining marketing approval for their NASs to recoup R&D investments before patent expiration. (Burstall, 1990; Davis, 1997; Rajan, 2017)

The process of drug development, as anthropologists argue, is characterized by a unique *social life cycle* (Kopytoff, 1986) and a *chronological life cycle*, encompassing manufacturing, marketing, distribution, usage, and post-use impact on well-being. Each stage involves distinct actors, ranging from scientists and entrepreneurs in production to health professionals, sellers, and consumers in prescription, distribution, and consumption. These stages operate within specific *regimes of value* (Appadurai, 1986), reflecting distinct ideas about medicines. Pharmaceuticals, serving as both technical devices and cultural symbols, exert influence on societal thoughts, actions, and relationships. The Biography of Pharmaceuticals involves their history through manufacturing, trading, prescribing, buying, and consuming. As products of human culture, pharmaceuticals shape society and impact social relationships, playing a role in human life that transcends mere tool functionality; they actively influence individuals while being utilized by them, bringing order to social and cultural intricacies and shedding light on their complexity (Geest et al., 1996).

Pharmaceuticals extend their cultural significance beyond therapeutic functions, influencing the identification and interpretation of illnesses while contributing to cultural constructions of health (Nichter, 1983). Managing the concept of risk and reifying notions, medicines also play a crucial role as carriers of ideologies and globalizing forces, particularly in the Global South where they are essential commodities (Nichter & Nichter, 1996). Their psychological

¹¹ Drugs, pharmaceuticals and medicines have been used interchangeably throughout the thesis.

efficacy is evident in instilling confidence in patients and healthcare providers, addressing health issues, and alleviating anxieties. Moreover, pharmaceuticals may possess metaphysical efficacy, confirming beliefs and serving as evidence for diverse explanatory models. Pharmaceutical efficacy is viewed diversely, with biopharmacologists emphasizing inherent healing power. Practices like singing or invoking personal power contribute to the perceived potency of medicines. Anthropologists recognize efficacy as a cultural construction, involving both biological and social dimensions. The total drug effect includes non-chemical attributes like color, name, and provenance, with the placebo¹² effect widely accepted. Medicines' provenance, whether foreign or native, influences their perceived strength. Socially, pharmaceuticals mark identity and facilitate transitions, serving as ritual objects (Comaroff, 1976). This approach follows Ingold's (2011, 2012) perspective, treating pharmaceuticals as dynamic and always on the way to becoming something else.

Hardon & Sanabria (2017) explored the intersection of anthropology and science and technology studies (STS) in the context of pharmaceutical efficacy, building upon Van der Geest et al., (1996) study published in the Annual review of Anthropology. Their study questions the understanding of drugs by examining efficacy as a processual, relational, and situated event. The analysis challenges dichotomies between the chemical properties of pharmaceuticals and their sociocultural interpretation, emphasizing that molecules are not discovered but made and remade in relation to their context (Barry, 2005). The review discusses ethnographic and STS research on pharmaceuticals, exploring key areas such as the production of 'informed materials,' the influence of the state–market nexus and regulatory environments, marketing and rescripting, care practices, and the dissolution of boundaries between pharmaceuticals, bodies, and environments. In the healthcare domain, social pharmacy in the Global North played a crucial role, with researchers exploring local realities of medicine availability and usage. They highlighted the significance of pharmaceutical transactions through commercial and informal channels, emphasizing that even regulated prescription-only drugs were often used for self-medication without formal health worker supervision (Ferguson, 1988).

¹² A placebo is a substance or treatment with no therapeutic effect. The placebo effect is the improvement in a person's condition based on the belief that they are receiving a beneficial treatment, even if the treatment itself is inactive.

Few scholars delved into pharmaceutical transactions within professional settings. A rising curiosity about Western culture and products led to a heightened examination of biomedicine as a cultural phenomenon (Douglas & Isherwood, 1979). As scholars from both the Global North and South engaged in fieldwork within their societies, previously ignored items like capsules, tablets, and syringes became the subjects for analysis. A renewed focus on material objects by anthropologists, influenced by newer Marxist approaches (Appadurai, 1986), provided a bridge between culture and economy. Medicines, with their tangible nature and role as commodities, aligned well with this theoretical development. This cultural economy approach dovetailed with the study of globalization and localization processes, and challenged older paradigms of modernization and development. The study of biomedicine, a prominent example of globalization, became a significant empirical base for addressing theoretical issues related to cultural globalization (Ellen, 1988; Thomas, 1991; Kleinman, 1998).

Examining the nuanced dichotomy between biomedical and local conceptions necessitates an exploration of contexts across diverse settings, including but not limited to manufacturing and advertising companies. Early studies of anthropology neglected these ethnographic sites that stem from a persistent interest in geographically delimited communities, necessitating a further exploration of the value patterns and meaning-making dynamics in mass-media consumer cultures. Pharmaceuticals offer a unique lens for studying the interplay between symbols and political economy, representing international flows of capital and commerce while symbolizing hope and advanced technology. They are deeply integrated and sought after, providing autonomy in healthcare but fostering dependence on distant markets. (Geest & Whyte, 1989; Tan, 1994).

The question arises: what renders medicines widely embraced as solutions in times of distress, making them contenders in *tournaments* where fundamental values are at stake, as suggested by Tan (1994), drawing on Appadurai (1986). The key to their perceived power is predominantly rooted in their concreteness (van der Geest and Whyte, 1988). Their material nature provides patients and healers with a tangible means to address the issue at hand. Medicines possess a material quality, allowing for concrete usage: they can be ingested, applied topically, or introduced into orifices – activities that promise a tangible physical impact. By employing a tangible entity, the state of dysphoria is transformed into something

palpable, a focal point for the patient and others to direct their efforts. The popularity and potency of medicines during moments of distress, rooted in their tangible nature, provide concrete solutions to health problems. This inherent *thinginess* aligns medicines logically with biomedicine and most other medical traditions, where the practice of medicine fundamentally involves concretizing disease (Van der Geest and Whyte, 1989).

This concreteness enables patients and healers to address health issues physically and practically, aligning seamlessly with biomedicine and other medical traditions. Anthropologists extended the cultural logic of medicines, initially associated with primitive societies as magic or fetishism, to pharmaceuticals in the 1980s. This period witnessed a surge in the widespread use of biomedicine and pharmaceuticals globally, leading to critiques of pharmaceutical invasions, particularly in the Third World countries. Illich's (1983) critique of biomedical expropriation of health in Western society triggered critical studies on medicalization¹³ and overconsumption of medical services, including pharmaceuticals. The 1980s also marked the emergence of the concept of essential drugs, prompting increased attention from policymakers and anthropologists to the provision and use of drugs in Southern settings. This acknowledgment underscored the policy implications associated with pharmaceutical practices. (Appadurai, 1986; Alland, 1970; Cunningham, 1970; Logan, 1973).

Drawing on Appadurai's (1986) 'social life of things' and Kopytoff's (1986) biographical framework, it can be concluded that pharmaceuticals, as commodities, possess lives and impacts beyond their shelf lives. Subject to enclaving and diversion, their potential in situations of suffering hinges on being connected to specific knowledge, contributing to the refinement of theories about the social life of medicines. The exploration of pharmaceuticals gained prominence within the Medical Anthropology Unit in Amsterdam, emphasizing the commercial significance of medicines (Hardon, 1990). The focus on their portrayal in media and their role in the survival struggles of impoverished individuals highlighted the intricate connections between medicines and processes of social transformation (Nichter and Vuckovic, 1994). They argued that medicines serve as vehicles of ideology, shaping perceptions of health, constructing illness identities, and reflecting social values, thereby creating consumer demands. The overuse of medicines sparked debates in medical anthropology, with critics denouncing the trend of viewing health as something achievable

¹³ Medicalization can be defined as the process by which some aspects of human life come to be considered as medical problems, whereas before, they were not considered pathological.

solely through pharmaceutical consumption, labeling it *defective modernization*, which is criticized for its potential to impoverish the concept of health and provide a false sense of security (Nichter, 1983; Ferguson, 1968). However, proponents of a more optimistic view, such as Plattner (1989), highlight the social character of face-to-face market transactions and argue that commercial activities can foster social relationships and mutual trust between buyers and sellers.

A review of the early anthropological study on Pharmaceuticals highlighted a significant gap in research during the initial phase of medicines' biographies, encompassing their manufacture and marketing. Anthropologists had largely neglected this aspect due to challenges in accessing pharmaceutical manufacturers' laboratories and offices. Manufacturers were hesitant to grant access, perceiving no advantage from anthropological observations. Anthropologists, in turn, were reluctant to delve into the pharmaceutical industry, finding more comfort in the familiar settings of rural communities (Van der Geest et al., 1996)¹⁴. Anthropologists recognized the importance of studying Pharmaceuticals within the broader societal and cultural context, but this realization had been a gradual process. Historically, medicines were often casually mentioned, mostly categorized as traditional or seen as magical and herbal remedies. Evans-Pritchard (1937) is an exception, extensively studying Zande local medicines to emphasize the rationality within Azande reasoning. Early Anthropology's tendency towards sentimental exoticism hindered the exploration of commonplace Western-produced pharmaceuticals as culturally significant subjects. Cunningham (1970) broke from this trend, examining 'injection doctors' in Thailand—an ostensibly exotic topic despite addressing a familiar Western practice of injections. This departure signified a shift towards recognizing the cultural relevance of Western medical practices (Van der Geest, Kleinman, & Lakoff, 2006).

¹⁴ Early anthropologists working on 'primitive' societies identified the cultural or symbolic significance of medicines, labeling it as magic, fetishism, or animism – reflecting the belief in forces that individuals seek to possess, control, and manipulate for personal gain. However, this cultural perspective was not widely applied to pharmaceuticals, the synthesized therapeutic substances at the core of biomedicine. Only a handful of pioneers delved into this cultural exploration, including Alland (1970), Cunningham (1970), and Logan (1973). A systematic examination of pharmaceuticals as social and cultural phenomena did not commence until the 1980s. By this time, it became evident that biomedicine enjoyed genuine popularity and extensive use in societies across Africa, Asia, and Latin America (Foster, 1981; Hardon, 1991; Van der Geest, 1984). Furthermore, some academics were drawn to the radical critiques of the pharmaceutical invasion in the Third World (Blum et al., 1983; Buhler, 1982; Melrose, 1982; Muller, 1982; Silverman, 1976), underscoring the social and cultural implications of widespread pharmaceutical use in these regions.

Over time, anthropologists have delved into the multifaceted nature of medicines, recognizing them as a convergence point for a diverse range of human interests encompassing material, social, political, and emotional dimensions. Moreover, they function as emblems of concern, commodities subject to the harsh realities of a competitive market, and wielded as political tools by those in power. Operating at various levels of social and political organization, medicines influence international policies, national politics, local health institutions, and individual households. They play versatile roles in formal and informal transactions, whether public or secret, legal or illegal. This intricate web of interactions is aptly described as a *Pharmaceutical nexus*, as articulated by the editors in the thought-provoking book on *Global Pharmaceuticals* (Petryna et al., 2006).

Pharmaceutical Nexus

The modern pharmaceutical industry originated in the nineteenth century with the isolation and mass production of potent compounds, such as morphine, strychnine, quinine, nicotine, and cocaine. Significant breakthroughs during and after World War II included the discovery and mass production of penicillin, streptomycin for tuberculosis, and the broad-spectrum antibiotic, chloramphenicol. Post-war, the industry transformed from being a commodity chemicals business to one dominated by a few large firms, emphasizing substantial investments in research and marketing (Angell, 2004). This evolution, however, is entangled with economic and moral paradoxes. Advertisements portray distinctive and highly contentious imagery that reinforces a consumption-oriented logic, reshaping well-being into a commodity and individual achievement. Alongside depictions of personalized health, there are images of collective suffering depicted as either ambiguous or incurable. These portrayals convey distinct moralities, suggesting varying values and treatment possibilities for different illnesses (Kleinman and Kleinman, 1996). As the moral economy aligns with the political economy, unequal treatment of populations and communities closes off possibilities and perpetuates violence. A pharmaceutical fostering of lifestyle is evident for some, while others experience benign neglect. A notable divide exists in pharmaceutical markets, driven by group behavior, culture, economic characteristics, and their potential to enhance industry profits. Lifestyle treatments and cures catering to diseases with established consumer demand receive substantial attention, whereas neglected diseases, often necessitating state intervention in economically disadvantaged countries, lack the economic incentives required

for research and development, and contribute to health inequality. (Lexchin, 2001; Moynihan, Heath, Henry, 2002).

Chen et al., 1994, Desjarlais et al., 1995, Kim et al., 2000, and Farmer, 2003 have significantly advanced the understanding of how health inequalities stem from socioeconomic and political divisions within and between countries and among racial and ethnic minority groups. These studies reveal how differences in the structure and organization of institutions dealing with health problems can lead to disparate programs and policies, influencing distinct courses of health and disease outcomes. Moreover, they challenge the conventional use of the concept of culture in explaining local health practices. Farmer (1999) has specifically shown how cultural assumptions in health planning can reinforce inequality by justifying certain interventions while rejecting others, dispelling the notion that the poor are less responsible regarding treatment adherence. This notion emphasizes the impact of international policy on local pandemic trajectories (Das, 1999). For Instance, the inadequate response to the HIV/AIDS pandemic has led to a significant increase in infections in South Africa, highlighting the consequences of delayed action (ibid). Similar patterns of delay were observed in regions undergoing political transitions, such as Eastern Europe in the early 1990s, where economic reforms overshadowed health concerns, resulting in threats to people's lives (ibid). The prevailing ethical discourse falls short in assessing health equity and rights in devastated communities, lacking an understanding of local moral worlds as social processes (Kleinman, 1998). They advocate moral engagement with unjust and chaotic worlds marked by violence and premature deaths (Scheper-Hughes, 1992; Bourgois, 1995; Das et al., 2000; Biehl, 2005).

This institutional inequality operates within and across traditional, territorially bounded governance structures. Analyses of medical professions, advertising agencies, audit companies, and contract research organizations indicate the recurring theme of territoriality, revealing how social and institutional geographies of healthcare are redefined and how physician practices and patient agency are reshaped. Studies on the global movements of pharmaceuticals expose a growing *values gap* (Kleinman and Kleinman, 1996), marked by disparities between populations with access to life-saving drugs and the financial means to afford them, and those lacking both, relying on alternative distribution methods. This gap is exacerbated by industry choices, favoring research and development for afflictions with

readily producible treatments and established markets. It is also reinforced by subtle judgments on the significance of others' well-being. The economic worth, particularly market readiness, can determine the fate of entire populations, raising crucial questions about whose illness is deemed worthy of treatment and whose life is considered worth saving. The globalization of pharmaceuticals introduces a new dimension to this issue, highlighting the extent to which action, resources, and coordination can be mobilized to counteract the extreme effects of pharmaceutical triage. Debates over access to new medical technologies necessitate consideration of complex care delivery systems for the poor, while the role of state and non-state actors in securing health as a fundamental right of citizenship becomes increasingly profound. As the pharmaceutical industry advances, it encounters ethical challenges. One issue is the increasing cost of drugs and the unequal access to them based on financial ability (Petryna, Lakoff, & Kleinman, 2006).

The consideration of the social good and its beneficiaries is inherent at every stage of pharmaceutical production, spanning from pre-clinical research to consumption. Each phase is characterized by distinct contexts, actors, and transactions, influenced by different sets of values and ideas (van der Geest et al., 1996). The development of therapeutic entities often aligns with institutional priorities rather than the actual needs of disease and treatment demand. The divergence between the settings for clinical testing and eventual drug sales prompts questions about the populations that researchers should include in their cohorts. Public pressure and activism from interest groups can expedite the development of innovative drugs, particularly for historically underrepresented groups in clinical research (Whyte et al. 2002).

Petryna, Lakoff, and Kleinman (2006) examine the burgeoning global institutional ecology of pharmaceuticals, shaped by fierce competition for regional markets and the tension between pharmaceutical importation in poorer countries and evolving drug production capabilities in medium-poor countries like China, India, and Brazil. This institutional ecology involves entities such as the World Bank, the World Trade Organization, and Trade Related Aspects of Intellectual Property Rights (TRIPS), along with emerging international and national regulations and laws, governing the global and regional circulation of pharmaceuticals. The global pharmaceutical market grapples with imperfections in its regulatory framework, emphasizing the pivotal role of reliable standards as drug production expands globally,

involving human testing in distant locations. Transnational regulatory bodies, like the International Conference on Harmonisation (ICH), play a central role in promoting standardization and regulating interactions between state health institutions and market actors. Standardization extends to patent rules and intellectual property rights, influencing fair drug pricing and access negotiations. However, these regulatory bodies are bound by the commercial interests (Rajan, 2017) of the pharmaceutical industry, a topic that will be addressed in Section II.

Studies on Asian medicines (Wahlberg, 2014, Blaikie, 2015; Hardon & Idrus, 2015; Pordié & Hardon, 2015) highlight how African and Asian nation-states aim to facilitate the market entry and export of herbal drugs through subsidies and relatively lax regulatory mechanisms. For instance, Pordié (2015) illustrates in India that Ayurvedic medicines are reformulated for local use and export, benefitting from expedited market entry without the need for clinical trials as long as they are referenced in ancient texts. This parallels the global market trend observed in modern pharmaceuticals. In Tanzania, Langwick (2015) discusses how, with Chinese support, the state commoditized local traditional medicines. Similarly, Hsu (2015) explores how Tanzania became a market for Chinese drugs, including purified artemisinin for malaria treatment. Pharmaceuticals frequently undergo a process of reinscription, particularly when facing generic competition or patent expiration. Companies may endeavor to extend the market life of their products by associating them with new indications. Examples include Pfizer's successful remarketing of fluoxetine (Prozac) as Sarafem for premenstrual dysphoric disorder and the repurposing of Ritalin for attention deficit hyperactivity disorder (ADHD) (Greenslit, 2005). Issues explored encompass ethical obligations, bioprospecting regulation, and monopolies over strategic knowledge, impacting information sharing in drug production and consumption domains (Bowker & Star, 2000). The uncertainty in drug development spills into the economic domain, affecting stock market shares based on clinical trial outcomes, while sales and marketing involve proprietary knowledge. Market forecasting relies on privately generated epidemiological data, and Andrew Lakoff (2000) underscores the industry entities' involvement in shaping 'interested knowledge'.

The pharmaceutical industry's 'interested knowledge' or secrecy raises critical questions, including the extent of industry knowledge about doctors' prescription practices and patient consumption patterns. The pervasive pharmaceutical advertisement and category construction

suggest that individuals are partly 'made up' through a process of 'dynamic nominalism' (Hacking, 1999). Historical transformations in pharmaceuticals, such as the antibiotics era or the analgesics era, contribute to shaping perceptions and experiences of vulnerability, risk, pain, and suffering. Global pharmaceutical production reveals non-standardized practices across various niches. Enormous differences in drug pricing, especially in the global prescription drug market, stand out as politically charged issues. Prescription drug promotion practices, varying across countries, involve financial grants and gifts to doctors, highlighting the pharmaceutical industry's influence. Mass advertising practices are non-standardized, with pharmaceutical companies marketing directly to laypersons through various channels in some countries. The internet further complicates the flow and control of pharmaceutical messages in the global market (Bowker & Star, 2000; Kleinman & Kleinman, 1996). These practices highlight regulatory lapses and the pharmaceutical industry's influence and power. Pharmaceutical influence can be seen in the process of medicalization and pharmaceuticalisation, as is discussed below.

Section II: Pharmaceuticalization

Pharmaceuticalisation involves the use of medical drugs to treat or enhance social, behavioral, or bodily conditions. Distinguished from 'medicalization,' which defines non-medical issues as medical problems, pharmaceuticalization can occur independently, highlighting its conceptual autonomy. The emergence of pharmacological power, separate from medicalization, is attributed to the utilization of new technologies, resulting in the 'pharmaceuticalization of domestic life.' This extension of pharmaceutical influence transcends traditional medical boundaries, reaching into everyday spaces such as bedrooms and kitchens (Fox and Ward, 2009).

Pharmaceuticals received limited sociological attention initially, with early works focusing on specific medications like minor tranquilizers or individual drugs such as Opren or Halcion. Scholars like Cooperstock and Lennard (1979), Helman (1981), Gabe (1990, 1991), and the collaborative works of Gabe and Lipshitz-Phillips (1982, 1984) contributed to these early studies, occasionally connecting the analysis to broader sociological concepts like medicalization and social control. However, the medicalization debate often overlooked pharmaceuticals explicitly. Conrad (2007) marked a shift, acknowledging pharmaceutical

companies as key drivers of medicalization. Subsequently, the term *Pharmaceuticalization* emerged to capture the growing significance of pharmaceuticals, introduced by Nichter (1983) in anthropology and Abraham (1997) in sociology. Pharmaceuticalization (Williams et al., 2011) involves transforming human conditions into opportunities for pharmaceutical intervention.

A crucial distinction lies in encompassing pharmacological interventions for non-medical purposes and advocating the use of medicines for lifestyle or enhancement reasons beyond traditional medical authority. Pharmaceuticalization is a dynamic socio-technical process within a 'pharmaceutical regime,' a network involving institutions, organizations, actors, and artifacts. This encompasses cognitive structures and affective processes associated with therapeutic creation, production, and use. The pharmaceutical regime considers upstream processes like development, testing, and regulation, along with downstream processes involving the meaning and use of pharmaceuticals in medical practice and everyday life (Williams et al., 2011).

The phenomenon of pharmaceuticalization in society (Abraham & Lewis, 2000) is characterized by the expansion of pharmaceutical markets, the identification of new medical conditions, and an increase in drug production. Pharmaceutical companies target both the public and physicians, sparking debates on the appropriate use of medicines (Fisher et al., 2015). A global perspective highlights Western-centric efforts, with a focus on pharmaceuticalization in low or middle-income countries, connecting public health to the right to treatment. Social resistance, potential de-pharmaceuticalization, and the coexistence of pharmaceuticals with other healthcare approaches also need to be considered (Bell and Figert, 2012; Davis and Abraham, 2012). Studies (Britten, 2008; Light, 2010; Petryna et al., 2006; Biehl, 2004; Sariola et al., 2015; Cloatre and Pickersgill, 2014; Moynihan, 2002) have explored the extensive process of pharmaceuticalization and its consequences, drawing on medical sociology, science and technology studies (STS), and related disciplines.

Busfield (2010) addresses the issue of overtreatment within the context of pharmaceuticalization and contributes to this understanding by identifying and assessing instances of overuse of medicines like antibiotics, antidepressants, and antihypertensives. She develops a typology of over and underuse based on the World Health Organization's criteria

for the 'rational' use of medicines. The framework considers medicines with limited evidence of effectiveness and those with doubtful clinical needs. Busfield explores factors contributing to overuse, including doctors' risk avoidance preferences and pharmaceutical companies' influence on clinical trial reporting. Courtney Davis (1997) further explores the theme of overuse, specifically in the context of expanding pharmaceutical use in treating patients with advanced, incurable cancer. Davis attributes the growth to both addressing unmet needs and 'inappropriate and overly aggressive' drug use. Davis highlights the role of physician and patient expectations, emphasizing pharmaceutical companies' control over research organization and funding as a crucial factor.

In response to Davis's contribution to pharmaceuticalization studies, Abraham (2010) acknowledges the systematic exploration of how industry-influenced information on cancer therapies can lead to patient expectations and over-treatment. Abraham contends that Davis's argument aligns with his analytic framework, emphasizing that pharmaceuticalization can occur without an expansion of medicalization, as some drugs are increasingly used to treat established medical conditions without transforming non-medical problems into medical ones. While unpacking another dimension within pharmaceuticalization, Pollock and Jones (2015) caution against oversimplifying judgments on excessive drug use, particularly in the context of coronary artery disease (CAD) in the United States. The argument revolves around the necessity to contextualize claims of excessive drug treatment within a therapeutic landscape encompassing pharmaceuticals, surgery, lifestyle changes, and inaction. Emphasizing the importance of considering treatment options in terms of stratification, the authors highlight potential overtreatment and under-treatment in different populations. Racial disparities in access to care for CAD are underscored, with African Americans less likely to receive medication, bypass surgery, or angioplasty compared to their white counterparts. The authors stress on how structural factors and health inequalities shape pharmaceuticalization patterns among social groups.

In a related study, Collin and Otero (2015) investigate the media's impact on promoting anxiety-depressive disorders to family doctors in Canada, leading to the (over) prescription of psychotropic drugs. Grounded in a pharmaceutical regime framework, the study explores the interconnected networks of actors, institutions, artifacts, and cognitive structures involved in medication promotion and use. Examining psychotropic advertising in Canadian medical

journals between 1950 and 1990, their research reveals a consistent emphasis on managing anxiety-depressive disorders through psychotropic medications, despite evolving disease classifications and developments in psychopharmacology. Collin and Otero highlight the non-linear and dynamic nature of pharmaceuticalization, illustrating the continual displacement and substitution of drug classes. They introduce the concepts of 'pharmacological enthusiasm' and 'pharmacological Calvinism,' wherein periods of enthusiastic drug introductions overlap with phases of increased scrutiny and regulatory interventions. The study emphasizes the crucial role of adaptable regulatory frameworks in responding to the dynamic pharmaceutical landscape.

These studies vividly depict the pharmaceutical industry's formidable influence across cultural, social, and economic dimensions, showcasing its ability to shape health accessibility. The processes of pharmaceuticalization and medicalization, driven by the pursuit of surplus and profit, emerge as key indicators of the industry's control over society, simultaneously impacting health by either alleviating or exacerbating inequalities. The pharmaceutical sector's pursuit of profits becomes evident as it navigates the delicate balance between removing health disparities and contributing to new forms of inequality.

Pharmaceuticals and Commercialisation

The political economy surrounding pharmaceutical drug development and concerns about the influence of profit-maximizing motives on research priorities were also studied widely (Healy, 2006; Dumit, 2012; Doshi et al., 2013; Sismondo, 2010, 2015; Sunder Rajan, 2017). Commercially driven research tends to prioritize pharmaceutical benefits over risks, with a focus on chronic conditions and drugs for lifelong use (Dumit, 2012). This commercialization is influenced by global harmonization strategies and transnational regulations, including intellectual property and trade agreements (Sunder Rajan, 2017). The study of generic drugs has provided valuable insights into the anthropology of pharmaceuticals, revealing the complex interplay of institutional rationalities governing therapeutic agents across national contexts (Greene, 2014; Hayden, 2007, 2012; Sanabria, 2014; Rajan, 2017). Regulatory contests over generic drugs' evaluations and the perception of chemistry as a stable anchor have been explored, challenging the reduction of a drug's efficacy or identity to its active chemical ingredients (Hayden, 2012). The pharmaceutical industry's acknowledgment that

efficacy extends beyond chemical composition highlights the fluidity of pharmaceutical matter in the face of generic competition. In Nigeria, the concept of *chemical arbitrage* highlights how market and regulatory dynamics influence the chemical content and efficacy of generic drugs, impacting health outcomes and contributing to antimicrobial resistance (Peterson, 2014). Market–state dynamics vary for different pharmaceutical categories, with vitamins, supplements, and herbal medicines facing less stringent regulations, facilitating their market entry and export (Pordié & Hardon, 2015; Wahlberg, 2014).

A House of Commons Health Committee (2005) report notes that the Department of Health has presumed an alignment between the interests of public health and the pharmaceutical industry, possibly due to its dual role as a sponsor and healthcare overseer. This leniency has allowed the industry's influence to grow unchecked, leading to practices that undermine public interests across various healthcare levels. Allegations include inadequately designed clinical trials, selective publication, and the suppression of negative findings, creating an incomplete evidence base for guidance. Post-licensing, aggressive promotions to prescribers, particularly general practitioners and patients, further distort prescribing practices, contributing to the unsafe use of drugs. The pharmaceutical industry's role in the 'medicalization' of society, fostering an unhealthy reliance on medicines, is also noted, exacerbating the trend to categorize more individuals as 'abnormal' or in need of drug treatment.

The pharmaceutical industry has also been accused of *disease mongering*¹⁵, defined as the expansion of diagnostic boundaries for economic gain. This involves altering perceptions of diseases to promote drug consumption and employing strategies like medicalizing common ailments to maximize market potential. Although disease-mongering is a genuine concern, caution is needed to avoid hasty conclusions about legitimate medical conditions. The industry utilizes various tools, such as sales representatives, advertising, and sponsored research, which, when misused, can distort perceptions of diseases, encourage off-label

¹⁵ Disease mongers seek to increase the perceived incidence of diseases so that they can sell drugs or other medical services. Disease mongers can either split current disease categories into multiple categories, or medicalize conditions which were previously considered normal. This medicalization has mixed effects. Disease mongers claim that they help relieve human suffering, as sufferers can receive the medical treatments that they need once a disorder is recognized. However, medicalization also changes the ways in which we relate to each other and think of ourselves. When a condition comes to be considered a disorder, this acts to place a problem under medical expert control. Simultaneously, medicalization acts to individualize and depoliticize problems that potentially could be seen in social or political terms (Cooper, 2020).

prescriptions, and disseminate unvalidated data. Pharmaceutical companies, advocacy groups, and the media, working alongside doctors, are not just manufacturers of medications but also, to some degree, contributors to the construction of diseases that these drugs are meant to address (Williams et al., 2009a, b). In essence, pharmaceuticalization involves a variety of practices designed to instill an inclination to use medication in individuals, transforming them into new self-medicated entities. These practices encompass strategies like prompted expert recommendations (medical prescriptions) to widespread media promotions.

The opioid crisis¹⁶ exemplifies the consequences of disease mongering, with companies promoting unapproved uses, downplaying addiction risks, and even introducing a concept called *pseudoaddiction* to shape public opinion. The industry's use of astroturfing and information laundering further blurred the line between impartial information and advertising, raising ethical concerns about its influence on disease perceptions and treatment practices (Kaczmarek, 2021).

Major drug companies today started by selling (now) illegal substances like heroin, morphine, cannabis, and cocaine-based medications, leading to substantial profits. The pharmaceutical industry's relationship with the regulatory bodies alternates between contentious and overly cozy. Over sixty years, it has succeeded in a prolonged battle over rewarding laboratory discoveries with exclusive patents, contributing to nations becoming one heavily medicated society. Successive waves of wonder drugs, real and hyped, generated massive profits while creating millions of dependent patients seeking the next pill for various illnesses (Posner, 2020).

The pharmaceutical industry's corruption of the medical sciences goes beyond conventional conflicts of interest, focusing on the pervasive influence of funding itself. According to

¹⁶ Opioid manufacturer Purdue Pharma LP pleaded guilty to federal charges, admitting to conspiracies involving defrauding the United States and violating the anti-kickback statute. Purdue acknowledged three felony offenses, including dual-object conspiracy to defraud the U.S. and violate the Food, Drug, and Cosmetic Act, along with two counts of conspiracy to violate the Federal Anti-Kickback Statute. The guilty pleas highlight Purdue's marketing and sale of opioids to healthcare providers, despite knowing the risk of diversion to abusers. The company deceived the Drug Enforcement Administration and paid kickbacks to encourage more product prescriptions. This case underscores the serious consequences of illegal pharmaceutical industry behavior, sending a message against prioritizing profits over public health in the opioid crisis.

<https://www.justice.gov/opa/pr/opioid-manufacturer-purdue-pharma-pleads-guilty-fraud-and-kickback-conspiracies>.

Srinivasan (2018), between 2005 and 2013, Indore faced a series of clinical trial scandals, with unethical practices at Indore in India. The Economic Offence Wing reported irregularities in 73 trials, involving nearly 3,300 patients, leading to deaths and substantial financial gains for six senior doctors. Simultaneously, private hospitals in Indore conducted around 60 trials, causing at least five deaths. The situation prompted public interest litigations in the Supreme Court of India, seeking a comprehensive cleanup of India's clinical trial landscape. In Bhopal from 2004 to 2008, an hospital engaged in ten drug trials, resulting in deaths, raising ethical concerns due to lenient government actions. While financial conflicts may lead researchers to favor funders, a more intricate corruption is observed in the management of clinical trials, often directed by contracted research organizations (CROs) under industry control. Approximately 70–75% of industry spending on trials is channeled through CROs, diminishing support for independent researchers. This "ghost-management" process grants pharmaceutical companies extensive control, impacting study design, data interpretation, and article composition. Examples include strategic manipulation of study parameters, data, and biased representation of positive trial outcomes in medical journals (Sismondo, 2021).

This corruption extends to the ghost-management of research, involving likely drafting by ghostwriters and controlled publication planning. The pharmaceutical industry utilizes tactics like citation manipulation and employs "key opinion leaders" for promotional talks. This multifaceted corruption significantly influences medical science and literature, necessitating a broader perspective beyond traditional conflicts of interest. The discussion widens to the body of medical science, portraying pharmaceutical companies as engaging in a grafting process. Similar to plant grafting, they seamlessly integrate their research into medical science, leveraging structures and traditions for legitimacy. Non-industry medical science lends credibility to these additions, creating a complex relationship where industry-sponsored research becomes a prominent aspect of the medical science landscape. While acknowledging the inherent imperfections of medical science, the pharmaceutical industry exploits the presumed purity of medical research's goal: knowledge creation for patient health. Standard narratives attributing purity to medical research obscure the intricate and pervasive influence of pharmaceutical companies, offering a nuanced perspective on corruption within the realm of medical science (Sismondo, 2021).

Katherine Eban (2019) examines the pharmaceutical industry, specifically focusing on the generic drug manufacturing sector. Eban meticulously exposes instances of fraud, data manipulation, and regulatory shortcomings within the generic drug industry through thorough research and interviews. The book reveals how certain drug manufacturers prioritize profit over quality and patient safety, highlighting cases where generic drugs, intended to be equivalent to brand-name counterparts, may fall short of required standards. Eban delves into the challenges posed by globalization, complex supply chains, and regulatory gaps that contribute to lapses in drug quality control and regulatory oversight in the pharmaceutical industry. While the book primarily centers on medications designed for the American market, the true and persistent sufferers of the deficiencies outlined in the book are consumers in developing nations, such as those in India.

The Indian Context

The manifestations of these irregularities by profit-making pharmaceutical companies are numerous. For instance, it illustrates the challenges faced by those attempting to confront profit-making pharmaceutical companies. In 2012, Dr. Chander Gulati¹⁷ faced criminal defamation charges for exposing safety concerns about the drug Deanxit in India. Despite bans by the health ministry, both were overturned by the Karnataka High Court. In 2013, Ranbaxy's criminal felony plea raised questions about dual quality standards for medicines in India¹⁸. The government and industry responded with a conspiracy theory rather than addressing the issue. In 2014, activists addressing drug quality faced threats of defamation lawsuits from the Indian government. Whistleblowers, challenging drug quality, were labeled 'anti-national' by the Drug Controller General of India. Such instances reveal the industry's tendency to deflect criticism with personal attacks, making it crucial for journalists and editors to prioritize substantive issues over sensationalism. The common diversionary tactics include emphasizing the affordability of generic drugs and the industry's role in addressing health crises, steering attention away from the core concern – the quality of the drug supply (Thakur,2019).

¹⁷ The editor and owner of the Monthly Index of Medical Specialities.

Lundbeck India Pvt. Ltd. v. Dr. Chandra Gulati & Others. Cri. Pet. No. 4683 of 2011 before the High Court of Karnataka dated July 26, 2012 available at <https://indiankanoon.org/doc/183428285/>

¹⁸ BT Online Bureau. (2013), Ranbaxy pleads guilty, and was directed to pay \$500mn in US settlement, as reported by Business Today.

In response to challenges and criticisms, the pharmaceutical industry has adopted new tactics, including distraction. Industry supporters often deflect attention from the issues of drug supply quality by emphasizing the positive contributions of the Indian pharma industry, such as making healthcare more affordable globally and aiding during the HIV epidemic. Another diversionary tactic is to highlight wrongdoings within Big Pharma, attempting to normalize such behavior. However, these distractions are irrelevant to the core issue being debated. It is important to critically engage with and acknowledge the achievements of the Indian pharma industry but emphasize that knowingly selling substandard, therapeutically ineffective medication to patients with limited means is detrimental. The lack of robust systems to study the long-term effects of poor-quality medicines in India emphasizes the importance of addressing structural issues within the supply chain. Encouraging two different standards of quality for life-saving medications and ensuring accountability for compliance with standards are crucial debates, especially in a country like India. When the pharmaceutical industry underperforms, it not only impacts shareholder interests but also jeopardizes the employment prospects of numerous young individuals who could have found opportunities in the sector. The focus should be on addressing systemic issues and ensuring the industry's accountability to maintain high standards in sterility, hygiene, and record-keeping (Thakur, 2019).

The pharmaceutical industry, with its immense budget and global reach, has undeniably contributed beneficial drugs to society. However, a delicate balance must be struck in regulating the industry to ensure public health is safeguarded from potentially harmful profit-mongering industries. The influence exerted by pharmaceutical companies on drug regulation, often at the expense of other stakeholders, suggests the need for a more robust regulatory system. Various methods employed by the industry to influence governments and regulatory agencies are discussed, prompting recommendations to mitigate such influence. The considerable economic power and political sway of pharmaceutical companies necessitate a careful examination of the regulatory frameworks governing drug development and marketing.

SECTION III

Having observed the operations of the pharmaceutical industry across different contexts, the role of the state becomes prominent. This section will explore regulatory challenges that impact health and contribute to health inequalities.

State and Regulation

The evolving relationship between regulatory agencies and the state within the context of pharmaceuticalization, emphasizes two key issues- firstly, the globalization of governance models aligned with the pharmaceutical industry's interests, exemplified by the World Trade Organisation's TRIPS agreement; and secondly, efforts to streamline regulatory processes, particularly in championing pharmacogenetics and addressing national security concerns. The implications of TRIPS on the pharmaceutical industry, ethical review practices in South Asia, the United States Food and Drug Administration's (FDA) role in promoting pharmacogenetics, and the governmental interventions worldwide for pharmaceuticalization driven by national security agendas reflect a shift in the regulatory role of states, from gatekeepers to enablers, as states actively promote innovation agendas within emerging knowledge economies (Gabe et al., 2015).

The pharmaceutical industry's influence has compromised drug regulation in the United States and the European Union, as outlined by the corporate bias theory (Abraham, 2008). This theory suggests that a proactive state collaborating with the industry may lead to pro-business deregulation. The industry's impact extends to regulatory agencies and government bodies through lobbying, financial contributions, and appointments to government task forces. Corporate bias is evident in the adoption of corporate-user fees by drug regulatory authorities in the U.S., such as the FDA, and in the European Union, including the UK MHRA and EMA. Resource constraints led to the introduction of user fees in the U.S., with concerns about prioritizing industry profits over public health. The Prescription Drug User Fees Act (PDUFA)¹⁹ of 1992 and Generic Drug User Fee Act (GDUFA²⁰) of 2012 focused

¹⁹ On September 30, 2022, the US President signed into law the FDA User Fee Reauthorization Act of 2022. This new law includes the sixth reauthorization of the Prescription Drug User Fee Act (PDUFA) that provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biologic products.

on expediting new drug reviews but raised concerns about compromising safety standards. Originally put into effect in 2012, GDUFA underwent reauthorization in 2017, extending its influence until September 2022. GDUFA has proven beneficial for generic drug manufacturers in India by enhancing their return on investment and promoting adherence to US regulations (Pardhe, 2019). In the UK, the transition to 100% user fees in 1989 reflected a government philosophy aligning science with industry needs. The European Union's acceptance of user fees since its inception raises questions about whether public or industry priorities are being served. Negative consequences for public safety arise, raising concerns about compromised safety standards and the potential for conflicts of interest in regulatory agencies that rely entirely on user fees for funding depicting a regulatory capture (Davis & Abraham, 2013).

The evolution of government roles into mere regulators has led to the pervasive issue of 'regulatory capture,' where agencies designed for public interest oversight become influenced by the industries they regulate. This results in a skewed regulatory framework favoring the industry over the public. Regulatory capture involves 'experts' with dual loyalties and a 'Revolving Door' phenomenon, where individuals seamlessly transition between regulatory bodies and the regulated industry, raising ethical concerns. Instances like the Novartis patent case highlight these issues. Rather than addressing ethical concerns, there is a trend toward institutionalizing such practices, evident in policies like India's 2011 National Health Research Policy, potentially reinforcing regulatory capture. Neoliberal reforms since the 1990s have amplified deregulation advocacy, compromising regulatory structures meant to safeguard the public (Sengupta, 2018). This transformation involves a complex interplay of policymakers, regulatory officials, corporations, and powerful lobby groups, complicating efforts to maintain a balanced and unbiased regulatory environment.

This regulatory capture and the pharmaceutical industry's profit-oriented focus indicate a lack of priority for public health. The current study intends to scrutinize the nature of pharmaceuticals, specifically honing in on their accumulation processes under the guise of promoting overall health. The pharmaceutical industry, receiving substantial concessions and

<https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027>

²⁰ The GDUFA, implemented by the US Food and Drug Administration (FDA), aims to expedite access to safe and effective generic drugs. The fees mandated by GDUFA contribute to funding the FDA's regulatory activities and improving the efficiency of generic drug application reviews. (Pardhe, 2019).

subsidies for its healthcare role, faces structural issues, with health in India falling under the family and welfare domain and pharmaceuticals under the Ministry of Chemicals and Fertilizers (India)—a problematic categorization that is addressed in Chapter 3. An attempt is made in this study to trace the repercussions of accumulation practices such practices on the industry's growth and how state support impacts a broader segment of the population. Unlike developmental projects where a section might be affected for the greater good, such as multi-purpose projects, roads, etc, dam construction, the issue here transcends the growth or profit motives of the pharmaceutical industries. It revolves around the conscious oversight of manufacturing process lapses by state officials and the government.

Pharmaceutical Scandals: Issues and Regulatory Lapses

The role of the state in pharmaceutical matters is a complex issue, especially considering the inconsistent global regulations that extend beyond standardization, leading to unexpected economic and political consequences. The state's varying degrees of control over pharmaceutical markets highlight the need for understanding regulatory practices. The cultural positioning of pharmaceuticals goes beyond official healthcare institutions, encompassing informal economies of exchange and use (Das et al., 2000).

Posner (2020) critically examines the evolution of major pharmaceutical companies such as Bayer, Merck, and Pfizer, portraying their transformation from early promoters of legal heroin and cocaine to today's trillion-dollar conglomerates. The narrative unveils a history marked by profit-driven decisions at the expense of patient well-being, with instances of companies pushing boundaries and regulators struggling to catch up. The antibiotic era, particularly the mass production of penicillin during World War II, led to both rebranding and overlooked risks, contributing to the pharmaceutical industry's lucrative yet contentious position by 1950. Posner also sheds light on the industry's role in the opioid epidemic, connecting it to its early reliance on addictive drugs, such as Bayer's introduction of heroin in 1900. Furthermore, he raises concerns about biotech companies benefiting from taxpayer-funded federal grants and assistance without reimbursing or sharing profits. Using Vertex's drug Kalydeco as an example, he illustrates how stock prices surged, executives profited significantly, and drug prices continued to rise despite initial public funding. The author highlights the lack of provisions in the Orphan Drug Act for reimbursing or sharing profits

with government agencies, with legislative attempts to address these issues proving unsuccessful. Researchers and physicians expressed outrage over the escalating prices of Kalydeco, highlighting the disconnect between public funding and private profit.

In the examination of the pharmaceutical industry in India, Srinivasan and Phadke (2018) made substantial contributions, shedding light on regulatory lapses and the production of irrational drugs. The research, as outlined in Lofgren's (2018) edited book, emphasized the necessity for evidence-based medicines within the context of therapeutic anarchy in India. Various issues within the pharmaceutical sector are explored in Srinivasan and Phadke's work, ranging from unethical practices in licensing, manufacturing, marketing, and prescription processes. They advocate for the illegality of unethical behavior and emphasize the crucial role of quality promotion at production, marketing, and storage levels, calling for the fair application of the law. The researchers critically assess the regulatory anarchy of the Central Drugs Standard Control Organisation (CDSCO), pointing out its prioritization of industry interests over consumer welfare. The central theme of their work revolves around ensuring medicine quality, evidence-based licensing decisions, and promoting affordability and accessibility. The emphasis is particularly placed on CDSCO's role in prioritizing legal provisions, scientific evidence, and policy objectives over pharmaceutical company profits.

In examining big pharma's dominance in Indian healthcare, Rajan (2017) delves into the moral, philosophical, legal, and emotive dimensions. By scrutinizing the impact of the biomedical industry and regulatory bodies, the author exposes the pervasive influence of multinational pharmaceutical corporations, framing it as a global *Pharmocracy*. Utilizing case studies such as the Gardasil Human Papillomavirus (HPV)²¹ vaccine scandal and the Gleevec patent denial²², Rajan unveils challenges in medical practice and accountability, particularly in the context of outsourced clinical trials in India. The narrative explores the ethical concerns surrounding informed consent and highlights conflicts between global corporate interests and the regulatory landscape of developing nations, raising questions about the value of health and life across different populations. *Pharmocracy* prompts critical

²¹ Gardasil is a vaccine supposed to protect against the cancer-causing strains of HPV (human papillomavirus), a sexually transmitted virus linked to cervical cancer.

²² Refer Arie S. Indian Supreme Court rejects Novartis's appeal on drug patent BMJ 2013; 346 :f2099 doi:10.1136/bmj.f2099

reflection on the intricate dynamics of the global pharmaceutical industry and the governance structures shaping the production and consumption of drugs worldwide.

Camargo & Reid (2015) note that in the contemporary pharmaceutical industry's political-economic structure, two significant facets emerge: (a) the trend of outsourcing clinical drug trials to developing nations characterized by weaker regulatory standards and a larger pool of potential volunteers, as evidenced by Shah (2007) and Petryna (2009); and (b) the imbalanced political economy that favors markets in developed countries while marginalizing or discriminating against those in underdeveloped countries, as brought to light by investigations conducted by Petryna et al. (2006), and Shah (2007). Consequently, this has spurred additional research delving into novel forms of socio-political identification rooted in health-related struggles among patient groups or local communities. This phenomenon is referred to as 'biological citizenship,' a concept articulated by Petryna (2002), Petryna et al. (2006), Biehl (2004), and notably explored by Rose (2007) and Rose and Novas (2005).

Abraham's (1995, 2002, 2007) extensive work exposes the covert influence exerted by the pharmaceutical industry on regulatory frameworks, shaped by neoliberal ideologies, ultimately undermining public health defense. Additionally, Busfield (2007) investigates the 'fabrication of scientific facts' in clinical drug trials, sparking a dialogue with Abraham. Goldacre (2012) uncovers negligent and willful malpractice in pharmaceutical companies conducting clinical trials for regulatory approval. (Badcott 2013) acknowledges the industry's pivotal role in scientific-pharmacological progress but advocates for a broader ethical basis, such as a triple bottom line policy, to address its shortcomings. Conversely, Calinas-Correia (2013) rejects centralized regulation, highlighting the need for subsidiary regulations to counteract the executive bypassing of existing regulations.

The aggregation of political power in the hands of Pharmaceutical giants has triggered a call for regulation from the public, a demand sometimes articulated by these corporations themselves (Braithwaite, 2008). Furthermore, the regulatory processes and competitive pressures, stemming partly from the increase in the scope and scale of corporations, transform what was previously unregulated in the nineteenth century into a regulated framework in the twentieth century. This is evident in the chemicals/pharmaceuticals industry, where significant public demand for regulation arises, fueled by incidents like

Bhopal in agricultural chemicals and thalidomide in pharmaceuticals, resulting in mass concern. The nineteenth-century regulatory state, constrained to responding to public outrage by blaming individuals within chemical firms and imprisoning them, could not establish a regulatory framework addressing the fundamental causes of disasters. The multitude of small chemical producers overwhelmed state inspectors, hindering their ability to monitor and adapt to technological changes that continually introduced new risks. State regulation and private regulation through tort contributed to the formation of larger chemical corporations, notably in pharmaceuticals where the costs of testing new drugs have soared to hundreds of millions of dollars. Global scandals prompting calls for more stringent regulation foster a sense of shared fate among large firms in the industry, as demonstrated in Rees's (1994) study on the nuclear industry following the Three Mile Island disaster, emphasizing a belief that another similar incident could cripple the industry (Braithwaite, 2008).

In the intricate landscape of regulatory capitalism (Braithwaite, 2008), the dynamics of risk management extend beyond the realms of large corporations. As industries grapple with shared destinies in a risk society, the regulatory framework not only involves the oversight of small producers by major entities but also delves into the intricate interplay between global and national industry associations. When confronted with a shared destiny in a risk society, large corporations adopt industry-wide risk management practices, managing risks both upstream and downstream (Beck, 1992). Regulatory capitalism extends beyond reliance solely on the regulatory state, representing a significant aspect in narratives related to chemicals, pharmaceuticals, and nuclear industries. It involves the regulation of industry associations over their major constituents and the oversight of small producers by large entities sharing the same chain of responsibility for a particular risk. The regulatory landscape is shaped not only by states, often with technical support from international organizations such as the World Health Organization and the Organisation for Economic Co-operation and Development (OECD), but also by global and national industry associations along with large multinational firms. This not only alleviates some of the logistical challenges faced by the regulatory state in monitoring numerous small firms but also addresses information issues that historically rendered chemicals unregulated in the nineteenth century (Gunningham and Grabosky, 1998).

This multifaceted regulatory environment, shaped by both states and international organizations, plays a pivotal role in addressing logistical challenges and information issues, historically hindering the regulation of chemicals. Expanding on these regulatory intricacies, the next tier in the enforcement hierarchy is the statutory compulsory licensing, in contrast to licenses granted within the context of a competition law settlement, offering a nuanced perspective on intellectual property rights and their role in promoting competition or safeguarding public health (Scherer, 2000; Reichman & Hasenzahl, 2003).

Compulsory licensing, allowing the use of an invention without the owner's approval, serves public interests like promoting competition and safeguarding public health. Despite opposition from the US pharmaceutical industry, TRIPS explicitly allows it, outlined in many countries' laws. While it addresses diverse purposes, from supplying medicines to countering anti-competitive practices, its implementation can be complex and costly. Government use provisions, however, typically only require official authorization. Nevertheless, its efficacy may be limited, as seen when a compulsory license in one nation may not impact primary competition markets in others. National governments may hesitate due to potential repercussions from US trade officials, driven by concerns from industry lobbyists, fearing adverse consequences during bilateral trade negotiations, including potential trade and security concessions. (Drahos, 2007; Drahos & Braithwaite, 2002; Braithwaite, 2004).

In the context of research-intensive companies operating within a nation, governments may hesitate to mandate licensing, particularly if the primary beneficiaries are outside their borders. However, defending the intellectual commons is not solely in the purview of nation-states. In cases where a company withholds critical knowledge, a foundation could potentially acquire the firm, release the essential knowledge to the public domain, and then sell it to a more transparent competitor. This strategy, akin to compulsory licensing, remains an option, and influential figures like Bill Gates and Warren Buffet could play a role. Foundations, such as the Gates Foundation, might also finance research aimed at unlocking technology, emphasizing the broader benefit of placing foundational knowledge in the public domain. However, challenges persist, as global political constraints hinder not only the adoption of compulsory licensing but also the escalation of reforms in intellectual property law. Despite widespread interest in shorter patent terms, concerns about market power wielded by the US and the EU during trade negotiations pose significant obstacles. Drahos and Braithwaite

(2002) propose that leadership from China and India on compulsory licensing is crucial, given their growing power and resistance to external pressure. They further advocate for the G-20 group of developing economies to prioritize rolling back globally monopolistic intellectual property regulations at the World Trade Organization. (Braithwaite, 2004).

Intellectual property laws that enhance monopolies within a country can be strategically manipulated to intensify scrutiny on firms known for exploiting monopoly power, particularly prominent players in sectors like pharmaceuticals who often secure extensive grants of monopoly power (Nicol & Nielsen, 2003). In the era of neoliberalism, characterized by market liberalization aiming to unleash capitalist entrepreneurial spirit and promote consumer choice by reducing government regulation, the late 2000s brought a global economic recession, highlighting inadequate regulation in the banking sector. In response, governments advocated for reduced regulation across various sectors to stimulate economic growth. Despite the transnational and lucrative nature of the pharmaceutical industry, it thrived during this era, with prescription drug sales tripling from the early 1980s (Davis & Abraham, 2013). The industry's remarkable growth, evident in soaring sales and profits, demands a critical examination of its growth on health and the role of the State.

State and Health

Prasad (2022) highlights the existing fractures in India's health system, revealing that over four-fifths of healthcare expenditure is private. The ongoing pandemic has exposed structural weaknesses, including workforce shortages, minimal public health spending, high out-of-pocket expenses, and regional disparities. Starting from the 1970s, a shift towards tertiary care and privatization gained momentum, intensified by liberalization policies in the 1990s, resulting in increased commercialization and private investment in the health sector. The health industry, encompassing hospitals, insurance, pharmaceuticals, and more, has undergone significant changes since the late 1990s, with private equity investments and foreign capital playing a substantial role. State health policy is characterized by a dual movement, where aggressive market-oriented strategies coexist with community health discourses, reflecting a nuanced approach to policy-making.

According to Kapilashrami and Baru (2019), the global health landscape is undergoing substantial changes marked by increased funding and recognition of global health as a crucial foreign policy issue. New actors, such as hybrid institutions, alliances, and front-line groups, are shaping health governance globally and nationally, challenging the traditional role of the World Health Organization (WHO). This transformation introduces uncoordinated structures and accountability issues. The authors advocate for a nuanced understanding of globalization's impact on population health, emphasizing the dialectical interaction between global, national, and local dynamics. They illustrate power dynamics in nutrition policy in India, revealing how global actors influence policy spaces. The book challenges the for-profit and nonprofit dichotomy in civil society, exposing diverse interests. The concept of commercialization is employed to analyze the transformation of public, private, for-profit, and nonprofit sectors in global health, breaking down rigid boundaries. The authors critique the Health Sector Reform (HSR) ideology of the 1980s, driven by commercialization, which weakened public provisioning and introduced inequalities in healthcare access in countries like India.

The interplay of nationalist and internationalist influences shaped the perception of health as a fundamental right for every human being, articulated in the World Health Organization's 1948 constitution. Indian nationalist leaders embraced this notion, critiquing the colonial state's welfare negligence. However, inherent contradictions in intellectual, cultural, and institutional forces guiding India's public health commitment led to its brief and constrained nature. The emergence of "national health" as a singular issue in India drew from concerns about racial purity, social reform, and modernization, contributing to a nuanced political culture of health. The post-colonial state inherited a feeble medical infrastructure and the bureaucratic indifference to public health, alongside conflicting notions of 'well-being'. Despite conceptualizing health as a national citizenship right, post-colonial India grappled with prioritizing citizens' well-being due to these challenges and ethical conflicts. The Bhore Committee's proposals in the Second World War marked a departure from colonial practices, laying the foundation for a national health service, yet subsequent efforts were perceived as falling short of the committee's standards (Bose, 1997).

In the post-independence, the Indian government has allocated a comparatively lower share of its resources to public health than most other governments globally. Despite being actively involved in various aspects and sectors, the concept that the state should bear responsibility for ensuring public healthcare has not become ingrained in Indian political culture (Amrith, 2007). Scholars like Amartya Sen and Jean Dreze (2002) contend that public health has been severely overlooked in India's development narrative. The role of the state in medical care and the pharmaceutical industry is marked by policies that support private sector involvement. Globally, medical care is seen as a lucrative market, with developed countries dominated by large corporations. This trend has extended to India, where economic liberalization and privatization policies have facilitated major business entities entering the healthcare market. The support from the Indian state, including reduced customs duties and tax concessions, has led to the establishment of high-tech hospitals by corporate entities. However, this shift has increased the cost of medical care, making it less accessible to the majority of the population dealing with diseases. Despite ranking as the third-largest economy globally, based on purchasing power parity, India faces inadequate healthcare facilities, limited physical and medical infrastructure, and a shortage of specialized medical personnel in smaller cities and rural areas. These shortcomings primarily stem from a lack of economic resources (Festa et al., 2021).

In the pharmaceutical industry, the Indian state has favored the interests of multinational companies (MNCs) over nationalization recommendations. Despite committee suggestions, drug policies continue to benefit MNCs, leading to the influx of numerous drug formulations that may be ineffective or harmful. The considerable influence of MNCs continues to shape bureaucratic and political decisions in the pharmaceutical sector in India. India holds a dominant position in the global pharmaceutical landscape, being the leading contributor of generic medicines with a substantial 20% share in overall international pharmaceutical exports (The Hindu, 2023). Moreover, the country stands as the foremost supplier of vaccines globally, manufacturing over 60%²³ of the world's total vaccine production by volume. Regulatory bodies act as an interface between the industries and government primarily to develop growth and develop the industry.

²³ "India's vaccine manufacturing prowess". www.investindia.gov.in. Retrieved 19 September 2023.

The subsequent chapter in the thesis provides an in-depth exploration of the State's role in the growth of the pharmaceutical industry in India. The worldwide pandemic pushed numerous economies and businesses to the brink, yet the pharmaceutical industry, especially in India, demonstrated resilience. The latest Hurun India Rich List (2021) indicates that 40 out of India's estimated 237 billionaires are from pharmaceutical companies. The pandemic underscored the industry's ability not only to swiftly produce vital goods for global needs but also the significant profit potential in the manufacturing of medicines. The dominance of pharmaceutical companies among India's billionaires raises concerns about how the accumulation of wealth in this sector may contribute to health inequality and suffering is discussed in the next section.

Section IV

Health Inequality

In the influential work "Dangerous to Your Health: Capitalism in Health Care" (1993), Spanish sociologist Vicente Navarro critically assesses the adverse impact of the pharmaceutical industry on public health. Navarro underscores the oppressive nature of the current healthcare system, emphasizing its profit-driven approach that exploits the suffering of many for the benefit of a few. He attributes the root of the problem to the economic system, particularly capitalism, which governs the financing and delivery of health services. Navarro argues that class control, especially by the capitalist class, significantly shapes how healthcare is funded and provided, limiting government responsiveness to societal needs.

Echoing this perspective, Sell and Williams (2020) further explore the structural pathogenesis of health under capitalism, focusing on the evolving nature of contemporary capitalism, particularly in the era of financialized capitalism. They discuss the expansion of vertically integrated global value chains and the concentration of wealth, highlighting how economic concentration contributes to increased income and social inequality. The authors connect capitalism's structural vectors, including inequality, poverty, and global markets, to the production and transmission of disease and ill health worldwide. They argue that capitalism's inherent structural and pathogenic qualities interact with super-structural elements, such as

global institutions governing health, influencing health outcomes on a global scale (Navarro, 1993; Sell & Williams, 2020).

Capitalism's structural pathogenesis contributes to the emergence of non-communicable diseases, particularly accentuating antimicrobial resistance (AMR) as a significant global concern. Chapter 4 addresses this concern in-depth, shedding light on the intricate relationship between capitalism's structural dynamics and the escalating threat of AMR. This, alongside other diseases, exacerbates health inequality within the population. The examination of the State and Pharma industry nexus revealed a dual nature, simultaneously promoting health and contributing to disease, thereby perpetuating health inequality and resulting suffering. To address the escalating global prevalence of Non-communicable diseases (NCDs), the health impacts of climate and environmental crises, and health disparities, it is essential to comprehend the fundamental influences on health and recognize the variations within and between populations.

While social determinants of health (SDoH) studies shed light on how inequality shapes health, there is a gap in understanding how capitalism, globalized corporate and commercial systems, and broader political-economic and global governance conditions, facilitate these influences, directly and indirectly, contribute to shaping inequality and health (de Lacy-Vawdon, Vandenberg, & Livingstone, 2022). Given their profound influence on population health and social circumstances, an understanding of commercial determinants of health (CDoH) and their conceptual integration within SDoH becomes crucial in this study. CDoH presents a significant global health concern for various reasons. The effects of CDoH, rooted in the globalized nature of modern commerce and the transnational presence of commercial actors, are experienced worldwide. This phenomenon is further facilitated by the weakening of global governance structures such as the World Trade Organization, the proliferation of multinational free trade policies favoring business, and the growing concentration of commercial actors into global oligopolies (Baum, Anaf, & Anaf, 2015). These systems, with historical roots in colonialism, witness commercial interests from high-income countries extracting resources and wealth from low-income and middle-income countries (LMICs) (Schrecker, Birn, & Aguilera, 2018). In the context of the present study, understanding and addressing CDoH are integral to mitigating the intertwined challenges of environmental pollution, NCDs, and health inequality exacerbated by the State and Pharma industry nexus.

As per the World Health Organization (2023), NCDs result in the annual death of Noncommunicable diseases (NCDs) resulting in the death of 41 million individuals annually, constituting 74% of the total global mortality. Many factors contribute to NCDs, with air pollution being the most impactful, causing 6.7 million deaths worldwide, of which approximately 5.7 million are linked to NCDs such as ischaemic heart disease, chronic obstructive pulmonary disease, stroke, and lung cancer. Concerning the socioeconomic consequences, the relationship between poverty and NCDs is intricate, and the swift rise in NCDs is expected to impede poverty reduction efforts, particularly in low-income countries. This is attributed to the associated increase in household healthcare costs. Individuals in vulnerable and socially disadvantaged positions face heightened risks of exposure to harmful products like tobacco, adopt unhealthy dietary practices, and experience limited access to health services. In settings with limited resources, healthcare expenses related to NCDs rapidly deplete household resources. The substantial costs of NCDs, encompassing prolonged and expensive treatments, along with income loss, annually thrust millions of people into poverty, hindering overall development. Recognizing the broader impact of commercial determinants of health (CDoH) becomes imperative in addressing the complex interplay between economic forces, health inequalities, and the prevalence of non-communicable diseases.

The core concept in comprehending CDoH revolves around the idea of power, which can be interpreted in various ways. Among these interpretations, Fuchs's (2005) definition of power, particularly his three forms of corporate power, is especially relevant to understanding CDoH. According to Fuchs, power is defined as the capacity of business entities to effectively pursue political objectives. Fuchs outlines three forms of power: (i) instrumental, which involves political and policy influences through mechanisms like lobbying or political donations; (ii) structural, which encompasses agenda-setting power through institutional processes such as private investment, employment, taxation, and economics; and (iii) discursive, which involves the power to pursue and shape interests by influencing societal values, norms, and ideas.

This conceptualization of power aligns with the understanding of Commercial Determinants of Health (CDoH), as unchecked corporate power, driven by these forms, impacts various facets of society. Contemporary systems, such as trade, employment, and public policy, play a role in the unrestrained growth of corporate actors, supported by carefully constructed discourses. Recognizing and responding to corporate power is crucial for population health, especially considering recent discussions on CDoH that emphasize systems thinking, power dynamics, and communication technologies for targeted marketing. Addressing CDoH effectively becomes imperative for countering global patterns of inequity, promoting ethical, legal, and social systems, and reducing the prevalence of non-communicable diseases and other harms. CDoH aligns with the familiar language of Social Determinants of Health (SDoH), offering conceptual accessibility and a holistic approach. It encompasses crucial concepts like corporate profit maximization, globalization, and industrialization, influencing contemporary disease patterns. The recognition of CDoH's significance, evident in institutional cores like the WHO Collaborating Centre, suggests that consolidating research under CDoH discourses can enhance communication and guide research, policy, and practice. CDoH aligns with the familiar language of Social Determinants of Health (SDoH), making it accessible conceptually and providing a holistic approach. It encompasses vital concepts such as corporate profit maximization, globalization, and industrialization influencing contemporary disease patterns. (de Lacy-Vawdon, Vandenberg, & Livingstone, 2022).

Examining health inequalities involves exploring fundamental concepts like SDoH²⁴ and CDoH, Intersectionality, Health Disparities, Health Equity, and Structural Violence. These concepts collectively provide a comprehensive framework for understanding the intricate interplay of social, economic, and environmental factors that shape health outcomes. SDoH focuses on conditions such as income, education, housing, employment, and healthcare access, while intersectionality recognizes the influence of multiple social identities on health risks. Structural violence, a term coined by Johan Galtung in the 1960s, is extensively examined through sociological lenses. According to Galtung, structural violence occurs when social structures or institutions negatively impact individuals by hindering their access to

²⁴ Social determinants of health (SDoH) are the environmental conditions in various aspects of life that significantly influence health, functioning, and overall quality of life outcomes. These determinants encompass economic stability, education access and quality, health care access and quality, neighborhood and built environment, and social and community context. SDoH includes factors such as safe housing, transportation, racism, caste, gender, discrimination, education, job opportunities, income, access to nutritious foods, physical activity opportunities, and environmental factors like air and water quality, along with language and literacy skills. SDoH plays a crucial role in shaping health disparities and well-being.

basic needs. Structural violence (addressed in chapters 4 and 5) becomes institutionalized in laws and social norms, particularly affecting marginalized communities.

Marxian political economy delves into how capitalism and class relations perpetuate inequalities, elucidating the role of economic systems in structural violence. Intersectionality offers insights into how various oppressions intersect, revealing the impact of structural violence on those marginalized across multiple dimensions. Postcolonial theory explores colonialism's influence on social structures, uncovering how historical processes contribute to contemporary structural violence. These theories collectively offer diverse perspectives for understanding and analyzing structural violence, aiding in identifying the root causes of health inequalities and developing strategies to address structural violence while promoting health equity. Health inequalities provide insights into the intricate interplay of social, economic, and environmental factors shaping health outcomes, emphasizing the link between structural violence and social suffering.

Power

The previous sections have explored the pharmaceutical nexus, commercial interests, pharmaceuticalization, regulatory lapses, scandals, and issues, along with the role of the state, health inequality, structural violence, and suffering. The alignment of pharmaceuticals and the state with commercial interests, prioritizing economic considerations over public health, prompts a fundamental question: How do we conceptualize the influence and power of the pharmaceutical industry?

In the context of the pharmaceutical industry, the concept of biopower, originally coined by French philosopher Michel Foucault in *The History of Sexuality, Volume 1* (1978), finds extensive theoretical exploration by scholars. These scholars collectively express a shared concern for the intersection of politics with life, encapsulated by the concept of 'the living'. Foucault's concept of biopower manifests through two distinct currents: disciplinary technologies and biopolitics²⁵ aimed at regulating the population (Foucault 2003, p. 243; 2007, p. 1). Disciplinary technologies involve techniques of power centered on individuals'

²⁵ Biopolitics refers to a power that does not exclude disciplinary technology, but rather, encapsulates it, integrating and partially modifying it; although it operates on another level (Foucault 2003, p. 242).

bodies, guiding and shaping their actions and behaviors. Simultaneously, biopolitics, as a regulatory force, ensures the standardization and control of life processes at the level of individuals and the broader human race or species (Foucault, 2003, p. 247).

Foucault refers to the amalgamation of these disciplinary and regulatory mechanisms as a 'technology of biopower' with the ultimate goal of maximizing and extracting forces from life (Foucault 2003, p. 246). This translates to the industry's power to influence and control not only individual bodies but also the biological processes of the population at large. The essence of biopolitics and disciplinary power within the pharmaceutical sector lies in the quest to optimize and harness life forces, whether derived from individual bodies or the collective human species (Castro 2011a, p. 41). This gives rise to a form of biopower that extends beyond mere disciplinary control and encompasses the regulation of biological processes at a broader societal level. Foucault's concept further alludes to the transformation of society into a normative structure, not exclusively disciplinary but characterized by the intersection of the norms of discipline and regulation. This implies a shift toward a normalizing society where the norms of discipline and regulation intersect, forming an orthogonal articulation that influences not only individual behavior but also the broader biological and medical landscape (Foucault 2003, p. 253).

Foucault's primary focus on power, discourse, and social identities, termed "subject positions," asserts that power is not something possessed by individuals; instead, it circulates throughout social relations, shaping people into subjects suitable for the prevailing political order. This pervasive, productive, socially distributed, and discursively managed power is central to understanding the nature of suffering. Foucault's original conception of biopower in the 18th and 19th centuries characterizes it as a form of power focused on taking control of life and biological processes at the population level. Biopolitics, the style of government regulating populations through biopower, shifts away from disciplining the body and emphasizes systematizing it.

Biopolitics manages life processes at the population level, necessitating experts to determine norms, deserving patients, and distinguishing from malingerers. Biopower operates as a form of bioregulation across various institutions in society, including medicine, nursing, and insurance. It treats individuals as economic subjects, evaluating them based on their

"productive" capacities as human capital. This analytical approach scrutinizes the interaction between bodies and institutions, fundamentally establishing or stratifying the value of human lives. Applying this theoretical framework to the suffering of people affected by pharmaceutical pollution underscores the systemic control exerted over their lives. Biopower, manifested through regulatory institutions, influences determinations about what is normal or abnormal, shaping the lives of individuals and populations. The environmental impacts of pharmaceutical pollution, their effects on health, and the subsequent suffering of affected communities can be analyzed within this context (Rosa & Ferrell, 2023).

Foucault's perspective defines medicine as a power knowledge applicable to both individual bodies and populations, resulting in disciplinary and regulatory effects (Foucault, 2003, p. 252). While Foucault did not witness the later 20th-century advancements, the subsequent rise of life sciences, particularly molecular biology, and its applications in biomedicine and biotechnology, including pharmacology, have been extensively documented over the past 30 years (Starr, 1982; Feinstein, 1967; Armstrong, 1995; Clarke et al., 2003). Scholars like Nikolas Rose (2007) and Sarah Franklin (2005) have explored the impact of these scientific transformations on the normalization of organic and biological life, as well as their social implications leading to a 'new way of life' (Rose, 2007a; Rose & Miller, 2008; Rose & Abi-Rached, 2013; Franklin, 1995, 2000, 2005). Rose identifies five key transformations around bioscience, influencing the emergence of a new way of life: molecularization, optimization, subjectivization, somatic expertise, and economies of vitality, culminating in the development of biocapitalism (Rose, 2007a, pp. 5–6). Foucault's genealogy could enhance the understanding of pharmacological practices as a principal component of this evolving power structure, extending beyond disciplinary and biopolitical aspects to the molecular level. (Rose, 2007a, pp. 9–39).

Foucault and Agamben's (1995) perspectives converge on the construction of subjectivity within relations of power. Foucault contends that subject positioning is a result of power dynamics rather than a pre-existing condition. Agamben builds on this idea in his work "Homo Sacer," asserting that all sovereign power involves the administration of life and death. This administration, termed biopower by Foucault and Agamben, is state-sanctioned and involves the normalization of individuals into categories of *bare life* or *bios*. (chapter 5). Those who deviate from socially constructed norms risk descending within the social strata,

losing power, and becoming vulnerable to violence and exclusion. The Zoe-bios dichotomy, systematically concealed through normalizing processes, manifests prominently in biopolitical spaces like prisons and hospitals, where the divide between those with the political agency (*bios*) and those without (*Zoe*) is perceived as *natural*. This construction of subjectivity becomes a taken-for-granted socio-structural process embedded in everyday life.

Achille Mbembe's concept of necropolitics is closely intertwined with Foucault's biopolitics but extends its scope to address contemporary forms of subjugation, such as slavery and colonialism. Achille Mbembe (2019), aligns with Foucault's biopower, and the shortcomings are addressed in explaining instances where people experience bodily suffering and death due to extreme violence and brutality. Mbembe illustrates how enslaved individuals were deliberately kept alive but in a state of injury, reduced to mere "instrument[s] of production" and devalued to the point of being regarded as "non-persons." He characterizes their lives as a "death-in-life," marked by the deployment of weapons to maximally destroy individuals, creating what he terms "death-worlds." These death worlds represent novel forms of social existence wherein vast populations endure conditions that render them akin to the living dead. Importantly, the violence in these death worlds doesn't always lead to immediate death but inflicts permanent wounds on entire populations through repeated, everyday forms of violence, such as environmental racism and climate change. This prolonged suffering becomes normalized, aligning with Agamben's concept of *homo sacer*. Mbembe's necropolitics (Chapter 5) provides a critical perspective on the enduring impact of violence, marking populations with a status akin to the living dead in contemporary society.

Camargo & Ried (2015) propose that adopting a more comprehensive theoretical framework, such as Foucault's genealogy, could foster a deeper understanding of pharmacological practices as a fundamental component of this evolving power apparatus. The concept of an 'apparatus' or 'dispositif,' as articulated by Foucault, analyzes a range of elements, both discursive (political, medical, scientific) and non-discursive (institutions, laws, regulations), shaping power dynamics (Foucault, 2005). Pharmacological practices investigate how advanced bio-knowledge, particularly in pharmacology, generates power technologies influenced by the strategic demands of the pharmaceutical industry. This involves identifying positive power relationships and exclusions within this complex interplay. The genealogy of pharmacological practice comprises two main aspects: (a) characterizing new technologies of

power, especially at molecular and neuromolecular levels, and (b) understanding struggles of resistance or counterpower.

Rajan (2017), engages and challenges Foucault's ideas on the interplay of knowledge and power (Chapter 3), and he applies the concept of pharmocracy. He explores the multifaceted nature of knowledge in highly capitalized biomedicine, examining its translations across domains and locations. He scrutinizes how knowledge intersects with value and politics, delving into questions of representation, authority, and the consolidation or contestation of hegemony. Drawing from Gramsci, his work emphasizes the bidirectional role of knowledge practices in shaping the dynamics of capitalized health, illustrating how specific practices contribute to both consolidation and contestation within various contexts. The emphasis is not solely on objective correctness but on understanding whose knowledge gains value and authority through complex mechanisms.

Rajan's work centers on developing the concept of contending relations of production, particularly within the pharmaceutical industry, examining the antinomies faced by the state in balancing health provision and biomedicine's use for economic expansion. The analysis underscores the significance of understanding speculative financialized logic in the multinational R&D-driven sector, emphasizing the nuanced nature of market value beyond monetary terms. Rajan explores diverse value forms in global pharmaceutical economies, highlighting power relations among these forms. He explores the extension of capital logic, especially when health transforms into surplus health, recognizing variations across time and place. Institutional mediation through governance regimes is crucial in materializing capital logic. Rajan differentiates between Euro-American R&D-driven and Indian generic pharmaceutical industries, outlining their distinct approaches to drug development and market terrains. Additionally, Rajan addresses the crisis within the pharmaceutical industry, marked by trends of privatization, speculation, and globalization. He critiques attempts to address the crisis, noting potential reinforcement of its root causes. The globalized nature of the crisis complicates understanding structural relationships, affecting individuals and industries worldwide. Rajan advocates for a critical and political response, highlighting the redefinition of health through globalizing, speculative capital appropriation. He calls for an institutionalized resistance to such appropriation, emphasizing the necessity to comprehend

the crisis's origin in the value form itself as appropriated by capital logic, deeming mere institutional responses insufficient without this foundational understanding.

A Discussion on the Political Economy of Pharmaceuticals:

This chapter extensively looks at the studies on pharmaceuticals as medicine, as an industry, and the practices and influence that this global sector has been exerting on multiple governments and international organizations over the years. This discussion, while examining various perspectives and concepts associated with Pharma within multiple works, foregrounds the political economy and power of the pharmaceutical industry. This issue is unpacked over the subsequent chapters.

The political economy provides a comprehensive analytical tool for understanding the sociological aspects of pharmaceutical pollution. This framework intricately examines the interplay between political, economic, and social factors that contribute to health disparities. Several key conceptualizations within this framework offer insights into the dynamics of pharmaceutical pollution. In the realm of corporate power and pharmaceutical industry influence, investigations focus on understanding how economic power and political sway contribute to the production, consumption, and disposal of pharmaceuticals. This involves analyzing lobbying, regulatory capture, and marketing practices, shedding light on how profit motives and market dynamics prioritize sales over environmental sustainability.

Access to healthcare and waste disposal infrastructure intersects with issues of inequality, highlighting how marginalized communities not only face challenges in obtaining affordable medications but also encounter barriers in accessing the judiciary to fight against corporate entities that impact their livelihoods. This contributes to an exacerbation of pharmaceutical pollution. Global trade and distribution dynamics are scrutinized to understand their influence on pharmaceutical availability, distribution, and subsequent pollution, emphasizing the impact of outsourcing production to countries with lax environmental regulations. Regulatory frameworks and policies are analyzed, questioning whether marginalized communities bear a disproportionate burden due to lax enforcement of disposal regulations.

Medicalization and consumption patterns delve into the influence of medicalization on pharmaceutical consumption, exploring its impact on health outcomes and pollution levels. Community resistance and advocacy initiatives are studied to understand how affected communities organize against pharmaceutical pollution, emphasizing the role of grassroots movements in challenging political and economic forces. By examining privatization of healthcare and environmental costs, one investigates the relationship between profit-driven healthcare models and pharmaceutical pollution, analyzing how cost-cutting measures within privatized systems may impact waste disposal practices.

Finally, an intersectional analysis considers how identities like caste, gender, and class intersect with pharmaceutical pollution and health inequalities, recognizing the multifaceted dimensions of disadvantage contributing to differential exposure and unequal health outcomes. In essence, the political economy of health inequality framework provides a robust foundation for unraveling the complex interplay between political, economic, and social factors shaping pharmaceutical pollution and its implications for health disparities. This chapter established a framework and examined various instances and studies illustrating the evolution of the pharmaceutical industry into a major influential force capable of shaping terms and policies at both national and global levels. The subsequent chapter will redirect its attention to India, investigating the complex interplay between the state and the pharmaceutical industry. It delves into the expansion of the pharmaceutical sector in India, scrutinizing the policies that facilitated its growth and the regulatory framework influencing its trajectory. This exploration aims to illuminate the ramifications of the industry's development on public health.

Chapter 3

From Policy to Hype: The State as the Architect of Pharma Vision

The previous chapter established a framework and examined various instances and studies illustrating the major influential force of the pharmaceutical industry which is capable of shaping terms and policies at both national and global levels. This chapter will examine the state's role in industrial growth, delving into various policies and incorporating the perspectives of 'Vision and Hype' (Rajan, 2006). The study of the State is highly relevant in social science research because it serves as the central agency responsible for mobilizing and distributing power and resources in society. To comprehend the nature of the state and its societal role, it is crucial to analyze its policies (Bardhan, 1984).

In crafting pharmaceutical policy, India, like many other nations, grapples with the intricate interplay of conflicting economic and social interests, often rooted in the divergence between the use value and exchange value of medicinal drugs as commodities, a concept derived from Marx's analysis. The use value of medicines, centered on their safety, efficacy, and quality, aligns with the goal of health policy—to prevent, cure, or alleviate illnesses. Government agencies are entrusted with regulatory oversight to optimize this use value by ensuring adequate safety and efficacy standards in the manufacturing, marketing, and distribution of medicines. However, regulation in this realm is a contentious issue globally, characterized by debates on industry influence over regulatory bodies, as observed in notable instances, including the US Food and Drug Administration (Angell, 2005; Law, 2006). The application of scientific-technological principles in regulation is inherently susceptible to biases driven by social and material interests.

This chapter is structured into four sections to analyze the State's role in nurturing the pharmaceutical industry. Section I examines the industry's development from pre-Independence to the 1970s, while Section II provides an overview of the drugs and pharmaceutical sector, covering the period from the 1970s to 2023, with a focus on key milestones such as the Patent Acts. These sections offer a chronological narrative of industrial growth, outlining policies and active state involvement. The third section starkly contrasts the health sector with the pharmaceutical industry, highlighting disparities in growth

despite the industry's intended role in promoting health. The exploration of these disparities prompts an examination of regulations and regulatory capture in the subsequent section. The fourth section delves further into this discussion.

Before going into the state policies, a brief overview of the technical aspects of the drug industry is provided. Following this introduction, subsequent sections will address policy shifts and the associated processes.

Pharma Industry: Technical Insights

The pharmaceutical industry comprises two pivotal sectors: drugs and medical devices. The drugs sector can be further categorized into three segments: Active Pharmaceutical Ingredients (APIs) or Bulk Drugs²⁶, Formulations, and Vaccines. APIs serve as the cornerstone of the pharmaceutical industry, constituting the fundamental chemical compounds essential for the production of any finished pharmaceutical formulation. An API is the active drug substance, responsible for delivering therapeutic effects, while other components are excipients or inert materials. According to the World Health Organization (WHO), an API is defined as "a substance used in a finished pharmaceutical product (FPP), intended to provide pharmacological activity or have a direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease. It may also directly influence the restoration, correction, or modification of physiological functions in human beings."

The definition employed by the U.S. Food and Drug Administration (FDA) further elucidates the pivotal role of APIs in drug production. It states, "Any substance or mixture of substances designed for use in the manufacture of a medicinal product and, when used in drug production, becomes an active ingredient of the drug product. These substances are intended to provide pharmacological activity or other direct effects in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to influence the body's structure and function"²⁷. Within the API segment, there are both patent-protected drugs and generic versions. Generics have been the primary emphasis of the Indian pharmaceutical industry for several decades. The World Health Organization (WHO) defines generic medicines as those manufactured without a license from the innovator company after the expiration of the patent or other exclusivity rights for the innovator product. Moreover, generics encompass medicines for

²⁶ API and bulk drugs are used synonymously

²⁷<https://www.registrarcorp.com/definitions/>

which there are no existing patents in the countries where they are produced and sold. These generic drugs are required to be bioequivalent²⁸ to the innovator drug and must receive approval from drug regulatory authorities, which entails providing evidence of their bioequivalence. Furthermore, these generic drugs must be therapeutically equivalent to the original drug, ensuring that there is no significant difference in the rate and extent to which the API or active component becomes available at the site of drug action when administered at the same dosage. It is the therapeutic effectiveness of generic medicines that has enabled the Indian pharmaceutical industry to compete with well-established, large companies in developed nations and emerge as a key source of affordable medicines worldwide (James, 2020).

API manufacturers employ raw materials or chemical substances in reactor plants to create these vital pharmaceutical ingredients. During the transformation from raw material to API, the chemical product is referred to as an ‘intermediate’ or ‘intermediary’. APIs may undergo various intermediaries in this process as they evolve from raw materials. Drug manufacturers utilize these APIs in conjunction with excipients (such as additives, binders, lubricants, disintegrants, colorants, sweeteners, preservatives, and more) to produce the final medicines. Similarly, vaccines also incorporate APIs, combined with other chemicals like suspending fluids, preservatives, stabilizers, adjuvants, and enhancers to create the end product. Given that pharmaceuticals directly impact human and animal health, the manufacturing process is of utmost importance. Pharmaceutical manufacturing is categorized into two main components: the production of bulk drug substances and the manufacturing of formulations²⁹.

Pharmaceutical formulation is a complex process that includes several stages where the active drug is blended with different components, considering factors like particle size, polymorphism, pH, and solubility. This transformation results in the creation of the final medicinal product with therapeutic advantages. Critical elements for a successful pharmaceutical formulation encompass understanding the pros and cons of active

²⁸ According to the Merriam-Webster dictionary, bioequivalence is the property where two drugs, whether they have identical active ingredients or are two different dosage forms of the same drug, exhibit similar bioavailability and produce the same effect at the site of physiological activity. Bioavailability is defined as the degree and rate at which the drug is absorbed into a living system or made available at the site of physiological activity.

²⁹ WHO Working document QAS/11.426/Rev.1 July 2011

pharmaceutical ingredients (APIs), essential excipients, associated interactions, and the manufacturing procedure (Afrin & Gupta, 2023).

The processes for creating pharmacologically active substances differ based on the original raw materials used. In the biotech industry, APIs are biologically engineered proteins and recombinant molecules developed for biotech medications, often derived from plants. APIs undergo various stages and processes. The preparation of an API involves a multi-step organic synthesis, with critical steps such as purification, crystallization, drying, milling, and packaging. Basic API production may entail three primary processes: fermentation for micro-organic substances, chemical synthesis for chemical substances, and biological and natural extraction from plant and animal tissues. Fermentation is commonly employed to produce antibiotics, steroids, and vitamins, while organic synthesis is used to create new substances. Fermentation utilizes selected microorganisms and microbiological technologies to generate chemical products, although it can produce substantial solid waste, raising environmental concerns in some regions. Some units may combine these processes, using both chemical and physical methods. The complexity of the molecule being manufactured often necessitates multistep complex chemistry employing a range of processing technologies, which poses significant technological challenges. The study focuses on bulk drugs rather than formulations. This distinction is crucial as bulk drugs are inherently hazardous and environmentally polluting, which is discussed in the third section of this chapter. With this brief introduction to pharmaceutical manufacturing, the subsequent sections will delve into the evolution of the pharmaceutical industry and its policies in India.

Section I

Pre-Independence

Before exploring the various initiatives implemented by the Indian Government post-Independence, it is essential to comprehend the history of the pharmaceutical industry in the pre-Independence era. The roots of the Indian pharmaceutical sector date back to April 12, 1901, with the establishment of Bengal Chemical and Pharmaceutical Works Pvt. Ltd. in Kolkata by Acharya Prafulla Chandra Ray, in collaboration with distinguished medical practitioners. Following this establishment, other pharmaceutical entities emerged, reflecting a burgeoning industry. Alembic Pharmaceutical Works started in Baroda in 1907, Zandu

Pharmaceutical Works Ltd. in Kolkata in 1910, Calcutta Chemical Company in Kolkata in 1916, and Bengal Immunity in Kolkata in 1919. These businesses initiated their activities with a profound sense of national pride, motivated by the objective of challenging the market dominance of imported medicines provided by British companies and multinational corporations (Ghosh, 2019).

In the 1930s, Bengal Chemicals and Pharmaceuticals Works initiated tetanus antitoxin production, but by 1939, indigenous production met only 13% of medical needs due to limited support, colonial policies, and technological constraints. World War II catalyzed indigenous drug production, reaching 70% of medical demands by 1943. However, the sector faced hurdles, with restricted chemical industry growth affecting pharmaceutical progress. Technological limitations and legal constraints impeded Indian companies' production of patented medicines. Despite challenges, Indian entrepreneurs established companies like Cipla, Amrutanjan Health Care, East India Pharmaceuticals, FDC Ltd, Dey's Medical Stores, Indoco Remedies, and IPCA Labs in the 1930s and 1940s. Before World War I, India's primary industries were the well-established cotton and jute textiles sectors. However, post-World War I, in 1922, the British Indian government implemented a policy of discriminatory protection. The pharmaceutical sector received minimal attention, with approximately 87% of therapeutic needs relying on imports. Despite the increased demand for medicines during World War II, manufacturing did not witness significant expansion. At the time of India's Independence, the pharmaceutical industry was valued at around Rs. 10 crores, and the majority of Active Pharmaceutical Ingredient (API) requirements were met through imports from the UK (James, 2020).

During this period, the Indian pharmaceutical industry saw the introduction of synthetic drugs and antibiotics, predominantly developed abroad and imported into India. This shift disrupted drug consumption patterns, hindering locally produced medicines, and competing with imports. Many Indian manufacturers, after attempting synthetic drug production during and after World War II, shifted focus solely to formulation. At India's Independence, the pharmaceutical industry mainly comprised units producing formulations based on imported bulk drugs, with a modest total production value of Rs. 10 crores in 1947 (Hathi Committee Report (HCR) 1974: 3). The underdeveloped state of the industry was acknowledged by the 1954 Pharmaceutical Enquiry Committee, characterizing it as nearly non-existent due to the

absence of essential drug manufacturing (Hathi Committee Report 1974: 2). Preceding Independence, there was a notable push for industrialization and planning. Prominent leaders like Dadabhai Naoroji and M.G. Ranade stressed industrialization's necessity to alleviate poverty, advocating for government support (Shah, 1944). The 1938-formed National Planning Committee, led by Jawaharlal Nehru, recognized industrialization's role in addressing poverty, unemployment, and national defense, proposing comprehensive planning for various industries. Sir M. Visvesvaraya and the Bombay Plan supported planned economic development, emphasizing the state's crucial role in managing industrial growth and ensuring fair financial distribution (Thakurdas, 1944).

1947-1970

Post-Independence, India faced underdevelopment, and calls for state protection and private investment arose. Jawaharlal Nehru and industrialists recognized the need for government support in industrialization. The 1948 Industrial Policy Resolution initially favored private capital and stressed the urgency for foreign capital, welcoming foreign drug companies. Influenced by Soviet planning, Nehru initiated the Five-Year Plans, a crucial step for industrialization, with support from nationalists and the industrial class (Chakrabarty, 1992; Kochanek, 1968). Key developments of these plans are as follows-

Industry Policy Resolution (IPR)-1948

The 1948 Industrial Policy Resolution marked the first step in shaping India's industrial policy post-Independence. It categorized industries into two groups: one where the state took exclusive responsibility of establishment based on strategic importance, and the other, open to private enterprise but with state intervention when necessary. The latter group included basic industries requiring substantial investment and technical skills, including the pharmaceutical industry. Jawaharlal Nehru believed in the role of private enterprise and welcomed foreign capital and industrial expertise, especially in areas lacking domestic technological resources. The policy statement emphasized the importance of foreign capital for rapid industrialization. To encourage foreign investment, it assured non-discrimination between foreign and Indian undertakings, provided facilities for profit remittances, and promised fair compensation in case of nationalization.

Pharmaceutical Industry

In 1948, the Industrial Policy Resolution (IPR) identified basic industries crucial for national economic development, characterized by the requirement of significant investment and technical expertise. The pharmaceutical industry, recognized as a fundamental sector, received special attention due to its crucial role in advancing public health. In the post-Independence era, the industry was predominantly influenced by foreign interests, prompting policymakers to stress the importance of ethical production aligned with national healthcare priorities rather than purely commercial motives. To address this, a dedicated panel for the Pharmaceutical Industry was established in 1951, responding to the disruptions caused by the country's partition. This panel aimed to assess raw material needs, expedite production, and recommend measures for capacity expansion. Recommendations included prioritizing domestic production of pharmaceuticals using basic chemicals, with a focus on synthetic drugs over imports. Quality, standardization, and ethical distribution were emphasized, along with a shift toward the domestic production of complex intermediates. The overarching goal was to reduce material costs and discourage practices that inflated production expenses (Hathi Committee Report 1974:3).

The First Five-Year Plan (1951-1956)

The First Five-Year Plan outlined ambitious goals for significant investments in the drugs and pharmaceuticals sector, allocating 8% of the funds for heavy chemicals, fertilizers, and pharmaceutical production. The primary objective was to enhance the domestic supply of essential drugs, including antimalarials, antibiotics, and synthetic drugs, to combat diseases and improve public health. Encouraging foreign participation, the plan attracted multinational pharmaceutical companies to establish manufacturing facilities in India. By 1954, a majority of the foreign trading companies had Indian subsidiaries.

Despite progress, the pharmaceutical industry faced structural weaknesses, heavily relying on imported fine chemicals and bulk drugs. Key drugs were not indigenously produced, leading to substantial imports. To address challenges, the Pharmaceutical Enquiry Committee in 1953 recommended measures covering licensing, foreign collaboration, bulk drug production, and distribution. The Indian government intervened by establishing the Indian Penicillin Committee and Hindustan Antibiotics Limited (HAL) in 1954, focusing on indigenous antibiotic production. In 1961, the Indian Drugs and Pharmaceuticals (IDPL) was established, contributing to technical expertise and laying the foundation for a robust bulk drug industry.

HAL operated a fermentation plant in Pune, receiving support from WHO and UNICEF, while IDPL, (IDPL-Hyderabad will be further explored in subsequent chapters). aided by the USSR, contributed to technical expertise, and laid the foundation for a robust bulk drug industry. HAL, with an initial capacity of 4.8 million mega units, became the first producer of bulk drugs like Streptomycin sulphate and Ampicillin (Ghosh, 2019; James, 2020).

Industrial Policy Resolution-1956

In 1956, the Indian government revised the Industrial Policy Resolution of 1948, aligning it with the First Five-Year Plan and socialist objectives. The new resolution categorized industries into three groups, designating Antibiotics and other essential drugs in the second category (Schedule B), allowing both public and private participation. The policy exhibited flexibility, enabling potential overlaps between the public and private sectors. It permitted privately owned units to produce items from Schedule A and allowed small-scale private activities in various sectors, reflecting an adaptable approach. The government committed to facilitating private sector development in line with successive five-year plans, emphasizing adherence to state policies and regulations while ensuring fair, non-discriminatory treatment for both private and public units³⁰.

Licensing Policy

The Indian Drug Regulation (IDR) Act of 1951 marked a pivotal moment for Indian industries, including the pharmaceutical sector. Enforced in 1952, the Act mandated registration, prohibited new establishments without a license, and required licensing for substantial expansions. Small-scale units initially had exemptions, subject to evolving investment thresholds. The pharmaceutical sector, within the Act's First Schedule, underwent registration with the Directorate General of Technical Development (DGTd), focusing on comprehensive development and growth. Licensing decisions were considered national needs, guided by expert groups. Until 1965, permission letters allowed drug manufacturing without specific capacities or product specifications. The Development Council, formed in consultation with industry, trade, and government representatives, guided on growth-related matters. In 1965, policy relaxation allowed industrial units, including pharmaceuticals, to diversify production and increase capacities by up to 25% without additional machinery. Amendments in 1970 oversaw foreign and larger industrial establishments, withdrawing

³⁰ Industrial Policy Resolution, 1956, No.91/CF/48, 30 April 1956. In Guidelines for Industries {New Delhi: Indian Investment Centre, 1982)

diversification concessions. Policies aimed to balance industrial growth, support small and medium entrepreneurs and prevent economic power concentration. In 1971, diversification policies required foreign firms to obtain industrial licenses, aligning with the Fifth Five-Year Plan's objectives of growth, social justice, and self-reliance. Industries were treated differently based on factors like foreign equity, technology, export potential, and balance of payments, reflecting a nuanced approach to industrial regulation and growth (James, 2020).

In the early 1950s, following Sardar Vallabhbhai Patel's demise, a political shift occurred, with Jawaharlal Nehru leading a radical faction that embraced the socialist model for India's social and economic strategies. The 1956 Industrial Policy Resolution (IPR) aimed to strengthen state influence, challenging the role of the private sector. Enforced through the Industries IDR Act of 1951, the IPR mandated licenses for new industrial units, emphasizing state-led industrial development. Despite perceptions, the 1956 Resolution allowed flexibility, encouraging collaboration between the public and private sectors. Post-1956, India's industrial policy saw a complex interplay between state control and private sector freedom, with shifts from socialist goals to incentives during Lal Bahadur Shastri's tenure, followed by a relaxation of controls post-1966 (Harris, 1982; Marathe, 1986; Harris, 1987).

State and the Drug Industry till the 1970s

In the pre-1970s era, the Indian pharmaceutical industry was dominated by foreign monopolies, resulting in high drug prices and substantial foreign exchange losses due to drug imports. The government recognized these challenges and initiated plans for a state-owned drug production facility in 1945, which were approved but not executed. After Independence, renewed efforts were made in 1948, emphasizing the establishment of public-sector drug manufacturing units. General Sokhey, who was the Assistant Director General of the World Health Organisation, was instrumental in the creation of the HAL, and highlighted the need for indigenous production, and discouraged reliance on U.S. or Western European firms. The subsequent phase involved Soviet assistance, with a team of Soviet experts advising on the establishment of an integrated public-sector drug industry, focusing on antibiotics and synthetic drugs. This marked the government's commitment to developing the pharmaceutical sector and overcoming challenges posed by foreign monopolies (Greene, 2007).

Despite the cost-effective and beneficial Soviet proposal³¹ for establishing an integrated drug industry in India, the government initially took no action. Subsequent proposals, presented in 1958, omitted crucial drug projects, downgraded antibiotic production, and included less significant projects. An agreement was then made with the American firm, Merck & Company, favoring their interests over the more advantageous offers from the Soviet Union. Intense lobbying efforts, secrecy in production processes, and personnel screening characterized the agreement with Merck & Company, compromising national interests without any apparent justification. The government's refusal of Soviet assistance, even with the expertise of General Sokhey available, led to significant royalties paid to Merck & Company, creating a loss for the country. This episode raised concerns about the pharmaceutical industry's influence on national decisions. The government sector played a pivotal role in fostering dynamism and innovation. The public sector led the way in pioneering the production of (APIs). Notably, Hindustan Antibiotics Ltd (HAL) and Indian Drugs and Pharmaceuticals (IDPL) had substantial technological and entrepreneurial spillover effects. The laboratories of the Council of Scientific and Industrial Research (CSIR) also contributed significantly to this innovative landscape (Chaudhuri, 2005). Shifts in policies since the 70's are discussed in the following section.

Drugs and Pharmaceutical Industry in the early 1970s

By the early 1970s, the Indian pharmaceutical industry had undergone substantial growth, comprising 116 organized sector units and over 2500 small-scale units. Despite this, foreign companies, constituting 70 percent of total drug sales and with substantial foreign equity in both sectors, held significant sway. The turnover data from 1973 underscored the foreign influence, with 80 percent of the Rs. 370 crores turnover in the organized sector originating from units with foreign equity and the public sector. Interestingly, foreign units, constituting less than 12 percent of bulk drug production, commanded 27 percent of the industry turnover, emphasizing their focus on low-tonnage, high-rupee-value drugs, and formulations. The subsequent development of the bulk drug industry in India was initiated by small-scale

³¹The agreement is very deceptive and seeks to create an impression that Mercks charged no royalties. Clause 6 (c) says- "The licenses granted in paragraph 8(a) (b) shall be royalty free etc..." But clause 8(a) unmasks the truth which reads as follows: "In consideration of additional research, administrative and other expenses that will be incurred by Merck in providing continuous technical assistance to the company shall pay Merck an amount equal to the following percentages of the net proceeds as defined in subparagraph (d) from sales of all streptomycin manufactured by the company : (i) 2.5 sales in countries other than India." Though the agreement refers to payments in consideration of additional research and continuous technical assistance, the fact is that the production of streptomycin had almost reached its final stage. Almost pure substance had to be produced and nothing starting was in store in the future. (Source : S.V.Parulekar. p.21.)

companies, often involved in minor activities, laying the foundation for growth. Despite their minimal presence in the pharmaceutical industry, these companies played a pivotal role in shaping the industry's trajectory (HCR, 1974).

During the early 1970s, multinational companies in the small-scale sector primarily concentrated on formulations production, aligning with India's heavy reliance on importing bulk drugs and resulting in substantial foreign exchange losses of approximately Rs. 35 crores in 1973-74. A crucial aspect was the foreign equity scenario in the pharmaceutical sector during the fiscal year 1973-74. Out of 66 companies with foreign equity, only 19 were actively involved in bulk drug production. The majority shifted focus to formulations, contributing to concerns about accessibility, affordability, and self-reliance in essential medicines. Foreign companies, while contributing approximately Rs. 19 crores to bulk drug production, were surpassed by both the public sector units and the Indian sector, including the small-scale industry, which generated around Rs. 24 crores and Rs. 32 crores in bulk drug production, respectively. Specific foreign multinational companies established a virtual monopoly in producing critical life-saving drug formulations, raising concerns about the accessibility and affordability of essential medicines. This potential monopoly led to higher prices, limiting access for a substantial portion of the population, especially those with lower incomes. Additionally, the shift of foreign companies towards formulation production raised concerns about the availability of raw materials for essential medicines, potentially impacting the country's self-reliance and increasing dependence on imports. Despite the expected influx of foreign investment in the pharmaceutical industry outlined in India's Industrial Policy, the reality did not align with these expectations (HCR, 1974).

Foreign units³², while making modest initial investments, subsequently expanded operations, primarily concentrating on formulation production. Their growth was evident in terms of capital assets, turnover, and profits. Importantly, the failure of anticipated foreign investment, coupled with foreign units accumulating equity, raised questions about the alignment of

³²One foreign unit, Glaxo, had an Rs.80 million equity, with Rs.8 million owned by another drug company and Rs.18 million held by Indians. Out of the remaining Rs.54 million, Rs.3 million was falsely classified as foreign investment, Rs.36 million as bonus shares, and Rs.15 million for trademark rights. The Rs.3 million foreign investment was not a fresh investment but assets from a former trading subsidiary with a Rs.0.15 million foreign equity capital. Another unit, Anglo-French, had a nominal Rs.10,000 equity, of which Rs.8,000 was foreign investment. Despite this, it annually remitted Rs.60,000 as dividends, royalties, etc. The unit, focused on formulations, had a Rs.17.4 million turnover and a Rs.3 million profit in 1970 (HCR, 1974).

foreign interests with broader health objectives. The concentration of certain foreign multinational companies in producing critical life-saving drug formulations highlighted concerns about health inequalities, pricing, and dependence on imports for essential pharmaceutical ingredients. The uneven distribution of bulk drug production and foreign dominance in critical formulations could exacerbate health inequalities, disproportionately affecting vulnerable populations. The pharmaceutical industry landscape in the 1970s in India was shaped by a complex interplay of domestic and foreign dynamics, significantly impacting health outcomes and the long-term sustainability of the industry (Rangarao, 1973; HCR, 1974). The next subsection delves into the legal provisions and regulatory acts to comprehend the growth of the pharmaceutical industry.

The Development of Different Acts and Legal Provisions

The Industries (Development and Regulation) Act of 1951 (I(D&R) Act) empowered the Government of India to issue licenses for industrial activities. Enacted to oversee industrial development, it brought the Drugs & Pharmaceuticals sector under its control, requiring all manufacturers, including multinational corporations, to obtain authorization. The act underwent significant changes upon India's entry into the World Trade Organization in 1995, reflecting the evolving global economic scenario. Between 1952 and 1965, Permission Letters under the I(D&R) Act aimed to boost domestic medicine production. However, multinational corporations (MNCs) primarily produced common remedies. In response, the government liberalized licensing policies in 1966 and 1967, leading to an increased focus on pharmaceutical formulation manufacturing by 1970. Concessions were withdrawn, and Carrying-on-business (COB) licenses were introduced, regulating activities and authorizing both foreign and Indian companies to manufacture formulations and bulk drugs. This move aimed to promote natural competitiveness and stimulate investments, particularly in essential bulk drug production.

The Monopolistic and Restrictive Trade Practices Act of 1969 supplemented the COB licenses, aiming to prevent monopolies in specific business activities. Led by Justice K. C. Das Gupta, a commission investigated economic power in sectors, including Drugs & Pharmaceuticals. The resulting report led to the enactment of the Monopolistic and Restrictive Trade Practices Act in 1969, designed to curb monopolistic situations and ensure the benefits of free competition. Motivated by a Soviet-style industrialization strategy, this

legislation reflected the government's substantial involvement in fostering free competition, aiming for swift and equitable industrialization. The MRTP-1969 Act played a crucial role in reassessing and streamlining the country's industrial licensing policy, fostering increased competitiveness (Vakil no 1. 2013).

The emergence of the welfare state post-war in Western Europe marked a pivotal recognition of the necessity for state intervention to aid recovery and enhance social conditions, particularly for the poor and working classes. This intervention aimed to address inefficiencies and injustices within capitalist societies, with a primary focus on alleviating poverty and unemployment. Encompassing health, education, housing, and social security, the welfare state sought to shift service provision from the private sector to ensure accessibility for all. While the 1960s witnessed a global expansion of welfare services, the late 1970s and 1980s saw contraction due to a worldwide recession. The momentum of privatization, notably spurred by Reaganomics and Thatcherism, advocated a diminished role for the welfare state in favor of market forces. This ideological shift led to an increased reliance on commercial and voluntary services, especially in countries like Britain, where efforts were made to dismantle or restrain the welfare state. Public investments in education and health dwindled, while the private sector received incentives for growth. In India, despite the state traditionally dominating medical care, public expenditure stagnated in the 1970s and 1980s, creating room for private sector expansion. The expansion of private medical care in India was propelled by global shifts and the widespread adoption of the Privatisation concept, leading to intricate relationships between the public and private sectors. The state facilitated the private sector's growth by providing concessions such as investments, loans, tax incentives, and reduced import duties on medical equipment. Privatization in India extended to the opening of private practice by government doctors, procurement of drugs and equipment from private entities for public hospitals, the introduction of 'service fee', and the government's handover of hospitals to the private sector.

Section II: Intellectual Property Rights (IPRs)

IPRs constitute the protective mechanism extended to creators or inventors of commercially applicable innovations. This safeguard encompasses various forms, including but not limited to Patents, Trademarks, Copyrights, Industrial Designs, Geographical Indications, Plant

Breeder's Rights, Integrated Circuits, Database Protection, and more (Upreti, 2021). The necessity for these safeguards stems from the need to prevent the unauthorized copying and commercial exploitation of the creation by competitors. Additionally, IPRs are believed to serve as an incentive for further research, encouraging the development of intangible assets. Post-Independence, India recognized the imperative to overcome production barriers for APIs dictated by IPR. Although government-established entities like IDPL and HAL produced some APIs, they could not meet the escalating demand. Until the early 1970s, API production, beyond IDPL and HAL, faced IPR restrictions, hindering manufacturing by other entities. The Patents Act of 1911 and its amendments granted exclusive product³³ patenting rights, limiting the industry's capabilities. The pressing need for patent law changes arose to foster API production and the overall expansion of the pharmaceutical sector in India (Lofgren, 2013).

Pre-1972 -Product Patents Period

From the mid-nineteenth century until Independence, and even beyond, India served as a lucrative market for foreign companies, enabling them to sell expensive drugs developed elsewhere. The introduction of patent legislation in 1856, in alignment with the British Patent Law of 1852, aimed to grant English patent holders control over Indian markets. This legislation underwent revisions in 1859 and amendments in the 1870s and 1880s, eventually being replaced by the Patents and Designs Act of 1911. This new act allowed patents in all product categories, including pharmaceuticals, for a sixteen-year duration, administered by the Controller of Patents. Despite resulting in monopoly pricing, these patents had a limited impact on fostering domestic pharmaceutical innovation during this period (Narayanan, 1998; Mueller, 2007).

The foundation of the Bengal Chemical and Pharmaceutical Works triggered the emergence of numerous firms in subsequent decades, with growth registered in local manufacturing during the World Wars. CIPLA in 1935, along with private firms like Ranbaxy, Torrent Pharmaceuticals, Lupin Laboratories, and Dr. Reddy's Laboratories in later years, became significant players. However, multinational corporations (MNCs) maintained dominance in the domestic market until the 1970s, conflicting with the national goal of providing affordable drugs. The pre-1972 period witnessed unhindered market exploitation by MNCs,

³³A product patent is granted for a specific product, like a drug, providing exclusive rights to the patent owner. This exclusivity aims to prohibit others from manufacturing, using for sale, selling, or importing the product.

focusing on importing bulk drugs at monopoly prices, formulating them under popular brand names, and delaying the introduction of newer drugs in India. Contrary to conventional economic theory, which associates patents with innovation, this wasn't the case in the Indian pharmaceutical industry before 1972 (Drahos, 2011). Instead, MNCs sought rule changes for increased protection, serving protectionist interests (Lall, 1974).

Domestic companies have been advocating for a more supportive policy environment since the 1940s. However, it took two major inquiries and prolonged deliberations in Parliament over many years to replace the Patents and Design Act of 1911 with an intellectual property rights (IPRs) regime that better aligned with the interests of consumers and domestic businesses. When India gained independence, Nehru's government pragmatically acknowledged that achieving self-reliance in the pharmaceutical sector could not be an immediate goal. Local companies faced challenges in immediately replacing MNCs as providers of essential medicines. In January 1948, the Tek Chand Committee was formed by the Indian government to review patent laws, aiming to align them with national interests. The Committee's 1950 Report suggested the establishment of effective measures to tackle patent abuses, including compulsory licensing (Mueller, 2007). Despite a bill based on these recommendations being introduced to the Parliament in 1953, it failed to pass. Subsequently, in 1957, a second Committee led by Justice Rajagopala Ayyangar found that the majority of Indian patents were held by foreigners, indicating a potential monopolistic control (Baldia & Adelman, 1996).

The Process Patent³⁴ Era- 1972-2005

The culmination of extensive reports led to the enactment of the Patents Act of 1970 in India, driven by a rising resistance against pharmaceutical product patents. This legislation aimed to create an environment conducive to the domestic production of affordable generic drugs. In 1981, Prime Minister Indira Gandhi, influenced by the vision of medical discoveries being free from patents, swiftly passed the bill within a week after a poignant meeting with Dr. Hamied, founder of CIPLA, who emphasized the life-saving nature of a particular drug and questioned the denial of access due to patent biases (Jack, 2008, as cited in Lofgren, 2018). The 1970 amendments to the Indian Patents Act facilitated the manufacture of Intellectual

³⁴ A process patent exclusively covers the method of manufacturing a product, not the final product itself. This form of patent doesn't prohibit others from producing the same product using a different method. This diminishes the inventor's monopoly and fosters increased competition.

Property Rights (IPRs)-protected bulk drugs through alternative, patentable innovative processes. The revised Act allowed patenting only 'novel processes' for New Chemical Entities (NCEs) or Active Pharmaceutical Ingredients (APIs), excluding new uses for known NCEs and APIs from patentability. This adjustment spurred the production of patent-protected NCEs or APIs using 'new' processes without patents. Indian manufacturers played a pivotal role in developing these innovative processes, contributing significantly to the country's progress. After the 1970 amendment, numerous Indian companies emerged, manufacturing bulk drugs with proprietary technologies, leading to the growth of large-scale production facilities. The abundance of local APIs, government-regulated prices, and higher import duties made local production financially viable (James, 2020).

The Patent Act of 1970, implemented in 1972, marked a significant turning point in India's pharmaceutical policy. It restricted patents on pharmaceutical, agrochemical products, and food, allowing only one production process to be patented for a maximum of seven years. The subsequent FERA limited foreign investment in companies with over 40 percent foreign equity. The drug price control system, initiated in 1963, peaked in 1979, proposing radical measures such as the nationalization of the pharmaceutical industry. After the implementation of the Patent Act, multinational companies faced challenges, leading some to withdraw from India. Domestic firms capitalized on policy changes, demonstrating reverse engineering skills³⁵ and collaborating with public sector research organizations, fostering the development of a self-sufficient domestic pharmaceutical industry within two decades (Iyer, 2002).

Hathi Committee Report 1975 (HCR 1975)

The 1975 Hathi Committee Report, commissioned by the Indian government and chaired by Mr. Jaisukhlal Hathi, provided crucial recommendations for the pharmaceutical industry. It underscored the pivotal role of the public sector in the nation's industrial development, specifically advocating its expansion in essential drug production to meet societal needs and prevent monopolies. Recognizing the public sector's capacity in synthesizing drugs, especially in high-tech areas, the report suggested addressing constraints and deficiencies in public sector units to enhance their involvement in manufacturing basic drugs and

³⁵ Reverse engineering in the pharmaceutical industry involves analyzing a competitor's product to understand its composition and manufacturing processes. This aids in generic drug development, quality control, and research. However, it must adhere to legal and ethical standards, respecting intellectual property laws. Unauthorized reverse engineering can lead to legal consequences, prompting careful navigation and legal advice for compliance.

formulations. Recommendations included improvements in organizational setups and management patterns, emphasizing industry expansion, technological advancements, and proposing the creation of a National Drug Authority (NDA) for policy coordination.

However, the report did not explicitly address protecting public sector units from financial losses or ensuring profitability in trade sales. Consequently, the Hathi Committee's recommendations influenced the introduction of the Drug Policy of 1978 and the Drugs Prices Control Order, 1979 (DPCO-79) in India. These policies aimed to regulate drug pricing and strengthen the public sector's role, especially in bulk drug and essential medicine production. The Drug Policy 1978 and DPCO-1979, framed by the Indian government in line with the Hathi Committee's suggestions, sought to maximize local bulk drug production, lead public sector units, reduce bulk drug imports, foster the growth of the local pharmaceutical industry, and lower prices of essential drugs and formulations. DPCO-1979 imposed price controls on 370 bulk drugs and formulations, categorizing them into groups with different markup percentages based on therapeutic efficacy. The policies introduced fair selling prices, calculated retail formulation prices, and established pricing mechanisms for imported formulations. Overall, these measures were designed to regulate drug prices, encourage local bulk drug production, and ensure the affordability and accessibility of essential medicines for the Indian population (Srinivasan & Phadke, 2018).

In the 1980s, India's pharmaceutical sector faced challenges due to the price controls of DPCO-1979, impacting the financial viability of domestic companies and public sector units. This led to obstacles in introducing new drugs, causing dissatisfaction in the industry. The 1986 Drug Policy, influenced by the Hathi Committee, introduced differentiated treatment for Foreign Exchange Regulation Act (FERA) companies and phased manufacturing, aiming to stimulate local production. The 1987 Drugs Prices Control Order replaced the 1979 version, categorizing formulations and bulk drugs to regulate prices. These measures aligned with the Hathi Committee recommendations, indicating a shift towards a more relaxed control compared to DPCO-1979.

The 1980s witnessed a significant shift in India's economic policy, marked by liberalization measures initiated during Indira Gandhi's second term (Jha, 1984). Rajiv Gandhi's³⁶ tenure, starting in 1985, furthered this shift, departing from the state-controlled model to embrace a more liberal development approach, evident in a new group of economic advisors with pro-liberalization inclinations. P.V. Narasimha Rao's ascent to power in 1991 accelerated the liberalization process, dismantling remaining controls and regulations in the industrial policy, with the overarching goal of reducing government discretion and enhancing market forces' role. This transition influenced the drug industry, reflecting a move from a self-reliant model to one that emphasized deregulation and decontrol. The historical context, post-colonial struggles, and the evolution of the mixed economy model under Nehru highlight the complex interplay of forces that shaped India's economic trajectory (Jha, 1989).

The economic policy changes initiated in the early 1980s gained momentum by mid-1991. Perceived as a 'retreat of the state,' this transition involved more than a shift in intervention techniques representing a shift towards a partisan state favoring private capital, in line with global transitions away from 'welfare capitalism'. The alterations in the Indian drug policy during the '80s and '90s signify a broader shift in state ideology, moving away from welfare economics towards supporting private capital, driven by both international pressures, such as those from the IMF and World Bank, and domestic monopoly capitalists. The evolution of policies, particularly post-1960s, underscores the influential role of industry lobbies, particularly in the pharmaceutical sector, emphasizing the need for attention to the entire production process for the health outcomes of the population (Patnaik, 1992).

State intervention shaped industrial change, especially in the drug industry. The significant shift that occurred in the drug policy was during the 1980s and 1990s, moving from a self-reliant, import-substitution model to a liberal approach emphasizing deregulation and decontrol. This shift prompts an examination of its implications for the nature of the state in India. The transfer of power from colonial rulers marked the end of a lengthy struggle for freedom. The Indian National Congress, inheriting British paramountcy, was not a cohesive group, with complex and contradictory forces led by figures like Nehru and Patel. Nehru's mixed economy model aimed at public sector growth while allowing space for private

³⁶ After winning the 1985 General Elections, Rajiv Gandhi articulated his government's strategy as a "judicious combination of deregulation, import liberalization, and easier access to foreign technology". Quoted in Times of India- 6 January 1986, New Delhi

enterprise diversification. The Nehruvian state interventionism was not a concession to the capitalist class but a strategic move to secure survival and growth against metropolitan capital. The mixed economy model suited political necessities and the constraints of the colonial economy. The state, even after independence, maintained the socialist rhetoric, acting on behalf of all classes, imposing curbs on monopoly capital, and providing a minimum social security network.

However, in 1991, India shifted its public policy towards neoliberal reforms, impacting its stance on intellectual property (IP) rights. The country became a WTO member and signed the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, influencing its IP landscape (Sengupta, 2018). By 1991, Indian pharmaceutical firms played a pivotal role, supplying the majority of the APIs and formulations for the domestic market. The absence of product patents prompted a focus on generic drug manufacturing, resulting in cost-effective methods for producing a diverse range of drugs. Although corporate investment in discovery research was minimal, the large-scale production of generics accumulated substantial technological expertise, significantly lowering domestic medicine costs and increasing exports globally. In the mid-1990s, discussions on TRIPS compliance shifted the industry landscape, with major companies altering their stance on product patents and engaging in limited-scale discovery research. Simultaneously, liberalization and amendments to the Patents Act dismantled the policy framework established in the 1970s, opening the sector to foreign direct investments and relaxing drug price control policies (Lanjouw, 1998).

The introduction of the Drug Prices Equalization Account aimed to encourage domestic bulk drug production but resulted in administrative complications, leading to dissatisfaction and legal disputes within the industry. Despite challenges, Indian firms adapted by accepting lower profit margins and continued to thrive. The 1990s saw further developments with the formation of a Standing Committee in 1990 to assess Drug Policy 1986 and DPCO-1987. This led to the introduction of the New Drug Policy-1994 and the Drugs (Price Control) Order, 1995 (DPCO-1995), emphasizing competition, liberalization, and intellectual property rights (Selvaraj & Takemi, 2007).

In 1999, comprehensive reviews resulted in the formation of the Pharmaceutical Research and Development Committee and the Drug Price Control Review Committee³⁷, which aimed to strengthen R&D and propose a product-based price control system. The 2002 Pharmaceutical Policy further aligned with global trends, significantly reducing price control, revamping the National Pharmaceutical Pricing Authority, and marking changes in the patent regime. These policy shifts reflected India's evolving pharmaceutical landscape over the years.

Indian Patents Act 2005 onwards-

Through liberalization, the Indian government implemented key legislative changes in the pharmaceutical sector. The first amendment aimed to align India's clinical trial guidelines with international standards set by the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. This legislative action sought to establish safe, efficient, and ethical drug testing processes. While the term 'harmonization' suggests an alignment with global norms, the analysis posits that these reforms were more about hegemony than harmony, raising questions about practically balancing global standards with safeguarding India's interests in the pharmaceutical sector (Rajan, 2017). Applying Gramsci's perspective, Rajan's (2017), analysis delves into the policy harmonization phase in India, questioning norms, cost distribution, power hierarchies, and governance systems. A closer look at the state policies reveals a transformation in the method and ideological principles of state intervention, shifting towards a redistributive framework favoring private capital, and private entities consistently influence policies.

The second amendment focused on bringing India's patent laws in line with the TRIPS agreement, necessitating substantial changes to the 1970 Patent Act. The evolution of the Indian pharmaceutical industry into a major supplier of affordable generic medicines for the developing world was the consequence of a pragmatic policy approach that prevented exclusive monopoly rights over medicines. However, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement mandated India to amend its Patents Act and introduce product patents by 2005.

³⁷Ministry of Chemicals & Fertilisers. 1999. "No. 5(1)/98-PI.I". Retrieved on January 23, 2019 from <http://www.nppaindia.nic.in/new/research.htm>
Min. of Chem. &Fert., No.5 (1)/98-PI.I dated 31st March, 1999, Constitution of DPCRC". Retrieved on January 24, 2019 from <http://nppaindia.nic.in/new/control.html>

In response to India's entry into the World Trade Organization (WTO) in 1995, amendments were made to the Patents Act in 2005 to adhere to WTO regulations. These changes reinstated 'product patenting rights,' covering products irrespective of the manufacturing process and allowing certain exclusions. The amended Act granted patents for 20 years, with provisions for compulsory licensing based on merit, omitting Section 5 related to process patenting and introducing Section 3(d), preventing the patenting of new uses for known substances. The revised Patents Act, alongside the 1970 Act, enabled Indian generic API manufacturers to provide affordable and high-quality generic drugs, particularly for antiretroviral medicines to developing nations. During the 2001 US anthrax crisis, the availability of cost-effective alternatives from Indian companies influenced negotiations for the patented drug ciprofloxacin. Open-market provisions in India led to reduced price protection for locally produced APIs and lowered import duties, impacting local manufacturers.

It is essential to note this intricate interplay between state policies and strategies within these networks, as they prioritize economic value for leading pharmaceutical firms and investors. The dynamic field of global biomedical science offers opportunities for innovative solutions and diverse health value strategies for state and civil society actors participating in these networks. Major pharmaceutical corporations, commonly known as 'Big Pharma,' engage in a global pursuit of markets and investments, demonstrating strategic competition among different countries and regions. Paradoxically, despite advocating for countries to compete for investments, these companies often avoid competition, sharing ownership with investor groups like BlackRock. The pursuit of market monopolization within global production networks (GPN) of bio-pharma has led to trends in rentier assetization, where profit-making focuses on acquiring and owning assets rather than fostering innovation or production. To extract rents from these assets, pharmaceutical companies assert their intellectual property (IP) rights aggressively, utilizing monopolistic patenting methods that integrate global IP regulations with context-specific state regulations (Keenan et al., 2022). Strategies such as creating 'patent thickets,' executing 'killer acquisitions' of potential competitors, and negotiating 'pay-to-delay' deals with developers of generics and biosimilars are employed to establish market exclusivity and wield cartel-like pricing power through the concentrated corporate control of IP on a global scale (Cunningham et al., 2021; Kapczynski, 2023; Robbins, 2023; Roy, 2023, as cited in Sparke et al., 2023). This intricate interplay between

state policies and corporate strategies reinforces the complex dynamics of the bio-pharma landscape, where economic interests often take precedence over health considerations (Rajan, 2017), which, in turn, leads to regulatory capture.

The Pharmaceutical Policy of 2002 faced resistance and a stay order in 2002, but was later lifted by the Supreme Court in March 2003. Despite this, the court directed the government to establish criteria to ensure that essential life-saving drugs remained subject to price control. In response, the Government of India introduced the Drug Policy of 2012 and DPCO 2013. The National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012), focused on evaluating and regulating prices³⁸ of essential medicines. This acted as a 'modified' version of the Drug Policy 2002, emphasizing price regulation for 'essential medicines' using market data.

The Drug Price Control Order 2013 (DPCO 2013), implemented on May 15, 2013, established guidelines for determining the maximum retail prices of pharmaceuticals, particularly focusing on 'essential medicines' from the National List of Essential Medicines (NLEM). Despite lacking a detailed explanation of its superiority over previous cost-based pricing, DPCO-2013 did not address the creation of a government information database, relying on ORG-MARG data (Kelkar, 2021). Srinivasan and Aisola (2018) emphasize that the lack of effective regulation and price control contributes to irrational medicine production and prescription practices, leading to escalating medicine costs. The coercive tactics of big pharma prioritizing profits over human costs persists even now, during the current pandemic, with developing countries facing challenges in resisting patent protection systematically.

In his essay, "Globalization, Intellectual Property Rights, and Pharmaceuticals," Amit Sengupta (2018) highlights the political conflicts surrounding the Patents (Amendment) Act of 2005. Sengupta illustrates the reluctance of the ruling dispensation to incorporate key health safeguards, such as compulsory licensing and stricter patentability criteria, influenced by Big Pharma and wealthy nations. Eventually, pressure from the left in the Parliament compelled the government to include these amendments. Despite India being recognized as

³⁸ In April 2009, the government initiated the creation of cheaper medicine shops through the JAN AUSHADHI CAMPAIGN, known as the Pradhan Mantri Bharatiya Janushadhi Kendra. These outlets were established in various parts of the country and aimed to make quality generic medicines available to the public. While these efforts were commendable, they have not yet significantly reduced private out-of-pocket expenses for medicines. The number of Pradhan Mantri Bharatiya Janushadhi Kendra shops remains inadequate, and often, essential prescribed medicines are unavailable.

the "pharmacy of the Global South" for providing access to affordable generic medicines, a significant portion of the population still lacks adequate access, leading to financial hardships due to out-of-pocket expenditures on medicines. Sengupta notes that the multinational pharmaceutical lobby has actively opposed the use of compulsory licensing provisions. The generic pharmaceutical industry in India has increasingly collaborated with multinational companies to access the global export market, while policymakers, influenced by pressure from the United States and the European Union, continue to advocate for further liberalization of the pharmaceutical industry. These trends have adverse effects on the structure and composition of the pharmaceutical industry in India. Under the Patents (Amendment) Act of 2005, complying with the TRIPS regime, India allowed multi-site clinical trials in 2005, creating new opportunities for the domestic clinical research community. This development led to the growth of the commercial clinical research industry, exposing classical political economy contradictions of powers and intellectual dominance (Sengupta et al., 2005).

In 2015, the government formed an 'IP Think Tank' to draft a new Intellectual Property (IP) policy. The resulting 'Draft Intellectual Property Policy' faced criticism for prioritizing IP over social and economic progress. The policy shift raised concerns, particularly regarding potential implications for the healthcare sector, as India plays a crucial role in supplying low-cost generics to developing countries. Reports of the government assuring the industry against using compulsory licenses added to the apprehensions, as compulsory licensing is a vital tool to counter the monopoly exercised by multinational companies through patents.

The evolving IP policy in India has broader implications, especially in the context of healthcare access for millions in developing countries relying on affordable Indian generics.

2017- Pharmaceutical Policy

In August 2017, the Department of Pharmaceuticals (DOP) presented an 18-page draft pharmaceutical policy to stakeholders, focusing on improving the global competitiveness of the Indian pharmaceutical industry in quality and pricing. The policy covered aspects such as drug formulation pricing, selection for price control, distribution, quality control, and patenting. It proposed an advisory board within the National Pharmaceutical Pricing Authority (NPPA) and advocated for a unified pricing approach. The draft addressed

concerns about branding and pricing discrepancies, emphasizing the need for streamlining. While no official executive order has been issued, the industry continues to be guided by Drug Policy 2012 and DPCO 2013.

Draft National Pharmaceutical Policy 2023

The COVID-19 pandemic has expedited various opportunities and challenges for the industry. The Department of Pharmaceuticals (DoP) has unveiled a draft National Pharmaceuticals Policy (NPP) 2023, emphasizing a comprehensive approach to tackling challenges in the Indian pharmaceutical industry. The draft, outlined in an approach paper, is open for stakeholder consultation, with the vision of ‘Empowering Health for All: Pioneering Excellence in Pharmaceuticals’. The Government of India has implemented various measures to address challenges in the pharmaceutical sector, such as production-linked incentives, Bulk Drug Parks, Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), the National R&D Policy, and Pharma MedTech Sector (PRIP) Scheme. The Vision of the National Pharmaceutical Policy aims to establish a healthcare ecosystem characterized by excellence, innovation, and inclusivity, reflecting the nation's aspirations for leveraging the full potential of its pharmaceutical industry to provide top-tier healthcare domestically and contribute to global well-being. Furthermore, the policy seeks to promote self-reliance in line with the ‘Atmanirbhar Bharat’ initiative, emphasizing the importance of sustainable domestic innovation meeting global standards (Draft- National Pharmaceuticals Policy, 2023).

The Indian government is actively enhancing its efforts to fortify the pharmaceutical industry's standing as a provider of high-quality generic medications on a large scale and at affordable prices. The primary focus is on transitioning from quantity to quality, emphasizing innovation as the key differentiator over the next 25 years. In a bid to ensure drug security, diminish import reliance, and promote domestic production, the Department of Pharmaceuticals has launched three Production-Linked Incentive (PLI) schemes covering Pharmaceuticals, Medical devices, and API/Key Starting Materials (KSMs)/bulk drugs. Additionally, financial backing has been extended for the establishment of three Bulk Drug Parks and four Medical Devices Parks to boost competitiveness. Several initiatives, such as the National Policy on Research & Development & Innovation in Pharma-MedTech Sector, Scheme for Promotion of Research & Innovation in Pharma MedTech Sector, and the PTUAS Scheme, aim to foster an innovation-centric environment for enhancing health outcomes. The overarching goal of these measures is to expand the industry's footprint in the

realm of innovation, particularly in the development of pioneering drugs and addressing antimicrobial Resistance (AMR). The objective is to ensure sustained growth, generate employment, and augment the industry's contribution to the Indian economy, setting India apart from other developing nations (Department of Pharmaceuticals, Annual Report 2022-2023).

The success of the industry and the state's cooperation is evident in this context. The Indian pharmaceutical industry, ranking third globally, is a crucial contributor to the economy, constituting 1.32% of the Gross Value Added in 2021-22. With an annual turnover of Rs. 3,44,125 crore, it encompasses various sectors such as generic drugs, OTC medicines, vaccines, and more. India stands out in supplying essential vaccines globally, manufacturing 60,000 brands across 60 categories. As the largest provider of generic medicines, the industry holds a significant position in the global API market. Particularly noteworthy is its role in making HIV treatment widely accessible worldwide, earning the distinguished title of the 'pharmacy of the world' (Annual Report, 2022-2023).

The policy aims to position India as a global pharmaceutical leader, supported by state-of-the-art infrastructure and an enabling ecosystem. It envisions cutting-edge research and development fostering innovative and affordable healthcare solutions, contributing to national prosperity and global health equity in alignment with the 'Amrit Kaal Vision@2047'³⁹. It introduces the transformative initiative "Vision Pharma 2047," which envisions India's leadership in affordable and innovative pharmaceuticals. This integrates an emphasis on the 'political economy of hope' and biocapitalism dynamics. Rajan's (2006) insights into the grammar of life, future-oriented discourse, and the political economy of hype, provide a critical lens to analyze India's vision. The nation's call for global pharma leadership mirrors high-tech capitalism's speculative nature, where vision and hype drive value generation. Rajan's exploration of biocapital's discursive apparatus echoes in India's emphasis on innovation as a differentiator. The convergence of language, labor, and biocapital's grammar underscores the transformative power of discourse in shaping India's pharmaceutical aspirations. This vision reflects the intertwining of economic goals, innovation, and

³⁹ Approach Paper on National Pharmaceuticals Policy (2023) – Draft for Discussions Page 2 of 21 Department of Pharmaceuticals Ministry of Chemicals and Fertilizers Approach Paper on National Pharmaceuticals Policy (2023).

discursive forms, aligning with the dynamics of speculative capitalism and showcasing the influential role of discourse in India's pharmaceutical trajectory.

The state's intervention demonstrated through various policies, orders, acts, and measures, has significantly contributed to the growth of the pharmaceutical industry. However, while actively promoting the pharmaceutical sector, the state has not mirrored the same level of commitment to the health sector, as discussed in the subsequent section. The following segment delves into this apparent disparity by focusing on health policies, their impact, and the issues surrounding regulations and regulatory capture.

SECTION III

Health Policies

The period following India's Independence (1946–1982) saw substantial policy advancements in response to the dismal state of the health system, as emphasized in the 1946 Bhore Committee report. Both male and female life expectancy remained below 30 years, primarily due to elevated infant mortality rates. The committee identified factors such as unsanitary conditions, inadequate health services, poor nutrition, and a lack of education as significant contributors to the health crisis. Despite the committee advocating for a comprehensive health service delivery system and addressing urban–rural health service disparities, limited political will, and inadequate funding impeded progress. In subsequent years, India prioritized economic growth through five-year plans, directing funds to the health sector. However, the focus persisted on preventive and promotive programs, following the colonial health approach. Vertical programs, particularly family planning, gained prominence, altering the overall funding landscape. The shortcomings of these programs resulted in skewed funding priorities, adversely affecting other health initiatives. At the state level, the primary focus was on curative care provided through hospitals and dispensaries. The timeframe between the Mudaliar Committee (1962) and the formulation of the National Health Policy (NHP) in 1983 witnessed the establishment of multiple committees to evaluate distinct facets of the public health system. Nevertheless, the outcomes echoed those of the Bhore Committee, revealing a disconnect between committee aspirations and tangible policy

changes and resource allocations for health (Planning Commission of India, 1974; Duggal, 1991; Qadeer, 2000).

The Alma-Ata Declaration of 1978 aimed for global health by 2000, emphasizing a shift from biomedical to holistic health models and urging governments to lead health reforms. Influencing India's Sixth Plan, the ICSSR-ICMR report in 1980 called for a community-based health system, leading to India's first NHP in 1983. This policy criticized Western biomedical models, promoted preventive community-based care, decentralized healthcare, and endorsed non-professional health workers and private sector expansion. The policy's impacts were influenced by economic changes in the 1980s and 1990s, marked by trade liberalization and increased public spending. However, heightened fiscal deficits and borrowing led to loans from the IMF and World Bank, driving economic reforms favoring private enterprise and reducing state roles in service provision. Despite declining public sector health spending, India's health outcomes improved, attributed to rising incomes and improved amenities rather than significant changes in the health system (Duggal et al., 1995; Duggal, 2001; Sen, 2001; Chandrasekhar & Ghosh, 2002; Mahendra Dev & Mooij, 2002; Varatharajan, 2003; Ravindran, 2010).

The 2002 National Health Policy (NHP) in India aimed to address the deficiencies in the health system by emphasizing equity, sustainability, efficiency, and quality. It committed the government to allocate 2% of GDP to health and increase Central Government funding to states while targeting marginalized groups. However, controversies arose over privatization and the proposed role of the private sector. Subsequently, the National Rural Health Mission (NRHM) was launched in 2005, which sought to bridge rural-urban health disparities. It prioritized accessible, affordable, and quality healthcare, introducing incentives, flexible budgets, and community participation through committees. Evaluations showed mixed results, with improved government health expenditure but concerns about states reducing funding. Despite challenges, innovations like referral transport and community health workers emerged, reflecting the NRHM's impact on health infrastructure and services at the state level (MoHFW, 2002b; Nandi et al., 2016).

During the implementation of the National Rural Health Mission (NRHM) in India, institutional deliveries, crucial for reducing maternal and neonatal mortality risks,

significantly increased from 39% in 2005–2006 to 79% in 2015–2016. This rise also contributed to a decline in interstate disparities, particularly favoring poorer states. Accredited Social Health Activists (ASHAs), numbering over a million, played a pivotal role in facilitating community-level care and promoting institutional births. Studies demonstrated the positive impact of ASHAs on maternal and child health, including increased antenatal care visits and facility-based deliveries. The Janani Suraksha Yojana (JSY), a conditional cash transfer program introduced in 2005, witnessed a substantial increase in beneficiaries from 0.73 million to over 10 million annually. However, independent evaluations revealed challenges such as gaps in health system preparedness, high OOP expenditures, and potential financial misappropriation.

Despite progress, there were concerns about insufficient skilled providers and administrators, high attrition rates, and shortcomings in health planning and evaluation. In response to the shortcomings of NRHM, the National Urban Health Mission (NUHM) was initiated in 2013 to address the primary healthcare needs of the urban poor. Subsequently, the NUHM was integrated into the NHM, covering both rural and urban programs. The low levels of financial risk protection prompted the introduction of government-funded health insurance schemes, including the Rashtriya Swasthya Bima Yojana (RSBY) in 2008 and later the Pradhan Mantri Jan Arogya Yojana (PM-JAY) in 2018, aiming to provide comprehensive health coverage for socioeconomically vulnerable populations. While these initiatives demonstrated efforts to improve healthcare accessibility and financial protection, challenges such as low enrolment rates, gaps in service utilization, and governance issues persisted, necessitating a continuous evaluation and refinement of health policies in India (Selvaraj et al., 2022).

The Pradhan Mantri Jan Arogya Yojana (PM-JAY) aims to integrate existing state government health insurance schemes. Yet, some states, including Delhi, Odisha, and West Bengal, have not embraced this merger due to perceived inequalities and inadequate financial incentives. The impact of state-sponsored insurance schemes on financial protection, access equity, and fiscal sustainability varies. Assessments of schemes like Rajiv Aarogyasri in Andhra Pradesh indicate unclear effects on catastrophic health expenditures. While Vajpayee Arogyashree in Karnataka showed decreased expenses for enrolled households, the overall effectiveness of existing government-funded health insurance remains questionable, with low coverage rates and insufficient financial protection. The RSBY, analyzed extensively, faced

challenges such as low enrollment among the poor and inadequate coverage, highlighting the limitations of existing schemes. Concerns about high fund outflows and fiscal sustainability have been raised for several state-funded health insurance programs, emphasizing the need for thorough evaluation and sustainability considerations (Selvaraj et al., 2022).

India is navigating a triple transition involving economic, demographic, and epidemiological shifts. The country experienced sustained economic growth, helping in the transition to a lower-middle-income status. Demographically, India has the potential for a demographic dividend with a growing working-age population. However, the epidemiological landscape poses challenges, encompassing a rising burden of noncommunicable diseases alongside persistent concerns about communicable diseases and reproductive health. While progress has been made in maternal and infant mortality, interstate variations exist. Despite achievements, issues like underfunding, unregulated private sector growth, and a shortage of health workers contribute to rising healthcare costs and financial burdens on households. Over 55 million people are pushed into poverty annually due to health expenditures. India's health system, characterized by a mix of public and private providers, presents strengths and weaknesses, with varying quality, cost, and effectiveness of services. Sustained underfunding and weak regulatory mechanisms pose challenges to the health sector's overall resilience and performance. The impact of these factors is underscored by the difficulties highlighted during the COVID-19 pandemic (Selvaraj et al., 2022).

Limited funding and inefficient procurement in the public sector impede access to medicines, vaccines, and diagnostics in government health facilities. The private sector offers easier access but at elevated costs, particularly for essential medicines. Despite being referred to as the 'pharmacy of the global south,' India's branded generic market is still beyond the financial reach of many. Inadequate regulatory oversight poses challenges in controlling unnecessary drug production and the inappropriate use of medications. The National Health Mission (NHM) primarily focused on maternal and neonatal conditions, displaying uneven progress. Notably, the NHM led to a substantial increase in institutional deliveries, especially in government health facilities, showcasing a pro-poor distribution.

However, concerns persist regarding the quality of delivery of services, infrastructure deficiencies, and inadequacies in addressing health facility data quality. Tax-funded health

insurance programs, initiated in the mid-2000s, expanded population coverage and service reach, but their success in providing financial risk protection has been mixed. The Pradhan Mantri Jan Arogya Yojana (PM-JAY), launched in 2018, replaced previous schemes and aimed to cover 500 million people but demonstrated a limited reduction in the households' out-of-pocket expenses. Underfunding of government health programs at both national and state levels remains a major concern, impacting the capacity of state governments to provide adequate healthcare. Efforts to increase tax devolution and introduce unconditional Health grants face challenges, including competition for resource allocation at the state level. Healthcare provider regulation in India, particularly in the private sector, is characterized by lax implementation of the Clinical Establishments Act and challenges in drug regulatory systems. Resistance from the medical fraternity has hindered effective implementation, and the pricing system lacks comprehensive coverage and substantial reductions for essential drugs under the Drug Price Control Order (DPCO), 2013 (Selvaraj et al., 2022). Through a critical assessment of the shortcomings in current health policies and their implementation, the subsequent exploration delves into a crucial dimension—engaging critically with the Alma-Ata Declaration. This involves unraveling its imperative for health for all and scrutinizing its continued relevance in shaping global health aspirations.

“Health for All”?

The Alma-Ata Declaration in 1978 committed governments globally to ensure the right to health for all by 2000, reaffirmed in the 2018 Astana Declaration, with a focus on a rights-based approach to health policy reform, particularly in rural areas of low- and middle-income countries (LMICs). Responding to these commitments, the World Health Organization (WHO) introduced its first global pharmaceutical policy in 1977, emphasizing the need for affordable medicines. However, multinational companies, mainly from high-income countries (HICs), resisted these policies, leading to conflicts at regulatory and legal levels, such as the establishment of ICH and TRIPS.

Health system reforms in the 1980s and 1990s, spearheaded by the International Monetary Fund and the World Bank, identified the pharmaceutical sector as crucial for efficiency gains. Pharmaceutical policies, encompassing clinical trials, regulatory requirements, pricing, and safety monitoring, became political tools reflecting debates on market-state roles, efficiency, and equity. The West African Ebola epidemic in 2013–2016 highlighted the experimental

nature of pharmaceutical policies, raising concerns about safety and ethics. Despite challenges, the 2018 Astana Declaration emphasized primary health care as a key step toward universal health coverage. In the realm of global, regional, and national public affairs, the interactions between the commercial interests of pharmaceutical manufacturers and the interests of public policy actors vary based on the prevailing political climate. The 1960s and 1970s witnessed corporate interests infiltrating national government domains through various means like lobbying and undue influence (Gautier & David, 2021).

Governance structures with higher centralization facilitated collaboration with pharmaceutical companies more effectively than with federal governments, as noted in Canada and the US, where federal rules were perceived as more protective of corporate interests than provincial norms. A noteworthy phenomenon, the *revolving door*, (Davis & Abraham, 2013) illuminates how public officials transition between regulatory agencies and the regulated industry, potentially compromising public interests, exemplified in the US opioid crisis. Governments, torn between safeguarding public health interests and supporting industrial interests for economic growth, face conflicting priorities. Internationally, the World Health Organization (WHO) emerges as a key policy influencer here, shaping international pharmaceutical norms and standards. The WHO recommends countries to formulate national pharmaceutical policies, though tensions arise in the global struggle over essential drug lists, illustrated by the US temporarily withdrawing financial support to WHO in 1986 (Gaudillière, 2014, as cited in Gautier & David, 2021).

In the 1990s, the establishment of the World Trade Organization (WTO) reshaped public-private dynamics in trade negotiations, particularly with the adoption of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. This provided a platform for multinational drug manufacturers to assert their interests, often at the expense of manufacturers in low- and middle-income countries (LMICs) and populations in high-income countries (HICs) seeking access to affordable medicines. Pharmaceutical policies, initially framed as means to enhance public health, evolved into tools for economic growth and power demonstration. Furthermore, the influence of international actors, such as the World Bank and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), on national decision-making processes has been critiqued, emphasizing the exclusion of public health advocacy groups and the wider public

from harmonization processes. The evolution of pharmaceutical policies from the 1990s to the 2010s emphasizes power relations, economic interests, and global health dynamics (Gautier & David, 2021).

Despite a discernible power disparity, documented instances of resistance within the pharmaceutical sector challenge the intellectual property regime. Notably, in Brazil, strategies involving exploiting loopholes and reverse engineering were employed to obtain more affordable and safer HIV drugs (Nunn et al., 2009; Hardon, 2017). Brazil has emerged as a key player contesting dominant corporate interests and global imperialism in the pharmaceutical realm. The nation, along with its allies, played a pivotal role in advocating for changes to the TRIPS Agreement at the WTO in Doha in 2001, resulting in the introduction of TRIPS ‘flexibilities’. This initiative aimed to improve transparency in medicine pricing and sustain and broaden global essential medicines policies, particularly benefiting populations in Low- and Middle-Income Countries (LMICs) (Nunn et al., 2009).

Prominent actions by non-governmental actors within the access movement have reshaped the narrative, redefining access to medicines as a developmental concern. This shift diverts attention from trade-related issues, advocating for alterations to global regulatory regimes like TRIPS Agreements, framing it as a developmental problem addressable through increased foreign aid, independent of national authorities and without addressing crucial legal issues such as pharmaceutical registration at the national level (Koivusalo & Mackintosh, 2011). In the 1990s, global pharmaceutical scandals and evidence of undue influence on regulatory bodies undermined public trust in both the industry and regulators, especially in High-Income Countries (HICs). This led to citizen mobilization aiming to reclaim healthcare, championing new treatments, and reacting to exorbitant drug pricing. While patient activism has proven impactful, concerns arise about potential biases influenced by disease affiliation and funding sources from the industry. The efficacy of patient activism in serving public health interests is debated, indicative of a shift toward the medicalization of society and increased patient autonomy (Davis & Abraham, 2013; Fisher, Wicks, & Babar, 2016).

The economic value of the pharmaceutical industry has spurred marketing-driven practices, prioritizing ‘me-too’ drugs and extending patent protection over research and development. Governments grapple with the delicate balance of safeguarding national trade interests,

fostering innovation, and ensuring equitable access to medicines within budget constraints. Cost containment policies, including price and profit controls, have been implemented in HICs since the 1990s, intensifying after the 2008 economic crisis, with significant ramifications on financial protection (Ess et al., 2003; Almarsdottir & Traulsen, 2005; Kheirandish et al., 2015; Petrou & VANDOROS, 2015). Comprehending the diverse forms of harmonization around pharmaceuticals necessitates acknowledging their economic value from both legal and scientific perspectives. Global discussions revolve around harmonizing clinical trial guidelines and safeguarding intellectual property rights. However, legal battles have witnessed MICs redirecting their focus to the national level, leading to improved drug access, particularly notable in countries like India (Patel, 2016).

Medicines, integral to financial considerations, are inherently social, reflecting societal values and patient needs. Davis and Abraham (2013) stress their moral responsibility to fulfill promised outcomes. Neglecting rare diseases, turning them into lucrative markets, and disease-mongering pose ethical concerns (Trouiller et al., 2002; Babar & Jamshed, 2008; Muscolo et al., 2012 as cited in Gautier and David, 2021). Corruption scandals reveal regulators' and companies' disregard for public health. The tension between profit-driven actions and societal health needs is evident, exemplified by the US *Right to Try* initiative (Dresser, 2015). Stricter transparency and marketing regulations are advocated to restore medicines' social value (Chakraborty & Lofstedt, 2012).

Pharmaceutical policies, shaped by global capitalist strategies, align with the agendas of multinational pharmaceutical industries and High-Income Countries (HICs). Resistance during the AIDS epidemic influenced trade policies, integrating public health exceptions. South Africa, Brazil, and India led contestations, addressing health as a human right, commercial fights, and promotion of generic manufacturing. Concerns arise as these countries integrate into the global economy. The rise of the bioeconomy, blending economics and biology, reconfigures pharmaceutical policies for increased economic value. Health economics tools and diverse pharmaceutical values contribute to this model, reflecting economic, therapeutic, and societal dimensions. Despite the aspiration for "health for all", the achievement of this goal remains elusive which was witnessed during the COVID-19 pandemic (Gautier & David, 2021).

The lack of synchronization between pharmaceutical and health policies for broader public health raises concerns about their regulation and capture. This issue is specifically examined in the context of India.

Regulations

In the early 20th century, India's pharmaceutical sector grappled with import dependence. However, the demand for affordable drugs surged during World War I, fostering the growth of domestic manufacturers. Responding to concerns about substandard products, regulatory measures such as the Poisons Act (1919) and Dangerous Drugs Act (1930) were introduced. The Drug Enquiry Committee in 1931 recommended a centralized drug control mechanism, culminating in the 1940 Drugs Act after World War II. Post-Independence, additional legislation, such as the Narcotic Drugs and Psychotropic Substances Act (1985), supplemented the regulatory framework. Current drug regulation in India is governed by several Acts and Rules, including the 1940 Drugs and Cosmetics Act and the 1948 Pharmacy Act. The Central Drugs Standard Control Organization (CDSCO) under the Directorate General of Health Services, manages various regulatory functions, including import control, new drug approvals, and licensing. It operates through zonal offices, sub-zonal offices, port offices, and laboratories. State and central authorities collaboratively manage drug manufacturing and distribution. The Drugs Controller General of India, leading the CDSCO in New Delhi, approves new drugs, establishes standards, ensures imported drug quality, and coordinates with State Drug Control Organizations.

The Drugs Control Administration, supervised by the Central Government, oversees diverse functions such as regulatory implementation, market authorization, clinical research, licensing, imported drug standards, advisory boards, drug testing, state-level coordination, policy guidance, technical advice, global certification schemes, monitoring adverse reactions, training programs, quotas for narcotic drugs, scrutiny of drug formulations, and evaluating applications for exporting unapproved or banned drugs. The drug approval process involves stages like clinical trials, marketing authorization, and post-marketing studies, with DCGI approval for new prescription drugs.

State regulators manage licensing and quality monitoring within their jurisdictions. India's involvement in pharmacovigilance began in 1986, leading to the establishment of the

National Pharmacovigilance Programme (NPVP) in 2004. Despite facing challenges and a suspension in 2009, the Pharmacovigilance Programme for India (PvPI) became mandatory in 2016 under the Drugs & Cosmetics Act. Challenges in the pharmaceutical industry include the absence of unified labeling standards, insufficient testing facilities, and a lack of comprehensive databases. Regulatory bodies, notably CDSCO and DCGI, are pivotal in overseeing India's drug regulation, with continuous efforts to address challenges and ensure pharmaceutical safety, efficacy, and quality.

As regulatory bodies oversee the pharmaceutical industry to ensure drug safety and efficacy, a parallel commitment to environmental protection is evident in the policies addressing the ecological impact of pharmaceutical waste discharge.

India took significant strides in environmental protection with the implementation of the Environmental Protection Act (EPA) in 1986, a response to the tragic incident in Bhopal⁴⁰. In contrast to the notion that ecological issues can be solely addressed through pricing mechanisms or compensation, India's EPA framework surpasses expectations by imposing stringent standards. One pivotal component of this framework is the establishment of the Pollution Control Board. Tasked with conducting environmental impact assessments, enforcing standards, and possessing executive powers to shut down activities violating regulations, the board plays a crucial role in maintaining environmental integrity. Industries are obligated to either have in-house treatment facilities or employ effluent treatment plants to ensure compliance with legal ambient standards before discharging waste. The authorization of Toxic Substances Disposal Facilities (TSDFs) for waste disposal further reinforces India's commitment to responsible environmental practices. (Vijay, 2018)

In 1992, the creation of the Environmental Protection Training and Research Institute, an independent body, aimed to raise environmental awareness and act as a third-party monitor for Pollution Control Board regulations. A significant development occurred in 1995 when an amendment mandated public hearings for industrial activities seeking environmental clearance. This inclusion serves as a participatory democratic mechanism, allowing citizens to voice concerns and contribute to the decision-making process. Moreover, local

⁴⁰ For more details refer- Broughton, E. (2005). The Bhopal disaster and its aftermath: A review. *Environmental Health*, 4, 6. <https://doi.org/10.1186/1476-069X-4-6>

governments or panchayats have been vested with the authority to shut down polluting industries, empowering grassroots governance. Citizens themselves hold a constitutional right to organize collective action for justice, adding a layer of accountability. India's EPA framework reflects a holistic approach to environmental protection, integrating regulatory measures, public participation, and institutional oversight (Vijay, 2018). Despite having regulations in both drug safety and waste disposal, the effective implementation of these measures faces challenges, frequently impeded by industry influence that prioritizes commercial interests. The government, often in the name of the larger good of safeguarding the economy and fostering business development, tends to acquiesce to these pressures.

The government in India since 2014 has relaxed environmental protection rules for 70% of polluting industries to facilitate business, according to an IndiaSpend analysis. State pollution control boards have exempted 146 out of 206 polluting industry categories from routine inspections, allowing self-certification or third-party certification. This change, aimed at improving the ease of doing business, raises concerns about hindering India's pollution control efforts. Studies indicate worsening pollution levels in India, with multiple cities ranking among the world's most polluted. The government's approach perpetuates poor compliance with environmental norms and contributes to health issues related to pollution (Kapur, 2020). The relaxation of pollution rules by governments raises crucial environmental concerns. However, even with stringent regulations, the implementation has been an issue, which is the focus of this study, where pharmaceuticals, driven by economic interests and influence over the state, have not been adequately regulated, particularly concerning waste management.

Unregulated pharmaceutical waste poses significant environmental risks, with active pharmaceutical ingredients detected in various environmental components. Even at low concentrations, pharmaceutical waste can lead to adverse effects on ecosystems, antimicrobial resistance, and disruptions in aquatic life. The discharge of pharmaceuticals into the environment is linked to ecological imbalances, impacting growth, reproduction, and behavior in aquatic species. Health inequalities arise as marginalized communities disproportionately experience the adverse health effects of poor environmental quality and social disparities. Environmental justice is crucial to ensure equal protection from environmental hazards and involvement in decision-making processes. The increasing

generation of healthcare waste contributes to a rise in chronic diseases, with vulnerable populations suffering the most while often contributing the least to the problem. Global health disparities emerge due to inequitable regulation and management of pharmaceutical pollutants, highlighting the need for comprehensive policies to address environmental pollution, especially in low-income countries. Overall, understanding and addressing environmental health disparities is essential for mitigating the risks associated with pharmaceutical waste and promoting a healthier environment for all (Desai et al., 2022).

The government's potentially lax approach to environmental compliance can exacerbate health inequality, particularly impacting marginalized communities residing near industries with inadequate regulations. This unequal distribution of environmental hazards subjects these vulnerable populations to higher levels of pollutants, resulting in increased risks of respiratory diseases, waterborne illnesses, and other health issues. Inadequate waste disposal and pollution control further contribute to long-term health risks, compounded by limited access to healthcare resources and socio-economic challenges. Consequently, the disparities in environmental risks create a scenario where marginalized communities bear a disproportionate health burden, emphasizing the need to strengthen the implementation of regulations for both environmental sustainability and the promotion of health equity across socio-economic groups.

These issues are addressed in the thesis in the upcoming chapter. The consequences of lax standards impacting health inequality, particularly within marginalized communities, pave the way for a closer examination of regulatory capture. Regulatory capture, characterized by industry-friendly perspectives dominating regulatory agencies, presents inherent challenges due to technical complexities. Moreover, the historical inclination of regulatory agencies to uncritically accept industry threats, leading to regulatory concessions, emphasizes the necessity for a more critical and independent regulatory approach. This regulatory capture and the pharmaceutical industry's profit-oriented focus indicate a lack of priority for public health. The current study scrutinized the nature of pharmaceuticals, specifically honing in on their accumulation processes under the guise of promoting overall health. The pharmaceutical industry, receiving substantial concessions and subsidies for its healthcare role, faces structural issues, with health in India falling under the family and welfare domain and

pharmaceuticals under the Ministry of Chemicals and Fertilizers (India)—a problematic categorization.

Regulatory capture

It poses a significant challenge as governments increasingly adopt the role of a mere regulator, limiting the effectiveness of public regulatory agencies. This phenomenon occurs when regulatory bodies, intended to oversee industries in the public interest, become *captured* by the very industries they are supposed to regulate. Such capture manifests through the influence of designated experts who may have dual loyalties, serving both as regulators and representatives of the regulated industry. Conflicts of interest are exacerbated by ‘Revolving Door’ practices, where individuals move between regulatory bodies and the industries they regulate. (Sengupta, 2018). This is, exemplified in Gopal Subramaniam, the Solicitor General of India at the case's commencement, who assumed the role of Novartis' lawyer during the proceedings, succeeding Rohinton Nariman, who, in turn, took over as Solicitor General of India to replace Subramaniam (Mathew, 2011). Likewise, Naresh Dayal, the former secretary of the Ministry of Health and Family Welfare, retired in September 2009, and shortly thereafter, he joined GlaxoSmithKline Consumer Healthcare as a non-official director (Pant, 2014). Regulatory capture extends beyond personnel movements and permeates through the promotion of neoliberal ideas and reforms by the Indian state since the 1990s. Regulatory capture is also evident in the promotion of neoliberal ideas in post-1990 India, where deregulation and private sector expansion have weakened regulatory structures. This shift favors powerful industrial interests over the public's welfare, forming an interlocking dynamic involving policymakers, regulatory officials, corporate players, and influential lobby groups (GoI, 2011; Stiglitz, 2009; Ghosh, 2010; Loepky, 2010; Chandrasekhar, 2014).

India's pharmaceutical sector thrived under the 1970 Patent Act, while the 1991 neoliberal reforms marked a policy shift, influencing the government's stance on intellectual property (IP) rights. Despite joining the WTO and signing the TRIPS Agreement, pro-health amendments to the 2005 Patents Act in 2004 resulted from political necessities rather than a commitment to fully utilize health safeguards. The government, constrained by circumstances, has not actively pursued the potential benefits of health safeguards in the Act. Regulatory capture in India's intellectual property (IP) policy formation is influenced by

global and national dynamics. The global chain begins with multinational corporations shaping IP legislation through developed country governments during the Uruguay Round of negotiations, culminating in the formation of the WTO. Subsequently, India's adoption of neoliberal policies in the 1990s impacted public policy, resulting in a potential conflict with IP safeguards. The formulation of the Intellectual Property Policy in 2015 by an 'IP Think Tank' raised concerns due to its industry-inclusive composition (Jishnu, 2014).

Criticized for prioritizing intellectual property over societal progress, the draft policy has been embraced by the US pharmaceutical industry, raising concerns about its implications for healthcare in low- and middle-income countries (LMICs). The reluctance to utilize health safeguards, as evidenced by reports of the Indian government's assurance against compulsory licenses, poses serious threats to the availability of low-cost generics, vital for treating diseases like HIV/AIDS. External pressures on India's IP policies, particularly from the US, involve diplomatic efforts, out-of-cycle reviews, and investigations into trade policies. The lobbying influence extends to US law and policymakers, emphasizing concerns over India's IP climate. Furthermore, technical assistance and judicial training offered by developed countries and pharmaceutical companies serve as tools to influence patent examinations and court decisions, highlighting the intricate ways in which regulatory capture operates in the formulation of IP policies in India (Flynn, 2015; Economic Times, 2015; Waning et al., 2010).

Technical assistance from developed country patent offices serves as a potent tool for administrative influence, fostering 'technocratic trust' that shapes decision-making processes in recipient offices (Draho, 2007, as cited in Sengupta, 2018). Additionally, multinational corporations utilize judicial training in developing countries to impact the interpretation and application of patent rights. Notably, concerns over Justice Dalveer Bhandari's attendance at conferences organized by the Intellectual Property Owners Education Foundation raised ethical issues. The 2011 International Judges Conference, funded by the United States Patents and Trademark Office, exemplifies the intricate ways pharmaceutical influence operates in shaping judicial perspectives on intellectual property (Mitta, 2011 as cited in Sengupta, 2018).

The collusion between regulatory authorities, pharmaceutical companies, and the medical profession in India has led to the approval and marketing of irrational Fixed-Dose Combinations (FDCs) with compromised safety and efficacy standards. This collusion is evident through negligence in approving these FDCs, the complicity of pharmaceutical companies in marketing illegal products, and the medical profession's indifference in prescribing them. The pharmaceutical-doctor nexus extends beyond irrational FDCs, encompassing deviations from treatment guidelines, lax adverse drug reaction reporting, and substandard pharmacovigilance. Voices of conscience from within the medical profession, as highlighted by Gadre and Shukla (2015), reveal the unethical influence of pharmaceutical companies on doctors, impacting treatment decisions and vaccine prescriptions.

The 59th Parliamentary Standing Committee Report (Srinivasan, 2012, 2018) underscores the regulatory capture in the Central Drugs Standard Control Organisation (CDSCO), pointing out collusion between drug regulators, manufacturers, and medical experts. The report exposes the vulnerability of the drug regulatory mechanism to corruption, with fixers influencing state licensing authority offices and the online submission system susceptible to manipulation. Clinical trials also witness collusion, highlighting a pervasive issue in the pharmaceutical industry's influence on regulatory processes and medical practices. The lax regulatory environment in India, influenced by collusion between the pharmaceutical industry and certain medical experts, is exacerbated by regulators aiming to establish India as a prime destination for clinical trials. Changes in Schedule Y of the Drugs and Cosmetics Act in January 2005 eased regulations for clinical trials of new chemical entities (NCEs) without adequate safeguards. The removal of mandatory phase lag in NCE trials, allowing simultaneous Phase 2 and Phase 3 trials, disregards potential serious adverse effects. The deaths in India related to the drug rivaroxaban highlight the consequences of inadequate trial planning. Clinical trials, often conducted by middlemen and contract research organizations (CROs) for Western pharmaceutical companies, lack substantial benefits for Indian researchers. The Ministry of Health and Family Welfare recorded 2,868 participant deaths during 2005–12, with only 89 acknowledged as trial-related, emphasizing the need for regulatory reforms (Gadre & Shukla, 2015; Srinivasan, 2012, 2018).

Clinical trials pose various issues, including selective publication of positive results, neglect of unfavorable data, and manipulation of trial outcomes. India faces challenges in clinical trial practices, such as permitting concomitant Phase 2 and Phase 3 trials for patented drugs without mandatory bridging Phase 3 trials for ethnic diversity. The call is to revert to the pre-January 2005 position, allowing selective waivers for health emergencies. Transparency in clinical trial data and agreements with sponsors is vital, highlighting the need for data sharing. The pharmaceutical–medical profession nexus involves code violations, corruption, and undue influence in endorsements. Recommendations include debranding non-patented drugs, price control, rational prescription, strict guidelines, and a mandatory code replacing voluntary practices. The prevailing shared consensus prioritizes pharmaceutical interests over public welfare, evident in government bodies favoring 'ease of business' for pharmaceutical companies, undermining essential interventions for equitable access to medicines (Smith & Roberts, 2016 as cited in Srinivasan, 2018).

Pharmaceutical companies prioritize profit over affordable medications, often influencing doctors to prescribe costly drugs through inducements like entertainment, overseas trips, or expensive gifts. The Citizen, Consumer, and Civic Action Group's 2011 survey revealed that doctors' prescriptions were tracked by pharmaceutical firms, and rewards correlated with drug sales. This practice, undisclosed in publications, raises ethical concerns. Additionally, the industry funds medical conferences, providing fellowships, which, in the medical fraternity, translates to consuming alcohol at someone else's expense. Despite the Medical Council of India's prohibition, professional associations like the Association of Physicians of India openly disregard such directives without consequences (Mani, 2011, 2018). The toxic influence of this collusion poses serious concerns for patient welfare, emphasizing the need for regulatory reforms and ethical practices within the healthcare system. Regulatory capture, characterized by industry-friendly perspectives dominating regulatory agencies, presents inherent challenges due to technical complexities. Moreover, the historical inclination of regulatory agencies to uncritically accept industry threats, leading to regulatory concessions, emphasizes the necessity for a more critical and independent regulatory approach. Joel Lexchin (2020) is well articulated this regulatory capture and the pharmaceutical industry's profit-oriented focus indicate a lack of priority for public health.

Joel Lexchin (2018)'s "The Pharmaceutical Industry in Contemporary Capitalism" provides a profound analysis of the pharmaceutical sector, dispelling the misconception that its profitability solely arises from innovative research. Lexchin highlights the industry's consistent financial success since 1980, revealing the prevalence of financial strategies over substantial investment in foundational research. In response to challenges like patent expirations and pricing pressures, Lexchin introduces the "nichebuster" model, illustrating the industry's adaptability through regulatory influence, strengthened intellectual property rights (IPRs), and control over drug prescription knowledge.

The shift from the blockbuster to the nichebuster approach signifies the industry's responsiveness to evolving market dynamics, focusing on smaller therapeutic markets with high-cost drugs. Lexchin (2018) critically examines the pharmaceutical industry's impact on drug regulatory processes in the United States and the European Union, uncovering collaborations, deregulatory reforms, and reliance on corporate-user fees. This scrutiny exposes potential compromises in public safety for expedience, deepening our understanding of challenges within pharmaceutical development and regulation. The analysis of intellectual property rights, emphasizing patents and premarket clinical trial data, underscores their pivotal role in pharmaceutical revenue and profits.

Lexchin (2020) elucidates the hurdles faced by developing countries due to stringent IPR provisions, leading to higher drug prices and restricted access. The industry's influence in international trade agreements and legal battles against compulsory licensing amplifies the global implications of these practices. Manipulation and selective reporting, such as Merck⁴¹ withholding mortality data and GlaxoSmithKline⁴² presenting misleading asthma drug data. Ghostwriting conceals corporate influence on academic publications, exemplified by Wyeth⁴³ defending Hormone Replacement Therapy drugs. Selective publication of trials with negative results skews perceptions of drug efficacy. GlaxoSmithKline's internal documents revealed misrepresentation of paroxetine's safety and effectiveness in adolescents.

⁴¹ For more details refer-Krumholz, H. M., Ross, J. S., Presler, A. H., & Egilman, D. S. (2006). What have we learnt from Vioxx? *BMJ: British Medical Journal*, 334(7585), 120-123. <https://doi.org/10.1136/bmj.39024.487720.68>

⁴² Refer Roehr B. GlaxoSmithKline is fined record \$3bn in US BMJ 2012; 345 :e4568 doi:10.1136/bmj.e4568

⁴³ refer Moynihan, R. (2003). Drug company secretly briefed medical societies on HRT. *BMJ : British Medical Journal*, 326(7400), 1161. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1126039/>

Lexchin (2020)'s exploration of the pro-corporate bias within pharmaceutical corporations during clinical trials adds depth to his work. From trial design and financial considerations leading to unethical terminations to data manipulation and selective reporting, he paints a vivid picture of the challenges surrounding trial integrity and transparency. The discussion on ghostwriting and the role of "key opinion leaders" (KOLs) bridges the credibility gap between corporations and doctors, raising valid concerns about their impact on medical knowledge and patient safety. He says

“Pharmaceutical corporations are extremely powerful due to their wealth. They achieve this power with the active collusion of regulatory authorities and the governments that oversee these authorities. The industry is able to manipulate knowledge about the value of pharmaceuticals not only to the detriment of what doctors know, but more important, to the detriment of people’s health” (Lexchin, 2020, p.48-49).

SECTION IV: Discussion

The pharmaceutical industry in India is characterized by a dynamic culture of innovation, driven by visionary endeavors and heightened expectations, leading to considerable value creation in a speculative market. Kaushik Sunder Rajan's (2006) exploration of this indigenous biocapitalism draws parallels with the speculative high-tech capitalism observed in the U.S., emphasizing the industry's focus on technological innovation and the production of scientific facts. Vision and hype play crucial roles, steering discussions toward the future and shaping the distinctive grammar of biocapital. This forward-looking orientation prompts contemplation on temporality, differentiating it from the U.S. focus on investor value. The industry in India has transitioned from a blockbuster model to a nichebuster approach, targeting smaller therapeutic markets with high-cost drugs. This aligns with India's economic priorities, emphasizing manufacturing success over investor value. The interplay of innovation, speculation, and the pursuit of manufacturing success defines the industry's identity within the broader socio-economic fabric of India. Intellectual property rights (IPRs), including patents and premarket clinical trial data, are pivotal for the industry's revenue and profits. Lobbying efforts, trade agreements, and legal battles reflect the industry's pursuit of stronger IPRs, impacting global drug access and raising concerns about conflicts with public health priorities.

Kaushik Sundar Rajan (2006) delves into the concept of 'venture science,' highlighting the overdetermination of research by market forces. The intertwining of scientific fact production and capitalist value generation emphasizes credibility over truth in corporate discourse. The tension between market values and Merton's scientific ethos defines 'venture science,' leading to the naturalization of pharmaceutical companies' claims about pricing control for research sustainability. The legal framework of forward-looking statements and the performative aspects of biotech "story stocks" illustrate challenges in delineating truth and intentional falsehood in corporate communication. The analysis explores the performative, institutional, and credibility dimensions within the biocapital grammar, revealing intricate dynamics involving capital, commodities, biological materials, therapeutic products, and information. The discussion extends to the discursive grounds of biocapitalist articulations, focusing on promissory conjuration and its prevalence in high-tech capitalism. Significant shifts in epistemic realms, particularly in genomics, redefine the notion of 'life itself' within a 'future perfect, present tense' grammatical framework. Corporate discourse and the epistemic articulation of facts from genomics are examined, unveiling commitments and fetishization surrounding scientific facts. Sunder Rajan's work provides an exploration of the multifaceted dynamics shaping the pharmaceutical industry in India and its implications for global biocapitalism. This sets the stage for understanding the intricate dynamics shaped not only by visionary pursuits and innovation but also by the broader influences of the state and global production networks, exemplified by the complexities within the Indian pharmaceutical landscape.

The roles that states play in the bio-pharma sector—provisioning, protecting, procuring, and producing—are intricately entwined with ongoing struggles to secure diverse values. Although the resolutions of these trade-offs typically favor capitalist economic value capture, aligned with the effects of financialization, monopolization, concentration, and cartelization in global bio-pharma production networks, there exists a potential for resistance and re-evaluation of health priorities, particularly at the peripheries where health costs accumulate more than the presumed economic benefits. The resulting economic geography is characterized by global variations, necessitating a comprehensive mapping and theorizing across historical and geographical configurations. Despite policymakers touting innovation in the life sciences as a cornerstone for economic growth and simultaneous health benefits, research reveals an uneven articulation and distribution of these promises globally. Where the

value flows and to whom, especially considering new strategies in the pharmaceutical sector confusing the calculus of economic and health values, needs to be addressed (Mazzucato & Roy, 2019; Roy, 2023).

A strategic–relational approach to conjunctural state formations is crucial, particularly when examining how states strategically couple innovation hubs with global networks. While the concept of 'strategic coupling' becomes more complex when focusing on state-led strategic coupling in the bio-pharma sector, it is essential and adaptable. The conjunctural analysis in Global Production Networks should not only consider where value capture occurs but also the kinds of value at stake. The COVID-19 pandemic has brought into focus the need for a more holistic approach to healthcare, one that considers the well-being of individuals and communities alongside economic growth. The pandemic has accentuated the importance of investing in public health infrastructure and research, emphasizing the need to integrate these efforts into global production networks (GPN) to ensure equitable access to healthcare services, particularly for developing countries and marginalized sections of society. (Sparke & Malpass, 2023). The Global Production Network (GPN) in pharmaceutical production exploits regulatory differences, contributing to environmental degradation in regions with weaker standards. States significantly contribute to facilitating pharmaceutical activities by leveraging regulatory loopholes and adopting lenient environmental policies. This prioritization of industry interests over public welfare is notably exemplified in the case of India.

India established itself as a significant global provider of generic drugs, particularly anti-infectives, with a dominant presence in the domestic market. The pharmaceutical sector has experienced substantial growth in the exports of bulk drugs with more than half of these exports directed to regulated markets like the United States and the European Union. To secure entry into these regulated markets, Indian manufacturers must adhere to Good Manufacturing Practices (GMP). It is worth noting that while GMP guidelines prioritize product quality, they lack provisions for monitoring environmental discharges from pharmaceutical production in developing nations such as India. The rationale behind such extensive pharmaceutical exports is linked to the historical development of environmental regulations in developed countries, particularly the United States.

Treatment storage and disposal facilities in the U.S. were initially established in areas predominantly inhabited by marginalized groups, leading to environmental justice and anti-racism movements. This institutional choice prompted the creation of the 'Superfund program', focusing on cleaning up hazardous waste and safeguarding public health. Consequently, the U.S. began outsourcing the production of "dirty goods," including pharmaceuticals and bulk drugs, to other countries, with India emerging as a primary destination. This outsourcing trend has positioned the U.S. as the largest importer of pharmaceuticals from countries like India. The varying regulatory policies of different societies regarding environmental protection and accumulation have played a role in this global supply chain shift. Developed countries, aiming to safeguard their environments, opted to offshore the manufacturing of bulk drugs to countries like India (Vijay, 2013). The study emphasizes the need to integrate economic and health concerns, including enduring concerns about the meaning and representation of value, in comprehending the ongoing growth of bio-pharma sector hubs globally. This is seen in Hyderabad becoming a global supplier of bulk drugs and a major exporter to developed countries.

The unaccounted costs associated with the pharmaceutical industry, including unsafe practices, lenient regulations, and environmental pollution, challenge the notion of it being a sunrise industry. Regulatory agencies treating manufacturers as above the law allows violations, imposing hidden costs on society. The thesis highlights the systemic failure in regulatory practices, contributing to the dumping of toxic effluents which is explored in the next chapter. Pollution's spillover effects, examined through exposure pathways, necessitate a holistic assessment of an industry's actual cost. Global value chain analysis reveals dispersed production processes, emphasizing the need for comprehensive evaluations. The transplantation effect in regulatory standards may not ensure effective implementation due to systemic failures. The historical context of environmental justice movements in the US, such as the rise of the superfund program, demonstrates the socio-political calibration of environmental policies. The outsourcing of dirty goods production to countries like India reflects the global trade patterns which in turn affects environmental regulation.

India's pharmaceutical and bulk drug industries systematically employ cost-shifting strategies (Vijay, 2013). The thesis attributes this regulatory failure to broader political economy dynamics, asserting that the shortcomings are systemic rather than isolated incidents. The

thesis views power as a constitutive element of the economic process, emphasizing the appropriation of surplus by capital. This involves the capture of value through the expropriation of lives and the exploitation of resources leading to health inequalities. This analysis highlights the crucial connection between state policies, global pharmaceutical networks, and prevailing economic power structures that, driven by capitalist motives, shape health outcomes on a global scale. The complex interaction of state policies and corporate strategies accentuates the dynamics of the bio-pharma field, where economic priorities often surpass health concerns (Rajan, 2017).

The practices of developed countries outsourcing drug manufacturing for environmental reasons are outlined by Rajan (2017) as follows:

“Capital operates within such cracks that emerge between experiential and structural politics of health and illness, prying them apart. Sometimes capitalist interests are adept at sprinkling a good dose of ethics into the mix while positioning their solutions as win-win, ... When it can, capital simply uses its power to coerce (... where the interests of corporate capital are underwritten by the geopolitical power of the American state)... The empirical scales at which the capitalized politics of health operate are often simultaneously too close and too far to easily allow for a simultaneous conceptualization of the experiential and the structural, except occasionally in a situational and contingent fashion. Across these scales, lives continue to be lived, loved ones continue to be lost, and health and democracy in all their contradictory complexity remain very much at stake. The problem space of pharmocracy is as immediate and proximal as it is global and dispersed” (Rajan, 2017, p. 246).

This chapter attempted to narrate the historical trajectory of pharmaceutical policies and the role of the state, particularly in the context of health policy. It sheds light on the existing health inequalities, emphasizing that if regulations are not effectively implemented, it adversely impacts overall public health, disproportionately affecting marginalized communities due to regulatory capture. Grounded in historical context, the chapter delves into how the state, driven by its vision and hype, contributes to the pharmaceutical industry, considering it vital for the national economy.

However, global production networks, outsourcing, and lapses in regulatory enforcement can lead to detrimental consequences, particularly evident in the industrial estate of Hyderabad, where the production of pharmaceuticals has severe implications. The subsequent chapter explores the implications of regulatory capture in a bulk drug manufacturing hub, a region with substantial exports and considerable profits. The narrative unfolds against the backdrop of the state's promotion of the pharmaceutical industry for economic growth. This scrutiny reveals how regulatory capture, when unchecked, poses significant risks to public health,

with a specific focus on areas like Hyderabad, known for manufacturing pharmaceuticals with potential negative consequences on the environment and local communities.

Chapter: 4

Pharma's Dark Curtain: The Unseen Costs of Medical Advancements

In the preceding chapter, an exploration of the state-industry nexus unveiled the industry's persistent replication of a profit-centric approach through diverse policies while also unraveling the dynamics of the capital accumulation process. Building on this exploration of the industry's operational dynamics, the current chapter investigates the technologies of power employed by the pharmaceutical sector. The emphasis is on comprehending how these technologies actively contribute to the generation of health inequalities. This chapter specifically presents the repercussions of the industry's growth within the industrial estate, transforming Hyderabad into a capital for bulk drug manufacturing. The key question guiding the inquiry is: What technologies and techniques of power does the industry employ to actively contribute to the creation of health inequalities? Departing from conventional environmental assessments, the primary goal is to unravel the intricate interplay between the pharma industry and the regulatory state⁴⁴.

As discussed in earlier chapters- India serves as a significant global provider of generic medications, placing notable emphasis on anti-infectives, including antibiotics, antivirals, and antifungals, thereby dominating the domestic market. According to the Ministry of Commerce & Industry (2022), Indian pharmaceutical exports have experienced a substantial growth of 103% since the fiscal year 2013-14, escalating from Rs. 90,415 Crores to Rs. 1,83,422 Crores in 2021-22. The export performance in 2021-22 represents the pharmaceutical sector's most commendable export achievement, marking a remarkable surge with exports increasing by nearly USD 10 billion over eight years.

More than half of India's pharmaceutical exports are directed to rigorously regulated markets, including the United States and the European Union. To gain access to these regulated markets, Indian manufacturers have to comply with Good Manufacturing Practices (GMP),

⁴⁴ The regulatory state has emerged as part of the wider shift from 'government' to 'governance' since the late 1970s. As part of the wider shift towards neoliberalism, 'government' has been largely replaced by 'governance', whereby resources, authority, and responsibility are dispersed to diverse public and private actors, while central state managers retreat to a 'regulatory' role, using 'negative coordination' to 'steer' these actors in broadly favored directions (Cit in Jones and Hameiri (2021).

which delineate the minimum standards for a medicines manufacturer's production processes. Adherence to these standards is subject to continuous monitoring and periodic inspections conducted by various national, regional, and international authorities, such as the U.S. Food and Drug Administration (FDA), the European Union and its Member States, and the World Health Organization (WHO). According to GMP requirements, pharmaceutical products must consistently exhibit high quality, be suitable for their intended use, and meet the specifications outlined in the marketing authorization (MA) or product specification. Notably, instances of GMP violations and product bans are prevalent within India's pharmaceutical manufacturing sector. There are instances where several Indian pharmaceutical companies, including Dr. Reddy's, Sun Pharma, Zydus Cadila, Wockhardt Ltd, and IPCA Lab, received warning letters from the U.S. FDA. Additionally, the European Union imposed a ban on 700 generic drugs supplied by Indian companies in 2015. (Financial Times,2015).

At present, Good Manufacturing Practice (GMP) guidelines do not include provisions that oversee the environmental discharges arising from the manufacturing of medicinal products. Consequently, regulatory bodies in controlled markets lack explicit authority to monitor the environmental consequences of pharmaceutical production that is outsourced to developing nations like China and India. In subsequent years after the enforcement of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), the industry underwent rapid restructuring, encompassing three distinct product categories: branded products with patent protection, quality generics (off-patent products with international approvals), and low-value generics (off-patent products primarily sold in developing country markets) (Haakonsson,2009).

In response to the alignment of Indian intellectual property laws with the TRIPs agreement in the 1990s, Indian pharmaceutical manufacturers were no longer permitted to produce and market reverse-engineered versions of drugs patented by foreign companies. This change significantly increased the challenges for Indian companies to replicate new drugs and develop "new" generics. Consequently, many leading manufacturers in the country shifted their focus to contract production for Western drug companies or engaged in research and development agreements, mergers, acquisitions, and other collaborations with foreign partners. (The Economic Times, 2002,2013).

The opening of India's economy to overseas players, facilitated by adjustments to the patent regime in the mid-2000s and the allowance of 100% inward foreign direct investment (FDI), has attracted substantial investment from foreign multinationals. (Mint,2014). The Indian pharmaceutical industry exhibits geographical dispersion, with production occurring at various locations throughout the country. States such as Maharashtra, Gujarat, Telangana, Andhra Pradesh, West Bengal, and Tamil Nadu have substantial manufacturing and processing facilities. Noteworthy multinational players, including Mylan, Sanofi, Daiichi Sankyo, Merck and Co., and Bristol Myers-Squibb, have injected billions of dollars in FDI into the country in recent years. These companies have also formed strategic alliances with prominent Indian manufacturers such as Dr. Reddy's, Aurobindo, and Ranbaxy. Several larger Indian firms, including Dr. Reddy's and Aurobindo, have expanded into foreign markets, positioning themselves as formidable contenders on the global stage. (Mazumdar,2013)

In response to India's economic liberalization in the mid-2000s, numerous multinational pharmaceutical companies, many headquartered in the U.S. and the European Union, have gravitated towards cities like Hyderabad and Visakhapatnam, establishing them as key manufacturing hubs. India's manufacturing capacity development is seen as an opportunity for Western economies to shift away from environmentally impactful or dirty goods manufacturing practices to India which is explained in the previous chapter. The outsourcing of manufacturing bulk drugs to developing countries has resulted in significant environmental impacts due to variations in regulatory standards, potentially leading to inadequate waste management practices and environmental pollution. Numerous studies (Mathew & Unnikrishnan,2012; Unnikrishnan,2011; Sudhi,2011; Fick,2009; Adams,2009,), including a comprehensive survey by Greenpeace (2004), have detailed the various ways in which pollution has adversely affected people, animals, crops, and land in industrial zones. These studies have consistently revealed significant contamination of air, water, and soil in Telangana and Andhra Pradesh by toxic chemicals and heavy metals, including copper, lead, mercury, and arsenic. Concerns have also emerged regarding the environmental and health impacts associated with antibiotic production, coinciding with the escalating threat of antimicrobial resistance in India and globally (Alliance for the Prudent Use of Antibiotics, 2014).

The pharmaceutical industry has come under scrutiny from multiple sources, notably the Comptroller and Auditor General of India (CAGI), for its failure to adhere to pollution control norms and a lack of compliance with the prescribed Good Manufacturing Practices guidelines. This lapse in compliance has led to the contamination of water bodies, soil, and crops, posing severe health risks and jeopardizing the livelihoods of communities residing near these manufacturing units, as highlighted in the Nordea Report of 2016. The subsequent section explores the implications of this noncompliance, shedding light on the environmental and public health consequences in the bulk drug capital of India-Hyderabad.

This chapter is structured into five sections for a comprehensive exploration. Section I delves into the factors driving Hyderabad's emergence as a bulk drug capital. Section II narrates the consequences of this industrial boom, specifically the severe pollution, elucidating the techniques employed by industries in effluent release and addressing challenges faced by effluent treatment plants. It also sheds light on the role of pollution control boards. Section III shifts focus to the specific villages affected, examining the repercussions on local communities, particularly the health hazards related to Antimicrobial Resistance (AMR) that could exacerbate health inequalities. This section further investigates the directives of the National Green Tribunal (NGT) and their implementation processes, exposing potential regulatory capture, the industry's use of the technology of power, and the exploitation of judicial loopholes as a shield. Section IV serves as a central point, amplifying the voices and concerns of the affected communities. Finally, Section V untangles the intricate dynamics between the industry, state, and society, offering a holistic understanding of the interconnected relationships within this industrial landscape.

Section I:

Hyderabad in Telangana, formerly part of Andhra Pradesh until its division in 2014, emerged as a prominent center for bulk drug manufacturing and is recognized as the "bulk drug capital" of India, contributing to nearly one-fifth of the country's pharmaceutical exports. The Environment Ministry in India categorizes pharmaceutical manufacturing (mainly bulk drugs) as a "red category" activity due to the substantial hazardous waste it produces. The founding of Indian Drugs and Pharmaceuticals Limited (IDPL) in Hyderabad in 1964 (discussed in previous chapter) marked the rise and concentration of the generic drug industry

in the city. Several former IDPL employees went on to establish their own companies, now among the leading pharmaceutical firms in India, including the founder of Dr. Reddy's, a major player in the industry (Bank, 2008).

The IDPL Hyderabad plant, situated in Balanagar/Kukatpally on 891 acres of land (equivalent to 3.61 million sq. meters), commenced operations in 1967, producing a diverse range of 47 synthetic drugs. Within a 2 km radius of the primary plant, a well-established township with 858 flats was constructed. The plant once housed both bulk and formulation facilities, but its operations ceased entirely in 1996 for bulk production and in 2003 for formulations with the growth of private industries that came up. Presently, only the Effluent Treatment Plant (ETP) operates to treat effluents from other industries (IDPL, 2019).

Noteworthy is the fact that when IDPL was established, an Effluent Treatment Plant was implemented. However, as other private industries emerged later, they did not incorporate such facilities until facing resistance, protests, and legal interventions. This raises questions about the evolving role of the state, as the knowledge and practices applied during IDPL's inception in 1967 were not adhered to by the private industries that were established in different industrial estates. This shift underscores the changing nature of state policies and the scientific experts who, conveniently or negligently, disregarded effluent treatment practices, opting to discharge waste into common resources instead.

Figure 4.1. Present condition of IDPL (which is dilapidated)



Source: Picture taken in 2022.

In the 1980s, the then prime minister Indira Gandhi, representing the Medak District constituency in Parliament, actively advocated for the industrialization of the area. Central and state governments provided funding, subsidies, tax exemptions, and loans to encourage industries. Industrialists sought subsidies by establishing industries in Medak, making it a major industrial hub. Patancheru⁴⁵ was chosen for its ample forest area, seen as ideal for expanding industrial units. The government regularized forest land under the Andhra Pradesh Industrial Infrastructure Corporation (APIIC), including Kazipally and Narsapur. APIIC, established in 1973, focused on industrial development through land acquisitions, particularly under the five-year plans of the 1960s and 70s. Entrepreneurs favored Medak due to low land rates, and farmers welcomed industries anticipating employment and income from non-agricultural sources and sold their lands at lower prices. The availability of water from

⁴⁵ Located at 17.52° latitude and 78.26° longitude, Patancheru served as a gateway to towns like Sanga Reddy and Medak. Situated on a major highway connecting the southern and western parts of the Deccan. The term "sarai" in the village's nomenclature suggests its connection to an ancient market town. Patancheru is believed to have originally been situated on the banks of a natural cheruvu (lake), contributing to its name. Scholars propose various etymologies, with one simple interpretation suggesting a combination of "pattana" meaning 'market-town' and "cheruvu" meaning 'lake.' This combination forms "Patancheru," indicating its historical significance as an important market town near a lake. The village had consistently been an active hub for habitation. (Sen,2021)

numerous water bodies and, the availability of labor further attracted industries. Subsequently, the bulk drug industry flourished on the outskirts of Hyderabad.

The pharmaceutical sector also gave rise to a wave of new-generation entrepreneurs from the Kamma community in the 1980s. Notable figures among them include Nimmagadda Prasad of Matrix Laboratories, Murali K. Divi of Divi's Laboratories, Venkaiah Chowdary Nannapaneni of Natco Pharma, and R.T. Ravi of Krebs Biochemicals & Industries Limited. Murali Divi, in 1984, co-promoted Cheminor Drugs with Anji Reddy of Dr. Reddy's Laboratories (DRL). Six years later, he left Cheminor (which subsequently merged with DRL) to establish Divi's Laboratories. Nannapaneni, holding a pharmacy master's from Andhra University in Visakhapatnam, worked in the US for fifteen years before founding Natco Pharma in 1981. The founder of Krebs Biochemicals is similarly a trained biochemist. These companies primarily focus on the manufacturing and export of generic active pharmaceutical ingredients (API), which are bulk drugs.⁴⁶(Damodaran, 2008)

The 1980s also witnessed the emergence of several prominent Reddy business groups. Dr. Reddy's Laboratories (DRL), established in 1984, was spearheaded by Kallam Anji Reddy. An alumnus of Pune's National Chemical Laboratory with a doctorate in chemical engineering, Anji Reddy had previously served at the public sector Indian Drugs and Pharmaceuticals Limited (IDPL) from 1969 to 1975. Notably, IDPL played a pivotal role in transforming Hyderabad into a pharmaceutical hub.⁴⁷Following his tenure at IDPL, Anji Reddy went on to become the founder-managing director of Uniloids Limited. Subsequently, in 1980, he co-founded Standard Organics Limited (SOL) with Chandrasekhar Reddy, a textile engineer who earned wealth from his ventures in Nigeria. In 1984, Anji Reddy embarked on establishing DRL, which has evolved to be one of the largest domestic drug producers. Aurobindo Pharma Limited, founded in 1986 by Penaka Venkata Ramaprasad Reddy—formerly associated with SOL—has rapidly ascended the ranks and nearly matches

⁴⁶ Additionally, there are smaller firms like Suven Life Sciences, led by Venkat Jasti (a pharmacy postgraduate from Andhra University), and Vimta Labs Limited, founded by S.P. Vasireddi (who is a Kamma). Both companies derive a significant portion of their revenues from contract research, clinical trials, and related knowledge process outsourcing work for global pharmaceutical and life sciences majors. Krishna M. Ella, a Kamma who earned a doctorate in molecular biology from the University of Wisconsin-Madison, launched Bharat Biotech International Limited in 1996. His company specializes in the production of vaccines (Hepatitis B and typhoid) and bio-therapeutics. Loosely associated with the pharmaceutical industry are hospitals, and Hyderabad hosts several owned by the Kamma community, such as Kamineni Hospitals, Bollineni group, Medwin Hospitals, Usha Mullapudi Cardiac Centre, and the L.V. Prasad Eye Institute. (Damodaran,2008)

⁴⁷ IDPL is akin to the contributions of Bharat Electronics and Hindustan Aeronautics in shaping Bangalore's information technology industry.

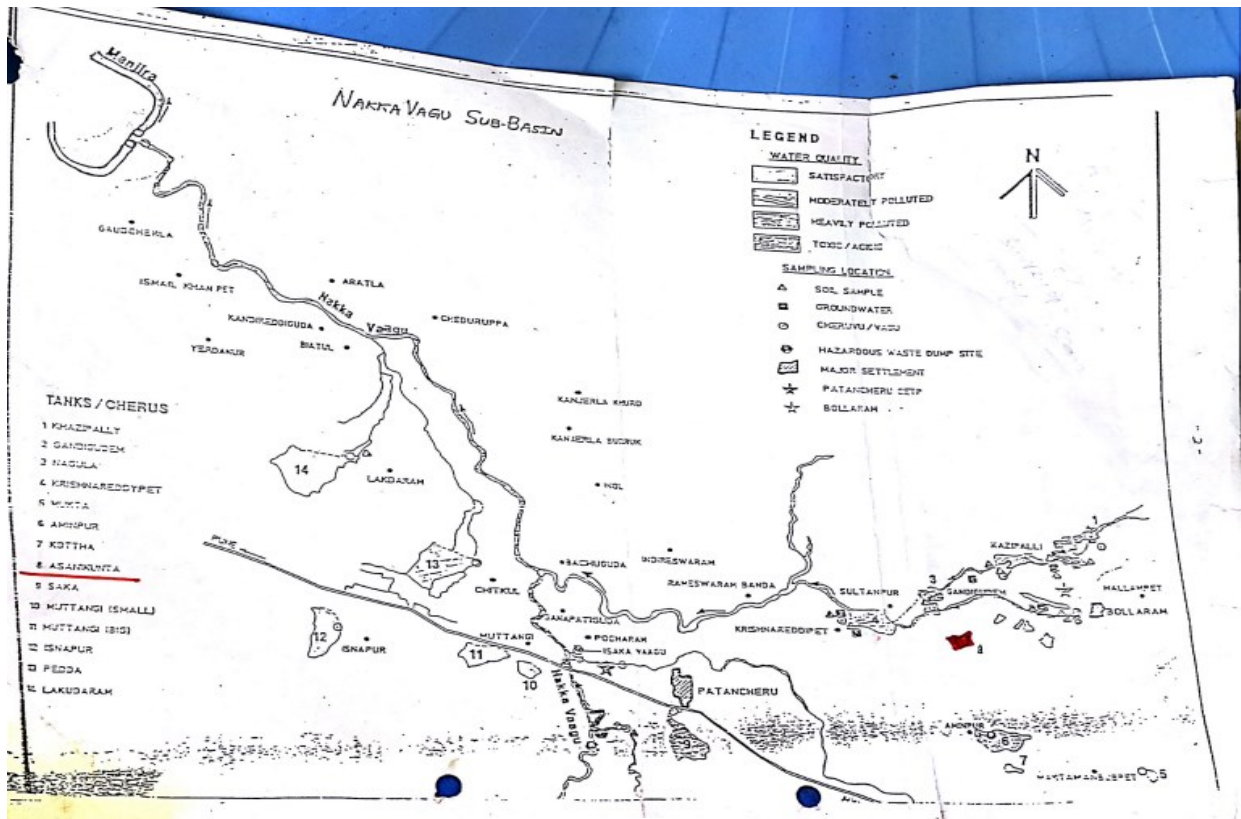
its counterparts in terms of sales. Another noteworthy addition is Bandi Parthasaradhi Reddy's Hetero Drugs Limited, which has solidified its position in the anti-retroviral (HIV/AIDS) segment⁴⁸ (Damodaran,2008).

Hyderabad has earned the distinction of being the bulk drug capital, primarily attributed to the concentration of industrial clusters in its neighboring districts. This recognition stems from the strategic placement of pharmaceutical manufacturing hubs and related facilities in the vicinity of the city. The Patancheru and Bollaram Industrial Development Areas (IDA) (Refer Map 1.2, Chapter 1), established on the outskirts of Hyderabad city, have experienced a surge in industrial growth, particularly along the Nakkavagu River (see Figure. 4.2) Patancheruvu is situated in the northwestern outskirts of Hyderabad, functioning as an industrial zone positioned approximately 32 km away from the city holding a pivotal position along National Highway, leading to Hyderabad-Solapur. Additionally, it is situated roughly 18 km from HITEC City, where the majority of the software industry offices are concentrated. This industrial enclave gained prominence with major investments from Non-Resident Indians (NRIs), encouraged by the state to contribute to its economic development. The local population had high expectations of improved employment opportunities and overall prosperity as a result of these developments.

However, the transition also witnessed the sale of agricultural land at nominal prices (Rs. 6000/- per acre), only to be subsequently resold by government agencies at exorbitant rates ranging from Rs. 10 to 14 lakhs per acre (Rao, 2001). The strategic selection of Patancheru as an industrial zone was influenced by several factors, including its proximity to Hyderabad, its strategic location along National Highway No. 9 connecting Mumbai, established infrastructure such as electricity, roads, and a reliable water supply from the Manjeera reservoir.

⁴⁸ Pratap C. Reddy, another prominent industrialist from the Reddy community, laid the foundation for Apollo Hospitals in Chennai in 1983. This cardiologist from Chittoor has transformed Apollo Hospitals Enterprise Limited into a healthcare giant.

Figure 4.2: Nakkavagu Sub-Basin



Source: Rao, A.K. (2011).

Additionally, being within the borders of Medak district made industries eligible for various incentives and subsidies offered by the governments of Andhra Pradesh and India. The state further facilitated industrial growth by providing soft loans and essential infrastructure.⁴⁹ The industrialization initiative in Patancheru brought forth a set of challenges rather than resolving them. Industries located in these estates display water-polluting characteristics that lack adequate infrastructure for wastewater treatment. As a result, untreated or partially treated effluents from these industries flow into nearby surface water bodies, including Cheruvu, eventually merging with the Nakkavagu⁵⁰ stream.

⁴⁹ As a result, renowned companies like Bharat Heavy Electrical Ltd. (BHEL), A.P. Scooters, Nagarjuna Steels, Allwyn Watches, among others, were established in the late sixties and early seventies, predominantly in the pharmaceutical and chemical sectors.

⁵⁰ Nakkavagu is a tributary of Manjira River, which drains the water of highly industrialised zone of Patancheru area. The Manjira River finally joins with the river Godavari. Nakkavagu basin lies between the longitudes 78 deg. 5 min. and 78 deg 25 min East and the latitudes 17 deg 25 min and 17 deg 45 min North. The basin extends over 734 sq. kms area Nakkavagu basin is covered in Patancheru, Ramachandrapuram, Jinnaram and Sangareddy Mandals of Medak District and to a lesser extent in Rangareddy District, and found in 'Survey of India', toposheet numbers – 56K/2, 56K/3, 56K/6 and 56K/7.

The Nakkavagu, in turn, converges with the River Manjeera, which ultimately joins the Godavari River. This cumulative impact of effluents being released into the water bodies poses a long-term threat to the Godavari River. Neither the industries nor the administration developed plans for the proper disposal of waste generated by industrial activities before establishing the industries. The IDPL (Indian Drugs and Pharmaceuticals Limited) was established with an effluent treatment plant, whereas subsequent industries that came up in this region lacked such facilities until the local communities protested and legal cases were filed in the courts. This lack of planning and negligence has resulted in significant hardships for the local population in this area.

The industries are water-polluting, and lack sufficient facilities and commitment to address the risks posed by the substantial volume of toxic effluents they generate. Consequently, numerous stagnant pools have emerged in the proximity of these industrial areas. These stagnant effluents seep into drains and *cheruvus*, causing contamination of the groundwater. The released effluents eventually reach the nearby surface waters and *cheruvus*, ultimately converging with the Nakkavagu stream. Unfortunately, environmentally friendly production processes have not been put in place.

By the late 1980s, both surface and groundwater, along with the soil in the Nakkavagu and Pamulavagu sub-basins⁵¹, had succumbed to pollution, as reported by the Andhra Pradesh Pollution Control Board. Beyond direct contamination, overflow from lakes further affected surface and groundwater, contaminating the entire irrigation system which in turn affected people dependent on it for their livelihood. It is noteworthy that the Nakkavagu functions as a paleo-channel, and the alluvial aquifer, possessing significantly higher transmissivity than the adjacent granite, clandestinely transports the river's contaminated water across extensive distances underground. A study conducted by the National Geophysical Research Institute (NGRI, 2002), under the sponsorship of the Central Pollution Control Board, covered an approximately 160 sq km area occupied by both large and small pharmaceutical industries.

⁵¹ Two of the major streams are named after a mammal and reptile, 'Nakka' means fox, 'Pamula' means 'of snakes' and 'vagu' means stream in Telugu. 'Nakkavagu' – 'fox-stream' as per the villagers this stream was habitat for foxes in the past. Similarly, 'Pamulavagu' – 'Stream of snakes' was the natural habitat for snakes. Whenever Pamulavagu was in spate, large numbers of snakes were seen everywhere, even in the nearby villages. The irrigation facilities led to growing crops like paddy, which attracts pests like rats; they in turn could have attracted snakes in large numbers, which helped in control of rats. In the past the forests in the District were active with wild life.

The findings of this study revealed elevated levels of heavy metals, including arsenic, strontium, barium, selenium, boron, manganese, and nickel in both ground and surface water bodies. Additionally, residual pesticides such as aldrin and endosulphan were detected. (Green Peace,2004).

Activists have persistently fought against pharmaceutical pollution for decades, albeit with limited success. In 1986, Citizens Against Pollution (CAP) initiated the Patancheru Anti-Pollution Committee, and the subsequent year witnessed nearly 2,000 people marching to then Chief Minister N. T. Rama Rao, demanding the construction of an effluent treatment plant for each industrial unit, adequate compensation for degraded agricultural land, and the provision of safe drinking water to affected villages. Unfortunately, even after 30 years since that march, there is no evidence that the implemented effluent treatment plants appear capable of managing the substantial volumes of waste generated by the bulk drug manufacturing industry. Another significant issue lies in the inadequate monitoring of pollution emanating from pharmaceutical manufacturing.⁵²

In 1989, 110 industries collectively established a Common Effluent Treatment Plant (CETP) intending to address the issue of effluent disposal. Instead, the CETP has exacerbated the problem, becoming a significant source of additional pollution. Post-treatment, the treated wastewater is released into the Peddavagu water stream, which subsequently merges with the main Nakkavagu stream. The Nakkavagu, receiving a combination of sewage, industrial effluents, and CETP discharges, eventually joins the Manjira river, which was a crucial potable water source for the region and a primary drinking water supply for the twin cities of Hyderabad and Secunderabad till Mission Bhagiratha⁵³ came up. As the Manjira converges with the Godavari, one of South India's longest rivers, the long-term integrity of the Godavari is also at risk.

Effluent treatment plants established to combat pollution have proven inadequate, allowing continued discharge of effluents into the Nakkavagu and other water bodies surrounding the manufacturing vicinity. Despite this, the approval of a Joint Action Plan (JAP) by the Central Pollution Control Board (CPCB) and the Telangana State Pollution Control Board (TSPCB)

⁵² Interviews with Prof.Purushotham Reddy, environmentalist and founder of CAP citizen against pollution December 16th 2014, and feb 15th 2020.

⁵³ Bhagiratha is a safe drinking water project for every village in Telangana State

in 1998 reportedly improved water quality. Numerous petitions have highlighted pollution concerns, leading to court orders and judgments. A review of the implementation of these orders reveals shortcomings by the Central and State Governments and the TSPCB, allowing violations by polluting industries to persist.

Independent laboratories, ostensibly private, receive remuneration from the pharmaceutical industry to conduct Environmental Impact Assessments (EIA) on pharmaceutical plants. These assessments consistently provide a favorable evaluation, offering certificates asserting that the plants adhere well to standards, even in the face of potential issues. Subsequently, this evidence serves as expert testimony in court when waste management standards come under scrutiny⁵⁴. The inherent conflict arises as private labs and rating agencies, being financially compensated by the industry they are meant to oversee, may develop a disincentive to produce negative reports. Commenting on this unholy nexus between pharmaceutical companies and regulatory authorities Srinivasan (2018) points out that this is not merely unethical but criminal, especially in the way it adversely impacts the lives of local communities. Over time, this cycle can result in partiality in audits. Organizations tasked with monitoring pollution lack effective regulatory power and, in some instances, are suspected of collusion with the very industries they are supposed to monitor. Even when authorities intervene, cases often progress to the Supreme Court, only to be diluted at critical stages, leading to a lack of essential action.⁵⁵

Section II

Examining Highly Polluting Industries and Treatment Plants

Pharmaceutical industries producing bulk drugs for global markets, forming a pharmaceutical cluster, have resulted in severe pollution, designating the area as a Critically Polluted Area. Numerous chemical units in these IDAs discharge their effluents into the Nakkavagu, rendering the water unsuitable for consumption. The repercussions include the death of livestock in the vicinity due to the harmful effects of the contaminated water and the emergence of genetic deformities among the local population. The environmental consequences of these effluent discharges have been dire, impacting both the ecosystem and

⁵⁴ Interviews with BV Subba Rao- founder member of SOUL-save our urban lakes and Dr.Vijay Gudavarthy, an activist and petitioner, who draws parallels between this practice and the relationship between ratings agencies and banks leading up to the 2007-08 financial crisis.

⁵⁵ Interview with Dr.Donthi Narsim Reddy ,public policy expert and activist.

the well-being of the community. On two occasions, in 2010 and 2013, the Indian Ministry of Environment and Forests (MoEF) imposed a ban on further expansion in this area due to its classification as a critically polluted zone. Images depicting polluted sites and effluent discharge are included (see Annexures) to provide insight into the situation from the 1980s. Apart from gathering historical photographs, the researcher has incorporated pictures captured at various time intervals to offer a comprehensive view of the evolving conditions.

The compilation of the "worst polluters" list stems from an examination of Telangana State Pollution Control Board (TSPCB) inspection reports conducted by India's Centre for Science and Environment (CSE) in November 2015. According to the findings, 15 drug manufacturers operating within the Patancheru-Bollaram cluster were found to be in blatant violation of environmental regulations and orders from the Indian Supreme Court. The CSE report revealed that most of these companies engaged in manufacturing pharmaceutical ingredients without proper authorization, exceeded permitted water consumption limits, and discharged more effluents and hazardous waste than allowed. Furthermore, two units were found to be operating without clearance from the Ministry of Environment and Forests (MoEF). The analysis raised concerns about the reliability of Telangana State Pollution Control Board inspection reports, citing significant discrepancies.

Many of these companies have a history of environmental violations and non-compliance with pollution control board norms, featuring in numerous legal cases, media reports, and exposes over the years. Alongside reports from state Pollution Control Boards and India's Central Drugs Standard Control Organisation, this list served as a crucial reference document. Field visits (from 2013 to 2023) to sites near Aurobindo's corporate units and discussions with my respondents have revealed that the company's manufacturing units are polluting their surroundings and the local water supply—a matter seemingly ignored by the company, despite several complaints. If the outsourcing of production to smaller units in the area is indeed occurring, the cumulative pharmaceutical manufacturing waste for which Aurobindo is responsible may exceed the quantities generated by its production units.

In addition to the Aurobindo industry, another industry operated in Gaddapotharam by the name Senor Organics, a subsidiary of Aurobindo, also pollutes the surroundings by letting their effluents and pollutants into open lands and nallas. An informant with firsthand

experience working on the premises of Unit V revealed that two adjacent independent factories functioned as subcontractors for Aurobindo⁵⁶. This suggests that smaller plants, not featuring the Aurobindo logo, are engaged in work for the company. Such operations potentially form part of the export supply chain, and these smaller entities might be contributing to higher pollution levels, given their lower level of scrutiny compared to larger companies.

A concise enumeration of industries identified as highly polluting in the court orders is mentioned here, by examining the techniques employed by these industries for the release of effluents. Pseudonyms for village names and company identities are not utilized in this context, as these issues are already documented in judicial records, documentaries, and reports. The study exclusively considers sources available in the public domain to analyze how, despite resistance, laws, and court orders, industries manage to persist or, more precisely, perpetuate their strategy of accumulation through the illicit and covert release of effluents. While various industries and villages underwent scrutiny as part of the study, only those explicitly mentioned in publicly available reports like the Nordea Report (2016) and the Vidhi Report (2020) are discussed here. This careful approach is adopted to navigate potential legal issues, especially considering that the matter is currently sub judice.

1. **Aurobindo Unit I:** The CSE (2015) report of Telangana State Pollution Control Board reveals that the unit produces an additional Active Pharmaceutical Ingredient (API) without proper consent. It consumes more water and generates more waste than officially consented. Shortly before the CSE report was published in late 2015, Aurobindo's Unit I received approval from the Ministry of Environment's Expert Appraisal Committee (EAC) to invest Rs. 300 crore (approximately \$40 million) in significantly expanding production (Economic Times, 2015). This expansion raises concerns about the increased pharmaceutical waste that will be generated, how it will be treated, and the quantity and source of water required for production. Village heads said that water will be procured from groundwater and through tankers from suppliers.⁵⁷ Antibiotic APIs currently constitute a significant share of production at

⁵⁶ Field visit to polluted places with supreme court advocate M.C.Mehta in 2015 (see Annexure 1).

⁵⁷ Interviews in 2017 with village head

the Unit I plant, and this is expected to continue in the future as per their vision and goals on their website.⁵⁸

2. **Aurobindo Unit V:** Situated a few hundred meters from Isnapur Lake, Pashamylaram, within the Patancheru industrial area, Aurobindo Unit V is a plant⁵⁹ known for producing drugs for the U.S., holding FDA approval. Effluents are let out in the *gullies* (lanes) directly emanating from the factory premises toward nearby polluted *gullies* leading to the lake. However, it's crucial to note that companies frequently run underground pipes from their sites, which emerge elsewhere in the industrial area and connect to the existing *gullies*.
3. **Aurobindo Unit VIII:** Notably, a large water body lies on the other side of the road from the plant, local informants reported that the lake water is considered polluted. Locals refrain from drinking the water or consuming fish from the lake due to pollution concerns. Fish caught in the lake are sold without disclosing the location to buyers. Additionally, locals report developing skin problems when swimming in the water. In July 2023, following a mass death of fish, the residents resorted to selling the affected fish at the Lingampally market, which is situated in proximity to the industrial area.
4. **Aurobindo Unit IX:** As per the CSE report, Unit IX is found to generate over four times more hazardous waste than permissible limits, and it reportedly treats its waste inappropriately. It is essential to ensure that all units, regardless of their size, adhere to stringent environmental standards, minimizing their collective impact on the surrounding ecosystem and safeguarding the well-being of local communities.
5. **Aurobindo Unit XII, Bachupally:** It is observed at regular visits, an open gully, seemingly emanating from inside the Aurobindo site, through which wastewater was flowing, potentially containing chemical effluent. Bachupally is situated adjacent to the Bollaram industrial area and seamlessly integrates into it. Notably, a gully was observed at the front right corner of the plant, appearing to emanate from inside the

⁵⁸ <https://www.aurobindo.com/about-us/business-units/api> Retrieved on 23-nov-2023

⁵⁹ The term "plant" here is used to denote industry.

site or the space between the site and its neighboring site. While mostly covered, it was open at the point where it joined the main gullies and seemingly contained effluent.

6. **Dr.Reddy's:** Dr. Reddy's Units I and III contribute waste to Patancheru CETP. It is reported that the company is delegating production to smaller units in the vicinity, and the total pharmaceutical manufacturing waste might surpass the quantities produced by its units (Down to Earth- DTE (2015). In November 2015, Dr. Reddy's received a cautionary letter from the U.S. FDA regarding two API manufacturing industries and one formulation industry in Andhra Pradesh and Telangana. The FDA identified multiple violations related to good manufacturing practices at these facilities and strongly recommended that the company promptly and comprehensively assess its global manufacturing operations to ensure compliance with GMP regulations (U.S.FDA, 2015).

During a field visit in monsoon in 2014 September to Dr.Reddy's Units, it was seen that the *gullies* (lanes) around the site were filled with effluents⁶⁰, connecting to various other channels transporting effluent downhill towards a substantial effluent lake at the edge of the industrial area. Dr. Reddy's sustainability report for the years 2013-15 recognizes the essential connection between good health and a clean environment, emphasizing the importance of clean water, air, and soil. The company asserts its dedication to ambitious environmental goals that surpass legal requirements, supported by substantial investments in talent and equipment. Additionally, they claim to conduct regular plant audits to assess performance against these goals and address any identified shortcomings. (Dr.Reddy's 2013-2015) However, the recurrent instances of pollution associated with Dr. Reddy's manufacturing plants raise significant doubts about the company's commitment to environmental responsibility and "Mother Earth.

7. **Hetero Drugs:** Hetero Unit I at Bonthapalle: One of my field respondents informed about boreholes within the plant premises being used for dumping chemical waste.

⁶⁰ Industries release a higher volume of effluents during monsoons as they tend to get diluted and mixed with rainwater.

Stagnant pools resembling chemical effluent and wastewater near the site were observed in 2015, 2017, 2020 and 2023. Local informants guided to the stream originating from the plant that emerges on the other side, forming the observed pools of effluent. From there, the waste infiltrates adjacent farming and grazing lands. The volume of effluent pools notably increases during the monsoon season, resulting in the formation of a lake. An informant who participated in the court case stated that, during the visit to the Hetero premises with members of the pollution control board, they observed large boreholes within the compound into which chemical effluent was being poured. This waste eventually seeps into the groundwater table, spreading into nearby land during the monsoon.⁶¹

8. **Hetero Unit IV (Bonthapalle):** An employee/informant at the plant disclosed the existence of several borehole wells on-site, where chemical effluent is dumped. Pipe openings behind the plant, discharging chemical effluent into the adjoining open land during the monsoon season were observed. The plant has been a constant source of pollution, as reported by local villagers since its inception. A wall behind the plant leads to a wide area that floods during the monsoon, forming a large lake named Nallah kunta (Black pond). An informant revealed that during this period, the plant releases substantial amounts of effluent through wall openings, contaminating the floodplain and mixing with rainwater, polluting the entire lake. Additionally, effluent from the ground seeps from the site and combines with the lake water. One of the plant employees said that there are 15-20 boreholes on-site, ranging from 70-100 feet deep, ostensibly drilled for water supply but allegedly used for waste disposal, seeping into the surrounding subsoil. In 2012, the pollution control board declared the entire Nallah kunta severely contaminated due to leaks from this plant. The company had to remove all the water by tankers, but pollution has persisted annually (Business Standard, 2012) Moreover, the company has expanded its perimeter into the surrounding common land and forest without proper authorization. An informant alleges a commercial interest of the Telangana former Chief Minister, Mr. Chandra Shekha Rao, in the Hetero factories. If true, this might explain the perceived impunity with which Hetero continues to pollute in this village, despite public campaigns and prosecution attempts.

⁶¹ Mallesh, 2015 in group discussion during advocate MC.Mehta's visit

9. **Hetero Unit I (Gaddapotharam):** In 2015, 2020 and 2023, what seemed to be chemical effluent flowing in an open concrete gully adjacent to the plant was observed. The source of this effluent was traced back to the side gates of the site. At this point, a covered pipe within the Hetero plant extended outward and connected to the effluent gully. This pipe was partially exposed just inside the gate, allowing the researcher to witness effluent emerging and joining the main flow. Stirring the effluent with a stick caused it to bubble, indicating a potential chemical reaction.
10. **Cirex Pharmaceuticals Unit** (Cirex is part of the Hetero Group): This unit also engages in inappropriate effluent treatment practices.
11. **Mylan Unit I:** informants convey that, it is plausible that this site conceals the source of its effluent discharge by routing pipes underground and linking to the main gullies elsewhere in the network.
12. **Mylan Unit III:** An open gully, seemingly containing chemical effluent, was observed behind the site, parallel to and adjacent to the perimeter. It was challenging to ascertain whether the gully originated from inside, as it was covered at the junction between the site wall and its entry into the gully at right angles. This gully merges with the network of gullies filled with effluent that runs throughout the industrial area.
13. **Astrix Laboratories Unit** (Astrix is a subsidiary of Mylan) was not visited by the researcher due to a lack of local informants. However, the analysis conducted by CSE includes this unit among the polluting industries.
14. **Neuland I:** In April 2022, there were allegations from a Neuland employee claiming that the company disposes of chemical waste within the site using underground containers sealed at ground level with concrete, which is deemed illegal as containers are required to be above ground for continuous leak inspection. The containers, reportedly covered with concrete, may allow seepage of chemical waste into the ground during the monsoon season.

15. Other industries listed as polluting are- Msn Laboratories, Lee Pharma Ltd, Granules India, Nestor Pharma, Saraca Laboratories Ltd, Covalent Laboratories Pvt Ltd, Virchow Laboratories. The scenario is similar to other industries.

Industrial waste treatment facility

The primary facilities responsible for treating pharmaceutical waste from factories around Patancheru are the Patancheru Common Effluent Treatment Plant (CETP), also known as PETL, and the Jeedimetla CETP. Established in the late 1980s to mid-1990s, these plants, along with the Ramky Hazardous Waste Plant, were part of my field visits from 2015 onwards. The observed evidence indicates a systematic dysfunction characterized by issues such as overcapacity, improper waste processing, and, in some cases, the temporary suspension of operations leading to the discharge of untreated effluent into the local water supply over several days. The establishment of the effluent treatment plants was significantly influenced by local industrialists, and regulatory violations are often treated leniently or with indifference by local authorities. This leniency contributes to the current failures of these plants. For instance, the Jeedimetla plant, around 20 km east of the Patancheru-Bollaram cluster, was initiated by a cooperative society formed by local manufacturers, placing it outside direct state control. The same model was replicated at the Patancheru plant, managed by a private company owned by manufacturers, effectively making the polluters owners of the effluent treatment plants, with the government and pollution control board assuming more of an oversight role⁶².

The Telangana State Pollution Control Board (TSPCB) is tasked with overseeing the Patancheru CETP. However, due to the plant's ownership by the industries it serves and alleged collaboration between PCB officials and companies, monitoring is deficient. Officials are supposed to record the quality and quantity of effluent entering the CETP, but, according to experts like Vijay Gudavarthy and Kankana Das (Personal communication in October 2015), checks are inadequately performed. The responsibilities of the PCB were reduced after the 2010 moratorium was lifted, focusing mainly on inspecting the discharge point at the Amberpet Sewage Treatment Plant (STP) rather than monitoring effluent discharge points at manufacturing plants and the entry to the CETP.

⁶² Personal communication with Mr. Kunchala Chidambaram and Dr. Kishan Rao at their respective residence in 2016.

In 1997, a Supreme Court order led to the construction of an 18-kilometer pipeline connecting the Patancheru CETP to the STP at Amberpet. Despite being Asia's largest, this pipeline project faced opposition from environmental campaigners who viewed it as a way of merely relocating the problem of pharmaceutical waste within Hyderabad. Activists have raised concerns about the pollution incidents spreading to new areas and the Musi River facing increased contamination. Both the Patancheru CETP and the Amberpet STP lack the capacity to remove hazardous compounds, merely diluting the concentration levels of toxic substances. Furthermore, certain manufacturing units are not utilizing the effluent treatment plants, engaging in illegal dumping through tankers or pipes directly from the plants. Despite efforts to regulate tanker visits to CETPs between 6 am and 6 pm, field data and letters written⁶³(See Annexure 5) to regulatory bodies suggest that illegal dumping persists, often occurring late at night. Widespread dumping of effluents at roadsides, open *nallash* (drains), and other water bodies negatively impacts nearby villagers and farmers, contributing to an increase in health problems, including elevated rates of miscarriage among pregnant women. Some pharmaceutical units attempt to distance themselves from illegal dumping, disclaiming liability and attributing blame to agents who supply tankers.

1. Patancheru Common Effluent Treatment Plant (CETP):

Various companies involved in every phase of the production cycle, from the synthesis of intermediates to APIs, utilize the Patancheru CETP, witnessing around 200 tankers carrying effluent entering the facility daily. In 2007, Swedish researchers raised concerns about the Patancheru CETP potentially serving as a reservoir for the proliferation of antibiotic-resistant bacteria. The researchers collected water samples from the plant, which then catered to approximately 90 bulk drug manufacturers in the local area. The samples exhibited the highest concentration of pharmaceuticals recorded in any sampled effluent, with notable levels of broad-spectrum antibiotics, particularly fluoroquinolones like ciprofloxacin, raising alarms about the development of drug-resistant bacteria. The daily discharge load was estimated at approximately 45kg of APIs, equivalent to the total consumption in Sweden (population 9 million) over a typical 5-day period. The researchers highlighted the potential cost of the equivalent amount of the most abundant APIs, emphasizing the significant economic impact (Larsson,2007).

⁶³ Retd Naval officer and Environmentalist, Captain Rama Rao consistently wrote letters to regulatory authorities which has been shared with the researcher.

In a follow-up study in 2009, researchers identified "unprecedented" contamination of surface, ground, and drinking water with pharmaceuticals in the region surrounding the Patancheru plant. They emphasized the urgent environmental concern, stating that elevated levels of broad-spectrum antibiotics could foster the development of highly antibiotic-resistant microorganisms can potentially lead to the horizontal transfer of resistance factors to human pathogens. The use of "activated sludge" containing approximately 20% of raw human feces, known to inevitably contain pathogens, was identified as an exacerbating factor, as close contact between pathogens, resistant bacteria, and antibiotics could facilitate the transfer of resistance to pathogens. The study revealed that a significant number of medicines available in the Swedish market contained APIs originating from Indian producers discharging their effluent to PETL. This finding underscored the "international responsibility" to address the environmental situation in Patancheru, particularly in the context of the global threat posed by the spread of antimicrobial resistance (AMR) (Larsson, 2009).

2. Ramky Hazardous Waste Plant:

This is the only facility designed for treating hazardous waste in Hyderabad. My field visits showed that the effluent seeping from beneath the perimeter wall into the open land behind. An informant highlighted a significant issue with the plant's original design, intended to store the final product sludge waste in containers buried in synthetic-lined pits to prevent seepage, with a planned lifespan of 25 years. However, there has been extensive seepage, and the capacity was exceeded well before the designated time frame due to the influx of hazardous waste from other regions not accounted for in the initial plans. The informant stated that leaking containers are causing seepage into the groundwater and surrounding areas during rain and the monsoon season. While the plant claims to have expanded to meet demand, external inspections are prohibited, and activists assert corruption within the pollution control board, responsible for oversight. Apparent chemical effluent in standing water pools behind the site, just a few feet from the perimeter wall was observed. Additionally, a large hill inside the site, exceeding the wall's height, was identified by the informant as a heap of waste piled above ground. Local people claim that effluents are dumped into nearby streams.

Figure 4.3.



PHARMA WASTE FLOWING OUT OF RAMKY HAZARDOUS WASTE TREATMENT PLANT COMPOUND

3. Jeedimetla Common Effluent Treatment Plant:

During the visit to the Jeedimetla CETP, heavy security measures were encountered, and tankers were observed entering and leaving the site from the public highway. confrontation with security guards, and there was an overall sense of paranoia, with any questions or attempts at documentation perceived as threats, prompting strict security responses and threats of police intervention in 2015.

4. Amberpet Sewage Treatment Plant:

Inputs into the Amberpet plant originate from a closed pipeline directly connected to the Patancheru CETP and the city sewage system, which reportedly contains effluent waste from the Jeedimetla CETP as well. The conditions surrounding these industries remained unaltered during the last visit in July 2023. The attached images will serve as a reference, highlighting that the situation has endured without improvement, particularly in terms of the ongoing malpractices.

The findings underscore the urgency of these plants to address environmental concerns associated with their manufacturing operations and take responsible measures to mitigate pollution. The potential outsourcing to smaller, less scrutinized units in the area adds complexity to the environmental impact of Aurobindo's pharmaceutical production. Swift and

comprehensive action is essential to ensure compliance with environmental regulations and protect the well-being of local communities and ecosystems.

Despite decades of advocacy by local NGOs and legal interventions, the pollution in the vicinity of manufacturing plants has not abated. Regulations targeting the pharmaceutical industry are becoming more lenient as the government removes restrictions on plant expansion and modifies the national pollution index. The Patancheru–Bollaram industrial area, consistently labeled as "critically polluted" by the pollution index since 2009, saw certain health and environmental criteria removed in 2017 (CPCB, 2017), raising concerns that these changes were made to favor polluting industries. Despite the Supreme Court's directive for "zero liquid discharge," mandating effective wastewater treatment and reuse (CPCB, 2016), there have been reported massive violations which are evident in the next section. Due to the diverse chemical compositions of effluents from manufacturing units, achieving zero liquid discharge requires specialized technologies, which are costly. Consequently, industries often clandestinely dispose of effluents directly to PETL or release them into the environment. While the installation of the Patancheru–Amberpet pipeline improved the quality of local rivers around PETL to some extent, the pollution has been transferred to the Musi River, impacting over 100 villages in its drainage basin. The major challenge lies in the inadequate capability of the Amberpet mega sewage treatment plant to handle pharmaceutical effluents with varying chemical compositions, leading to their discharge into the Musi River (CPCB, 2010). Nordea report (2016) revealed antibiotic concentrations in the Musi River that were 1000 times higher than typical levels in rivers in developed countries (Gothwal, 2016).

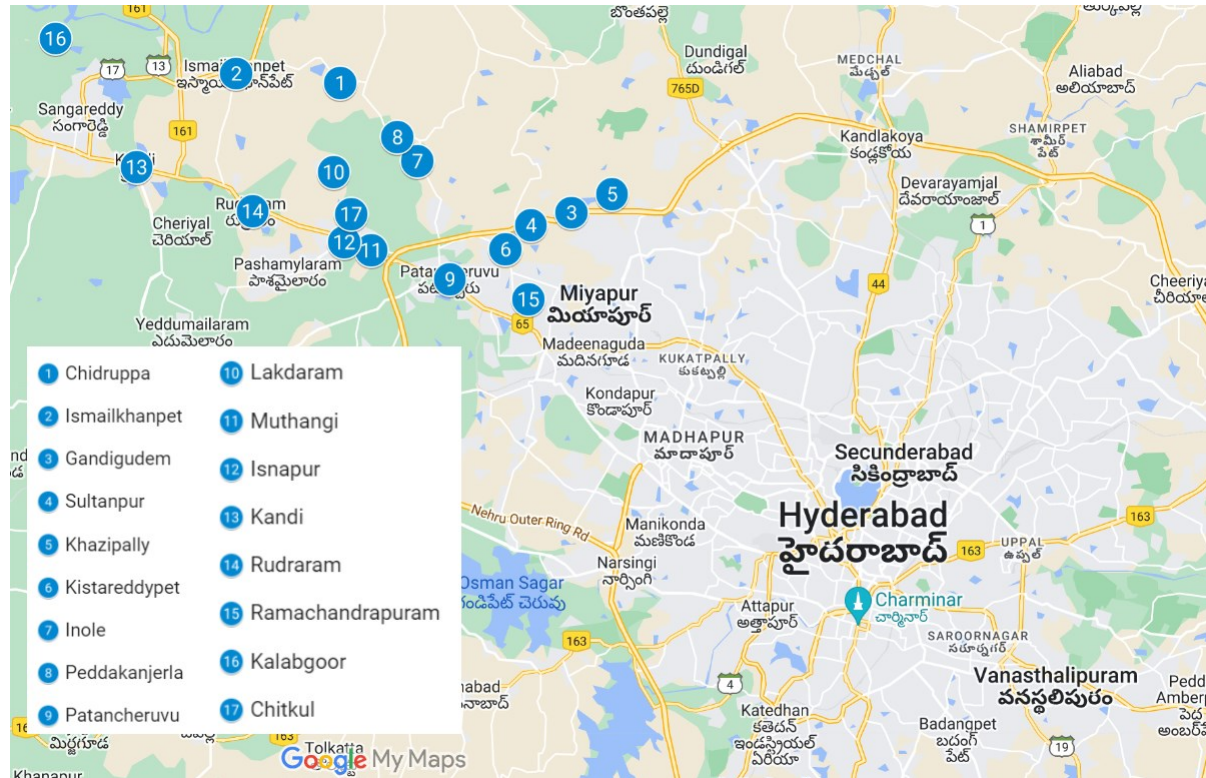
Section III

Toxic Shadows: Villages Battling the Environmental Fallout of Industries

As per court orders, Arutla, Baithole, Chidruppa, Ismailkhanpet, Gandigudem, Sulthanpur Khazipalli Kistasreddypet, Inole, Peddakanjarla, Patancheru, Lakdaram, Muthanghi, Isnapur, Kandi, Rudraram, Ramachandrapuram, Kalabgoor, Chitkul, Pocharam all of it is in the industrial Patancheru-Bollarum industrial zone hosting pharmaceuticals and bulk drug manufacturing units (see Map 4.1). Furthermore, there are several villages located along

streams carrying pollutants. (Gudavarthy,2012). Problems in all the villages are similar- Few of them are highlighted below.

Map 4.1. Pollution Affected Villages



Source: Google Maps

1. At Chinna Vagu, Chaitanya Nagar Colony

Presence of chemical effluent was observed streaming along an open nallah originating from the Patancheru industrial area. Although designated as a general water/sewage channel, the stream's surface was covered in thick white froth, accompanied by a strong chemical odor. Adjacent to the mainstream, a small pond had formed, where farmers were employing plastic hose pipes to transfer water, heavily contaminated with chemicals, to adjacent land where guava and other fruits and vegetables were cultivated. In the pond, catfish were observed, deemed the sole species capable of surviving in such polluted water and subsequently caught and sold for human consumption. The Chinna Vagu nallah contributes to the broader network of sewage system channels, theoretically intended for sewage treatment (excluding chemical waste) at Amberpet STP before discharge into the Musi River.

2. Isnapur Lake in Pashamylaram

Across all the seasons, the lake held a significant volume of water, all stemming from waste entering through open nallahs from the industrial area. Observable chemical effluent was seen flowing into the lake, creating thick crusts in some areas and exhibiting apparent chemical reactions beneath the surface. The lake bed was covered in a deep layer of black tarry sediment, extending to considerable depths emitting an obnoxious odor which is intolerable. A local cattle herder in the vicinity reported that buffaloes brought for grazing in the area suffer from illnesses and fatalities due to drinking the contaminated water or consuming the polluted grass. Instances of cattle deaths date back to the early 90s and persist into the late 2020s. Seeking compensation for these losses has become a herculean and bureaucratic task, often avoided by the cattle herders. The process involves government veterinary doctors conducting tests and providing reports, a time-consuming and effort-intensive endeavor. Farmers persist in bringing animals for grazing despite the risks, given the forceful acquisition of their agricultural land for development, leaving them with diminishing public grazing spaces and a reliance on whatever is available, even if contaminated.

Figure 4.4. Cattle death in 2020 due to consuming effluent water



3. Gaddapotharam

It poses a significant concern, with *nallahs* (drains) from its industrial area, housing numerous pharmaceutical companies without an on-site CETP, merging into an existing irrigation system. The network of gullies originating from various factories on the site is interconnected, leading in one direction towards an expansive, now desiccated lakebed emitting a strong chemical odor, with apparent chemical salt formations on its surface. In the opposite direction, these *gullies* (lanes) converge and discharge into an open concrete well, constructed around 2005, approximately 25 feet deep, filled with effluent. Due to a continuous influx of effluent from the entire Gaddapotharam industrial area, the excess is channeled through a side channel, flowing robustly down an open nallah into the broad valley below. An informant revealed that the well was officially constructed under the Model Industry Association's guidance, although it is illegal to collect untreated chemical effluent in open tanks. During the rainy season, the well overflows, incorporating more effluent into the existing flow toward the valley.

4. Kazipally village

The Kazipally lakebed exhibited crusted chemical salts and rust-colored deposits on granite boulders. Below the surface crust, digging with a stick revealed thick black tarry sediment, reaching depths of up to 200 feet, as indicated by the informant. The extensive irrigation system, along with the surrounding water table and fields, has been significantly contaminated with industrial effluent for decades, exacerbated by the growth of the pharmaceutical industry in the region. Villagers are unable to consume water from the lake, wells, or even the bore well intended for safe drinking water. Limited weekly access to municipal water from the Manjeera river via a pipeline is provided, but it is primarily intended for urban Hyderabad, faces pressure constraints, and cannot be allocated in substantial quantities. Notably, the area was classified as "critically polluted" on the Central Environment Pollution Index (CEPI) assessed by the Central Pollution Control Board (CPCB) until the early 2000s. It was de-notified around 2009 when its overall score fell below 70, then re-notified in 2013 when the score rose to 76, coinciding with a significant increase in pharmaceutical pollution in the industrial area.

Despite herds of buffalo and goats grazing in the vicinity, the toxic soil severely hampers agricultural productivity. Village informants shared a multitude of severe health issues, such as miscarriages, skin disorders, cancers, and intestinal problems among women. Livestock, particularly goats, experience frequent miscarriages due to the consumption of contaminated grass. Kazipally village reportedly faces challenges in cultivating anything safe for human consumption.

5. Bonthapalle and Domudugu

Village locals refrain from consuming locally grown food due to high pollution levels, leading to various health problems like miscarriages, cancers, and livestock deaths. The village well is contaminated and rendered unusable, forcing residents to dig a bore well at a considerable distance for drinking water. Bore wells in the area reveal the release of effluents, signaling widespread groundwater contamination. The once-reliable source of groundwater has now become a carrier of pollutants from the industrial activities in the region. This poses a significant threat to the local residents who depend on bore wells for their water needs. The contamination of groundwater not only jeopardizes the drinking water supply but also has far-reaching consequences for agriculture and other essential activities in the affected villages. As the community grapples with the visible effects on the surface water and the challenges of seeking compensation for livestock losses, the compromised groundwater further intensifies the environmental crisis.

Figure 4.5. Effluents released directly into the water streams



Figure 4.6. Contaminated groundwater from a borewell in one of the study villages



In 2017, Changing Markets Foundation sampled water from this borewell and found 10,900 micrograms/liter of hexavalent chromium which is beyond the maximum level of 50 micrograms/liter according to the WHO guideline. Villagers have stopped using this water for agricultural irrigation.

Despite assurances during land purchase, no locals are employed at the Hetero factory, and villagers who complain face threats from local police colluding with plant owners. The plant receives a significant number of tankers daily, yet only a minimal amount of wastewater is transported to the CETP, raising concerns about the unaccounted-for discrepancy. Effluent pollution reportedly leaks into privately owned land between Hetero I and Horner Labs, with the landowner refraining from action due to a business arrangement with the companies.

6. Edulabad Village

Residents have faced extensive pollution, livelihood destruction in fishing and farming, and significant health issues. Fish in the village tank regularly perish when chemical effluent enters the water body beyond the tolerable limits. Local government Veterinary doctor revealed that buffaloes no longer mate naturally and require costly artificial insemination, often taking 3-4 attempts for success. The resulting milk fetches a minimal price due to its unpleasant odor, with animals yielding as little as 3 liters, significantly below the norm of 10 liters. Other livestock face health issues stemming from contaminated water and feed. Health problems are widespread, with children experiencing eyesight issues, individuals of various ages suffering from joint pains and skin diseases, and both humans and animals facing frequent episodes of diarrhea.

Toxic chemical in Gandigudem lake, don't eat or sell fish, warn officials

Role Of Local Politician Also Being Probed

U.Sadhakarreddy
@timesgroup.com

Hyderabad: Traces of chloromethane, a solvent used in the pharma industry that triggers neurological and reproductive ill-effects in humans, was found in the samples analysed from Gandigudem Lake near Kasipally industrial area that saw death of lakhs of fish after heavy rain on October 3.

"On Saturday, we received results of 10 of the 72 samples collected. They contained chloromethane, an industrial solvent used in pharma companies. The diluted traces of the chemical in the lake confirm contamination. As the lake is huge with a spread of 300 acres, dilution occurs quickly," Telangana State Pollution Control Board (TSPCB) member secretary P. Satyanarayana Reddy told TOI.

The Telangana fisheries department advised fisheries cooperative societies of Gandigudem lake and Gaddapoti

TOI EXCLUSIVE

Officials dispute ₹10cr loss claim

The claim of the fishermen societies that fish worth nearly ₹10 crore were destroyed due to the contamination in Gandigudem and Gaddapoti lakes was disputed by state authorities. "Over 100 tonnes of fish weighing between 300gm and 5kg were killed. That amounts to a loss of ₹10 and not ₹100," said Sangareddy district fisheries officer G. Sujata.

human lakes not to sell or consume the leftover fish. "Fish from tanks with mass mortality shall not be consumed. In polluted tanks, there could be heavy metals in the fish and when they are consumed, it automatically affects humans," V. Srinivas, deputy director of the department, said.

On Saturday, fisheries commissioner C. Sivaramaiah held a video conference with all dis-

DANGER IN THE WATER

Here's the lowdown on chloromethane that has been found in the water in Gandigudem lake near Kasipally

Also known as Methyl chloride or Refrigerant-40

WHAT IS IT?
A hydrocarbon used as industrial solvent. It has been used as aerosol propellant, a refrigerant and even as local anesthetic. Its use as refrigerant was discontinued due to its toxicity and flammability. Low levels of methyl chloride occur naturally in the environment.

WHAT DOES IT LOOK LIKE?
Colorless gas with a faint sweet odour.
Shipped as a liquid under its vapor pressure.
A leak may either be liquid or vapor.
Easily ignited.

USES
Manufacture of active pharmaceutical ingredients by bulk drug industries.
Dichloromethane (Methylene dichloride) used in pharma companies.

HARMFUL EFFECTS
Acute short-term exposure to high concentrations of methyl chloride can cause severe neurological effects in humans.
It affects heart rate, blood pressure, liver and kidneys.
Causes drowsiness, dizziness, confusion and difficulty breathing, walking or speaking.

Sangareddy Kasipally lake, Isapur lake and Kistaredipet tank, said Sangareddy district fisheries officer G. Sujata. PCB gave a report that these three tanks have high level of organophosphoric pollution. Village revenue officers have labelled seven other lakes under the jurisdiction of local panchayats as contaminated. In all, we are steering clear of these 10 tanks," she said.



On Saturday, the PCB officials continued collecting samples, an exercise it commenced on October 2. Satyanarayana Reddy told TOI, "All 13 companies who were issued notices were found erring. When PCB environmental engineers inspected the industries, there were discharges from the plants into the drains. Those companies named in the FIR but not in the notice

Residents complain of air pollution too

Residents of colonies on the Outer Ring Road and in Ameerpur, Bachupally and Miyapur have been filing complaints with Pollution Control Board for the past one week regarding air pollution from pharma firms.

Satish Javala, resident of Sunway Opus Grand Neville, told TOI, "Several colonies like Salarnurg Colony, Kauhahya Colony and gated communities like Opus Grand, Mahavilas, Empire Meadows, Prime Meadows and Maytas Hill County in and around Ameerpur are facing severe air pollution. For the past seven days, we are getting foul smell like a rotten egg from around 4.30pm to 7pm. We are forced to stay indoors."

Others alleged the stink lasts for 6-7 hours. "Whenever we complain on toll-free number, PCB officials check the pollution with meters, but no action has been taken so far," said Tarun Bhattacharya.

Sangareddy environmental engineer Bhadra Girish said, "We received complaints from gated communities near ORR. Usually, this situation occurs when scrubbers controlling release of pollutants fail. The smell persists till the factory rectifies the error." **TOI**

USA has classified chloromethane as a Group D carcinogen. Research on mice has shown that it causes cancer, but it has not been proved scientifically that it causes cancers in humans. The chemical causes sterility and fertility issues both in men and women as well as gynaecological problems in the latter.

Dr N. Jaya Latha (DIRECTOR, HSE, MINISTRY OF INDUSTRY, HYDERABAD)

Source: Times of India (2017, October 8)

Crossing the Musi River downstream in 2015, a new bridge under construction about 40 feet (12 meters) higher than the existing one. This construction is necessitated by the piles of white foam, a chemical pollutant, reaching 10-20 feet (3-6 meters) higher than the river at times, obscuring the visibility of the existing road bridge and resulting in fatal accidents.

7. Peddakanjeerla Village

Local informants demonstrated skin conditions caused by working in the water in their paddy fields, where the water table is entirely contaminated, affecting the crops. The village relies on tanker-delivered drinking water, incurring costs for its supply. The Tankers, observed by a farmer are regularly seen illegally dumping into the river, bypassing the CETP. Attempts by farmers to address this issue with the police proved futile, as the drivers were released, and the farmers faced threats. In addition to pollution entering the sewage system, numerous informants report widespread tanker dumping at roadsides, into open nallahs, and other water bodies. A doctor informed about numerous cases directly linked to chemical pollution, including menstrual problems, miscarriages, low fertility, birth abnormalities, organ failures, skin problems, high levels of heavy metals present in the breast milk of mothers, fluoride poisoning causing bone defects, and various other illnesses.

Local NGOs and activists addressing these environmental issues face challenges when communicating these problems and mobilizing villagers. Industries employ private security firms to intimidate villagers attempting to hold them accountable for pollution, and the police appear complicit, as per multiple firsthand accounts. Overall, the impression from interlocutors is pessimistic, the manipulation or disregard of regulatory legislation by the industry in pursuit of profit-driven production is likely to be overlooked or tolerated. Dr. Krishna Rao, an 82-year-old doctor turned environmentalist, and his friend in the cause, Chidambaram Kunchala, fought for more than three decades before the latter's passing in 2020. He has witnessed the calamity unfold over decades, with once-fertile land turning infertile and water pollution reaching depths of 145 feet, the consequences include dire health outcomes and even a village where no children are being born due to repeated miscarriages.

The transformation of Hyderabad into a bulk drug capital has been a consequential outcome of industrial growth and development, particularly driven by the contributions of neighboring villages or rural areas. However, this development has raised not only ethical concerns, but

basic livelihood, health, and well-being especially when considering the impact on the environment and the health of the local population. The prevailing evidence suggests that the urban-centric models of spatial development in India have often failed to extend the benefits of development to rural areas. This disparity is reflected in the wide gaps in demographic, functional, and spatial aspects, hindering the equitable distribution of developmental inputs to rural regions. Vital services crucial for rural well-being, such as education, healthcare, transportation, communication, trade, agricultural supplies, retail services, and veterinary services, are concentrated in urban areas, rendering them inaccessible to rural populations. Consequently, the benefits of a burgeoning metropolitan economy often elude the rural areas.

Amidst these challenges, the court-issued directives, though seemingly relieving on paper, are marred by discrepancies revealed in field studies. The compliance reported by the Pollution Control Boards appears to be manipulated, with periodic submissions portraying industries as compliant, contrary to the non-compliance witnessed by researchers on the ground.

Technologies of Power: Court Directives - Contradictions Exposed

The National Green Tribunal Directives stem from decades of petitions and sustained activism by villagers and advocates, underscoring ongoing struggles against powerful industries and supportive state entities. However, the effectiveness of the directives depends on their implementation by the state, which is lacking in this case, revealing a nexus between the state and industries prioritizing profit over the health of the villagers. In the National Green Tribunal (NGT) order delivered by Justice Dr. P. Jyothimani on 24 October 2017, numerous critical concerns raised by the affected parties have been given due consideration, highlighting the persistent challenges faced by the victims. Drawing upon this pivotal order, this thesis endeavors to comprehend regulatory capture, the *techniques* and *technologies of power*⁶⁴ by investigating the extent to which the stipulated directives have been adhered to. The exploration further aims to delve into the perspectives of the affected community. This investigative journey, initiated in 2013 and spurred by the directive in 2017, illuminates a stark reality where prescribed measures are not consistently followed but are instead often reported as adhered to. The intention is to bring to light the practical implementation, or lack

⁶⁴ For details refer- Behrent, M. C. (2013). Foucault and Technology. *History and Technology*, 29(1), 54-104. <https://doi.org/10.1080/07341512.2013.780351>

thereof, of the mandated measures. This thesis serves as a platform to amplify the voices of those adversely impacted, providing a comprehensive analysis of the gap between stated adherence and actual implementation by examining these directives-

Direction No.1:

"[B]y impleadment of various respondents during the pendency before the Tribunal after transfer from the High Court it does not affect either by the principle of res judicata or dominus litis, as the proceedings ever since initiated in the Hon'ble Supreme Court, has continued throughout While 'transferred to the Hon'ble High Court of Andhra Pradesh and thereafter to this Tribunal and therefore there is no question of introduction of any fresh cause of action or any of the reliefs either barred by limitation or struck by delay or laches".

Principles of Delay and Laches: The doctrine of 'Delay or Laches' is a fundamental principle rooted in equity, emphasizing that justice aids those who are vigilant in asserting their rights. The villagers vocalize their frustration over the prolonged delays in the execution of court orders. The absence of fair and prompt justice is underscored, suggesting a perceived collaboration between the state and industries that prioritizes financial gains over the welfare of the affected community. The protracted legal proceedings place a considerable financial burden on the complainants/petitioners, especially given the substantial distance between the tribunal in Chennai and the villagers location in Hyderabad—approximately 688 kilometers apart. The villagers, overwhelmed by the distance and the sluggish pace of judicial procedures, have reluctantly ceased attending court sessions.

Direction No. 2:

"The transport of treated effluents from CETP for 18 KM to Amberpet STP for dilution and thereafter letting into Musi River need not be interfered at this stage and there is no violation of Hazardous Waste Rules or Basel Convention".

This directive is regarding Regulation of Hazardous Waste Management: The directive says that there is nothing to interfere about this aspect as the industry is compliant based on the

report submitted by the TSPCB. The victims question the efficacy of state authorities' reports claiming compliance with regulations. Field visits and the images annexed show that the effluents are openly let into drains and are clearly visible.

The Sarpanch (village head) of Isnapur village expresses her concerns, questioning, "[W]ho determines that regulations are not being violated? Can we unquestionably accept the PCB report claiming compliance as the ultimate verdict?" She urges the NGT counsel to visit their villages during the night and assess the air's toxicity firsthand. Recounting distressing incidents she has encountered in her village, she vividly describes how children woke up crying due to a burning sensation in their noses and throat constriction. Expressing frustration with the delayed response from the pollution control board, she shares, "[U]nable to endure the smell, we approached the company directly, questioning its staff and documenting the situation through photos and videos." With a sense of urgency, she paints a vivid picture, stating, "The entire village was engulfed in gases released by these industries, creating an atmosphere akin to a dense fog." Highlighting the evident predicament, she questions why complaints are only acknowledged over the phone, and by morning, authorities claim that everything is clear. In a tone of desperation, she asks, "How can we substantiate our suffering? Why are we burdened with the responsibility of providing evidence to courts to prove that the compliance of waste management is not followed when we are already enduring the consequences?" Concluding with a plea, she questions, "In the middle of the night, where can we relocate our children for safety?" (Sarpanch, Isnapur Village, in Jan 2020).

Direction No.3: A. Restoration of water bodies:

"Even after the passage of decades there is no significant improvement in the groundwater quality particularly in the I Manjira River Basin with specific reference to Kazipally Lake, Isnapur Lake, 'Kistareddypet Lake and Gandigudem Lake which ultimately lead to Nakkavagu and therefore it is incumbent on the part of the State Government to completely restore all these water bodies to their original position and recover the entire cost from the industrial units proportionately".

The court has officially recognized the lakes for restoration, and the periodic reports submitted by the TSPCB to NGT assert that there has been successful restoration, with zero

discharge. However, a starkly contrasting narrative emerges when one examines the images depicting the current state of these water bodies. The villagers raised a question: "If there is truly zero discharge, then what is the source of the persistent filth and chemical odor that envelops our surroundings? Who is responsible for contaminating our lakes, and when can we expect genuine restoration efforts?" Their lament echoes the harsh reality of daily life: "Visitors to Isnapur Lake, Gaddapotharam Lake, and Kazipally Lake are immediately struck by nausea, a noxious experience that has become a constant in our lives. We implore the judiciary to conduct surprise visits to these locations without prior notification to bureaucrats, unveiling the harsh truth of our existence—a life marred by the neglect of authorities and the avarice of companies."

The plea is clear: all the water bodies remain contaminated, and without swift intervention, this contamination is poised to persist. The photos annexed captured at different time intervals offer a visual testament to the current state, with a somber note that the situation worsens during the monsoons. It is a call for immediate action, emphasizing the urgency of addressing the dire conditions faced by the affected communities, who endure the consequences of environmental negligence and corporate interests.

Restriction on the extraction of groundwater by industrial units & framing of appropriate guidelines by the Government:

"Until complete restoration of the said tanks / lakes is done, the drawal of water by the industries shall be restricted by the Government by framing appropriate guidelines in consultation with the Central Groundwater Authority and Expert from Osmania University, particularly Department of Hydrology. Framing of such guidelines regarding extraction of groundwater by the industrial units of Patancheru and Bollaram shall be completed within a period of three months and till then no unit shall be permitted to extract groundwater and the periodical report shall be filed by the State of Telangana to the Registry of NGT (SZ) once in six months, the first of such report shall be filed on or before 26th April, 2018 and the Registry shall place the said report before the Tribunal for passing appropriate direction".

In the reports regularly submitted to the National Green Tribunal (NGT), the industries claim compliance with regulations, yet direct observations paint a different picture. While the reports assert the installation of surveillance cameras that are purportedly continuously monitored, on-the-ground assessments reveal a stark contrast – many of these cameras are non-operational. This discrepancy raises questions about the accuracy and transparency of the information presented in the periodic reports. It underscores the importance of independent and thorough assessments to ensure that the reported measures and systems are genuinely in place and functioning as intended, as opposed to being merely stated on paper.

Direction No.4:

“The arrangement of supply of drinking water of adequate quality and quantity to the Villages... shall be continued by the State Government which shall be entitled to recover the cost thereof from the industrial units proportionately. The said activity shall be done by the Government through the Hyderabad Metropolitan Water Supply and Sewerage Board until complete restoration of the lakes”.

During the visits to the villages, from 2013 to 2023 it has been observed that not a single village was found to have its own safe drinking water supply; all relied on purchasing water from tankers or alternative sources. This scarcity of safe water has adverse effects on agriculture. Pharmaceutical companies appear to operate with near-total impunity, repeatedly polluting despite community efforts to take action.

One of the residents in Kazipally village says “The official records in the panchayat office may indicate that our village receives an allocated water supply, but the harsh truth is that we are compelled to purchase water. When authorities come for inspections, they often confine their assessments to the panchayat office or households that maintain favorable relations with the local administration. Inevitably, the reports generated from these visits paint a picture of water adequacy and reliability that sharply contrasts with the daily struggles faced by us”.

Direction No. 5: Periodical status report to be filed "The shortcoming pointed out by the report of CAG of March, 2014 shall be rectified and periodical status report filed".

The status reports presented to the courts by pollution control boards, and industries appear to be nothing more than mere eyewash. A substantial gap exists between what is documented on paper and the actual ground reality. Prof Purushotham Reddy states

“Without the active involvement of ethical environmentalists and local communities in the assessment and reporting processes, there remains a significant risk of data manipulation—a deceptive practice that undermines the integrity of the information presented to the judiciary. The call for genuine transparency and accountability underscores the need for unbiased, community-driven assessments to ensure that reports accurately reflect the true environmental conditions. Without such measures, the potential for misinformation persists, hindering the effectiveness of judicial proceedings and obstructing meaningful efforts towards environmental conservation and restoration” (Personal communication on Nov 14th, 2019).

Direction Nos. 6, 7 & 8: Entitlement of Compensation-

Between 1986–1987 and 2001–2002, a directive was issued entitling villagers to compensation at the rate of Rs. 1,000 per acre per annum for dry land and Rs. 1,700 per acre per annum for wet agricultural land. Despite this order, not all of them have received the complete promised compensation. Villagers who were yet to get compensation said, “Our lands continue to remain contaminated, and the assurances made during the establishment of industries, pledging employment opportunities for the local populace, have not materialized. The reality is that very few local residents are hired, with the majority of the workforce being brought in from other states. Moreover, these workers, along with us, are experiencing adverse health effects due to their employment in the industries. The consequences of this negligence extend beyond our barren lands; we witness the alarming frequency of deaths among cattle, fish, dogs, peacocks, and various bird species, all of which have been attributed to the consumption of polluted water. The gravity of our situation is compounded by the fact that, in addition to the losses we have already endured, we are now burdened with the responsibility and expenses of proving that these animal deaths result from drinking contaminated water. This includes the cumbersome process of engaging with government veterinarians for verification and follow-up. The cumulative impact on both our livelihoods

and the well-being of our environment demands urgent attention and redressal from the concerned authorities” (Group discussion, Kazipally Village, 2022)⁶⁵.

Direction No. 9: Expert Committee on Health Studies:

“The said committee shall be constituted by the State Government within a period of two weeks from the date of receipt of copy of this judgment and the committee shall be directed to submit its report within three months thereafter and recommendations of the committee shall be implemented by the Government and status report regarding implementation to be filed periodically before this Tribunal once in six months. The report of the committee and the status of implementation shall also be placed in the public 25 domain by uploading on the website of the Director of Medical Education and Health and Family Welfare Department of Government of Telangana”.

Expert committee has to recommend on the following;

“(i) As to whether the health hazard of the people living in the area due to the industrial pollution continues and if so, what relief should be granted? (ii) Whether the activities of the pharmaceutical industries have led to Antimicrobial Resistance to drugs and if so, what are the consequences on the health of the people and the remedial measures to be taken? (iii) A broad Epidemiological and Genetic Study and survey to be made including remedial measures to be taken.”

There has been a noticeable surge in health issues, encompassing skin allergies, respiratory ailments, carcinogenic problems, and particularly alarming rise in Antimicrobial Resistance (AMR). Although establishing direct evidence linking AMR to pollution and the release of antibiotics into water bodies may be challenging, the undeniable reality is that a significant number of antibiotics are proving ineffective. Dr. Dayakar Reddy, Director of Dr. Ram Reddy Memorial Hospital, Patancheru emphasizes the looming specter of drug resistance in the industrial township in 2019. He says “patients frequently present with challenging skin problems, where standard medications often prove ineffective, thereby referring the patients to super specialty hospitals in Hyderabad”.

⁶⁵ The narratives were the same in other villages too.

Direction No. 10: Establishment of Super Specialty Hospital:

As of July 2023, the court-mandated establishment of the hospital is still pending, and the promised detoxification centers are yet to materialize. This delay has left the community without essential healthcare infrastructure. The absence of proper primary healthcare facilities, let alone super-specialty hospitals, has forced villagers to endure long journeys for any necessary diagnosis or treatment. In many villages, the healthcare provision is limited to Asha workers and a nurse, focusing predominantly on the reproductive age group and providing medication only when stocks are available. The inadequacy of these services compels residents to resort to private healthcare facilities for essential tests, further exacerbated by the lack of accessible and well-equipped public sector hospitals.

Direction Nos. 11 & 13: Establishment of Corpus Fund and Relief Fund: The researcher, unfortunately, lacked access to verify the progress in this direction, even though the periodic report asserts the initiation of follow-up actions. Setting up of corpus fund and relief. The researcher had no access to check on this direction although the periodical report claims to have taken up follow-up action.

Direction No. 12: "All the existing units shall have their primary effluent treatment system inside the unit, whether they are members of CETP or not and the same has to be scrupulously enforced by the Regulatory Authority".

Due to the lack of permission to enter the premises of the industries, it remains unknown whether this directive has been complied with or not. However, despite this direction effluents are being constantly released.

Direction No. 14: "At present there is no necessity for any direction against any of the units to pay any amount under 'polluter pays' principle (PPP) except leaving it to the authority to invoke the same in appropriate cases".

Tracking the facts becomes challenging as this directive operates between regulatory bodies and the industry. However, the Polluter Pays Principle is imperative for committees and lawmakers to recognize that anything hazardous should be strictly prohibited, regardless of the level. The grievances that originated in 1989 persist, and the issues raised then remain

largely unchanged. However, the tactics employed by polluting industries have evolved. Presently, these industries assert zero discharge, evading compensation responsibilities, and government agents often provide reports supporting these claims. This leaves us to grapple with the repercussions of the illegal and unethical practices implemented by the industries. Speaking out against these practices necessitates burdening ourselves with the responsibility to prove their existence. It is crucial that the funds collected from industries are managed transparently, with consideration for the concerns of locals and environmentalists. Activists assert that state agents, driven by personal interests, continue to mask information, underscoring the need for increased accountability and transparency in environmental governance.

Direction No. 15: "On the factual matrix of the case, there is no necessity for appointment of any permanent authority by the Central Government by invoking powers under Section 3 of the Environment (Protection) Act, 1986. However, it is open to the Central Government to appoint any such authority for supervising and implementing various directions given in the judgment since the directions are already existing directions from various authorities and are continuing the process". This directive amounts to a clear relaxation granted to the industry, leading to lax standards.

Direction No. 16: "CSR of the units as governed under the Companies Act, 2013 are independent of various directions contained in this judgment including setting up of a Super Speciality Hospital, amounts to be contributed for restoration etc".

Captain Rama Rao (2019) emphasized that Corporate Social Responsibility (CSR) should be subject to monitoring rather than being solely at the free will of the company. Notably, this aspect was not included in the study.

Regulatory authorities, in their periodic reports, assert industry compliance and zero discharge, contradicting visible evidence apparent even without technical expertise. Despite the observable realities, the reports consistently favor the industry instead of presenting the factual state of affairs. This pattern raises concerns about regulatory capture and also the different techniques adopted by the industry and the state, illustrating the reciprocal

relationship between power and knowledge. (Behrent, 2013) describes discourse as the location where power and knowledge intersect which is discussed in the last section.

SECTION IV: Concerns of Residents in Industrial Zones

The situation in the villages surrounding industrial areas in Hyderabad presents a grim reality, with communities enduring pollution for over forty years, tracing back to the initiation of heavy industry in 1980. The pharmaceutical industry has contributed to the escalating pollution crisis, as evidenced by steadily increasing pollution index readings, coinciding with the booming bulk drug industry in the region. This study conducted based on court documents, shed light on the significant impact of health issues, and dual challenges within these communities. Most of the villagers belong to lower-income groups. There is a significant health-related debt that is on the rise, signaling a pressing need for improved healthcare accessibility, affordability, or support mechanisms in these villages. Additionally, the distribution of income levels emphasizes the economic disparities within the community, shedding light on potential areas for intervention and support to uplift the financial well-being of the residents.

Villagers in the group discussions state that the Right to clean air is not an optional policy objective. It's a fundamental human right. That billions of people today are breathing dirty, deadly air constitutes a global health, environmental, and human rights crisis. While this is the general trend across the globe- the villagers in this industrial zone are at double risk and double burdened. Among the victims, spanning across generations from the elderly to the youth and children, narratives detail the profound impact on their lives, ranging from compromised health to sleepless nights attributed to the toxic air they are forced to breathe.

The establishment of industries brought with it the expectation of employment opportunities, yet this hope remains unfulfilled. The local residents not only find themselves without job prospects but also grapple with infertile lands affecting their main source of livelihood. The very air they breathe poses health risks, resulting in high out-of-pocket expenditures and accumulating debts. Even the migrants brought in from other states to work in these industries are not immune, experiencing adverse health effects as a consequence of their labor.

Srinivas, a resident of Gaddapotharam, reached out to the researcher (G. Srinivas, telecommunication, April 8, 2022, around 10 pm), expressing concern about his two young children and neighboring kids suffering from persistent coughing and a sense of choking. The issue was attributed to airborne pollutants released by nearby industries during the night. Despite making multiple attempts to contact the pollution control board, no assistance was provided. In response to the situation, villagers tracked down the responsible industry during the night and confronted them. As tensions escalated, the industry ceased its pollutant release. This has become a recurring scenario, with industries often choosing to discharge pollutants and effluents during the night, especially during monsoons. The residents recount their struggle, venturing into the industry themselves, capturing visual evidence of the pervasive gases, and sharing their ordeal. They emphasize the disparity between official reports declaring compliance and the harsh reality faced by the community, urging authorities to acknowledge their suffering without imposing the burden of providing evidence. The victims plea for justice, questioning the sustainability of enduring such hardships and whether their cries will ever be truly heard and addressed.

A poignant moment occurred when a young girl named Fathima, observing the researcher covering her nose to avoid the noxious odor, remarked, *"Akka (sister), if you are unable to endure wearing a mask for a few hours, just imagine how we are living here"* (Urla Aarthi, Personal communication, Isnapur Lake on July 5th 2018). The narratives from these regions tell a story of pervasive health issues, including respiratory disorders, cancers, congenital problems, chronic depression, and reproductive challenges. The industries in the region, however, have been negligent in sharing information about pollutants and their effects with local residents, authorities, and healthcare professionals, violating the Factories Act and Rules under the Environment Protection Act 1986. A few case studies are presented below:

Kanthamma, a 60-year-old resident of Pocharam, shares her distress, citing skin diseases, stomach pains, arthritis, and tumors in the stomach. The air carries industry-released smoke, causing frequent headaches. The fight against the government resulted in sanctioned money for affected lands. In another household, one-and-a-half-year-old Kumar battles vomiting and diarrhea, while 25-year-old Pentaiah suffers from stomach pain and breathlessness. Nanaiah, a 55-year-old from Pocharam, emphasizes the dire situation, stating that stopping the supply of drinking water would worsen conditions. He grapples with severe cough, vision loss,

swollen legs, and arthritis. His son Anthaiah, employed in one of the companies,' shares similar afflictions.

Dr. Kishan Rao, a private medical practitioner and activist, describes the indiscriminate dumping of chemicals, painting a bleak picture of villagers suffering silently for three decades. He recounts heartbreaking cases— a blue baby, a blind child, a disabled girl due to congenital anomalies, and a young lady losing 11 pregnancies. Rao notes that 80% of the people are afflicted with multi-toxic syndrome, emphasizing the medical fraternity's inability to halt or cure these toxic impacts on the community's well-being. Despite this, the response from both the central government and state authorities has been notably inadequate, if not complicit. Drug manufacturers have been allowed to discharge substantial amounts of untreated or inadequately treated pharmaceutical waste into the environment without restraint.⁶⁶ Residents living and working near drug manufacturing units have borne the brunt of these environmental hazards. The consequences extend to their livelihoods, evident in livestock deaths and diminished agricultural yields. Additionally, detrimental effects on health include higher abortion rates, birth defects, stunted growth in children, and an increased incidence of skin diseases⁶⁷.

The predominant section of the population in the region comprised traditional farmers, fishermen, washermen, and agricultural laborers cultivating a variety of crops such as jowar, paddy, groundnut, chilies, tomato, cotton, and wheat. The onset of aggressive industrialization led to a significant shift, with many transitioning to jobs in industries or indirectly associated roles. Paradoxically, while the industrial estates in Patancheru were established to spur development and job creation, they ended up displacing over 30,000 people, predominantly farmers, due to groundwater pollution (Green Peace, 2004). Although around 250 industries were set up, intended to provide approximately 25,000 jobs initially, the adverse impact on the livelihoods of the local population was severe. The deliberate disposal of industrial waste into nearby lands and water bodies has taken a toll on the Nakkavagu stream, which bears the burden of waste from industries in the Patancheru industrial estate (Green Peace, 2004). Presently, a significant number of farmers are compelled to sell their land to real estate developers, primarily attributable to the contamination of their lands and a substantial decline in agricultural productivity. The

⁶⁶ Interview with Dr. Jasveen Jairath-founder member of SOUL-Save our Urban Lakes.

⁶⁷ Interviews with- Dr.Kishan Rao-Petitioner and activist

compromised water quality, coupled with industrial pollution, has not only diminished crop yields but has also resulted in widespread income losses among the farming community. Thereby, over the period villagers are not actively engaged in addressing pollution concerns⁶⁸. This lack of participation can be attributed to the lack of resources, delay in justice, Inappropriate actions, expense to prove⁶⁹ their suffering, and economic incentive of selling unproductive land at favorable prices amid the real estate boom for the emergence of new gated community projects in the affected regions.

With the escalation of pollution, industrial workers began to experience health issues, leading to a surge in compensation claims and complaints. In a bid to mitigate complaints and health-related problems among the local workforce, many industries have turned to recruit migrants from Bihar, Assam and Orissa as a comprehensive package. This exploitative practice not only jeopardizes the well-being of the labor force but also perpetuates a cycle of health hazards without proper acknowledgment or recourse. These migrant workers are not only employed but are also provided accommodation within the industrial premises, creating an environment that is conducive to prolonged working hours. However, the dark side of this arrangement emerges when health issues arise. When these migrant workers experience health problems, the industries have devised a system that discourages them from seeking external medical assistance. Instead, they are directed to contact Registered/Rural Medical Practitioners (RMP)⁷⁰ who maintain a pre-established understanding with the pharmaceutical industry contractors. This network ensures that the health concerns of the laborers are managed internally, minimizing the chances of official complaints or legal repercussions. The RMP doctors, often influenced or pressured by their association with the industry, provide these laborers with basic medications to alleviate symptoms. Subsequently, the workers are promptly sent back to their villages, unaware that the health issues they face are a direct result of the hazardous working conditions within the industries. This deceptive cycle perpetuates a lack of awareness among the laborers about the true nature of their health concerns, further compounded by their economic vulnerability and dependence on the

⁶⁸ Their voices and perspectives are dealt with in the next chapter

⁶⁹ Only if there is evidence to prove the loss can one actually claim compensation and raise an alarm, the mental agony, their everyday suffering and the “smell” which haunts them throughout is addressed in the next chapter.

⁷⁰ A Registered Medical Practitioner (RMP) is an individual authorized to practice medicine after obtaining registration with a State Medical Council, following completion of a recognized undergraduate medical course. Despite the legal right to use the suffix "RMP" exclusively for qualified medical professionals, in practice, many without medical qualifications, particularly in rural areas, misuse the term, referring to themselves as Rural Medical Practitioners. This illegal practice raises concerns about the treatment of people with already compromised health conditions in these regions.

industries for livelihood. This exploitative practice raises serious ethical and legal questions, as it not only compromises the health and well-being of the migrant workforce but also denies them the right to proper healthcare and information about the occupational hazards they are exposed to.

Local doctors observe that workers tend to experience improvements in their health upon returning to their villages. However, those employed in these industries for the long-term face severe health issues, and a significant portion of the medications administered does not yield fruitful results. This has raised suspicions among doctors, suggesting a potential link to antimicrobial resistance (AMR). The rising threat of Antimicrobial Resistance (AMR) raises concerns among doctors about potential resistance in residents, posing a significant health crisis. This situation could lead to an increase in Out-of-pocket Expenditures (OOPEs), further exacerbating health inequalities. Currently, OOPEs constitute a substantial 58.7% of India's national health expenditure, contributing to catastrophic expenses and perpetuating income disparities. Despite a 2020 economic survey recommending an increase in public health spending to 3% of GDP, India continues to allocate only 1% of its GDP to healthcare. Medicines, diagnostic tests, and doctor consultations collectively make up almost 40-50% of OOPE. Existing state insurance schemes and tax-funded care initiatives are inadequate in alleviating OOPE burdens, as highlighted by concerns about the implementation of the National Health Policy (2017) and fund allocation. The 2018 health consumption survey is pivotal in providing a dissected analysis of OOPE components, offering insights into sociodemographic, geographic, and disease-specific variations and facilitating informed decision-making for fund allocation and health package formulation (Ambade et al., 2022).

The considerable volume of antibiotic pollution, coupled with runoff from agriculture and human waste, provides an environment conducive to the proliferation of multidrug-resistant (MDR) bacteria in water bodies and sewage treatment plants. Consequently, India has emerged as a focal point for drug resistance, resulting in severe clinical consequences, including the annual death of over 56,000 newborns due to infections caused by bacteria resistant to first-line antibiotics (Lubbert et al 2017). Microbes possess the capability to traverse human hosts, traded animals, or goods, allowing multidrug resistance to circulate globally within a matter of a few hours (Mutreja, 2012). Travelers visiting countries with a high prevalence of antibiotic resistance often return home carrying multidrug-resistant

(MDR) bacteria, facilitating easy transmission to others, including 5–10% of household members (Arcillia, et al.2012). Therefore, AMR poses a severe global health threat and is projected to push 24 million people into extreme poverty by 2030 if not urgently addressed, jeopardizing multiple sustainable development goals (SDGs).

The interconnected ecosystems involving humans, animals, and the environment act as reservoirs facilitating the spread of AMR. The emergence of antibiotic-resistant bacteria and genes in water environments, primarily influenced by the pharmaceutical industry, is a significant environmental health concern. The industry, expanding globally to meet demand, contributes to hotspots of environmental contamination and AMR spread through its effluent. The lack of interventions in many countries' National Action Plans on AMR and a global absence of regulations for antibiotic residues in pharmaceutical effluent exacerbate the issue. Antibiotics, pivotal in modern medicine, are now threatened by excessive and indiscriminate global use, leading to a surge in AMR. Recognized by the World Health Organization (WHO) as a top-ten public health threat, AMR impacts the economy and development, potentially affecting 444 million people by 2050. Interconnected sectors—human, animal, and environmental—are pivotal in their development and transmission of AMR. The Global Action Plan (GAP) on AMR and subsequent National Action Plans address AMR, yet they often neglect the environmental sector's role, particularly in effluent treatment and disposal. The pharmaceutical industry, a significant contributor to AMR through antibiotic residues in effluent, is a key reservoir. Despite the industry's critical role in providing essential antibiotics, its effluent contributes to AMR development. The absence of emphasis on environmental aspects in AMR plans calls for collaborative efforts among policymakers, regulators, manufacturers, researchers, civil society, and communities to ensure sustainable antibiotic production and effective treatment of bacterial infections (Kotwani, Joshi, & Kaloni, 2021).

The concentration of pharmaceutical manufacturing in specific areas often reflects economic considerations, including reduced regulatory oversight and lower operational costs. This economic prioritization can result in environmental negligence and pollution, adversely affecting the health and well-being of nearby residents. The influence of pharmaceutical power further exacerbates these issues, as these industries wield significant economic and political clout, potentially overshadowing local concerns. The asymmetric power dynamic

between pharmaceutical corporations and the affected communities can lead to insufficient accountability and a lack of effective measures to mitigate pollution and its associated health risks. The suffering of people living near pharmaceutical manufacturing vicinities thus becomes a manifestation of the interplay between economic interests, regulatory shortcomings, and the formidable power held by the pharmaceutical industry.

Governmentality, as manifested in regulatory frameworks and policies, delineates the formal structures governing pharmaceutical production. The promotion of these industries, at the cost of human lives, reveals the biopolitical decisions that prioritize economic interests over the well-being of local populations. The exertion of biopower is evident in the regulation of pharmaceutical processes to ensure product safety, yet the localized environmental hazards and health risks expose the complex intersection of politics and biology. Biopolitics, in this context, determines where these industries are situated and to what extent the associated risks are distributed among different communities. The suffering experienced by those living in proximity to pharmaceutical manufacturing sites is not merely a byproduct of industrial processes but a result of intricate power dynamics, regulatory capture, and the prioritization of economic considerations over the health and quality of life of the affected populations.

SECTION V-Discussion

In post-independence India, the pharmaceutical industry was initially perceived as a "sunrise industry" with the potential to offer skilled employment, facilitate technology transfer, and contribute to foreign exchange generation. However, critics argue that this approach has resulted in substantial costs for local populations, including the loss of assets, health, natural resources, and environmental quality (Gudavarthy,2009). Between 1990 and the present, activists have submitted numerous petitions and engaged in forums to address industrial pollution. Despite evidence indicating that pollution may be responsible for an annual toll of 8,000 to 10,000 deaths in the city (TOI,2023), with a considerable number suffering from severe lung ailments, leukemia, miscarriages, and various physical and psychological disorders, the problem persists. The proposed solution from the courts was for all the industries in Patancheru to contribute funds to build a hospital for affected residents, a gesture seen as insufficient by the affected community.

Numerous petitions recommending the closure of industries near lakes and farmlands and a ban on new industries are still pending with the National Green Tribunal in Chennai, the Telangana High Court, the District Court, Telangana State Pollution Control Board, and the Collector's Office. Activists and Residents advocate for stringent monitoring of industrial waste management, the strengthening of effluent treatment plants, and the integration of technologies to minimize waste generation. According to the Water Act of 1974, the Air Act of 1981, and the Hazardous and Waste Management and Transboundary Rules of 2016, no industrial waste should be released into the environment, and all waste must be treated within the plant. Environmentalists stress that Telangana State Pollution Control Board officials must ensure strict adherence to these regulations. Various protocols, such as installing dust control measures like dusters in chimneys and diverting effluent water streams to treatment plants, exist but are often neglected due to high costs. Ongoing petitions highlight the need for effective enforcement and continued efforts to address environmental and health hazards caused by industrial activities.

The Pollution Control Board's interventions, when they occur, often lack deterrence, as companies pay fines—typically minimal—and continue their polluting practices unabated. Activists face challenges in bringing cases to India's Supreme Court and Green Tribunal, encountering prolonged legal battles and the need for personal funding to avoid accusations of bias. The nexus between politicians and the industry has deepened, marked by a push for "ease of doing business" and the promotion of India as a destination for outsourcing polluting industries. Regulatory bodies have been weakened through pressure or influence from the industry.

The state of Telangana is pushing ahead with industrial development, evident in its ambitious project⁷¹, the "Hyderabad Pharma City," a 19,000-acre industrial park exclusively for pharmaceutical manufacturing. This underscores the government's preference for pro-industry policies, even in the face of potential human, social, and environmental consequences. This proposed development raises concerns, particularly regarding the significant forested area that would be affected. Dissenting voices within the villages

⁷¹As of November 2023, the Telangana government is actively engaged in allocating land for the Hyderabad Pharma City project, with the IT minister actively promoting it. With elections on the horizon, the fate of the project may hinge on potential changes in political leadership. It remains to be seen how the status of the project will be affected in the event of a shift in political parties.

allocated for Pharma City are stifled, and the shrinking political space for public debate is evident in many of the public hearings in which the researcher participated. The Pharma City project is perceived as a solution to industrial pollution in these industrial estates, with its vision of employing zero liquid discharge technology. This technology is wielded as a shield in legal battles, placing the burden of proving its inefficiency on the victims or activists.

During a meeting conducted on April 21, 2017, at The Federation of Telangana Chambers of Commerce and Industry (FTCCI) (formerly known as FTAPCCI) concerning Pharma City, the General Secretary of the Bulk Drug Manufacturing Association expressed apprehensions about regulatory obstacles hindering the industry's advancement and presented several demands. Among the demands discussed during this meeting, in addition to the technical requirements for establishing a pharmaceutical sector, are:

Land Acquisition and Environmental Clearances: The industry advocated for obtaining environmental clearances for the entire Industrial Estate before providing land to industries, all at a reasonable cost. Additionally, it proposed the waiving of registration charges and the implementation of a Single Window System for streamlined permissions. Efforts were to be directed towards creating large-scale pharma clusters to promote vertical integration, shared infrastructure, and economies of scale. The industry urged for the provision of required land without encumbrances and litigations. Environmental clearances for the Industrial Estate, zoning into specific categories, and the establishment of Buffer Zones/No Development zones were also emphasized. The demand included the waiving of stamp duty, registration charges, land conversion, and panchayat charges.

Labor: The demand extended to declaring the API Industry under the Essential Services Act, aiming to exempt it from potential disruptions such as strikes, bandhs, and agitations. The proposal suggested forming a Park Level Authority to streamline regulatory approvals under a single window concept.

Capital: The industry sought the rationalization of fund blockages in CenVAT & VAT, offering options for rebates on unutilized credits, and providing interest on blocked funds. Importantly, the demand extended to permitting duty-free import of essential manufacturing components, exempting finished goods for import substitution from excise duty, and allowing

credits for taxes and excise duty on specific usage of diesel. The industry also called for income tax and GST/VAT exemptions, reduced interest rates on soft loans, and an extended moratorium period for CAPEX loan repayments.

Timely and effective handling of export consignments at ports was highlighted. The demand involved releasing blocked working capital funds held by the government and providing working capital at internationally competitive rates for exports. The industry proposed capital grants for R&D facilities, soft loans for import substitution products, and support for upgrading manufacturing and testing facilities to meet international standards. There was also a call for the partial reimbursement of fees paid to regulatory authorities for facility registration.

These demands that were put forth were, without questioning, agreed upon by the FTCCI members and the industrial minister who was present. The minister actively took part in promoting the Pharma City and saw it as a solution to the pollution problem that he would acknowledge. The demands clearly articulate the industry's requisites concerning land, labor, capital, and also environmental clearance without any hurdles aiming for a smooth operation: labor without agitations, land with subsidized taxes, and capital loans at a subsidy. The industry staunchly advocated for favorable conditions, including clear environmental clearances.

Furthermore, the demands highlighted the importance of considering APIs as essential products, and seeking exemptions. However, a crucial question emerges: even if APIs are acknowledged as essential, will the resultant drugs be offered at marginal prices, or will the industry prioritize exorbitant profits? Can these industries, expecting unhindered access to all factors of production at subsidized rates, effectively address health inequalities prevalent in the regions where they operate? The study refutes the industry's claim of zero discharge at the NGT, exposing ongoing effluent release. Despite active promotion by the industry minister and assurances of zero discharge with stringent precautions, lenient state monitoring raises doubts about history repeating itself. Despite prolonged legal battles spanning four decades, industries persist in polluting while masking their actions. How can public health be safeguarded against pathogens originating from criminal practices that the industry has maintained for four decades? Will the proposed new pharma city effectively address the

existing problems in the manufacturing vicinity? Will these drugs that are manufactured in the regions mitigate health inequalities present among the marginalized sections? These apprehensions need to be awaited and seen.

Pharmaceutical industries strategically leverage Zero Liquid Discharge (ZLD) technology as a powerful narrative to assert their commitment to environmental responsibility and compliance with regulations. The claim of zero liquid discharge is presented as a technological solution, positioning these companies as environmentally conscious and responsible corporate citizens. However, beneath this veneer lies a more complex reality where these technologies become instruments of power (Allen & Hecht, 2001), allowing industries to manipulate public perception and legal scrutiny. The use of ZLD technology becomes a form of power as industries embed their authority in these sophisticated systems. By showcasing their technological prowess in effluent management, they aim to shape narratives that deflect attention from potential malpractices, creating an illusion of environmental stewardship. This manipulation of perception becomes a strategic move to project a positive image to the public and the courts, ultimately shielding the industries from deeper scrutiny and accountability. The machines and knowledge constituting ZLD systems play a crucial role in strengthening or reshaping social, political, and cultural power dynamics. Industries, by investing in and implementing such advanced technologies, position themselves as leaders in innovation and environmental sustainability. This not only impacts their social standing but also influences political and regulatory perceptions.

The relationship among the state, expertise, and authority is evident in how industries navigate regulatory frameworks. The adoption of ZLD technology becomes a tool to negotiate with regulatory bodies, presenting a facade of compliance while potentially engaging in practices that may harm the environment. This power dynamic involves the state relying on industry expertise, creating a delicate balance between regulatory enforcement and industrial influence. The construction of a national identity around these industries, particularly when they showcase cutting-edge technologies, reinforces the idea that technological advancement is synonymous with national progress. This narrative contributes to shaping a positive image for the nation, further solidifying the power of these industries in the cultural and national context. Changes in the structure and distribution of labor also come into play as industries prioritize technology over labor-intensive processes. This shift in

power dynamics within the workforce reflects broader trends in industrial development, where technological innovation becomes a key determinant of economic success. Political ideology surrounding industrial development and environmental responsibility is intricately woven into the use of ZLD technology. Industries align themselves with prevailing political ideologies that emphasize economic growth while attempting to present a sustainable and responsible front. This alignment influences not only public perception but also political practices and decision-making. The use of ZLD technology by industries in the pharmaceutical sector goes beyond mere effluent management. It becomes a strategic tool to wield power, influence perceptions, and navigate the complex interplay of social, political, and cultural dynamics. As technologies shape the discourse around environmental responsibility, a critical examination is essential to understand the true implications and ethical dimensions of these technological narratives.

The burden of proof emerges as a significant power apparatus in the context of the NGT directive, raising concerns about inequalities in accessing justice. In the event of non-compliance by industries, where the state reports compliance, proving the industry's wrongdoing becomes challenging. The burden of proof shifts to the victims or activists, demanding evidence to substantiate claims of non-compliance. However, producing scientific evidence is a costly endeavor, beyond the financial means of both the victims and activists. Thus, the power dynamics inherent in the burden of proof intensify the challenges faced by those seeking justice. Scientific technology and knowledge further compound this power asymmetry, serving as tools to suppress the truths of the villagers. The inability to afford scientific proof exacerbates health inequalities triggered by the power apparatus of ignorance. This intricate web of power relations, encompassing burden of proof and scientific knowledge, is explored in-depth in the subsequent chapter, shedding light on the complex dynamics that perpetuate injustices in the face of environmental hazards.

Chapter 5

Pathopolitics and Social Suffering

In the realm of biopolitics, the governance of bodies in the pursuit of health and the management of life chances involves the manipulation of who is shielded from or exposed to risks. The fusion of biopolitics into bioeconomics, leading to the extraction of value from vitality, occurred due to a profound shift in the interpretations of health, disease, and risk. The advancement of medical technologies did not result in an enhanced sense of security, but rather, an intensified awareness of risk (Dean, 2009). Dumit (2012) also highlights this dynamic, emphasizing the increasing recognition of risk despite the growing knowledge about nutrition, disease, and medicine. The widespread commodification and regulation of both drugs and bodies have assumed a new and concerning form. The pharmaceutical industry's role in reshaping the concept of surplus health is to establish new markets and stimulate demand for novel medications, as health is not only about disease prevention, but also on risk reduction. However, for the residents living in industrial areas like the field site of this study, the challenges extend beyond general risks to include the double risk posed by industrial malpractices leading to suffering (Dumit, 2012; Atuk, 2020).

Medical anthropologist and physician Paul Farmer (2003) encapsulates the function of biopolitics with the term, 'pathologies of power,' emphasizing its role in determining who suffers abuse and who is safeguarded from harm (Farmer, 2003). Pathopolitics, as a concept, directs attention to the pathological nature of biopolitics within the pharmaceutical industry. The term 'pathos' in ancient Greek signifies suffering and pathology (pathos-logia) inherently denotes suffering. Therefore, pathopolitics can be defined in terms of politics of treating and /or reproducing pathologies and the suffering they induce (Atuk, 2020). The primary actor in pathopolitics is, thus, the pharmaceutical industry. Paradoxically, the contemporary pharmaceutical industry, akin to biopolitics, prevents certain pathologies while reproducing others. In some instances, it even produces specific pathologies to treat others. Like biopolitics, pathopolitics has the power to make life or let die, albeit in a nuanced manner. While biopolitics can lead to death through various means, death under pathopolitics manifests predominantly as a disease or pathology, often preventable (Ibid).

Despite its purported purpose of curing pathologies, the pharmaceutical industry sustains itself by perpetuating both biological and social pathologies. Pathopolitics represents the enactment of biopolitics by the pharmaceutical industry, functioning as a distinct approach to addressing the population as both a political and medical issue. Unlike broader biopolitics, pathopolitics relies on corporate strategies of risk distribution rather than governmental or non-governmental techniques for managing life and death (Atuk, 2020).

In this context, the concept of social suffering comes to the forefront, elucidating the consequences of actions undertaken by political, economic, and institutional powers on individuals. The genesis of social suffering lies in oppressive systems that penetrate various facets of everyday life, operating at the levels of individuals, interpersonal relationships, and institutional structures (Kleinman, 1997). The manifestation of social suffering is intricately connected to health disparities, presenting a link between the experiences of specific communities and the broader spectrum of diverse populations. Social suffering stems from established norms dictating the distribution of life opportunities, rendering certain individuals more susceptible to violence, exclusion, harm, and mortality. To effectively address and acknowledge social suffering, it is crucial to comprehend its political dimensions, which are intricately woven into all facets of society (Shook, Narruhn, & Espina, 2023).

In this manner, pathopolitics and social suffering are interconnected concepts that explain the complex interplay between political structures, healthcare systems, and the lived experiences of individuals and communities. On the one hand, pathopolitics refers to how political power and decisions impact health outcomes, often leading to the unequal distribution of resources, access to care, and health disparities. On the other hand, social suffering delves into the broader societal and structural factors that contribute to human distress and hardship. Together, they emphasize how political decisions and social structures influence health, creating a landscape where marginalized groups bear a disproportionate burden of suffering. The nexus between pathopolitics and social suffering underscores the urgent need for political and social reforms to address the root causes of health inequalities, ensuring a more just and equitable healthcare system that prioritizes the well-being of all members of society.

The preceding chapter examined pathopolitics and extensively discussed the methods and tactics employed by the pharmaceutical industry in the release of effluents and toxic gases,

particularly in light of the Pollution Control Board's biannual reports claiming zero discharge. The burden of proof, involving challenging these reports filled with scientific and statistical details, falls on the affected communities. This poses a significant and costly challenge for the residents who must substantiate the inaccuracies in the state officials' submissions. The need for scientific evidence complicates the case not only for the villagers but also for the activists and environmentalists. Having explored the conditions in the industrial zone in the previous chapter, particularly for the residents living in proximity to industrial operations, it becomes imperative to grasp their narratives. Beyond economic considerations and regulatory complexities, it is crucial to delve into the narratives of this subjugated population.

This chapter delves into their narratives, examining them in three Sections. In Section I, on 'Invisibility and Invisible Suffering', the hidden stories and silent struggles of the community are unveiled, shedding light on aspects of suffering that often go unnoticed. In Section II, the exploration of 'Structural Violence' navigates the complexities of societal structures contributing to persistent inequalities, particularly within the realm of health and well-being. Focusing on the examination of the Double Body Burden, this section dissects the unique challenges faced by individuals and communities, revealing how external factors intensify the burden of existing health issues and the changing dynamics due to real estate growth. Section III, contains the ensuing discussion, synthesizing insights from these narratives, and offering a comprehensive analysis that interweaves the themes of invisibility, structural violence, and the double body burden.

Section I

Invisibilization of Suffering and Invisible Suffering

Agamben's (1995) concept of *zoe* can be applied to the invisibilization of suffering in the context of the people residing in pharmaceutical zones affected by pollution, where their plight is intentionally concealed by the state authorities in collusion with the pharmaceutical industry. *Zoe* refers to the bare life, stripped of political significance and reduced to a state of mere biological existence. In the pharmaceutical zones, the residents' suffering becomes a form of *zoe* as their health challenges are depoliticized and marginalized. State authorities, entwined with the pharmaceutical sector, contribute to the invisibility of this suffering by downplaying environmental and health concerns for the sake of economic interests. By

reducing the residents' struggles to a mere biological existence, their grievances are kept at the margins of societal awareness. Agamben's concept sheds light on the deliberate strategies employed by those in power to render the suffering of these communities invisible, emphasizing the need to reclaim the political significance of their struggles and advocate for a more just and transparent societal framework. The population here is not recognized as humans who are dehumanized and their suffering is rendered invisible as *zoe* (Agamben, 1995); their life is not comprehended as life and becomes what Butler describes as *a living figure outside the norms of life* (Butler, 2009; pg: 8).

The notion of invisibility is apparent in the state's consistent reporting of zero discharge to the National Green Tribunal where cases are ongoing, despite the continuous complaints and releases of effluents and gases. In doing so, they seek to suppress the problems faced by the affected communities, essentially working to render their issues invisible. The subjugated population here can only grasp the invisible problems, and are yet to comprehend the process by which the state attempts to conceal its issues. Narratives of these unseen problems often go unnoticed, even in their legal complaints. Smell (bad odour) is rarely reported or treated as complaints. If gases cause breathing issues, at least it is acknowledged and addressed, but the mere presence of a smell is normalized.

‘Smell’

The pervasive pollution in these areas has given rise to a distinctive form of suffering that infiltrates the air, becoming an integral part of the daily lives of the population. The unpleasant odours, often stemming from industrial effluents and gases, have become an inescapable aspect of their social existence. The impact of this pollution is not solely a result of manufacturing practices, but also arises from malpractices aimed at cost-cutting by neglecting proper treatment and opting for an expedient disposal method during the night. This subtle reality was not immediately apparent to the affected communities or the broader public. While the judiciary, often viewed as a savior, assesses the impacts based on visible and quantifiable scientific parameters, the suffering endured by these people due to the noxious smells remains largely unnoticed. Compensation and relief are frequently contingent on scientifically proven evidence, leaving the intangible burden of living amidst such odors largely unaddressed.

The ensuing narratives will portray the challenges and suffering experienced by the villagers, with pseudonyms used in the place of individuals' names.

Anjali, 38, a homemaker says:

Every morning, as I step out of my door, I am greeted by this overpowering smell. It is nauseating, to say the least. It seeps into everything – our clothes, our furniture, and the food we eat smell of this obnoxious odor (Gabbu Vasana/Kampu). Sometimes we do not feel like eating, especially when they release both effluents and gases during the nights. It becomes unbearable. My kids complain of headaches, and I worry about the long-term effects on their health. But what choice do we have? We cannot escape it.

Raj, 45, a tea shop owner near the industry says:

The stench hangs in the air like a heavy cloud. My shop, once bustling with customers, now sees only migrant workers working in the industries. People avoid this area because of the bad smell(durvasana). It is affecting my livelihood, and the worst part is, that I breathe in this environment and have to live in it since this is my village, and we have our land and people here. Unfortunately, I have developed a persistent cough, and despite various medications prescribed by doctors, the issue persists. Each time I seek medical help, doctors change the prescribed medicines, but relief remains elusive.

Sunita, 32, works in housekeeping in the medical devices industry (which is not a red-category industry) set up close to her village. She says:

I work in a large factory, and fortunately, there is no unbearable smell within the factory premises. However, the situation is quite the opposite in the area where I live. Witnessing the challenges that most children face here, I have made the difficult decision to leave my children in my mother's house. It saddens me to live separately from my children, but I believe it is necessary for their well-being. Both my husband and I fall sick frequently, and at least by keeping the kids away, they can lead a healthier and happier life. Whenever my children come home during school vacation, they immediately fall ill, experience vomiting, and complain that everything in the house smells of the factory.

Arjun, 50, Retired Farmer says: *I used to till the fields, a proud farmer providing for his family. Now, the fields lie barren, and the air is thick with this foul odor. It is like a constant reminder of what we have lost. I cannot even sit outside and enjoy the simple pleasures anymore. My grandchildren complain about the smell, and it breaks my heart. We never asked for this.*

Lata, 28, a homemaker says:

I find myself unemployed because I had to frequently apply for leave due to the overwhelming smell at my workplace. The shop I used to work at dismissed me, citing irregular attendance. The impact of this smell extends beyond my employment prospects; it directly affects our health. I wake up every day with a persistent headache that lingers until night. The constant struggle to get through each day makes job hunting seem impossible. The suffocating environment takes a toll on both my well-being and the understanding of those around me, as it feels like nobody cares.

Mangaama, 60, says:

The river that used to be our life source now carries the poison of progress. I remember when its waters were pure, and now, fetching it feels like drawing sickness into my home. The plants wither, the animals are gone, and we are left with a tainted existence. I have spent my entire life in this neighborhood, and now, it feels like the very ground beneath my feet is betraying me. The soil, the water, everything is tainted. The plants I nurture seem to wither faster than I can heal. The pollution seeps into every crevice of my life. My body, worn with age, struggles against the onslaught of chemicals in the air. I look around, and what was once my home has become a battleground where my health is the casualty of an invisible war waged by these politicians who are eating money from the industries and not giving us anything. At times, the scent of jasmine flowers is overpowered by the odors emanating from these factories. Why must we endure the repercussions for the sake of the English people? (The villagers perceive the industries' exports as selling to foreigners, whom they essentially equate with English people.)

Radhamma, who is 50 years old, has children are well-settled and working in Dubai. She says:

This is my husband's birthplace, and he is very sentimental, not wanting to leave despite the challenges. Otherwise, it is tough to live here. When my children visit, they bring air fresheners and air purifiers; otherwise, it is not feasible for us to stay. All my relatives have moved to Hyderabad, but we are the only ones who stayed behind. (They own 20 acres of land; her husband plays a pivotal role in mobilizing the people to sell their lands to real estate agents.)

The Village Sarpanch says:

Over time, we have all adapted to the constant presence of this pervasive smell, finding a way to carry on despite its unwelcome intrusion into our lives. While we are still enduring its impact; there is a collective hope among us that we would not have to endure this much in the future. Many women in our community share a belief that the potential shift of industries to the new pharma city holds the promise of resolving our ongoing challenges. It is a beacon of hope, offering the prospect of relief from the daily struggles that have become an unfortunate part of our lives. While we have learned to live amidst this challenging reality, there is a shared anticipation for a future where cleaner air, improved health, and a sense of normalcy will prevail. The hope for change resides in our collective consciousness, inspiring us to look forward to a time when we would not have to survive in the shadows of this pervasive smell. Until then, we persevere, adapt, and maintain an optimism for a better future.

The above narratives vividly unravel not only the external adversities, but also the internal disparities within the affected population. The pervasive smell affects everyone, indiscriminative of their socio-economic status, yet the burden is disproportionately borne by the poor. Those with financial means have the privilege to make modifications, such as investing in air fresheners or air purifiers, creating a stark contrast in the coping mechanisms between the affluent and the economically disadvantaged. This internal disparity further magnifies the social injustices embedded in the experience of suffering, highlighting how the consequences of pathopolitics exacerbate existing inequalities within the community.

‘Normalizing’ Suffering

It is crucial to recognize how individuals normalize and silently accept the everyday violence that they experience. Only when the violence exceeds the tolerable levels of conditions, do people file complaints with the pollution control boards. The flexibility of this limit adds complexity to the situation, and the threshold for bearing these conditions is not within conventional standards. As a researcher, I find it challenging to comprehend how the residents can endure and persist living under such circumstances.

During my research in the villages, I have been confronted with the stark reality of the toll that pharma pollution has taken on the community. The devastating impact is not only evident in the 25 human deaths that I have witnessed succumb in the duration of my research, but also in the heart-wrenching scenes of 10 goats and 5 buffaloes lying lifeless near contaminated water bodies at various intervals. The loss of cattle is not just a numerical figure but a profound blow to the herders who depend on them for their livelihoods. The magnitude of this loss adds an extra layer of tragedy to an already dire situation. What struck me the most was the acceptance of these deaths as 'natural' by the community, a normalization that is deeply ingrained. The 25 individuals who passed away did not undergo any autopsy, reflecting a resignation to fate, with the community seemingly accustomed to such losses due to the bureaucratic procedures and the costs involved in the same. The disconnect between these deaths and the environmental conditions they live in is alarming. It is when the pollution reaches intolerable levels, notably with the overwhelming smell and the choking sensation in their throats, that the community becomes concerned. Their reaction is a testament to the silent suffering they endure, where the insidious nature of pollution becomes apparent only when it breaches their tolerance thresholds. This also underscores the need for intervention and raises questions about the long-term health consequences of living in such contaminated environments. The stories of these lives lost, both human and animal, demand attention and action to address the systemic issues contributing to this silent crisis.

The silent suffering is expressed in the following pages.

1. In the focus group discussions, Leela, a resilient woman in the community, expressed the frustration shared by many.

Everyone takes us for granted; we have pushed ourselves to get used to the situation, but we do not understand the severity of the issue. When educated people come here and ask about

our health problems, it sparks worry among us. We cannot live in perpetual suffering; our bodies have become resistant.

2. Aisha's (a Science graduate) concerns:

After the fish deaths, the fishermen were worried about the sustainability and the loss of their income crucial for their survival. But how do we educate them that the deaths occurred because the dosage exceeded permissible limits? It does not mean that the hazards are immediately resolved; the issue persists. People think we have adapted, but it is not true. When outsiders enquire about our health, it triggers anxiety. We need relief; we cannot keep enduring this. We have become accustomed to being overlooked.

3. Preeti, usually silent in the discussions, spoke up.

People assume that we have resigned ourselves to our fate, but do we truly have a choice? Many of us here do not have children, and for those who do, the journey has been arduous—countless visits to temples and clinics, significant financial investments and ultimately, a reliance on divine intervention for the gift of parenthood. However, a puzzling disparity exists: why are so many of us in this village facing infertility issues, labeled as barren (Godralu), while our sisters married to individuals from other villages in Karnataka seem to be good? The burden of seeking fertility treatments falls heavily on our shoulders, draining our savings as we navigate the complexities of clinics and procedures. Compounding our struggles, there is a lack of government insurance support for these crucial treatments. Despite investing substantial resources, I find myself among those who, despite their best efforts, remain unable to conceive. All of us feel that we are having health issues due to pollution. It is disheartening to note that health problems like infertility are often overlooked during election campaigns. Political parties pledge to address environmental concerns, promising resolutions to pollution issues, yet the problem persists. It is high time that our elected representatives turn their attention to the pressing health matters. Our voices and concerns deserve acknowledgment and action in the political arena, ensuring that essential healthcare becomes a priority in policy-making.

Preeti raises pertinent questions; it is undeniable that critical health issues often go unaddressed during electoral campaigns. While pollution concerns are acknowledged, promises are made to ensure access to clean drinking water alone. However, experts highlight

a stark reality – the water mandated by the tribunal is not adequate, and the inclusion of mixed contaminated groundwater exacerbates health problems. This predicament unfolds under the watchful eyes of elected representatives. Unfortunately, many Sarpanchs and their teams act as intermediaries, supplying water tankers while facilitating transactions between the community and industries. This intricate web of actions perpetuates the health challenges faced by the people, with the mixing of groundwater into the regular drinking water supply being a significant contributor. The authorities must address these concerns, ensuring that the promises translate into tangible improvements in the quality and accessibility of water resources for the well-being of the community.

These narratives show that there exists a form of authority over the individuals, wielding the power to determine life or death, akin to the administration of life and death. Similar to Foucault's perspective, Agamben contends that this power, termed biopower, is endorsed by the state. In Agamben's framework, it involves managing what he refers to as bare life, *Zoe*, or 'non-person'. This denotes a critical juncture where an individual's humanity is obscured to the extent that they become exceptionally susceptible to violence, exclusion, and mortality. Crucially, this process is one of normalization, seamlessly ingrained into societal structures and everyday existence. It is perceived as the 'natural' order of things (Agamben, 1995).

Section II

Structural Violence/Suffering

Structural violence (Galtung, 1969) encompasses situations where a social framework sustains inequality, resulting in avoidable suffering. The examination of structural violence involves analyzing how various social structures, including economic, political, medical, and legal systems, disproportionately affect specific groups and communities. In comprehending the intricate forces contributing to inequality at various levels for both individuals and communities, structural violence proves invaluable. Additionally, it underscores the historical underpinnings of contemporary disparities, emphasizing that the injustices and suffering witnessed today are often rooted in a broader history of marginalization. This concept provides a framework to understand the nature and manifestations of these adverse impacts and explores potential measures to mitigate such harm. Examining suffering and inequality in the realm of health is effectively facilitated by the concept of structural violence. This

perspective underscores the intricate and interrelated factors impacting health outcomes, as seen in instances of health disparities among various communities. (Lewis, 2021)

Structural suffering is vividly exemplified in three poignant cases and a few narratives, each encapsulating the pervasive and systemic nature of hardship, which are examined in this section. In Case 1, is that of a 23-year-old male whose father owns 15 acres of land which became uncultivable due to soil contamination and pollution directly affecting their fields. In response, he joined the bulk drug industry to support himself, as suitable marriage matches proved elusive. He had completed his 12th grade and he joined the industry in the packing section. Unfortunately, after six months, he encountered health issues that led to complete paralysis. His father spared no effort, seeking treatment in the best hospitals, including those in Mumbai after selling some of his land to the gated community builders. Through these efforts, there was an improvement, allowing him limited mobility. The government provided a motorcycle tailored for physically challenged individuals, aiding in his transportation.

The emotional toll on the family here is profound, especially for the father who laments the unfortunate situation. The young man, once healthy and able-bodied, is now unable to perform any work. The family, shattered by these circumstances, must now navigate the challenges of caring for him, all while grappling with the stark contrast to the health and success of their two other daughters, who are both well-settled. Remarkably, there is no family history of health issues, adding to the complexity of this unexpected hardship. The father's plea for his son to find a job to secure a suitable match now seems like an unattainable goal, leaving the family to cope with the unexpected turn their lives have taken.

In Case 2, a 10-year-old boy confronted an array of unidentified diseases, plunging his single mother into a state of profound helplessness. The boy's father, who worked in the industry, suffered from health issues leading to his demise. The mother, lacking literacy, struggled to identify the specific health problems her husband faced. She only knew that he was healthy when they lived near Zaheerabad, but upon moving to her in-laws' house, where her husband started working in the industry packing department as a regular wage laborer on a contract, his health deteriorated. She noted that he faced regular health issues after commencing work.

Despite being a native of the village, the boy's father grew up at his maternal grandmother's house in Zaheerabad. His health worsened after he shifted to his native village, which is the field site of this study. His illness led to frequent hospital visits and drained the family financially. Following the birth of their son, within two months, the husband passed away, leaving the mother to fend for and provide care for a child who gradually developed physical and mental disabilities. The mother expressed that the doctors referred to the son's issues as 'nerve' problems and the lack of access to tertiary care facilities hindered the pursuit of advanced treatment, ultimately leading to the child's demise. The family's struggles extend beyond the individual's illness, also highlighting deficiencies within the healthcare system. The mother, unable to secure a clear diagnosis or afford advanced treatment, had to witness her child's suffering. Her consent to share the child's image reflects a desperate plea for an acknowledgment of her plight and assistance. Tragically, the young boy in Case 2 passed away in September 2023. His story emphasizes how structural violence permeates individual lives, culminating in devastating outcomes, emphasizing the pressing need for systemic changes to address the root causes of their suffering.



This picture was captured in 2020. The child succumbed to his illness in September 2023.

Case 3

Case 3 is that of migrants, which provides insights into the health issues that the industry is aware of and conceals. Migrants from Orissa, Bihar, and Assam predominantly comprising young boys aged between 14 to 19, face multiple health challenges due to their work environment and living conditions. The young workers, hailing from various regions, arrive in search of employment in the pharmaceutical sector. However, a disturbing trend has emerged here where a significant number of them fall sick, experiencing various health issues related to their place of work. Most commonly, they report rashes and skin problems, attributing them to their exposure to contaminated water sources and the consumption of fish caught in these polluted waters. Upon falling ill, these workers are taken to local Registered Medical Practitioners (RMP) by middlemen, also known as "saab," who act as intermediaries between the workers and the pharmaceutical industries. The RMPs, often unqualified and lacking proper medical expertise, administer treatments that only provide temporary relief. In cases where the illness persists, the workers are sent back to their native places with a sum of money equivalent to a one-way ticket.

Interestingly, upon returning home, many of these workers recover from their ailments. However, a concerning pattern emerges as several of them fall sick again upon returning to work in the pharmaceutical industry. Those who experience sickness more than twice do not recover even after going back to their native places. The contaminated water sources in the industrial area are identified as a potential source of the health issues. The young workers play in these water bodies and consume fish from them, under the assumption that the treatment provided by their *Saab* (middlemen) will address any resulting health concern. The situation raises questions about the overall health and safety measures in the pharmaceutical industries, as well as the exploitation of vulnerable young workers.



Migrants playing and fishing in a pool of effluents - Photo taken in July 2023. During the monsoon season, industries discharge untreated effluents into the drains.

Narratives

Aruna's Daily Battle:

Every morning, I embark on a silent battle to shield my family from the pervasive contamination. As a working woman, the stark reality is that the food that I cook at home becomes tainted quickly, infused with the unpleasant odors of pollution. Food gets stale by the noon. It is disheartening to witness the struggle to maintain the freshness of our meals, a struggle that extends beyond my workplace and into my home. The worries for my family's health are a constant companion and I find myself juggling the responsibilities of work and home, attempting to shield my loved ones from the ever-looming threat of contaminated food. The daily stress of ensuring a wholesome meal is, at times, overwhelming, as I navigate the challenges posed by the pervasive pollution.

Radha's Struggle for finding matches for her daughter:

Finding suitable matches for our children becomes a daunting task. The polluted environment has become a factor when being considered by potential suitor families, adding an unexpected layer to the already intricate process of finding suitable matches. Families are apprehensive about potential fertility issues among the women, leading them to believe that such unions may face challenges in bearing children.

The above narratives were deeply moving, portraying a blend of struggle, despair, strength, and courage. The residents possessed abundant wisdom to share, and I had much to absorb. Whenever industries released harmful gases, I was summoned to witness, and the night visits became particularly unsettling. The atmosphere would be saturated with air pollution, reaching its peak and shrouding everything in an unsettling stillness. The residents would gaze at my face, their distress palpable. All I could do was alert the pollution control board officials, rallying them to address their plight by confronting the industries. The next day, the incident would make news, district officers would visit, make assurances, and things would revert to their usual routine. These occurrences were not merely distressing; witnessing the residents' helplessness in situations where they knew they were vulnerable and had nowhere else to turn was a profound suffering for me as a researcher as well. There was no hope for relocation for these people; the government only promised to shift the industries. In those moments, the suffering arises from a sense of helplessness, and this dejection constituted the structural violence against them. It was a form of violence that was inflicted and met with anguish.

The pharmaceutical pollution in these regions has emerged as a significant environmental and socio-economic concern, leading to socio-economic challenges. The affected areas, primarily agricultural, are grappling with severe consequences that range from the loss of arable land to contaminated water sources. The repercussions extend beyond environmental degradation to profound socio-economic challenges, impacting the lives of the inhabitants.

As mentioned, other than health issues, another major issue faced by the population in these regions is the depletion of agricultural resources. The contamination of water sources and soil due to pharmaceutical pollution has led to a decline in agricultural productivity. Farmers find themselves grappling with diminished yields and an increased reliance on chemical inputs to maintain crop health, exacerbating the economic strain on local communities. The socio-economic challenges faced by the population are further exacerbated by the limited opportunities for employment within the affected areas. Among the 400 local respondents interviewed, a mere 25 of them were currently employed in industries. Contrary to expectations, the industries in the region do not serve as a viable source of employment for the local population. The industries, likely aware of the potential protests and issues related to wages and health, also prefer hiring outsiders. This situation leads to a vicious cycle of

structural suffering for the local inhabitants who fall sick frequently due to environmental pollution and are compelled to seek employment outside their communities. Pointing out similar situation in north coastal Andhra, Prasad (2017) point out that:

“Thousands of acres have been acquired in Achyutapuram, Rambili SEZ, Jawaharnagar Pharma city..... These industrial units employed workers on contract and casual labour initially, however later recruited outside labour, making the local workers unemployed despite serious suffering due to pollution and dispossession”

The health implications of pharmaceutical pollution contribute significantly to the socio-economic challenges faced by the affected population. Individuals in these regions experience frequent illnesses due to their exposure to contaminated air, water, and soil. Moreover, the lack of comprehensive insurance schemes further compounds the problems. Existing insurance schemes primarily cater to hospitalization, leaving everyday medical expenses unaddressed. The out-of-pocket health expenditure continues to rise as individuals have to bear the costs of regular medical treatments in clinics.

The socio-economic challenges faced by the population residing in pharmaceutical-polluted areas are multifaceted. Loss of agricultural land and contaminated water sources have led to a decline in local livelihoods, while the industrial sector, rather than providing a solution, adds to the problems by avoiding the local workforce. The resulting structural suffering, coupled with inadequate healthcare support, paints a bleak picture for the affected communities, calling for urgent attention and comprehensive solutions.

Rajaiah, a 55-year-old farmer says:

When the pharmaceutical factories were set up near our village, we thought it would bring progress. Little did we know that it would destroy our way of life. The water from our wells, once crystal clear, now reeks of chemicals. Our crops have suffered, and we struggle to make ends meet. The fields that were once our pride are now barren, and we are forced to use more and more chemicals just to keep the crops alive. It is a losing battle. My children grew up in this village, but there is no work here anymore. The industries prefer outsiders because they will not raise their voices when things go wrong. I have seen migrants fall sick, coughing

from the polluted air, but the factories do not care. It is heartbreaking to see my village suffer like this. I worry about my grandchildren every day. The air they breathe, the water they drink, it is all tainted. They fall sick often, and the medical expenses are draining us. The worst part is that even if we had insurance, it does not cover the regular visits to the clinic. We have to pay from our pockets every time they have a cough or fever. It is a choice between buying medicines and putting food on the table. We feel abandoned, and no one seems to care.

Harish, a 50-year-old former farmer says:

I made a decent living from my farm, but now it is all gone. The industries promised jobs, but they only brought diseases. The chemicals not only ruined our fields but also made us sick. I cannot work anymore, and my family struggles. We thought progress would come, but all we got was suffering. The government needs to do something, anything, to help us. We cannot survive like this.

These narratives shed light on the personal struggles of those living in pharmaceutical-polluted areas. It is not just about the environment; it is about the people losing their way of life, their health, and their hope for a better future. The primary concerns of the people in these affected areas predominantly revolve around their day-to-day living and survival, overshadowing their considerations about the broader, long-term health effects. The immediacy of the problems they face takes precedence, particularly concerning their ability to afford treatment in case of any health issues. For women without land, the focus is squarely on their everyday health, directly impacting their ability to work and provide support to their families. A recurring issue among them is the severe headaches experienced early in the morning, debilitating to the extent that it hinders their capacity to engage in work. This immediate health challenge becomes a crucial aspect of their daily struggle, intertwining with their economic well-being and, by extension, the overall survival of their families. The juxtaposition of these pressing concerns against the backdrop of larger, long-term health implications showcases the intricate balance individuals in these areas must navigate in their pursuit of basic living and sustenance.

Double Body Burden

The villages located in the neighboring bulk drug industries endure similar challenges as the people who reside outside these areas also encounter issues such as air pollution, water pollution, soil pollution and adulterated foods. However, these issues and experiences become an opportunity for capital to exploit. The rise in infertility and respiratory issues, even in non-industrial zones, adds to the double burden of these residents. They not only bear the common problems faced by the rest of the population but also must endure these issues due to their geographical and social positions. This results in significant health inequalities, emphasizing the disparities in the impact of environmental factors on different communities. Body burden refers to the amount or concentration of a chemical present in the body. The Global Burden of Disease study (2017) emphasizes the severe impact of air pollution in India, leading to 1.24 million deaths, comparable to the consequences of tobacco use. The population in these affected regions grapple with a dual burden, facing the consequences of both state negligence and industry malpractices. This challenge is heightened by the pharmaceutical industry's export-oriented approach, disproportionately affecting the health of those near bulk drug production sites.

Despite the nationwide impact of air pollution, water pollution and the presence of chemicals in food due to economic 'development', the residents in these areas experience a unique double body burden, worsening the health inequalities. Health inequality, stemming from pharmaceutical malpractices, reveals an unfair distribution of burdens and benefits, favoring the global north while inflicting health consequences on the local population. Pollution's impact extends beyond health, incurring additional costs for medical care and disrupting livelihoods, particularly in agriculture. The once-hospitable village has become unlivable, leading residents to seek relocation. These villagers, casualties of industries and economic expansion, illustrate the social injustices associated with pollution's negative effects. Their situation underscores that pollution's consequences are not only economic inefficiencies but also profound social injustices.

Figure 5.1. Farmers showing loss of their crop



A government employee working in the railways and residing in the study village says-
I frequently lodged complaints with the pollution control board officials regarding the headaches and breathlessness at night, attributing these issues to the release of pollutants in the air, particularly during nighttime. Surprisingly, a pollution control official dismissed my concerns, suggesting that we were associating our health problems with pollution unnecessarily. I find it challenging to endorse this viewpoint. In our daily lives, pollution is a pervasive presence, and it is only natural for us to correlate our health challenges with it. I reminisce about a time when our families enjoyed good health, surrounded by fertile soil and pristine water bodies. The striking contrast between then and now makes it plausible to link our current health struggles to the environmental changes we have witnessed over time, emphasizing the relevance of addressing pollution-related issues.

I strongly agree with the opinion of this respondent. Before starting my research, I rarely experienced headaches and nausea. However, once I began working in this area and became closely associated with the community, I found myself facing severe headaches and nausea during the initial days of each fieldwork visit. Over time, I gradually became accustomed to these challenges.

The escalating prevalence of infertility issues and the proliferation of fertility clinics contribute to a shared phenomenon, even in areas without industrial activities. This observation accentuates the disproportionate impact on marginalized communities, subjecting them to a double burden when specific health challenges afflict the broader population. The nexus between the rise in health issues and political and regulatory capture is particularly concerning. Instances where state entities are influenced or controlled by powerful interests can further amplify existing health inequalities and contribute to social suffering. The unique experiences of these communities emphasize a distinct double burden, showcasing the intricate interplay between health issues, political dynamics, regulatory capture, and social suffering.

The recognition that not everyone in the broader population undergoes the same health challenges as those faced by marginalized villagers or *Zoe* highlights a significant aspect of health inequality.

Changing Dynamics

Interesting dynamic is that land values in most of these villages have escalated and become prime real estate projects over a period of time. Amidst the promising rise of real estate in these areas affected by pharmaceutical pollution, the narrative reveals a complex web of interests and consequences. The local populace has been lured by the assurance that the industries causing pollution will soon be relocated to a new pharmaceutical city in the making. The surge in real estate has proven beneficial for the sections of the population that own land. However, despite a field visit in July 2023 witnessing the release of effluents into water bodies and a German documentary team confirming elevated levels of contamination beyond permissible limits, a surprising shift in dynamics has occurred. The landowners are mobilizing the community to keep silent about pollution issues, fearing that any disclosure may adversely impact their land prices—their perceived lifeline. This mobilization is driven by the desperate hope that selling unproductive land for construction purposes will bring economic relief to those who own it. For them, real estate has become the last bastion of financial stability in the wake of agricultural decline. Those without land, unfortunately, bear the double burden of real estate pressures and the ongoing pollution from industries.

The authorities, seemingly aware of the pollution concerns, have granted permissions to major builders for gated communities close to these industries. The allure of affordable prices, especially when compared to other parts of Hyderabad, has spurred a rush among the larger middle-class section to invest in these areas. Unbeknownst to them, they are stepping into a complex scenario where economic opportunities clash with environmental hazards. In this unfolding story, the struggle for survival intertwines with economic aspirations, creating a delicate balance between individual gain and community well-being. The consequences of industrial pollution are not just confined to the environment; they permeate through the social and economic fabric, revealing the intricate layers of a narrative that transcends the boundaries of progress and challenges faced by those caught in its midst.

In the 1980s, the challenges faced by the villagers were collectively acknowledged, and a shared understanding prevailed among all of them. However, a significant shift has occurred over the last few years, transforming this collective suffering into individualized struggles. In recent times, industries, under the guise of Corporate Social Responsibility (CSR) activities, have directly engaged with and influenced some sections of the local population. This has led to a noticeable fragmentation in the unity among the villagers, resulting in a clear demarcation that has become more pronounced since 2018. What was once a collective effort has gradually transformed into a series of individualized problems, particularly for those who do not own any land. The rise of the real estate market has only intensified these challenges. The impact of industrial activities, once a shared concern, is now experienced on an individual level, creating a sense of isolation for those without land. The complexities of the situation have deepened, and the struggles faced by individuals have become more pronounced in the face of evolving economic and environmental dynamics. In this landscape, the intersection of pharmaceutical influence, real estate expansion, and individualized suffering underscores the need for renewed collective efforts to address the multifaceted challenges confronting them.

The malpractices of the pharmaceutical industry, particularly the pollution of the commons and private lands, have transformed collective suffering into individualized struggles. This shift embodies a structural suffering, where the community faces hardships imposed by the above structural conditions.

Figure 5.2. Real Estate-Gated community projects in the study area



Villas in a gated community built on contaminated land with a compromised underground water table.

Section III: Discussion

In this pharmaceutical region, inequality is being naturalized, resulting in the invisibility of certain forms of suffering. The suffering that is 'invisible' around them extends beyond mere 'health disparities' (Georges, 2004). Biopolitics serves to justify and veil state-sanctioned violence, consigning entire populations to realms of invisibility. People living in industrial areas endure the ongoing exposure to pollution, residing in locations already identified as heavily contaminated. This sustained exposure results in both immediate and prolonged health issues. The extensive impact on the populace requires prompt intervention from governmental authorities. Furthermore, the social and economic fabric of these communities has been substantially disturbed, resulting in a forfeiture of their former way of life.

In the context of pharmaceutical pollution and its impact on local communities, the content underscores Foucault's idea that causing harm can extend beyond direct physical harm to encompass indirect forms of 'murder,' where certain individuals are placed in conditions that increase their risk of death. Achille Mbembe's (2019) concept of necropolitics aligns with Foucault's biopolitics and expands on it, suggesting that some individuals are devalued to the point of being considered 'non-persons,' leading to a state of 'death-in-life.' Necropolitics accounts for contemporary forms of subjugation, describing conditions where large

populations are subjected to living as the 'living dead' (Davies, 2018). This form of violence does not necessarily result in immediate death, but involves enduring harm inflicted on entire populations through repeated exposure to everyday forms of violence due to hazardous pollution. This slow violence is akin to Agamben's *homo sacer*, coined by Rob Nixon (2011), signifying a delayed destruction dispersed across time and space, often going unnoticed. It interacts with marginalization, affecting disproportionately those already affected 'casualties of accumulative environmental injury.' The distribution of environmental injustice is heavily rooted in long-standing social inequalities that render certain groups more vulnerable. In the realm of pharmaceutical malpractices, necropolitics, and slow violence contribute to an understanding of the invisible and normalized forms of suffering, shedding light on how the politics of suffering are structured around persistent health inequalities and power imbalances. It emphasizes the importance of recognizing and addressing these dynamics within the context of the pharmaceutical industry's influence on the state which, in turn, affects the people.

The population within industrial zones bears the brunt of pharmaceutical greed, where the pursuit of surplus comes at the expense of people's lives. This insatiable greed leads to disease-mongering, with pharmaceutical companies prioritizing profits over the broader public's health. The state's bias in favor of such practices constitutes a form of structural violence against the larger public. While the environmental hazards resulting from industrial activities have an immediate impact on the residents, the repercussions extend far beyond. This situation is a looming public health crisis, and many are unaware of its root causes. The nexus of pharmaceutical greed and state bias not only jeopardizes the well-being of residents in industrial zones but also poses a significant threat to the health of the larger population. This interconnectedness highlights the need for systemic changes to address the profound and far-reaching consequences of prioritizing profit over public health.

The challenges within the pharmaceutical industry and its pathopolitics are rooted in two main issues. Firstly, the industry deeply penetrates individuals' lives and bodies, transforming them into commodified assets. The human body, with its biological functions, becomes a source of profit as long as it remains alive and, in certain cases, stimulated. This extensive and powerful presence of the pharmaceutical regime constitutes a form of intense violence. Secondly, a significant problem arises from the selective focus of the pharmaceutical regime,

which does not equally prioritize populations whose medicalization does not promise a continuous profit source. In this context, the violence does not stem from direct subjection to pharmaceutical regimes, but rather, from neglect or erasure. The pharmaceutical management of bodies, thus, serves as a two-sided weapon, causing both over-treatment for some and under-treatment for others. (Tomes, 2016).

What is at stake here goes beyond the lives of the subjugated population; it extends to broader public health issues that require attention. The residents in this area contend with drug resistance, which could evolve into a severe public health crisis in the future. The challenges faced by these villagers are not confined to the local, regional, or national levels alone; they have the potential to become a global issue, as exemplified by the case of COVID-19. Multidrug-resistant (MDR) or antimicrobial resistance (AMR) poses a looming and significant public health crisis in the future.

The nexus of pathopolitics and social suffering, coupled with the concept of *Zoe* unveils a distressing narrative within the pharmaceutical industry zones where profits take precedence over the well-being of the local populace. The pathopolitics of the pharmaceutical industry, marked by a disregard for Good Manufacturing Practices (GMP) and environmental regulations, contributes to the social suffering of the people inhabiting these zones. The intentional negligence by the industry, in collusion with authorities, perpetuates health inequalities as residents endure the consequences of pollution without recourse. The concept of *Zoe* accentuates the reduction of these individuals to a state of bare life, stripped of political significance, as their suffering is depoliticized and their struggles marginalized. The pervasive smell, loss of livelihood, and economic hardships faced by the residents underscore the social suffering inflicted upon them, emphasizing the urgent need to address the pathopolitical dimensions and advocate for a more ethical and equitable pharmaceutical industry that prioritizes both health and justice.

Chapter 6: Conclusion

Reflections on Pharmaceuticals, State, and Health Inequalities

“I still shudder at the thought of the nasty chemical smell that pervaded the air ... like a sickening miasma, sucking all cheer from the lives of the hapless villagers ... the rape and the destruction of our land, our rivers, and our groundwater because of the greed and the irresponsibility of a few rogue companies ... a company which is the true beacon of the new, mint-fresh globalized capitalist India and its remarkably effervescent pharmaceutical sector, any efforts spent on proper waste disposal and treatment of toxic effluents are perfectly dispensable. After all, this great Indian “economic war” is being fought solely on the underpinning of low costs of production. Sustainable development means greater costs, lower profit margins, higher prices, and lower salaries.

Drug companies can ill-afford to waste money on processes that would make even a minor dent in profit margins. So what if the surrounding fields have fallen fallow and a few thousand people have lost their source of livelihood and so what if a few people have “allegedly” contracted chronic illnesses (the reports of illnesses anyway never get validated)? All this is just “collateral damage”, a necessary price that has to be paid on the path towards “growth” and a thriving economy. (Dr. Aparna Hegde as cited in Greenpeace⁷², 2004 pg-47).

The thesis, titled "Pharmaceuticals, State, and Local Communities - A Study of Health Inequalities in Hyderabad," resonates with the narrative of Dr. Aparna Hegde, a collaborator and expert from Lokmanya Tilak Medical College, Mumbai, involved in the Greenpeace Health Report of Medak District. The report was published almost two decades ago and the narrative remains relevant even now. Several subsequent reports and documentaries came up in due course and shed light on the issues in this area. The documented pollution issue aligns with Joseph Dumit's (2012) perspective, emphasizing that simply exposing problems is insufficient for critique; it is crucial to demonstrate how the system perpetuates harmful tendencies despite awareness. This piqued the researcher's interest in investigating why and

⁷² The Greenpeace India team along with experts from LTM Medical College & OHSC, Mumbai, Community Health Cell, Bangalore- health study was undertaken to estimate the impact of pollution on the health of the community at Medak.

how the pharmaceutical industry, despite its significant economic contributions, has not adhered to good manufacturing practices.

The thesis investigates the intricate connections among the pharmaceutical industry, the state, and the local populace within the healthcare context. It aims to reveal how the pharmaceutical sector has expanded at the expense of the lives of people impacted by the industry's non-compliance with Good Manufacturing Practices (GMP). Additionally, the study seeks to comprehend the power dynamics and mechanisms employed by the industry, including regulatory capture as a form of power. In brief, it scrutinizes the pharmaceutical industry's influence on health inequalities in the Hyderabad region, exploring the logic behind the industry's sustained power over the state and people, the technologies of power contributing to health inequalities, and the social suffering experienced by affected communities. The pharmaceutical industry, while pivotal in providing healthcare services and saving lives, has faced controversy, particularly exemplified in the case of Hyderabad since the 1980s.

There are very few studies investigating the production process and the industry's methods for surplus accumulation. Existing research predominantly concentrates on drugs, their life cycle, and associated processes, highlighting surplus generation from conception to consumption. In contrast, this study explores the production process, emphasizing surplus generation not only through the manufactured drugs but also via the intricacies of the manufacturing process itself. This concluding chapter attempts to recapitulate and reflect on the pharmaceutical industry, the state, and the affected population.

In Hindsight: Recapitulating Essential Elements

The introductory chapter in the thesis offers a comprehensive view of the global healthcare landscape, categorizing stakeholders as payers, providers, and producers. It explores the financial intricacies of healthcare accessibility, spotlighting the roles of governments, private insurers, and individuals. Focusing on pharmaceuticals as producers, the chapter delves into the global impact of the pandemic, revealing health disparities, especially in countries like India. It unravels the intersection of market-oriented policies, exposing structural inequities based on class, caste, and gender. It illuminates controversies surrounding the profit-driven nature of the industry, its reliance on state patronage, and its influence on global health

policies through lobbying. Sociological issues related to drug safety testing and regulatory influence are explored, leading to the assertion that the pharmaceutical sector, despite socio-economic objectives, primarily exists to contribute to medicine and therapy for patients.

The chapter goes beyond environmental considerations, employing a Marxian political economy approach to explore the historical evolution of the pharmaceutical industry. Emphasizing societal impact, it addresses social and economic disparities within advanced capitalist societies, particularly focusing on surplus generation in the production process. The chapter also delves into the methods, self-reflections, and limitations of the thesis. The underlying thread of discussion in this thesis was in understanding the various ways in which the power of the Pharmaceutical industry has been retained and reproduced over the last four decades, exploring the strategies and structures that enable its continued influence despite challenges, resistance, and legal conflicts.

Chapter 2, titled *Paths of Power: Mapping Accumulation, Regulation, and Health Inequality in the Pharmaceutical Landscape*, scrutinizes the operational mechanisms of the pharmaceutical sector, investigating the power apparatuses that strengthen its influence. The chapter explores the efficacy of medicines, processes of medicalization and pharmaceuticalization, and regulatory capture as integral contributors to this power. The discussion encompasses economic forces, power dynamics, and global governance conditions that impact health outcomes and inequalities. Additionally, the chapter delves into challenges and transformations in India's health system, critically assessing the influence of capitalism, particularly financialized capitalism, on public health. It examines non-communicable diseases (NCDs) and antimicrobial resistance (AMR) within the structural pathogenesis of health issues. The exploration of Commercial Determinants of Health (CDoH) reveals the global impact of corporate power. It broadens the discussion on conceptual tools such as Foucault's biopower, structural violence, intersectionality, and Marxian political economy, providing a comprehensive framework for understanding health inequalities.

Incorporating perspectives from Agamben and Mbembe, the chapter explores subjectivity, necropolitics, and the enduring impacts of violence on populations. The overarching theme emphasizes the necessity of recognizing and addressing the intricate interplay of economic forces, power dynamics, and global governance conditions that shape health outcomes and

inequalities. The chapter further explores theoretical frameworks, such as Foucault's genealogy and Rajan's *Pharmocracy*, to comprehend pharmacological practices, highlighting the multifaceted nature of knowledge, power dynamics, and contending relations of production within highly capitalized biomedicine. Rajan's analysis focuses on the crisis within the pharmaceutical industry, emphasizing the globalized and speculative nature of capital appropriation. The discussion then transitions to pharmaceutical pollution, analyzing it through the lens of political economy and providing a comprehensive analysis of the complex interplay influencing health disparities.

Pharmaceutical Industry and State

In the third chapter, titled *From Policy to Hype: The State as an Architect of Pharma Vision*, the focus is on understanding the state's role in shaping India's pharmaceutical sector. The analysis delves into the complexities of policies, examining various phases and policy shifts. It scrutinizes the early growth phase and provides a thorough overview of the drugs and pharmaceutical industry, emphasizing key developments like the Patent Acts. This exploration aims to unravel the intricate interplay of policies and actors that have contributed to the evolution of the pharmaceutical landscape in India.

The chapter delves into India's generic pharmaceutical industry collaborating with multinational companies under global pressures, exploring policymakers' advocacy for industry liberalization and its structural impact. It emphasizes ineffective regulation, rising medicine costs, and coercive profit-centric tactics. The Patents (Amendment) Act of 2005, aligned with TRIPS, introduces opportunities for multi-site clinical trials, revealing contradictions in powers and intellectual dominance. The chapter explores India's role as a major global provider of generic drugs, focusing on anti-infectives, and its extensive pharmaceutical exports, with over half directed to regulated markets like the U.S. and the EU. To enter these markets, Indian manufacturers adhere to Good Manufacturing Practices (GMP), emphasizing product quality but lacking environmental monitoring provisions. The outsourcing trend, driven by environmental regulations in developed countries, positions the U.S. as the largest pharmaceutical importer from countries like India. Rajan (2017) points out how capitalist interests, sometimes masked with ethics, intersect with geopolitical power dynamics, shaping the immediate and global complexities of pharmocracy and its impact on health and democracy.

The chapter critically examines the assessment of Indian pharmaceutical firms based on manufacturing success, emphasizing the impact on revenues and profits. It introduces the transformative initiative "Vision Pharma 2047," which envisions India's leadership in affordable and innovative pharmaceuticals. This forward-looking vision is analyzed as a 'political economy of hope,' driven by speculative capitalism, shaping a future-oriented perspective. This shows the profound influence of future narratives on valuation processes with far-reaching implications for the pharmaceutical sector and beyond (Rajan, 2007).

The chapter also critically examines India's pharmaceutical and bulk drug industries in the global context with a robust environmental regulatory framework. It highlights systematic cost-shifting strategies within the industries and attributes regulatory failures to broader political economy dynamics. The thesis asserts that these shortcomings are systemic, emphasizing the constitutive role of power in economic processes, leading to health inequalities. The analysis highlights the intricate interplay between state policies, global pharmaceutical networks, and economic power structures, driven by capitalist motives. It explores the global pursuit of markets by major pharmaceutical corporations, revealing trends in rentier assetization and aggressive use of intellectual property rights to establish market exclusivity. The chapter emphasizes the dominance of economic interests over health considerations, reinforcing the complex dynamics of the bio-pharma landscape and illustrating regulatory capture.

Having unraveled the intricate relationship between the state's promotion of the pharmaceutical industry and the global production networks (GPN) that resulted in the outsourcing of highly polluting industries to India, the subsequent chapter delves into how Hyderabad emerged as a bulk drug capital through this nexus. The chapter scrutinizes the impact of GPN on the pharmaceutical landscape, unveiling the economic and environmental consequences of this globalized production process. It sheds light on the far-reaching ramifications of the industry's growth, providing insights into both its economic expansion and the associated problems.

Bulk drug Capital and Regulatory Capture

Chapter 4 titled 'Pharma's Dark Curtain: The Unseen Costs of Medical Advancements' delves into the transformation of Hyderabad into a prominent hub for pharmaceutical exports,

focusing on bulk drugs and generics. The chapter traces the historical roots, particularly the catalytic role of IDPL and government initiatives in the 1980s, leading to Patancheru's strategic selection as an industrial hub. The industrialization drive, although fostering economic prospects, is marred by environmental challenges and local hardships. The study brings out persistent issues of water pollution, insufficient wastewater treatment, and environmental degradation. Legal battles since the 1980s highlight allegations on the pharmaceutical industry, impacting local communities. Despite legal interventions, environmental pollution continues, revealing a lack of balance in addressing conflicting interests among pharmaceutical companies, communities, and regulators. Activists have aimed to address industrial pollution, particularly in Patancheru, but challenges persist due to enforcement issues, minimal fines, and a weakened regulatory system.

The chapter expresses concerns about further industrial development plans like 'Pharma City' and highlights the suppression of dissenting voices. The countervailing forces in raising ethical concerns about environmental and health impacts on the industry's profit-driven production have not been as strong. The concentration of pharmaceutical manufacturing in specific areas is criticized for prioritizing economic considerations over environmental and health concerns, contributing to spatial and developmental disparities between urban and rural regions. The influence of pharmaceutical power exacerbates these issues, potentially sidelining local concerns due to the industry's economic and political clout.

The focal point of the thesis centers around regulatory capture, which is examined through an investigation into the National Green Tribunal's (NGT) directives and the periodical reports submitted by the Telangana State Pollution Control Board. The study dissects the aftermath of the NGT order in October 2017, offering a comprehensive analysis of the court directives, their implementation, and the challenges faced by the affected communities.

The study extensively examines these directives and exposes a troubling inconsistency: none of them are currently being put into effect. The addressed directives cover a range of issues, including principles of delay and laches, the transport of treated effluents from the Common Effluent Treatment Plant, which is reported as not violating Hazardous Waste Rules or the Basel Convention, the regulation of hazardous waste management, restoration of water bodies, the provision of drinking water of sufficient quality and quantity to the villages, the

periodic submission of status reports, entitlement of compensation, the establishment of an Expert Committee on Health Studies, the setting up of a Super Specialty Hospital, and the formation of Corpus Fund and Relief Fund. Despite these directives, the study exposes a lack of implementation, casting doubt on the accuracy of compliance reports provided by pollution control authorities.

The chapter critically evaluates the implementation status of NGT directives, revealing a complex web of challenges faced by the affected communities. In essence, this section in the chapter serves as a powerful critique of the state's vision and hype around the Pharmaceutical industry, unveiling the paradox and the dark side of the industry. It skillfully navigates the legal intricacies, bringing to light the industry's persistent defiance of court orders and the enduring suffering of the affected communities. The juxtaposition of court directives and the harsh realities faced by the community highlights how the regulatory authorities are captured in the hands of the industry which in turn leads to health inequalities.

Health Inequalities

The thesis unveils a disconcerting reality within the villages surrounding industrial zones, where a persistent pollution crisis, spanning over four decades, has wreaked havoc on the lives of the residents. This dire situation has resulted in a plethora of health issues, economic disparities, and environmental degradation, disproportionately affecting lower classes and caste groups. The devastating impact spans generations, with residents facing respiratory disorders, cancers, and reproductive challenges due to toxic air, water, and negligent industrial practices. Skin diseases and tumors further compound their plight, exacerbated by a lack of information about pollutants.

The exploitation of industrial workers, particularly migrants, exacerbates the crisis, as industries manipulate healthcare access, perpetuating a cycle of health hazards. Despite widespread pollution affecting everyone, there is a stark stratification in addressing the issue. Affluent individuals seek treatment in tertiary hospitals, while marginalized populations rely on local Registered Medical Practitioner for healthcare. Doctors near industries express concerns about the effectiveness of prescribed medicines, refraining from extensive testing due to affordability issues. The absence of well-structured primary health centers aggravates health issues in these communities. The environmental hazards and suffering due to the

industry's practices are further compounded by companies expanding operations and surreptitiously releasing effluents. The asymmetry in responsibility, with companies denying wrongdoing and putting the burden of proof on affected victims, heightens the challenges faced by the communities in seeking justice. Moreover, the socioeconomic consequences are profound, with an intricate relationship between poverty and non-communicable diseases (NCDs). Understanding the broader impact of commercial determinants of health (CDoH) becomes crucial, with Fuchs's concept of corporate power offering insight into comprehending CDoH's instrumental, structural, and discursive forms.

The study also highlights a crucial global health concern: the escalating threat of Antimicrobial Resistance (AMR) in chapter 4. It focuses on India's pivotal role in the global crisis, notably with the identification of the multidrug-resistant strain "New Delhi Metallo-beta-lactamase-1," NDM-1 in a Swedish traveler in 2008. This discovery, signifies a pivotal moment, elucidating the intricate challenges faced by Indian authorities in combatting AMR. Despite the World Health Organization's (WHO) early warnings, it wasn't until 2016 that the Indian government officially declared AMR a serious crisis. This declaration paid attention to self-medication and inappropriate antibiotic usage, prompting a comprehensive evaluation of other issues that are ignored. The chapter advocates for a nuanced understanding, recognizing the complexities surrounding medication practices. Furthermore, the chapter delves into reports that underscore the impact of industrial effluents on the rise of AMR which is often downplayed by the bulk drug industry and overlooked by the state.

The chapter spotlighted a pressing concern among the doctors, centering around the perceived ineffectiveness of medicines and raising suspicions of antimicrobial resistance. This predicament is not merely a medical challenge but a significant form of health inequality, especially impactful for an already suffering population. The consequences of medication ineffectiveness, compound the financial strain on individuals. Moreover, the financial constraints faced by the affected population hinder their ability to conduct investigations into the underlying causes of drug inefficacy. This financial limitation creates a significant knowledge gap, preventing individuals from fully comprehending the intricate technical and scientific dimensions involved in the development and spread of antimicrobial resistance.

Another important issue addressed in the study is the repercussions of the industry and the state's endorsement of zero-discharge technology. While touted as a groundbreaking advancement, this technology which has gained legitimacy in the courts, becomes a substantial hindrance for individuals who wish to voice the malpractices of the industry. Those directly impacted, often through their everyday observations of discharged effluents, face obstacles in challenging the narrative surrounding non-adherence to zero discharge technology. This discrepancy amplifies health inequality by sidelining the perspectives of affected communities and restricting their ability to advocate for their well-being. Chapter 4 sheds light on the alarming health inequalities, regulatory capture, and the intricate challenges encountered by affected communities, setting the stage for the examination of social suffering discussed in Chapter 5.

Social Suffering

Chapter 5-titled 'Pathopolitics and Social Suffering' explores narratives of the affected population in three sections. The first section, 'Invisibility and Invisible Suffering,' uncovers the hidden stories and silent struggles of communities, exposing often overlooked aspects of suffering. The second section, 'Structural Violence,' delves into societal structures contributing to persistent inequalities, particularly in health and well-being. Focusing on the Body Burden, third section, dissects the unique challenges faced by individuals and communities, revealing how external factors intensify existing health issues. The chapter synthesizes insights and analyzes the intertwined themes of invisibility, structural violence, and the body burden. It applies Agamben's concept of Zoe to highlight the deliberate invisibilization of suffering in pharmaceutical zones, emphasizing the need to reclaim the political significance of these struggles. The chapter demonstrates how the population's suffering is intentionally rendered invisible by state authorities in collusion with the pharmaceutical industry. The concept of invisibility is exemplified in the state's consistent reporting of zero discharge, aiming to suppress problems faced by communities and render their issues invisible. The subjugated population grasps these invisible problems, highlighting the state's attempts to conceal them.

Pollution, becomes an integral part of daily life, with odors from effluents and gases permeating the air. The residents, despite various challenges, adapt to the constant presence of noxious smell. However, their narratives underline the substantial socioeconomic disparities in addressing the issue. Affluent individuals can invest in air purifiers, while

economically disadvantaged ones endure the burden disproportionately. The villagers anticipate relief from ongoing challenges with the potential shift of industries to a new pharma city. The chapter not only uncovers external adversities but also internal disparities within the affected population, emphasizing how the consequences of Pathopolitics exacerbate existing social injustices.

The chapter delves into the intricate dynamics of normalizing suffering within communities affected by pharmaceutical pollution. It highlights how individuals silently endure environmental violence until it breaches their tolerance thresholds, leading to complaints with pollution control boards. The flexible limit for bearing these conditions complicates the situation, emphasizing the residents' remarkable ability to adapt to intolerable levels of pollution. The heartbreaking scenes of human and animal lives lost, deepen the profound impact of pharmaceutical pollution on both livelihoods and the community's well-being. The acceptance of these deaths as 'natural' reveals a deeply ingrained normalization, raising concerns about the long-term health consequences of living in such contaminated environments. The disconnect between deaths and environmental conditions, emphasizes the need for intervention and questioning the systemic issues contributing to this silent suffering. The residents assert that essential health issues, particularly those related to pollution and infertility, often go unaddressed. The victims call for elected representatives to prioritize healthcare in policymaking and address the complex web of actions perpetuating health challenges. Drawing parallels with Foucault and Agamben's perspectives on biopower, the chapter critically analyzes the authority wielded over individuals, leading to the normalization of suffering within societal structures.

The chapter also delves into the concept of structural violence, emphasizing its role in perpetuating health inequalities within communities affected by pharmaceutical pollution. The cases presented vividly exemplify structural suffering within the affected population. Case 1 narrates the paralysis of a young man who joined the pharmaceutical industry after his family's land became uncultivable due to pollution. Case 2 depicts a 10-year-old boy's struggle with unidentified diseases, revealing deficiencies in the healthcare system. Case 3 sheds light on the health challenges faced by migrant workers in the industry, questioning overall health and safety measures. Narratives further illustrate the daily battles faced by working women and struggles to find suitable matches due to infertility problems. The

chapter emphasizes the systemic impact of pharmaceutical pollution on livelihoods and well-being. It discusses the depletion of agricultural resources, diminished yields, increased reliance on chemicals, and limited local employment opportunities. The vicious cycle of structural suffering emerges as the local population, frequently falling sick due to pollution, is compelled to seek employment outside their communities.

The chapter underscores the profound health implications of pharmaceutical pollution on the socio-economic challenges faced by affected communities. Exposure to contaminated air, water, and soil leads to frequent illnesses, aggravated by the absence of comprehensive insurance schemes that primarily focus on hospitalization, leaving everyday medical expenses unattended. The lack of insurance coverage for regular clinic visits becomes a significant challenge, forcing families to choose between buying medicines and putting food on the table. The out-of-pocket health expenditure rises, burdening individuals with the costs of regular medical treatments. The concept of a ‘double body burden’ is used here as residents in pharmaceutical-polluted areas not only face common health problems that the general population face but also endure additional issues due to their geographical and social positions. Health inequality becomes evident, emphasizing disparities in the impact of environmental factors on different communities. The recognition that not everyone in the broader population undergoes the same health challenges as marginalized villagers highlights a significant aspect of health inequality.

Changing Dynamics

In regions grappling with pharmaceutical pollution, an intricate narrative unfolds amidst the burgeoning real estate growth. The local population, enticed by promises of relocating industries, witnesses a real estate surge benefiting landowners. However, a shift occurs when landowners see speculative value of their lands thus remaining silent and passive about pollution concerns, fearing repercussions on land prices. For those without land, the dual burden of real estate pressures and ongoing pollution persists. Authorities permit gated communities near industries, attracting middle-class investment, unknowingly juxtaposing economic opportunities with environmental hazards. Industrial pollution's consequences permeate the social and economic fabric, revealing layers of progress and challenges. In the 1980s, villagers collectively faced challenges, fostering shared understanding. However, a notable shift transformed collective suffering into individualized struggles. Industries,

through Corporate Social Responsibility (CSR) initiatives, influenced some local communities, leading to the fragmentation of unity since 2018. Once a collective effort, challenges became individualized, intensifying with the real estate boom, isolating those without land. The intersection of pharmaceutical influence, real estate expansion, and individualized suffering underscores the need for renewed collective efforts to address multifaceted challenges.

In a nutshell -

- The study, in examining regulatory capture, employs a unique method centered on studying court directives and their implementation. Recognizing the impracticality of directly understanding lobbying and corruption, the study strategically utilizes court interventions as a tool to grasp the dynamics of regulatory capture. This approach provides insights into how regulatory agencies operate within the legal framework and respond to external pressures.
- Thesis unravels the intricate pathways of power within the pharmaceutical landscape, exploring facets like therapeutic efficacy, medicalization, pharmaceuticalization, and regulatory capture. The thesis focuses on the regulatory capture of the state, choosing the highly polluted Pattancheru industrial zone, known for maximum USFDA-approved industries and high exports, as a case study. This region, with well-documented pollution problems and legal disputes, serves as a lens to unravel the industry's influence over the state. The field of study is pharmaceuticals and the impact of pollution provides insights in understanding this field.
- The conflict of interest between the Department of Pharmaceuticals, which falls under the Ministry of Health, and the Ministry of Chemicals and Fertilizers is a significant issue raised in the thesis. The Ministry of Health is oriented towards ensuring public welfare, while the Ministry of Chemicals and Fertilizers, by its inherent nature, is inclined towards promoting industries.. This inherent contradiction raises concerns about the balance between public health priorities and economic considerations within the pharmaceutical sector.

- The state views the pharmaceutical industry as crucial for achieving self-sufficiency and reducing dependency on China, given its significant contribution to the nation's economy. This perception has become advantageous for the industry, leading to easier environmental clearances and state assistance in overcoming various hurdles. The state supports the industry by providing exemptions from labor issues, tax relaxations, subsidies, and other incentives, recognizing its role in contributing to the economy. The pharmaceutical sector is considered a source of national pride, as it has positioned India as the pharmacy of the world.
- The burden of proof and the adoption of zero discharge technology serve as new tools of power for the pharmaceutical industry, shielding their malpractices. This power dynamic is evident in the analysis of court documents. The burden of proof, coupled with the unaffordability of legal representation and the costs involved in accessing the judiciary for the affected, establishes a formidable power apparatus favoring the industry.
- Affected individuals rely on activists and environmentalists for advocacy, lacking their legal representation. Activists, who are aging, struggle against industry suppression. The dependency on proofs, tests, and advocates further accentuates the industry's power. The stark reality of pollution remains obscured, as whistleblowers are stifled.
- To substantiate their claims, affected individuals require scientific evidence, which often proves to be financially unattainable, thereby ensuring power with the industry.
- The thesis delves into the analysis of social suffering through the lenses of normalizing suffering, invisible suffering, and the invisibility of suffering, ultimately culminating in the concept of body burden.
- Invisibilization in two distinct ways. Firstly, at the industry level, efforts are made to camouflage non-compliance and disregard for environmental concerns. Secondly, affected individuals, facing the repercussions of pollution, contribute to its invisibility, driven by the rise in real estate values, where acknowledging pollution

could adversely affect land prices. Consequently, a dual process unfolds: the industry actively conceals its actions, and the affected population, influenced by real estate dynamics, participates in concealing the industry.

Prospect or Uncertainty?

With the changing landscape and rapid urbanization, the potential concealment of pollution issues may occur, reminiscent of the ongoing plight faced by victims of the Bhopal gas disaster. The current perspective of viewing real estate growth as a beacon of hope and the state considering Pharma City as a solution to pollution issues represents a critical juncture in the region's well-being, saturated with effluents. As the region witnesses expanding real estate development, the suppression of ongoing pollution raises a developmental challenge, impacting the lives of both current and prospective residents, including those in upcoming gated community projects. This juxtaposition poses critical questions about the viability of Pharma City as a solution, the potential rehabilitation of contaminated groundwater and lakes, and the fate of residents whose villages are transforming due to the rise in land rates and sales.

The plight of the landless, the toxic disease-breeding lakes, the accessibility and affordability of the judiciary, and the role of the state in the future all emerge as pressing concerns. The study prompts further inquiries: will migrants working in these regions find healing? How will school children exposed to risks cope with it? Is the environmental impact a by-product of a modernity project or a crime requiring swift trials, perhaps an "unequal fight" (Rana, 2020)? What will happen to fishermen, vendors, barbers, and the low-income population? The rising concerns expressed by doctors about locals not responding to medicines and the overarching question of whether the polluter pays principle alone is a sufficient solution add layers of complexity. Beyond these concerns, challenges emerge, such as preventing the Mudirajus/fishermen from selling contaminated fish, controlling the entry of pollutants into food grains to market, and stopping tainted milk from reaching households. These multifaceted issues underscore the need for comprehensive strategies and thoughtful regulations to address the myriad challenges arising from the intersection of economic transformation, environmental degradation, and public health in the region which percolates to other regions as well.

In this context, the thesis concludes by revisiting and completing the narrative of Dr. Aparna Hegde, as was quoted at the beginning of the chapter.

How long will it take for our apathy to rebound on us? How long will it take for the great Manjira waters, which supply the whole of Hyderabad to get polluted? How long will it take for the groundwater and the pure streams of our country, which form the source of all our bottled water to get irreparably polluted? We choose to ignore the warning signs only at our own peril. What kind of India have we created in which poor villagers ... have to fight a court battle for years only to earn the right to get clean drinking water: water which is the fundamental right of all and not the preserve of a few. What kind of people are we that we cannot empathize with the plight of the poor farm labourers who are being squeezed from all sides. It was heartbreaking to hear the same stories being repeated in every village I visited: barren fields forcing farm labourers to search for odd jobs in the city. Not only was there no security of a steady income, most families I visited had a string of health complaints ranging from headaches to major illnesses, adding greatly to their financial burden.... And the irony of the entire situation was that the root cause of the illnesses was the apathy and the lack of accountability of the very drug companies whose function it is to manufacture drugs, ostensibly to help people recover from illnesses... the irony of saving lives on the one hand and destroying others in the process of doing so. What kind of a lesson are we teaching our children: that it is okay to steal from the environment and strip poor people of their livelihood for the development of the already developed? What kind of a world are we, the present generation, leaving behind for them? A world, in which global warming, polluted rivers, and deforestation will wreak havoc and ruin countless lives. Why should they be made to pay a heavy price for our apathy and callousness? It is time to act before it is too late. It is time to wake up and smell the bacon. It is time to take responsibility and learn to value the beauty and life-sustaining nature of Mother Earth. Each one of us can make a difference and the time to do so is now before it is too late” (Green Peace, 2004 p.47).

Bibliography and References

Abhishek, D. (2023, January 23). Lowest Among BRICS Nations To 2.1% Of GDP: India's Healthcare Spending Looks Up But Is That Enough? *ABP Live*. Retrieved from <https://news.abplive.com/india-at-2047/india-healthcare-spending-looks-up-following-covid-pandemic-lowest-among-brics-nations-neighbours-1579245>

Abraham, J. (1993). Scientific standards and institutional interests: Carcinogenic risk assessment for benoxaprofen in the UK and the US. *Social Studies of Science*, 23, 387–444.

Abraham, J. (1995). *Science, politics and the pharmaceutical industry: Controversy and bias in drug regulation*. London: UCL Press.

Abraham, J. (1997). The science and politics of medicines regulation. In M.A. Elston (Ed.), *Sociology of health and illness special monograph issue on the sociology of medical science and technology*. Oxford: Blackwell.

Abraham, J. (2002). The pharmaceutical industry as a political player. *Lancet*, 360, 1498–1502.

Abraham, J. (2007). Building on sociological understandings of the pharmaceutical industry or reinventing the wheel? Responses to Joan Busfield's 'pills, power and people'. *Sociology*, 41, 727–736.

Abraham, J. (2008). Sociology of pharmaceuticals development and regulation: a realist empirical research programme. *Sociology of Health & Illness*, 30(6), 869–885.

Abraham, J. (2009). Partial progress: Governing the pharmaceutical industry and the NHS, 1948–2008. *Journal of Health, Politics, Law and Policy*, 34, 931–977.

Abraham, J. (2010). Pharmaceuticalization of society in context: Theoretical, empirical and health dimensions. *Sociology*, 44, 603–622.

Abraham, J. (2023). *Science, politics and the pharmaceutical industry: Controversy and bias in drug regulation*. Taylor & Francis.

Abraham, J., & Ballinger, R. (2012). The neoliberal regulatory state, industry interests, and the ideological penetration of scientific knowledge: Deconstructing the redefinition of carcinogens in pharmaceuticals. *Science, Technology, & Human Values*, 37(5), 443-477.

Abraham, J., & Davis, C. (2005). A comparative analysis of drug safety withdrawals in the UK and the US (1971–1992): Implications for current regulatory thinking and policy. *Social Science and Medicine*, 61, 881–892.

Abraham, J., & Davis, C. (2007). Interpellative sociology of pharmaceuticals: problems and challenges for innovation and regulation in the 21st century. *Technology Analysis & Strategic Management*, 19(3), 387-402. <https://doi.org/10.1080/09537320701290459>

Abraham, J., & Lawton Smith, H. (Eds.). (2003). *Regulation of the Pharmaceutical Industry*. Palgrave Macmillan.

Abraham, J., & Lewis, G. (2002). Citizenship, medical expertise and the regulatory state in Europe. *Sociology*, 36(1), 67–88.

Abraham, J., & Lewis, G. (2003). Europeanization of Medicines Regulation. In Abraham, J., Smith, H. L., & Smith, H. L. (Eds.), *Regulation of the pharmaceutical industry* (pp. 42–81). Springer.

Abraham, J., & Reed, T. (2001). Trading risks for markets: The international harmonization of pharmaceuticals regulation. *Health, Risk and Society: Special issue on Globalisation*, 3, 113–128.

Abraham, J., & Reed, T. (2003). Globalization of medicines control. In J. Abraham & H. Lawton Smith (Eds.), *Regulation of the pharmaceutical industry*. Palgrave: Basingstoke.

Adams, C. P., & Brantner, V. V. (2006). Estimating the cost of new drug development: is it really \$802 million?. *Health affairs*, 25(2), 420-428.

Adams, M. (2009, March 26). Cocktail of Pharmaceuticals Found in the Fish Caught Near Major US Cities. *Natural News*. Retrieved on 21 September 2011, from <http://www.naturalnews.com/025933.html>

Adelman, M. J., & Baldia, S. (1996). Prospects and limits of the patent provision in the TRIPs Agreement: the case of India. *Vand. J. Transnat'l L.*, 29, 507.

Afrin, S. & Gupta, V. (2023, August 30). *Pharmaceutical Formulation*. National Library of Medicine. Retrieved from <https://www.ncbi.nlm.nih.gov/books/NBK562239/>

Agamben, G. (1998). *Homo sacer: Sovereign power and bare life*. Stanford university Press.

Alliance for the Prudent Use of Antibiotics (APUA) (2014). General Background: About Antibiotic Resistance, http://www.tufts.edu/med/apua/about_issue/about_antibioticres.shtml

Ambade, M., Sarwal, R., Mor, N., Kim, R., & Subramanian, S. V. (2022). Components of out-of-pocket expenditure and their relative contribution to economic burden of diseases in India. *JAMA Network Open*, 5(5), e2210040-e2210040. <https://doi.org/10.1001/jamanetworkopen.2022.10040>

Amrith, S. (2007). Political culture of health in India: A historical perspective. *Economic and Political Weekly*, 114-121.

Amrutanjan. (2019). History of Amrutanjan. Retrieved multiple times, on January 22, from <https://www.amrutanjan.com/Note/History.html>

Anderson, E. S. (1999). What Is the Point of Equality? *Ethics*, 109(2), 287–337. <https://doi.org/10.1086/233897>

Angell, M. (2005). *The truth about the drug companies: How they deceive us and what to do about it*. Random House Trade Paperbacks.

Angell, M. (2006). The truth about the drug companies. *TRIAL*, 42(7), 66.

Angus, D. E., & Karpetz, H. M. (1998). Pharmaceutical policies in Canada: issues and challenges. *Pharmacoeconomics*, 14(Suppl 1), 81-96. DOI: 10.2165/00019053-199814001-00011.

AP Pollution Control Board. (2020). *FINAL ACTION PLAN FOR IMPROVEMENT OF ENVIRONMENTAL PARAMETERS IN CRITICALLY POLLUTED AREAS OF “PATANCHERU-BOLLARAM CLUSTER” ANDHRA PRADESH*. Retrieved from <https://cpcb.nic.in/displaypdf.php?id=UGF0YW5jaGVydS1Cb2xsYXJhbS5wZGY=>

Arcilla, M.S., van Hattem, J.M., Haverkate, M.R., et al. (2017) Import and Spread of Extended-Spectrum β -Lactamase-Producing Enterobacteriaceae by International Travelers (COMBAT Study): A Prospective, Multicentre Cohort Study. *The Lancet Infectious Diseases*, 17, 78-85. [https://doi.org/10.1016/S1473-3099\(16\)30319-X](https://doi.org/10.1016/S1473-3099(16)30319-X).

Armstrong, D. (1983). *Political anatomy of the body: Medical knowledge in Britain in the twentieth century*. Cambridge: Cambridge University Press.

Armstrong, D. (1995). The rise of surveillance medicine. *Sociology of Health & Illness*, 17(3), 393–404.

Attard, J. (2020, March 24). Pandemics, profiteering and big pharma: how capitalism plagues public health. *Marxist*. Retrieved from <https://www.marxist.com/pandemics-profiteering-and-big-pharma-how-capitalism-plagues-public-health.htm>

Atuk, T. (2020). Pathopolitics: Pathologies and biopolitics of PrEP. *Frontiers in Sociology*, 5, 53. <https://doi.org/10.3389/fsoc.2020.00053>

Babar, Z. U. D., & Jamshed, S. (2008). Social pharmacy strengthening clinical pharmacy: why pharmaceutical policy research is needed in Pakistan?. *Pharmacy world & science*, 30, 617-619. <https://doi.org/10.1007/s11096-008-9246-z>

Balakrishnan, K., Dey, S., Gupta, T., Dhaliwal, R. S., Brauer, M., Cohen, A. J., ... & Dandona, L. (2019). The impact of air pollution on deaths, disease burden, and life expectancy across the states of India: the Global Burden of Disease Study 2017. *The Lancet Planetary Health*, 3(1), e26-e39. <http://www.ncbi.nlm.nih.gov/pubmed/30528905>

Balakrishnan, K., Dey, S., Gupta, T., Dhaliwal, R. S., Brauer, M., Cohen, A. J., ... & Dandona, L. (2019). The impact of air pollution on deaths, disease burden, and life expectancy across the states of India: the Global Burden of Disease Study 2017. *The Lancet Planetary Health*, 3(1), e26-e39. [https://www.thelancet.com/journals/lanplh/article/PIIS2542-5196\(18\)30261-4/fulltext](https://www.thelancet.com/journals/lanplh/article/PIIS2542-5196(18)30261-4/fulltext)

Ballance, R., Pogany, J., & Forster, H. (1992). *The world's pharmaceutical industries*. Edward Elgar Publishing.

- Bambra, C., Fox, D., & Scott-Samuel, A. (2005). Towards a politics of health. *Health promotion international*, 20(2), 187-193. <https://doi.org/10.1093/heapro/dah608>
- Bardhan, P. (1984). *The Political Economy of Development in India*. Oxford University Press.
- Basak, S.C. (2008, January 09). The genesis of drug price control. *PharmaBiz*. Retrieved from <http://pharmabiz.com/PrintArticle.aspx?aid=42905&sid=960>
- Baum, F. E., & Margaret Anaf, J. (2015). Transnational corporations and health: a research agenda. *International Journal of Health Services*, 45(2), 353-362.
- Bauman, Z. (2013). *Wasted lives: Modernity and its outcasts*. John Wiley & Sons.
- Beck, U. (1992). *Risk society: Towards a new modernity* (Vol. 17). Sage.
- Bell, L, Michelle and Samet Jonathan. (2010). Air pollution. In Frumkin H, (Eds). *Environmental Health: From Global to Local*, 2nd Ed, 387-415. San Francisco: John Wiley & Sons.
- Bengal Chemicals & Pharmaceuticals Ltd. (2019). “Our Founder- Acharya Prafulla Chandra Ray (1861-1944)”. Retrieved on January 21 from <https://bengalchemicals.co.in/our-founder-history/>
- Bergh, A., Nilsson, T., & Waldenström, D. (Eds.). (2016). *Sick of inequality?: An introduction to the relationship between inequality and health*. Edward Elgar Publishing.
- Bergheim, M., Helland, T., Kallenborn, R., & Kümmerer, K. (2010). Benzyl-penicillin (Penicillin G) transformation in aqueous solution at low temperature under controlled laboratory conditions. *Chemosphere*, 81(11), 1477–1485. <https://doi.org/10.1016/j.chemosphere.2010.08.052>
- Bhan, N., Rao, K. D., & Kachwaha, S. (2016). Health inequalities research in India: a review of trends and themes in the literature since the 1990s. *International journal for equity in health*, 15(1), 1-8. <https://doi.org/10.1186/s12939-016-0457-y>

- Bhattacharya N. (2016). Between the Bazaar and the Bench: Making of the Drugs Trade in Colonial India, ca. 1900-1930. *Bulletin of the history of medicine*, 90(1), 61–91. <https://doi.org/10.1353/bhm.2016.0017>
- Biehl, J. G. (2004). The activist state: Global pharmaceuticals, AIDS, and citizenship in Brazil. *Social Text*, 22(3), 105-132.
- Black, J. (2008). Constructing and contesting legitimacy and accountability in polycentric regulatory regimes. *Regulation & governance*, 2(2), 137-164. <https://doi.org/10.1111/j.1748-5991.2008.00034.x>
- Boehringer, S. K. (2004). What's the best way to dispose of medications. *Pharm Lett*, 20(4), 200415.
- Bose, S. (1997). Instruments and idioms of colonial and national development: India's historical experience in comparative perspective. In F. Cooper and R. Packards (Eds.), *International Development and the Social Sciences: Essays in the History and Politics of Knowledge* (pp. 45-63). University of California Press.
- Bossen, L. (1994). Death Without Weeping: The Violence of Everyday Life in Brazil. <http://www.jstor.org/stable/41799903>
- Bound, J. P., & Voulvoulis, N. (2005). Household disposal of pharmaceuticals as a pathway for aquatic contamination in the United Kingdom. *Environmental health perspectives*, 113(12), 1705–1711. <https://doi.org/10.1289/ehp.8315>
- Bourdieu, P. (1999). Rethinking the state. In Steinmetz, G. (Ed.) *State/culture: State Formation after the Cultural Turn*. Ithaca: Cornell University Press.
- Bourgois, P. I. (2003). *In search of respect: Selling crack in El Barrio* (No. 10). Cambridge university press.
- Bowker, G. C., & Star, S. L. (2000). Invisible mediators of action: Classification and the ubiquity of standards. *Mind, Culture, and Activity*, 7(1-2), 147-163.
- Boyer, R., & Drache, D. (Eds.). (1996). *States against markets: the limits of globalization*. Psychology Press.

Bradley, P. J., Lahti, C. J., Plümper, E., & Johnson, P. J. (1997). Targeting and translocation of proteins into the hydrogenosome of the protist *Trichomonas*: similarities with mitochondrial protein import. *The EMBO journal*, 16(12), 3484-3493. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1169974/pdf/bmj32500913.pdf>

Braithwaite, J. (1984). *Corporate crime in the pharmaceutical industry (Routledge Revivals)*. Routledge.

Braithwaite, J. (2008). *Regulatory capitalism: How it works, ideas for making it work better*. Edward Elgar Publishing.

Braithwaite, J., & Drahos, P. (2000). *Global business regulation*. Cambridge university press.

Britannica, T. Editors of Encyclopaedia (2023, December 14). Hyderabad. Encyclopedia Britannica. <https://www.britannica.com/place/Hyderabad-historical-state-India>

Brown, L. R. (2001). *State of the world 2001: A Worldwatch Institute report on progress toward a sustainable society*. WW Norton & Company.

Brundtland, G. H. (2005). Public health challenges in a globalizing world. *The European Journal of Public Health*, 15(1), 3-5. <https://doi.org/10.1093/eurpub/cki134>

Burns, L. R. (Ed.). (2014). *India's healthcare industry: innovation in delivery, financing, and manufacturing*. Cambridge University Press.

Butler, J. (2016). *Frames of war: When is life grievable?*. Verso Books.

Carlsson, G., Örn, S., & Larsson, D. J. (2009). Effluent from bulk drug production is toxic to aquatic vertebrates. *Environmental Toxicology and Chemistry*, 28(12), 2656-2662.

Carpenter, D., Zucker, E. J., & Avorn, J. (2008). Drug-review deadlines and safety problems. *New England Journal of Medicine*, 358(13), 1354-1361.

Carré, J. L. (2004). *The Constant Gardener*. New York: Scribner.

Cassels, A. (2005). *Selling sickness: how drug companies are turning us all into patients*. Allen & Unwin.

CDSCO (2019). Retrieved on January 22, from <http://www.cdsco.nic.in/forms/Default.aspx>

CDSCO. (2001). Schedule M of Drug and Cosmetics Act and Rules- Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products. Retrieved on January 22, 2019 from <http://cdsco.nic.in/html/GMP/ScheduleM>.

Central Pollution Control Board of India (CPCB). (2010). Final action plan for improvement of environmental parameters in critically polluted areas of Patancheru–Bollaram cluster, Andhra Pradesh. Retrieved from <http://cpcb.nic.in/divisionsofheadoffice/ess/PatancheruBollaram.pdf>. Accessed 20 Jan 2017

Chakrabarty, B. (1992). Jawaharlal Nehru and planning, 1938–41: India at the crossroads. *Modern Asian Studies*, 26(2), 275-287.

Chakraborty, S., & Lofstedt, R. (2012). Transparency Initiative by the FDA's Center for Drug Evaluation and Research (CDER): Two qualitative studies of Public Perceptions. *European Journal of Risk Regulation*, 3(1), 57-71.

Chakravarty, S., Chikkatur, A., de Coninck, H., Pacala, S., Socolow, R., & Tavoni, M. (2009). Sharing global CO₂ emission reductions among one billion high emitters. *Proceedings of the National Academy of Sciences of the United States of America*, 106(29), 11884–11888. <https://doi.org/10.1073/pnas.0905232106>

Chandra Sekhar, K., Chary, N. S., Kamala, C. T., Venkateswara Rao, J., Balaram, V., & Anjaneyulu, Y. (2003). Risk assessment and pathway study of arsenic in industrially contaminated sites of Hyderabad: a case study. *Environment international*, 29(5), 601–611. [https://doi.org/10.1016/S0160-4120\(03\)00017-5](https://doi.org/10.1016/S0160-4120(03)00017-5)

Chandra, U., Sridharan, S., & Shwetha, G. S. (2016). Opportunities and Challenges of Indian Pharmaceutical Sector: An overview. *International Journal of Scientific Research & Management*, 4(6), 4287-4302. <http://www.ijstrm.in/v4-i6/11%20ijstrm.pdf>

Charatan, F. (2004). The Truth About the Drug Companies: How they deceive us and what to do about it. *BMJ*, 329(7470), 862. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC521592/>

Chaudhuri, S. (2005). *The WTO and India's pharmaceuticals industry: Patent protection, TRIPS, and developing countries* (Vol. 16, p. 358). New Delhi: Oxford University Press.

Chaudhuri, S. (2012). Multinationals and monopolies: Pharmaceutical industry in India after TRIPS. *Economic and Political Weekly*, 46-54.

Chennai, P. (2011, July 07). Andhra bulk drug industry facing rough weather. *Pharmabiz*. Retrieved from <http://www.pharmabiz.com/ArticleDetails.aspx?aid=64131&sid=21>.

Choi, C. Q. (2007). Pollution in Solution, Drug-Resistance DNA as the Latest Freshwater Threat. *Scientific American*, 296, 22-23.

CIDRAP. (2004, June 14). FDA approves generic forms of ciprofloxacin. Retrieved from <https://www.cidrap.umn.edu/anthrax/fda-approves-generic-forms-ciprofloxacin>

Cipla. (2019). Corporate Information: At a Glance. Retrieved on January 22, 2019 from <http://www.cipla.com/en/corporate-information/at-a-glance.html>

Cirex Pharmaceuticals Ltd. (2017). *Environmental Impact Assessment Report*. Submitted to Ministry Of Environment, Forest And Climate Change Government Of India.

Retrieved from <https://environmentclearance.nic.in/DownloadPfdFile.aspx?FileName=EAI4eCUEOAddVela80VzNoQXvhrfC9XJF1LNF3V66+icSpJangZH+i7SF7URLxUfi4OBHNAuM/tFXLe3vV/G4CXf0mp5uWQxEQqMCzYN1k/pmE4Wt7qL521XesVNOeMfcWiM25ZGkuXOIUSWBGsWA==&FilePath=93ZZBm8LWEXfg+HAIQix2fE2t8z/pgnoBhDIYdZCxzU58BnhvJgYCYZmnh7L8vuUpAjRIPQFm4dqIX0YXm9oQdIXvs4CpAbUBzBfrV7e1RFE=>

Cirex Pharmaceuticals Ltd. (n.d). *Executive Summary*. Submitted to Telangana State Pollution Control Board, Regional Office, Sangareddy.

Retrieved from <https://tspcb.cgg.gov.in/publichearings/Cirex%20Pharma,%20Sangareddy%20Dist.%20-%20EXE%20SUM%20ENG.pdf>

Cohen, A. J., Brauer, M., Burnett, R., Anderson, H. R., Frostad, J., Estep, K., Balakrishnan, K., Brunekreef, B., Dandona, L., Dandona, R., Feigin, V., Freedman, G., Hubbell, B., Jobling, A., Kan, H., Knibbs, L., Liu, Y., Martin, R., Morawska, L., Pope, C. A., 3rd, Forouzanfar, M. H. (2017). Estimates and 25-year trends of the global burden of disease attributable to ambient air pollution: an analysis of data from the Global Burden of Diseases Study 2015. *The Lancet* (London, England), 389(10082), 1907–1918. [https://doi.org/10.1016/S0140-6736\(17\)30505-6](https://doi.org/10.1016/S0140-6736(17)30505-6)

Comaroff, J. (1976). A bitter pill to swallow: placebo therapy in general practice. *The Sociological review*, 24(1), 79-96.

Conrad, P. (1985). The meaning of medications: another look at compliance. *Social science & medicine*, 20(1), 29-37.

Conrad, P., & Bergey, M. (2015). Medicalization: Sociological and anthropological perspectives. In *International encyclopedia of the social & behavioral sciences* (pp. 105-109). Elsevier Ltd.

Cooper, R. (2013). Disease mongering. *International Encyclopedia of Ethics*, 1-3. <https://doi.org/10.1002/9781444367072.wbiee039.pub2>

Cosminsky, S. (1994). All roads lead to pharmacy: use of pharmaceuticals on a Guatemalan plantation. *Medicines: Meanings and Contexts, Health Action Information Network, Queton City, Philippines*, 103-124.

Das, K. (2015, November 28). Pharma still pollutes Patancheru. *The Hans India*. Retrieved from <https://www.thehansindia.com/posts/index/Telangana/2015-11-28/Pharma-still-pollutes-Patancheru/189407?infinitemscroll=1>

Das, R. J. (2023). Capital, capitalism and health. *Critical Sociology*, 49(3), 395-414. <https://doi.org/10.1177/08969205221083503>

Daughton, C. G., & Ruhoy, I. S. (2009). Environmental footprint of pharmaceuticals: the significance of factors beyond direct excretion to sewers. *Environmental toxicology and chemistry*, 28(12), 2495-2521.

Davies, T. (2018). Toxic space and time: Slow violence, necropolitics, and petrochemical pollution. *Annals of the American Association of Geographers*, 108(6), 1537-1553. <https://doi.org/10.1080/24694452.2018.1470924>

Davis, C., & Abraham, J. (2013). Unhealthy pharmaceutical regulation. *Andrew Webster Sally Wyatt*, 245.

de Lacy-Vawdon, C., Vandenberg, B., & Livingstone, C. H. (2022). Recognising the elephant in the room: the commercial determinants of health. *BMJ Global Health*, 7(2). Doi: [10.1136/bmjgh-2021-007156](https://doi.org/10.1136/bmjgh-2021-007156)

Dean, T. (2015). Mediated intimacies: Raw sex, Truvada, and the biopolitics of chemoprophylaxis. *Sexualities*, 18(1-2), 224-246. DOI:10.1177/1363460715569137

Deol, T. (2023, February 2). Budget 2023-24: Marginal rise in health budget not enough to keep up with inflation, experts say. *Down to Earth*. Retrieved from <https://www.downtoearth.org.in/news/governance/budget-2023-24-marginal-rise-in-health-budget-not-enough-to-keep-up-with-inflation-experts-say-82015>

Department of Biotechnology. (2019). Medical Biotechnology. Retrieved on January 23, 2019 from <http://www.dbtindia.nic.in/program-medical-biotechnology/>

Department of Chemicals & Petrochemicals. (2005). *Report by Task Force to explore options other than price control for achieving the objective of making available Life-saving drugs at reasonable price*. Government of India. Retrieved on January 23, 2019 from http://pharmaceuticals.gov.in/sites/default/files/Dr.%20Pronab%20Sen%20Committee%20Report1_0.pdf

Department of Environment, Forests and Wildlife. (1989). Hazardous Wastes (Management and Handling) Rules. Notification. Retrieved on January 23, 2019 from <http://envfor.nic.in/legis/hsm/hsm1.html>

Department of Pharmaceuticals (2014). Constitution of Pharmaceutical Advisory Forum. Ministry of Chemicals and Fertilizers, Government of India http://pharmaceuticals.gov.in/sites/default/files/PharmaForum_0.pdf

Department of Pharmaceuticals. (2012). National Pharmaceutical Pricing Policy, 2012 (NPPP 2012). Ministry of Chemicals and Fertilizers, Government of India. http://pharmaceuticals.gov.in/sites/default/files/National%20Pharmaceutical%20Pricing%20Policy%202012_1.pdf

Department of Pharmaceuticals. (2012). *National Pharmaceuticals Pricing Policy*. Government of India. Retrieved from <https://pharmaceuticals.gov.in/important-document/national-pharmaceutical-pricing-policy-2012>

Department of Pharmaceuticals. (2014). Constitution of Pharmaceutical Advisory Forum. *Government of India*. Retrieved on January 23, 2019 from <https://pharmaceuticals.gov.in/>

Department of Pharmaceuticals. (2019). Information from the official website. *Government of India*. Retrieved on January 22, 2019 from <http://pharmaceuticals.gov.in>

Department of Scientific and Industrial Research. (2019). Retrieved on January 23, 2019 from <http://www.dsir.gov.in/>.

Desai, M., Njoku, A., & Nimo-Sefah, L. (2022). Comparing Environmental Policies to Reduce Pharmaceutical Pollution and Address Disparities. *International Journal of Environmental Research and Public Health*, 19(14), 8292. <https://doi.org/10.3390/ijerph19148292>

Devulapalli, R. (2020, January 04). Lakes on drugs. *The Week Magazine*. Retrieved from <https://www.theweek.in/theweek/cover/2020/01/03/lakes-on-drugs.html>

Dewey, J. (2000). *Liberalism and Social Action*. Amherst, New York: Prometheus Books.

Dey's Medical. (2019). About us- Journey. Retrieved on January 22, 2019 from <http://www.deysmedical.com/journey.aspx>

Differding, E. (2014). Drug discovery alliances in India—indications, targets, and new chemical entities. *ChemMedChem*, 9(1), 43-60. <https://doi.org/10.1002/cmdc.201300341>

DIPP. (1951). The Industries (Development and Regulation) Act. Retrieved on January 23, 2019 from https://dipp.gov.in/sites/default/files/IndustriesAct_1951_11June2018.pdf

Doron, A and Broom, A. (2019). The Spectre of Superbugs: Waste, Structural Violence and Antimicrobial Resistance in India. *Worldwide Waste: Journal of Interdisciplinary Studies*, 2(1):

Dresser, R. (2014). The right to try investigational drugs: science and stories in the access debate. *TEx. L. REv.*, 93, 1631.

Dumit, J. (2012). Prescription maximization and the accumulation of surplus health in the pharmaceutical industry: The_BioMarx_Experiment. In Rajan, K.S. (Ed). *Lively capital: Biotechnologies, ethics, and governance in global markets*, 45-92. Duke University Press.

Dumit, J. (2012). *Drugs for life: how pharmaceutical companies define our health*. Duke University Press.

Dwyer J. (2019). Environmental justice. In Mastroianni, A. C., Kahn, J. P., & Kass, N. E. (Eds.). *The Oxford handbook of public health ethics*. Oxford University Press.

Dwyer, J. (2009). How to connect bioethics and environmental ethics: health, sustainability, and justice. *Bioethics*, 23(9), 497-502.

Dwyer, J., & Sambath, V. (2019). Power, pollution, and ethics. *Indian journal of medical ethics*, 4(3), 203-206. Retrieved from <https://ijme.in/articles/power-pollution-and-ethics/>

E. T. (2002, December 17)). Cipro royalty to start flowing to Ranbaxy soon. *Economic Times*. Retrieved from <https://economictimes.indiatimes.com/cipro-royalty-to-start-flowing-to-ranbaxy-soon/articleshow/31501283.cms>.

East India Pharmaceutical Works Limited. (2019). History. Retrieved on January 22, 2019 from <http://www.eastindiapharma.org/history.html>

Eban, K. (2019). *Bottle of lies: the inside story of the generic drug boom*. HarperCollins Publishers.

EIP. (2019, March 04). Coal's poisonous legacy: groundwater contaminated by coal ash across the US. *Environmental Integrity Project*. Available from: <https://www.environmentalintegrity.org/wp-content/uploads/2019/03/National-Coal-Ash-Report.pdf>

Escher, B. I., Baumgartner, R., Koller, M., Treyer, K., Lienert, J., & McArdell, C. S. (2011). Environmental toxicology and risk assessment of pharmaceuticals from hospital wastewater. *Water research*, 45(1), 75-92.

ET. (2015, October 12). Green Panel Okays Aurobindo Parma's Telangana unit expansion. *Economic Times*. Retrieved from <http://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/green-panel-okays-aurobindo-pharmastelangana-unit-expansion/articleshow/49321968.cms?>

Evans-Pritchard, E. E. (1937). *Magic among the Azande*. London: Oxford Clarendon Press.

Farmer, P. (2004). *Pathologies of power: Health, human rights, and the new war on the poor* (Vol. 4). University of California Press.

Faure, P. (2003, November). Hospital and environment: waste disposal. In *Annales pharmaceutiques françaises* (Vol. 61, No. 6, pp. 373-377).

FDC. (2019). Corporate Profile. *Fair Deal Corporation*. Retrieved on January 22, 2019 from <http://www.fdcindia.com/company.php>

Fick, J., Söderström, H., Lindberg, R. H., Phan, C., Tysklind, M., & Larsson, D. J. (2009). Contamination of surface, ground, and drinking water from pharmaceutical production. *Environmental Toxicology and Chemistry*, 28(12), 2522-2527.

Fine, B. & Saad-Filho. (1975). *Marx's capital*. Red Global Press: London.

Fisher, D., Wicks, P., & Babar, Z. U. D. (2016). Medicine and the future of health: reflecting on the past to forge ahead. *BMC medicine*, 14(1), 1-4. <https://doi.org/10.1186/s12916-016-0717-0>

Fitzpatrick, M. (2006). Big pharma—paper tiger. *British Journal of General Practice*, 56(525), 309-309. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1832249/>

Foucault M. (1978). *The History of Sexuality, Volume 1: An Introduction*. Random House.

Foucault, M. (2003). *"Society Must Be Defended": Lectures at the Collège de France, 1975-1976* (Vol. 1). Macmillan.

Freudenberg, N. (2021). *At what cost: modern capitalism and the future of health*. Oxford University Press, USA.

Freudenberg, N. (2021a). Why do we ignore capitalism when we examine the health crises of our time. *The BMJ Opinion*. Retrieved from <https://blogs.bmj.com/bmj/2021/05/06/why-do-we-ignore-capitalism-when-we-examine-the-health-crises-of-our-time/>

FT. (2015, August 05). Generic drugs ban prompts India to freeze EU trade talks. *Financial Times*. Retrieved from <http://www.ft.com/cms/s/0/4ded8ca4-3b8a-11e5-bbd1-b37bc06f590c>

Fuchs, D. (2005). Commanding heights? The strength and fragility of business power in global politics. *Millennium*, 33(3), 771-801. <https://doi.org/10.1177/03058298050330030501>

Gabe, J., Williams, S., Martin, P., & Coveney, C. (2015). Pharmaceuticals and society: power, promises and prospects. *Social Science & Medicine*, 131, 193-198. <https://doi.org/10.1016/j.socscimed.2015.02.031>

Gadre, A., & Shukla, A. (2016). Dissenting diagnosis: voices of conscience from the medical profession. *Gurgaon: Penguin Random House India*.

Gagnon, M. A., & Dong, M. (2023). What did the scientific literature learn from internal company documents in the pharmaceutical industry? A scoping review. *Cochrane Evidence Synthesis and Methods*, 1(3), e12011. <https://doi.org/10.1002/cesm.12011>

Gaudillière, J. P. (2014). De la santé publique internationale à la santé globale: l'OMS, la Banque mondiale et le gouvernement des thérapies chimiques. In *Le gouvernement des technosciences* (pp. 65–96). La Découverte.

Gautier, L., & David, P. M. (2022). “Health for all” and the challenges for pharmaceutical policies: A critical interpretive synthesis over 40 years. *Social Sciences & Humanities Open*, 5(1), 100255. <https://doi.org/10.1016/j.ssaho.2022.100255>

Geest, S. V. D., Whyte, S. R., & Hardon, A. (1996). The anthropology of pharmaceuticals: a biographical approach. *Annual review of anthropology*, 25(1), 153-178.

Georges, J. M. (2004). The politics of suffering: implications for nursing science. *Advances in Nursing Science*, 27(4), 250-256.

Georges, J. M. (2008). Bio-power, Agamben, and emerging nursing knowledge. *Advances in Nursing Science*, 31(1), 4-12.

Georges, J.M. (2014). Compassion, biopower, and nursing. In Kagan, P. N., Smith, M. C., & Chinn, P. L (Eds). *Philosophies and practices of emancipatory nursing*. Social Justice as Praxis, 2014.

Ghosh, P. K. (2001). IPR issues in Biotechnology in Developing Countries and India. *Journal of Intellectual Property Rights*, 6(1), 1-17.

Ghosh, P. K. (2003). The Rules for Handling Transgenic Organisms and Biopharmaceuticals Produced There from in India. *Journal of Scientific & Industrial Research*, 62(6), 554-572. <http://nopr.niscair.res.in/bitstream/123456789/26298/1/JSIR%2062%286%29%20554-572.pdf>

Ghosh, P. K. (2019). *Government's Policies and Growth of Pharmaceutical Industry in India 1947-2018: A Review*. Research and Information System for Developing Countries. <https://www.ris.org.in/sites/default/files/Publication/DP%20236%20P%20K%20Ghosh%20D-P-min.pdf>

Ghosh, P. K., & Ramanaiah, T. V. (2001). IPR issues in biotechnology in the context of developing countries and India.

GK Today. (2013, November 22). Monopolies Inquiries Commission. Retrieved on January 23, 2019 from <https://www.gktoday.in/gk/monopolies-inquiries-commission/>

Glassmeyer, S. T., Hinchey, E. K., Boehme, S. E., Daughton, C. G., Ruhoy, I. S., Conerly, O., ... & Thompson, V. G. (2009). Disposal practices for unwanted residential medications in the United States. *Environment international*, 35(3), 566-572.

Gogoi, N., & Sumesh, S. S. (2022). The Political Economy of Public Health Inequalities and Inequities in India: Complexities, Challenges, and Strategies for Inclusive Public Health Care Policy. *International Journal of Health Services*, 52(2), 225-235. doi:10.1177/00207314211066748

GoI. (1979). Drugs (Prices Control) Order. *Government of India*. Retrieved on January 23, 2019, from <http://pharmaceuticals.gov.in/sites/default/files/DPCO1979.pdf>

GoI. (1986). Chapter IV-Pricing of drugs in the Pharmaceutical Industry. *Government of India*. Retrieved on January 24, 2019, from <https://www.nppaindia.nic.in/wp-content/uploads/2020/07/Drug-policy-1986.pdf>

GoI. (1986). Drug Policy 1986 Annexure I. *Government of India*. Retrieved on January 24, 2019, from <http://www.nppaindia.nic.in/dp868.html>

GoI. (1986). Drug Policy 1986 Annexure II. *Government of India*. Retrieved on January 24, 2019, from <http://www.nppaindia.nic.in/dp869.html>

GoI. (1986). Drug Policy of India. *Government of India*. Retrieved on January 23, 2019, from http://nppaindia.nic.in/drug_pol86/txt1.html

GoI. (1995). DPCO. *Government of India*. Retrieved on January 24, 2019, from http://nppaindia.nic.in/drug_price95/txt1.html

Gold, D. (1995). Uncharitable donations?. *GMHC treatment issues: the Gay Men's Health Crisis newsletter of experimental AIDS therapies*, 9(1), 10.

Govil, P., Reddy, G., & Krishna, A. (2001). Contamination of soil due to heavy metals in the Patancheru industrial development area, Andhra Pradesh, India. *Environmental geology*, 41, 461-469. <http://dx.doi.org/10.1007/s002540100415>

Govinda, R., & Poornima, M. (Eds.). (2019). *India's social sector and SDGs: problems and prospects*. Taylor & Francis. <https://doi.org/10.4324/9780367341824>

Govindaraj, R., & Chellaraj, G. (2002). The Indian Pharmaceutical Sector: Issues and Options for Health Sector Reform. *World Bank Discussion Paper No 437*. Retrieved from <http://documents.worldbank.org/curated/en/739031468750314031/pdf/multi0page.pdf>

Greene, J. A. (2016). *Generic: The unbranding of modern medicine*. Johns Hopkins University Press.

Greene, W. (2007). *The emergence of India's pharmaceutical industry and implications for the US generic drug market*. (Office of Economics Working Paper No. 2007-05-A). U.S. International Trade Commission.

Greenslit, N. (2005). Depression and consumption: Psychopharmaceuticals, branding, and new identity practices. *Cultural Medical Psychiatry*, 29(4), 477-502. <https://doi.org/10.1007/s11013-006-9005-3>

Gunnarsson, L., Kristiansson, E., Rutgersson, C., Sturve, J., Fick, J., Förlin, L., & Larsson, D. J. (2009). Pharmaceutical industry effluent diluted 1: 500 affects global gene expression, cytochrome P450 1A activity, and plasma phosphate in fish. *Environmental Toxicology and Chemistry*, 28(12), 2639-2647.

Gunningham, N., Grabosky, P., & Sinclair, D. (1998). *Smart regulation: Designing environmental policy*. Oxford University Press.

Haak, H., & Hardon, A. P. (1988). Indigenised pharmaceuticals in developing countries: widely used, widely neglected. *Lancet (London, England)*, 2(8611), 620-621.

Haakonsson, S. J. (2009). The Changing Governance Structures of the Global Pharmaceutical Value Chain. *Competition & Change*, 13(1), 75-95. <https://doi.org/10.1179/102452909X390574>

Halliburton, M. (2017). The View from Hyderabad: The “Indian” Pharmaceutical Industry and the New Patent Regime. In Halliburton, M. *India and the Patent Wars: Pharmaceuticals in the New Intellectual Property Regime* (pp. 116–139). Cornell University Press.

Halling-Sørensen, B. N. N. S., Nielsen, S. N., Lanzky, P. F., Ingerslev, F., Lützhøft, H. H., & Jørgensen, S. E. (1998). Occurrence, fate and effects of pharmaceutical substances in the environment-A review. *Chemosphere*, 36(2), 357-393.

Hamscher, G., Pawelzick, H. T., Sczesny, S., Nau, H., & Hartung, J. (2003). Antibiotics in dust originating from a pig-fattening farm: a new source of health hazard for farmers?. *Environmental Health Perspectives*, 111(13), 1590-1594.

Hancher, L. (1996). Pharmaceutical policy and regulation: setting the pace in the European Community. *Contested ground: Public purpose and private interest in the regulation of prescription drugs*, 179-193.

Hannerz, U. (1992). *Cultural complexity: Studies in the social organization of meaning*. Columbia University Press.

Hardon, A., & Sanabria, E. (2017). Fluid drugs: Revisiting the anthropology of pharmaceuticals. *Annual Review of Anthropology*, 46, 117-132.

Harris, M. (2022, December 13). Why Capitalism Needs Sick People. *Intelligencer*. Retrieved from <https://nymag.com/intelligencer/2022/12/why-capitalism-needs-sick-people.html>

Harriss, J. (1982). Indian Industrialisation and the State: (A Background Paper). In J. Harriss, R. Sudarshan, et al. (Eds.), *The State in South Asia, Papers Presented at the First Workshop of the South Asia Research Group*. School of Development Studies, University of East Anglia, June (pp. 1-33).

Hathi, J. (1974). *Report of the Committee on Drugs and Pharmaceutical Industry*. Ministry of Petroleum and Chemicals, Government of India.

Hayden, C. (2020). *When nature goes public: The making and unmaking of bioprospecting in Mexico* (Vol. 1). Princeton University Press.

Healthy Energy Initiative India. (2018). A community based phenomenological study on the impact of coal ash on human health in Seppakkam village, Thiruvallur district, Tamil Nadu. Oct Available from: https://storyofennore.files.wordpress.com/2018/11/final_sepakkamreport.pdf

Helmreich, S. (2008). Species of biocapital. *Science as culture*, 17(4), 463-478. <https://doi.org/10.1080/09505430802519256>

High Court of Karnataka. (2002). Retrieved on January 24, 2019 from <http://judgmenthck.kar.nic.in/judgments/bitstream/123456789/455238/1/WP21618-02-12-11-2002.%20pdf> <http://commerce.nic.in/publications/gazette.pdf>

Hinchliffe, D. (2005). *The Influence of the Pharmaceutical Industry: Fourth Report of Session 2004-05* (Vol. 42). The Stationery Office.

House of Commons Health Committee. (2005). The influence of the pharmaceutical industry. Fourth report of session 2004–05. Vol. I.

IBEF. (2023). *Pharmaceuticals*. Indian Band Equity Foundation. Retrieved from https://www.ibef.org/download/1700035735_Pharmaceuticals_August_2023.pdf

IDPL. (2019). History. *Indian Drugs & Pharmaceuticals Ltd*. Retrieved on January 22, 2019 from, http://www.idpl.gov.in/about_us.html

IIFL Wealth Hurun. (2021). *IIFL Wealth Hurun India Rich List 2021*. Retrieved from <https://iiflwealth.com/sites/default/files/inline-files/IIFL%20Wealth%20Hurun%20India%20Rich%20List%202021.pdf>

India Infoline News Service. (2016). FDA's strict scrutiny may drag India's drug export down.

Indian Bar Association. (n.d). Constitutional Provisions for the Protection of Environment with Relevant Case Laws. Retrieved from <https://www.indianbarassociation.org/wp-content/uploads/2013/02/environmental-law-article.pdf>

Indian Patent Office. (2019). Retrieved on January 23, 2019 from <http://www.ipindia.nic.in/>

Indian Pharmaceutical Alliance. (2019). The Indian Pharmaceutical Industry- A way forward. Retrieved from <https://www.ipa-india.org/wp-content/uploads/2020/10/indian-pharmaceutical-industry-way-forward.pdf>

Indian Pharmacopoeia Commission. (2019). Retrieved on January 22, 2019 from <http://ipc.gov.in/index.html>

Indian Trade Mark Office. (2019). Retrieved on January 23, 2019 from <http://www.ipindia.nic.in/>

Indian Trade Marks Registry. (1940). The Trade Marks Act, 1940. Retrieved on January 23, 2019 from <http://www.ipindia.nic.in/trade-marks.htm>

Info Change News & Features. (2013). Battling for cheaper essential drugs. Retrieved on January 23, 2019 from <http://infochangeindia.org/pharma.html>

Infosys. (2013). Why is India the right destination for biotechnology? Retrieved on January 23, 2019 from Inhalation Aspects of Therapeutic Aerosols. *Toxicologic Pathology*, 35, 23-6.

Jack, A. (2008, March 29). 'The Man Who Battled Big Pharma'. *Financial Times*. Retrieved from , <https://www.ft.com/content/bd8dccee-f976-11dc-9b7c-000077b07658>

Jack, A. (2012, April 24). 'Pharmaceuticals: Philanthropy and Business Join Forces'. *Financial Times*. Retrieved <https://www.ft.com/content/0d2b135a-887b-11e1-a727-00144feab49a>

Jagannathan, M. (2019, May 13). Most of the profit in the health-care industry is going to drug companies — here's why you should care. *MarketWatch*. Retrieved from <https://www.marketwatch.com/story/most-of-the-profit-in-the-health-care-industry-is-going-to-drug-companies-heres-why-you-should-care-2019-05-13>

Jain, K. (2022, January 19). The boom in India's healthcare firms isn't showing signs of slowing. *The Economic Times*. Retrieved from https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/the-boom-in-indias-healthcare-firms-isnt-showing-signs-of-slowing/articleshow/88966321.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Jeffrey, R. (2020). Major actors influencing health policy in India: A historical perspective. In Mehdi, A. & Rajan, I. (Eds), *Health of the Nation: India Health Report*. Oxford University Press.

Jha, P. S. (1982). The End of the Tunnel: Return to sanity in Economic Policy. *Times of India*. Cited in Kohli, A. (1989). *Politics of Economic Liberalization in India*. World Development, 17(3), 305-328, 1989.

Jha, P. S. (1984). Seventh Plan Perspectives: A New Direction for Industry. *Times of India*. August 13.

K.T. Shah. (1949) (Ed.). *Report of the National Planning Committee*. Bombay: Vora & Co.

Kaczmarek, E. (2022). Promoting diseases to promote drugs: the role of the pharmaceutical industry in fostering good and bad medicalization. *British Journal of Clinical Pharmacology*, 88(1), 34-39. <https://doi.org/10.1111/bcp.14835>

Kantele, A., Lääveri, T., Mero, S., Vilkin, K., Pakkanen, S. H., Ollgren, J., ... & Kirveskari, J. (2015). Antimicrobials increase travelers' risk of colonization by extended-spectrum beta lactamase-producing Enterobacteriaceae. *Clinical Infectious Diseases*, 60(6), 837-846.

Kapilashrami, A., & Baru, R. V. (Eds.). (2018). *Global Health governance and commercialisation of public health in India: Actors, institutions and the dialectics of global and local*. Routledge.

Kapur, M. (2020, January 17). Govt Push for Ease of Doing Business Is Compromising Environment. *The Quint*. Retrieved from <https://www.thequint.com/news/environment/how-govt-push-for-ease-of-doing-business-is-compromising-environment-regulations#read-more>

Karvonen, S., Kestilä, L. M., & Mäki-Opas, T. E. (2018). Who needs the sociology of health and illness? A new agenda for responsive and interdisciplinary sociology of health and medicine. *Frontiers in Sociology*, 3, 4. <https://doi.org/10.3389/fsoc.2018.00004>

Kathuria, V. (2001). Pollution: prevention vs control: is EOP treatment the solution?. *Economic and Political Weekly*, 2745-2748.

Kethineni, V. (1991). Political economy of state intervention in health care. *Economic and Political Weekly*, 2427-2433.

Kim, J. H., & Scialli, A. R. (2011). Thalidomide: the tragedy of birth defects and the effective treatment of disease. *Toxicological sciences*, 122(1), 1-6. <https://doi.org/10.1093/toxsci/kfr088>

Kleinman, A., Das, V., & Lock, M. M. (Eds.). (1997). *Social suffering*. Univ of California press.

Kochanek, S. A. (1968). *The Congress Party of India*. Princeton. NJ: Princeton.

Kochar, A. (2011). B. R. Barwale, The Father of the Indian Seed Industry. In K. D. Rane & P. S. Rao (Eds.), *Pioneer and Leader of Indian Seed Industry* (pp. 51-67). <https://www.worldseed.org/wp-content/uploads/2021/06/pioneer-and-leader-in-seed-industry-2011.pdf>

Koivusalo, M., & Mackintosh, M. (2011). Commercial influence and global nongovernmental public action in health and pharmaceutical policies. *International Journal of Health Services*, 41(3), 539-563. Retrieved from <https://journals.sagepub.com/doi/pdf/10.2190/hs.41.3.h>

Kotwani, A., Joshi, J., & Kaloni, D. (2021). Pharmaceutical effluent: a critical link in the interconnected ecosystem promoting antimicrobial resistance. *Environmental Science and Pollution Research*, 28(25), 32111-32124.

Kumar, R. R. (1999). Pesticide Industry in India: A Historical Perspective. In K. Parikh (Ed.), *Environment and Development: Essays in Honor of Dr. U. Shankar* (pp. 55-72). <http://www.iimahd.ernet.in/publications/data/1999-06-03ravipdf.pdf>

Kumarasamy, K. K., et al. (2010). Emergence of a New Antibiotic Resistance Mechanism in India, Pakistan, and the UK: A Molecular, Biological, and Epidemiological Study. *The Lancet Infectious Diseases*, 10, 597-602.

Kummerer, K. (2001). Drugs in the Environment: Emission of Drugs, Diagnostic Aids and Disinfectants into Wastewater by Hospitals in Relation to Other Sources – A Review. *Chemosphere*, 45, 957-69.

Lall, S. (1974). The international pharmaceutical industry and less-developed countries, with special reference to India. *Oxford Bulletin of Economics and Statistics*, 36(3), 143-172.

Larsson, D. J., & Fick, J. (2009). Transparency throughout the production chain—a way to reduce pollution from the manufacturing of pharmaceuticals?. *Regulatory Toxicology and Pharmacology*, 53(3), 161-163. <http://dx.doi.org/10.1016/j.yrtph.2009.01.008>

Larsson, D. J., de Pedro, C., & Paxeus, N. (2007). Effluent from drug manufactures contains extremely high levels of pharmaceuticals. *Journal of hazardous materials*, 148(3), 751-755. <http://dx.doi.org/10.1016/j.jhazmat.2007.07.008>

Latour, B., & Woolgar, S. (2013). *Laboratory life: The construction of scientific facts*. Princeton university press.

Lave, R., Mirowski, P., & Randalls, S. (2010). Introduction: STS and neoliberal science. *Social studies of science*, 40(5), 659-675.

Lee, K., & Freudenberg, N. (2020). Addressing the commercial determinants of health begins with clearer definition and measurement. *Global Health Promotion*, 27(2), 3-5. DOI: <https://doi.org/10.1177/1757975920931249>

Lewis, E. (2021, February 21). What is Structural Violence? *ThoughtCo*. Retrieved from <https://www.thoughtco.com/structural-violence-4174956>

Lexchin, J. (2017). The pharmaceutical industry and the Canadian Government: Folie à Deux. *Healthcare Policy*, 13(1), 10.

Lexchin, J. (2018). The pharmaceutical industry in contemporary capitalism. *Monthly Review*, 69(10), 37-50.

Li, W. Y. (2023). Regulatory capture's third face of power. *Socio-Economic Review*, 21(2), 1217-1245. <https://doi.org/10.1093/ser/mwad002>

Liebenau, J. M. (1981). Medical Science and Medical Industry, 1890-1929. *disser-tation, University of Pennsylvania*.

Lin, A. Y. C., Wang, X. H., & Lin, C. F. (2010). Impact of wastewaters and hospital effluents on the occurrence of controlled substances in surface waters. *Chemosphere*, 81(5), 562-570.

Löfgren, H. (Ed.). (2017). *The politics of the pharmaceutical industry and access to medicines: World pharmacy and India*. Taylor & Francis.

Looft, T., Johnson, T. A., Allen, H. K., Bayles, D. O., Alt, D. P., Stedtfeld, R. D., ... & Stanton, T. B. (2012). In-feed antibiotic effects on the swine intestinal microbiome. *Proceedings of the National Academy of Sciences*, 109(5), 1691-1696.

Lübbert, C., Baars, C., Dayakar, A., Lippmann, N., Rodloff, A. C., Kinzig, M., & Sörgel, F. (2017). Environmental pollution with antimicrobial agents from bulk drug manufacturing industries in Hyderabad, South India, is associated with dissemination of extended-spectrum beta-lactamase and carbapenemase-producing pathogens. *Infection*, 45(4), 479–491. <https://doi.org/10.1007/s15010-017-1007-2>

Maani, N., Nason, E., Petticrew, M., & Galea, S. (Eds.). (2022). *The Commercial Determinants of Health*. Oxford Academic. <https://doi.org/10.1093/oso/9780197578742.001.0001>

Mann, S. (2010). *Bioethics in Perspective: Corporate power, public health and political economy*. Cambridge University Press.

Marathe, S. S. (1986). *Regulation and Development: India's Policy Experience of Controls over Industry*. Centre for Policy Research, Sage Publications, New Delhi.

Markets, C. (2016). Ecostorm. *Superbugs in the supply chain: how pollution from antibiotics factories in India and China is fuelling the global rise of drug-resistant infections*. Retrieved from <https://changingmarkets.org/report/superbugs-in-the-supply-chain/>

Mathew, G., & Unnikrishnan, M. K. (2012). The emerging environmental burden from pharmaceuticals. *Economic and Political Weekly*, 31-34.

Mayer, D. K. (1992). Hazards of chemotherapy. Implementing safe handling practices. *Cancer*, 70(4 Suppl), 988-992.

Mazumdar, M. (2012). *Performance of pharmaceutical companies in India: a critical analysis of industrial structure, firm specific resources, and emerging strategies*. Springer Science & Business Media. DOI 10.1007/978-3-7908-2876-4_2

Mbembe, A. (2019). *Necropolitics*. Translated by Steven Corcoran.

McCartney, G., Dickie, E., Escobar, O., & Collins, C. (2021). Health inequalities, fundamental causes and power: towards the practice of good theory. *Sociology of health & illness*, 43(1), 20-39. <https://doi.org/10.1111/1467-9566.13181>

McCartney, G., Popham, F., McMaster, R., & Cumbers, A. (2019). Defining health and health inequalities. *Public health*, 172, 22-30. <https://doi.org/10.1016/j.puhe.2019.03.023>

Medicine, B. (2019). Retrieved on January 22, 2019 from https://bengal.ajkal.in/jmsol3/pdfs/AJ2019_02272.pdf

Mehta, P. B. (2017). *The burden of democracy*. Penguin Random House India Private Limited.

Ministry of Chemicals & Fertilisers. (1999). No. 5(1)/98-PI.I. Retrieved on January 23, 2019, from <http://www.nppaindia.nic.in/new/research.htm>

Ministry of Chemicals & Fertilizers. (1999). No.5 (1)/98-PI.I dated 31st March 1999, Constitution of DPCRC. Retrieved on January 24, 2019, from <http://nppaindia.nic.in/new/control.htm>

Ministry of Chemicals and Fertilizers. (2022, August 02). *Import and Domestic Production of APIs*. PIB. Retrieved from <https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1847446>

Ministry of Commerce and Industry, Government of India. (2012). The Gazette of India: Extraordinary. Retrieved on January 24, 2019 from https://commerce.gov.in/wp-content/uploads/2020/03/NTESCL_637153945990098973_Establishment_Transfer_Posting_Orders.pdf

Ministry of Corporate Affairs. (2018). National Action Plan on Business and Human Rights: Zero Draft. *Government of India*. Retrieved from https://www.mca.gov.in/Ministry/pdf/ZeroDraft_11032020.pdf

Ministry of Health and Family Welfare. (2019). Retrieved on January 22, 2019 from <http://www.mohfw.nic.in/>

Ministry of Petroleum & Chemicals- Govt of India. (1975). “Report of the Committee on Drugs & Pharmaceutical Industry, 1975- Hathi Committee Report”. Retrieved on January 23, 2019 from https://pharmaceuticals.gov.in/sites/default/files/Hathi_Committee_report_1975_0.pdf

Ministry of Science and Technology, Department of Biotechnology. (2019). Biotechnology Industry Research Assistance Council. Retrieved on January 22, 2019 from http://www.birac.nic.in/desc_new.php?id=227

Mitman, G., Murphy, M., & Sellers, C. (2004). Landscapes of exposure: Knowledge and illness in modern environments. *Osiris (Philadelphia, PA)*, 19.

Mitnick, B. M. (1980). *The Political Economy of Regulation: Creating, Designing, and Removing Regulatory Forms*. New York: Columbia University Press

Mordor Intelligence. (n.d). India Active Pharmaceutical Ingredients (API) Market Size & Share Analysis - Growth Trends & Forecasts (2024-2029). Retrieved from <https://www.mordorintelligence.com/industry-reports/india-active-pharmaceutical-ingredients-market>

Mossinghoff, G. J. (1999). Overview of the Hatch-Waxman Act and its impact on the drug development process. *Food & Drug LJ*, 54, 187.

Moynihan, R., CG, P., Heath, I., & Henry, D. (2002). Selling sickness: the pharmaceutical industry and disease mongering Commentary: Medicalisation of risk factors. *Bmj*, 324(7342), 886-891.

Mueller, J. M. (2006). The tiger awakens: the tumultuous transformation of India's patent system and the rise of Indian pharmaceutical innovation. *U. Pitt. l. rev.*, 68, 491.

Mulinari, S., Davis, C., & Ozieranski, P. (2021). Failure of responsive regulation? pharmaceutical marketing, corporate impression management and off-label promotion of enzalutamide in Europe. *Journal of White Collar and Corporate Crime*, 2(2), 69-80. <https://doi.org/10.1177/2631309X20970477>

Murphy, P. (2001). Affiliation bias and expert disagreement in framing the nicotine addiction debate. *Science, Technology, & Human Values*, 26(3), 278-299.

Muscolo, L. A. A., Deriu, D., Sammarco, A., Siviero, P. D., & Pani, L. (2012). PHP39 The “Weight” of Orphan Drugs in the European Pharmaceutical Policy. A Focus on the Expenditure and the Utilization of Orphan Drugs in Five European Union Countries. *Value in Health*, 15(4), A20. <https://doi.org/10.1016/j.jval.2012.03.115>

Musson, S. E., & Townsend, T. G. (2009). Pharmaceutical compound content of municipal solid waste. *Journal of hazardous materials*, 162(2-3), 730-735.

Mutreja, A. (2012). Bacterial frequent flyers. *Nature Reviews Microbiology*, 10(11), 734-734.

Narayana, P. L. (1984). *The Indian pharmaceutical industry: problems and prospects*. National Council of Applied Economic Research.

Narayanan, P. (1998). *Patent Law* (3rd ed). Eastern Law House, Calcutta.

National Health Service Health Scotland. (2021, December 24). *Measuring Health Inequalities*. Public Health Scotland. Retrieved from <https://www.healthscotland.scot/health-inequalities/measuring-health-inequalities>

National Informatics Centre. (2005). Chapter 1. Retrieved on January 22, 2019 from http://www.envfor.nic.in/acts/Clauses_Enforcement_Rule%202005.pdf

National Institute of Immunology. (2019). The Role of the NII. Retrieved on January 22, 2019 from <http://www.nii.res.in/research.htm>

National Institute of Science Communication and Information Resources. (2019). Retrieved on January 23, 2019 from <http://www.niscair.res.in/>

Navarro, V. (1990). Race or class versus race and class: mortality differentials in the United States. *The Lancet*, 336(8725), 1238-1240.

Navarro, V. (2001). *The political economy of social inequalities: consequences for health and quality of life*. Routledge.

Navarro, V. (2004). *The political and social contexts of health*. Amityville, NY:Baywood.

Navarro, V. (2004, June 01). Inequalities are unhealthy. *Monthly Review*. Retrieved from <https://monthlyreview.org/2004/06/01/inequalities-are-unhealthy/>

Navarro, V., & Muntaner, C. (Eds.). (2020). *Political And Economic Determinants of Population Health and Well-Being:: Controversies and Developments*. Routledge.

NEERI. (1991). *Environmental Pollution caused by Patancheru and Bollaram Industrial Estates in nearby Villages of Medak District*. Andhra Pradesh.

Nehru, J. (1947) (2008). *Discovery of India*. Penguin Books.

Nichter, M., & Nichter, M. (1996). *Anthropology and international health: Asian case studies* (Vol. 3). Psychology Press.

Nichter, M., & Nordstrom, C. (1989). A question of medicine answering: Health commodification and the social relations of healing in Sri Lanka. *Culture, medicine and psychiatry*, 13(4), 367-390.

Nichter, M., & Vuckovic, N. (1994). Agenda for an anthropology of pharmaceutical practice. *Social Science & Medicine*, 39(11), 1509-1525.

Nightingale, P., & Martin, P. (2004). The myth of the biotech revolution. *TRENDS in Biotechnology*, 22(11), 564-569.

Nixon, R. (2011). *Slow Violence and the Environmentalism of the Poor*. Harvard University Press.

Nordberg, E. (1974). Self-portrait of the average rural drug shop in Wollega province, Ethiopia. *Ethiopian medical journal*, 12(1), 25-32.

Novas, C. (2006). The political economy of hope: Patients' organizations, science and biovalue. *BioSocieties*, 1(3), 289-305. [doi:10.1017/S1745855206003024](https://doi.org/10.1017/S1745855206003024)

Novo, A., & Manaia, C. M. (2010). Factors influencing antibiotic resistance burden in municipal wastewater treatment plants. *Applied Microbiology and Biotechnology*, 87, 1157-1166.

Nunn, A., Fonseca, E. D., & Gruskin, S. (2009). Changing global essential medicines norms to improve access to AIDS treatment: Lessons from Brazil. *Global public health*, 4(2), 131-149. <https://doi.org/10.1080/17441690802684067>

Oaks, J. L., et al. (2004, July 07). Diclofenac Residues as the Cause of Vulture Population Decline in Pakistan. *Nature*,

O'Donovan, O., & Glavanis-Grantham, K. (2008). *Power, Politics and Pharmaceuticals: Drug Regulation in Ireland in the Global Context*. Cork University Press. <https://www.ncbi.nlm.nih.gov/books/NBK507623/>

Organisation of Pharmaceutical Producers of India. (2019). About OPPI. Retrieved on January 22, 2019 from <https://www.indiaoppi.com/>

Panda, S. (2002, August 08). India at 75: Important healthcare achievements of the country since gaining independence. *Financial Express Healthcare*. Retrieved from <https://www.financialexpress.com/healthcare/news-healthcare/india-at-75-important-healthcare-achievement-of-the-country-since-gaining-independence/2621945/>

Pardhe, S. P. (2019). A descriptive cross-sectional study to evaluate the Generic Drug User Fee Act: A boon or loss to the Indian generic pharmaceutical industry. *Journal of Applied Pharmaceutical Science*, 9(2), 044-051.

Parliamentary Standing, C. (2012). 59th report on the functioning of the Central Drugs Standard Control Organisation (CDSCO): Department Related Parliamentary Standing Committee on Health and Family Welfare (2011-2012). *New Delhi, Rajya Sabha*.

Patel, J. (2016). India's Crack down on the Practice of Pharmaceutical Evergreening: The 2013 Novartis Decision. *UMKC L. Rev.*, 85, 503.

Patent Office, Indian. (2002). The Patents (Amendment) Rules, 2002. Retrieved on January 23, 2019 from http://www.ipindia.nic.in/writereaddata/Portal/ev/sections/pspatents_act_2002.pdf

Patent Office, Indian. (2003). The Patents (Amendment) Rules, 2003. Retrieved on January 23, 2019 from http://www.ipindia.nic.in/writereaddata/Portal/ev/sections/pspatents_act_2003.pdf

Patent Office. (2005). The Patents Act, 1970. Retrieved on January 23, 2019 from http://www.ipindia.nic.in/writereaddata/Portal/ev/sections/pdf/The_Patents_Act_1970_updated_till_23rd_June_2017.pdf

Patent Office, Indian. (2011). The Patents (Amendment) Rules, 2011. Retrieved on January 23, 2019 from http://www.ipindia.nic.in/writereaddata/Portal/ev/sections/pspatents_act_2011.pdf

Petryna, A. (2004). Biological citizenship: The science and politics of Chernobyl-exposed populations. *Osiris*, 19, 250-265. Retrieved from <https://www.jstor.org/stable/3655243>

Pfizer Ltd. (2019). History of Pfizer. Retrieved on January 22, 2019 from http://www.pfizerindia.com/Our_History.aspx

Pharma, I. (2020). Propelling Access and Acceptance summary: Realizing True Potential: Pharmaceutical and Medical Products Practice. McKinsey report. http://www.pharmexcil.com/data/cepages/news_files/54.pdf

Pharmaceuticals Export Promotion Council of India. (2013). Newsletter. Retrieved on January 23, 2019 from <http://pharmexcil.com/uploads/NewsFiles/101132116.pdf>

Pharmaceuticals Export Promotion Council of India. (2019). About Pharmexcil. Retrieved on January 22, 2019 from <http://www.pharmexcil.com/indprofile.htm>

Pharmexcil. (2006). Incentives Scheme of Department of Pharmaceuticals, Government of India for pharmaceutical industry. Retrieved on January 24, 2019 from <http://www.pharmexcil.com/uploads/NewsFiles/250724110154.pdf>

Pollock, A., & Jones, D. S. (2015). Coronary artery disease and the contours of pharmaceuticalization. *Social Science & Medicine*, 131, 221-227. <https://doi.org/10.1016/j.socscimed.2014.06.035>

Posner, G. (2021). *Pharma: Greed, lies, and the poisoning of America*. Simon and Schuster.

Prasad, N. P. (2018). New migrant question: Exploitative forms of transit labour in three regions of Andhra Pradesh. In *India Migration Report 2017* (pp. 188-205). Routledge India.

Prasad, P. (2018). Introduction: Health Inequities in India—The Larger Dimensions. In Prasad, P & Jesani, A. (Eds.), *Equity and access: health care studies in India* (pp. 1-22). Oxford University Press. <https://doi.org/10.1093/oso/9780199482160.003.0001>

Prasad, P. (2022). State and Health Markets in the Time of Pandemic. *Economic & Political Weekly*, 57(23), 41.

Prasad, S., & Banerjee, S. (2002). Is pharmaceutical research and development suffering from an imbalance between east and west? *BMJ: British Medical Journal*, 325(7362), 913.

Prasad, V., & Sengupta, A. (2019). Perpetuating health inequities in India: global ethics in policy and practice. *Journal of Global Ethics*, 15(1), 67-75. <https://doi.org/10.1080/17449626.2019.1582553>

Preidt, R. (2012, February 21). Pig-to-Human ‘Superbug’ May Be Due to Animal Antibiotics. *Health News*. Retrieved on 22 February 2012, from <http://news.health.com/2012/02/21/pig-to-human-superbug-may-be-due-to-animal-antibiotics/>.

Priya, R and Ghodajkar,P (2018).The Structural Basis of Corruption in Healthcare in India In S. Nundy, K. Desiraju, & S. Nagral (Eds.), *Healers or Predators: Healthcare Corruption in India* (pp. 30- 69). OUP India.

Rabinow, P. (1995). *French modern: Norms and forms of the social environment*. University of Chicago Press.

Rabinow, P. (1997). *Essays on the Anthropology of Reason*. Princeton University Press.

Rabinow, P. (2004). *Anthropos today: Reflections on modern equipment*. Princeton University Press.

Rabinow, P. (2022). Artificiality and enlightenment: from sociobiology to biosociality. In *The ethics of biotechnology* (pp. 101-122). Routledge.

Rajan, K. S. (2006). *Biocapital: The constitution of postgenomic life*. Duke University Press.

Rajan, K. S. (2017). *Pharmocracy: Value, politics, and knowledge in global biomedicine*. Duke University Press.

Rajan, K. S. (Ed.). (2012). *Lively capital: Biotechnologies, ethics, and governance in global markets*. Duke University Press.

Rajani, A. (2023, November 20). 8k deaths a year as 2k industries choke Hyd. *The Times of India*. Retrieved from <https://timesofindia.indiatimes.com/city/hyderabad/8k-deaths-a-year-as-2k-industries-choke-hyd/articleshow/105352649.cms>

Rangarao, B. V. (1973). *Indian Drug Industry—Its Status Perspective*. Centre for Studies in Science Policy, Jawaharlal Nehru University.

Rao, A. K. (2001) Patancheru - A Hell on Earth: A Saga of People's Struggle Against Industrial Pollution. A.V.R.R Memorial Charitable Trust.

Reddy, T. P. (2022). Crusade against Environmental Pollution in Patancheru in Hyderabad City. *Economic and Political Weekly*, 57(41). 13-16. Retrieved from https://www.epw.in/system/files/pdf/2022_57/41/CM_LVII_41_081022_T%20Prabhakar_Reddy.pdf

Reporter, BS. (2012, July 14). APPCB slaps notices on 12 bulk drug units. *Business Standard*. retrieved from https://www.business-standard.com/article/economy-policy/appcb-slaps-notices-on-12-bulk-drug-units-112071402001_1.html

Rosa, W. E., & Ferrell, B. R. (Eds.). (2023). *The Nature of Suffering and the Goals of Nursing*. Oxford University Press.

Rosaldo, M. Z. (1983). The shame of headhunters and the autonomy of self. *Ethos*, 11(3), 135-151.

Ross, L. F., Norton, J. W., & Young, S. A. (2000). Is academic medicine for sale. *N Engl J Med*, 343(7), 508-10.

Roy, S. (2020). *Contours of Value Capture: India's Neoliberal Path of Industrial Development*. Cambridge University Press.

Roy, V. (2023). *Capitalizing a Cure: How Finance Controls the Price and Value of Medicines*. University of California Press.

S. B. (2012, January 25). Antibiotics in Animals. *The New York Times*. Retrieved on 22 February 2012, from <http://www.nytimes.com/2012/01/26/opinion/antibiotics-in-animals.html>.

Sahu, G. (2007). *People's participation in environmental protection: A case study of Patancheru* (No. 180).

Samuelson, P. A., & Nordhaus, W. D. (2009). *Macroeconomics 19e*. McGraw-Hill Education.

Santoro, M. A., & Gorrie, T. M. (2005). *Ethics and the Pharmaceutical Industry*. Cambridge University Press.

Sassen, S. (1996). *Losing control?: sovereignty in the age of globalization*. Columbia University Press.

Sassen, S. (1998). *Globalization and Its Discontents*. New York: New Press.

Sassen, S. (2000). Spatialities and Temporalities of the Global: Elements for a Theorization. *Public Culture*, 12(1), 215-232.

Scheper-Hughes, N. (1993). *Death without weeping: The violence of everyday life in Brazil*. Univ of California Press.

Scheper-Hughes, N. (1994). An essay: AIDS and the social body. *Social Science & Medicine*, 39(7), 991-1003.

Schrecker, T., Birn, A. E., & Aguilera, M. (2018). How extractive industries affect health: political economy underpinnings and pathways. *Health & place*, 52, 135-147.

Seehusen, D. A., & Edwards, J. (2006). Patient practices and beliefs concerning disposal of medications. *The Journal of the American Board of Family Medicine*, 19(6), 542-547.

Sell, S. K., & Williams, O. D. (2020). Health under capitalism: a global political economy of structural pathogenesis. *Review of International Political Economy*, 27(1), 1-25.

Selvaraj, S. (2007). How Effective Is India's Drug Price Control Regime. *Harvard School of Public Health*. Retrieved from <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/114/2012/10/RP256.pdf>

Selvaraj, S., Karan, A. K., Srivastava, S., Bhan, N., Mukhopadhyay, I., & Mahal, A. (Eds.). (2022). *India health system review. Health Systems in Transition*, 11(1). World Health Organization Regional Office for South-East Asia.

Sen, A. P. (2021). *Settlement and local histories of the early Deccan*. Routledge.

Sengupta, A. (2018). Globalization and Corruption in the Health Sector. In S. Nundy, K. Desiraju, & S. Nagral (Eds.), *Healers or Predators: Healthcare Corruption in India* (pp. 107-124). OUP India.

Sengupta, A. (2018). Globalization, Intellectual Property Rights, and Pharmaceuticals. In P. Prasad, A. Jesani, & S. Patel (Eds.), *Equity and Access: Health Care Studies in India*. Oxford India Studies in Contemporary Society. Delhi: Oxford Academic.

Sim, W. J., Lee, J. W., Lee, E. S., Shin, S. K., Hwang, S. R., & Oh, J. E. (2011). Occurrence and distribution of pharmaceuticals in wastewater from households, livestock farms, hospitals and pharmaceutical manufactures. *Chemosphere*, 82(2), 179-186.

Sismondo, S. (2015). The ghost in the data: Evidence-based medicine and the paradox of exactitude. In S. B. P. D'Souza & B. J. Hoffmaster (Eds.), *Evidence, Ethos and Experiment: The Anthropology and History of Medical Research in Africa* (pp. 71-88). Berghahn Books.

Sismondo, S. (2018). *Ghost-managed medicine: Big pharma's invisible hands*. Matterring Press.

Sismondo, S. (2021). Epistemic corruption, the pharmaceutical industry, and the body of medical science. *Frontiers in research metrics and analytics*, 6, 2. <https://doi.org/10.3389/frma.2021.614013>

Sismondo, S., & Chloubova, Z. (2016). “You’re not just a paid monkey reading slides”: How key opinion leaders explain and justify their work. *BioSocieties*, 11, 199-219.

Sparke, M., Malmberg, E., & Malpass, T. (2023). Bio-pharma hub development in global production networks: contrasting state policies and conjunctural value strategies. *Area Development and Policy*, 1-28.

Srinivas, S. (2012). *Market menagerie: health and development in late industrial states*. Stanford University Press.

Srinivas, S. (2018). The Unholy Nexus: Medical Profession, Pharmaceutical Companies, and Regulatory Authorities. In S. Nundy, K. Desiraju, & S. Nagral (Eds.), *Healers or Predators: Healthcare Corruption in India* (pp. 234- 255). OUP India.

Srinivasan, S. (2011). Medicines for All', the Pharma Industry and the Indian State. *Economic and Political weekly*, 43-50.

Srinivasan, S. (2011a, November 12). *Pharma Industry gets away lightly*. The Hindu Business Line. Retrieved from <https://www.thehindubusinessline.com/opinion/pharma-industry-gets-away-lightly/article22995141.ece>

Srinivasan, S. (2012). A stinging indictment of India's drug regulation authority. *Economic and Political weekly*, 10-13. <http://www.jstor.org/stable/23215023>

Srinivasan, S. (2012a). Medicines for all: Unexceptionable recommendations. *Economic and Political Weekly*, 58-61.

Srinivasan, S., & Phadke, A. (2017). Challenges of Regulation Of Medicines In India. In Löfgren, H. (Ed.), *The politics of the pharmaceutical industry and access to medicines: World pharmacy and India* (pp. 24-54). Taylor & Francis.

Stuer-Lauridsen, F., Birkved, M., Hansen, L. P., Lützhøft, H. C. H., & Halling-Sørensen, B. (2000). Environmental risk assessment of human pharmaceuticals in Denmark after normal therapeutic use. *Chemosphere*, 40(7), 783-793.

Sudhi, K. S. (2011, September 20). Proscribed Drug Poses a Threat to Vulture Population. *The Hindu*. Retrieved on 21 September 2011, from <http://www.thehindu.com/sci-tech/energy-and-environment/article2470926.ece>.

Tan, M. L. (1996). *Magalin na Gamot: pharmaceuticals and the construction of knowledge and power in the Philippines*. PhD thesis. University of Amsterdam, Amsterdam.

Tan, M. L., & Etkin, N. L. (1994). The meanings of medicines: examples from the Philippines. *Meanings and contexts. Quezon City, Philippines: Health Action Information Networks*.

Taylor, P. (2011). Sweden Seeks GMP Revisions to Tackle Environmental Pollution. In Pharm, 19 July. Retrieved on 21 September 2011, from The Economic Times.

Telangana State Pollution Control Board. (2019, March). *Action Plan for Restoration of Environmental Qualities with Regard to the Identified Polluted Industrial Cluster of Patancheru-Bollaram*. Government of Telangana.

Thakur, D. (2019, July 03). The Indian Pharma Industry Can Do Better Than Conspiracy Theories and Ad Hominem Attacks. *The Wire*. Retrieved from <https://thewire.in/health/the-indian-pharma-industry-can-do-better-than-conspiracy-theories-and-ad-hominem-attacks>

Thakurdas, P., Tata, J. R. D., & Bīṛālā, G. (1944). *A plan of economic development for India* (Vol. 1). The Commercial Printing Press.

The Economic Times, (2019, September 19). Hyderabad Pharma City to attract Rs 64k investments: T'gana Min. Retrieved from <https://health.economictimes.indiatimes.com/news/pharma/hyderabad-pharma-city-to-attract-rs-64k-investments-tgana-min/71204929>

The Hindu Bureau. (2022, November 12). Ground breaking for Hyderabad Pharma City likely soon, says KTR. *The Hindu*. Retrieved from <https://www.thehindu.com/news/cities/Hyderabad/ground-breaking-for-hyderabad-pharma-city-likely-soon-says-ktr/article66128647.ece>

The Hindu. (2018, March 23). Pharma City to come up on 19,000 acres. Retrieved from <https://www.thehindu.com/news/cities/Hyderabad/pharma-city-to-come-up-on-19000-acres/article23337233.ece>

The Hindu. (2020, January 01). Pharma City to be launched this year. Retrieved from <https://www.thehindu.com/news/national/telangana/pharma-city-to-be-launched-this-year/article30452887.ece>

The Patents and Designs Act (1911). Retrieved on January 23, 2019 from https://www.indiaip.com/product_image/1399278119.pdf

Thirumalachar, M. J. (1966). *U.S. Patent No. 3,261,751*. Washington, DC: U.S. Patent and Trademark Office. <https://patents.google.com/patent/US3261751>

Thomas, N. (2009). *Entangled objects: exchange, material culture, and colonialism in the Pacific*. Harvard University Press.

Thormodsen, M., Fonneløp, H., Rytter, E., & Tørisen, H. M. (1997). " Brukes etter avtale med legen"-årsaker til at pasienten får medisin til overs" [To be used as directed by your physician"--reasons why patients do not use prescribed medicines]. *Tidsskrift for Den norske legeforening*.

Tomes, N. (2016). *Remaking the American patient: How Madison Avenue and modern medicine turned patients into consumers*. UNC Press Books.

Tomson, G. (1990). *Drug utilization studies in Sri Lanka: towards an understanding of medicines in society*. Kongl Carolinska Medico Chirurgiska Institutet.

Tong, A. Y., Peake, B. M., & Braund, R. (2011). Disposal practices for unused medications around the world. *Environment international*, 37(1), 292-298.

Toscano, A. (2020). The state of the pandemic. *Historical Materialism*, 28(4), 3-23.

Trouiller, P., Oliaro, P., Torreele, E., Orbinski, J., Laing, R., & Ford, N. (2002). Drug development for neglected diseases: a deficient market and a public-health policy failure. *The Lancet*, 359(9324), 2188-2194. <https://doi.org/10.1016/S0140-6736%2802%2909096-7>

Tsoumanis, C. M., Giokas, D. L., & Vlessidis, A. G. (2010). Monitoring and classification of wastewater quality using supervised pattern recognition techniques and deterministic resolution of molecular absorption spectra based on multiwavelength UV spectra deconvolution. *Talanta*, 82(2), 575-581.

United States Environmental Protection Agency. (2019). EJSCREEN: Environmental justice screening and mapping tool. Available from <http://www2.epa.gov/ejsreen>.

University of Delhi. (2019). "Economics Study Material". Retrieved on January 23, 2019 from <https://sol.du.ac.in/mod/book/view.php?id=1267&chapterid=945>

Unnikrishnan, C.H. (2014, March 24). Indian Pharma Sector still attractive for foreign investors. *Live Mint*. Retrieved from <http://www.livemint.com/Industry/PwT7zsLRodSjrKZh6ga1N/Pharma-still-attractive-forforeign-investors.html>

Unnikrishnan, M. K. (2011). Environmental Regulation of Pharmaceutical Production in India, with Special Emphasis on International Collaboration (abstract). *FIP-International Pharmaceutical Federation*. Retrieved from <http://www.fip.org/abstracts?page=abstracts&action=item&item=6631>.

Upreti, P. N. (2021). The Role of National and International Intellectual Property Law and Policy in reconceptualising the definition of investment. *IIC-International Review of Intellectual Property and Competition Law*, 52, 103-136. <https://doi.org/10.1007/s40319-020-01009-7>

Vakilno1. (2013). The Monopolies & Restrictive Trade Practices Act, 1969". Retrieved on January 23, 2019 from <https://www.vakilno1.com/bareacts/mrtpact/mrtpact.html>

Van der Geest, S. (2006). New Release: Anthropology and the Pharmaceutical Nexus. *Anthropological Quarterly*, 79(2), 303-314.

- Van der Geest, S., & Whyte, S. R. (1989). The charm of medicines: metaphors and metonyms. *Medical Anthropology Quarterly*, 3(4), 345-367. <https://doi.org/10.1525/maq.1989.3.4.02a00030>
- Vasu, G.S. (1985, March 20). Fear of MIC-based plant at Patancheru. *The Indian Express*.
- Venkateswaran S. (2022). Health Status in India: Challenges and Opportunities. *CSEP Working Paper 25*. <https://csep.org/wp-content/uploads/2022/02/Health-status-in-India.pdf>
- Vijay, G. (2009). Defragmenting “Global Disintegration of Value Creation” and Labour Relations. *Economic and Political Weekly*, 44(22), 85–94.
- Vijay, G. (2017). Chemicals and Pharmaceuticals in South India: ‘Sun Rise’ Industrialisation or Global Cost-shifting of Dirty Goods Manufacturing. In Löfgren, H., & Sarangi, P. (Eds.). *The Politics and Culture of Globalisation* (pp. 158-180). Routledge.
- Vogel, D. (1998). The globalization of pharmaceutical regulation. *Governance*, 11(1), 1-22.
- Vuckovic, N., & Nichter, M. (1997). Changing patterns of pharmaceutical practice in the United States. *Social Science & Medicine*, 44(9), 1285-1302.
- Waddington, C. J., & Enyimayew, K. A. (1989). A price to pay: The impact of user charges in Ashanti-Akim district, Ghana. *The International Journal of Health Planning and Management*, 4(1), 17-47.
- WHO. (2023, September 16). Noncommunicable diseases. Retrieved from <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases>
- Whyte, S. R., Van der Geest, S., & Hardon, A. (2002). *Social lives of medicines*. Cambridge University Press.
- Williams, M. L., Beevers, S., Kitwiroon, N., Dajnak, D., Walton, H., Lott, M. C., ... & Holland, M. (2018). Public health air pollution impacts of pathway options to meet the 2050 UK Climate Change Act target: a modelling study. NIHR Journals Library, Southampton (UK).
- WIPO. (2019). *The Patents Act 1970*. Retrieved on January 23, 2019 from <https://wipolex.wipo.int/en/text/128091>

Young, I. M. (2010). Responsibility for justice. Oxford University Press.

Zelenay, J. L. (2005). The Prescription Drug User Fee Act: Is a Faster Food and Drug Administration Always a Better Food and Drug Administration?. *Food and Drug Law Journal*, 60(2), 261-338.

Annexure I

Pictures taken in 2015 during Senior Advocate Mr M.C. Mehta's visit to the polluted place before the case in NGT in Chennai



A private land leased by the pharmaceutical industry to let out their effluents, which in turn affects the underground water table and neighbouring lands.

Villagers gathered to share their problems and inform to Dr.Kishan Rao and Mr. Chidambaram who have been fighting case since 1980s in the presence of Mr.Mehta



Researcher listening to a farmer's problems in the presence of Mr. Mehta



Farmers showing the sample of polluted water and their crop which did not yield to be taken to the court to be shown before the judge.



They are discussing about the distance involved and the difficulty in commuting to Chennai for the court cases.



The girl (in the centre) draped in red dress was born blind and a study was conducted on her mother, which showed a direct correlation to pollution as she was a washer woman who would wash clothes in the water from the polluted lakes and consume the same unknowingly.



When farmers dig borewells, effluents are what they receive due to underground water contamination.



Women sharing their concerns about fertility issues with Dr. Kishan Rao.



ISNAPUR Lake-is surrounded by industries and the smell around this lake is obnoxious.



A resident collecting sample to be given in the court.



Annexure II

Pictures taken in 2019

These pictures indicate noncompliance of NGT directives

The Private land (mentioned in annexure 1- 2015) being used to let out untreated effluents is same in 2019 after NGT directives.







Effluents being Released into water bodies.

NGT directive2 and 3-hazardous waste management and Restoration of Water bodies are violated. This was taken during monsoon when the effluents released are very high.



Annexure III

Pictures taken in 2022



A farmer accidentally slipped near the polluted lake and his legs got infected.

Effluents being released into drains



Nallakunta – Heavily Polluted





PHARMA WASTE FLOWING OUT OF RAMKY HAZARDOUS WASTE TREATMENT PLANT COMPOUND



DISPLAY OF HAZARDOUS WASTE INFO BEING TREATED BY RAMKY UNIT AT HYDERABAD WASTE MANAGEMENT PRODUCT WITH EXPIRED DATES OF TSPCB CONSENT



PHARMA POLLUTION FLOWING OUT OF THE PREMISES OF SMS PHARMA-

PATH SHOWING FLOW OF PHARMA WASTE INTO A WELL AND DOWNSTREAM
(front of SMS Pharma Dundigul)





INDUSTRIAL WASTES FLOWING IN THE OPEN, ON THE WAY TO VASANI KUNTA LAKE.



INDUSTRIAL WASTES FLOWING IN THE OPEN, ON THE WAY TO VASANI KUNTA LAKE.



Isnapur lake





ANNEXURE IV

Source: Images collected from Activists

Activists Prof. Purushottham Reddy, Dr. A Kishan Rao and Advocate MC Mehta discussing with the villagers regarding their



Farmers' livelihood affected due to death of livestock





Farmers livelihood affected due to loss of crops



Villagers' health problems



Pollution of Water bodies and common resources



Annexure V

Capt.J.Rama Rao VSM, FIE,
Indian Navy (Retd)

1511, Valley View; Road No.12,
Banjara Hills; Hyderabad- 500 034

JRR/2011

September 21, 2011

1) Sri.N. Kiran Kumar Reddy
Hon'ble Chief Minister,
Govt. of AP

2) Smt. Jayanthi Natarajan
Hon'ble Minister of State
MOEF, GOI

Namaskar

Sub : Lifting of Ban on New Bulk Drug Units in Prohibited Areas

This has reference to MOEF Memo of 26-10-10 lifting Moratorium, on consideration of projects for E.C of projects to be located in Pattancheru-Bollaram area and the reported proposals under consideration of AP Govt for lifting the ban imposed by G.O.Ms No. 62 of 28-4-1999 as per the directive of Supreme Court in W.P. No 1056/1990

Seriousness of Pollution Problem from Bulk Drug Units

The seriousness of the pollution problem from the Bulk Drug industries at Pattancheru was highlighted in 2007, by an environmental scientist of Sweden, when he found at PETL the discharge load of Ciprofloxacin, corresponding to approx 45 kg of active ingredient per day. It is likely to raise antibiotic bacterial resistance in the world, making it a Global Concern.

In addition to Ciprofloxacin, the supposedly treated effluents of PETL had 21 different active pharmaceutical ingredients, used in generics for treatment of hypertension, heart disease, chronic liver ailments, depression, gonorrhea, ulcers and other ailments. It was reported that half of the drugs detected were at the highest levels of pharmaceuticals ever detected in the environment.

Lifting of Moratorium by MOEF

The CPCB clarified that lifting of moratorium, vide MOEF Memo of 26-10-10, is not applicable for the establishment / expansion of Bulk Drug units & all types of Water Polluting industries in Pattancheru –Bollaram Industrial areas stipulated in Supreme Court Order and AP Govt G.O.Ms. No 62 on the subject.

MOEF Memo of 26-10-10 lifting Moratorium, is understood to have been based on the actions initiated by the local stake holders for improving environment quality of the area. One of the actions is transferring of treated effluents of PETL through 18 KM pipeline into municipal sewers to Amberpet STP, instead of discharging into the nearby Nakka Vagu

-2-

Violation Of Ban Order

It is reported that many of the Bulk Drug Industries of international repute around Hyderabad are producing the Bulk Drugs far in excess of Types and Quantities permitted by MOEF and APPCB prior to 01-01-1997, the effective date of the Ban.

By transferring the treated effluents of PETL through 18 KM pipeline into municipal sewers to Amberpet STP, the pollution problem of Antibiotics and the 21 different active pharmaceutical ingredients found in excess quantities in the treated effluents, is only being shifted from Pattancheru to down stream of Musi River, cleverly camouflaged in the pipeline.

Appeal

It is requested that necessary action be taken to strictly implement the Ban Order imposed by G.O.Ms No. 62 of 28-4-1999, by making violation a High-Risk Business through stringent and swift penal action against the violators.

It is also requested that expansion of capacity of existing units or setting up new units in the banned areas, particularly Pattancheru- Bollaram area, be not permitted in relaxation of the G.O. Ms.No. 62, in violation of Supreme Court directive in W.P. No 1056/1990.

It is further requested that strict Vigil, Monitoring and Control be exercised on discharges of the so called treated effluents into Bay of Bengal, by the Bulk Drug Units located in Srikakulam and Visakhapatnam districts, having serious adverse impacts on Marine and Coastal Environment and the livelihoods of the communities depending on them

Looking forward for an early response

Yours Cordially

J.Rama Rao

Copy to: 1) Secretary, MOEF, GOI

2) Chairman, CPCB

3) Chairperson, APPCB

4) Special Chief Secretary, Dept of E&F , Govt,. of AP

5) Member Secretary, APPCB

Capt.J.Rama Rao VSM, FIE,
Indian Navy (Retd)

1511, Valley View; Road No.12,
Banjara Hills; Hyderabad- 500 034

JRR/2012

March 27, 2012

1) T.Chatterjee
Secretary, MOEF, GOI

2) J.M.Mauskar
Special Secretary, MOEF GOI

Namaskar

Sub: Lifting of Ban on New Bulk Drug Units in Prohibited Areas

Further to letter of 21-12-11 addressed to Chief Secretary, Govt of AP and Secretary, MOEF, GOI (copy enclosed for ready reference) this is to bring to your kind notice once again, the confusion created by MOEF Memos of 26-10-10 and 07-10-11, lifting Moratorium, on consideration of E.C of Projects to be located in Pattancheru-Bollaram Area, in spite of the ban imposed by G.O.Ms No. 62 of 28-4-99 as per the directive of Supreme Court in W.P. No 1056/1990.

Lack of Clarity in spite of CPCB Clarification

The CPCB, vide letter B-29012/ESS(CPA)/2010/2163 of 23-12-10 clarified that lifting of moratorium, vide MOEF Memo of 26-10-10, is not applicable for the establishment / expansion of Bulk Drug units & all types of Water Polluting industries in Pattancheru– Bollaram Industrial areas stipulated in Supreme Court Order and AP Govt G.O.Ms. No 62 on the subject. But this has not been specified even in subsequent MOEF Memo dated 07-10-11, leave alone giving any clarification on the subject, in response to my letter dated 14-01-11 addressed to CPCB , with copy endorsed to Secretary, MOEF.

Reported Violations by Bulk Drug Industry

It is being widely reported that violations of the Ban Order, had been taking place and the State Administration was not responsive to the representations made in this regard. It is reported that serious efforts are being made by Bulk Industry to get the ban order lifted in the name of industrial development.. It is also understood that IICT Hyderabad has been approached by APPCB/BDMA for a report on the status of Water Pollution from Bulk Drug Industries in and around Hyderabad

Appeal

It is requested that expansion of capacity of existing units or setting up new units in the banned areas in & around Hyderabad, be not permitted in relaxation of the G.O. Ms.No. 62 and in violation of S.C Directive in W.P. No 1056/1990.

Yours Cordially

J.Rama Rao
Copy to. Member Secretary, CPCB



SAVE OUR URBAN LAKES

www.soulhyd.org

To
Ms. Minnie Mathews, IAS
Chief Secretary
GOAP, Hyderabad, AP.



Citizens initiative for saving water bodies in Hyderabad

December 3, 2012

Received
(1880)
3/12/12

Sub: Proposed lifting of the ban on Bulk Drugs Industry for capacity increase and manufacture of un-consented products leading to – POLLUTION OF GROUND WATER & WATER BODIES.

Dear Madam,

With reference to various submissions to you and other concerned authorities by Captain J. Rama Rao & Shri. K. Veera Reddy (copies enclosed) regarding the above – please note the following:

- APPCB had ordered closure of 12 out of 18 BDMs on 10-7-2012 based on the report of Expert Committee (EC) constituted by Appellate Authority (copy of front page enclosed) that submitted its report in June 2012. This order was suspended by Appellate Authority 21-7-2012 based on consideration of industrial losses – **notwithstanding damage to environment and dangers to human life** - with stipulation of **stopping excess production and un-consented products**.
- Honorable High Court has also ordered the same in WP 44/2011 filed by President of Ma Telangana Party
- As of date - there has been **no compliance by industry** - neither has any action been taken against them.

The EC report was based on personal site visits to concerned manufacturing units and was based on exhaustive documentary evidence.

- Findings of EC clearly believe claims of the industry about ZLD/ZPLD as is clear from page 19 of EC (copy enclosed) that **only 4 out of 18 units have full fledged ZLD/ZPLD facilities – and even these are not functional as per EC page 45 (copy enclosed)**
- In view of the above and acceptance by industry about increased production as well as production of un-consented products – the pollution load due to sanctioned as well as unsanctioned production - has not only continued but increased.



Chairman
APPCB
Hyderabad.

3/12/12

Eden Banjara, Ave - 8, St 7, Aurora Colony, Banjara Hills, Hyd - 500 034
Tel - 9949519113, 9052311911, 9441233967

Research Scholars' Epistemological Predicament

A CHANDRASEKHAR REDDY, GITANJALI JOSHUA, IPSITA PRADHAN, JANGKHOSAI TOUTHANG, LALATENDU KESHARI DAS, MITAJA CHAKRABORTY, PRIYAM SHARMA, SATHEESH PERUMALLA, SHILPA KRISHNA

What is the position of research scholars in the knowledge food chain? Are they merely consumers of knowledge or can they also produce it? The University Grants Commission Regulations, 2009 and 2016 enforced two important rules: mandatory coursework on research methods and theory for MPhil and PhD programmes, and publication of at least one research paper in a peer-reviewed journal to be eligible to submit a doctoral thesis. An analysis of these regulations through the lens of research scholars offers an insight into the complexity of relationships between academic institutions, journals, and research scholars in the process of knowledge production.

In the introduction to her book, *Southern Theory: The Global Dynamics of Knowledge in Social Science*, Australian sociologist Raewyn Connell (2008) notes that “social science is, at best, ambiguously democratic. Its dominant genres picture the world as it is seen by men, by capitalists, by the educated and affluent.” Notwithstanding the provocative stance of the work, Connell fails to mention that this dominant knowledge is produced by institutional academicians, with a little help from international governmental and non-governmental organisations (Zapp 2018).

The purpose of this article is not to critique Connell, either for presuming a homogeneous “south” (Muller 2009; Collins 1997) or for being ignorant of the segment of research scholars. As we will discuss a little later, research scholars, throughout the world, have predominantly been relegated to the position of consumers of knowledge that is produced by agents who decry their own helplessness in getting recognition as producers of knowledge. Our aim is to analyse the reasons, particularly in the case of India, that have caused research scholars to stay away from the production of knowledge debate and remain mere consumers of knowledge.

We take as the backdrop the University Grants Commission (UGC) (Minimum Standards and Procedure for Award of MPhil/PhD Degrees) Regulations of 2009 and 2016, which made courses on research methods and theories mandatory in MPhil and PhD, and required PhD scholars to publish at least one research paper in a peer-reviewed journal to be eligible to submit their thesis. Thus, we¹ attempt to discuss, through empirical data, the problematic aspects of the relationships between academic institutions, journals, and research scholars in knowledge production. The article is divided into four sections. In the first, we discuss the debate around the politics of knowledge production in India and, while doing so, we try to demonstrate how it has bypassed the domain of research scholars. The next section discusses, in brief, the methods we used to collect empirical data to justify our claim. In the third section, we present data on five academic journals in India and show how research scholars view their relationship with these journals. Finally, we offer suggestions for the way forward.

The Debate So Far

By focusing on the training of research scholars in the theory and methods of social enquiry, on the one hand, and the dissemination of their work to the academic peer group in the form of published research papers, on the other, the UGC 2009 and 2016 regulations necessitated a greater engagement on the part of academic institutions and journals to create “competent”

The authors would like to thank Sundar Sarukkai and N Purendra Prasad for their comments on an earlier draft, which helped the authors refine their ideas, and for their continuous encouragement. The authors also thank the anonymous reviewer for their insightful suggestions, which helped them streamline the arguments.

The position of the authors' names is in alphabetical order and does not represent any difference in their contribution to the study.

A Chandrasekhar Reddy (socio.hcu@gmail.com), Gitanjali Joshua, Ipsita Pradhan, Jangkhosai Touthang, Lalatendu Keshari Das, Mitaja Chakraborty, Priyam Sharma, Satheesh Perumalla, and Shilpa Krishna are research scholars at the Department of Sociology, University of Hyderabad.

research scholars in India. The issue of competency is of seminal importance here. Veena Das (1993) claimed that research scholars (she uses the term research students) in India were not competent enough to take the discipline of sociology forward. Apart from the students themselves, Das blames academic institutions, the UGC, and professional bodies like the Indian Sociological Society for the situation.

Following Das, the “crisis” debate in Indian sociology, some of which took place in the pages of *Economic & Political Weekly* (EPW) and elsewhere, took a new lease of life, with contributions putting the blame on the nature of sociology itself (Deshpande 1994), the international politics of knowledge production in the style of Connell (Patel 1997), the decreasing importance attached to funding institutions like the Indian Council of Social Science Research (ICSSR), the increasing regionality in knowledge production (Chatterjee 2002), and on identity politics (Harshe and Patel 2003). These lines of reasoning, which in a subtle way decried the decreasing “merit” and “competency” in both students and researchers alike, culminated in the publication of the book, *Doing Sociology in India* (Patel 2011).

These “meritocratic” views of social science research in India can be seen as on par with self-help books on publishing journal articles (Sword 2012; Belcher 2009) and other works which put the blame on individuals for a so-called lack of rigour. In other words, what restricts the growth of social sciences in India, according to these scholars, is the diminishing rate of “originality” in research. To give further sustenance to the “meritocratic” thesis, a study by Guetzkow et al (2004: 198) dissected meritocracy, specifically in the humanities and social sciences, into various segments by equating them with “originality.” The study held benchmarks such as “original approach, understudied area, original topic, original theory, original method, original data, and original results” to be crucial to understanding “originality” in research. However, what concerns us here is the language used to describe the researchers whose proposals and academic papers do not get accepted by the concerned committees for funding. As the authors argue,

Applicants’ whose proposals were deemed original were often described with such adjectives as adventurous, ambitious, bold, courageous, curious, independent, intellectually honest, and risk-taking. They were also viewed as “going out of the way,” “challenging the status quo,” “thinking for themselves” and “having a passion for ideas.” Likewise ... scholars whose proposals lack originality ... were deemed to be unmotivated or incapable of independent thought and were described with terms that include: conformist, complacent, derivative, facile, gap-filling, hackneyed, lazy, parochial, pedestrian, rehashing, tried, traditional, uncritical, “spinning their wheels;” or alternatively, fashionable, trendy, “shambolic,” slavish, “riding on the band wagon” or “throwing around buzzwords.” (2004: 203)

So, for Guetzkow et al, and for the participants in their study, it is always desirable to be part of the group which produces original works and not the ones which refrain from doing so. In order to attain “merit” and “originality,” scholars need to follow the formulae presented in the study; otherwise they will forever remain among the class of underachievers, roaming in the wastelands of the academic world. It is highly possible that similar judgments are made of other scholars who can/cannot get their works published in credible journals.²

Looking at the above debates, two lines of thought emerge. First, for established institutional academics (both in India and elsewhere), research scholars do not even constitute a footnote in the field of academic knowledge production. Second, despite the self-help nature of the recommendations, no real change has happened in the publication scenario. To give an example, between 2007 and 2016, the journal *Contributions to Indian Sociology* has published only four papers which were written by research scholars based in India (out of a total of 65). This is not more than 2% of the published work. Going by the discussion previously outlined, one might conclude that this status quo is a result of research scholars being a “lazy” lot, who are “incapable” and “incompetent” producers of knowledge. Teaching standards, pedagogy, and inclusiveness in the disciplinary practices did not figure as prominently in these debates as the hypothetical notion of a crisis in the discipline.

We suggest that the debates on the “crisis in Indian sociology,” as they have been conducted so far, need to be seen merely as a friendly, internal critique of the established paternal figures (who are also the gatekeepers) of the discipline. In the following pages, we try to reopen this debate. Weaving it around the UGC 2009 and 2016 regulations, we attempt to problematise the so-called meritocratic notions of the privileged sections of the Indian academia about research scholars through empirical data and bring the latter’s voices to the forefront.

Data and Methods

The study has at its backdrop two Young Researchers’ Workshops³ and one academic writing workshop organised by research scholars of the Department of Sociology, University of Hyderabad in 2015, 2016, and 2017, respectively. The participants (from Departments of Sociology) of these workshops came from institutes of repute⁴ from across India: from the north, Jawaharlal Nehru University and Delhi University; from the west, Gujarat Central University, Indian Institute of Technology (IIT) Bombay, and Tata Institute of Social Sciences (TISS) Mumbai; from the south, National Institute of Advanced Studies, Mahatma Gandhi University, Kerala, IIT Madras, Madras Institute of Development Studies, University of Hyderabad and TISS Hyderabad; from the east, Utkal University, Centre for Studies in Social Sciences, and North East Hill University. The purpose of this sampling was not to draw a boundary between good and bad institutions or research scholars, but to decipher the position of research scholars coming from these institutes in the knowledge production hierarchy.

To broaden the data pool for this article, we also included PhD students from other disciplines within the social sciences. In total, we interviewed (via email) 40 participants (20 male and 20 female) belonging to various disciplines of the social sciences. The aim of the survey was (i) to look at the interaction between research scholars and the journals that they would like to publish in; (ii) the challenges in pursuing academic writing and academic research with respect to the language(s) of the social sciences; (iii) other constraints that research scholars have to confront during their research; and (iv) their views on research scholars as consumers and/or producers of knowledge.

As we wanted to show the correlation between institutions of repute and academic publication on the one hand, and researchers as knowledge producers, on the other, we selected journals accordingly. Through discussions with our respondents, we came across a number of journals in which these research scholars wanted their works to be published. These are: *EPW*, *Contributions to Indian Sociology*, *Sociological Bulletin*, *Social Change*, *Indian Economic and Social History Review*, *Social Science and Medicine*, *Journal of Indian Anthropological Society*, *Social Scientist*, *Labour and Development*, *Indian Journal of Labour Economics*, *Man-and-Development*, *Sage Journals*, *Journal of Religion*, *Indian Political Science Association Journal*, *Journal of Northeast India Studies*, *Indian Journal of Medical Ethics*, *Indian Journal of Gender Studies*, and *History and Sociology of South Asia*.

However, almost all our participants wished to see their authored articles in the following five journals:⁵ *EPW*, *Sociological Bulletin*, *Contributions to Indian Sociology*, *Indian Economic and Social History Review*, and *Social Change*. All these journals have their editorship based in India and are considered by both publishers and contributors as the gatekeepers of academic knowledge production. Therefore, we decided to focus on these five journals for a more detailed analysis.

To collect data from the above-mentioned journals, a total of 1,450 articles were reviewed. This includes all the research papers published between 2007 and 2016 in *Sociological Bulletin* (154), *Contributions to Indian Sociology* (129), *Indian Economic and Social History Review* (166), and *Social Change* (252) respectively. Owing to the large number of articles published in *EPW*, only 50% (749) of research papers published in the Special Articles section were considered. The papers were further sub-divided into categories based on institutional affiliation, regional location (both within and outside the country), gender, research scholar, and single or joint authorship. The results were tabulated and codified using Microsoft Office. In the following sections, we will discuss the results of this exercise in detail.

Discussion

We have divided this section into three subsections in which we analyse (i) the disaggregated data from the five journals in terms of regional location of authors, their gender division, and representation of research scholars in the published works as authors or co-authors; (ii) the research scholars' opinions regarding their interactions with the journals, the predicaments that resulted from the UGC notifications, challenges in pursuing academic writing and academic research in the social sciences, other constraints that the research scholars face while they are engaged in research, and finally, their views on themselves in the consumer/producer debate; and (iii) a way forward.

Representation in Journals

Disaggregated data on the regional location of authors (Table 1) shows that East and North East India contribute very little to these journals. Central India's contribution is also close to marginal, except in the case of *Social Change*, wherein 11% of authors are from academic institutions located in Central India. As both Chatterjee (2002) and Guru (2002) have noted previously,

academicians located in institutes in North India are overwhelmingly represented in all these five journals. Even within this group, institutions like Jawaharlal Nehru University and Delhi University post a larger share than others. Given the data we have at hand, we cannot help but agree with Guru's (2002: 5004) assertion that the "apex court of social sciences (is) in Delhi" and this has created an ecosystem in which academicians located in Delhi have positioned themselves as the guiding light in the production and distribution of knowledge about themselves as well as others. It has created a form of cultural hegemony of these academicians over the Indian social sciences. Incidentally, these academicians also happen to be the same ones who periodically amuse themselves by writing obituaries of the disciplines they are part of; in this case, that of sociology.

Table 1: Institutional Affiliations of Authors, 2007–16 (%)

Journal	East	West	Central	North	South	North East
<i>Sociological Bulletin</i>	9.7	22.7	0	31.8	14.2	7.1
<i>EPW</i>	5.8	12.6	0.4	39.6	13.7	2.2
<i>IESHR</i>	6.6	1.2	0	12.6	7.2	1.2
<i>Contributions to Indian Sociology</i>	0.8	7.8	0.8	21.7	6.2	0
<i>Social Change</i>	8	5.6	11.2	46.1	11.6	2.8

The distribution of regional institutional affiliations points at the creation of a centre with knowledge disseminating from that place, through publications, to the rest of the country. It shows a practice of social sciences that is involved in the othering of institutions that are not located in this created centre (Oommen 2013). This centre systemically puts those researchers who do not belong to it at a disadvantage, thereby producing marginalisation in the group of researchers in India. The global distribution of institutional affiliations tells a similar story. While the knowledge produced is about India, the high proportion of contributions from institutions located in the United States and the United Kingdom shows who can be authentic producers of knowledge. It will be interesting to see data from institutions affiliated to India that are actively engaged in producing knowledge about countries of the global North.⁶ The geographical locations of institutions that the authors are affiliated to, therefore, prove to be vital. So, to use Connell's (2008) argument, the global South further creates a north and a south within itself, which is indicative of the privileged status that this north has in terms of publications and, hence, control over what gets to be produced and distributed for consumption.

In order to check the contentions made by Connell (2008) and others that the social sciences have a preponderance of male researchers over their female counterparts, we also looked at gender as a parameter. Historically, women have been subjects about whom knowledge is created. In a context where institutional and familial set-ups are still largely patriarchal, it is not surprising that almost all the journals (*Contributions to Indian Sociology* turned out to be an exception) have a higher proportion of male authorship (Table 2). However, it can be seen that amongst research scholars, female authorship is

Table 2: Gender Distribution in Authorship (%)

Journal	Female	Male
<i>Sociological Bulletin</i>	37.9	62.1
<i>EPW</i>	28.2	71.7
<i>IESHR</i>	34.4	65.6
<i>Contributions to Indian Sociology</i>	51.4	48.6
<i>Social Change</i>	26	74

higher than male authorship. Among publications authored by research scholars, *Sociological Bulletin* had 77.7% female authorship, while *Social Change* had 35.4% female authors. However, when it comes to institutional academicians as authors, both these journals, follow the same trajectory as elsewhere, with male authors outnumbering their female counterparts by a large margin. It is contrary to the actual situation in India's social sciences departments, which more often than not see women research scholars outnumber their male counterparts.⁷ The data, we believe, is indicative of the fact that despite being more productive than their male counterparts in terms of journal papers at the stage of being research scholars, the careers of these young women researchers do not automatically translate to the same trajectory in knowledge production.

After looking at the data on the hegemony of New Delhi and males over knowledge production in India, we looked at the proportion of articles published in these journals that are authored by research scholars. The data from 2007 to 2016 shows an abysmal picture. It is difficult to make sense of the fact that out of 1,447 papers published over a span of 10 years, only 12.88% of articles, on average, came from research scholars. *Sociological Bulletin*, with 17.5%, had the highest proportion of contributions from research scholars, while *Contributions to Indian Sociology* had the lowest, with 6.2% (Table 3). However, it needs to be taken into consideration that these articles by research scholars came in two categories, namely, single authors (this includes research scholars based in India and abroad), and joint authorship with a senior academician. To give an example, *EPW* published 69 research papers in which research scholars were credited. Of these, while 36 papers belonged to research scholars (Indian, foreign, and Indians working in foreign universities), 33 papers were co-authored with an established academician. In this scenario, the adjectives like "lazy lot" and "incompetence," as suggested by Guetzkow et al (2004), appear insufficient to account for the huge gap in the number of publications by research scholars vis-à-vis senior researchers. Nor can they help us answer our question: How can research scholars be producers of knowledge, as demanded by both academicians of repute and institutions like the UGC?

To investigate further on this question of knowledge hierarchy we moved to our counterparts located in the social science departments of different universities in India. The following section shows how research scholars viewed their relationship with the journals, the challenges they confronted, and their position in the knowledge food chain.

Producers of Knowledge

As we discussed at the beginning of this article, the purpose of this study is not merely to critique academicians who have been writing obituaries of sociology or journals for not giving enough space to the work of research scholars. It is important not to externalise the issues of research scholars to gain sympathy from

our readers. Rather, the agenda for the study is to showcase, by following an empirical method, the reality of the ecosystem that involves academic institutions, journals, and research scholars and how it has the ability to create both "lazy lots" and "fearless producers of knowledge" among research scholars in India. On this path, let us continue further on our discussion about research scholars and their interaction with academic journals.

Interaction between research scholars and journals: Of the 40 respondents that we interviewed, only half have publications in peer-reviewed journals. Further, among those who have publications, only 20% were the sole authors of their work while 80% were credited as co-authors along with their supervisors. One of our participants shared his experience with *EPW*: According to him, when he sent his manuscript on a political movement in North East India as the sole author, *EPW* rejected it stating that the journal had already published enough on that topic. However, when he resented the same paper to the journal with a few minor changes, this time co-authored with his research supervisor, *EPW* had no issues in accepting the same (after revising it as per the reviewer's suggestions). Although the research scholar got his paper published in *EPW*, his experience with the journal remained sour with respect to the status of research scholars in academic knowledge production.

Other reasons mentioned for rejection by journals were that the papers did not comply with the requirements of the respective journals, that they lacked "rich" empirical work, or that the papers did not have strong theoretical justifications, among others. One of the researchers said, "rejection of the papers also depends on the ideology of the journals. Left-oriented reviewers have labelled my article as pro-industry and right-oriented ones had problems with my critical analysis of genetically modified technology that the corporates like Monsanto tried to bring in Indian markets." Echoing the concern of our above respondent, all the 40 research scholars we interviewed expressed that the "right networks" and "social capital" are important to get papers published, particularly in India's top journals.

So, does it mean that in order to comply with the UGC guidelines for submission of PhD theses, the research scholars should look at "alternative" journals, some of them also known in colloquial language as "paid journals"? Among our respondents, 10% accepted paid journals as an option to meet the requirements of the UGC. One of them said,

As per new UGC guideline for submission, at least one research paper should be published related to the PhD topic. I know many of my seniors who had opted for paid journals as there was no other way to submit the thesis on time. One of my seniors was waiting for his work to be published as a part of an edited book for almost one year, but it came very late and hence he had to opt for the paid one. There are many similar cases which I know [of]. In my case, I am in my last stage of submission and have sent two different articles to two different peer-reviewed journals, but they have not responded till date. So, I may have to opt for paid journals. If UGC keeps making life miserable and unbearable, we will have no other option but to rely on these paid journals to get published, which in turn can mean finishing PhD, which in turn makes [the] unequal space of academia more unequal.

However, 90% of our respondents opined that they do not want to get their work published in paid journals. They felt that

Table 3: Papers Authored by Research Scholars (%)

Journal	Research Scholars (%)
<i>Sociological Bulletin</i>	17.5
<i>EPW</i>	9.2
<i>IESHR</i>	14.5
<i>Contributions to Indian Sociology</i>	6.2
<i>Social Change</i>	17

paid journals have poor quality papers. The practice of paying in order to get one's work published, our participants argued, needs to be seriously discouraged as it is also unethical. They felt that there should be no business in academics, further explaining the point made by our last respondent that paid journals accentuate inequality among research scholars based on their ability to spend money to buy publications. One of the respondents said,

The obsession to publish, which is also many a times structurally/institutionally created, leads the researchers to opt for such journals. In the world of asymmetric information, publications work as market signaling about the quality of an academician. This is exactly where the paid journals are counterproductive. Simply put, since one can "buy" the publication(s), it is hardly reflective of the true ability of the researcher. In most cases, those are substandard because anyone can buy a publication for himself/herself. It actually reinforces inequality. The more I can pay, the more publications get added to my cv, and in turn, [the] more market value I derive. It basically creates a downward spiral in terms of both academic quality and material distribution in the society at large.

Apart from the journals, the research scholars we interviewed also questioned the bureaucratisation of UGC guidelines regarding the number of publications needed for submission of PhD theses and for faculty promotions. As one respondent noted with irony,

Academic journals in India are not compatible with social sciences in India. UGC compares natural sciences with social sciences. We cannot conduct research in a short span of time, nor is that kind of research fruitful for knowledge production. Writing two papers, three papers should not be the goal. There are fake publishing houses which publish underdeveloped papers, then are they really contributing to the social science knowledge?

As research scholars struggle to get their work published, so as to meet the minimum criteria to submit their theses, the plea to both the UGC and journals is not that research scholars be treated as a special group. Rather, the concern here is that the bureaucratisation of academic processes, which gives a lot of power to the management, overshadows the constraints faced by research scholars working in the social sciences in general, and sociology and social anthropology in particular, since the latter have to spend considerable amount of time doing fieldwork and then writing their descriptive analysis of the incidents and processes in the field. With journals of repute not giving enough space to research scholars, the UGC is effectively forcing these students to adopt means that are not always ethical to get their work published.

Certain private deemed-to-be-universities demand two published papers from PhD students (enrolled in the university and in research centres that award degrees from that university), but with the added provision that these have to be in journals indexed in Scopus. This is an absurd requirement as it is not applicable to the social sciences and humanities. To add to the problem, they do not accept peer-reviewed papers in edited books, which, unlike in the natural sciences, is a standard practice in these fields. The bureaucratic structures in the university are applying this rule without thought and arbitrarily, affecting the research culture of PhD students. In this situation, research scholars are becoming producers of knowledge for sure, but the launching pad they are able to get is too fragile to give them a firm ground to grow as serious researchers. This brings us to another crucial aspect which has concerned

the research scholars we interviewed, namely how to strengthen academic writing and research.

Challenges in Pursuing Academic Writing

Notwithstanding the seven parameters proposed by Guetzkow et al (2004) to judge originality in humanities and the social sciences, a common problem that was raised by our respondents was that there is little to no training in academic writing in the coursework offered by universities and research institutes. An argument that was highlighted in our interviews with research scholars, and universally suggested during the academic writing workshop in 2017, was that without adequate training in academic research and academic writing, research scholars and junior researchers find it difficult to even decipher the notion of originality in their work. A scholar explained this with a suggestion:

Often, PhD Students find themselves in a lonely world where there are few others doing the same thing. So, if there is coursework that integrates the PhD process it may help. Let me illustrate with an example. The PhD duration is on average five-six years. Less for humanities and perhaps more in the social sciences. But let us take an average of five years as the duration to start work, register or qualify for candidacy, pursue field work and write the thesis. The first year is when most students have the bulk of the coursework and then [they] are off to field stations and sites by the second year. Assuming that the field occupies the student for two years, the rigour of an academic space is no longer present and the students often return with a changed perspective and different questions. At this stage, it would be of great help to do another round of rigorous coursework that helps students assimilate and understand their data/material. So, a suggestion here would be to run through some basic coursework in the specialised field or have the batch of students work on their data together. For interdisciplinary subjects like art practice and visual anthropology, this would be helpful as the data that is brought in from the field is varied and often unstructured. This year-long exposure to [a] higher level of coursework will help the articulation and therefore, the writing process. It is also important to run writing programs of different levels of specialisation or advancement as the thesis is meant to be a work of academic merit and not a set of articles. So, to make the point again, coursework outside of regular or mandated coursework is necessary and not an option as it is a very difficult task to get from data sets and material from the field to a fully developed thesis.

An overwhelming majority (70%) of the research scholars interviewed were of the opinion that there is a need for training in converting data from the field into paper or chapters. Only 30% of the scholars interviewed believed that the research methodology coursework that is currently offered helped them in their research. A scholar said,

Of course, we have coursework, then we have group projects during MA, MPhil to get training on methodology. But what happens is that on the field, one finds it difficult because the supervisor is not involved; you are on your own. You keep on writing field notes, do interviews, but you hardly know if that is the way. Then you submit group reports. Does that experience then really help? I am not sure. There is no engagement. You have to apply your common sense based on contingencies. It greatly depends on how sociable you are. I really think there should be a proper training so that when we have data we should not be confused. There should be more engagement from the supervisor's side. Our university conducts workshops and academic writing courses, but not much difference is seen. There should be a regular class for academic writing and academic research just like other classes, with a proper course. Workshops help, but regular mandatory training should be there.

The lack of structured training in research impacts the quality of research output and prevents the creative potential

of research scholars in Indian universities from coming to the fore. In this scenario, language, particularly the so-called academic language, becomes a chimera for most students, including those in India's elite universities. According to 80% of our respondents, academia is often inaccessible due to language barriers. They believe that academia is exclusionary because it relies heavily on comprehensive English language skills that are often limited to a few social groups. One respondent coming from a top university located in New Delhi stated that,

language is a crucial factor here. I have mostly studied in Bengali medium and therefore suffer from vocabulary poverty as compared to my friends who have studied in English all throughout. In one of the seminars of sociology, where I heard one of my friends presenting a paper, I was wondering whether she was speaking English. Later I realised that it is a mixed effect of subject-specific terminology and vocabulary opulence. Obviously, I didn't feel included. Terminology too develops from social context. Some fixed body of language terminology and vocabulary poverty and elite-dominance structurally bar the flow of knowledge from alternative (native/local/subaltern) sources and traditions of knowledge.

Although 20% of our respondents indicated that the discipline of sociology is not completely exclusionary, they also insisted that it was not open about itself. The way it is practised marginalises female academicians and restricts the ability of researchers to bring forth data and ethnographies from diverse journals at the subnational level. Similarly, scholars who are not fluent in English are seen to be working on "less important themes" even if their ideas are absolutely original. They also face suspicion from established figureheads in their disciplines as to whether their work is "really sociological." As some of our respondents noted, this kind of branding decreases the job prospects of these practitioners.

Another issue, which was reported by about 90% of our respondents, is financial exclusion. Our respondents pointed out three ways in which financial exclusion works to keep a large mass of underprivileged students from getting fully integrated in the disciplines they had the opportunity to be a part of.

First, they speak of the uncertainty that exists in institutions that do not have a fellowship system, which leaves many research scholars coming from rural and semi-urban areas in distress. They make it to such prestigious institutions only after facing intense competition. Confronting the lack of financial assistance at that point is really heartbreaking. It creates a psychological insecurity among students and increases the pressure to qualify for a Junior Research Fellowship, the process for which is arbitrary. Second, financial assistance can be sustained in a dignified manner if the governing bodies of institutions have autonomy. Unfortunately, this has not been the case. This has hampered both student intake and faculty recruitment, leading towards mediocrity. Third, the Council of Scientific and Industrial Research (CSIR) has been asked to grade the performance of scientists and research scholars in the scientific fields. This approach—of objectively quantifying performance based on which governing body will approve aids, grants, and fellowships—will create a precarious situation for research scholars in the social sciences and humanities. Our participants feared that given the UGC's and other quasi-state institutions' inclinations towards natural science, the matrix suggested by CSIR

(which funds natural science research only) might be implemented for the social sciences and humanities as well.

Support of the Educational System

After analysing a number of issues that affect relationships between academic institutions, journals, and research scholars, now let us address the question which constitutes the title of this article: Can research scholars be producers of knowledge? Our respondents did not provide us with any easy-to-preach, ready-made answers. Research scholars claimed that they are both consumers and producers of knowledge at the same time, although the former outweighs the latter by a considerable margin. The reasons range from worries about being perceived as inadequate by the scholarly community to the challenges of writing in ways required by academic journals. Nevertheless, they strongly felt that creating valuable producers of knowledge out of research scholars needs support from the whole education system, primarily to sustain the passion to be part of the knowledge production process. A few of our respondents felt that research scholars are not a uniform category and are divided by institutional and social locations. One of them elaborated on it in the following manner:

It depends on who, when, with whom, where is he/she doing the research, irrespective of the topic. The motivation for research is very critical here. It also depends significantly on the supervisor. One may be motivated to engage seriously with her/his topic, but if the supervisor's objective is to maximise the number of PhD-holders under her/his supervision, then it is totally research for research's sake. In many cases, it has been observed that the supervisor is too big to be of any help. The role of supervisor in this regard of knowledge consumption vis-à-vis knowledge production is of utmost importance for two main reasons: (a) the supervisor has more knowledge and experience so she/he would be in a better position to guide the research scholar in either direction; (b) PhD is done in most cases under a feudal setup. The power enjoyed by the supervisor and [the] vulnerability of the scholar could be detrimental to the main purpose of research. A frustrated scholar might shift from [having] enthusiasm to produce knowledge to being a mere consumer.

Apart from the research scholar-supervisor relationship, our respondents raised other pertinent concerns regarding them being considered producers of knowledge. The accounts of three respondents presented below lay out these arguments.

Respondent 1: "For good quality field study-based work, you need good funding. We don't have [it]. The government decisions are regulated by corporate companies. [Due to the] lack of adequate funds, the quality of our research is comparatively bad with [respect to] EU academia. To be a good producer of the knowledge, we need to invest greatly in the area, otherwise we are consumers of them from the western world."

Respondent 2: "Depends on the particular policymaking of the government with respect to higher education. Right now, I am a bit sceptical and I hope that the research in India does not turn itself into a passive entity rather than an area of inclusion as it should be. The less stifling the information flow, the better. Otherwise, the research scholars are both receptors as well as innovators."

Respondent 3: "The role of institution is another important factor. A liberal environment is the basic need for knowledge. If the state and administration put hands together to kill the free-thinking ability of the scholars for their own political agenda, then certainly it is a clear case of state-sponsored production of mere consumers of knowledge. The larger political scenario in a society plays a fundamental role. Knowledge is what liberates us, but it cannot be produced without a liberal environment. The state policies too decide it. If the UGC, for

example, promotes maximisation of publications, then that would certainly increase the number of publications through paid journals which as argued above is detrimental to knowledge production.”

Conclusions

The neo-liberal construct of the academic world (Connell 2013), with rules regarding publication in UGC-approved journals, and “points” for attending national and academic conferences systemically manufactures underachievers amongst research scholars. Connell (2008) has written about the international politics of knowledge production with the creation of the global North and the global South. The global South is an object of study for the global North. It refuses to become a homogeneous entity. Within the global South itself, there are hierarchies constructed along various axes, which affect research scholars in myriad ways. Within this paradigm, while studies on originality in the social sciences and humanities might remain a goal for many, the structural constraints posed by the practitioners of the discipline on the one hand and the exclusionary nature of quality journals on the other, serve to keep research scholars out of the purview of knowledge production. Even if they are becoming producers, a vast majority of research scholars’ work is published in journals that are not considered to be trailblazers in their fields. Thus, despite the attempts of the UGC to make research scholars

producers of knowledge, the latter are not getting much help from journals. This is as true about the research scholars in India, as it is about their counterparts located in the elite academic institutions in the global North. A cursory look at journals like *Current Sociology*, *Current Anthropology*, *Journal of Peasant Studies*, and *Journal of Agrarian Change*, to name a few, would not show much difference from what our study has highlighted regarding the position of research scholars.

Therefore, we suggest that the wasteful “sociology in crisis” debate be relegated to the dustbin of history. In its place, a more inclusive approach, as suggested by our respondents, needs to be considered. The relationship between research scholars and institutional researchers should be a non-hierarchical structure. Established academic journals can open their gates to more papers solely authored by research scholars without compromising on the quality of work. This will reduce the patron–client relationship that has emerged in academic publishing in which research scholars need the name of their supervisors or some other senior researchers to get their work published. Journals can commit to publishing at least one paper by a research scholar per issue. Thus, research scholars can become worthwhile producers of knowledge, with or without the UGC’s publication requirements.

NOTES

- 1 Institutions like Mysore University require PhD students to get at least two research papers published.
- 2 In another line of argument, Guru (2002) and Kumar’s (2016) have deconstructed the bubble of meritocracy, objectivity and originality theses of the studies published on India. By bringing the question of “egalitarianism” in social sciences in general and sociology in particular, both Guru and Kumar, with their articles spread over a gap of 14 years, have argued that knowledge production in the Indian social sciences is deeply “inegalitarian” with “upper caste, male academicians” making and breaking the rules of the game. It is the deeply subjective biases of these gatekeepers of knowledge that has curtailed the growth of new concepts, theories and ideas emerging from the Dalit-bahujan hinterland. Although, there has been considerable volume of work that has emerged in India endorsing Guru and Kumar’s line of argument, neither our study nor our respondents see this as the only way we can look at the issues of research scholars and their special relationship with academic institutions—academic journals dynamics. To the extent that a majority of our respondents refused to share their caste affiliation with us. Of the 40 respondents, only one said that caste can be considered as a special marker in the hierarchy. According to our other respondents, while it might be true of the established academicians in which researchers who belong to marginalised castes and tribes and also work on them might not get adequate representation in the academic publications, however, research scholars as a group itself are severely underrepresented in the field of academic publications. It was also not possible for us to locate the caste and tribe of all the authors, whose papers got published in the five journals under our scanner. A more detailed aspect of caste discrimination and research scholars was out of scope of this study.
- 3 The 2015 YRW was sponsored by University Grants Commission-Special Assistance Programme

(UGC-SAP) of the Department of Sociology, University of Hyderabad. The 2016 YRW was jointly sponsored by University Grants Commission-Special Assistance Programme (UGC-SAP) and Indian Council of Social Science Research (ICSSR). The 2017 academic writing workshop was again sponsored by the UGC-SAP.

- 4 The notion of “repute” comes with the consciousness that both the participants as well as the Indian state (through its National Assessment and Accreditation Council (NAAC) scoring) considers these institutes to be representative of quality education, pedagogy and research. As we will show in a while, faculty from these institutes also contribute the most in terms of academic journal publication.
- 5 Except the journal *Economic & Political Weekly* which is published by the Sameeksha Trust, all other journals are published by Sage Publications.
- 6 It is beyond the scope of this study but can provide fertile ground for further research.
- 7 One just has to check the websites of Jawaharlal Nehru University, Delhi University in New Delhi and University of Hyderabad in Hyderabad, to give just a few examples, to get a sense of the gender composition of both research scholars and faculty members alike.

REFERENCES

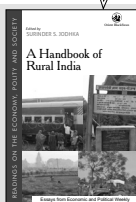
- Belcher, Wendy Laura (2009): *Writing Your Journal Article in 12 Weeks: A Guide to Academic Publishing Success*, Princeton: Princeton University Press.
- Chatterjee, Partha (2002): “Institutional Context of Social Science Research in South Asia,” *Economic & Political Weekly*, Vol 37, No 35, pp 3604–12.
- Collins, Randall (1997): “A Sociological Guilt Trip: Comment on Connell,” *American Journal of Sociology*, Vol 102, No 6, pp 1558–64.
- Connell, Raewyn (2008): *Southern Theory: The Global Dynamics of Knowledge in Social Science*, Crow’s Nest: Allan & Unwin.
- (2013): “The Neoliberal Cascade and Education: An Essay on the Market Agenda and Its Consequences,” *Critical Studies in Education*, Vol 54, No 2, pp 99–112.

- Das, Veena (1993): “Sociological Research in India: The State of Crisis,” *Economic & Political Weekly*, Vol 28, No 23, pp 1159–61.
- Deshpande, Satish (1994): “Sociological Research in India: The State of Crisis,” *Economic & Political Weekly*, Vol 28, No 23, pp 1159–61.
- Gouldner, Alvin W (1970): *The Coming Crisis of Western Sociology: The Social Origins of Social Theory*, New York: Basic Books.
- Guetzkow, Joshua, Michele Lamont and Gregoire Mallard (2004): “What Is Originality in the Humanities and the Social Sciences?,” *American Sociological Review*, Vol 69, No 2, pp 190–212.
- Guru, Gopal (2002): “How Egalitarian Are the Social Sciences in India,” *Economic & Political Weekly*, Vol 37, No 50, pp 5003–09.
- Harshe, Rajen and Sujata Patel (2003): “Identity Politics and Crisis of Social Sciences,” *Economic & Political Weekly*, Vol 38, No 6, pp 525–27.
- Kumar, Vivek (2016): “How Egalitarian Is Indian Sociology?” *Economic & Political Weekly*, Vol 51, No 25, pp 33–39.
- Muller, Johann (2009): “Southern Theory: The Global Dynamics of Knowledge in Social Science,” *Globalisation, Societies and Education*, Vol 7, No 4, pp 505–09.
- Oommen, T K (2013): *Knowledge and Society: Situating Sociology and Social Anthropology*, New Delhi: Oxford University Press.
- Patel, Sujata (1997): “Challenges to Indian Sociology,” paper presented at All India Sociological Conference, Hyderabad, India, 23–25 November.
- (ed) (2011): *Doing Sociology in India: Genealogies, Locations, and Practices*, New Delhi: Oxford University Press.
- Sword, Helen (2012): *Stylish Academic Writing*, Cambridge: Harvard University Press.
- Zapp, Mike (2018): “The Scientization of the World Policy: International Organisations and the Production of Scientific Knowledge, 1950–2015,” *International Sociology*, Vol 33, No 1, pp 3–26.
- Zeitlin, Maurice and Alain Touraine (1971): “Review: The Coming Crisis of Western Sociology,” *American Journal of Sociology*, Alvin W Gouldner (ed), 77(2): 312–23.

Readings on the Economy, Polity and Society

Essays from the Economic and Political Weekly

NEW



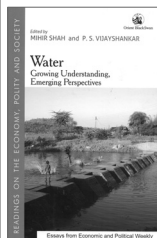
A Handbook of Rural India
Pp xvi + 472 | Rs 825
ISBN 978-93-5287-198-8
2018

A Handbook of Rural India

Edited by **SURINDER S JODHKA**

'Rural' and 'urban' are the foremost categories through which social life has been visualised and engaged with in modern and contemporary times. The idea of the 'rural' or the 'village' has been of particular significance in India. Gandhi advocated 'a return to the village' as the only genuine way to gaining swaraj, or self-rule.

This volume provides a historical perspective on the subject of the 'rural' and covers a wide range of topics that have been critical to the imaginings and empirics of village life in contemporary India.



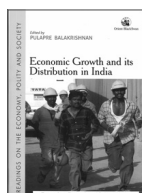
Water: Growing Understanding, Emerging Perspectives
Pp xiii + 559 | Rs 895
ISBN 978-81-250-6292-9
2016

Water: Growing Understanding, Emerging Perspectives

Edited by **MIHIR SHAH AND P S VIJAYSHANKAR**

For decades after independence, Indian planning ignored the need for sustainability and equity in water resource development and management. There was just one way forward, that of harnessing the bounty in our rivers and below the ground. It was only in the 1990s that serious questions began to be raised on our understanding and approach to rivers.

This collection of essays, reflecting the multi-dimensional, multi-disciplinary character of water, is arranged thematically and chronologically.

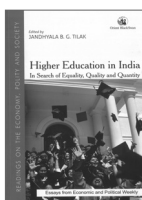


Economic Growth and its Distribution in India
Pp xvi + 497 | Rs 745
ISBN 978-81-250-5901-1
2015

Economic Growth and its Distribution in India

Edited by **PULAPRE BALAKRISHNAN**

India has witnessed a macroeconomic reversal, a slow-down in growth lasting a little longer than the boom preceding it. This volume represents a range of perspectives: a long view of growth, a macro view of recent history, a study of the economy covering agriculture, industry and services, and the inclusiveness of recent growth.

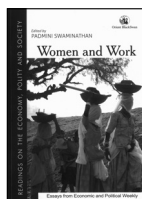


Higher Education in India
Pp xiv + 538 | Rs 745
ISBN 978-81-250-5131-2
2013

Higher Education in India

Edited by **JANDHYALA B G TILAK**

The story of higher education has seen many challenges over the decades, the most serious being a high degree of inequity. The articles in this volume discuss, issues of inclusiveness, impact of reservation, problems of mediocrity, shortage of funds, dwindling numbers of faculty, and unemployment of the educated young.



Women and Work
Pp xii + 394 | Rs 645
ISBN 978-81-250-4777-3
2012

Women and Work

Edited by **PADMINI SWAMINATHAN**

For women, the notion of work is a complex interplay of economic, cultural, social and personal factors. This volume analyses the concept of 'work', the economic contribution of women and gendering of work, while focusing on women engaged in varied work all over India.

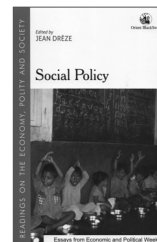
Social Policy

Edited by **JEAN DRÈZE**

The reach of social policy in India has expanded significantly in recent years. Reaching larger numbers of people than before, some benefits now take the form of enforceable legal entitlements.

Yet the performance of social programmes is far from ideal, with still a long way to go in directly addressing the interests, demands and rights of the unprivileged.

This collection of essays is clustered around six major themes: health, education, food security, employment guarantee, pensions and cash transfers, and inequality and social exclusion.

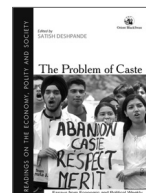


Social Policy
Pp xiv + 478 | Rs 795
ISBN 978-81-250-6284-4
2016

The Problem of Caste

Edited by **SATISH DESHPANDE**

The general perception about caste changed irrevocably in the 1990s post the Mandal Commission recommendations. This volume discusses established perspectives in relation to emergent concerns, disciplinary responses, the interplay between caste, class and politics, challenges in law and policy, emergent research areas, and post-Mandal innovations in caste studies.

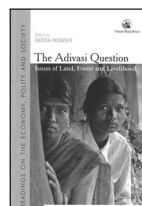


The Problem of Caste
Pp xi + 425 | Rs 595
ISBN 978-81-250-5501-3
2014

The Adivasi Question

Edited by **INDRA MUNSHI**

Depletion of forests has eroded the survival base of Adivasis, displacing them and leading to systematic alienation. This volume discusses questions of community rights and ownership, management of forests, the state's rehabilitation policies, and the Forest Rights Act.

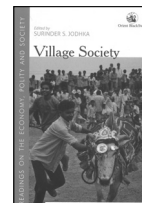


The Adivasi Question
Pp xi + 408 | Rs 695
ISBN 978-81-250-4716-2
2012

Environment, Technology and Development

Edited by **ROHAN D'SOUZA**

The concepts of environment, technology and development have shaped our understanding of the world. This volume presents articles across disciplines, perspectives and ideologies that map the main conceptual lines and identify where they converge and diverge.



Village Society
Pp x + 252 | Rs 325
ISBN 978-81-250-4603-5
2012

Mumbai • Chennai • New Delhi • Kolkata • Bengaluru • Bhubaneswar •
Ernakulam • Guwahati • Jaipur • Lucknow • Patna • Chandigarh • Hyderabad
Contact: info@orientblackswan.com

Orient Blackswan Pvt Ltd
www.orientblackswan.com

See discussions, stats, and author profiles for this publication at: <https://www.researchgate.net/publication/267929898>

Ethical issues in recruitment of "healthy volunteers": study of a clinical research organisation in Hyderabad

Article in *Indian Journal of Medical Ethics* · October 2014

DOI: 10.20529/IJME.2014.057 · Source: PubMed

CITATIONS

6

2 authors:



Shilpa Krishna

University of Hyderabad

2 PUBLICATIONS 7 CITATIONS

[SEE PROFILE](#)

READS

321



Purendra Prasad

University of Hyderabad

30 PUBLICATIONS 147 CITATIONS

[SEE PROFILE](#)

Ethical issues in recruitment of “healthy volunteers”: study of a clinical research organisation in Hyderabad.

SHILPA KRISHNA¹, N PURENDRA PRASAD²

¹Research scholar, Department of Sociology, University of Hyderabad, Gachibowli, Hyderabad 500 046 INDIA e-mail: sksocio@gmail.com ²Professor, Department of Sociology, University of Hyderabad, Gachibowli, Hyderabad, 500 046 INDIA Author for correspondence: purendra.prasad@gmail.com

Abstract

This paper raises some of the ethical issues involved in the recruitment of healthy volunteers (HVs) by clinical research organizations (CROs) for bioavailability and bioequivalent (BA/BE) studies. It also explores the underlying reasons for the participation of the HVs and their interaction with the CROs. The findings are based on the data collected from 50 HVs participating in a BA/BE study conducted by a CRO in Hyderabad and from the key officials involved in it. The findings indicate the existence of various complex networks, throw some light on the role of middlemen (“Anna”) and the negotiation process, and give us an insight into the social norms and values that compelled the HVs to participate in the study. The paper offers a critical analysis of a few ethical concerns.

Introduction

The rising cost of medicines has been one of the important factors that have contributed to the overall health expenditure across nations. Finding generic equivalents of brand name drugs has always been the strategy for reducing the cost of medicines. As a consequence, the number of bioavailability and bioequivalent (BA/BE) studies aimed at obtaining approval of generic equivalents of branded drugs is on the rise (1). HVs required for BA/BE studies are recruited by the clinical research organisations (CROs), but the regulatory mechanisms are quite inadequate. The Drugs Controller General of India (DCGI) is trying to make it mandatory for BA/BE studies to be registered with the Clinical Trial Registry of India (CTRI). However, this is yet to become a reality as the National Institute of Medical Statistics (NIMS) has expressed its inability to cope with the work pressure, given the fact that it does not have enough scientists or funding to launch the project (2).

CROs (also called contract research organisations) are an integral part of the overall biomedical economy and are usually private, for-profit service providers. Their sole purpose is to conduct trials for pharmaceutical companies. Kaushik Rajan (3) states that CROs are a major force to reckon with within the clinical trial industry. This, in fact, indirectly influences the regulatory framework in many ways, weakening it and creating scope for ethical violations. The present paper examines the intricate relationship between CROs and HVs, and also, the process of the recruitment of HVs.

Methodology

We carried out a case study of XYZ (a pseudonym for a CRO) to gain a deeper understanding of the factors underlying

the participation of HVs in trials. XYZ is a sister firm of a pharmaceutical company. Their therapeutic targets include AIDS, allergies, Alzheimer disease, arthritis, asthma, cancer, diabetes, pain, pediatric illnesses, reproductive health, stroke, and cardiovascular, dermatological, urological, orthopedic, respiratory and neurological problems. The infrastructure of XYZ and its facilities and level of hygiene are comparable to the high standards maintained in a corporate office. XYZ is engaged in facilitating clinical trials and conducts BA/BE studies. It has conducted over 200 BA/BE studies, as well as several phase II and III trials to date. This CRO is well equipped and can accommodate more than 500 volunteers. After an initial rapport-building session, eight key officials [vice president, manager of the clinical unit, three principal investigators, public relations officer, voluntary mobilisation team's [VMT] manager and coordinator] were interviewed in depth. A group discussion was held with 50 HVs (all men, who were residing in the CRO for 15 days) who were participating in a BA/BE study. In addition, we observed 40 volunteers (men who were observed but not interviewed) in the CRO premises who were participating in the informed consent form (ICF) session. The present research study was conducted over seven days during office hours.

The researchers submitted all the required documents, including the proposal to the CRO from time to time, explaining the purpose of the study. However, obtaining the CRO's permission proved to be a challenging task. It was only after five months of repeated requests to the CRO that we were finally permitted to conduct the study, that too, within a short period of time. Once permission had been granted, the researchers took great care to explain the purpose of the study and obtained an oral consent from the HVs. In order to protect confidentiality, the names of the respondents and the CRO have not been disclosed.

The recruitment process

The VMT mobilises and recruits HVs from different sources, such as shanty towns (*bastis*), NGOs, hostels, villages and colleges. The VMT's manager says:

Over a period, we have developed a network wherein we need not put in the same effort as before to procure the subjects [the term used by the scientific community for HVs]. We now have a list of subjects who would participate in BA/BE studies whenever intimation is sent as we have developed a good rapport.

Once the HVs have been recruited to participate in a study, they are counseled and screened, and the implications of the study are explained before their written consent is obtained on the ICF. After signing the ICF, the HVs are supposed to submit all their credentials, such as the birth certificate, voter ID and ration card. They must also undergo a complete health check-up, starting from basic blood and urine tests to an ECG and enzyme-linked immunosorbent assay (ELISA). This is necessary so that the CRO can confirm whether the potential volunteers are healthy or not. The volunteers are chosen on the basis of the inclusion and exclusion criteria of the study. A CRO screens considerably more people than are required for the study because not everyone who is screened will be deemed healthy enough to enrol himself/herself in the study. The HVs are paid an amount of Rs 200–500 for having themselves screened, according to the VMT coordinator. All HVs who are screened are paid regardless of whether or not they are selected. After the ICF session and screening, the HVs are selected for participation in the study.

Once the HVs are enrolled in a study, they are constantly under the medical gaze¹. The HVs are known by code numbers, and their names and details are kept confidential. The research coordinators document the study. Individual data is documented meticulously. Biostatisticians analyse the markers of the pharmaco-dynamics and kinetics of the drug and then submit their report.

Table 1			
Profile of the healthy volunteers (HV)s in the CRO			
S. No.	Occupation	No. of HVs	Education
1	Laboratory assistants in a pharmaceutical company	7	Diploma
2	School teachers	2	Graduation
3	Salespersons	4	Higher secondary
4	Security guards	5	Higher secondary
5	Painters, plumbers, masons, electricians, mechanics	15	Secondary
6	Tea stall owners	5	Primary
7	Housekeepers in hotels	6	Secondary
8	Gardeners in companies	4	Primary
9	Unemployed	2	Higher secondary
Total		50	

Healthy volunteers

A group discussion was held with 50 HVs. The age of the HVs participating in the BA/BE study ranged from 18 to 46 years. Of the 50 HVs, 64% had studied up to higher secondary level, 14% were diploma-holders (technical), 18% had completed only primary school and the remaining 4% were graduates. Their occupations were diverse. They included laboratory assistants, painters, plumbers, salespersons, electricians, field technicians, mechanics, security guards, helpers, tea stall

owners and housekeepers. Two were school teachers and two were unemployed. The group discussions with all 50 volunteers were held on the same day. All of them wore a uniform provided by the CRO. The day on which they were interviewed corresponded to the third day of the trial. Table 1 presents the profiles of the HVs.

The profile of the HVs indicates that all 50 participants belonged to the low-income group, mostly to the unorganised sector. One can see that their decision to become HVs was driven by several types of constraints, particularly financial. Initially, they gave the impression that they participated in the trials for the “larger good” of society. When probed further, they revealed that they had chosen to participate in the trials due to insufficient income and unstable jobs. They believed that they would receive better remuneration in the CROs. The remuneration is based on the risks involved and the number of days the HV stays in the CRO. One of the respondents, a laboratory assistant in a pharmaceutical company, said:

My job is based on a contract. The company pays me Rs 7000 per month, while the clinical research organization pays me around Rs 10,000, with all the other facilities.

None of the 50 HVs knew anything about the study in which they were participating. It was surprising that even the volunteers who were graduates did not remember any of the details of the trial (the name or purpose of the study). They only remembered that blood would be drawn from them, that they may develop rashes or a headache, and that they should report any other symptoms that crop up. They were quite confident that the doctors and the facilities available would suffice to deal with any health risk they might encounter in the course of the trial. Several HVs said that participating in these studies was like an alternative profession for them.

During the ICF session² it was noted that the volunteers were more concerned about the issue of payment than their health. The amount mentioned or agreed upon in the protocol document does not match the amount paid to the volunteers. While the ethics committee laid down that the HVs are paid Rs 2500, the VMT coordinators promised Rs 5000, but the HVs demanded Rs 10,000. It was finally negotiated that the HVs would be paid Rs 8200 for seven days, in addition to allowance for travel, accommodation and food. It was observed during the ICF session that there were good relations between the HVs and officials. This is one of the ways in which a CRO attempts to retain its pool of volunteers. If it maintains good relations with the HVs, the latter are more likely to be available whenever they are called for. The CROs have thus created a “reserve army” of HVs.

The group discussion revealed that the HVs participate in trials frequently. Table 2 shows the frequency of volunteering serially, and it can be seen that on an average, one HV has volunteered for at least five studies.

Table 2**Distribution of HVs by frequency of volunteering**

Number of HVs (%)		Frequency of volunteering
9	(18)	1
6	(12)	2
3	(6)	3
8	(16)	4
5	(10)	5
2	(4)	8
5	(10)	9
8	(16)	10
4	(8)	11
Total	50 (100)	Average number of times volunteered: 5.13

The table shows that the HVs have been participating in BA/BE studies repeatedly, subjecting themselves to trials "voluntarily". Except for the nine volunteers who were participating for the first time, the rest had participated more than once. The volunteers had also participated in the trials of other CROs in Hyderabad, Bangalore, Pune and Chennai. The data show that HVs participate in trial after trial so as to earn a living or supplement their meagre incomes. Just as the CROs establish networks to gather a pool of volunteers, the HVs establish their own networks to receive information about trials. They have colleagues or friends who share such information with them and sometimes, they also pool in volunteers themselves, making the CROs' job easier. An HV who was participating for the first time said:

I got to know about the trials through my friends. Initially, I was apprehensive, but after hearing that nothing happened to them, I also joined them.

With the help of the "network" they have formed among themselves, the volunteers have established themselves as potential participants and, therefore, they would be called when required for a trial, whether in Hyderabad, Bengaluru, Pune, or Chennai.

Another HV, who was participating for the eleventh time, said:

We get to know of the trials as all the CROs in Hyderabad, Bengaluru, Pune and Chennai have our contact numbers. They contact us when required. Or else we have a brother, "Anna"³, who would inform us and we would join.... "Anna" is the common friend of the CROs and us. The CROs contact him first and then he pools us together, while a few CROs call us directly.

"Anna" also negotiates between the HVs and the CRO, whenever the former file a complaint against the CRO in the police station for not making the due payment. The CRO has a public relations department which looks into complaints lodged by the volunteers. The VMT coordinator says:

The complaints are not filed as first information reports. They are resolved mutually between the parties and a bribe is paid to the local police.

The HVs revealed that they had lodged a complaint with a view to receiving higher remuneration from the CRO and that their intention was not to create any problems. The study respondents also said that they could not afford to fight with the CROs. However, the study respondents felt somewhat assured because the CROs fear the media and human rights organisations and hence, tend to accommodate some of their demands. One of the HVs, who was participating in a trial for the eighth time, said:

Sometimes we demand more money than what was agreed upon because a few of us developed severe rashes during the trials. When we questioned the officials as to why we were not informed, they did not have proper answers. So, we demanded more money. The CRO agreed to pay during the trial, but when the trial was over, they refused to pay, so we filed a complaint.

Ethical dilemmas and social values: some key issues

Recruitment: Although the ethics committee fixes the remuneration on the basis of the type of study, the commuting distance and other factors, HVs bargain for a higher amount than had initially been offered by the CRO. Subsequently, the CRO persuades the sponsor to pay the additional money, thus violating the ethical guidelines. According to the VMT coordinator, a volunteer earns anything between Rs 3000 and Rs 15,000, depending on the requirements of the study, and could take part in three trials a year. The coordinator said that even if the HVs participate in one study every three months, they earn money the rest of the year by participating in screening tests for other CROs.

According to the ethical guidelines for biomedical research (4), no volunteer can participate in more than one study every three months. However, the VMT coordinator revealed that there were instances of HVs offering their services several times, thus forcing the CROs to develop a bar coding system for the identification of the HVs' fingerprints. However, not all CROs have this system, which means that many HVs participate in more than the stipulated number of trials.

During the ICF session, it was observed that the HVs were concerned only about monetary incentives. There was no discussion on the effect of the drug on their health. There was a great deal of bargaining between the VMT and the HVs. The latter were issuing mild and subtle threats that they may not join or might quit if they were not paid higher incentives. In fact, there was an argument in which the HVs pointed out to the VMT that higher incentives were being offered in Bengaluru and Pune than in Hyderabad.

According to the protocol for BA/BE studies and the biomedical research guidelines (4), if the participants are illiterate, they should be accompanied by an impartial witness. For this, a separate registry, called the impartial registry, needs to be maintained. However, it was observed during the ICF session that the HVs who had agreed to participate were not accompanied by anybody.

Healthy volunteers: The HVs had already decided to give their consent to participation in the study prior to the ICF session and, therefore, the session appeared to be a mere formality. This was, in fact, confirmed during our discussion with the VMT manager, who indicated that most HVs decide to participate before visiting the study centers or even seeing the consent forms. The role played by “Anna”, who acts as a middleman/ intermediary or an agent for the CROs and HVs, gives rise to several ethical concerns. He is paid a commission by the CROs to help form a pool of HVs. The activities of these external parties must be taken into account by the regulatory authorities.

Another important issue is that of the ethical dilemma faced by the HVs. Except for the two school teachers, none of the others had informed their family members that they were participating in the study. The study respondents said that if they had told their family members, they would not have agreed and their kin and kith would have looked down on them. One of the HVs said:

Donating blood enhances our prestige, whereas if we subject our body to trials, people consider us very cheap and greedy, and they would look down on us and treat us as outcast. People would say that we are selling our bodies like prostitutes for the sake of making money.

These are the social norms which volunteers have to struggle against and this gives rise to certain ethical dilemmas. HVs resolve these dilemmas by subjecting their bodies to clinical trials clandestinely, keeping their participation a secret from their family or community members. On the one hand, they feel empowered by the fact that they have been able to make a “rational choice”, i.e. participating in a study to supplement the family's income. On the other, they are “disempowered” or constrained by “social norms”, according to which some of their choices are valued negatively and also stigmatised in Indian society.

Discussion

The data on poverty across the country indicate that about 836 million people live on less than Rs 20 a day (5). Poverty compels many to enrol in clinical trials as a way to make a living. The majority of the workforce is in the unorganised sector and it is sheer monetary compulsions that force them to participate in these studies. It is this context which leads HVs to provide consent even before the ICF sessions. The ICF sessions are just a routine matter for the HVs, whose participation in these sessions is passive. The sole point of interest for them is negotiating the remuneration for their participation. Adriana Petryna remarks that the phenomenal growth in global pharmaceutical sales and the quest for innovation are driving an unprecedented search for human volunteers, particularly in middle- and low-income countries. Medical progress increasingly depends on the willingness of the world's poor to participate in clinical drug trials (6).

Fisher points out that the neo-liberal state and its decreased commitment to health, education, employment and wages

have pushed people to the margins. Experimental trials are perceived of as “choices” and “opportunities” rather than exploitation or dependency, though one may say that the pharmaceutical industry makes enormous profits from the existing social and economic inequalities (7). As far as the concept of medical neo-liberalism goes, HVs are consumers in the context of capital-intensive scientific experimental trials.

The role of the state, particularly its regulatory leniency with the medical industry, has made it possible for clinical trials to draw heavily on the less educated, less skilled and marginalised class and caste groups. The irony is that the systematic use of economically disenfranchised people like HVs in pharmaceutical clinical development is not seen as being exploitative, but is instead presented as an opportunity for the members of these groups (7). This framework tries to provide an explanation about the ethical dilemmas individuals face in the current neo-liberal capitalist phase.

It is important to have an efficient regulatory mechanism to overcome these ethical issues. Though the 59th report of the Standing Committee on Health and Family Welfare (8) on the functioning of the Central Drugs Standard Control Organisation (CDSCO) recommends certain measures to do away with various violations, it does not address the root cause of the problem. Regulation of the recruitment procedures of volunteers should also be considered. Provisions should be made for auditing ongoing trials rather than merely examining the documents.

Acknowledgements: We thank the anonymous reviewer whose comments and suggestions have helped us revise this paper thoroughly. We also thank the participants of the 4th National Bioethics Conference held at the University of Hyderabad from December 5–6, 2012 for their critical comments and suggestions on the paper presentation.

Notes

- 1 Michel Foucault, a French philosopher, coined the term “medical gaze” to indicate the medical separation of the body from the person/identity. For more details, see Michel Foucault's *The Birth of the Clinic: An Archaeology of Medical Perception*, 1973.
- 2 The volunteers participating in the ICF session were different from the 50 who were already participating in the study. This analysis is based on the HVs' conversation with the VMT members during the ICF session.
- 3 “Anna” is the Telugu word for elder brother. In south India, particularly Andhra Pradesh, this word is used to refer to any adult male held in respect, whether or not he is a blood relation.

References

1. Mastan S, Thirunagari BL, Sathe A. The basic regulatory considerations and prospects for conducting bioavailability/bioequivalence (BA/BE) studies – an overview. *Comparative Effectiveness Research*. 2011 Mar 21 [cited 2014 Sep 2];1:1–25. Available from: <http://share.pdfonline.com/fc6d211610ab42eb9705e96dff4899d2/regulatory%20requirement%20for%20bioavailability%20study.pdf>
2. Shankar R. Registration of BA/BE studies may not become mandatory now due to staff shortage in NIMS [Clinical Trials][Internet]. *Pharmabiz.com*. 2012 Jun 18 [cited 2014 Sep 2]. Available from: <http://pharmabiz.com/NewsDetails.aspx?aid=69603&sid=1>
3. Rajan K.S. Experimental values: Indian clinical trials and surplus health. *New Left Review*. 45. 2007 May–June: 67–88.
4. Indian Council of Medical Research (ICMR). Ethical guidelines for biomedical research on human participants [Internet]. New

- Delhi:ICMR;2006 [cited 2014 Sep 2]. Available from: http://icmr.nic.in/ethical_guidelines.pdf
5. National Commission for Enterprises in the Unorganised Sector. Report on conditions of work and promotion of livelihoods in the unorganised sector. New Delhi: NCEUS; 2007 [cited 2014 Sep 2]. Available from: http://www.prsindia.org/uploads/media/Unorganised%20Sector/bill150_20071123150_Condition_of_workers_sep_2007.pdf
 6. Petryna A. When experiments travel: clinical trials and the global search for human subjects. New Jersey: Princeton University Press; 2009: 272 pp.
 7. Fisher JA. Coming soon to a Physician Near You: Medical Neoliberalism and Pharmaceutical Clinical Trials [Internet]. *Harvard Health Policy Rev.* 2007 Spring [cited 2014 Sep 2];8(1):61–70. Available from: <http://www.jillfisher.net/papers/hhpr.pdf>
 8. Department-related Parliamentary Standing Committee on Health and Family Welfare, Government of India. Fifty-ninth report on the functioning of the Central Drugs Standard Control Organisation (CDSCO). New Delhi; Rajya Sabha Secretariat, Parliament of India; 2012 May [cited 2014 Sep 2]. Available from: <http://164.100.47.5/newcommittee/reports/englishcommittees/committee%20on%20health%20and%20family%20welfare/59.pdf>

Health equity for internal migrant labourers in India: an ethical perspective

AJOKE BASIRAT AKINOLA¹, ANIL KUMAR INDIRA KRISHNA², SATISH KUMAR CHETLAPALLI³

¹Research Scholar, ²Associate Professor, ³Dean, School of Public Health, SRM University, Kancheepuram District, Tamil Nadu INDIA Author for correspondence: Ajoke Basirat Akinola e-mail: publichealth2010@hotmail.com

Abstract

In the developing countries, internal migration is a survival strategy for many labourers in search of a better livelihood and opportunities. It is inevitable that many of them will leave their home towns and villages in the coming years, and that the future will see an increase in the number of migrant labourers in developing countries such as India. Migrant workers face unique health problems and it is important for the health system to prepare itself to face these. In this context, the system will need to address certain key ethical issues. There is plenty of published literature on international migration and its ethical aspects. However, there is a scarcity of information on ethical issues relating to internal migration. This article examines these issues in the context of India. It addresses the issues of equity, non-discrimination, the provision of culturally competent care to migrants, allocation of scarce resources, and achieving a balance between benefits and risks for migrants. Our analysis should be considered while planning any healthcare intervention for internal migrant workers in all developing countries.

Introduction

Situation of internal migrant labourers in India

Historically and culturally, internal migration as a coping strategy for earning a livelihood has been a pronounced trend in the entire world. There is ample evidence of both voluntary and forced migration, which may result from cultural and religious persecution, natural disasters, developmental projects such as dams, a failed monsoon and the consequent famine, and the search for better livelihood options (1). Poverty and indebtedness are the most important factors that lead to migration. Workers migrating within a country usually move from less developed regions to more developed ones. In India, there are significant inequities in the development of the various states, with states such as Kerala, Tamil Nadu, Gujarat and Maharashtra having attained a higher level of development than Uttar Pradesh, Bihar, Jharkhand and

Chhattisgarh (2). Thus people move from the underdeveloped to the developed states. The total number of migrants as per the census of 1971 was 167 million. This rose to 213 million in 1981, 232 million in 1991 and 315 million in 2001. The figure was revised to about 400 million in 2004-5 (3).

Some scholars argue that the actual number has been grossly underestimated. They claim that the census and National Sample Surveys do not capture short-term migration, rural-rural migration, and women's migration for non-marital reasons and trafficking, all of which contribute significantly to migration (4). The insufficiency of data on internal migration is typical of most developing countries and does not allow one to appreciate the true magnitude of the issue. Migrant labourers, who account for roughly one-third of India's population, form a special group as far as the delivery of healthcare is concerned. Internal migrants the world over remain on the fringes of society. They work long hours, are paid low wages and work in unsafe environments, besides the other ills of social isolation and poor access to basic services, such as education, water, sanitation and health (5). This paper focuses mainly on unskilled and semi-skilled migrant labourers who migrate from low-income states to higher-income states in India.

Social determinants of health among migrant labourers

As mentioned in the introductory paragraph, the main reasons for internal migration in India are poverty and indebtedness. Labourers migrate from the underdeveloped states to the more developed ones to find work to fight poverty and indebtedness. Poverty is a universal determinant of health among most migrant workers, strongly influencing their health status. It is associated with malnutrition, a poor overall health status, poor access to preventive and curative health services, and higher mortality and morbidity rates (5). This determinant remains unchanged despite the migrant workers' relocation to greener pastures. Sometimes, the reason for migration



CERTIFICATE

This is to certify that

Ms. Shilpa Krishna,

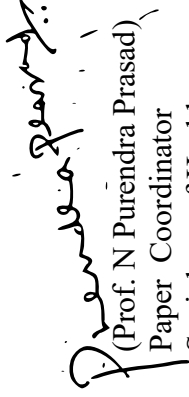
Research Scholar at the University of Hyderabad has contributed

Module No 16: Issues of Accessibility and Affordability to Medicines in India

For the Paper entitled **Sociology of Health (08)** of Sociology as part of UGC
“e-PG Pathshala: e-Content Creation for Postgraduate Students”.

Place: University of Hyderabad

Date: 18 December 2016


(Prof. N Purendra Prasad)
Paper Coordinator
Sociology of Health
UGC- e-PG Pathshala



(Prof. Sujata Patel)
Subject Coordinator
Sociology
UGC- e-PG Pathshala



CERTIFICATE

This is to certify that

Ms. Shilpa Krishna,

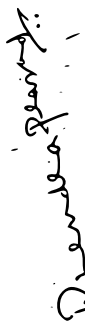
Research Scholar at the University of Hyderabad has contributed

Module No 17: Drugs and Patents

For the Paper entitled **Sociology of Health (08)** of Sociology as part of UGC
“e-PG Pathshala: e-Content Creation for Postgraduate Students”.

Place: University of Hyderabad

Date: 18 December 2016


(Prof. N Purendra Prasad)
Paper Coordinator
Sociology of Health
UGC- e-PG Pathshala



(Prof. Sujata Patel)
Subject Coordinator
Sociology
UGC- e-PG Pathshala



CERTIFICATE

This is to certify that

Ms. Shilpa Krishna,

Research Scholar at the University of Hyderabad has contributed

Module No 18: Irrational Use of Drugs and Unethical Practices

For the Paper entitled **Sociology of Health (08)** of Sociology as part of UGC
“e-PG Pathshala: e-Content Creation for Postgraduate Students”.

Place: University of Hyderabad

Date: 18 December 2016


(Prof. N Purendra Prasad)
Paper Coordinator
Sociology of Health
UGC- e-PG Pathshala



(Prof. Sujata Patel)
Subject Coordinator
Sociology
UGC- e-PG Pathshala



CERTIFICATE

This is to certify that

Ms. Shilpa Krishna,

Research Scholar at the University of Hyderabad has contributed

Module No 19: Medicalisation and Pharmaceuticalization

For the Paper entitled **Sociology of Health (08)** of Sociology as part of UGC
“e-PG Pathshala: e-Content Creation for Postgraduate Students”.

Place: University of Hyderabad

Date: 18 December 2016


(Prof. N Purendra Prasad)
Paper Coordinator
Sociology of Health
UGC- e-PG Pathshala



(Prof. Sujata Patel)
Subject Coordinator
Sociology
UGC- e-PG Pathshala



CERTIFICATE

This is to certify that

Ms. Shilpa Krishna,

Research Scholar at the University of Hyderabad has contributed

Module No 21: Clinical Trails and Ethical Issues in India

For the Paper entitled **Sociology of Health (08)** of Sociology as part of UGC
“e-PG Pathshala: e-Content Creation for Postgraduate Students”.

Place: University of Hyderabad

Date: 18 December 2016

(Prof. N Purendra Prasad)
Paper Coordinator
Sociology of Health
UGC- e-PG Pathshala

(Prof. Sujata Patel)
Subject Coordinator
Sociology
UGC- e-PG Pathshala

INDIAN JOURNAL OF MEDICAL ETHICS
FOURTH NATIONAL BIOETHICS CONFERENCE (NBC 4)
6-8 DECEMBER 2012

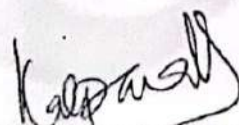
*This is to certify that SHILPA KRISHNA
is a student participant/ Participant/ Paper presenter/Plenary speaker/ Volunteer
at the Fourth National Bioethics Conference on the Theme
“Ethical and regulatory challenges in health research”,
from 6-8 December 2012 organised at, University of Hyderabad, Hyderabad*

INDIAN JOURNAL OF
MEDICAL ETHICS



Council for Social Development
Southern Regional Centre, Hyderabad




Conference Coordinator

Indian Journal of Medical Ethics

Sixth National Bioethics Conference (NBC 6)

13-15 January 2017

This is to certify that SHILPA KRISHNA.....has
participated/presented

at the Sixth National Bioethics Conference on the theme
"Healing and Dying with Dignity: Ethical issues in Palliative care,
End-of-life care and Euthanasia"

from January 13 to 15, 2017

organised at the campus of YASHADA, Pune.



S. Bandewar
Sunita Bandewar

Sanjay Nagral
Sanjay Nagral

RCAwasthi
Ramesh Awasthi
Conference Organising Committee

L. Chaudhuri
Leni Chaudhuri

Hemlata Pisal
Hemlata Pisal

International Conference on Health and Air Pollution : Effects and Management 7-8 September 2018



Science & Engineering Research Board



Directorate General of Health Services
Govt. of NCT of Delhi



ORGANIZED BY :



IDC Foundation
अंतराष्ट्रीय विकास केंद्र संस्थान
ISO 9001:2015 Certified

International Development Centre Foundation

Certificate Of Participation

This is to certify that Prof./Dr./Mr./Ms. SHILPA KRISHNA, UNIVERSITY OF HYDERABAD
has participated as Chairperson | Speaker | Rapporteur | Delegate in the International Conference on Health and Air Pollution : Effects and Management (ICOHAP-EM-2018)
at India International Centre, New Delhi and presented a paper/submitted/oral/poster entitled POLLUTION AND ITS IMPACT- A CASE STUDY IN HYDERBAD

Rav S.

Dr Ravinder Singh
Sr Scientist, ICMR, New Delhi.
Chairman Organising Committee, IDC Foundation



S. Suresh Chand Tyagi

Prof. Suresh Chand Tyagi.
DR Opt. MSc. MTech.
BETE, MBES, MCSI, MISTE.
Executive Director, IDC Foundation
Science Convener

Pharmaceuticals, State and Local Communities: A Study of Health Inequalities in Hyderabad

by Shilpa Krishna



Librarian
Indira Gandhi Memorial Library
UNIVERSITY OF HYDERABAD
Central University P.O.
HYDERABAD-500 046.

Submission date: 05-Feb-2024 03:10PM (UTC+0530)

Submission ID: 2286836374

File name: shilpa_full_thesis_without_footnotes_and_bibliography_5.2.24.pdf (1.91M)

Word count: 58890

Character count: 365677

Pharmaceuticals, State and Local Communities: A Study of Health Inequalities in Hyderabad

ORIGINALITY REPORT

7%

SIMILARITY INDEX

5%

INTERNET SOURCES

4%

PUBLICATIONS

1%

STUDENT PAPERS

PRIMARY SOURCES

1

www.nordea.com

Internet Source

2%

2

ris.org.in

Internet Source

1%

3

Ricardo Camargo, Nicolás Ried. "Towards a genealogy of pharmacological practice", Medicine, Health Care and Philosophy, 2015

Publication

<1%

4

wrap.warwick.ac.uk

Internet Source

<1%

5

Lara Gautier, Pierre-Marie David. "'Health for all' and the challenges for pharmaceutical policies: A critical interpretive synthesis over 40 years", Social Sciences & Humanities Open, 2022

Publication

<1%

6

ebin.pub

Internet Source

<1%

7

www.ncbi.nlm.nih.gov

<1 %

8

Anita Hardon, Emilia Sanabria. "Fluid Drugs: Revisiting the Anthropology of Pharmaceuticals", Annual Review of Anthropology, 2017

Publication

<1 %

9

Matthew Sparke, Edwina Malmberg, Ted Malpass. "Bio-pharma hub development in global production networks: contrasting state policies and conjunctural value strategies", Area Development and Policy, 2023

Publication

<1 %

10

Tankut Atuk. "Pathopolitics: Pathologies and Biopolitics of PrEP", Frontiers in Sociology, 2020

Publication

<1 %

11

changingmarkets.org

Internet Source

<1 %

12

www.science.gov

Internet Source

<1 %

13

monthlyreview.org

Internet Source

<1 %

14

"Universalising Healthcare in India", Springer Science and Business Media LLC, 2021

Publication

<1 %

15 Kaushik Sunder Rajan. "Pharmocracy", Walter de Gruyter GmbH, 2017 <1 %
Publication

16 www.spiked-online.com <1 %
Internet Source

17 "Multinational Corporations from Emerging Markets", Springer Science and Business Media LLC, 2014 <1 %
Publication

18 archived.greentribunal.gov.in <1 %
Internet Source

19 www.orfonline.org <1 %
Internet Source

20 epdf.pub <1 %
Internet Source

21 www.coursehero.com <1 %
Internet Source

22 "Global Pharmaceuticals", Walter de Gruyter GmbH, 2006 <1 %
Publication

23 www.news18.com <1 %
Internet Source

24 Submitted to Instituto de Empress S.L. <1 %
Student Paper

link.springer.com

25	Internet Source	<1 %
26	vdoc.pub Internet Source	<1 %
27	www.unboundmedicine.com Internet Source	<1 %
28	Susan K. Sell, Owain D. Williams. "Health under capitalism: a global political economy of structural pathogenesis", Review of International Political Economy, 2019 Publication	<1 %
29	dokumen.pub Internet Source	<1 %
30	doczz.net Internet Source	<1 %
31	Ajay Bhaskarabhatla. "Regulating Pharmaceutical Prices in India", Springer Science and Business Media LLC, 2018 Publication	<1 %
32	gsmi-ijgb.com Internet Source	<1 %
33	Submitted to Teerthanker Mahaveer University Student Paper	<1 %
34	vidhilegalpolicy.in Internet Source	<1 %

35	mohfw.gov.in Internet Source	<1 %
36	www.jmedsoc.org Internet Source	<1 %
37	www.sebi.gov.in Internet Source	<1 %
38	pure.bond.edu.au Internet Source	<1 %
39	Submitted to Heriot-Watt University Student Paper	<1 %
40	Walshe, Kieran, Smith, Judith. "Healthcare Management", Healthcare Management, 2011 Publication	<1 %
41	fdocuments.in Internet Source	<1 %
42	www.medrxiv.org Internet Source	<1 %
43	www.nishithdesai.com Internet Source	<1 %
44	Submitted to British College of Applied Studies Student Paper	<1 %
45	Submitted to Queen Mary and Westfield College	<1 %

46

www.biodiritto.org

Internet Source

<1 %

47

Peckham, Stephen, Meerabeau, Elizabeth.
"Social Policy for Nurses and the Helping
Professions", Social Policy for Nurses and the
Helping Professions, 2007

Publication

<1 %

48

timesofindia.indiatimes.com

Internet Source

<1 %

49

Submitted to Brunel University

Student Paper

<1 %

50

Submitted to London School of Economics
and Political Science

Student Paper

<1 %

51

Submitted to University of Hong Kong

Student Paper

<1 %

52

Submitted to University of South Australia

Student Paper

<1 %

53

academic.oup.com

Internet Source

<1 %

54

www.benthamscience.com

Internet Source

<1 %

Exclude quotes On

Exclude bibliography On

Exclude matches

< 14 words