# THE BODY COMMODIFIED AS NATURE: CAPITALISM AND THE BIOTECHNOLOGICAL TURN

by

Micah A. Pyles

B.A., Valdosta State University, 2014

A thesis submitted to the

Faculty of the Graduate School of the

University of Colorado in partial fulfillment

of the requirement for the degree of

Doctor of Philosophy

Department of Sociology

2022

Committee Members:

Liam Downey

Don Grant

Mathieu H. Desan

Jill L. Harrison

David N. Pellow

## ABSTRACT

Micah A. Pyles (Ph.D., Department of Sociology)

The Body Commodified as Nature: Capitalism and the Biotechnological Turn

Thesis directed by Associate Professor Liam Downey

Recent decades have seen rapid technological innovation and development in the life science industries, which have facilitated the increasing exploitation of human biological materials, information, and in-vivo processes as sources of commodifiable value. These developments have, in turn, spurred a new body of social science research in which the commercial, legal-ethical, and property rights implications of bodily commodification are intensely analyzed and debated. Within this literature, "bioeconomy" scholars argue that experimental subjects, and others from whom biological value is extracted, should be understood to engage in a novel form of "embodied," "regenerative," or "clinical" labor, with those who perform this labor constituting "an extensive yet unacknowledged labor force."

This dissertation departs from the above line of thought by investigating how new biopharmaceutical and biotechnological advances are radically transforming the long-understood role of human bodies in economic production. More specifically, this study problematizes the concept of embodied, regenerative, and clinical labor, drawing attention to the various ways in which human bodies are now actively incorporated as key *sites* and *resources* in the production of human-derived biocommodities. In this context, it establishes that the bodies of human test subjects, and others from whom in-vivo biological value is extracted, cannot be understood to engage in any meaningful form of self- or object-directed labor, but rather constitute the very objects upon which others' exploited labor is enacted – a fact that transforms the human body

from a source of value creation via its status as labor to a source of value creation via its status as nature.

Upon establishing the importance of this historically unprecedented shift, this study advances a theoretical reconceptualization of the human body as natural capital. To demonstrate the validity and significance of this reconceptualization, it presents an extended case study analysis of the U.S. biopharmaceutical industry, its mass medicalization of U.S. society, and the increasingly normalized practice of clinical trial outsourcing to less developed nations. The findings of this research suggest that within the biopharmaceutical industry, humans are increasingly being used as natural capital and that this form of bodily utilization is highly disproportionate to structurally disadvantaged populations around the world.

## ACKNOWLEDGEMENTS

I would like to express my deep gratitude to the many people who contributed to the completion of this dissertation. First and foremost, I would like to thank Lauren Powers, whose love, support, and unrivaled laughter has served as a constant source of inspiration and sanctuary during the completion of this project. I would also like to thank Andrea Tilstra, Ade Modile, Joshua Goode, Bertha Bermudez, and Derek Lee, whose collective friendship and shared experiences have been of great comfort over the last several years. I would furthermore like to thank Grant and Jenn Boerhave, who started off as friends, became roommates, and who I now consider to be family. I could not have done this without their love, support, late night conversations, and "Disney dancing" throughout the years. I can only hope to one day repay all the kindness they have shown me, for which I will always be grateful.

The intellectual work presented in this dissertation reflects contributions made by each of the members of my committee, including Liam Downey, Jill Harrison, Don Grant, Mathieu Desan, and David Pellow. I am extremely thankful to each committee member for their willingness to share their time, advice, and insights. I also owe a debt of gratitude to Carl Hand, Dana Williams, and Suzanne Slusser, all of whom are passionate and dedicated professors who introduced me to the field of sociology and encouraged me to pursue this goal. Together, these individuals have taught me so much and I am certain will continue to do so in the future. Finally, I would like to specifically acknowledge Liam Downey. When I look back at my work, it is more than clear how much it has improved due to his intellectual and professional mentorship. Beyond my academic pursuits, he has been a true friend, advisor, and father figure. I cannot express how grateful I am for all that he has done to support and encourage me. Thank you, Liam.

**CONTENTS**

## LIST OF TABLES

# Chapter 1

# INTRODUCTION

Recent years have seen a dramatic proliferation of industries and markets predicated on the commodification of human biological materials, information, and processes (Nahavandi 2016; Jafar 2009; Sunder Rajan 2006; Wilson 2004). The most prominent of these markets include the international organ and tissue trade, systems of transnational surrogacy, and numerous sectors of life science and biotechnological production. The rapid growth of these industries, and the unprecedented scientific advances that make them possible, has spurred a new body of social science research in which the legal, commercial, ethical, and property rights implications of bodily commodification are intensely analyzed and debated (Dickenson 2017; Kierans 2015; Prasad 2009; Petryna 2009; Sunder Rajan 2006). This research, however, largely neglects an additional set of implications that pertain directly to the labor process and to dominant theoretical understandings of what constitutes value, labor, and nature. For example, within this newly emerging literature, the bodily contributions of human research subjects, and others from whom biomaterials are extracted, are most commonly delineated as contributions made via a novel but largely unproblematized form of "experimental" "regenerative" or "clinical labor." Further, while processes of human-based bioproduction are understood to valorize the intellectual labor of scientific researchers, the full ramifications of exploiting researched bodies as *objects* of scientific labor remain largely unaddressed. Both positions, I argue, lead many body commodification scholars to overlook the various ways that human bodies are now actively exploited as key sites and resources in the production of human-derived biocommodities.

Thus, the above scholarship is correct to identify rapid technological innovation as the driving force behind new and historically unprecedented processes of bodily commodification, and to differentiate between the role of the researcher and the role of the researched in the creation of surplus biological value. However, it fails to account for the end implications of these processes as they relate to evolving systems of human-based bioproduction that compel human beings to enact labor on their own living species, thereby transforming the human body from a source of value creation via its status as labor to a source of value creation via its status as nature. These transformative implications are best illustrated with three examples drawn from the pharmaceutical industry, which I argue both rationalizes and exploits the human body as a unique form of natural capital.[1]

One of the most central components of pharmaceutical production is pharmacological research and development (R&D), and the most central component of pharmacological R&D is clinical trial experimentation. In fact, between 60% and 70% of the global pharmaceutical R&D budget is allocated to clinical trials, or $80 to $90 billion of the $130 billion spent annually (Berne Declaration Magazine 2013). Within the three primary phases of clinical trial research, synthetic and/or biologically derived compounds are introduced into the bodies of experimental test subjects. The body's molecular and cellular responses to these chemical interventions are then quantified and exploited as a source of commodifiable bio-data. These data, for example, are processed, refined, packaged, and sold as any other commodity in market exchange. Once commodified through this exchange, pharmaceutical firms deliver this highly valuable biodata to various regulatory agencies in order to demonstrate the efficacy and thus marketability of new

[1] Natural Capital is typically defined as the elements of nature that directly and indirectly produce value or benefits to people, including ecosystems, species, freshwater, land, minerals, the air and oceans, as well as natural processes and functions (The UK Natural Capital Committee).

drugs. The pharmaceutical industry is, therefore, entirely dependent on the production, sale, and transport of human-derived biodata as the initial and ultimate source of all revenue streams subsequent to regulatory approval. However, in order for the industry to derive these commodifiable bio-data, the body must be subjected to rigorous scientific scrutiny and is therefore acted upon as an object of labor performance. In this way, the body is transformed into a locale of production that is exploited, not as labor itself, but as the principal object upon which scientific labor is enacted. The human body is therefore analogous to an environmental resource from which the pharmaceutical industry extracts commodifiable value.

A similar example of bodily commodification can be found in the production of human therapeutic biologics, which unlike traditional medications are *not* derived through chemical synthesis, but through the manipulation of biological processes. In short, the production of biologic medications (i.e., complex proteins, nucleic acids or multiplex combinations of these materials) requires that specific human genes be isolated and extracted from human "donors" and then introduced into nonhuman host cells (U.S. FDA 2015; Trusheim 2010). Once spliced into the genetic structure of these cells, the human gene is instructed to coopt cellular production processes, thereby tricking the host cell to produce a desired biological *product* (Trusheim 2010; Marrow 2004). In this way, the production of biologic medications literally requires the extraction or harvesting of genetic material from the human body. The human body is, therefore, again exploited as the initial site of production – the location from which raw biological materials are extracted. These materials are then incorporated as a key resource in the production processes itself. Thus, the human body is commodified, not as labor, but as the primary *site* and *resource* upon which labor is enacted.

The body's status as natural capital is further illustrated via the practice of clinical trial offshoring – a production strategy now normalized within the pharmaceutical industry. The outsourcing of these trials is directly associated with the mass medicalization of U.S. society, which by overmedicating, and thus polluting, U.S. bodies has inadvertently rendered a growing proportion of U.S. citizens unfit for use in clinical trial research.[2] Put differently, treatment saturation (i.e., mass overmedication) has proven to reduce the body's ability to show drug efficacy due to complex drug-on-drug interactions that render test results less statistically reliable (Petryna 2005, 2009; Prasad 2009; Goldstein 2012). Thus, from a drug testing perspective, the industry has contaminated its own domestic resource pool via overconsumption of its products.

To circumvent this problem, the industry now outsources a growing percentage of its experimental trails to underdeveloped nations, which provide pharmaceutical firms with unfettered access to large populations of "treatment naïve," "virgin," or unpolluted bodies (Goldstein 2012; Prasad 2009; Petryna 2007; Shah 2006). Indeed, these populations are considered to be valuable assets in clinical trial testing precisely because their bodies lack exposure to any background medications that might interact and thus obscure test results (Petryna 2007; Goldstein 2012).

Treatment *saturated* populations are, therefore, analogous to stocks of natural capital that have been polluted, or contaminated, by the industry's own production activities. In contrast, treatment *naïve* populations are analogous to untapped and unpolluted stocks of natural capital, which pharmaceutical firms, like traditional industries in pursuit of ecological resources, aggressively seek out and exploit in the interest of economic gain. The outsourcing of clinical

[2] Sociologists use the term medicalization "…to describe the historical process through which conditions, complaints, normal variation, and socially undesirable traits are turned into medical conditions and interventions" (Dumit 2012: 66).

trial research is, therefore, not primarily due to labor constraints or spikes in production costs, though outsourcing certainly reduces such costs, but to the pollution of human bodies in the context of pharmacological research and development (Petryna 2009; Shah 2006).

These three examples suggest that within specific production contexts the human body is likely not commodified as labor, but as an ecological resource which, if true, raises several important questions regarding the body, the performance of labor, and the subsequent creation of value. For example, how and when are scholars to differentiate the human being as laborer from the human being as natural resource? Is such a distinction theoretically necessary or, as some might argue, does the "compensation" often paid out to experimental subjects – and to others from whom biological resources are extracted – relegate their "services" to the realm of labor performance? If such a distinction is necessary, then how are we to conceptualize and articulate the body's commodifiable properties? Do these properties constitute a new form of human *or* natural capital? In addition, we must ask what theoretical traditions have historically differentiated the human world from the natural world and whether or not new and/or expanding modes of bio-economic production call these traditions into question? The increasing significance of these questions seems clear. However, they remain largely unaddressed in the environmental sociology, sociology of labor, feminist, commodification, and bioeconomy literatures.

The goal of this dissertation is thus to answer these questions and in doing so, to fill several important theoretical and empirical gaps in these literatures. In addition, I hope to focus environmental sociologists' gaze on (i) the various ways that life science firms come to exploit and commodify the human body as natural capital and (ii) the substantive and theoretical implications of this exploitation and commodification. In doing this, I hope to set forth a novel

sociological perspective through which to analyze processes of bodily commodification, thereby bringing the human body under the analytical purview of environmental sociology. This dissertation therefore makes a unique contribution to environmental sociological scholarship, which has not explored the ecological commodification of human bodies in any decidedly comprehensive way. However, it also contributes to a small but growing body of literature that challenges social scientists in general to rethink society's relationship to the natural world and to reconsider the body's role within contemporary capitalism.

The importance of these theoretical and empirical tasks is clear given the bioeconomy's increasing prominence in the global economy[3] and the numerous ways in which it opens up human life to a molecular and cellular rescaling of economic production. Indeed, as rapid new scientific advances in the fields of biotechnology, biopharmaceutical, and biogenetic research continue, so too will opportunities for the human body to be seized upon and exploited by new modes of human-based bioproduction. It is therefore essential that social science scholars begin to grapple, both substantively and theoretically, with the various ways in which the human body is and will continue to be incorporated into newly emerging projects of capital accumulation.

This dissertation contributes to these new substantive and theoretical efforts by first demonstrating that new and/or expanding modes of bio-production increasingly transform the human body into an object of labor enactment and therefore into an ecological resource. Upon reconceptualizing the human body as natural capital, I then trace the developmental history of

[3] To provide support for this statement, one can look to the pharmaceutical industry, which is a leading sector in the broader bioeconomy. According to the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the global pharmaceutical market is projected to reach $1,485 billion in 2021, an increase of $350-$380 billion from the $1,105 billion recorded in 2016. In addition, and in the context of R&D spending, the pharmaceutical industry spends more than any other industrial sector. Compared with other high-technology industries, for instance, the industry's annual spending is "5.5 times greater than that of the aerospace and defense industries, 5 times more than that of the chemicals industry, and 1.8 times more than that of the software and computer services industry" (IFPMA 2017: 13).

the U.S. pharmaceutical industry, paying particular attention to how its approach to clinical trial research has evolved since the early 1970s. In doing this, I show that the pharmaceutical industry has experienced three ecologically unique crises of overaccumulation in which its access to experimental body supplies was blocked or otherwise severely inhibited. I further show how efforts to resolve these crises, culminated in a serious of spatial fixes that allowed the industry to incorporate previously unexploited, pharmacologically uncontaminated, populations into new rounds of pharmaceutical investment and production. Finally, I show how each of these spatial fixes have intensified the practice of clinical trial outsourcing to underdeveloped nations – a production strategy now common within the pharmaceutical industry.

In documenting the above history, I not only show how the pharmaceutical industry comes to exploit and commodify the human body as natural capital, but also how its use of bodies is analogous to traditional industries' use of environmental resources. That is, both the pharmaceutical and traditional industrial sectors exhibit an overwhelming tendency to deplete and/or contaminate the domestic resource bases that are necessitated by dominant modes of production. Upon exhausting these resources, both industry sectors exhibit a pattern of transnational expansion into less developed countries (LDCs), a process that has historically facilitated the acquisition of previously unexploited natural capital stocks and ergo the continuation of economically competitive production strategies.

Indeed, the global North's traditional industrial sector has long benefited from unequal ecological exchanges with the global South and, as a vast body of literature demonstrates, these unequal exchanges are most often facilitated by structural conditions that are imposed onto developing nations via the macroeconomic policies of specific international governing bodies (Downey 2015; Yu et al. 2014; Downey and Strife 2010; Bello 1999). This scholarship has

further established these unequal ecological exchanges as factors of central importance in understanding the economic might of Northern nations and how this might translates into the environmentally destructive lifestyles of developed nation's citizens (Schnaiberg 1980; Gould et al. 1995, 2004; Rice 2007; Bonds and Downey 2012; Jorgenson 2012; Downy 2015)

Following the above line of research, I correspondingly document the degree to which an unequal exchange of bodily (i.e., ecological) value is taking place between the global North and South via the practice of clinical trial outsourcing to LDCs and how this unequal exchange disproportionality benefits citizens of developed nations. I then examine the role that a leading set of international financial institutions (IFIs) play in creating the socio-economic and institutional conditions that allow pharmaceutical firms to exploit LDCs in this way. Finally, I explore the degree to which this novel system of exploitative outsourcing typifies broader strategies of human-based bioproduction and its increasing expansion into underdeveloped nations.

In addition to accomplishing these goals, I develop a set of predictions drawn primarily from leading sociological theories of the environment and human capital theory. I then test these predictions by presenting 3 case studies of the U.S. biopharmaceutical industry and its historical development since the early 1970s. Specifically, I argue that if pharmaceutical firms do in fact exploit the human body as natural capital, then the industry's developmental trajectory should follow a theoretically expected set of patterns. Testing these predictions and establishing empirical consistency or inconsistency with their expectations will therefore allow me to (i) better determine whether or not bioeconomic modes of production require the commodification of human bodies as nature and (ii) make a greater intellectual contribution to the environmental sociology literature.

**Overview of the Dissertation and the Logic of Case Selection**

In what follows, I provide a brief discussion of the cases. Before doing so, however, a few words on chapter 4, which I consider to be a situating chapter, rather than an empirical case study. In this chapter, I engage in a prolonged dialogue with Cooper's and Waldby's highly influential work, *Clinical Labor* (2014). In the context of this dialogue, I provide a definitional review of the terms "labor" and "bodily commodification." I then use and build upon these definitions in order to establish a working definition of the body's ecological commodification. Following this, I provide a brief overview of historical instances in which the body's reproductive and generative capacities have been incorporated into systems of economic production – showing, in each case, the differences and similarities in bodily utilization across time and frame of reference. This chapter further documents (i) the various phases of clinical trial research, (ii) the organizations and institutions involved in the execution of this research, (iii) the socio-demographic characteristics of U.S. research participants, and (iv) the nature of clinical trial research as it pertains to the exploitation of human biological material, information, and in vivo processes as sources of commodifiable value. In conjunction with the latter of these, I present data from a qualitative content analysis of a popular online information and discussion portal often used by members of the professional clinical test subject community.

The three case studies I undertake in this dissertation have been strategically selected to elucidate the various ways that human bodies are now incorporated into newly emerging modes of capital accumulation – ways that include but also go far beyond human's traditional and theoretically accepted role as producers and consumers in market exchange. The first of these cases examines the historical evolution of clinical trial experimentation within the U.S. itself. In

exploring this case, I use the work of David Harvey and James O'Connor, who provide two key theoretical frames I will use to determine (i) whether the pharmaceutical industry exploits the human body as natural capital or, as many might argue, as a mere form of experimental labor, (ii) whether or not the industry has experienced crises that are unique to processes of bodily commodification as natural capital, and (iii) whether or not these crises have been circumvented via the industry's use of spatial fixes, which allow for the incorporation of previously untapped body supplies as sources of commodifiable value.

The second case study I construct focuses on the practice of clinical trial outsourcing to underdeveloped nations and the multibillion-dollar contract research industry that has emerged in its wake. In exploring this case, I use ecological unequal exchange theory to determine the degree (if any) to which an uneven extraction of bodily (i.e., ecological) value is taking place between more and less developed nations. To do this, I (i) examine the production strategies of contract research organizations (CROs), (ii) investigate the various international agreements that – in the execution of outsourced experiments – standardize a profound degree of ethical variability between more and less developed nations, and (iii) highlight the actual mechanisms by which this ethical variability is exploited by the pharmaceutical industry. In addition – and to further adjudicate between processes of bodily commodification as labor and bodily commodification as natural capital – I conduct content analyses of the various ways that CROs market their body supplies to pharmaceutical firms.

My third and final case study examines a specific set of international financial institutions (IFIs), which include the World Bank and International Monetary Fund (IMF). It further examines the macroeconomic policies these institutions formulate and implement in developing nations, the effect of these policies on the underdevelopment of health and healthcare systems

within these nations, and how this underdevelopment allows the pharmaceutical industry to access and exploit new human-based environments abroad. In examining this case, I both utilize and build upon four leading sociological theories of the environment: The Treadmill of Production theory, Ecological Unequal Exchange theory, and James O'Conner's and David Harvey's theoretical articulations of the 1st and 2nd contradictions of capital.

While these cases, taken together, demonstrate the degree to which pharmaceutical firms exploit and commodify human bodies as nature, each case also demonstrates the utility of applying an ecological analysis to processes of human-based bioproduction. This dissertation, therefore, makes a unique contribution to both environmental sociology and the rapidly emerging bioeconomy literature. However, given the vast number of social science disciplines concerned with the socio-economic, legal, ethical, and cultural consequences of bioeconomic production, it also contributes to the broader commodification scholarship and to scholarship in feminist theory, international development, labor, indigenous, and cultural studies.

These contributions will be made evident in the following chapters. In Chapter Two, I present a review of the relevant literatures and more fully develop the theoretical models that will be applied and assessed throughout each of the three case studies. In Chapter Three, I describe my methods of data collection, case construction, and evaluation procedures. Chapter Four, as addressed above, is a situating chapter that engages with the work of Cooper and Waldby (2014) and provides a broad overview of the clinical research industry and its general functioning. The first half of Chapter Five presents the first of my case studies, which documents the nature of clinical trial research as it relates to the exploitation of human biological material, information, and processes as sources of commodifiable value. It then documents three distinct evolutionary phases of U.S.-based clinical trial research and how each of these phases was

engendered by the emergence and resolution of three ecologically unique crises of overaccumulation. The second half of Chapter Five is a case study on the practice of clinical trial outsourcing to undeveloped nations and how this practice allows pharmaceutical firms to capitalize on an unequal extraction of bodily value from populations in the periphery. This case will direct specific analytical attention at the advertisements and production strategies of contract research organizations (CROs).

Chapter Six provides an examination of the IFIs introduced above. The analysis of this case will be informed by two key questions: First, what role do the World Bank and IMF play in creating the institutional basis for exploiting LDCs via the mass outsourcing of pharmaceutical and biotech R&D projects? Second, to what degree does this novel system of outsourcing mirror historical pattens of traditional industrial offshoring and thus reflect observable similarities between conventional industry's dependence on LDC procured environmental value and the bioeconomy's increasing dependence on LDC procured bodily value? In answering these two questions, I further establish the extent and ways in which this exploitative system of outsourcing allows biopharmaceutical firms to overcome the ecological and resource-based limits they face via a displacement of market contradictions abroad.

The final chapter of this dissertation provides a discussion of my research findings and the implications of these findings for the relevant literatures and for the theorical models that are evaluated throughout each case study. The relevance of these findings will be further addressed in relation to capitalism's broader biotechnological turn and its many social, economic, and environmental consequences. Before proceeding to an extended examination of this turn and its consequences, however, a few words about the importance of the biopharmaceutical industry as a case, the reasoning for its selection, and the logic for analyzing it with an ecological lens.

I have chosen to focus analytical attention on the U.S. pharmaceutical industry for two primary reasons. First, it is the largest, best established, and most economically powerful sector of all life science and biotechnological fields (IFPMA 2017). Second, and as this dissertation will demonstrate, the production strategies unique to this industry shed important differentiating light on processes of bodily commodification as labor and bodily commodification as nature. Sociologist, therefore, have much to potentially gain from a case study analysis of the U.S. pharmaceutical industry. However, and despite these realities, the pharmaceutical sector remains the least utilized case for analyzing processes of bodily commodification.[4] For example, within the bioeconomy literature, far more attention is paid to the biotechnology sector (in its many capacities), organ and tissue trade, the egg and sperm industry, systems of transnational surrogacy, the transnational hair trade, genomic sequencing, biopiracy and bio-colonialism (Dickenson 2017; Nahavandi 2016; Kowal et al. 2013; Scheper-Hughes and Wacquant 2002). I have, therefore, elected to study the pharmaceutical industry because it (i) provides a relatively underexamined case, typified by less obvious but equally important instances of bodily commodification and (ii) has a much longer history than those of other life science sectors, which allows for a more in-depth and complete analysis of how, historically, the industry has (a) come to renationalize and exploit human bodies as commodifiable resources and (b) maintained access to the domestic and international body supplies upon which its reproduction depends.

With regard to analyzing this case with an ecological lens: In short, processes of bodily commodification, and their dramatic intensification under the life sciences, have generated an abundance of recent literature. In the social sciences, for example, debates over the body's

[4] This fact is likely attributable to the pharmaceutical industry's longstanding, culturally normalized, and outwardly beneficent function in U.S. society (Dumit 2012; Petryna 2009).

commodification have and continue to rage in economics, science and technology studies (STS), cultural studies, sociology, anthropology, and feminist scholarship. Indeed, these disciplines and the various analytical frameworks with which they approach the topic of bodily commodification, have done much to illuminate its historical, gendered, classist, and highly racialized nature. Within these literatures, however, a peculiar gap exists in that they are almost entirely devoid of an environmental/ecological analysis of bodily commodification processes. I, therefore, highlight the theoretical and substantive insights of environmental sociology because the existing bioeconomy literature is almost entirely devoid of environmental analyses of bodily commodification processes and because these insights provide a highly effective lens through which to analyze systems of human-based bioproduction.

# Chapter 2

## THEORETICAL FRAMEWORK AND LITERATURE REVIEW

Recent decades have seen leading segments of the global economy undergo a series of profound transformations consequent to rapid new technological innovation and development in the life science industries (Cooper 2008; Birch and Tyfield 2012). These new technological advances increasingly allow for a growing percentage of global economic production to be rescaled at the molecular and cellular levels of human life (Waldby 2002; Scheper-Hughes and Wacquant 2002; Rajan 2006; Rose 2007; Prasad 2009; Cooper and Waldby 2014). This point is made especially clear in the United States where the biopharmaceutical industry (independent from the life science industry as a whole) accounts for more than $1.3 trillion in U.S. economic output per annum, while also accounting for one-sixth of total R&D spending by all U.S. economic sectors – making it the single largest R&D investor in the United States (International Trade Administration 2018; PhRMA 2018). As a consequence of these burgeoning R&D investments, recent years have seen a literal opening up of life, both human and non-human, to the various exploits of capital – exploits that increasingly rely on human biological materials, information, and processes as sources of commodifiable value.

As a result of these developments, a new bioeconomy is now said to exist. For example, in 2006 the Organization for Economic Cooperation and Development (OECD) published a policy agenda that identifies the life science industries as constituting a new bioeconomy, which it defines as "…the aggregate set of economic operations in a society that use the latent value incumbent in biological products and processes to capture new growth and welfare benefits for

citizens and nations" (2006: 1). Similarly, the European Commission (EC) has been quick to recognize the inherent value potential of this newly emerging economy, although it provides a somewhat less clear definition: "The bio-economy is one of the oldest economic sectors known to humanity, and the life sciences and biotechnology are transforming it into one of the newest" (2005: 2).

In the wake of this newly emerging bioeconomy, a number of social science disciplines – including economics, science and technology studies (STS), cultural studies, indigenous studies, sociology, anthropology, and feminist scholarship – have begun debating the significance of bodily commodification. These debates have resulted in a plethora of recent publications that have greatly advanced our knowledge of both the commodification process itself and its overtly gendered, classist, and highly racialized nature.[5] This literature has examined when cycles of intensified commodification are likely to occur, which populations, bodies, and body parts are most likely to be commodified, and the legal, ethical, and socio-cultural consequences of bodily commodification. Key contributions to this literature come from scholarship in feminist theory, racial capitalism, and indigenous studies, scholarship that has firmly documented the various ways in which certain bodies have come to be understood as more closely associated with, or less removed from, the natural world (Vasudevan 2019; Pulido 2017; Clearly 2016; Moore 2015; Smith 2012; Grosz 1994; Galeano 1973). Because of this association, these scholars posit that it is female bodies (Dickinson 2017; Clearly 2016; Nahavandi 2016), indigenous bodies (Breske 2018; Whitt 2009; Hawthorne 2007), and bodies of color (Vasudevan 2019; Melamed 2015; Pellow 2007) that suffer disproportionate risk of bodily objectification, exploitation, and

[5] See, for example, Vasudevan 2019; Dickenson 2017; Nahavandi 2016; Kierans 2015; Cooper and Waldby 2014, Birch and Tyfield 2013; Guthman 2011; Wilson 2011; Jafar 2009; Petryna 2009, Prasad 2009; Cooper 2008; Helmreich 2008; Haraway 2007; Rose 2007; Rajan 2006; Healy 2006; Wilkinson 2003; Waldby 2002, 2000; Scheper-Hughes and Wacquant 2002; Dickens 2001

commodification. In addition to this scholarship, there is the particularly influential work of Michel Foucault, which has proven invaluable to scholars thinking through the relationality between bodies, power, and discourse (Chadwick 2018).

Given the longevity and relevance of these four literatures, I briefly consider each independently before proceeding to an overview of the broader bioeconomy scholarship to which they have so much contributed. I then turn to an overview of the environmental sociology literature which, like scholarship on the bioeconomy, is deeply influenced by Marxian political economy. Finally, because scholarship in both environmental sociology and the bioeconomy is so often informed by Marxian political economy and because at the core of Marxian political economy rests the labor theory of value, I also review the latter while drawing parallels between the labor theory of value and human capital theory (Birch and Tyfield 2012, Foster 2005; Steedman et al. 1981). In doing this, I highlight key gaps in both the environmental sociology and bioeconomy literatures, which ultimately block what would otherwise be a mutually advantageous integration of these literatures' research agendas.

### *Foucault, Power, and the Body*

Any review of scholarship pertaining to the human body would be remiss without addressing the Foucauldian reading of bodies and their relationship to power. According to Foucault, or at least Foucauldian poststructuralism, the body is best conceptualized as a social text that is inscribed and brought into existence via sociocultural practices, power relations, and normative discourses (Tremain 2010; Ojakangas 2005). Thus, according to Foucault, there is no historically contingent body or bodily materiality that is prediscursive – i.e., no body exists "before it speaks or is spoken about" (Tremain 2010: 561). Upon establishing this theoretical

perspective, Foucault attempts to delineate which sociocultural discourses most commonly inscribe the body and the relation of these discourses to a novel system governmental power that he argued permeates every facet of modern social life.

At the end of the 18th century, Foucault claims, human society saw the emergence of an entirely new form of governmental rationality that he termed "biopower" (Foucault 1978). According to Tremain (2010: 583), Foucault defined biopower as:

> the endeavor to rationalize (usually by "authorities" of some kind) the problems that the phenomena characteristic of a group of living human beings, when constituted as a population, pose to governmental practice: problems with respect to the birthrate of a population, its health and longevity, race, sanitation, and other conditions of its environment, and so on. Since the late eighteenth century, these problems have occupied an expanding place in the government of populations and individuals.

Put differently, the governmental rationality of biopower emerged as a byproduct of modern nation-state development, which saw an explosion of human populations and the subsequent need to steer and regulate these populations. In attempting to do this, nation states devised and implemented a multitude of diverse techniques and measures that would allow them to bring life and its mechanisms into the realm of explicit calculation and to achieve the subjugation of bodies and the control of ever-growing populations (Foucault 1976, 1979). Bodies, therefore, emerged as the principal object of biopower, which operates via systems of surveillance, discipline, categorization, and institutionalization (as well as through state-sponsored discourses that normalize these systems) to "inscribe" and produce "docile bodies" (Foucault 1979; Chadwick 2018). Thus, according to Foucault, bodies are the products of power relations that no longer (exclusively) represent systems of top-down domination, oppression, and coercion; rather, these relations of power are "capillary-like" (ubiquitous throughout the sociocultural matrix), often generative, and constitutive of selves, bodies, and citizens (Chadwick 2018).

When most productive, these relations of power become internalized as forms of self-discipline and self-policing, which result in the subject becoming "the principle of his own subjugation" (Foucault 1979: 203). This point is made clear when considering biopower's management of life via the modern medical system, which, according to Foucault, uses its centralized power to normalize and propagate expectations of public hygiene, fertility, and broader processes of medicalization that standardized the logic of health risks, guidelines, and recommendations by which populations regulate themselves (Tramain 2010; Ojakangas 2005).

In contemporary times, scholars of the bioeconomy assert that the advent and increasing visibility of new biotechnologies represents a profound deepening and extension of the bio-political project articulated by Foucault. That is, the practice of governance (biopower) that brought "life and its mechanisms into the realm of explicit calculations" is being transformed in that it is no longer just individuals and populations being rationalized, regulated, and surveilled but now also human cells, molecular processes, genomes, and genes (Foucault, 1978: 143; Helmreich 2008). In addition to this deepening of biopower's rationalizing gaze, Foucauldian oriented scholars of the bioeconomy posit that the use and normalization of new biotechnologies will likely alter the sociocultural norms and discourses by which people are inscribed and inscribe others. Put differently, if the body is best conceptualized as a social text that is inscribed and brought into existence via normative discourses of rationality and bodily control, then how will people view themselves and others when biotechnological interventions increasingly allow some bodies to be more easily rationalized and controlled than others? What new forms of personhood and citizenship will these novel interventions and systems of knowledge-power engender?

### *Racial Capitalism*

Similar to the Foucauldian emphasis on power and bodily inscription, scholars in the tradition of "racial capitalism" use the term "bodily inscription" to express how the social production of racial difference acts as the key structuring logic of capitalism, in both its historic and contemporary articulations. These scholars assert that capitalism, as an economic system, is fundamentally shaped by, dependent upon – and indeed, born of – racialized categories that denote an institutionalized hierarchy of humanity (Robinson 1983; Vasudevan 2019; Kelly 2017). This hierarchy is, in turn, critical to the accumulation of capital in that it allows capitalists to naturalize and therefore legitimize the very structural arrangements that facilitate the disproportionate exploitation and domination of certain racial groups by others (Pulido 2017; Vasudevan 2019; Pellow 2007). As noted by Melamed:

> Capital can only be capital when it is accumulating, and it can only accumulate by producing and moving through relations of severe inequality among human groups – capitalists with the means of production/workers without the means of subsistence, creditors/debtors, conquerors of land made property/the dispossessed and removed. These antinomies of accumulation require loss, disposability, and the unequal differentiation of human value, and racism enshrines the inequalities that capitalism requires (2015: 77).

Scholars of racial capitalism, therefore, underscore how the production of social and racial difference is integral to processes of accumulation and how these processes have historically relied on the devaluation of marginalized, nonwhite bodies – bodies that are then disproportionately incorporated into various forms of hazardous and exploitative economic production.

Researchers in this tradition have found ample evidence of capitalism's racial character in (i) U.S. manufacturing industries, which historically relied on Black, male laborers to withstand working conditions considered too harsh, dangerous or extreme for Whites (Vasudevan 2019), (ii) the disproportionate use of racially devalued bodies and communities as "sinks" for the

disposal of hazardous industrial waste and pollution (Kuzawa and Sweet 2009; Moore 2015; Pulido 2017; Vasudevan 2019), (iii) the transnational movement of toxic chemicals and bio hazardous materials from more-to-less developed countries – a practice that forces racially devalued nations to contend with the many negative externalities of Northern-based production strategies (Pellow 2007; Pellow and Brulle 2005; Faber 2008), and (iv) the rapid expansion of international contract surrogacy systems, transnational organ and tissue trade networks, and life science R&D outscoring from more-to-less developed nations. Indeed, the latter of these practices are understood to be highly reliant on the persistence of racialized poverty, social inequality, and thus the ready availability of racially devalued bodies and body parts for sale (Nahavandi 2016; Dickinson 2017; Wilkinson 2003).

***Feminist Scholarship***

In contrast to scholars of racial capitalism, scholars of feminist theory hold that the dominant tradition of Western intellectualism has produced an implicitly suspicious and gendered view of the body (as opposed to the mind) as being closer to nature via its status as a "source of unwieldy and base desires and functions" (Cleary 2016: 1). This suspicion and its association with femininity finds expression in the mind/body opposition so prevalent in the feminist literature. Within this dichotomy, the mind (either explicitly or implicitly) is rendered equivalent to that which is associated with masculinity (logic, reason, achievement, self-control, etc.), while the body is rendered equivalent to that which is associated with femininity (illogical, irrational, incapable male achievement, etc.) (Clearly 2016; Grosz 1994; Bordo 1993). Thus, according to feminist scholars, dominant Western philosophy has engendered what are now

culturally normalized and highly gendered assumptions of the female body. As stated by Grosz (1994: 14):

> Relying on essentialism, naturalism and biologism, misogynist thought confines women to the biological requirements of reproduction on the assumption that because of particular biological, physiological, and endocrinological transformations, women are somehow *more* biological, *more* corporeal, and *more* natural than men"

It follows that because female bodies are disproportionately associated and identified with the natural environment, they suffer from a disproportionate risk of being exploited and commodified via processes of human-based bioproduction (Hawthorne 2007; Nahavandi 2016; Pulido 2017). This point is made clear in recent feminist critiques of the life science industries. For example, in her seminal work, *Property in the Body*, Donna Dickenson (2017) documents how recent advances in biotechnology are rapidly transforming extracted human biomaterials into objects of research and commodification. These scientific advances, according to Dickenson, have led to widespread concern that human bodies are increasingly becoming more like objects and less like social subjects. Dickenson (2017: 8) refers to this concern as "a fear of the feminization of property in the body because it is a fear of becoming an object in ways that mirror how women's bodies have been objects of property-holding throughout history." Thus, according to Dickenson, the increasing visibility and knowledge of bodily commodification poses a significant threat to many (in particular males) because it reduces both sexes to the condition of objects. As an example of this "fear of bodily feminization," she cites the "*clinical labor*" that both males and females perform in the context of clinical trial research (Dickenson 2017: 9). However, for the reasons addressed above and because "female tissue and *labor* are generally far more valuable [than males]," Dickenson is quick to conclude that processes of bodily commodification remain highly disproportionate to female bodies (2017: 10).

### *Indigenous Studies and Biocolonialism*

Like scholars of racial capitalism, indigenous studies scholars underscore the historical function of racial ideology in the execution of colonialism – a project which, they assert, was facilitated via racial constructs of indigenous people as being less than fully human (Galeano 1973; Blackhawk 2008; Smith 2012; Dunbar-Ortiz 2014). In contemporary times, scholars of indigeneity use the term "biocolonialism" to denote a continuing form of dispossession and conquest that operates through an essentially new system of transnational corporate power (Breske 2018; Whitt 2009; Shiva 1999). This system, according to Breske (2018), was made possible via the hegemonic propagation of neoliberal economic policies in LDCs – policies that institutionalized a global regime of intellectual property rights, patent law, and various free trade agreements that are strictly enforced by international governing bodies such as the World Trade Organization (WTO).

A central component of systems of biocolonialism is the practice of bioprospecting or biopiracy in biologically diverse and/or genetically isolated regions of the world. Researchers in this tradition find that bioprospecting claims are made on two primary sources: (i) on the land and resources that are owned by indigenous and traditional peoples and (ii) on the actual bodies of women, indigenous, and genetically isolated populations (Hawthorne 2007; Breske 2018). In the latter case, researchers identify a number of ways that the bodies of indigenous people and people of color are disproportionately targeted and "colonized" by various forms of human-based bioproduction (Smith 2008). These ways include but are by no means limited to instances of indigenous genealogies and identities (e.g., cell lines) being stolen, copied and patented, the targeted farming of umbilical cord blood from aborted indigenous fetuses, and the appropriation

of indigenous brains, blood, and DNA as the intellectual property of transnational life science firms (Hawthorne 2007; Whitt 2009; Breske 2018). As observed by Anderson:

> Scientific objectification of the bodies of indigenous people has occurred for centuries, but generally any collected material has either gone out of circulation (often into museums) or become part of a scientific exchange regime. Now, however, governments and corporations – the new medical-industrial complex – can designate brains, blood, cells, and DNA as intellectual property, and having thus "immortalized" these body parts, they can trade them as commodities in a global market (2000: 735).

As noted by many other indigeneity scholars, bioprospecting practices are most often legitimized via Western scientific arguments for economic development and biological conservation (Smith 2008; Whitt 2009). Hawthorne notes, for example, that life science firms champion bioprospecting as a beneficial event for indigenous and racially marginalized communities since it can generate capital for social and family services in poverty-stricken regions (2007). However, researchers find sparse evidence that bioprospecting practices have actually delivered any such short or long term benefits to indigenous communities and provide ever-mounting evidence of corporate malfeasance and misuse of indigenous biospecimens (Kowal et al. 2013; Whitt 2009; Hawthorne 2007).

It is, therefore, clear that scholars in the traditions of racial capitalism, feminist theory, and indigenous studies share a common concern with regard to the human body and relations of power that leave some bodies more vulnerable to exploitation than others. As addressed above, all three literatures argue that capitalism, inequality, and oppression rely fundamentally on the historical production of social difference – whether based upon race, gender or indigeneity – which allows dominant social groups to define others as being closer to, or less removed from, the natural world. By way of this differencing and the subsequent ability to identify some people as closer to nature than others, dominant groups are able to naturalize and thus legitimize the relational systems of exploitation and oppression through which capitalism moves and expands.

Indeed, and as addressed below, capitalism's latest expansion has been into the very bodies of human beings, the subject matter to which I know turn.

### *The Bioeconomy*

Drawing from the theoretical and substantive insights of Marxism and the four previously addressed literatures, scholars of the bioeconomy turn their attention to processes of bodily commodification under the life science industries and how these processes increasingly open up human life to a molecular and cellular rescaling of economic production (Helmreich 2008; Birch and Tyfield 2012). Central to this scholarship are a number of theoretical and conceptual frames that articulate a variety of bioconcepts such as biovalue, genetic capital, the biotech mode of production, the organic phase of capitalism, genomic capital, life as surplus, the bioeconomy, and, perhaps most recognizable, biocapital (Helmreich 2008). The theoretical foundation of these various bioconcepts is overwhelmingly Marxian political economy, a fact that is made self-evident via their adoption of Marxist terminology (e.g., value becomes "biovalue", capital becomes "biocapital", surplus becomes "genomic surplus", surplus value becomes "surplus biovalue", etc.) However, and with few exceptions, the bioeconomy literature is also marked by a strong Foucauldian influence and is thus best understood as being Marxist-Foucauldian in orientation. (Helmreich 2008; Birch and Tyfield 2012).

Because this body of scholarship integrates these two distinct theoretical traditions, it is well adapted to both identifying and delineating two key sociological dimensions of the newly emerging bioeconomy. First, given its Marxist roots, this scholarship is resolutely committed to addressing the novel dynamics of exploitation and commodification that characterize the production and marketing of new life science biocommodities. For example, much of this

research analyzes how the life science industry has become increasingly commodified and coopted by speculative venture capital and how – in its search for genomic capital, biocapital, biovalue, etc. – the industry comes to rely on the disproportionate exploitation of structurally disadvantaged populations around the world (Waldby 2001; Rajan 2006; Rose 2007; Cooper 2008; Patryna 2009). Researchers in this area illustrate how the acquisition of biocapital is often associated with pre-existing colonial and neocolonial structures of subordination and how the legacy of this subordination has left underdeveloped nations, and their citizenry, as eager participants in outsourced pharmaceutical and biotech R&D projects – projects from which these nations and citizens garner little benefit (Scheper-Hughes and Wacquant 2002; Rajan 2006; Cooper 2008; Goldstein 2012). This research further delineates how the industry's increasing movement into non-traditional research areas – i.e. areas and/or nations with elevated rates of poverty, unemployment, and declining healthcare infrastructure – allows pharmaceutical and biotech firms to capitalize on lower production costs, looser ethical regulations in experimental research, and unfettered access to high quality body supplies from which a surplus of biovalue is extracted (Rajan 2006; Cooper 2008; Petryna 2007, 2009; Prasad 2009; Goldstein 2012). Thus, a central goal of this literature is to underscore how systems of inequality, exploitation, and oppression often undergird the industry's acquisition of human derived biovalue.

But despite these advances, a key theoretical oversight is observed in that the prevailing majority of these Marxist-oriented scholars problematically assume that human biological materials and processes constitute pre-existing and ready-made sources of surplus value and profit generation (Birch and Tyfield 2012; Helmreich 2008). This assumption, as noted by a number of recent scholarly critiques, results from these scholars' efforts to rework Marxian political-economic categories. According to Birch and Tyfield (2012), this task is being

undertaken in order to create a novel set of conceptual frames and terminologies with which to analyze the many newly emerging social and economic conditions that both produce and are produced by the bioeconomy (Birch and Tyfield 2012). In the process of reworking these terminologies, however, scholars of the bioeconomy tend to neglect these terms' original formulation in the labor theory of value, which – as addressed in full detail below – is a theory that emphasizes value creation as being based in labor and labor alone. This neglect, in turn, leads to a misrepresentation of biological materials and processes as constituting ready-made sources of surplus value and profit generation, which in turn, leads to a misrepresentation of the body's "natural" capacities and functions as constituting a novel form of "naturally" occurring labor. On this point, Palsson (2009: 307) asserts that:

> Clearly…cell lines, tissue cultures, and genomic databases do valuable work, but to see such work as "labor" seems to presuppose consciousness of a relationship to that which is being produced, given Marxian theory, which is hardly the case for biosocial assemblies of this kind.

The majority of bioeconomy scholars thus tend to conflate the biological functionality of organisms – be they human or non-human – with labor. To do this, however, is to identify the body's internal, biological functionality as a self-sustaining and self-regenerating factory that yields a surplus of biological value while failing to account for the active and exploited human scientific labor that is enacted on the body in order to have this value extracted (Birch and Tyfield 2012; Helmreich 2008). Put differently, and from a Marxian political-economic perspective, biological entities, materials, and in vivo processes can only become sources of surplus value and profit generation under specific labor relations – relations that are inherent to all modes of production. As stated by Birch and Tyfield (2012: 312):

> Commodities, be they "bio-commodities" (i.e., fragments of vitality) or normal commodities, are products of a labor process. Value is realized through market exchange, but it is constituted by production…and it is the (exploitable) capacities and capabilities

> of workers (as embodied labor power) that construct value rather than any latent characteristic of a biological product, commodity, or resource.

Thus, despite their Marxist orientation, scholars of the bioeconomy fail to recognize that the creation of human derived biovalue requires that human beings enact labor on their own living species and that this act fundamentally transforms the human body from a source of value creation via its status as labor to a source of value creation via its status as nature. It is my contention that this oversight represents a profoundly significant gap within the bioeconomy literature, one that this dissertation endeavors to address and fill.

The second, more prominent, and more Foucauldian-based commitment of the bioeconomy literature is to examining how – and the ways in which – newly produced biocommodities are creating novel sets of identities, socialities, and subjectivities within contemporary core nations. This point is made especially clear with regard to how innovative biotechnologies (e.g., genomic sequencing, immortalized cell lines, stem cells, genetic mapping, genetic testing, genetic profiling, biopharmaceuticals, etc.) are informing the construction of entirely novel forms of personhood, citizenship, race, and criminality within more developed countries (MDCs). In examining these transformative effects, scholars of the bioeconomy rely heavily on Foucault's concepts of biopower and biopolitics, ultimately calling for a "molecular reworking" of these concepts (Rajan 2006; Rose 2007; Helmreich 2008; Tremain 2010). This adaptation, they claim, will provide social science scholars with the appropriate theoretical lens through which to analyze the human body, contemporary social relations, and how the bioeconomy is reorganizing the elements and boundaries of both.

A key goal of the above scholarship is thus to understand how once naturalized relations between human beings, human identities, and social systems are being destabilized and reconstructed as people position themselves in relation to newly emerging biotech goods and

services (Waldby 2000, 2002; Rajan 2006; Rose 2007; Cooper 2008; Dickenson 2017) Scholars of the bioeconomy assert, therefore, that the life sciences have engendered a new "biotechnical trajectory" within global society – a trajectory that has and will continue to have profound implications for how human beings view themselves, each other, and the world in which they live (Waldby 2000, 2002; Scheper-Hughes and Wacquant 2002; Rajan 2006; Rose 2007; Cooper 2008; Petryna 2009). Here again, however, a key theoretical oversight is made in that only one transformative aspect of human-based bioproduction is being recognized and articulated.

Indeed, what is also new and increasingly relevant about life science production processes is not just how biocommodities come to reconfigure human subjectivities, but also how processes of bodily exploitation and commodification come to transform the human body, and the human being, into a mere ecological resource via the body's altered status as an object of labor enactment. Thus, the ever-more salient question – a question that remains unaddressed in the bioeconomic literature – is, how will human beings come to view themselves and others when the bodies and body parts of the *some* (e.g., female bodies, indigenous bodies, impoverished bodies, developing-nation bodies, and bodies of color) are disproportionately acted upon as mere *ecological resources* and thus are ever more controlled, manipulated, and commodified to the benefit of *others*? What novel forms of personhood and citizenship will this unsettling dynamic of the bioeconomy yield? What will be the nature of *these* newly emerging subjectivities, and how will they shape social relations both within and between nations in the decades to come?

***Environmental Sociology***

The literature discussed in the previous section illustrates the bioeconomy's increasing visibility within the academic community. With few exceptions, however, sociologists have been slow to engage with this literature and topic in any meaningful way (for exceptions see Waldby 2000; Rose 2007; Cooper 2008; Cooper and Waldby 2014). Most surprisingly – given their research interests – environmental sociologists and scholars of environmental political economy have neglected this body of research in its entirety, a fact that reduces their capacity to both generate and critique important theoretical arguments regarding a key aspect of the modern world and environment. However, it is my position that the theoretical and substantive insights of environmental sociology provide a highly effective lens through which to analyze systems of human-based bioproduction – a position that I hope to validate in the following two sections of this chapter. First, though, I provide a brief review of leading environmental sociology scholarship, which at present fails to address the human body as a commodifiable resource or the ways in which this resource is incorporated directly into the production process – realities of the bioeconomy that potentially challenge dominant theoretical understandings of what both constitutes and differentiates human beings from the natural world.

Take, for instance, the Treadmill of Production theory, which asserts that capitalism is driven by an expansionary logic that requires industry to constantly seek out and exploit new markets and natural resource deposits (Schnaiberg 1980). This expansionary logic, according to treadmill theorists, is the product of intense competitive pressures within the global market, which force industry to constantly expand production while simultaneously lowering its cost. To reduce production costs, businesses invest in new labor-saving technologies, which prove to be more energy and resource intensive than those previously utilized. The use of these technologies, in conjunction with expanding production, leads to ever-greater social and environmental decline

due to (i) the required use of ever-more harmful chemicals in the production process, (ii) increasingly harmful extraction processes to sustain this production, (iii) increases in industrial waste, pollution, and resource depletion, and (iv) the creation of a surplus labor pool in the global North that provides political support for the treadmill via its attempts to revive declining employment through a speeding up (rather than a reversal) of treadmill production processes (Schnaiberg 1980; Gould et al. 1995, 2008; Rice 2009; Bonds 2016). In this way, the capitalist treadmill yields an international system of perpetual economic growth and socio-environmental degradation – a system that relies on the disproportionate exploitation of developing nation labor, resources, and resource sinks (Gould et al. 1995; Bunker 2005; Rice 2009). Once on this treadmill, theorists assert, it is virtually impossible to step off because doing so would jeopardize corporate profitability, government tax revenues, and labor security, all of which are directly linked to continued economic growth (Schnaiberg 1980; Gould et al. 2008; Bonds 2016).

Treadmill theory thus focuses on key structural arrangements in the economy and the ways in which these arrangements both produce and maintain government and labor dependency on industry and its ever-growing expansion (Gould et al. 1995; Downey 2015). Within this theoretical frame, however, human beings are conceptualized as either capitalists, consumers or laborers, and the body's potential status as a commodifiable environmental resource is overlooked in its entirety.

Another theory central to environmental sociology is "ecological unequal exchange theory," which is an environmental variant of world systems theory. In short, this theory asserts that global economic production occurs within a world system hierarchy composed of core (high income), semi-periphery (middle income), and periphery (low income) nations. Within this hierarchy, theorists assert, asymmetrical power and trade arrangements between the global North

(core nations) and South (periphery nations) allow the former to benefit disproportionately from the latter's socio-economic and political subjugation. As a result, the core is able to exploit the labor power and natural resources of the periphery which, due to low wages and weak labor and environmental laws, greatly reduces production costs, thereby producing an unequal exchange of labor and natural recourse wealth that benefits the global North – a dynamic that will be addressed in greater detail in later sections of this dissertation (Jorgenson 2009, 2016; Rice 2009; Downey 2010). In addition, this theory posits that unequal power and trade arrangements allow developed nations to benefit from an unequal exchange of ecological goods and services. For example, the core benefits from both an uneven extraction of natural resource wealth from the periphery and from its ability to export environmentally harmful industries to the South which, in turn, places an unequal ecological burden on periphery nations (Jorgenson 2009; Rice 2009; Downey et al. 2010, 2015).

Unequal ecological exchange theorists therefore hold that a nation's position within the world system hierarchy predicts its ability to benefit from unequal exchanges of labor, natural resource wealth, pollution, waste, and other ecologically disruptive activities such as mining and agricultural production. Because of this unequal exchange, the core is able to augment its ecological carrying capacity at the expense of periphery nations, which are left to contend with the negative social and environmental externalities of production (Rice 2009; Jorgenson 2009; Downey 2015). Again though, this theory fails to acknowledge that human beings can be anything other than capitalists, consumers or workers. As such, bodily commodification is understood to occur along the lines of labor and labor alone.

Of additional interest are two theoretical arguments known respectively as the "first and second contradictions of capitalism," articulated by David Harvey and James O'Connor.

Following Marx, Harvey (1982, 2010) posits that the first of these contradictions is the crisis of "overaccumulation," which occurs when surplus pools of investment capital are unable to be absorbed into new rounds of profitable investment, thereby threatening profits, economic growth, and the overall stability of the capitalist economy. Harvey posits, for example, that the economy must constantly expand and that a central component to this expansion is the availability of new investment opportunities. Without this availability, capitalists lack the capacity to reinvest profits, which deprives them of the ability to generate additional wealth. Under such conditions, the market will stagnate and eventually slip into decline (Harvey 1982, 2010).

One of the most historically important solutions to this overaccumulation crisis has been geographic expansion into new global markets – markets that have yet to be fully subsumed under capitalism (Harvey 1982; Guthman 2011). This solution, as articulated by Harvey (1989), is known as a "spatial fix," which is best understood as a geographic displacement of a crisis of overaccumulation (Guthman 2011).

Capitalism's second contradiction, per O'Connor (1989, 1996), is its tendency to destroy the very ecological conditions that allow for its reproduction. From this perspective, endless efforts to resolve crises of overaccumulation result in the overexploitation of ecological systems and thus to the "crisis of underproduction," which can be understood as the exhaustion of nature's free subsidies into the economy (O'Connor 1996; Robbins and Fraser 2003). O'Connor therefore theorizes that there are environmental and resource-based limits to perpetual economic growth and that these limits will eventually spur many of the accumulation crises experienced by capitalists. As thus, Harvey's spatial fix is at best temporary in that each round of geographic expansion will yield subsequent environmental destruction and resource depletion that reduces the availability of viable investment opportunities for the absorption of surplus capital

(O'Connor 1989, 1996). In this way, the first contradiction of capitalism is both the cause and consequence of the second.

Strong empirical support for the four environmental sociology theories described above has been established via decades of research (Schnaiberg 1980; Harvey 1982, 2010; O'Connor 1996; Gould et al. 1995, 2004, 2008; Bunker 2005; Rice 2009; Jorgenson 2009, 2012; Downey 2015). These theories thus do a very good job of explaining the underlying mechanisms that produce and maintain an increasingly transnational and socio-environmentally destructive system of economic production (Schnaiberg 1980, 2000; O'Connor 1989, 1996; Bunker 2005; Gould et al. 2008; Bonds & Downey 2012). These theories have also convincingly shown that socio-economic and political inequalities in the world system have placed a highly uneven socio-ecological burden on the global South (Gould & Schnaiberg 1995; Rice 2007; Jorgenson & Clark 2009; Parks & Roberts 2010; Yu et al. 2014).

However, despite their many successes in explaining socio-environmental relations, these theories cannot fully explain all the "labor" and environmental processes they seek to explain because they fail to recognize the body as anything more than an instrument (as opposed to an object) of labor enactment. But as this dissertation will demonstrate, human bodies are now involved in capitalism in ways that go far beyond their traditional and theoretically accepted role as producers and consumers in market exchange (Guthman 2011). Failure to recognize this newly emerging reality results in a lack of analytical leverage necessary to fully understand (1) the rise and/or intensification of human-based bioproduction, (2) the structural forces driving its geographic expansion, (3) the processes of bodily commodification that sustain it, and (4) the social, environmental, and theoretical consequences of this expansion. This, as I argue below, is because these theories all rely on a neo-Marxist framework and are thus informed by Marx's

labor theory of value, which establishes a strong distinction, or dualism, between humans and nature – a distinction that currently inhibits the capacity of environmental scholars to conceptualize the human body as natural capital. It is, therefore, essential to discuss Marx's labor theory of value in some detail. In doing this, I hope to convince environmental sociologists that the very theoretical suppositions that have traditionally served to separate human beings from nature can and, when situationally appropriate, should be used to reinsert them back into the natural world, thereby bringing the human body and processes of bodily commodification under the analytical purview of environmental sociology.

### *The Labor Theory of Value, Marxian Political Economy, and Human Capital Theory*

The theoretical foundation of much leading environmental sociology is Marxian political economy, and at the core of Marxian political economy rests the labor theory of value (Birch and Tyfield 2012, Foster 2005, 2001; Steedman et al. 1981). Although much controversy and debate has occurred with regard to the overall legitimacy of Marx's labor theory of value, it is an unequivocal fact that several leading sociological theories of the environment are informed by this theory via their adherence to broader Marxian political economy. Today, though, it is almost impossible to talk about the labor theory of value without evoking a whole battleground of theoretical positions and counterpositions regarding the ultimate source of surplus value creation in the capitalist economy (Steedman et al. 1981; Cooper 2008; Birch and Tyfield 2012). To engage in this decades' old battleground, however, would be to detract from a novel and pressing set of sociological questions that arise in conjunction with the newly emerging bioeconomy – questions that have yet to be fully formulated or posed in any decidedly comprehensive way. It is, therefore, not the goal or within the scope of this dissertation to participate in a sustained

dialogue with the existing and vast literature on the relative merits of the labor theory of value. Rather, it is simply to (i) identify the association between leading socio-environmental scholarship and the Marxist tradition and (ii) elucidate the implications of this association for how environmental sociologists have come to understand and conceptualize the human/nature divide. That said, and to vastly oversimplify, the labor theory of value and Marxist political economy posit three general suppositions relevant to the current conversation.

First, the labor theory of value asserts that all value creation results from the enactment of labor. Put differently, labor power (i.e., the ability to enact labor via the transformation nature) is the sole source of surplus value (i.e., value created over and above what the laborer is paid for). This surplus value is then appropriated by the capitalist class and realized via market exchange (Tucker 1978; King and Ripstein 1987; Cardao-Pito 2016). Following in this tradition, King and Ripstein (1987: 3-4) state that human labor power "is the only factor in production that increases the value of a product…All other [natural] factors merely transfer their value to it. Because it is the only commodity that adds value, labor-power is thus the only productive commodity" within the production process. To reiterate, then, the labor theory of value understands the creation of all value to lie solely within the realm of labor performance, while labor itself is understood to be any waged human activity or exploitable human characteristic that produces said value (Marx 1976; Tucker 1978; King and Ripstein 1987; Birch and Tyfield 2012; Cardao-Pito 2016).

Second, the labor theory of value – along with broader Marxian political economy – asserts that all labor (i.e., labor power) is the act of human beings actively and consciously transforming the materials of nature to their own ends. Marx states, for example:

> Labor is, first of all, a process between man and nature, a process by which man, through his own actions, mediates, regulates and controls the metabolism between himself and nature. He confronts the materials of nature as a force of nature. He sets in motion the natural forces which belong to his own body, his arms, legs, head and hands, in order to

> appropriate the materials of nature in a form adapted to his own needs. Through this movement he acts upon external nature and changes it (Marx 1976: 283).

It follows that the production of value via labor performance is always dependent on nature's own value potential. That is, ecological systems produce stocks of natural resource wealth with inherent or naturally occurring value *potential* and it is these stocks – *reordered and modified through the application of exploited labor* – that produce the surplus value of any given commodity (King and Ripstein 1987; Foster 1999; Birch and Tyfield 2012).[6] Thus, Marx fully recognized and incorporated the primacy of nature into his theories of economic production, for "without nothing, nothing can be created" (Marx 1976: 23).

Third, through the enactment of labor, human beings are understood to exercise an elevated state of consciousness that allows them to express their species being (i.e., that which makes them human). Put differently, and according to Marx, labor is the primary human activity that differentiates human beings from the natural world via humans' ability to control, manipulate, and transform the materials of nature to their own ends (Steedman et al. 1981; Rajan 2006; Birch and Tyfield 2012; Foster 1999). As observed by Marx:

> It is just in his work upon the objective world, therefore, that man really proves himself to be a *species-being*. This production is his active species-life. Through this production, nature appears as *his* work and his reality. The object of labor is, therefore, the *objectification of man's species-life*: for he duplicates himself not only, as in consciousness, intellectually, but also actively, in reality, and therefore he sees himself in a world that he has created (1959: 32)

The ability to transform nature is thus the primary mechanism by which human beings create and transform themselves into conscious, social beings – a transformation that in turn separates humanity from nature via collective recognition of its own species being (Marx 1959; Steedman et al.: 198; Foster 1999)

[6] Put differently, labor is nothing more than the appropriation and manipulation of nature which, per Marx, contains the "means of production already produced" (Franklin 2007: 106).

To reiterate, Marx understood (i) value creation to be the sole product of labor, (ii) labor itself to be the manipulation and transformation of nature, and (iii) nature's transformation via labor to be the primary process by which human beings differentiate themselves from the natural world. In fact, Marx (1959: 126-127), explicitly refers to "nature" as "inorganic body; that is to say *nature, excluding the human body itself*" (author's emphasis). It is, therefore, clear that Marx's labor theory of value – along with broader Marxian political economy – establishes a strong dualism, or separation, between humans and nature, a distinction that remains prevalent within contemporary environmental sociology and sociological scholarship in general. In establishing this dualism, however, Marx failed to account for the body's own naturally occurring value potential and for the ability of human beings to exploit and commodify this value. He thus also failed to account for instances in which human beings enact labor on their own living species and therefore exploit the human body as nature.[7] We therefore need to ask, when human control over nature (achieved via labor) is turned inwards, extended *into* and *upon* the human body itself, does the human/nature duality espoused by Marx stand, or does humanity slip back into a "natural" existence? (Palsson 2009). Because such questions remain unanswered and undertheorized, Marxian-environmental scholarship is deprived of a key analytical reference point from which to examine newly emerging markets and modalities of capitalist expansion – modalities that increasingly subsume the human body as a primary site and resource in the production process.

This theoretical oversight is also evident in another key theory of labor, human capital theory, which asserts that human capital – defined as an individual's stock of knowledge,

[7] This, of course, was an almost entirely unavoidable oversight given the limited technological capacities of Marx's day. Thus, prior to the advent of biotechnology, assisted reproduction, genomic sequencing, etc., there was simply no place for human bodies and body parts (as I address them here) in Marx's theoretical framing of the labor process.

education, skills, and health – is a type of asset that facilitates the performance of labor and thus the production of economic value (Becker 1964; Nilsson and Wallenstein 2013; Cardao-Pito 2016). In the context of the life science industries, however, it is most often a structurally induced deficit of human capital that (i) makes test subjects valuable and (ii) facilitates the disproportionate inclusion of marginalized populations as experimental test subjects – subjects' whose bodies are exploited as objects (as opposed to instruments) of labor enactment.

Take, for instance, the pharmaceutical industry and the increasingly normalized practice of outsourcing clinical trials to low-and middle-income nations. Within this context, it is most often a structurally induced deficit of human capital – along with a lack of opportunities to use what little human capital is possessed – that facilitates the disproportionate exploitation of marginalized populations as experimental test subjects. Research has shown, for instance, that the outsourcing of pharmaceutical R&D is, in large part, driven by the search for treatment naïve populations and that these populations exist because of structural barriers that block or inhibit the acquisition of human capital and thus the ability to secure steady wages that would otherwise allow for access to systems of healthcare and medical treatment (Petryna, 2009; Prasad 2009; Goldstein 2012). In this context, it is therefore the economically non-productive (i.e., those who lack human capital and general economic opportunity) who serve as the basis of value creation via the body's commodification as natural capital.[8]

Leading theories of labor, along with Marxian political economy in general, therefore fail to account for the various ways that life science production processes come to transform the

[8] In other words, the structurally disadvantaged populations incorporated into outsourced experimental research do not sell their human capital (i.e., knowledge, information, skills, health, etc.) to pharmaceutical and biotech companies. Rather, they are left with few other alternatives, but to sell their ecological capital (i.e., the body's internal biological conditionality, materiality, and functionality), which is then labored upon and incorporated as a key input resource in the production of human-derived biocommodities.

human body into an object of labor enactment and thus into an ecological resource that is commodified as any other resource derived from nature. What's more, these traditions have failed to account for the many profound implications of such bodily commodification processes. For example, if the transformation of nature via labor is to be accepted as the primary mechanism by which both surplus value is created and humanity's species-being is expressed – assertions that few Marxist scholars would oppose – then what are the implications of human-based bioproduction for the emergence of an entirely new set of human subjectivities under the bioeconomy? What does it mean when the act that once extricated *all* human beings from nature (the act that once bound the species together via collective recognition of its own common humanity) now functions to alter the status of *some* humans into mere objects of nature – the very objects upon which *other* humans now enact labor and thus express that which makes them human? Surely, these historically unprecedented patterns of bodily exploitation and commodification will yield novel forms of personhood and citizenship both within and between societies. The question is, what will be the nature of these new subjectivities? How will human beings come to view themselves and others when the bodies and body parts of the structurally disadvantaged (e.g., female bodies, indigenous bodies, impoverished bodies, developing-nations bodies, and bodies of color) are disproportionately acted upon as mere ecological resources and thus increasingly controlled, manipulated, and commodified to the benefit of the structurally privileged? What new hierarches of humanity and systems of social stratification will emerge in conjunction with capitalism's late biotechnological turn?

The forgoing discussion underscores the degree to which leading sociological theories of the environment are constrained by existing theoretical parameters, which deny or otherwise confine the body's naturally occurring value potential to the realm of labor performance.

However, when human biological materials, information, and in vivo processes are incorporated into new projects of capital accumulation we are forced to rethink this theoretical limitation and to reconsider humanity's position within and relationship to the natural world. This is especially true given the bioeconomy's increasing prominence in the global economy and the various ways in which it opens up human life to a molecular and cellular rescaling of economic production – a phenomenon that arguably transforms the human body into the very object upon which exploited labor is enacted, surplus value extracted, and humanity's species being expressed.

It is therefore the principal objective of this dissertation to establish sufficient empirical support for a theoretical reconceptualization of the human body as natural capital and for the critical application of this conceptualization when situationally appropriate. To achieve this objective, the following chapters will demonstrate several key points. First, the body (like nature) possesses inherent value potential. Second, the body (like nature) can be an object of labor enactment. Third, the body's value potential (like that possessed by nature) can be extracted and commodified. Fourth, once commodified human bio-products enter a globalized market in which they are bought and sold like any other good derived from nature. In demonstrating these points, it is hoped that the following chapters will provide environmental scholars, and social scientists in general, with a new and ecologically unique perspective with which to analyze (i) the rise and/or intensification of human-based bioproduction, (ii) the structural forces driving its geographic expansion, (iii) the processes of bodily commodification that sustain it, and (iv) the social, environmental, and theoretical consequences of this expansion.

# Chapter 3

# METHODOLOGY

In this dissertation I utilize a case study approach – based on both primary and secondary data – to (i) determine if and the degree to which life science firms come to exploit and commodify the human body as natural capital, (ii) identify the various causal mechanisms that initiate and intensify processes of bodily commodification by these firms, and (iii) document the degree to which macroeconomic policies imposed by International Financial Institutions (IFIs) facilitate the expansion of bodily commodification processes from more-to-less developed nations, and (iv) test the explanatory power and thus applicability of leading sociological theories of the environment to bioeconomic modes of production. To narrow the scope of this research, I direct primary analytical attention on the U.S. biopharmaceutical industry and the increasingly normalized practice of clinical trial outsourcing to underdeveloped nations.

Case study methodologies are ideal for evaluating the potential value or inadequacies of existing theoretical models in that they facilitate intimate observation of complex causal processes and outcomes. This, in turn, allows researchers to compare these empirical processes and outcomes to hypothesized processes and outcomes (Steinmetz 2004. Collier 2011; Bonds 2011; Yin 2009; George and Bennett 2005). Case study approaches are thus very useful for the development and/or revision of existing theoretical models.

In order to assess the validity of prevailing explanatory models, Collier (2011) advocates the use of "process tracing," which is a concise and historically analytic method of case study analysis. Using this strategy, the researcher identifies a specific set of theoretical models relevant

to the established line of inquiry. The investigator then derives a set of predictions, or empirical expectations, from each specified theory, which will be observed if the casual model is indeed valid. Case study observations are then analyzed for consistency or inconsistency with theoretical expectations, allowing researchers to determine the validity of each explanatory model (Hall 2003; Collier 2011).

When relying on case study observations to determine theoretical validity, Mahoney (2000: 412) emphasizes the importance of identifying causal mechanisms, which "…can be defined as the processes and intervening variables through which an explanatory variable exerts a causal effect on an outcome variable." In compliance with this assertion, process tracing stresses the significance of description and temporal sequence. As stated by Collier (2011: 823), "[p]rocess tracing inherently analyzes trajectories of change and causation, but the analysis fails if the phenomena observed at each step in this trajectory are not adequately described. Hence, what in a sense is an extended 'static' description is a crucial building block in analyzing the processes being studied." Attention to description and sequence is thus paramount to the identification of casual mechanisms which, in turn, allows the investigator to both generate and test nuanced theoretical suppositions (George and Bennet 2005; Mann 1986; Skocpol 1979). The logic of process tracing is, therefore, to compare one or more nuanced explanatory models with the historical record. This, in turn, allows the researcher to establish which predictions are most commonly observed and thus, which theoretical model is best substantiated by empirical evidence (Bonds 2011).

In sum, then, the method of process tracing first requires that the case study researcher develop a set of theoretically informed expectations, and that the researcher postulate the casual mechanisms that are related to and/or drive the expected set of outcomes. In accordance with this

approach, I have operationalized a set of process-based expectations from leading sociological theories of the environment and Human Capital Theory. Although these theories fail to conceptualize the human body as natural capital, the preceding theoretical discussion allows me to generate multiple theoretical predictions regarding what the historical development of the pharmaceutical/biopharmaceutical industry should look like if it exploits and commodifies the human body as either natural capital or labor. These expectations are as follows:

First, if the industry does indeed exploit the human body as natural capital (e.g., as the primary site and input resource in both clinical trial experimentation and biologics production) then the ability to secure access to this form of capital represents one of the most important investment opportunities in pharmaceutical research and development.[9] Thus, in accordance with Harvey (1982; 2010), the industry should face periodic crises of overaccumulation in which pharmaceutical firms are deprived of access to this profitable investment option (See table 1 below for a summary of predictions 1-10). To resolve this crisis the industry should subsequently pursue a series of spatial fixes in which previously unexploited populations are incorporated into new rounds of pharmaceutical investment and production (prediction 2). In accordance with O'Connor, however, these "fixes" should eventually encounter ecological limits that inhibit the industry's own reproduction. In the context of pharmaceuticals, this would imply that the industry will (a) eventually deplete newly acquired pools of experimental bodies and/or (b) contaminate the human populations upon which its reproduction depends (prediction 3).

[9] In the pursuit of profitability, pharmaceutical firms invest in the development of new chemical compounds, new drug categories, new technologies to develop these categories and new patents to protect them (Petryna 2007). However, in order for these investments to become profitable (i.e., to culminate in a marketable drug), the industry must have access to a large base of human test subjects through which it can demonstrate drug efficacy and thus garner regulatory approval. Without such a base, all other preceding investments are rendered irrelevant. Thus, the process of locating and securing access to large pools of test worthy subjects is an investment of paramount importance to the industry (Petryna 2009; Prasad 2009; Shah 2006).

Table 1
Summary of Theoretical Predictions

| Modal | Prediction # | Prediction |
|---|---|---|
| Capitalism's 1st Contradiction | Prediction 1 | The pharmaceutical industry will encounter periodic crises of overaccumulation. |
| Capitalism's 1st Contradiction | Prediction 2 | To resolve these crises the industry will pursue a series of spatial fixes. |
| Capitalism's 2nd Contradiction | Prediction 3 | The industry will eventually encounter ecological limits that inhibit its reproduction. |
| Ecological Unequal Exchange & Treadmill of Production | Prediction 4 | The industry will eventually relocate production to the periphery for inexpensive access to labor and natural resources. |
| Ecological Unequal Exchange | Prediction 5 | The industry will benefit from an uneven extraction of labor value and natural resource wealth from periphery nations. |
| Nature and Timing of Spatial Fixes | Prediction 6 | The nature and timing of spatial fixes will be determined by the exploitation of bodies as either labor or natural capital. |
| Marketing of Human Bodies | Prediction 7 | The body will be marketed in such a way as to denote its use as either labor or natural capital. |
| Human Capital Theory | Prediction 8 | Test subjects will possess a baseline of human capital that must be applied and/or exploited to perform labor. |

| | | |
|---|---|---|
| Reversal of Human Capital Theory | Prediction 9 | A deficit of human capital will function to purify the body, making it a more readily exploitable and commodifiable resource. |
| International Financial Institutions | Prediction 10 | The outsourcing of Pharmaceutical R&D will be highly dependent on the implementation of IFI policies. |

Similarly, the theories of Treadmill Production and Ecological Unequal Exchange would expect that if pharmaceutical companies exploit the body as natural capital or labor then they will eventually be forced to relocate production to periphery nations where access to human bodies will be both less expensive and less polluted (prediction 4) (McMichael 2004; Rice 2009; Jorgenson 2009). Furthermore, if the industry treats human bodies as natural capital, then Ecological Unequal Exchange theory would expect pharmaceuticals to benefit from an unequal extraction of bodily value from test subjects in the periphery (prediction 5).

As previously noted, however, none of the preceding theories conceptualize the human body as natural capital, but rather as a source of labor and labor alone. Because of this oversight, researchers employing these theories are unable to fully understand and adequately explain either the timing of or causal processes that drive treadmill expansion, unequal ecological exchange or the contradictions highlighted by Harvey and O'Connor. It is therefore important to develop predictions that allow researchers to differentiate between processes of bodily commodification as labor and bodily commodification as natural capital. By establishing this distinction researchers will be better able to explain the timing and structural processes that spur specific industries' geographic relocation, either domestically or abroad. This, in turn, will allow

researchers to more fully understand treadmill processes, unequal ecological exchange, and the emergence of market contradictions. In developing these predictions, I draw from human capital theory and from the work O'Connor.

Although O'Connor does not conceptualize human beings as natural capital, his argument can be used to predict that the pharmaceutical industry will exhaust or pollute human bodies to such a degree that it will be forced to pursue a series of spatial fixes (i.e., locate new and uncontaminated bodies) and that these fixes will occur as a direct consequence of this bodily exhaustion or contamination as opposed to high or relatively high wages (predictions 2 & 3, discussed above).[10] In order to test these theoretical expectations, I will first examine the nature and timing of these spatial fixes and ask whether their execution was predicated on the industry exhausting or contaminating its body supply. Put differently, the nature and timing of these spatial fixes will be determined by how the pharmaceutical industry views and acts upon the human body – either as a source of labor or a natural resource (prediction 6).

Second, I will examine how developing nations and contract research organizations (CROs) advertise their "body supplies" to pharmaceutical firms. In other words, do these entities market the human body in such a way as to denote its use as labor or natural capital? In the former case, low wages and a pliant workforce (or in some instances high skilled labor) will likely be advertised. In the latter case, the body will likely be advertised as diseased and treatment naïve and thus, from a drug testing perspective, as a pristine resource (prediction 7).

In similar fashion, human capital theory understands the human body as producing economic value through the enactment of labor. More importantly, this model posits that higher levels of human capital acquisition will determine the body's level of economic productivity

[10] This form of bodily exhaustion and/or pollution can take place either at the point of production or consumption.

within a given market. Human capital theory also holds that some form of skill, knowledge, and health is required to produce economic value and that this assertion is valid even for the most menial forms of labor (Becker 2002; Wright and McMahan 2011). Thus, in the context of clinical trial research, human capital theory would expect experimental subjects to possess a baseline of human capital (i.e., skill, knowledge, education, health, etc.) that must be actively applied or exploited in order for test subjects to engage in the act of labor (prediction 8).

As previously addressed, however, treatment naïve populations are overwhelming those that suffer from a structurally induced deficit of human capital. I, therefore, contend that bodily commodification within clinical trial research constitutes a reversal of human capital theory. If this assertion is correct, we would expect to observe that a deficit of human capital will actually function to increase both the desirability *and* productive potential of treatment naïve populations via their status as untapped and uncontaminated body supplies. In other words, we should expect to observe that a deficit of human capital will function to purify the body – from a drug testing perspective – thereby transforming once economically nonproductive populations into highly sought after and commodifiable resources (prediction 9).

Finally, a large body of social science research has addressed the increasing transnational character or "tilt" of global economic production and the role that IFIs such as the World Bank and IMF play in facilitating the expansion of capital abroad (Langan 2018; Downey 2015; Babb 2010; Harvey 2010; Rice 2009; Chang 2008; Vreeland 2007; Goldman 2005; Peet 2003; Woods 2006; Gould et al. 1995, 2004). More specifically, this research focuses on the macroeconomic policies these institutions formulate and implement in developing nations and how these policies provide the institutional basis for the core's continued exploitation of periphery nations in the global South (Downey 2015; Babb 2010; Vreeland 2007; Woods 2006). For example, Downey

(2015) convincingly demonstrates how World Bank and IMF structural adjustment policies (SAPs) produce severe social, economic, and environmental harm in LDCs, which occurs via an undermining of national sovereignty and the forced transition to export oriented economies that benefit MDCs. This research further demonstrates how SAP implementation leaves underdeveloped nations dependent on inflows of direct foreign investment (DFI) as a leading strategy of economic development and how these inflows open up LDC economies to neocolonial systems of exploitation and resource extraction that disproportionately benefit industries based in the global North. Research in this area thus shows how the ability of capitalists to overcome market contradictions (i.e., crises of overaccumulation and underproduction) is intimately interwoven with the formation and implementation of IFI policies, which provide the primary institutional mechanisms that allow capitalists to secure continued access to profitable investment opportunities and natural resource wealth (Downey 2015). IFI policies are, therefore, of central importance in that they provide the institutional means by which capitalists pursue and achieve spatial fixes, which in turn, allow for the ongoing expansion of capital abroad.

Thus, if the pharmaceutical industry does indeed exploit and commodify the human body as natural capital, then researchers should not only expect to observe an intensification of pharmaceutical R&D outsourcing to LDCs (predictions 2 and 4 discussed above), they should also expect to observe the ways in which this outsourcing is dependent on the implementation of IFI policies and how these policies produce the structural conditions that encourage the relocation of pharmaceutical production abroad. For example, researchers should expect SAP host countries to suffer from a variety of negative social, economic, and political outcomes that result in an underdevelopment of health and healthcare systems. They should also expect these

declining structural conditions to encourage the outsourcing of pharmaceutical R&D because such circumstances will produce a surplus pool of experimental bodies that are inexpensive, treatment naïve, and easily mobilized for use in clinical trial research (prediction 10).

### *Data Collection and Case Study Construction*

This research project utilizes archival documents and secondary sources to construct a set of case studies that delineate the various ways in which life science firms exploit and commodify the human body. The archival documents I utilize are publicly available and include official statements and reports by the Food and Drug Administration (FDA); proceedings and documents from industry-relevant international conferences; US Congressional reports and testimony; industry reports, websites, and publications; NGO and INGO reports and investigations; and newspaper and magazine articles. Through close analysis of these documents and secondary sources, I collected the evidence I use to test the theoretical predictions discussed in the previous section. Throughout this process, I directed specific attention to the temporal sequence of observed events which, in accordance with process tracing, is an essential component in analyzing trajectories of change and causation. I then organized the collected evidence into specific case studies, which I used to adjudicate the merits of each explanatory model and report my overall research findings.

In addition to the above methods, I also employ content analysis to examine the various ways in which international contract research organizations (CROs) advertise their body supplies to pharmaceutical clients. In addition, I conduct content analysis of a popular online information and discussion portal (*Just Another Lab Rat* or *JALR*) that is often used by members of the professional clinical test subject community, which allows me to assess how the interpersonal

communications of test subjects reflect their collective thoughts, ideas, and understandings of the broader clinical research experience. According to Berg (2009: 303-304), content analysis is the "careful, detailed, systematic examination and interpretation of a particular body of material in an effort to identify patterns, themes, biases, and meanings." These analyses therefore provide invaluable information and insight into how (i) both CROs and pharmaceutical firms understand and act upon the bodies of experimental test subjects and (ii) research subjects, themselves, understand the processes of clinical experimentation and their role within the clinical research industry. As such, these analyses help determine the empirical bases for differentiating between processes of bodily commodification as labor and bodily commodification as natural capital.

In conducting these analyses, I followed the broader definition of qualitative content analysis, which specifies a technique of data analysis that is solely qualitative – i.e., without the use of counting, coding, or statistical analysis (Mayring 2000; Patton 2002; Hsieh and Shannon 2005). The sample of CRO advertisements I analyze were selected from the 10 largest international CROs as ranked by IgeaHub, which is best understood as a "pharmaceutical club" that (i) links life science industry executives, researchers, investors, and health policymakers together and (ii) "provides these actors with critical news, perspectives, and analysis on the rapidly changing global healthcare environment" (IgeaHub 2018). My decision to conduct analysis of *JALR* was based on the uniqueness of the portal, its members, and the research questions at hand.

The evidence I collected to develop my case studies allows me to more fully document the chain of historical events and outcomes that have led to the rise and intensification of human-based bio-production under the life science industries (Yin 2008). In the process of collecting this data and constructing case narratives, I remained cognizant that the goal is not to select

information that simplifies reality, biasedly substantiates my theoretical claims or privileges one theoretical perspective over another (Bonds 2011). Rather, my goal in data collection and narrative construction was, as advocated by Flyvbjerg (2001: 84), to capture "all the complexities and contradictions of real life."

### *Theory Testing and Development: Introduction to the Cases*

This dissertation, as previously addressed, will utilize a case study approach that is based on both primary and secondary data collection. Case study methodologies are ideal for evaluating the potential value or inadequacies of existing theoretical models in that they facilitate intimate observation of complex causal processes and outcomes, allowing researchers to compare these empirical processes and outcomes to those that are theoretically hypothesized (Steinmetz 2004. Collier 2011; Bonds 2011; Yin 2009; George and Bennett 2005). Following this logic, I have selected three specific cases that will allow me to (i) test the overall validity of leading socio-environmental theory, (ii) highlight the theoretically-specified casual mechanisms that drive specific empirical outcomes, and (iii) determine the overall applicability of socio-environmental theory to processes of bodily exploitation and commodification under the life science industries.

George and Bennett (2005) and Flyvbjerg (2001) contend that case study researchers can effectively test theories and contribute to theory development by identifying critical cases (or crucial cases) of an existing theory. A critical case is an incident or set of occurrences that are identified by the researcher as closely matching a set of conditions specified in an existing theory (Bonds 2011). Such cases provide ideal situations for validating, falsifying, or revising an existing theory because – despite the presence of conditions specified by the theory – its end

expectations and the causal processes will not necessarily be substantiated through empirical observation (Flyvbjerg 2001; George and Bennett 2005). A critical case will fall into one of two categories – the first being the "least likely" category and the second being the "most likely" category (Flyvberg 2001). In the latter variety of cases, a researcher identifies the conditions that are theoretically hypothesized to most likely result in a particular outcome or set of outcomes. Upon documenting either the presence or absence of these outcomes, the researcher will have strong empirical grounds for claiming that the existing theory is valid, invalid or should undergo revision. The studies I intend to undertake are critical cases for the Treadmill of Production theory, Ecological Unequal Exchange theory, Human Capital theory, and the 1st and 2nd contradictions of capital as articulated by James O'Conner and David Harvey. Each of these theories, however, have also been selected because they provide ideal opportunities to identify and assess the causal mechanisms that are hypothesized to drive specific empirical observations.

**Chapter 4: Situating Labor, Bodily Commodification, and Clinical Trials Research**

As noted in the introduction of this dissertation, chapter four is best understood as a situating chapter, rather than an empirical case study. In this chapter, I engage in a prolonged dialogue with Cooper's and Waldby's highly influential work, *Clinical Labor* (2014). In the context of this dialogue, I provide a definitional review of the terms "labor" and "bodily commodification." I then use and build upon these definitions in order to establish a working definition of the body's ecological commodification. Following this, I provide a brief overview of historical instances in which the body's reproductive and generative capacities have been incorporated into systems of economic production – showing, in each case, the differences and similarities in bodily utilization across time and frame of reference. This chapter further

documents (i) the various phases of clinical trial research, (ii) the organizations and institutions involved in the execution of this research, (iii) the socio-demographic characteristics of U.S. research participants, and (iv) the nature of clinical trial research as it pertains to the exploitation of human biological material, information, and in vivo processes as sources of commodifiable value. In conjunction with the latter of these, I present data from the qualitative content analysis of the *JALR* portal addressed above.

**Chapter 5, Case 1: Domestic Clinical Trial Research (predictions 1-3 and 8)**

The first of my proposed case studies examines the historical evolution of U.S. clinical trial experimentation since the early 1970s. In exploring this case, I test David Harvey's and James O'Connor's predictions as well as the overall applicability of their theoretical frames to processes of bodily commodification under the life science industries. The goal of this case study is, therefore, to determine (i) whether the pharmaceutical industry exploits the human body as natural capital or, as many might argue, as a mere form of experimental labor, (ii) whether or not the industry has experienced crises – both of overaccumulation and underproduction – that are unique to processes of bodily commodification as natural capital, and (iii) whether or not these crises have been circumvented via the industry's use of spatial fixes – fixes that have relied on the incorporation of previously untapped body supplies as sources of commodifiable value. In exploring this case, I examine how changing ethical standards in U.S. medical research functioned to block the pharmaceutical industry's disproportionate exploitation of prison populations in clinical trial research and how this shortage of experimental bodies was overcome. In addition, I examine the drug pipeline explosion of the 1980s, how this phenomenon deprived the industry of its ability to develop and market a backlog of pipeline drugs, and how this

obstacle was overcome via the International Conference on Harmonization (ICH) – an agreement that ultimately allowed pharmaceutical companies to intensify their transnational hunt for untapped body supplies. Finally, I examine key provisions within the FDA Modernization Act of 1997, how these provisions intensified processes of U.S. mass-medicalization, which from a drug testing perspective dramatically reduced the industry's access to test-worthy body supplies within its own borders, and how the industry was able to overcome this crisis by initiating the first truly globalized regime of clinical trial experimentation.

**Chapter 5, Case 2: International Clinical Trial Research (Predictions 4-9)**

The second case study I construct focuses on the practice of clinical trial outsourcing to underdeveloped nations and the multibillion-dollar contract research industry that has emerged in its wake. In exploring this case, I use ecological unequal exchange theory to determine the degree (if any) to which an uneven extraction of bodily (i.e., ecological) value is taking place between more and less developed nations. This theory, as previously addressed, posits that unequal power and trade arrangements between the global North and South allow the former to benefit from (i) the uneven extraction of natural resource wealth from the periphery and (ii) the exportation of environmentally harmful industries to the South, which in turn leaves periphery nations to contend with the negative externalities of production. In accordance with these theoretical expectations, I examine (i) the production strategies of contract research organizations (CROs), which specialize in locating impoverished, and therefore "clean," body supplies on which to conduct experimental research for pharmaceutical clients, (ii) the various international agreements[11] that standardize a profound degree of ethical variability in the execution of these

[11] I examine specific regulatory provisions within the International Conference on Harmonization and Good Clinical Practice guidelines (ICH-GCP), which function to synchronize regulatory standards between more and less

outsourced experiments, thereby allowing the core to benefit from an uneven extraction of bodily (i.e., ecological) value from the periphery, (iii) the mechanisms by which this ethical variability is exploited by the pharmaceutical industry. I then examine the actual unequal ecological exchanges that result from this variability as measured by (a) the rate of increase at which U.S. pharmaceuticals have outsourced clinical trial research over the last 25 years, (b) the percentage of new drug discoveries – over the last 25 years – that have been dedicated to the tropical diseases that plague underdeveloped nations, and (c) the percentage of the annual global pharmacological research budget that is allocated to conditions that make up 90% of the global disease burden.

In addition – and to further adjudicate between processes of bodily commodification as labor and bodily commodification as natural capital – I conduct content analyses of the various ways that CROs market their body supplies to pharmaceutical firms. Specifically, I ask whether these entities market the human body in such a way as to denote its use as labor or natural capital? If the industry does indeed exploit these bodies as natural resources, then CRO advertisements will in no way attempt to market experimental subjects as sources of labor. For example, these ads will not showcase increasing levels of human capital, low wages, and/or pliant workforces. In contrast, clinical trial body supplies will be advertised as diseased and treatment naïve and thus, from a drug testing standpoint, as pristine and untapped ecological resources from which commodifiable value can be extracted.

**Chapter 6, Case 3: The Bretton Woods and Clinical Trial Research (prediction 10)**

developed nations, thereby making international research data more easily transferable to the FDA and other regulatory agencies in leading pharmaceutical markets.

My third and final case study examines two IFIs: the World Bank and the International Monetary Fund (IMF). Specifically, it examines the macroeconomic policies these institutions have formulated and implemented in developing nations and the effect these policies have had on the underdevelopment of health and healthcare systems within LDCs. It further examines how this underdevelopment aids pharmaceutical and biotech firms in accessing and exploiting new human-based environments that allow for the displacement of market contradictions, thereby achieving continued rounds of capital expansion. In examining this case, I will both utilize and build upon four leading sociological theories of the environment,[12] which despite their many successes fail to pay sufficient analytical attention to the primary institutions and institutional mechanisms that facilitate the expansion of capitalist markets abroad (Downey 2015). The goal of this case study, therefore, is to answer the following two questions: First, what role do international institutions such as the World Bank and IMF play in creating the institutional basis for a novel system of LDC exploitation via the mass outsourcing of pharmaceutical and biotech R&D projects to periphery nations. Second, to what degree does this novel system of outsourcing mirror historical pattens of traditional industrial offshoring and thus reflect observable similarities between conventional industry's dependence on LDC procured environmental value and the bioeconomy's increasing dependence on LDC procured bodily value?

[12] The four theories include: The Treadmill of Production theory, Ecological Unequal Exchange Theory, and the 1st and 2nd contradictions of capital as articulated by James O'Conner and David Harvey.

# Chapter 4

## SITUATING LABOR, BODILY COMMODIFICATION, AND CLINICAL TRIALS RESEARCH

As noted in Chapter 2, environmental sociologists do not conceptualize the human body as natural capital or account for the ways in which the body, commodified as nature, is likely to be incorporated directly into evolving modes of human-based bioproduction. This, I have suggested, is because leading sociological theories of the environment are rooted in a tradition that understands (i) the creation of value to be solely the product of labor enactment and (ii) labor itself to be any waged human activity or exploitable human characteristic that produces said value. This tradition, in turn, leaves environmental scholars unable to account for specific instances in which human beings enact labor on their own living species and, by extension, instances in which human beings commodify the body as a mere ecological good.

In contrast, scholars of the bioeconomy *do* acknowledge that life science production strategies often result in the commodification of human bodies and body parts. Yet, they too fail to account for the transformative implications of these production strategies. For example, rather than account for how evolving modes of bioproduction may reduce the status of the human body to that of natural capital, these scholars understand experimental subjects, and others from whom biological value is extracted, to engage in a novel form of "embodied," "reproductive," "clinical," or "experimental labor." Those who perform this labor are understood to constitute "an extensive yet unacknowledged labor force whose service consists in the visceral experience of experimental drug consumption, hormonal transformation, more or less invasive biomedical procedures, ejaculation, tissues extraction, and gestation (Cooper and Waldby 2014: 7)." In legal

and public discourse, these activities are regarded in terms of altruism and gift exchange rather than work (Smith 2001; Healy 2005; Dickenson 2017). Nevertheless, bioeconomy scholars assert that "such services should be regarded as labor when the activity is intrinsic to the process of valorization of a particular bioeconomic sector and when therapeutic benefits to the participants and their communities are absent or incidental (Cooper and Waldby 2014: 8; Dickenson 2017)."

From this perspective, then, the bioeconomy is understood to incorporate and transform the *work* of human biology (i.e., the body's internal, "naturally" occurring capacities and functions) into a novel form of economic labor (Palsson 2009; Cooper 2008; Cooper and Waldby 2014). As I will show, however, the body's in vivo biological processes cannot be accurately construed as labor. Rather, I argue that newly emerging modes of human-based bioproduction actively transform the body's reproductive and generative capacities into that which is ecologically exploitable. The goal of this chapter, therefore, is to demonstrate four key points. First, that the body (like nature) possesses inherent value potential. Second, that the body (like nature) can be an object of labor enactment. Third, that the body's value potential (like that possessed by nature) can be extracted and commodified. Fourth, that once commodified human bio-products enter a globalized market in which they are bought and sold like any other good derived from nature. To achieve this goal, I divide the chapter into three sections.

The first of these sections will provide a definitional review of the terms "labor" and "bodily commodification." I both use and build upon these definitions in order to (i) establish a working definition of bodily commodification as natural capital and (ii) demonstrate the merit of analyzing life science, body commodification practices with an ecological lens (see chapter 2). To further differentiate the ecological commodification of human bodies from those forms more commonly recognized, I provide a brief overview of historical instances in which the body's

reproductive and generative capacities have been incorporated into systems of economic production – showing, in each case, the differences and similarities in bodily utilization across time and frame of reference. In this context, I acknowledge instances of commodification that have likened the human body to that of natural capital but demonstrate how evolving modes of bioeconomic production mark a clear divergence from and deepening of such instances.

Section two identifies (i) the various phases of clinical trials research, (ii) the organizations and institutions involved in the execution of this research, and (iii) the socio-demographic characteristics of U.S. research participants. Section three documents the nature of clinical trial research as it pertains to the exploitation of human biological material, information, and processes as sources of commodifiable value. Through this detailed description of the clinical research industry, I collect and compare evidence to the definitions of labor and commodification developed in section one so as to determine whether clinical trial participants are exploited as labor or natural capital. This process, in turn, allows me to demonstrate the various ways that pharmaceutical production necessitates the efficient and systematized incorporation of human bodies as natural capital. I therefore argue that clinical trial test subjects cannot be understood to engage in the act of labor, but rather constitute the very objects upon which exploited labor is enacted. To further substantiate this claim, I present data from a content analysis of a popular online information and discussion portal (*Just Another Lab Rat*) often used by members of the professional clinical test subject community. Through this analysis, I am able to assesses how research subjects, themselves, understand the processes of clinical experimentation and their role within the larger clinical trials industry.

**Section I: Defining Labor and Bodily Commodification**

In the context of human-based bioproduction, innovation economics and patent law understand human biological materials, information, and processes to constitute "dumb biological resources," or "matter in the public domain" (Cooper and Waldby 2014). Thus, the moment of creation (i.e., commodity production) is the moment in which scientists innovate and transform the body's dumb biological materials and/or capacities into a useful product or service of some kind. Increasingly, however, bioeconomy scholars push back at this thesis, arguing that systems of human-based bioproduction now actively transform the *work* of human biology into a novel form of economic labor (Palsson 2009; Cooper 2008; Cooper and Waldby 2014). However, *work*, by definition, is labor exerted, with the word "labor" denoting two distinct, even oppositional, forms of action that are not easily equivalized.

In conventional political economy, the term "labor" is defined as *either* (a) work/toil performed by women during the birthing process – i.e., women "go into" labor *or* (b) work applied on nature/matter to produce a commodity, good, or service (Qadeer 2016; Cooper and Waldby 2014; Gunderson 2017). It follows that in their highly influential book *Clinical Labor,* Melinda Cooper and Catherine Waldby assert that:

> The first kind of labor dramatizes the productivity of biology; the second kind supports the productivity of the economy. The labor of human reproductive biology produces children and is conventionally located in kinship relations and family formation. Hence, it is thought of as *hors commerce*, beyond market relations, while the worker's labor is sold on the market. However, we argue that today the labor of human reproductive biology has become precisely a form of economic labor in certain key sectors of the bioeconomy (2014: 33).

Thus, according to Cooper and Waldby, the bioeconomy is literally integrating the body's reproductive and generative capacities (from metabolism and ova production to spermatogenesis and gestation) into a novel form of economic production – an assertion that I find to be fully valid. It is clear, for example, that the internal, "naturally" occurring capacities and functions of

human bodies do real and valuable "work," just as ecological systems do real and valuable "work." It is also clear that the bioeconomy incorporates and commodifies the body's reproductive and generative capacities, just as the traditional economy incorporates and commodifies nature's reproductive and generative capacities. What is *not* clear, however, is that the bodily contributions of experimental subjects – and others from whom biological value is extracted – are constitutive of labor. For indeed, the social and natural sciences do not attempt to define the *work* of ecological systems as *labor*.

If bioeconomy scholars therefore wish to define the bodily contributions of clinical trial test subjects as labor, it would seem necessary that, consistent with the political economy definition of labor, they convincingly demonstrate *at least* one of two empirical points. First, they must establish that clinical trial participants actively and consciously preform labor on their body's own reproductive and generative capacities (i.e., act upon themselves as objects) and that this labor is actually productive of the bodily good, commodity or service that they exchange on the market. Or, secondly, they must establish that clinical trial participants engage in some meaningful form of traditionally understood labor during the course of experimentation and that this labor is exploited and commodified as such.

In the context of clinical trial research, I demonstrate that this is not the case – i.e., experimental subjects do not engage in any meaningful form of self- or object-directed labor, but rather constitute the very objects upon which others' exploited labor is enacted. The bodies of human test subjects are therefore commodified, not as labor that transforms nature/matter to produce a commodity, good, or service, but as nature/matter itself. To expound on this point, I next provide a working definition of bodily commodification before proceeding to an overview

of the structural nature of clinical trials research and its mobilization of human bodies as sources of commodifiable value.

The term commodification is not easily defined, and this is especially true when it comes to the commodification of human bodies and body parts. For example, many scholars do not agree on what qualifies as commodification or what even constitutes a "body" or its parts (Nahavandi 2016). Notwithstanding, there is broad consensus that the commodification process changes human subjects into objects and that these objects are then incorporated into some form of economic exchange (Radin and Sunder 2005; Scheper-Hughes 2001). Sharp, for example, asserts that "commodification insists upon objectification in some form, transforming persons and their bodies from a human category into objects of economic desire. Thus, the presence of objectification in a host of forms is significant because it flags the possibility that commodification has occurred" (2000: 293). Going a bit further, Marway, Johnson, and Widdows (2014) contend that there are two interconnected elements that are central to any definition of commodification:

> The first aspect of commodification is that it turns "persons" into "things." Instead of taking human beings to be ends in themselves that ought to be respected as such (a broadly Kantian position), it takes persons and their parts to be objects and commercializes them – or, as Marx puts it, it attributes a "use" and "exchange" value to them… The second feature of commodification is that it reduces bonds with other human beings to formal covenants; it moves "relationships" into the territory of "contracts" …[Thus,] to commodify, is to de-emphasize that individuals are, constitutively, relational beings that have interdependent ties and instead is to shift toward seeing the connections between individuals as interchangeable, established and disestablished as the market requires, and valued only in extrinsic monetary terms. That is "relationships" between individuals become mere services for "contracts" …Importantly, for both elements of commodification, it need not be the case that these kinds of trades are in fact happening to qualify as commodificatory. What matters is how persons and relationships are regarded; if they are treated (through language or conception, for instance) as being objects where trade could legitimately occur, then commodification has occurred (2014: 582-583).

To summarize, then, bodily commodification denotes the ascription of both use and exchange value to human bodies. That is, the body is first acted upon as an external object (e.g., it is subjected to processes that liken it to the status of a "thing") with properties that satisfy some form of human needs and/or wants (Marway et al. 2014; Nahavandi 2016; Dickenson 2017). These properties are then commercialized by assigning them an exchange value within a given market (Marway et al. 2014). However, and as noted above, the move towards commodification goes beyond the actual buying and selling of the body, its properties, and/or parts to include the use of market rhetoric to describe or think of individuals as if they *could* be bought or sold – a process that reduces the human body and human being to the level of a tradable "thing." According to Marway et al. (2014), if any combination of these processes occur, individuals and their parts are no longer thought of as "persons" but as "things."

Historically, and with exception to slavery and prostitution, the defining elements of human commodification have been understood and analyzed in the context of traditional human labor. However, and as previously addressed, the bioeconomy now blurs the line between traditional forms of value production (achieved via the exploitation human labor power) and new bio-social forms of value production (achieved via the exploitation of in vivo biological processes). In the context of these rapidly changing bio-economic and bio-social relations, scholars of the bioeconomy challenge the long-held notion that clinical trial test subjects – and others from whom biological value is extracted – are merely willful participants in an altruistic gift economy, as legal and public discourse have traditionally held them to be. Instead, these scholars posit that such bodily contributions denote a new and actual form of "experimental," "reproductive," "embodied" or "clinical" labor which, like traditional labor, is both commodified and productive of surplus value.

It is my assertion, however, that evolving modes of human-based bioproduction mark a divergent and new form of bodily commodification. Indeed, this form of bodily commodification differs from those previously recognized (slavery, prostitution, labor power) in that it requires: (i) the enactment of waged, human labor on its own species (i.e., waged labor performed on the would be laborer), (ii) the targeting, technological manipulation, and extractive valorization of the body's internal, "naturally" occurring materials, capacities, and functions, and (iii) the consequent production and commercialization of human derived biocommodities that are bought and sold as any other goods derived from nature. When strategies of bioeconomic production necessitate these three human-directed processes in tandem, it is my position that a novel form of commodification has likely occurred – the commodification of human bodies as nature.

One could argue, of course, that there is nothing new per se, about these three human-directed elements of bioeconomic production. After all, traditional forms of commodification have not only diminished the body's status to that of an "object" or "thing," and reduced traditional social relations to relational contracts, they have also sometimes incorporated the body's internal, reproductive and generative capacities. To defend this position, one would likely point to the often-cited practice of wet nursing, the use of cadavers, and the bodily exploitation of enslaved women (Sharp 2001; Marway 2014; Cooper and Waldby 2014; Dickenson 2017). This argument certainly holds a degree of merit, and I have no desire to detract from it by claiming or in any way implying that historical instances of bodily commodification that liken the body to that of a natural resource have not occurred. What I am claiming, however, is that contemporary modes of human-based bioproduction, and the technological advances that make them possible, mark a clear divergence from these historical (and in the case of slavery,

deplorable) forms of bodily exploitation. To elaborate this point, I will first address the use of bonded female bodies in the antebellum South.

In the context of chattel slavery, the female body was often considered more valuable than that of males because her body could "generate three income flows: from labor, prostitution, and reproduction" (Beckles 1989: 144). Indeed, the female slave's labor power was commodified, and so too was her body (as an object of sex that could be bought and sold) and her reproductive capacities – for she was a marketable object with the ability to produce yet another marketable object (a bonded child). Unsurprisingly then, the Southern, slave-based economy does provide an historical instance in which the body's reproductive capacities were commodified (i.e., given explicit use and exchange value). However, the exploitation of these reproductive capacities did not necessitate the enactment of waged labor upon the enslaved woman's body, nor did it require that her in vivo biological processes be manipulated via external, technological intervention – as is the case, for example, with assisted reproductive technology (ART), traditional contract surrogacy (ex vivo fertilization of eggs *belonging* to surrogate), and gestational contract surrogacy (ex vivo fertilization of eggs *not belonging* to surrogate). Thus, while the female slave's reproductive capacities were incorporated into the larger, slave-based economy, her body was not commodified as an ecological resource (as defined above) because its internal, naturally occurring materials, capacities, and functions were never targeted, extracted or manipulated by the transformative forces of human labor power.

This distinction is of central importance for two key reasons. First, in Marxian political economy, labor is the act of human beings actively and consciously transforming the materials of nature to their own ends. Second, through the enactment of labor, human beings are understood to exercise an elevated state of consciousness that allows them to both recognize and express that

which makes them human. Labor, in other words, is the primary human activity that distances and differentiates human beings from the natural world via humans' ability to control, manipulate, and transform the materials of nature. As echoed by Schmidt (1973: 82), "where men succeed in universally mastering nature technically, economically and scientifically by transforming it into a world of goods and machines, nature congeals into an abstract in-itself external to men." Thus, to extend the gaze of economic production onto the body itself – i.e., to labor upon it, to control, manipulate, and extract biological material from its internal, "natural" conditionality – and to do so with the conscious intent of producing a good that can be bought and sold, is to fundamentally transform the body into that which is ecological. As noted by Palsson (2009):

> What happens, then, when human mastery is turned inwards, extended to the bodies of the laborers themselves? Do they, perhaps, "lapse" once again into a natural existence? Prior to the development of biotechnology and assisted reproduction, there was no place for human body parts in the Marxian scheme of the labor process…While the extension of human mastery to the body itself complicates the Marxian scheme, it also invites intriguing questions about labor and production… Clearly, with modern biotechnology the "natural" capacities of the body have been turned into instruments for production, redefining both human labor and human bodies (297-98).

Drawing from the institution of chattel slavery, it is clear that instances of bodily commodification that liken the body to that of natural capital have occurred. It is further clear, however, that the bioeconomy represents a profound deepening of such instances. This deepening is signaled by the bioeconomy's very functioning, which requires that the production process be relocated *inside* the human body, thereby "enrolling" the body's internal value potential (i.e., its in vivo processes, materials, and/or services) in novel forms of bio-social commodity production. Certainly, the enslaved female body (and person) was commodified as chattel – a human possession legally deprived of the right to self-ownership and thus also of the right to control her reproductive abilities – which allowed its internal value potential to be

appropriated and incorporated into broader systems of value generation. However, her body's internal ecology was never the immediate target of human labor power, nor was it the direct target of technological manipulation that, in turn, rendered a human-derived product produced by the productive labor (i.e., work) of an external other.

Similarly, in the context of wet-nursing – the long-abandoned practice of working-class women breast-feeding posthumously born children in hospitals or (more commonly) the children of wealthy domestic employers – the woman's reproductive capacities were given both a use and exchange value (Golden 2001). Hence, the body that housed these capacities was commodified – informally bought and sold for the product it rendered (breast milk). Again, however, this form of commodification did not reduce the wet-nurse's body to the status of an ecological resource because the product rendered (breast milk) did not result from the enactment of waged labor on her body, nor did its production require any external, technological intervention into her in vivo biological processes.

In contrast, the historical use of cadavers did require that waged labor be performed on human corpses, which from the 13$^{th}$ to the 19$^{th}$ centuries were bought and sold as any other commodity in market exchange. As observed by Linebaugh (1975):

> The corpse became a commodity with all the attributes of a property. It could be owned privately. It could be bought and sold. A value not measured by the grace of heaven nor the fires of hell but quantifiably expressed in the magic of the price list that was placed upon the corpse.

Once procured (often through the practice of "body snatching"), medical scientist and anatomists would quickly direct the attention of their scalpels and saws on the cadaver, laboring for hours to dissect the body and its parts in front of large audiences of aspiring medical professionals (Scheper-Hughes and Wacquant 2002; Roach 2003). In this context of academic dissection, the buying and selling of cadavers certainly marks an historical instance of bodily commodification.

Nevertheless, the scientific labor performed on these corpses cannot be understood as productive in that its purpose and consequence was never the organized production of human-derived biocommodities that were bought and sold in regular market exchange. Rather than biocommodities, Wallace (2018) argues that such labor was for the advancement and dissemination of collegiate anatomical knowledge (e.g., organ preservation, academic publications, medical presentations, etc.), which served as an important source of cultural capital exchanged freely among lecturers, students, researchers, and doctors. For these reasons, the historical use of cadavers does not qualify as an instance of ecological commodification. Today, however, the bioeconomy moves to repurpose the use of cadaveric bodies, transforming them into sites of resource extraction and commodity production.

In contemporary times, the supply of cadavers is twofold: the first and less common source is direct philanthropic donation for the advancement of scientific knowledge. The second and more regular source is organ and tissue donation – i.e., the families of individuals who in an unquestioned act of altruism relinquish their loved ones as a "last best gift" to society. Indeed, the cultural account of donation is altruistic (non-profit), gift exchange and organ procurement organizations (OPOs) actively use this rhetoric when engaging with the families of potential donors. In order to make this "last best gift," OPOs require that the deceased's family sign a donor consent form that specifics both "organ" *and* "tissue donation." As observed by Healy (2006), many families agree to both forms of donation, being unaware of the difference in terms. Having agreed to both forms of procurement, and subsequent to organ removal, the donation will quickly enter a secondary (for-profit) market of rapidly expanding biotechnological, biomedical, and pharmaceutical production (Healy 2006). In this market, the cadaver's tissue ("tissue" designating everything that can be procured from the donor after organ removal – i.e., corneas,

heart valves, tendons; ligaments, skin, bones, etc.) is "processed" and actively transformed into innumerable secondary products ranging from dental implants and "bone mud" to acellular dermal matrixes used to treat burn victims, remove facial wrinkles, reshape lips, and enlarge penises (Healy 2006). Thus, in this context and in accordance with the three human-directed production processes outlined above, the contemporary use of cadaveric bodies does qualify as an instance of ecological commodification.

I have made this brief diversion into historical instances of bodily commodification to emphasize how contemporary modes of human-based bioproduction differ from previous instances of bodily utilization and commodity production. Bioeconomy scholars who advocate for the concepts of "clinical", "experimental," "reproductive" or "embodied labor" ubiquitously cite the examples of chattel slavery and wet nursing so as to situate their claims in historical precedent. Scholars of labor and the environment, reluctant to reconceptualize the body's commodifiable properties as ecological goods, will likely point to the historical use of cadavers and ask, "what has changed – why should the body now be thought of in ecological terms?" Echoing Palsson (2009), much has changed: the bioeconomy now opens up human life to a molecular and cellular rescaling economic production, redefining both human labor and human bodies in historically unprecedented ways. This process of definitional metamorphoses marks a highly contentious, if not explosive, battle ground of theoretical positions and counter positions. As of today, many of these positions remain deeply informed by a tradition of anthropocentric thought, which (consciously or not) functions to safeguard the uniqueness of humanity and preserve its elevated station over nature. However, theories are useful only to the degree that they explain and provide novel insights into empirical reality; if they fail or are inadequate in this task, they must be abandoned or amended (Fligstein 2001). It is my argument that the theoretical

concepts of “clinical” or “embodied labor” are inadequate in explaining many instances of human-based bioproduction and that such concepts reify age-old anthropocentrisms laid bare by the bioeconomy.

## Section II: The Phases and Socio-demographics of U.S. Clinical Trial Research

Clinical trial research is an essential aspect of pharmaceutical production and its increasing transnational expansion. This point is made clear when considering that between 60% and 70% of the global pharmaceutical R&D budget is allocated to clinical trials, or $80 to $90 billion of the $130 billion spent in 2012, with total R&D spending surpassing $186 billion in 2019 (Berne Declaration Magazine 2013; Statista 2021). Less evident to most people, however, are the kinds of clinical trials that are being conducted, the organizations and institutions involved in their execution, and the populations that serve as experimental subjects within these trials. To illuminate these often-obscured dynamics of pharmaceutical research and development, I briefly consider each respectively before proceeding to an overview of the nature of clinical trial research and its mobilization of human bodies as sources of commodifiable value.

In the current *U.S. context*, the drug approval process follows a well-established sequence of events. After a pharmaceutical sponsor identifies a drug (biologic or medical device) with potential therapeutic benefit to humans, it will first conduct experimental testing on animals. This phase of preclinical investigation involves intensive stages of iterative testing that are designed to collect data on the overall feasibility and safety of the investigational agent. Once a sponsor is confident that the therapeutic product is ready to undergo testing in humans, it must file an investigational new drug application with the FDA (Cooper and Waldby 2014). If this application is not rejected within thirty days of being filed, the sponsor can proceed to the first

primary phase of in-human clinical testing. As an aside, it is interesting to note how this one-month period marks the unqualified transition from human exploitation of nature (use of animals in experimentation) to human exploitation of "labor" (use of humans in experimentation), regardless of the fact that both animals and humans are being used in the same ways.

Having secured FDA approval, in-human clinical trial research occurs in four distinct phases. Phase 1 studies often pay participants several thousand dollars for extended inhouse trials and typically rely on twenty to eighty healthy test subjects to determine the tolerable dose range of a new investigational agent. It is important to note that many of these studies are experiments that offer no therapeutic benefit to research participants (Grady et al. 2017). Rather, the sole purpose of these experiments is to identify the safety and pharmacology[13] of a first-in-human therapeutic agent. The first of these goals (safety) is achieved by determining the agent's maximum tolerated dose (MTD), or point of toxicity, in the human body. As observed by Daugherty et al. (2000),

> Through a process of dose escalation, [experimental] cohorts are given higher doses [of an experimental agent] until toxic levels are reached, at which there is believed to be (based on dose response information) the greatest chance for therapeutic benefit. It thus becomes necessary to give increasing doses of an agent until the MTD is identified before concluding that an agent has been adequately tested.

The second goal (pharmacology) is achieved via pharmacodynamic and pharmacokinetic testing, which allows experimental researchers to determine how the body absorbs, metabolizes, and excretes an experimental agent (Cooper and Waldby 2014). Once these two goals are deemed adequality achieved, the experimental agent can be moved into Phase 2 trials.

[13] Pharmacology is the study of the interactions between drugs and the body. The two broad divisions of pharmacology are pharmacokinetics and pharmacodynamics. Pharmacokinetics (PK) refers to the movement of drugs through the body, whereas pharmacodynamics (PD) refers to the body's biological response to drugs.

Phase 2 studies typically recruit between one and three hundred research subjects who have the disease or condition being investigated. This phase of experimentation is undertaken to provide further evidence of an agent's safety and to establish preliminary evidence of the drug's efficacy in treating targeted patient populations (Elliott 2008; Petryna 2009). Phase 3 studies, the last stage of research before a drug is submitted for FDA approval, recruit from a much larger and (ostensibly) diverse pool of research subjects who suffer from the disease or condition being targeted. These investigations are generally multicentered and can involve up to 10,000 people in 10-20 countries (Petryna 2007). Phase 3 studies not only seek to confirm the continued efficacy of an experimental agent within a larger research population, they also seek (and *must*) establish that the agent is equal to or better than any preexisting medication on the market. In developed nations, this is demonstrated by comparing the therapeutic effects of the experimental drug to that of the best-known standard of care (i.e., "standard treatment"). If no such standard of care exists, the experimental drug is tested against a placebo (Petryna 2009; Goldstein 2012). Phase 4 studies provide additional safety and efficacy data after the drug has been approved and marketed for a number of years – i.e., once long-term drug uptake data can be collected and analyzed (Petryna 2007).

Throughout much of the 1980s and 1990s the first three primary phases of clinical trial research were carried out in academic research centers and teaching hospitals in the United States. The use of academic medical centers in this capacity began in the early 1980s, which saw a transition in pharmaceutical R&D practices, in which pharmaceutical sponsors would continue along the path of drug discovery and development but contract out clinical trial experimenters to medical research institutions. In fact, as recently as 1991, 80% of all U.S. industry-sponsored clinical trials were conducted in academic health centers (Elliott 2007; 2014). However, by the

late 1990s, the pharmaceutical industry had identified an alternative strategy to clinical trials that yielded lower cost data faster and with less bureaucratic oversight and ethical scrutiny.

This alternative, as addressed in the following chapter, was the private contract-research sector. To capitalize on this alternative, the pharmaceutical industry began outsourcing clinical experiments to contract research organizations (CRO). These for-profit organizations are highly competitive research companies that not only specialize in conducting clinical trials for pharmaceutical, biotechnology, and medical device firms but also in locating research sites, recruiting test subjects, gaining IRB approval, providing monitoring services, and in many cases developing research designs and conducting analyses (Elliott 2007 Petryna 2007, 2009; Prasad 2009). Put differently, almost every aspect of pharmaceutical development – beyond the initial phases of drug discovery and patenting – is now outsourced to the contract research industry, which has exploded over the last two decades, generating well over $100 billion in annual income (Elliott 2007). Indeed, the outsourcing of clinical trials to CROs was so rapid and comprehensive that by 2006 the contract research industry was conducting over 70% of all pharmaceutically sponsored, in-human clinical studies (Fisher 2009; Elliott 2014).

As an important aside, one should note how the above shift in the execution of clinical trials – from academic research centers to for-profit CROs – was followed by yet another transition in pharmaceutical research and development, namely the rise of for-profit IRBs. As observed by the bioethicist Carl Elliott (2007):

> For the past three decades, institutional review boards, or IRBs, have been the primary mechanism for protecting subjects in drug trials. FDA regulations require that any study in support of a new drug be approved by an IRB. Until recently, IRBs were based in universities and teaching hospitals, and were made up primarily of faculty members who volunteered to review the research studies being conducted in their own institutions. Now that most drug studies take place outside academic settings, research sponsors can submit their proposed studies to for-profit IRBs, which will review the ethics of a study in exchange for a fee. These boards are subject to the same financial pressures faced by

> virtually everyone in the business. They compete for clients by promising a fast review. And if one for-profit IRB concludes that a study is unethical the sponsor can simply take it to another.

This clear and concerning conflict of interest (i.e., for-profit CROs contracting with for-profit IRBs) begs the question: Which U.S. populations typically serve as experimental test subjects in clinical trial research? Do CROs recruit disproportionately from demographic groups that are socially or economically disadvantaged and, if so, which ones?

According to the relevant literature, Phase 1 clinical test subjects in the United States are primarily men drawn from low-income, minority groups with a greater representation of African Americans in the Eastern and Midwestern U.S. and of Hispanics in the Western United States (Fisher and Kalbaugh 2011; Fisher 2015; Grady et al. 2017). For instance, in their study of 180 Phase 1 research participants, Walker et al. (2018), report that 72.8% of test subjects were men and that 60.5% of the total sample were members of a minority group (40.5% African American, 20.0% Hispanic). Of additional interest, Walker et al. report that Phase 1 test subjects are typically repeat volunteers, or "serial participants," with more than half of the sample having completed at least five Phase 1 trials and a quarter having completed *between 11 and 200 studies* (2018). Finally, predicting the likelihood of "serial participation," Walker et al. note that Phase 1 test subjects were largely underemployed or unemployed, with only 16.9% of the sample reporting full-time employment (2018).

In a similar but larger study, Grady et al. (2017), find that 83% of Phase 1 test subjects are men and that over half of the sample self-identified as African American. In addition, Grady et al. observe that over half of the total sample reported annual household incomes of less than $25,000 – placing the majority of Phase 1 trial participants just marginally above the lowest fifth of U.S. income earners. Finally, this study reports that the total unemployment rate among

research participants was three times the national average and that 71.7% of test subjects reported "prior clinical research experience" (Gradey et al. 2017).

Unlike higher paying phase 1 studies, Phase 2 and 3 studies do not always compensate trial participants and when compensation is offered, it is much less than that in Phase 1 trials. This lack of renumeration is due to the fact that Phase 2 and 3 trials are efficacy oriented and therefore tend to attract populations that are desperate for actual and effective medical treatment. Thus, Phase 2 and (in particular) Phase 3 clinical trials tend to recruit a majority of white women (on the pretext that racial and ethnic minorities are less reliable)[14] – most of whom are un- or underinsured – who participate in clinical research in order to receive medical care they otherwise could not afford (Fisher 2009).

According to Cooper and Waldby, clinical trial participation in Phase 2 and 3 studies "is best categorized as a type of 'workfare,' in which wages for clinical trial work are received in kind, in the form of free drugs, health care, and tests (2014: 157)." Although I disagree with the assertion that clinical trial participation constitutes a system of "work for health care," it is clear that the contract research industry disproportionately targets and recruits structurally disadvantaged populations whose bodies serve as the primary source of value creation in pharmaceutical research and development.

Having identified (i) the various phases of clinical trial research, (ii) the organizations and institutions involved in the execution of this research, and (iii) the socio-demographic characteristics of U.S. research participants, I am able to better address the more nuanced aspects

[14] As noted by Fisher (2011), this demographic shift in recruiting is most readily explained by racial-ethnic biases and stereotypes held by physicians. For example, physicians often believe that (i) racial and ethnic minorities are not as dependable, intelligent, or respectful as Whites; (ii) racial and ethnic monitories are (on average) of lower SES and therefore lack the resources and flexibility to be in clinical experiments that require multiple inhouse check-ins; and (iii) racial and ethnic minorities lack access to systems of healthcare and are therefore more likely to have undiagnosed health conditions that could negatively impact study data, etc. (Fisher 2011).

of pharmaceutical production and its incorporation of human bodies as natural capital. In doing this, I account for specific instances in which human beings enact labor on their own species and therefore commodify the body as a unique ecological resource. As I demonstrate below, this resource (like nature) possesses latent value potential that is appropriated and valorized via the application of exploited scientific labor.

**Section III: Bodily Commodification in Pharmaceutical Research and Development**

In the context of clinical trial research, the body's value potential is inherent to the test subject's unique individual physiology, which is exploited as a source of commodifiable biodata. For instance, in these experiments the test subject's in vivo biological processes are manipulated and altered via the introduction of synthetic compounds into the body. Throughout experimentation, as noted above, researchers conduct pharmacodynamic and pharmacokinetic tests on clinical subjects. These tests are not only conducted to determine dose toxicity. More importantly, they allow contract researchers to determine how a drug is absorbed, metabolized, and excreted and how the compound moves through the body, binds with molecules, and collects and is distributed throughout tissues (note: my description of clinical research in this section draws from Shah 2006; Petryna 2009; Goldstein 2012; Cooper and Waldby 2014; Dickenson 2017).

Once adequately observed, the body's cellular, molecular, and metabolic responses are carefully aggregated and quantified for statistical analysis – a process that will ultimately determine the efficacy and thus marketability of a new drug. To obtain these data, however, the body is subjected to rigorous scientific scrutiny during its metabolic transition. Phase 1 studies, for example, are typically conducted in-house at CRO trial sites and last anywhere from three

days to four weeks. During this time, clinical investigators and their staffs regularly dose test subjects and monitor the physiological responses that follow. For instance, the body's temperature, respiratory rate, pulse rate, and blood pressure are routinely observed and recorded. In addition, blood, urine, and stool samples are regularly collected and analyzed to gauge metabolic responses to dosing. Finally, depending on the experimental agent being investigated, researchers may also conduct a number of procedures on experimental subjects. The most common of these procedures are electroencephalograms (brain scans), electrocardiograms (EKGs), MRIs, and CT scans, all of which provide more detailed information (i.e., data) on how the brain, heart, inner organs, and reproductive systems are responding to the experimental compound. In this way, the experimental subject is mined for valuable data and is therefore acted upon as a key site in the production process – the locale from which raw bio-commodities are extracted. Thus, within clinical trial research, the body is literally worked upon – its physiology manipulated, its biochemistry altered – in order to derive commodifiable biodata.

Once extracted from the body these data are subsequently processed, refined, and commodified via market exchange. As addressed at length in the following chapter, this exchange increasingly takes place within a globalized market of pharmaceutical research and development. Within this market, numerous contract research organizations (CROs) produce, package, buy and sell these highly valuable bio-products, which the biopharmaceutical industry depends on in order to demonstrate drug effectiveness. Indeed, the increasing scale and utilization of multinational CROs is exemplified by the industry's expanding market value of $62.7 billion in 2021, $73.3 billion in 2022, and a projected $163.4 billion in 2029 (Fortune Business Insights 2022). Thus, the production, sale, and international transfer of these biodata produce an industry specific bioeconomy – an economy that relies on the exploitation of human

biological materials, information, and processes as a source of commodifiable value. It is, therefore, clear that the pharmaceutical industry acts upon the human body as a unique ecological system which, like nature, contains inherent value potential that is first appropriated and valorized via the application of exploited scientific labor. *Experimental subjects, thus, do not engage in the act of labor, but rather constitute the very objects upon which exploited labor is enacted.*

This assertion garners further credence when considering the production of human therapeutic biologics (henceforth biologics), which as of 2009 accounted for over 40% of pharmaceutical products in late-stage research and development and approximately 30% of newly FDA-approved medications (Kornfield 2013; Trusheim 2010). Unlike traditional or small molecule medications, biologics are *not* derived through chemical synthesis, but through the external engineering of in vivo biological processes. Specifically, second-generation biologics consist of complex proteins, nucleic acids or multiplex combinations of these materials. Given their organic composition, the production of biologics requires the exploitation of living cells – harvested from animals or microorganisms – that are then manipulated via biotechnological intervention. (U.S. FDA 2015; Trusheim 2010).

In short, cells are responsible for the production of all proteins and nucleic acids, the blueprints for which are stored within the genetic structure of a given cell. The production of biologics, therefore, requires that scientists identify, isolate, and extract a designated human gene from the body's cellular makeup and then introduce or "splice" this gene into the genetic structure of a non-human host cell. Upon achieving this transfer, the human gene will subsequently instruct the host cell to produce the desired protein or nucleic acid (Trusheim 2010; Marrow 2004). Thus, the production of biologic medications literally requires *the extraction or*

*harvesting of genetic material from the human body*, which is then inserted into the host cell's genetic structure, thereby coopting or tricking the cell to produce a *human-derived biological product* (Trusheim 2010; Marrow 2004). Here, it is interesting to consider the anthropocentric demarcation that is made between human exploitation of nature (human use of nonhuman cells and genes) and human exploitation of "labor" (human use of human cells and genes). That is, although the production of biologics requires that both human and non-human cells and genetic materials be extracted, manipulated, and altered, one process (according to Cooper and Waldby) is to designate human exploitation of nature while the other is to designate human exploitation of "labor."

Once manufactured, second-generation biologics are then cycled into the system of clinical trial research outlined above, which again relies on the exploitation of human biological material, information, and processes as sources of commodifiable value. In this way, the human body is directly incorporated as a key *site* and *resource* within two pivotal stages of pharmaceutical production and is thus acted upon as a unique form of natural capital. Put differently, the processes of biopharmaceutical production clearly demonstrate that the body is now an object of labor enactment. And as a number of scholars have shown, labor is nothing more than the appropriation of nature – a usurpation and reordering of the natural world's latent value potential (Marx 1976; Foster 1999; Birch and Tyfield 2012; Qadeer 2016; Gunderson 2017). The above findings thus provide strong empirical support for a theoretical reconceptualization of the human body as natural capital and for the critical application of this conceptualization when modes of production entail: (i) the enactment of waged, human labor on its own species, (ii) the targeting, technological manipulation, and extractive valorization of the body's internal, "naturally" occurring materials, capacities, and functions, and (iii) the

consequent production and commercialization of human derived biocommodities that are bought and sold as any other goods derived from nature.

Scholars, in general, who oppose this position will surely point to the wages or "compensation" that experimental subjects receive for their "services" and conclude that the processes I have outlined above constitute a mere form of "experimental" or "embodied labor" and ergo require no theoretical adaptation. In responding to this critique, it is first useful to cite the official position of the U.S. Department of Labor and the non-precedential position of the U.S. Internal Revenue Service, which hold that human test subjects (i) are not employees of the firm conducting research, (ii) do not receive "wages" for income tax with-holding or federal employment tax purposes, and (iii) do not have rights to workers' compensation or unemployment benefits (U.S. Department of Labor 1996: viii-ix). In lieu of being defined as employees who engage in traditional forms of labor, these agencies understand clinical trial participants to constitute "independent contractors who do not provide products as such but, rather 'samples of blood and [access to] normal bodily functions'" (U.S. Department of Labor 1996: viii-ix; Cooper and Waldby 2014: 146). U.S. labor law and federal tax policy thus speak to the ambiguous status of human test subjects in clinical trial research and the degree to which the bodily contributions of experimental subjects' deviate from any form of traditionally understood labor.

Of course, bioeconomy scholars will argue that this failure to recognize "in vivo labor" as a legitimate form of labor is exactly the problem. To reiterate the position of Copper and Waldby:

> In the United States alone, the epicenter of the global pharmaceutical industry, growing numbers of contingent workers engage in high-risk Phase 1 clinical trial work in exchange for money, while uninsured patients may take part in clinical trials in exchange for medication that would otherwise be unaffordable. With the expansion of assisted

> reproductive technologies, the sale of tissues such as eggs and sperm or reproductive services such as gestational surrogacy has also emerged as a flourishing labor market, one that is highly stratified along lines of class and race. We refer to these forms of work as *clinical labor*. The terminology is novel because, generally speaking, tissue donation and research participation are not understood or analyzed as forms of work (2014: 7).

While I certainly do not wish to detract from the risk potential that is inherent to in-human clinical trial *experimentation*, risk is not constitutive of labor. I have, therefore, suggested that any steps toward defining the bodily contributions of clinical trial test subjects as labor necessitate that bioeconomy scholars convincingly establish one of two points. First, they must establish that clinical trial participants actively and consciously preform labor on their body's own reproductive and generative capacities (i.e., act upon themselves as objects) and that this labor is actually productive of the bodily good, commodity or service that they exchange on the market. Or, secondly, they must establish that clinical trial participants engage in some meaningful form of traditionally understood labor during the course of experimentation and that this labor is exploited and commodified as such. In their most direct and succinct attempt to satisfy these criteria, Cooper and Waldby assert that:

> Human subject experimentation can be described as a form of transformative exposure, where the recruit is called upon to both experience the sometimes unpredictable metabolic effects of pharmaceutical compounds and perform a number of second-order tasks, such as adhering to strict regime of diet and drug administration, self-monitoring, and recording of information….Trial participants undergo a strict washout period prior to the commencement of trials, during which they are unable to consume a designated range of other drugs. Once a trial has begun, they must adhere to specific diet, sleep regimen, and other protocols and are required to carefully monitor and record the effects of drug compounds on their body. Hooked up to machines, monitored, scanned, and examined, the clinical trial recruit undergoes a process of intensive biochemical exposure involving greater or less degrees of risk, discomfort, and endurance. Unlike the industrial laborer, he or she participates in a labor of ingestion and metabolic self-transformation rather than expending energy in transforming the physical object. One self-identified professional "guinea pig" has described this as "pissing and bleeding work" (2014: 135).

To further underscore the laborious nature of clinical trial experiments, Cooper and Waldby designate what are ubiquitously termed "inhouse" or "inpatient" studies as "intensive

periods of confinement," while also highlighting outlier instances of experimentation that "*might require*" several invasive procedures (2014: 136). For example, "A randomized placebo-controlled trial of an experimental agent for gastroesophageal reflux might require a three-day admission, an endoscopy, a stomach biopsy, and three or four nasogastric tube insertions" (Cooper and Waldby 2014: 135).

While such extreme procedures in the context of experimentation cannot be entirely discounted, they are just that, *extreme* (anything but generalizable) and when necessitated by serious cases of disease such as gastroesophageal reflux disease, such procedures would also be performed in the context of standard medical diagnoses and treatment of patients who are already sick (Mayo Clinic 2022). Nevertheless, Cooper and Walby's audience is left with a stark, and arguably inaccurate, rendering of clinical trial participants as being forced to endure thirty day stretches of self-restraint and bodily purification (washout period), prior to experiencing long stints of self-confinement and restrictive dieting in which they must engage in a constant state of self-surveillance and self-recorded data collection, while also being subjected to numerous, invasive medical procedures. Although qualitative research directed at the lives and experiences of trial participants is limited, this portrayal is not consistently reflected in the broader literature. Indeed, one would otherwise be left to question – given that the vast majority of experimental subjects are "serial participants" or "professional lab rats" – how the test subject's body (and mind) is able to sustain repeat exposure to clinical trials experimentation over an extended period of years. This, in fact, begs the question, how do research subjects, themselves, understand the processes of clinical experimentation and their positions within the larger clinical trials industry?

To derive a better understanding of such questions, I conducted content analysis of a popular online information and discussion portal (*Just Another Lab Rat* or *JALR*) that is often

used by members of the professional clinical trials community. By way of this analysis, I was able to assess how the interpersonal communications of test subjects reflect their collective thoughts, ideas, and understandings of the broader clinical research experience. To expedite the assessment of these thoughts, ideas, and understandings, dozens of portal pages were scanned for titles and conversations of seeming relevance. Upon identifying any such relevant postings, content was dated and recorded for sequent analysis. In qualifying this analysis, it should be noted that the majority of "lab rat" postings were solely informational – pertaining only to advertisements for upcoming clinical trials, screening requirements for admission, travel and lodging recommendations, etc. I, therefore, when required, supplement my analysis with secondary research findings and interviews; I also, in one instance, rely on a *Reddit* discussion thread that was posted to *JALR* by a longtime member.

*The "Labor" of Mandatory Washouts*

To reiterate, the purpose of clinical trial research is to measure the effects of an experimental agent in the body – how the body absorbs, metabolizes, and excretes the compound – and to determine its safety and efficacy in treating a specified medical condition. Researchers, therefore, wish to minimize the number of chemical variables in the body so as to accurately determine if the observed effects are actually attributable to the experimental agent as opposed to the latent effects of another medication or an interaction between two or more medications. Hence, the requirement of mandatory "washout periods" – i.e. the often cited, self-directed labor that test subjects supposedly enact on their own bodies – that clinical trial participants undergo prior to admission into clinical trials, which is designed to ensure that any background medications have been washed from their bodily systems.

With regard to these mandatory washouts, Walker et al. (2018: 107) observe that: "Despite much discussion about, and some movement toward, co-ordination across study sites to keep track of serial participants, the 30-day break between studies is loosely enforced and largely reliant on subject self-reporting." This point is made clear in one of several interviews in which clinical test subjects describe how they organize trial participation so as to avoid detection in back-to-back enrollments:

> They're one of the ones [research sites] that has this kind of tracker thing where they coordinate with all the other facilities that are in this network so that they can know if you've done a study at one of these other facilities in the network. But the thing is [Clinic A] and [Clinic B] aren't in that network, so you can do a [Clinic A], and then the next day hop into [Clinic C], and [Clinic C] won't know (Walker et al. 2018: 107)

The "tracking network" referenced above is a commercial participant database known as Verified Clinical Trials (VCT), which is designed to aid CROs in cracking down on serial participants who spend a given year "jumping" from one research site to another without observing the thirty day washout period. A constant theme that emerged during my analysis of *JALR* was the obstacle of VCT. Lab rats would often express anger and resentment towards CROs that bought and implemented the system and would advise their peers as to which research sites were using the database so as to avoid detection:

Lab rat 1: Parexel just got beamed up on VCT!

Lab rat 2: I thought it had been that way for a while?

Lab rat 3: VCT is scum!

Lab rat 4: [Parexel's] facilities are NOT the only facilities doing this and it is very important to share this info, so other Rats can make choices with all the info…Can we please expand the boards to include more facilities so we can share this info as a public service? (*JALR* 2016).

In a similar posting, one Lab Rat who self-identifies as having "been out of the [clinical trials] game for a while" inquires as to where the majority of trials are taking place and is warned to make plans around VCT:

> Middle of Texas is good but lot of travel times. KC area yes also Southern Cal or NY/NJ area... but some VCT there of course...so do your research on that so [you're] not caught in waiting long periods to get in another [study]. Could also consider southern Wisconsin/norther Illinois. Only one clinic VCTs (spaulding) of the 3 big ones (*JALR* 2019).

Moreover, as noted by Walker et al (2018), less than half of all CROs in the United States currently use the VCT system, which renders the CRO apparatus (as a whole) largely powerless to enforce mandatory washout times. Thus, disregard for mandatory washouts was the frequently observed case on *JALR*:

> Kansas/Missouri is probably [the] best location for studies, along with the low cost of living. 2 major study clinics (PPD, Quintiles), and 2 smaller but decent, can't remember the names. I got a $6,000 with all overnights and no outpatients, then 3 days after checking out, [I] managed another $5,000 at the other place! (2017).

Scholars who advocate for the concept of "clinical labor," often portray mandatory washouts as a period of bodily detoxification – a form of arduous, self-directed labor that clinical test subjects must endure before enrolling in research. "Washing out" is therefore construed as a period of self-enacted labor performance that is productive of the body's reproductive/generative capacities – *a process of making the body ready* for experimentation and subsequent data production (Cooper and Waldby 2014). As I (and others) have shown, however, mandatory washouts are little more than lip service to the credibility of an incredulous research industry that is wholly dependent on the bodily value of serial research participants who actively disregard this requirement (Walker et al. 2018; Grady 2017; Elliott 2014; Zhu et al. 2011).

In addition to commonly ignoring "mandatory" washouts, one can rightfully inquire as to how the act of *not consuming* a designated range of drugs, in itself, is constitutive of labor?

These periods of time are not commissioned or compensated for in any way. Moreover, Phase 1 clinical test subjects are overwhelming healthy subjects and therefore do not (typically) require any such medications. Certainly, Phase 1 subjects who are serial participants, jumping from one trial to another as a primary source of income, are officially required to come off an experimental agent before ingesting another, but is the in vivo process of metabolizing a chemical compound now productive labor? Phase 2 and 3 subjects – as Cooper and Waldby (2014) make clear – are most often ill, uninsured, and *seeking treatment* and hence (typically) lack access to medications that need to be "washed out." It would seem, therefore, that in the context of clinical trial experimentation, the act *of consuming* experimental medications is to be understood as an act of labor while the act of *not consuming* approved medications is also to be understood as an act of labor.

*The "labor" of Clinical Labor*

Clinical trial participants are overwhelmingly those who suffer from structural inequalities – the socially marginalized, the uneducated, the unemployed, the uninsured, the sick – that limit their participation in the formal labor market (Sunder Rajan 2006; Shah 2006; Petryna 2009; Prasad 2009; Goldstein 2012). Upon turning to experimentation (either for compensation or for medical treatment), it is true that some test subjects are occasionally required to undergo unpleasant medical procedures and to observe restrictive diets, experiences that are mostly unique to specific studies concerned with disorders of the gastrointestinal tract (Elliott 2007). It is also true that test subjects are encouraged to report any negative potential side effects to investigational staff. However, the claim that this reporting constitutes a system of

rigid self-surveillance and self-recorded data collection (i.e., labor) is dubious at best, a point made clear by David Gray, creator of the *JALR* portal:

> Even healthy people with no medical problems can have side-effects, even severe. This is of course why clinical studies are conducted. Bottom line, don't hesitate to tell a clinic staff member if you are feeling anything but normal. You won't get in trouble for reporting side-effects!

Here, one observes the standard expectation of experimental subjects with regard to the reporting of potential side effects, which is simply that one should inform a clinical staff member if he or she is not feeling well. Clearly, such a post would not be necessary if the standard and normalized expectation was that test subjects "carefully self-monitor and record the effects of drug compounds on their bodies." It should also be noted that a ubiquitous feature of the *JALR* portal is clinical trial advertising, which typically stipulates the requirements associated with each study. In analyzing approximately two dozen of these ads, I came across only one outpatient investigation (on female urinary incontinence) that required participants to keep and report a log of medical events (i.e., episodes of bladder incontinence).

The question then becomes, what is the "labor" of clinical labor in general? Even in experiments that require invasive medical procedures, do such procedures translate into labor performed by the test subject? Or, does the entire (modern) clinical research apparatus, including the invasive procedures that grant access to the body's in vivo state, more accurately represent a deepening of the bioeconomy and a more intensive opening up of human life (and human ecology) to novel forms of bodily commodification? In order to provide a comprehensive answer to the first of these questions, I briefly consider this deepening of the clinical research apparatus and how experimental subjects commonly respond to it and the effects of what it yields – i.e., value taken from the body as opposed to the exploitation of labor power.

Capsule endoscopy (commonly cited by Cooper and Waldby) is itself a new technology that received FDA approval in 2001. Its occasional, condition-specific use in clinical research thus represents a relatively novel and unique deepening of the bioeconomy and its opening up of human ecology for the generation of value. This deepening, however, goes far beyond the capacity of researchers to record and observe live images of the body's internal systems, it extends even into the genetic makeup of potential experimental subjects, allowing CROs to screen out those deemed genetically impotent in trial execution.

> Lab Rat 1: Has anyone had to do a 2nd screen for a genome type, like one study told me I'd need to [do]? If so, what can you tell me about it? The recruiter couldn't tell me any more than that they needed to see if I'd be the correct genome type.
>
> I seem to remember someone on here going on an epic rant about not selling your genome type. Would this be similar, a least possibly? Or do they just check your genome and then destroy/discard whatever they got? Thanks, I really need to understand what is going on with this and make a decision soon (*JALR* 2017).
>
> Lab Rat 2: They are trying to see if you are genetically unable to process the drug. Some gene types just pass the meds through your system without absorbing them so if that is u they cant study how the drug is processed. Makes sense, they do not [want] to pay u if they dont get usable data (*JALR* 2017).

Here one observes not only anxiety about genetic screening and the potential of study exclusion based on these screenings, but also concern over the body's genetic information (i.e., biodata) being taken without permission or compensation. One also observes a degree of resigned acceptance with regard to the exploitation of experimental bodies (and persons) as mere sources of data collection and capitulation to this station in life. This passive acceptance is grounded in an unpleasant reality that is firsthand knowledge to experienced lab rates: "The main business of clinical research is not enhancing or saving lives but acquiring stuff: data. It is an industry not a social service. The people who sponsor and direct clinical trials do it for the data, not to please

patients or to help bolster ailing heath facilities, although they may point to these side effects to justify their activities" (Shah 2006: 176). Indeed, Veteran "lab rats" or "rats" as they would often self-identify, commonly expressed resentment towards this data industry and the cumulative effects that years of experimentation wrought on their bodies.

> It is the law of unintended consequences. More people over all are making studies. And there are reasons for that…Collateral upside, verification…may result in long term stability [for you "rookies"]. It means that you have to keep your resume current which means you don't wake up one morning and are totally unemployable because you prostituted your self out to Big pharma.
>
> You may think you are trying to fix a bad ECG [experimental subjects are also used to test medical devices] but you are really stuck with [a] jacked up heart! Yes, [there're] many sad stories of individuals no longer able to do studies. The subject becomes the patient after drug tails at the bar of EZ Study Money! If the real rats did not make it through the phase 0 trial what makes you think you are so special? We are the experiment as they [the rats] are expected to outlast our species.
>
> Stop telling people you are going back to school after the 21st study! Do it. Stop telling people you are going to be rich. Crawl out from your 6 feet under study rotation plan! (*JALR* 2018).

This professional lab rat delivers a dire warning to her younger peers enthralled with the prospect of "easy study money." In decrying the financial obstacle of VCT, she alludes to the instability inherent to the clinical trials "game" and to the long-term health consequences of "prostituting" one's body to the pharmaceutical industry. Having been called to test the accuracy of an EKG machine, she depicts a moment of horror and regret – the machine has not delivered a faulty reading; rather, after years of experimentation, the test subjects' heart has been damaged. The veteran lab rat will now be ineligible for Phase 1 studies. What will she do? How will she live? She has not worked in years, she has no resume, she is not employable. *She was the experiment* – a person who spent years having her in vivo biological processes manipulated and altered, a person reduced to the status of an observable thing, a series of observable metabolic events, *data*.

What, then, attracts clinical test subjects to this "6 feet under rotation" of clinical trial research and do they understand themselves as performing labor?

Many CRO trial sites do their best to attract and retain test subjects by providing a number of amenities such as video games, pool tables, cable television, wireless Internet access, and free food. As observed by Elliott (2007):

> If all goes well, a guinea pig can get paid to spend a week watching "The Lord of the Rings" and playing Halo with his friends, in exchange for wearing a hep-lock catheter on one arm and eating institutional food. Nathaniel Miller…was once paid fifteen hundred dollars in exchange for three days and two G.I. endoscopies at Temple University, where he was given a private room with a television. "It was like a hotel," he says, "except that twice they came in and stuck a tube down my nose."
>
> They treat you well. You watch TV. They have DVD, CD, PlayStation, Xbox. They order out meals three, four times a week. Chinese food, cheese-steak hoagies, Buffalo wings, pizza. They gave me a birthday party a few years ago. I had to cut the cake. They sang me 'Happy Birthday,' and they were on-key (Elliott 2014).

Indeed, the perception and experience of clinical trial research as a source of "easy money" devoid of "real work" was a consistent theme that emerged during my analysis of *JALR*. To convey these understandings, I use the following (2013) Reddit thread, which a longtime *JALR* member posted to the portal (presumably, as the principal participant below). I use this discussion thread because it involves direct questions that provide direct insight into the supposed "labor" of clinical trial research (typos are original to thread).

Lab Rat 1: Title: "I'm a paid medical research subject, ask me anything!"

I do in-patient medical studies, where I stay at a research clinic for any wear between three days to three weeks and take an investigational drug before it is approved by the FDA and given to the general public. One of my checks for proof: http://imgur.com/rTqc5

Question: Do you do it purely for the money or do you get some sort of sick kicks out of it?

Lab Rat 1: Primarily I do it for the money, but I legitimately enjoy coming in, it's a bit of a vacation for me.

Question: WHAT DO DEY DOO TA YA?

Lab Rat 1: I'm a medical tester because its a really [great] way to make a lot of money fast…Typically I'll dose in the morning an[d] they'll take my vital signs periodically throughout the day. Sometimes I'll have electrocardiography throughout the day, along with various blood draws.

Question: What is the weirdest thing/side effect that has happened to you? And from what?

Lab Rat 1: I haven't really had any weird side effects, the study I'm in now the drug has made it really hard to pee. I'll feel like [I'm] going to burst and once I get to the bathroom I push and push but all I get [is] a weak trickle. It's more frustrating than anything else. I've had studies that turn my shit into powder. There aren't really too many weird side effects that I'm aware of, it's generally just the kind of stuff you'd read off the side of a pill bottle (dizziness, nausea, etc).

Question: I heard that it is not worth it due to the hours to pay ratio. In addition, if you experience any irreparable damage you're basically screwed…How do the people who care for you feel about it? How do you justify the risk to money ratio?

Lab Rat 1: I worked it out once and at the clinic I frequent we make about minimum wage if you break it down. Keep in mind that includes sleeping, and the rest of the time your just siting around watching tv playing games etc. I personally select studies that have been done multiple times already, and I stay away from anything that sounds potentially dangerous. The way I see it is, I'm in a hospital being constantly monitored by doctors. This is the safest place for me to be. It's more likely that I'll be killed getting robbed behind a counter somewhere that'll pay me minimum wage, where I'll have a boss that'll treat me like shit an ill have to actually work. Plus, I can't work 24 hours a day there. I make more money in studies in two weeks than I can in three months elsewhere. So if you are selective there really is no risk. As far as medical costs, if anything comes up while your in [the] study it will be taken care of at no cost to you.

Lab Rat 2: The risk is pretty low. All of the studies are approved by institutional review boards, and there are on-call doctors in case anything bad happens…Pay is very good depending on what the study is. I got $1400 for a 40-hour admission simply because an A-line was involved; I don't mind A-lines, especially because local anesthetic is involved, so I got paid $35 an hour, 16 or so of which I was sleeping and the rest of the time I watched TV and listened to music.

The ones that pay poorly are generally the psych ones. They involve no drug or procedure and typically only last 2-4 hours…Also note, "procedure" is not as bad as it sounds. Often times the only "procedures" I undergo are things like MRI's or CT scans, and they're done to validate new imaging techniques, etc. Totally non-invasive, you just lay there and wait. These still involve blood draws most of the time, though, but just IV.

Question: I wouldn't mind doing this, is it hard to get into it? Any special requirements? Also how did you get started?...can you actually LIVE off doing this? or is it just good for some extra money?

Lab Rat 1: If you're willing to travel and hit studies in other states its very easy to live off the money. In the three ish years I've been doing studies I haven't worked a day, and live very comfortably. I met someone who made 50,000 dollars last year, before taxes.

Lab Rat 2: You can scrape a living out of it. I'm having a rare good year, i'll make $19k for the year if my next study goes ok. So it beats mcdonalds but most real jobs will pay more. there are rumors of pros who make $50K but i haven't met them. the real money is being the doc who runs the study.

Here, one observes how two experienced test subjects understand their participation in clinical trial research. Nowhere in this content is there any articulation of or even the slightest indication that either test subject understands their participation in clinical research to be constitutive of labor. In contrast, clinical research is constructed as an easy and financially viable alternative to "real work" at a "real job," a period of vacation during which one is paid 24 hours a day – while sleeping, while eating, while watching television.

Interestingly, one also observes a rather cavalier disregard for the potentially harmful long-term health consequences of serial participation – consequences that are often communicated by veteran test subjects. Indeed, both the short and long-term health risks associated with clinical trial research are undeniable and concerning. Advocates for the concept of clinical or embodied labor often point to this systematic risk-exposure as yet another constitutive aspect of the labor performed by test subjects – i.e., clinical labor *is* "risk-bearing labor." As posted by Cooper and Waldby (2014: 137):

> Clinical trial participants are engaged in a peculiar kind of risk-bearing labor…While many kinds of labor are hazardous or unprotected by workers' compensation, very few derive their intrinsic value from the worker's ability to bear bodily risk. But this is the case for participants in a drug study, *who truly labor only inasmuch as they subject themselves to the possibility of metabolic transformation* (my emphasis).

However, risk is not constitutive of labor and the ability to bear risk is not the primary productive force in the clinical research industry. Rather, as held by innovation economics and patent law, it is the waged and exploited labor of scientists and medical professionals, consciously enacted *on* and *within* the bodies of experimental subjects, that is productive of human-derived biological value. Because the production of human-derived biocommodities requires that waged human labor be performed on its own species, the body is transformed into that which is ecological – its internal, naturally occurring materials, capacities, and functions incorporated directly into the production process. This system of production, as the previous *JALR* passages make clear, is in no way dependent on the labor power of experimental test subjects but wholly dependent on the in vivo biological processes that occur *within* test subjects. These processes, as previously addressed, do real and valuable work – just as ecological systems do real and valuable work – but this internal, naturally occurring *work* is not constitutive of *labor*, for labor presupposes a conscious relationship to that which is produced (Marx 1976; Helmreich 2008; Palsson 2009; Birch and Tyfield 2012; Cardao-Pito 2016).

The negative health outcomes associated with and often communicated by veteran test subjects, therefore, do not accurately translate into bodily injury sustained during the process of "labor," as argued by Cooper and Waldby (2014). Rather, the cumulative effects of experimentation result from the exploitative process of commodifying human bodies as mere ecological goods. In this process, the body's internal ecology is transformed into a site of production that is made equally as vulnerable to patterns of overuse, contamination, and

disequilibrium as is the "natural" environment itself. Indeed, this reality finds voice in the words of veteran test subjects who routinely refer to themselves as animals ("rats") and warn of the long-term physiological effects of being commodified as such: "If the real rats didn't survive Phase 0, what makes you think you'll survive Phase 1?" (*JALR* 2018).

**Conclusion**

In addition to providing a working definition of the body's ecological commodification, this chapter has demonstrated several key empirical points. First, the body (like nature) possesses inherent value potential. Second, the body (like nature) can be an object of labor enactment. Third, the body's value potential (like that possessed by nature) can be extracted and commodified. Fourth, once commodified human bio-products enter a globalized market in which they are bought and sold like any other good derived from nature (the last of these points will be further established in chapter 5). These findings thus clearly differentiate between processes of bodily commodification as labor and bodily commodification as natural capital. As such, they provide broad empirical support for a theoretical reconceptualization of the human body as natural capital and for the critical application of this conceptualization when modes of production require: (i) the enactment of waged, human labor on its own species, (ii) the targeting, technological manipulation, and extractive valorization of the body's internal, "naturally" occurring materials, capacities, and functions, and (iii) the consequent production and commercialization of human derived biocommodities that are bought and sold as any other goods derived from nature.

In the following chapter I further develop and substantiate this claim by testing 9 of the 10 theoretical predictions outlined in chapter 3. In doing this, I provide additional evidence that

allows me to more thoroughly adjudicate between processes of bodily commodification as labor and bodily commodification as natural capital. To test these predictions, I present the first two of my three case studies. In the first of these cases, I trace the developmental history of the U.S. pharmaceutical industry, with particular attention paid to how its approach to domestic clinical trial research has evolved since the early 1970s. In the second case, I focus analytical attention on the practice of clinical trial outsourcing to underdeveloped nations and the multibillion-dollar contract research industry that has emerged in its wake. My findings demonstrate that within the biopharmaceutical industry, humans are increasingly being used as natural capital. They also yield numerous insights into the bioeconomy's disproportionate exploitation of structurally disadvantaged populations and the unequal ecological exchange relations that allow flows of bodily value to be extracted from the periphery to the core.

# Chapter 5

## PRISON EXPERIMENTATION, THE DRUG PIPELINE EXPLOSION, AND FDA DEREGULAITON

As noted in Chapter 3, case study methodologies are ideal for evaluating the potential value or inadequacies of existing theoretical models in that they facilitate intimate observation of complex causal processes and outcomes. This, in turn, allows researchers to compare these empirical processes and outcomes to those that are theoretically hypothesized (Steinmetz 2004. Collier 2011; Bonds 2011; Yin 2009; George and Bennett 2005). Case study approaches are thus ideal for the development and/or revision of existing theoretical models.

This chapter is divided into two empirical sections in which I present two of the three case studies outlined in Chapter 3. The first of these sections, which includes two subsections, will examine the historical evolution of U.S. clinical trial experimentation since the early 1970s. In exploring this case, I test the theoretical arguments of David Harvey and James O'Connor as well as the overall applicability of their theoretical frames to processes of bodily commodification under the life science industries. The goal of section I is, therefore, to provide additional evidence that will aid me in determining (i) whether the pharmaceutical industry exploits the human body as natural capital or as a mere form of experimental labor, (ii) whether or not the industry has experienced crises – both of overaccumulation and underproduction – that are unique to processes of bodily commodification as natural capital, and (iii) whether or not these crises have been circumvented via the industry's use of spatial fixes – fixes that have relied on the incorporation of previously untapped body supplies as sources of commodifiable value.

In exploring the above case, I examine how changing ethical standards in U.S. medical research functioned to block the pharmaceutical industry's exploitation of prison populations in

clinical trial research and how this shortage of experimental bodies was overcome. In addition, this case examines the drug pipeline explosion of the 1980s, how this phenomenon deprived the industry of its ability to develop and market a backlog of pipeline drugs, and how this obstacle was overcome via the International Conference on Harmonization (ICH) – an agreement that ultimately allowed pharmaceutical companies to intensify their transnational hunt for untapped body supplies (subsection I). Finally, this case examines key provisions within the FDA Modernization Act of 1997, how these provisions intensified processes of U.S. mass-medicalization, which – from a drug testing perspective –dramatically reduced the industry's access to test-worthy body supplies within its own borders, and how the industry was able to overcome this crisis by initiating the first truly globalized regime of clinical trial experimentation (subsection II).

Section II of this chapter focuses on the practice of clinical trial outsourcing to underdeveloped nations and the multibillion-dollar contract research industry that has emerged in its wake. A key goal of this section is to test the overall applicability of ecological unequal exchange theory to processes of uneven bodily (i.e., ecological) value extraction between more and less developed nations. This theory, as previously addressed, posits that unequal power and trade arrangements between the global North and South allow the former to benefit from (i) the uneven extraction of natural resource wealth from the periphery and (ii) the exportation of environmentally harmful industries to the South, which in turn leaves periphery nations to contend with the negative externalities of production. In accordance with these theoretical expectations, I examine (i) the production strategies of contract research organizations (CROs), which specialize in locating impoverished, and therefore "clean," body supplies from which biological value is extracted via the outsourcing of experimental research, (ii) the various

international agreements[15] that standardize a profound degree of ethical variability in the execution of these outsourced experiments, thereby allowing the core to benefit from an uneven extraction of bodily (i.e. ecological) value from the periphery, (iii) the mechanisms by which this ethical variability is exploited by the pharmaceutical industry, and (iv) the actual unequal ecological exchanges that result from this variability.

In addition – and to further adjudicate between processes of bodily commodification as labor and bodily commodification as natural capital – I conduct content analyses of the various ways that CROs market their body supplies to pharmaceutical firms. Specifically, I ask whether these entities market the human body in such a way as to denote its use as labor or natural capital? If the industry does indeed exploit these bodies as natural resources, then CRO advertisements will not attempt to market experimental subjects as sources of labor. For example, these ads will not showcase increasing levels of human capital, low wages, and/or pliant workforces. In contrast, clinical trial body supplies will likely be advertised as diseased and treatment naïve and thus, from a drug testing standpoint, as pristine and untapped ecological resources from which commodifiable value can be extracted.

**Section I: A Brief history of U.S.-Based Medical Research**

Historically, experimental subjects in U.S. state-sponsored medical research were routinely and disproportionally recruited from socially vulnerable populations (e.g., racial minorities, children, mentally disabled persons, incarcerated persons, etc.) who often participated in research without full knowledge of their involvement, compensation or willing consent

[15] I examine specific regulatory provisions within the International Conference on Harmonization and Good Clinical Practice guidelines (ICH-GCP), which function to synchronize regulatory standards between more and less developed nations, thereby making international research data more easily transferable to the FDA and other regulatory agencies in leading pharmaceutical markets.

(Harkness 1996; Guerrini 2003; Shah 2006; Petryna 2009; Cooper and Waldby 2014). One of many such examples includes the Tuskegee syphilis experiment, lasting from 1932 to 1972, in which scientists from the U.S. Public Health Service conducted non-therapeutic research on 399 African American males with late stage syphilis. Throughout this experiment, test subjects – consisting solely of impoverished and mostly illiterate sharecroppers – were led to believe they were receiving "free treatment" for their condition. In reality, however, standard treatment was withheld so that scientists could monitor the disease's "natural course" and its effects on the human body (Shah 2006; Petryna 2009). In the late 1940's, penicillin was proven effective in curing syphilis. Yet, in order to protect the integrity of their data, scientists again denied standard treatment and petitioned local clinicians and military draft boards to follow suit (Humphrey 2003; Shah 2006). Although the numbers are disputed, up to 100 subjects are estimated to have died as a direct consequence of the untreated disease (Shah 2006).

From 1956 to 1970, state-funded researchers infected children at the Willowbrook State School, a state-run institution for the mentally disabled, with the hepatitis virus (Petryna 2009). As Shah (2006: 73) recounts, the "…team obtained hepatitis-laden feces, centrifuged, heated, and treated it with antibiotics, and then mixed it with five parts of chocolate milk to one part of feces. They fed the contaminated concoction to uninfected children and tracked their deterioration." In addition, from 1944 to 1960, government scientists secretly dispersed radioactive contaminants over predominantly Native American and Hispanic communities in order to determine the material's effect on human health (Shah 2006). And from 1952 to 1960, both state- and industry-sponsored researchers tested experimental polio vaccines on mentally handicapped children at the Polk State School in Pennsylvania; official permission to conduct these trials was granted by state officials (Guerrini 2003).

While the pharmaceutical industry engaged in similar forms of experimentation, its primary source of human bodies was the bourgeoning U.S. prison system (Harkness 1996). In fact, "[a]n estimated 90 percent of drugs licensed in the United States prior to the 1970s were first tested on prison populations" (Petryna 2009: 23). These populations served as ideal test subjects in that they lacked many of the rights and privileges afforded to the average citizen. As such they were especially attractive in "liability testing" and Phase 1 toxicity studies, which as previously addressed, allow for a more intensive examination of the adverse side effects associated with a given compound (Petryna 2005, 2009). In addition, prison systems provided a more ideal environment in which to observe, monitor, and control experimental subjects, a fact that generated more statistically valuable data in demonstrating drug efficacy. Finally, use of incarcerated populations reduced the industry's overall cost of production. That is, inmates were most often denied monetary compensation for the value extracted from their bodies and were instead offered "nominal rewards" such as reprieves from manual labor, more generous food rations, and greater leisure time (Petryna 2009). These factors, in short, made prisoners "…fine experimental material and much cheaper than [using] chimpanzees" in clinical trials (Mitford 1973a: 64).

In their attempts to capitalize on these conditions, pharmaceutical firms regularly competed for exclusive access to large prison systems, often constructing state-of-the-art research facilities adjacent to or nearby prisons (Petryna 2009; Shah 2006). In instances where such brazen modes of recruitment and experimentation met resistance, the industry used more covert methods to secure its body supply. As documented by Mitford (1973a), drug companies would often enlist the services of private physicians who – working in collaboration with doctors within the correctional facility – could more easily obtain access to prisoners. Prison wardens,

facility physicians, and correctional officers functioned as brokers in the selection process, and all were paid directly by pharmaceutical firms, while contracts were kept verbal and solidified through handshakes (Mitford 1973a, 1973b). Indeed, this period of prison-based experimentation marked the golden age of post-WWII industry-sponsored clinical research. Beginning in the early 1970s, however, this mode of experimentation fell under increasing public scrutiny.

In 1972, for instance, the *New York Times* reported on the Tuskegee Study of Untreated Syphilis (Shah 2006). Similar disclosures of many other clinical trial abuses soon followed, creating a firestorm of public and scientific outrage. This outrage culminated in a general societal consensus that the federal government should regulate the medical research industry just as it regulated factories, mines, and traditional industry's use of ecological goods (Shah 2006). Due to this mounting political pressure, Congress passed the National Research Act of 1974. This Act required the establishment of independent oversight committees – now known as institutional review boards, or IRBs – to determine the ethics of human experimentation. It also called for the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Petryna 2009; Shah 2006).

Congress charged this commission with the task of identifying and developing the basic ethical principles and guidelines that would inform future scientific experiments involving human subjects (Petryna 2009). However, just prior to the commission's recommendations being made public, the Bureau of Prisons – in an apparent attempt to avoid future liability and to demonstrate its own capacity to self-regulate – severely restricted the use of prisoners in clinical trial research (Toulmin 1987; Petryna 2009). Directly after this, in 1979, the commission issued what came to be known as *The Belmont Report*, which set forth a host of new ethical and procedural recommendations that revolved around issues of justice, beneficence, self-

determination, informed consent, privacy protections, and the mandatory use of IRBs. In 1980 the Department of Health and Human Services along with the Food and Drug Administration (FDA) issued regulations based on these recommendations, which effectively banned, or otherwise highly restricted, the use of prisoners in clinical trial experiments (Petryna 2009). As a result of these policy shifts, the pharmaceutical industry lost almost its entire base of human test subjects and was therefore deprived of the ability to reinvest profits in the development and subsequent marketing of new chemical compounds (Shah 2006; Petryna 2007; Prasad 2009). Thus, and as expected by Harvey (prediction 1), the industry was forced to contend with a crisis of overaccumulation that threatened its economic reproduction and long-term viability as a leading sector in the national economy.

In response to this government-induced crisis, the industry intensified domestic recruiting efforts among the general population and also began to carry out a small percentage of its experimental trials in several Western European nations (Shah 2006; Petryna 2009; 2011). In both the U.S. and Europe, these trials were primarily conducted within academic research centers and teaching hospitals, which provided sufficient access to experimental subjects while also ensuring that ethical standards were being met (Relman and Angell 2002; Petryna 2009). Consistent with Harvey's expectation, this geographic expansion – from U.S. prison systems into mainstream U.S. and Western European society – can be analyzed as the industry's first spatial fix, which was pursued in order to resolve the crisis of overaccumulation caused by changing ethical standards in U.S. medical research. This finding is consistent with Harvey's prediction that in response to an accumulation crisis the industry will pursue a spatial fix in which previously unexploited populations are incorporated into new rounds of pharmaceutical production (prediction 2). This fix adequately satisfied the industry's demand for experimental

bodies throughout the early 1980s. In subsequent years, however, the industry would experience two phases of rapid economic expansion that produced two additional accumulation crises.

In the following two subsections I address the legislative origins of these phases of economic expansion and how their realization forced the industry to contend with a series of unanticipated *ecological* (i.e., bodily) limits that would ultimately intensify the practice of clinical trial outsourcing. I further show how efforts to resolve these crises drove the practice of clinical trial outsourcing to underdeveloped nations. In the first of these subsections, I discuss the 1980s "drug pipeline explosion," which by the end of the decade had depleted the industry's access to newly acquired pools of experimental bodies, thereby producing a second accumulation crisis. I further show how measures to circumvent this crisis resulted in the transnational harmonization of clinical trial research standards, which allowed the industry to intensify its hunt for international body supplies.

*The Pipeline Explosion – A Spatial Fix Exhausted*

In the 1980s and 1990s the pharmaceutical industry enjoyed a period of rapid economic growth that was realized in large part via the ratification of two industry-friendly legislative Acts – the 1980 University and Small Business Patent Procedures Act (the Bayh-Dole Act) and the 1984 Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act) (Jorgensen 2013; Petryna 2009; Shah 2006). The Bayh-Dole Act gave academic institutions and small development firms the right to patent drug discoveries made under federally-funded research grants and then license these patents to pharmaceutical firms. The Hatch-Waxman Act extended the life of pharmaceutical patents and allowed drug manufactures to obtain multiple

patents on the same chemical compound spread throughout the life of the first patent (Relman and Angell 2002). As posited by Relman and Angell (2002: 36),

> Since the [Hatch Waxman] act was passed, brand-name drug companies routinely file not just one patent on their drugs but a series of them spread throughout the life of the first patent. These secondary patents are on every conceivable attribute – never mind usefulness, novelty, or non-obviousness.

The Bayh-Dole and Hatch-Waxman Acts therefore allowed pharmaceutical firms to (i) capitalize on drugs that were developed through publicly-funded research, (ii) benefit from scientific knowledge and research that they did not pay for, (iii) extend the standard life of pharmaceutical patents, and (iv) profit from multiple patents held on the same chemical compound. The culmination of these legislative provisions was the 1980s "drug pipeline explosion," a dramatic surge in the number of chemical compounds being developed followed by a deluge of patent applications to protect these compounds (Petryna 2005; 2009). This spike in pharmacological R&D can be observed in the number of new drug approval applications submitted to the FDA, which more than tripled between 1980 (~ 4,000) and 1989 (~ 12,000) (Shah 2006). Following this spike, the industry also observed a dramatic increase in overall profits, with prescription drug sales more than tripling between 1980 and 2000 (Relman and Angell 2002; Shah 2006). However, by the late 1980s this growth had begun to exhaust the body supply capacity of both U.S. and Western European clinical research sites. That is, academic research centers became backlogged because they could no longer satisfy increasing industry demand for experimental subjects, which the industry required in ever-greater numbers in order to demonstrate the safety and efficacy of its many newly developed and patented compounds (Shah 2006; Petryna 2009, 2005).

The pipeline explosion thus produced a crisis of overdemand in that the industry's rapid economic expansion outpaced and depleted its access to newly acquired pools of experimental

bodies. The industry, therefore, encountered the ecological limits of unabated economic growth, which negated its original spatial fix, the geographic expansion of clinical trials from U.S. prison systems into mainstream U.S. and Western European society. These ecological limits, in turn, triggered a second accumulation crisis in that the industry was deprived of sufficient access to human test subjects, which restricted its ability to develop and subsequently market a backlog of new pipeline compounds (Shah 2006; Petryna 2007).

In order to circumvent the above crisis, the industry was once again forced to seek out new environments and new populations it could use to sustain itself. To facilitate this search, the FDA – which receives 40% of its annual budget from the pharmaceutical industry – maneuvered as a key player in initiating the International Conference on Harmonization (ICH), "…declaring that the search for sites and sources of data [not labor] is part of its mandate to determine the safety and efficacy of new drugs" (Petryna 2009: 37; Kirsch 2009).[16] First occurring in 1991, this biennial conference brought both industry representatives and regulatory authorities from the U.S., Western Europe, and Japan into a joint and ongoing project to standardize international drug approval requirements (Kidd 1996; Petryna 2009, 2011). A central component to this project was the development of the Good Clinical Practice guideline (GCP), which is defined as:

> A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected (ICH Harmonized Tripartite Guideline 1996: 4).

Put somewhat differently, the ICH-GCP functioned to synchronize regulatory standards between the U.S., Western Europe, and Japan, thereby making international research data more easily transferable to the FDA and other regulatory agencies in leading pharmaceutical markets.

[16] Over 40% of the FDAs annual budget is derived from the pharmaceutical industry via drug approval fees; as such, the FDA has a vested interest in the development, testing, and approval of new chemical compounds (Kirsch 2009).

Regardless of this standardization, however, a number of ICH-GCP provisions allow for a concerning degree of ethical variability to exist between more and less developed countries. This is especially true in the context of trial design variation and execution between such nations, the implications of which are discussed in the last subsection of this chapter (Shah 2006; Petryna 2005; 2009).

Throughout the 1990s, a considerable number of countries, mostly in the European Union (EU), adopted the ICH-GCP standard, initiating a truly globalized regime of clinical trial experimentation (Petryna 2009; 2011). It is estimated, for example, that the number of human subjects involved in international U.S. clinical trials increased from 4,000 in 1995 to over 400,000 in 1999 (Office of Inspector General 2001), while the actual number of foreign-operated investigator sites seeking FDA approval increased sixteen-fold between 1990 and 1999 (Shah 2006). By exploiting this ICH-GCP-facilitated regime, the industry was thus able to achieve a second (transnational) spatial fix, allowing it to resolve the crisis of overaccumulation produced by its own growth and ensuring further rounds of capital accumulation and overall industry profitability.

Thus far, I have delineated two industry-specific accumulation crises and the subsequent spatial fixes that were pursued to resolve them. The first of these crises was a direct consequence of changing ethical standards in U.S. medical research, which blocked the industry's highly disproportionate use of prison populations in clinical trial testing. To resolve this crisis the industry shifted the majority of its experiments to medical research centers and teaching hospitals in both the U.S. and Western Europe – with Western Europe claiming but a small percentage of total U.S.-sponsored clinical trials. This spatial fix, however, eventually encountered ecological limits when the 1980s pipeline explosion began to exhaust the body

supply capacity of these newly exploited research centers. This predicament, in turn, triggered a second overaccumulation crisis in which the industry was deprived of sufficient access to experimental bodies and was thus deprived of the ability to develop and market a backlog of pipeline drugs. In order to circumvent this ecological crisis, the industry once again pursed a spatial fix, this time via the ICH-GCP, which ultimately allowed pharmaceutical companies to intensify their international hunt for untapped body supplies, thereby displacing the crisis elsewhere in space.

These findings are consistent with the first three of my theoretical predictions 1-3, which hold that if the industry does in fact exploit the human body as natural capital, then it should face periodic crises of overaccumulation in which pharmaceutical firms are deprived of access to sufficient body supplies (prediction 1). Further, that efforts to resolve these crises will result in a series of spatial fixes in which previously unexploited populations are incorporated into new rounds of pharmaceutical investment and production (prediction 2). And finally, that such fixes should eventually encounter ecological limits in which the industry (a) exhausts newly acquired pools of experimental bodies and/or (b) contaminates the very populations (i.e., resources) upon which its reproduction depends (prediction 3).

In the following subsection I document the legislative origins of yet another accumulation crisis, which resulted from a second period of rapid economic growth brought on by a phase of radical FDA deregulation. In particular, I show how (i) this growth resulted in the mass pharmaceutical contamination of U.S. bodies, (ii) this contamination is constitutive of an ecological crisis, and (iii) efforts to resolve this ecological crisis have and continue to drive the practice of clinical trial offshoring to underdeveloped nations, a practice that has dramatically intensified over the last twenty years.

*FDA Deregulation and the Mass Medicalization of U.S. Society*

In 1997 the Food and Drug Administration Modernization Act (FDAMA) was signed into law. This legislation came to fruition after both the FDA and Congress held weeks of official hearings in which pharmaceutical representatives, medical societies, consumer groups, and health advocacy organizations testified as to the need and likely benefits of FDA deregulation (Donohue 2006).[17] Once ratified, this Act greatly reduced the FDAs capacity to regulate medical marketing in several important ways, thereby facilitating an intensified phase of industry-induced mass medicalization. It did this, in particular, by transforming the ways in which pharmaceutical firms were able to advertise to both physicians and consumers – a transformation that occurred via the rise of off-label drug promotion and direct-to-consumer advertising of prescription medications.

When the FDA approves a new and/or rebranded drug, it is approved for the specific medical condition (otherwise known as an "indication") and age group for which it was tested. When a doctor's use of medication deviates from these FDA-approved specifications it is termed "off-label" drug use. Although physicians have always possessed the professional authority to prescribe off-label, industry sales representatives were strictly prohibited from marketing off-label applications to doctors (Conrad 2007). After the FDAMA, however, this restriction was lifted. As a result, pharmaceutical companies and their sales representatives can now actively promote the use of drugs for any given number of *non-FDA approved indications* while also endorsing their use for numerous *non-FDA approved age categories*. The only prerequisite of

[17] It should be noted that the overwhelming majority of these organizations have been shown to be either directly or indirectly linked to the pharmaceutical industry via sponsorship, grants, and/or research and to likewise, have pursued policy agendas that advanced the economic interests of the industry as a whole (Rothman et al. 2011; Harris 2009; Henderson 2007; Epstein 2007).

this marketing strategy is that "adequate scientific documentation" is provided and/or clinical trials are in place so that supplemental FDA approval can be gained (Conrad 2007: 17).

However, extensive research has demonstrated that drug firms are key players in both producing and determining what is and is not accepted as adequate scientific evidence within the medical community (Sah and Fugh-Berman 2013; Ebeling 2011; Sismondo 2007; Conrad 2007; Radley et al. 2006; Relman and Angell 2002). This research has further shown that pharmaceutical firms are able to both influence and alter the professional beliefs, practices, and prescribing patterns of practicing physicians (Avorn et al. 2015, Larkin et al. 2014; Sah and Fugh-Berman 2013; Ebeling 2011; Poitras and Meredith 2008; Horwitz 2007; Campbell et al. 2007; Sismondo 2007, 2009; Radley et al. 2006; Relman and Angell 2002; Chew et al. 2000).

Thus, since 1997, a growing number of medications have become regularly prescribed off-label. This is true regardless of the fact that clinical trial research has consistently failed to demonstrate drug effectiveness for the specific indications and age categories for which these medications are prescribed (Huskamp et al. 2016; Domino and Swartz 2008; Radley et al. 2006). As observed by Radley et al. (2006: 1021), "Scientific evidence documenting the efficacy of off-label uses in routine practice settings commonly falls short of what the drug's manufacturer would be required to provide the FDA to receive approval for that indication."

The FDA Modernization Act thus produced a dramatic spike in off-label drug use which, in turn, increased overall industry sales and profitability (Conrad 2007; Frank and Conti 2005). By 2001, for example, nearly one-fourth of all drug prescriptions made by office-based physicians were for off-label indications, with 73% of these prescriptions "ha[ving] little or no scientific evidence to support drug efficacy" (Radley et al. 2006: 1021). This trend is made

further apparent when examining psychotropic drug use among children and adolescents. As stated by Huskamp et al. (2016: 1):

> The medical community has long recognized that children are not small adults, particularly in terms of medication effectiveness and safety, and that psychotropics and other medications with central nervous system effects can be harmful to the developing brain. Nevertheless, the practice of treating young children with psychotropics lacking U.S. Food and Drug Administration (FDA) approval (off-label prescribing) remains common.

Regarding this subject, Thomas et al. (2006) find that office-based psychotropic prescriptions to U.S. adolescents (aged 14 to 18 years) rose from 3.4% in 1994-95 to 8.3% in 2000-2001. Thus, within an eight-year period, the number of adolescents receiving psychotropic medications increased from 52.2 per 1,000 to 141.8 per 1,000. It is important to note that the vast majority of this growth occurred in the post-1999 period, when the rate of increase nearly doubled (Thomas et al. 2006). The rise of this phenomenon can, therefore, be attributed to the FDAMA, which was passed in 1997, enacted in 1998, but not fully implemented until 1999 (Thomas et al. 2006; Dumit 2012).

In a similar study Huskamp et al. examined elevated rates of off-label antipsychotic use among young children. In analyzing the prescribing patterns of 31,713 physicians, the authors found that 42.2% of doctors "…wrote at least one [off-label] antipsychotic prescription to a patient between the ages zero and nine during the three-year period" between 2008 and 2011. (2016: 3). Among these physicians, nearly two-thirds (64%) had prescribed an off-label antipsychotic for a young child (Huskamp et al 2016). It would be a mistake, however, to conclude that the highest rates of off-label prescribing are among psychotropics. In fact, off-label use is most common among cardiac medications (46%), anticonvulsants (46%), and antiasthmatics (42%), with the greatest proportion of off-label use occurring with the specific drugs gabapentin (83%) and amitriptyline (81%) (Radley et al. 2006).

It is therefore clear that pharmaceutical marketing can both shape and drive prescribing practices among medical professionals. It is also clear that the FDA Modernization Act significantly enhanced this influential power via the industry's ability to freely disseminate off-label information throughout the medical community. However, the FDAMA also fundamentally altered the ways in which drug firms were able to interact with the public at large.

Prior to this Act, for example, direct-to-consumer advertising (DTCA) via television and radio broadcast was a marketing strategy seldom utilized by the industry. The reason for this was the level of information that the FDA required pharmaceutical firms to include in direct television and radio ads. These regulations specified that the industry disclose *all* potential risks and side effects associated with the drug being advertised, a disclosure that was made during the "brief summary requirement" at the end of an advertisement (Dumit 2012; Conrad 2007). However, the sheer number of risks associated with the average drug was considered too severe an obstacle for the effective use of direct advertising to the public (Donohue 2006; Conrad 2007). After all, who would purchase a medication when the summary of its concomitant risks and side effects was disturbingly long and communicated in explicit detail? The brief summary requirement therefore inhibited the industry's ability to achieve continued economic growth by blocking its access to the general public. As a result, drug manufacturers were at the forefront of petitioning Congress for the FDAMA.

Once ratified, this legislation allowed pharmaceutical advertisers to replace the brief summary requirement with (i) the "major statement provision," which required that only the *most* dangerous risks associated with the advertised drug be communicated to the viewer, and (ii) the "adequate provision requirement," which stipulated that the ad provide an alternative mechanism by which the viewer could access a complete disclosure of all drug risks and side effects (e.g. a

toll free number, a print ad, a website *or simply the suggestion to consult a doctor*) (Gellad and Lyles 2007; Conrad 2007; Donohue 2006).

This policy shift facilitated a mass proliferation of medical advertising in the U.S., which is only one of two nations that permits the direct marketing of prescription medications for non-life-threatening conditions (Donohue 2006; Law 2006; Dumit 2012). For example, between 1996 and 2000, industry expenditure on direct-to-consumer ads increased six-fold, to $2.5 billion (Conrad 2007). By 2003, this sum had swelled to $3.2 billion, representing a 400% increase between 1996 and 2003, according to Gellad and Lyles (2007). In 2006, total DTCA spending reached a staggering $5.9 billion, with every $1.00 invested in advertisements returning $4.20 in prescription drug sales (Kornfield et al. 2013; Conrad 2007). Indeed, direct-to-consumer marketing became so intensely utilized that in 2002 98% of U.S. citizens reported routinely seeing or hearing prescription drug ads (Donohue 2006). Moreover, it is estimated that for every minute the average patient spends with his or her physician, 100 minutes are spent watching drug advertisements (Gellad and Lyles 2007). In this significant way, direct-to-consumer advertising allowed the pharmaceutical industry to create vast new medical markets in which patients were actively transformed into avid consumers of health. As observed by Ebeling (2011: 823):

> The patient-cum-consumer becomes a 'rational and autonomous' agent through marketing who can challenge the paternalism of the medical establishment, who can shop around for and demand to purchase medical treatment just as any other commodity…This is the type of patient-consumer, at least, that drug marketers seek to develop through promotional work.

This assertion is supported by a 2002 GAO study which found that in the year 2000 8.5 million Americans received a prescription medication after viewing a drug ad and asking their physician to provide the advertised drug. In a similar 2002 study, the GAO finds that 32% of those who reported seeing a drug advertisement discussed it with their doctor, which "…translates into 61.1

million additional consumers asking about specific medications in a single year" (cited in Gelland and Lyles 2007: 478).

The rise of direct-to-consumer advertising thus served to stimulate and increase consumer demand for prescription medications, thereby fueling unprecedented industry growth. As documented by Dumit (2012, see fig. 3 pg. 9), prescription growth rates for almost every class of drug have increased substantially since the late 1990's. Of these classes, psychotropics constitute the fastest growing proportion of medications that are prescribed each year. For instance, between 1997 and 2001 the sale of antipsychotics *alone* increased by 43 percent, with the rate of use among children more than tripling between 1997 and 2005 (Frank, Conti, and Goldman 2005; Domino and Swartz 2008). It follows that total U.S. spending on prescription medications increased dramatically in the years following passage of the FDAMA, reaching $212 billion in 2001, $276 billion in 2005, and $307 billion in 2010 (Kornfield et al. 2013).

It is therefore clear that FDA deregulation significantly enhanced the pharmaceutical industry's ability to influence both the medical community and society at large. As documented above, off-label promotion has facilitated entirely new patterns of drug use for non-FDA approved indications and age groups, thereby jeopardizing public safety while augmenting pharmaceutical profitability (Radley et al. 2006; Avorn et al. 2015). Similarly, DTC advertising has enabled the industry to engage in aggressive campaigns of medical market-making, which function to stimulate and increase consumer demand for pharmaceutical goods. The FDAMA thus facilitated an intensified phase of industry-induced mass medicalization, the primary engines of which are off-label drug use and direct-to-consumer marketing (Conrad 2007). However, this intensification has also produced a number of unanticipated ecological

consequences with which the industry must now contend. Chief among these is a shrinking pool of domestically accessible experimental bodies.

In 2011, for instance, U.S. citizens consumed over 4 billion prescription medications. In the same year, global pharmaceutical sales reached $880 billion, with the U.S. accounting for approximately half of total sales (Dumit 2012). Indeed, the average U.S. citizen is now prescribed between 10 and 13 prescriptions per year, with the average medical visit resulting in at least two "drug mentions" (i.e., the prescription and/or continuation of a drug prescription) (Dumit 2012; Prasad 2009). While from the industry's perspective these trends would seem anything but problematic, they in fact denote the mass over-medication of U.S. society. As a result, the United States has now reached a point of "treatment saturation," which increasingly renders its citizens unfit for use in clinical trial research (Prasad 2009; Dumit 2012; Goldstein 2012). As observed by Petryna (2011: 955):

> Treatment saturation…is making Americans and Western Europeans less usable from a drug-testing standpoint. We exhibit the late-stage symptoms of a pill-taking life. Our bodies, saturated with treatments, produce too many drug-to-drug interactions and are thus less able to show specific drug effectiveness, making test result less usable.

The industry has therefore produced a site of domestic ecological ruin in that it has over-medicated and thus contaminated the very populations upon which its reproduction depends. This finding is not only consistent with my theoretical prediction that holds that the industry will eventually pollute its domestic supply of experimental bodies. It is also consistent with a wider body of literature, which documents an overwhelming tendency for traditional industries to deplete and/or contaminate the very resources that are needed for production – the timber has been cut, the mine has been exhausted, the soil and fisheries can no longer produce (Tsing 2015). Treatment saturation has thus produced the pharmaceutical industry's third accumulation crisis. Unlike those previously encountered, however, this crisis is not rooted in insufficient access to

experimental bodies (i.e., resources), but in insufficient access to clean or treatment naïve bodies (i.e., uncontaminated resources) (Dumit 2012). Without such access, the industry cannot produce high quality statistical data (i.e., bio-commodities) and thus cannot garner regulatory approval for new or rebranded drugs, which are in ever-greater demand as a consequence of increasing medicalization.

The pharmaceuticalization of U.S. bodies thus represents a profound ecological crisis with which the industry must now contend. In the following section I show that efforts to resolve this crisis have resulted in the intensification of clinical trial offshoring, which has increased exponentially over the last 25 years (Li et al. 2015; Schipper and Weyzig 2008). Although pharmaceutical firms have exploited this form of spatial fix in the past, I show that the current wave of experimental offshoring differs in two fundamental ways. First, the sheer number and rate at which U.S.-based clinical trials are being exported is unprecedented in the industry's historical development and thus represents a radical deviation from previous instances of experimental outsourcing which, while significant, constituted a relatively small percentage of total U.S. trials being conducted. Second, and in contrast to previous instances of offshoring, clinical trials are being disproportionately exported to middle- and low-income nations, which provide the industry with untreated and therefore pristine body supplies, fast and easy recruitment of cheap experimental subjects, and industry-friendly regulations that allow for an unequal extraction of bodily value from populations in the periphery.

**Section II: The Structure of Clinical Trials Abroad**

As previously noted, the current number and rate at which U.S.-based clinical trials are being exported oversees is historically unprecedented (Petryna 2009; Shah 2006). It is estimated,

for example, that between 50% and 60% of all clinical trials are now conducted in low and middle-income nations – an increase from less than 10% in 1991 (Li et al 2015; B.D. 2013; Glickman 2009; Schipper and Weyzig 2008). This level of experimental outsourcing has, in turn, given rise to an entirely new contract research industry that is increasingly international in scope. Within this industry, a host of for-profit research organizations, monitoring services, and data mining companies compete for the chance to win pharmaceutical research and development contracts. Once obtained, contract research companies go about the complex process of producing, refining, and packaging highly valuable bio-data – a process that most often involves subcontracting to second-, third-, and fourth-party research organizations that ultimately coalesce to form a globalized supply chain of human-based biological production (Petryna 2009; Goldstein 2012). Thus, prior to being delivered to their original pharmaceutical sponsors, these biologically derived commodities are produced, packaged, bought, and sold within a globalized market network of pharmaceutical research and development.

The principal players in globalized pharmaceutical production are contract research organizations (CROs), which, to reiterate, are highly competitive research companies that conduct clinical trials for pharmaceutical, biotechnology, and medical device firms (Petryna 2009; Shah 2006). These research service providers specialize in locating research sites, recruiting test subjects, gaining what is in most cases for-profit IRB approval (i.e., providing monitoring services), and in many cases developing research designs and conducting analyses (Petryna 2005, 2007; Elliott 2007; Prasad 2009). CROs are attracted to and increasingly operate in non-traditional research areas or "frontier zones" (i.e., areas with elevated rates of poverty, unemployment, and declining healthcare infrastructure) within less developed countries (LDCs), which allow them to capitalize on lower operating and production costs, looser ethical

regulations, and unfettered access to "treatment naïve" body supplies (Petryna 2007; Prasad 2009; Goldstein 2012). While the former two pull factors are certainly significant, the latter is of paramount importance, as addressed below.

The term treatment naiveté refers to populations that experience high rates of both common and uncommon disease states, but that lack access to health care services and treatment (Prasad 2009; Petryna 2007). As addressed in Chapter 1, these populations are overwhelmingly those that suffer from a structurally induced deficit of human capital. The theory of human capital posits that this form of capital is a type of asset that facilitates the performance of labor and thus the production of economic value (Becker 1964; Cardao-Pito 2016). Human capital is therefore defined as an individual's stock of knowledge, information, skills, and health which, in turn, positions the individual as a productive asset within the labor market (Becker 1964; Prasad 2009; Cardao-Pito 2016). However, in the context of clinical trial research, it is a structurally induced *deficit* of human capital that most clearly identifies experimental test subjects.

As addressed in Chapter 4, clinical trial participants are overwhelmingly those who suffer from structural inequalities – the socially marginalized, the uneducated, the unemployed, the uninsured, the sick – that limit their participation in the formal labor market (Grady et al. 2017; Fisher 2015; Goldstein 2012; Fisher and Kalbaugh 2011; Petryna 2009; Prasad 2009; Sunder Rajan 2006; Shah 20006). And yet, *it is exactly their nonproductive status as labor that distinguishes these individual's as desirable test subjects* (Prasad 2009; Petryna 2009; Goldstein 2012; Elliott 2014). This is especially true in the context of clinical trial outsourcing to underdeveloped nations where structurally constrained populations (due to a lack of employment, employment opportunities, and therefore wages) typically lack access to (already limited) healthcare services and thus exposure to background medications that might interact

with the experimental drug, thereby obscuring test results (Petryna 2009; Goldstein 2012). As stated by one CRO executive, "[treatment naïve] populations offer a more likely prospect of minimizing the number of variables affecting results and a better chance of showing drug effectiveness" (Petryna 2005: 3). It is, therefore, a deficit of human capital – in conjunction with opportunity deficits to use what little human capital is possessed – and thus exclusion from formal labor markets that purifies the body (from a drug testing perspective) making it a valuable asset in clinical trial research. *In this way, a structurally induced deficit of human capital becomes the experimental subject's greatest asset as natural capital.* Structurally constrained test subjects are thus compelled to sell their bodies, not as labor, but as commodifiable resources in the execution of outsourced pharmaceutical R&D.

The contextual circumstances of clinical trial experimentation thus clearly negate theoretical prediction 8, which posits that even the most menial forms of labor require a baseline of human capital (i.e., knowledge, information, skills, and health) that must be actively applied and/or exploited in the context of labor enactment. As I and others have shown, there is a complete lack of evidence to suggest that the vast majority of experimental subjects are required to possess any such baseline (Shah 2006; Rajan 2006; Petryna 2009 Goldstein 2012; Elliott 2007, 2014). In the context of clinical trial research, the empirical evidence thus suggests a reversal of human capital theory in that it is a deficit of human capital that makes experimental subjects in LDCs valuable by depriving them of the ability to participate in formal labor markets and thus secure wages with which to purchase medical care. (Prasad 2009). This, in turn, purifies their bodies – from a drug testing perspective – by keeping them free of any background medications that might obscure test results (Shah 2006; Petryna 2007; Goldstein 2012). Put differently, a lack of marketable human capital transforms once economically nonproductive and

diseased populations into coveted sources of value creation. This, of course, is consistent with prediction 9, which holds that a structurally induced deficit of human capital will be the defining characteristic of experimental subjects and that which distinguishes treatment naïve populations as desirable test subjects.

*CROs and the Marketing of Human Bodies*

The above findings are further substantiated via analysis of the marketing strategies employed by CROs. To reiterate, in order to win pharmaceutical contracts, CROs must demonstrate effectiveness and efficiency in their ability to locate and recruit large communities of the structurally constrained – the socially marginalized, the uneducated, the unemployed, the uninsured, the sick – whose most valuable assets are their own untreated and therefore pristine bodies (Shah 2006; Rajan 2006; Petryna 2009 Goldstein 2012). This disconcerting point is made clear in a self-promotional advertisement by Quintiles India, a subsidiary of a North Carolina based CRO:

> India has a vast population. Patient access is fast; full a third of the population lives in urban areas. Large portions of the population have not been exposed to prior treatment. Tropical diseases and diseases of developed countries are both common in India. Trials opportunities include cardio-vascular diseases, diabetes, degenerative neurological diseases, cancers, psychiatric illnesses, and infectious diseases…These readily accessible patient populations – and our experience in reaching out to them – result in significant time savings for Quintiles India customers (Prasad 2009: 5-6).

Clearly, the above advertisement does not attempt to market human bodies as a source of labor as traditional economic theory and human capital theory would predict. Instead, the body is advertised as diseased and treatment naïve and thus, from a drug testing standpoint, as a pristine

and untapped ecological resource from which commodifiable value can be extracted.[18] This point is made further evident in an additional CRO advertisement, which boasts of quick and easy access to unpolluted bodies as a source of high quality bio-data:

> The lack of saturation in [Latin America], coupled with high enrollment rates…make the region a potentially lucrative emerging market for pharmaceuticals…One of the key benefits of conducting clinical trials in Latin America and the Caribbean is access to large populations, concentrated in urban areas, who can for the most part be categorized as treatment naïve (not on other medications that could interfere with the intended experimental treatment) (CIDAL 2017).

In this way, high disease rates and treatment naivete, which are the literal embodiment of poverty, neglect, and structural inequality, are marketed as national goods, as key environmental resources that are used to attract U.S.-based pharmaceutical investment. As observed in another CRO advertisement entitled "India Advantage," iGate Clinical Research (an Indian CRO) lists the top 10 reasons for outsourcing to India, the first of these reasons being its "huge patient base with a diversity of diseases." To further convince potential pharmaceutical investors of the "advantage" to be found in India, iGate lists the disease characteristics of the national population:

- 40 million asthmatic patients
- 34 million diabetic patients
- 8–10 million people HIV positive
- 8 million epileptic patients
- 3 million cancer patients
- 2 million cardiac related deaths
- 1.5 million patients with Alzheimer's disease
- 15% of population is hypertensive
- 1% of population suffers from schizophrenia

[18] CRO advertisements commonly boast of their "access to large, previously untapped patient populations…Ski where the snow is, conduct clinical trials where the patients are" (Neeman Medical International 2003).

Consistent with my argument, the populations disproportionately burdened by these disease states were long considered an obstacle to India's economic development. Now, however, they are constitutive of national assets that can be sold to pharmaceutical investors (Prasad 2009), allowing these investors to abandon the site of domestic contamination they have produced. That is, having overmedicated and thus contaminated its own domestic population – our bodies now unable to produce little more than statistical noise – the pharmaceutical industry travels abroad in order to locate new social environments and new bodies that will serve as an appropriate spatial fix to its own internal ecological crisis. These findings, of course, shed important adjudicating light on prediction 6, which posits that the nature and timing of spatial fixes will be determined by the exploitation of bodies as *either* labor or natural capital, with the former determining factoring appearing highly unlikely and the latter appearing most likely.

As previously noted, however, developing nations offer more than just access to uncontaminated bodies. They also allow the industry to drastically reduce the cost of production while providing loose ethical regulations in which to pursue this production. Regarding the first of these points, it should be underscored that between 60% and 70% of the global pharmaceutical R&D budget, or $80 to $90 billion of the $130 billion spent annually, is allocated to clinical trials (B.D. 2013) Cost efficiency in clinical research is therefore a matter of central importance to the industry. This efficiency is more easily achieved in LDCs because they provide rapid recruitment of low-cost experimental bodies. In the U.S., for example, only 7% of trials start on time due to under-enrollment of test subjects, while over 30% fail to meet enrollment targets at all (Petryna 2009; VOI 2009). In developing nations, however, subject recruitment is on average three times faster than in the U.S., which reduces the average length of outsourced trials by six months, thereby saving pharmaceutical firms millions of dollars per trial and hundreds of

millions of dollars throughout the patent life of the drug (Law 2006; Petryna 2009; Prasad 2009; Berne Declaration 2013).[19]

In addition to fast recruitment times and reduced clinical trial duration, LDCs provide the industry with far cheaper body supplies. In India, for example, per subject cost in a top medical research center is typically one tenth the cost at a second-tier center in the United States (Glickman et al. 2009). In Russia, per subject clinical trial cost is typically 50% cheaper than in the U.S., whereas in Latin American and China per subject cost is approximately one third of that in the United States (Shah 2006; Pertyna 2009; B.D. 2013). Indeed, Li et al. cite a "$600M cost savings per year (assuming 60,000 trial participants) through shifting 50 percent of [a firms] late phase trials from the U.S. and Europe to less costly locales such as India and South America" (2015: 1). Thus, clinical trial outsourcing not only provides the industry with a surplus pool of uncontaminated bodies, but also with bodies that yield far more valuable data at a far lower cost.

*The ICH-GCP and Ethical Variability Between Nations*

Beyond securing quick access to low cost, treatment naïve populations, clinical trial offshoring allows the industry to benefit from a number of loose ethical regulations within LDCs. As Shah (2006: 112) poignantly observes, "the modern hunt for bodies leads drugmakers to places almost entirely short of [ethical] oversight. Such is the case in India, where a one billion body bounty entices industry investigators." As addressed below, these loose ethical regulations are one of several mechanisms that facilitate an uneven extraction of bodily value

[19] This is especially true given that patents are made on experimental compounds as soon as they are discovered. As such, there is tremendous pressure to get the experimental agent approved and on the market – for each day this has not occurred, the patent life is nonetheless expiring and thus millions in potential profit are lost (Petryna 2009; Dumit 2012).

from populations in the periphery and are thus a key reason for experimental outsourcing to LDCs. One way this unequal ecological exchange takes place is through specific regulatory provisions within the International Conference on Harmonization and Good Clinical Practice guidelines (ICH-GCP), which govern the industry's use of placebo-controlled clinical trials.

When the U.S. pharmaceutical industry tests an experimental drug, it does so using either a placebo-control or active-control trial design. In the former of these designs, the efficacy of the experimental compound is tested against a non-therapeutic agent, which is given to 50% of the experimental subjects (i.e., the control group/arm). In the active control design, the safety and efficacy of the experimental drug is tested against the best known or "standard treatment," which must be shown as inferior or equal to the experimental compound. In the U.S. and other developed nations, the use of placebo-controlled trials is considered unethical (given that standard treatment already exists) because such trials would deprive human subjects of effective and potentially lifesaving therapy for the condition being studied (Shah 2006; Goldstein 2012). In developing nations, however, the ethical ambiguity of placebo arms can be circumvented via the industry's provision of "equivalent medication" – i.e., not the best known or standard treatment, but the most readily available *local equivalent* – in clinical trial research (Petryna 2005, 2007; Goldstein 2012). Thus, industry-sponsored CROs – often operating in the most poverty-stricken regions of the world – can substitute the proverbial sugar pill with vitamin C and, in doing so, claim ethical adherence to the active-control design (Petryna 2009, 2007, 2005; Shah 2006).

The origins of this ethical loophole lie in regulatory provisions within the ICH-GCP, which states that:

> Whether a particular placebo controlled trial of a new agent will be acceptable to subjects and investigators when there is a known effective therapy is a matter of patient,

> investigator, and IRB judgment, and acceptability may differ among ICH regions. Acceptability could depend on the specific trial design and population chosen (cited in Temple 2002: 213).

Thus, in the context of clinical trial offshoring, the ICH-GCP functions to standardize a profound degree of ethical variability between more and less developed countries (Temple 2002; Petryna 2009). By exploiting this variability U.S. pharmaceutical companies are able to secure further economic advantage within LDCs. That is, the "equivalent medication provision" not only allows the industry to avoid providing costly standard treatment to thousands of experimental subjects, *it also allows CROs to keep treatment naive subjects exactly that, naïve,* throughout the duration of experimentation. This, in turn, facilitates the efficient production of high-quality statistical data (read products) with which the industry can more effectively demonstrate drug efficacy and thus garner regulatory approval for the marketing of new medications (Petryna 2009; Prasad 2009; Goldstein 2012).

The pharmaceutical industry therefore benefits from a highly uneven extraction of bodily (i.e., ecological) value from low and middle-income nations, which provide (i) a surplus of untreated and therefore pristine body supplies, (ii) fast and easy recruitment of cheap experimental subjects, and (iii) industry friendly regulations for the efficient production of human-derived biodata. By exploiting these factors, the industry engages in profound instances of ecological unequal exchange with LDCs, which has allowed it to overcome the ecologically rooted crisis of overaccumulation brought on by the FDAMA. As of 2016, for example, U.S. pharmaceutical firms controlled approximately half of the global pharmaceutical industry, which was valued at $1.1 trillion, an increase of more than $551 billion since 2006 (IFPMA 2017). Similarly, between 2006 and 2015 the average annual profit margin for U.S. pharmaceutical

firms was between 15% and 20%, which dwarfed the margins of 4% and 9% among non-pharmaceutical economic sectors (GAO 2017).

Clearly, such staggering economic gains are not easily divorced from the industry's outsourcing of R&D projects to underdeveloped nations and its subsequent extraction of bodily value from populations therein. However, this form of unequal ecological exchange goes beyond the immediate realm of industry profitability to further encompass an uneven distribution of the risks and benefits inherent to pharmaceutical research and development. This point is made clear when recalling that over 50% of all U.S. clinical trials are now conducted in low and middle-income nations – up from a mere 10% in 1991 (Li et al. 2015; B.D. 2013; Schipper and Weyzig 2008; Glickman 2009). Thus, in the approximate 25 years between the early 1990s and twenty-teens there was a 400% - 500% increase in the rate of clinical trial outsourcing to LDCs. Globally, however, only 1% of all new drug discoveries during this time period were for tropical diseases of underdeveloped nations – diseases that killed tens of millions each year (Nundy and Gulhati 2005; Dumit 2012). Even more concerning is that a mere 10% of current drug research and development is committed to the conditions that make up 90% of the global disease burden (Petryna 2009; Dumit 2012).

Beyond providing additional support for the first three of my theoretical predictions, the above findings are consistent with predictions 4 and 5, which hold that if the industry exploits the human body as natural capital then it will (a) eventually be forced to relocate production to periphery nations where access to human bodies will be both less expensive and less polluted (prediction 4) and (b) benefit from an unequal extraction of bodily value, in the form of natural capital, from experimental populations in the periphery (prediction 5). The above findings are also consistent with prediction 7, which holds that if the industry does in fact commodify the

human body as an ecological resource, then the ways in which human bodies are marketed to pharmaceutical firms should reflect this reality. This point is made clear when examining the ways in which CROs advertise their body supplies, which in no way denotes bodily commodification as labor, but rather as natural capital.

## Conclusion

This and the preceding chapter have presented a sociological investigation of the newly emerging bioeconomy and how the production strategies unique to this economy fundamentally transform the human body, and the human being, in historically unprecedented ways. More specifically, these chapters have examined how various modes of human-based bioproduction transform the human body into a mere ecological resource via its altered status as an object of labor enactment. They have further addressed how this transformation allows for (i) the increasing exploitation of human biological materials, information, and in-vivo processes as sources of commodifiable value and (ii) the spatial displacement of market contradictions that inhibit the perpetual expansion of capital. The two case studies presented in this chapter – domestic clinical trial research and international clinical trial research – were strategically selected to test 9 of my 10 theoretically-informed predictions (see Table 1 in Chapter 3), which, in conjunction with Chapter 4, has allowed me to address the following 4 suppositions: First, the body (like nature) possesses inherent value potential. Second, the body (like nature) can be an object of labor enactment. Third, the body's value potential (like that possessed by nature) can be extracted and commodified. Fourth, once commodified human bio-products enter a globalized market (the bioeconomy) in which they are bought and sold like any other good derived from nature.

In addressing these 4 suppositions, I was able to both test and build upon leading sociological theories of the environment. Although these theories have made invaluable contributions in advancing our knowledge of socio-environmental relations, and the ever-changing character of these relations, they have overlooked the increasing significance of human-based bioproduction in its entirety. These theories, for example, acknowledge that the dictates of capital drive capitalists to constantly seek out and exploit new environments and production strategies for the ongoing accumulation of capital, but fail to account for how rapid scientific advances in the fields of biotechnology, biomedical, and biogenetic research open up the human body – and human life itself – to these dictates. Leading sociological theories of the environment thus fail to account for how the body's traditional and theoretically accepted role in economic production – as producer and consumer in market exchange – is undergoing an historically unprecedented transformation via the incorporation of human bodies as a key *sites* and *resources* in life science production processes.

It has, therefore, been the goal of chapters 4 and 5 to demonstrate both the utility and the limitations of these theoretical models, while simultaneously establishing a strong line of empirical support for a theoretical reconceptualization of the human body as natural capital. By incorporating this reconceptualization into their analytical toolkits, environmental scholars and social scientists in general will possess a new and ecologically unique perspective through which to analyze (i) the rise and/or intensification of human-based bio-production, (ii) the structural forces driving its geographic expansion, and (iii) the processes of bodily commodification that sustain it.

In addition, this chapter has allowed me to both critique and extend human capital theory, thereby making a direct contribution to a leading (non-Marxian) theory of labor. I have made this

contribution by documenting (i) the degree to which life science production strategies rely on the disproportionate exploitation of populations that suffer from a structurally induced deficit of human capital and (ii) how this deficit functions to increase both the desirability and productive potential of structurally disadvantaged groups via their status as untapped and uncontaminated body supplies. Because of this, I have argued that instances of human-based bioproduction – more often than not – represent a reversal of human capital theory in that it is the observable deficit of human capital that transforms once economically nonproductive populations into highly sought after and commodifiable resources. To date, scholars of human capital theory have yet to account for these observations – an oversight that will have to be amended if this theoretical model is to accurately reflect the current biotechnological trajectory of the empirical world.

# Chapter 6

## THE BRETTON WOODS AND STRUCTURAL ADJUSTMENT: ACCESSING THE BODIES OF STRUCTURALLY DISADVANTAGED NATIONS

Beyond confirming the first nine of my theoretical predictions, chapter 5 demonstrated that the mass pharmaceuticalization of U.S. bodies represents a profound ecological crisis with which drug firms must now contend. It further established that industry efforts to resolve this crisis have led to an exponential increase in the offshoring of clinical trials, and that the current wave of this offshoring is exceptional in two important ways. Frist, the sheer number and rate at which U.S.-based clinical trials are being exported is unprecedented in the industry's historical development and thus represents a radical deviation from previous instances of experimental outsourcing. Second, and in contrast to previous instances of offshoring, clinical trials are being disproportionately exported to low- and middle-income nations, which provide the industry with untreated and therefore pristine body supplies from which to extract uneven flows of biological (i.e., ecological) value. This process, I have argued, represents a novel form of unequal ecological exchange between more and less developed nations, the policy pathways, institutional mechanisms, and end consequences of which heretofore remained unaddressed by environmental sociologists and bioeconomic scholars alike.

In order to more fully address these pathways, mechanisms, and consequences, this chapter builds upon the last empirical section of chapter 5. To do this it will examine two key international financial institutions (IFIs), the World Bank and International Monetary Fund (IMF). Specifically, it will examine the macroeconomic policies these institutions formulate and implement in developing nations, the socio-economic and environmental pathways by which these polices shape the underdevelopment of health and healthcare systems within these nations,

and how this underdevelopment aids pharmaceutical firms by enhancing their ability to access and exploit new, structurally produced human environments that allow for the displacement of market contradictions abroad. Although non-exhaustive in scope, this chapter's focus on the World Bank and IMF underscores a *primary* set of overlapping institutional arrangements that facilitate this form of displacement.

In examining the World Bank and IMF (known collectively as the Bretton Woods institutions), I make an important contribution to the four environmental theories addressed in chapter 2. Certainly, these theories and theoretical arguments have proven invaluable in explaining many socio-economic-environmental relations. Despite their many successes, however, and despite the fact that they recognize the increasing transnational character of global economic production, they do not pay sufficient analytical attention to the primary institutions and institutional mechanisms that facilitate the expansion of capitalist markets abroad (Downey 2015). Further, while these theories agree that the capitalist mode of production will inevitably encounter environmental and resource-based limits to perpetual economic growth, they fail to account for the increasing significance of human-directed bioproduction and its potential role in expanding the bounds of traditional conceived resource systems. This specific theoretical gap will be addressed in the concluding chapter of this dissertation, with the current chapter providing keys insights into the structural arrangements and policy pathways through which such an expansion would likely occur.

The goal of this case study, therefore, is to answer the following two questions: First, what role do international institutions such as the World Bank and IMF play in creating the institutional basis for a novel system of LDC exploitation via the mass outsourcing of pharmaceutical and biotech R&D projects to periphery nations. Second, to what degree does this

novel system of outsourcing mirror historical pattens of traditional industrial offshoring and thus reflect observable similarities between conventional industry's dependence on LDC procured environmental value and the bioeconomy's increasing dependence on LDC procured bodily value? In answering these two questions, I further establish the extent and ways in which this exploitative system of outsourcing allows biopharmaceutical firms to overcome the ecological and resource-based limits they face via a displacement of market contradictions abroad.

To achieve this goal, I divide the chapter into 2 sections. The first of these sections provides a brief overview of the Bretton Woods institutions, their history, institutional character, and legacy of policy implementation within LDCs. In doing this, I underscore how the transnational tilt of global economic production, as well as the systems of unequal ecological exchange unique to it, are inextricably dependent on policy implementation by the Bretton Woods institutions. Here, I follow the work of Downey (2015) who argues that IFIs, as well as the policy pathways they provide, should be more thoroughly analyzed and incorporated as decisive theoretical constructs within leading sociological theories of the environment.

Section two further presents the North-to-South outsourcing of pharmaceutical and biotechnological research and development. In this context, I examine the degree to which the outsourcing of this R&D (read production) is dependent on the same institutional policies and mechanism that have historically, and to a significant degree, allowed MDCs to access and exploit the economies and environmental resources of LDCs. Here, I build upon the work of Downey (2015) by extending his analysis of IFIs to the bioeconomy itself – as opposed to an inclusive focus on traditional industries and their international expansion. To do this, I test the last of my theoretical predictions (prediction 10)[20] by identifying the general pathways through

[20] Prediction 10 expects that the outsourcing of life science research and development will be highly dependent on the implementation of World Bank and IMF policies. More specifically, this prediction expects that SAP host

which Bretton Woods policies negatively affect the health and healthcare systems of LDCs. Through this process of identification, I establish clear consistency with the theoretical expectations of prediction 10, the implications of which will be briefly considered in the chapters concluding remarks.

**Section I: The World Bank and International Monetary Fund**

The World Bank and IMF were established in 1944 at the Bretton Woods conference in Bretton Woods, New Hampshire. This U.S.-led conference brought together policymakers from 43 allied nations with the mandate to create a postwar system of global financial governance with the capacity to (i) promote and maintain international monetary stability, thereby preventing a second global economic depression and (ii) finance various development projects around the world (Downey 2015; Peet 2003). Within this system, the IMF would act to facilitate currency exchanges, ensure stability in rates of exchange, and sustain global trade through loans to nations experiencing balance of payment crises (Domhoff 1990). The mission of the World Bank would be reconstruction of the war-torn economies of Western Europe and, later in its history, the financing of large-scale economic development projects in less developed countries (Babb 2009; Downey 2015).

Although seemingly altruistic in their joint missions, a number of scholars have argued that the actual institutional function of the World Bank and IMF is (and always has been) to ensure U.S. economic, military, and political dominance in an increasingly globalized, post-

countries will suffer from a variety of negative social, economic, and environmental outcomes that result in the underdevelopment of health and healthcare systems. It further expects that these declining structural conditions will encourage the outsourcing of biopharmaceutical R&D because such circumstances will produce a surplus pool of inexpensive experimental bodies that are diseased, impoverished, treatment naïve, and easily mobilized for use in clinical trials research.

colonial world (see, for example, Langan 2018; Downey 2015; Woods and Lombardi 2006; Choussudovsky 2003; Osabu-Kle 2000; Bello 1999; Domhoff 1990). Often using a neocolonial lens, these scholars delineate how Western powers were able to regain, and/or maintain, control of post-colonial nations via stabilization and development lending by the World Bank and IMF. These scholars have further addressed how the re-establishment, and/or continuation, of colonial-like North-South exchange relations continues to be a matter of central importance to Western nations, as the economies of these nations remain highly dependent on (i) the extraction and export of primary commodities from the periphery to the core and (ii) the creation of import markets for the transfer (and subsequent absorption) of manufactured goods and services from the core to the periphery. Choussudovsky (2003: 20) terms this modern form of colonialism "market colonialism," which he defines as a "new form of economic and political domination…[that] subordinates people and governments through the seemingly 'neutral' interplay of market forces."

Of course, the above specified version of neocolonial domination is not the sole product of World Bank and IMF lending practices. Rather, such practices are understood to seize upon pre-existing asymmetries in North-South power relations, which, to a highly significant degree, are the direct consequence of over 400 years of colonial exploitation, the legacy of which has left former colonized states uniquely dependent on former colonial states for trade, aid, and political support (Bello 1999; Osabu-Kle 2000; Choussudovsky 2003; Babb 2009; Downey 2015; Langan 2018). By exploiting these asymmetries, Western powers are able to dictate the terms and conditions of development lending, which, many scholars argue, effectively subordinates low-and-middle income nations to the economic and political interests of the core (Downey 2015; Babb 2009; Woods and Lombardi 2006; Bello 1999). By way of this subordination, Western

states, but in particular the United States, are able to usurp authority over key aspects of developing nations' structural organization, a point that is made clear via brief analysis of World Bank and IMF structural adjustment lending.

The term "structural adjustment" is shorthand for a broad and far-reaching set of policy-based reforms that are attached to World Bank and IMF development loans made to low-and middle-income countries. More commonly known as structural adjustment programs, or SAPs, these policy-based loans are designed to effectuate a fundamental, sweeping, and enduring overhaul of institutional and policy arrangements within LDCs (Kentikelenis 2017; Pfeiffer and Chapman 2010). Most often bundled into aggressive policy packages, SAPs execute this overhaul by enforcing the four "…ations" of structural adjustment – stabilization, deregulation, privatization, and liberalization (Summers and Pritchett 1993).

In short, the four "…ations" of Fund- and Bank-imposed structural adjustment have radically transformed the macroeconomic environments in which LDCs pursue modernization. They have, for example, (a) drastically curtailed the role of government in the economy, (b) increased the role of markets and the profit incentive in national production, (c) slashed state expenditures, especially on social programs, education, and state employment, (d) barred or significantly reduced state subsidies for the production of basic goods such as food, (e) increased national interest rates, (f) removed protectionist barriers to imports and foreign direct investment, (g) strengthened private and intellectual property rights, (h) imposed extractive and agricultural sector reforms, and (i) "shift[ed] the focus of economic activity away from production for domestic consumption toward production of goods and natural resources for export" (Downey 2015: 66; Babb 2009; Labonté and Schrecker 2007; Vreeland 2007; Bello 1999). These deep structural changes, the World Bank and IMF insist, promote economic growth within adjusted

nations, providing them with the means to service national debts, reduce poverty and inflation, and address their balance of payment deficits (Peet 2003; Babb 2009). The question, of course, is whether this is actually true.

Indeed, after some 40 years of SAP implementation, an extensive body of social science research casts doubt on the overall effectiveness and legitimacy of Bank and Fund adjustment lending. This research shows, for instance, that SAPs have little to no effect on inflation, diminish economic growth – especially in nations that have fully enacted IMF programs, contribute to impoverishment while increasing income inequality, increase environmental degradation and natural resource depletion, and in democratic nations, decrease state expenditure on public health, education, and utilities provision (for two comprehensive reviews of these studies, see Vreeland 2007 and Kentikelenis 2017). The negative effects of structural adjustment can be further assessed by examining trends in the total stock of external, periphery debt over time.

Initiated in 1980 with two loans to Turkey and Kenya, structural adjustment lending became ubiquitous throughout the global South by the mid-1980s. Prior to this, in 1981, the total stock of external debt for all low-and-middle income nations stood at approximately $600 billion; thirteen years later, in 1994, this sum had swelled to well over $2 trillion (Caufield 1996; Robbins 1999). Of course, one could reasonably argue that this increase did not represent a failure in World Bank and IMF policy. Rather, that debt reduction, the principal, if perhaps ostensible, goal of SAP lending, might take several years or even decades to materialize – i.e., given the extent of adjustment LDCs were required to undergo. However, 16 years later (in 2010), total periphery debt had doubled to over $4 trillion, representing a debt burden that was 21% of the total gross national income (GNI) of all developing nations (Hurt 2018). In 2018,

total periphery debt increased still further, reaching $7.9 trillion before exploding to over $11 trillion in 2020 (World Bank 2019; Kharas 2020).

This rising level of debt has proven to have profound implications for many developing nations, particularly in the context of debt amortization and worsening rates of extreme poverty. Africa, for example, is the most heavily adjusted continent in the world and yet, by 2002, its nations had repaid $4 for every $1 of debt owed in 1980, while still owing an additional $4 for each $1 of their original debt (Toussaint 2005). In addition, between 1998 and 2002, "the governments of sub-Saharan Africa received $34.83 billion in fresh loans but repaid $49.27 billion on previous loans, thus transferring nearly $15 billion to creditors in the North. Each year, sub-Saharan Africa also pays more in debt servicing than the total of all health and education budgets for the entire region" (Downey 2015: 70). In this way, capital flight via the servicing of Bank and Fund development debt has, ironically, become a key structural impediment to the modernization of developing economies, with much of this flight being driven by a massive, SAP-induced redistribution of natural resource wealth from the core to the periphery.

This redistribution, many scholars argue, is effectuated by the specific development strategies that SAPs mandate which, to a highly disproportionate degree, stipulate the increased production of agricultural goods (e.g., cash crops, fishing, livestock production, etc.) for export and the intensification of extractive operations (e.g., metals, minerals, oil/gas/coal deposits, etc.), while holding a noteworthy bias against industrial development and the broader diversification of national economies (Bello 1999; Osabu-kle 2000; Choussudovsky 2003; Woods and Lombardi 2006; Downey 2015; Langan 2018). This focus on export-oriented agricultural and extractive sectors in the overall structuring of economic activity has proven to have a number of profoundly negative social and ecological consequences within LDCs. And indeed, this is precisely because

such developmental approaches mirror earlier colonial “development” strategies, thereby facilitating unequal ecological exchange relations between the core and periphery.

In the context of agricultural production, for instance, SAPs have mandated a dramatic intensification of cash crop production for export to the global North, which serves to enhance the accumulation of capital in the core while degrading peripheral resources at unsustainable rates. A well-documented example includes the mass rise of export-oriented monocultural production as a defining feature of SAP-sponsored economic development. While it is true that this developmental approach has increased both (i) aggregate output of agricultural goods and (ii) access to modern industrial farming technologies, it has not, in general terms, delivered on the promise of economic modernization. This is principally because an increase in total peripheral output results in an increase in total global supply, which decreases the per unit cost of goods produced. These disadvantages terms of trade are then worsened by the SAP-levied devaluation of LDC currencies against the U.S. dollar (the currency of choice in international trade), which further diminishes real revenue received per unit of production. This loss of profit is then compounded by the SAP-imposed reduction and/or removal of agricultural subsidies, which would otherwise allow LDC governments to offset the loss of revenue per productive acre, thereby allowing developing nations to improve their terms of trade through a reduction of agricultural supply that would increase international demand and thus the price per unit of production.

In addition to the above specified market dynamics, monocultural production monopolizes vast tracts of the most productive agricultural land within LDCs. This, in turn, has (i) drastically reduced the incomes and viability of small-scale farms that are simply unable to compete with large-scale monocropping and (ii) led to the mass displacement of subsistence

farmers, forcing entire populations of the poor and indigenous to expand agricultural activities into marginal land, further degrading these already strained environments (Downey 2015; Rice 2009; SAPRIN 2004). At the same time, mono-cultivation for large-scale export drastically reduces biodiversity and soil fertility, over-exhausts water tables, erodes soil, and relies on large quantities of pesticides, herbicides, and synthetic fertilizers, all of which are leading causes of farmland and waterway contamination in many developing nations (Smith 1994; SAPRIN 2004; Rice 2009; Downey 2015). Finally, multinational research has consistently shown that as mono-cultivation increases, agricultural production for domestic consumption decreases, thereby elevating national food prices and thus hunger (Kerbo 2005; SAPRIN 2004). Ironically then, developing nations compelled to pursue export-oriented agricultural production as a primary model of economic development suffer from disproportionality high rates of malnutrition and associated poor health (Rice 2009; Waitzkin and Jasso-Aguilar 2015).

In the context of extractive operations, SAP loans forced many periphery nations to implement far-reaching mining sector reforms that significantly increased the production of raw materials for export to the core. As with the agricultural sector, however, these reforms have proven largely ineffectual in promoting economic growth. This is primarily because such reforms facilitated the privatization of state-owned extractive industries, lifted restrictions on inflows of foreign direct investment (FDI), and severely limited the royalties and taxes that foreign owned extractive companies were required to pay to LDC governments, thereby allowing such companies to repatriate far greater sums of profit and to assume a far greater share of sector ownership (Downey 2015). The intensification of extractive activities associated with these reforms also required the large-scale acquisition of quarriable land, which led to often violent

instances of wholesale land grabbing and to the residential displacement of hundreds of thousands via acts of forced resettlement (Social Watch 2012; Downey 2015).

Mining reforms have also significantly impacted the extraction and South-to-North export of fossil fuels (petroleum, natural gas, and coal),[21] which has imposed many social and environmental externalities on the global South while benefiting the North in both economic and ecological terms. (Vallette et al. 2004; Lee and Doukas 2017; Urgewald 2020). Given that fossil fuels make up 85% of the world's total energy usage and that, as a whole, more and less developed nations remain globally positioned as net importers and exporters of energy and other raw commodities, the intensification of extractive operations under SAPs disproportionately harms LDCs. This is not only because SAPs encourage the increasing privatization, and thus foreign ownership, of once state-controlled extractive industries, it is also because such industries depend on the extraction, export, and *eventual depletion of finite resources* so-that economic and resource gains in the core necessarily imply economic and resource losses in the periphery. These unequal exchange relations further benefit the core for as the periphery's most easily assessable resources are depleted, industrialized economies gain both flexibility and complexity as they invest in, develop, and implement novel technologies and approaches for the discovery, extraction, and transport of increasingly inaccessible resource reserves. In stark contrast, peripheral nations, locked into an extractive model of economic development, "…become increasingly rigid, inflexible, and vulnerable to the shifting demands of transnational capital accumulation" (Rice 2009: 222).

[21] In addition to these reforms, it should be noted that of all other multilateral development banks (MDBs), the World Bank is the single largest financer of fossil fuel exploration and expansion projects, with "clean energy" projects attracting less than one-third of its total energy specific lending in 2016 (Lee and Doukas 2017).

Finally, the acceleration of extractive operations under SAPs has proven to exact a heavy environmental toll on developing nations. As reported in a cross-national SAPRIN study:

> [Bank and Fund polices have] …allowed large-scale mining to expand without effective environmental controls, thereby polluting local and regional environments and degrading sensitive, biologically rich zones. Mechanisms to conduct environmental impact assessments exist[ed], but adjustment measures [such as reduced government spending] . . . left the governments of those countries with little capacity to enforce this requirement effectively or to ensure compliance with environmental quality standards. As a result, mines . . . often lowered water tables, diverted watercourses, and caused water pollution through the use of chemicals and the unleashing of heavy metals. The widespread removal of trees and vegetation . . . also resulted in soil erosion and decreased soil fertility, which . . . made land unsuitable for agricultural purposes (2004: 171).

These environmental costs, in turn, significantly impair the health of local populations that are disproportionately exposed to particulates and polluted air, toxic chemicals used in the fracturing of oil and gas wells, contaminated soils and waterways, and regular contact with unprocessed or semi-processed ores and minerals (SAPRIN 2004; Rice 2009; Downey 2015).

In addition to the above specified social, economic, and environmental consequences of SAP implementation, these polices have engendered a fundamental shift in the international division of labor that allows MDCs to engage in various forms of productive outsourcing and "environmental load displacement" (Foster and Holleman 2014). In particular, the four "…ations" of structural adjustment have facilitated the mass transfer of labor intensive-manufacturing to low-wage nations in the global South (Labonté and Schrecker 2007; Frey 2003). Most often, this manufacturing is outsourced to export processing zones (EPZ), which are vast industrial areas that are designed to attract foreign direct investment and promote export-led economic growth via the provision of incentives to transnational corporations (TNCs).[22]

[22] These incentives include but are not limited to: significantly relaxed import-export restrictions, concessional taxes, concessional interests rates, reduced utilities rates, reduced infrastructural attainment and construction costs, surplus labor pools, negligent labor laws, and remiss environmental regulations (Labonté and Schrecker 2007; Frey 2003; Subrahmanian and Pillai 1988).

Although the SAP facilitated rise of EPZs was ostensibly geared towards the industrial development of LDCs, which would occur via (i) inflows of DFI, (ii) industrial base expansion, (iii) new technologies acquisition, (iv) increased employment and human capital gains, and (v) the creation of interlinkages between EPZs and the domestic economy, few such outcomes have been realized (Labonté and Schrecker 2007; Frey 2003; International Labor Organization 1998). Of course, North-to-South industrial outsourcing has more closely integrated LDC economies into the broader global economic system. However, economic integration via EPZs leaves developing nations highly vulnerable to fluctuations in the global economy, as these zones represent commodity production for export – the demand for which is almost exclusively determined by market cycles and consumption patterns in the core. In addition, and as a direct consequence of SAP imposition, LDC governments lack the capacity to implement policies ensuring that zone investors transfer technology and skills to national industry and labor, which retards human capital gains and results in a "…pervasive absence of meaningful linkages between EPZs and the domestic economies of most host countries" (International Labor Organization 1998; Kway 2014). Finally, the overwhelming majority of productive facilities, technologies, semi-processed imports, and end consumer goods assembled in EPZs are *foreign owned* (Frey 2003). As such, the profit realized through value-added EPZ production does not remain in LDCs, but rather hemorrhages out in whatever fashion so wished by transnational capital (Galeano 1997; Frey 2003; Rice 2009; Prell et al 2014).

With regard to employment, EPZs are synonymous with low wages, high work intensity, unsafe working conditions, exposure to industrial hazards, unrivaled labor turnover, sexual and physical abuse of workers, suppression of labor rights, and increased social and economic inequality between workers (Labonté and Schrecker 2007; Frey 2003; International Labor

Organization 1998). With regard to the environment, Frey (2003: 317) asserts that EPZs allow transnational corporations [to] appropriate 'carrying capacity' for the core by transferring the core's hazardous products, production processes, and wastes to the peripheral countries of the world-system. And indeed, there is broad consensus among environmental scholars that EPZs facilitate a general "distancing" of socio-environmental externalities in that the actual costs of industrial production are increasingly displaced to LDCs and therefore rendered invisible to consumer and voter populations in the core (Prell et al. 2014; Rice 2009).

The policy agendas that typify the Bretton Woods system therefore clearly effectuate a general "opening up" of LDC economies which, beyond guaranteeing access to the periphery's labor power, has allowed Western powers to systematically seize and syphon off the natural resource wealth of former colonized states. The extent of this "wealth drain" is laid bare by the astounding flight of capital from less-to-more developed nations, which ironically positions developing nations as net-creditors to the rest of the world. In 2012, for example, the global South received $1.3 trillion in total aid, investment, and income from the global North; in the same year, however, the outflow of South-to-North wealth reached over $3.3 trillion (Schjelderup and Baker 2015).[23] From 1980 (the first year of SAP implementation) to 2012, net South-to-North capital outflows totaled a staggering $16.3 trillion, with an additional estimated $13.4 trillion lost to the North through unrecorded and/or illicit capital flight (Schjelderup and Baker 2015). Thus, the contemporary narrative of international development is indeed backwards for it is not the global North that is developing post-colonial nations, but rather the periphery,

[23] These findings come from a comprehensive study conducted by the Centre for Applied Research, Norwegian School of Economics, Global Financial Integrity, Jawaharlal Nehru University, el Instituto de Estudos Socioeconômicos, and the Nigerian Institute of Social and Economic Research.

locked in a neocolonial model of economic development, that continues to sustain and develop the economies of the core.

As demonstrated above, the imposition of this neocolonial model is uniquely dependent on the implementation of World Bank and IMF policies that, among other things, (a) enforce unequal terms in patterns of international trade, (b) ensure corporate access to stocks of foreign-owned natural capital, (c) increase corporate control over systems of transnational production, (d) lock LDCs into an export-oriented model of economic development, and (c) diminish the sovereignty of underdeveloped nations, thereby reducing the capacity of these nations to effectively self-govern and, therefore, resist the deleterious effects of such policies (Downey 2015; Bello et al. 1999; Wallach and Woodall 2004; Cooper 2008, Babb 2010). These policies, therefore, represent key structural mechanisms that drive the increasing transnational character or "tilt" of treadmill acceleration, as well as the systems of unequal ecological exchange that are unique to it, both of which facilitate the acquisition of new global markets and production strategies that allow for the reinvestment of otherwise overaccumulated capital via the displacement of market crises elsewhere is geographical space.

And yet, because leading sociological theories of the environment privilege certain aspects of social life and social structure over others (like all theories do) the potential mutability of structural forces that drive treadmill acceleration, unequal ecological exchange, and the market contradictions theorized by Harvey and O'Conner are largely overlooked, diminishing the overall theoretical robustness of social, economic, and environmental relations postulated thereby. To safeguard against such outcomes, environmental scholars must look to the increasing relevance of IFIs, which should be not only more thoroughly incorporated, but *highlighted* as decisive theoretical constructs within these models (Downey 2015). In doing so, environmental

scholars will be better equipped to specify a key set of evolving institutional factors that, to a highly significant degree, determine the scope, scale, and character of treadmill expansion, ecological unequal exchange, and the North-to-South displacement of market contradictions that allows for continued rounds of accumulation in the core.

**Section II: Structural Adjustment and Developing Nation Health**

The previous section has established that the World Bank and IMF are U.S. and European controlled financial institutions that provide loans to developing nations. It has further established that Bank and Fund development lending serves as a key institutional mechanism that opens up developing nations to foreign investment and to labor and natural resource exploitation, thereby facilitating unequal, colonial-like exchange relations between the global North and South. Finally, it has argued that while leading sociological theories of the environment acknowledge the increasing transnational organization of global economic production, they too often fail to pay adequate theoretical and analytical attention to the foremost set of neoliberal institutions that make this organization possible.

In making the above argument, I have attempted to underscore the potential mutability of the structural forces that drive the social, economic, and environmental outcomes that these theories posit. Put differently, it is apparent that the structural drivers of these outcomes are contingent on a complex set of ever-evolving institutional arrangements, which environmental scholars must repeatedly specify in the context of shifting global-economic history (Downey 2015). If this position is valid, it would seem equally as requisite that environmental sociologists look not only to the shifting institutional arrangements that propel specific socio-economic and environmental outcomes but also to the shifting, and heretofore unrecognized, frontiers of newly

acquired resource systems that hold the potential to transcend the traditionally theorized limits of capital. Indeed, it is my position that life science bio-production increasingly necessitates the acquisition of new, human-derived resource systems and that the very same set of neoliberal institutions play a pivotal role in "opening up" these systems by both producing and providing access to the bodies of structurally disadvantaged nations. It is the latter of these points to which I now turn.

*Identifying the Causal Links between Structural Adjustment and LDC Health*

Leading research into the casual links between Bretton Woods policy and developing nation health identifies three general pathways through which structural adjustment impacts public health outcomes. These include polices that *directly* affect health and healthcare systems, polices that *indirectly* affect health and healthcare systems, and polices that affect *the social determinants of health* (SDH) (Kentikelenis 2017; Thomson et al. 2017; McNamara 2016; Labonté and Schrecker 2007). Below, I provide a summary of these research findings and their implications for the North-to-South outsourcing of pharmaceutical and biotech R&D projects to low- and middle-income nations.

The four "…ations" of structural adjustment *directly* impact LDC health in a number of important ways. First, studies on the effects of stabilization and austerity measures show that adjusted nations are routinely forced to alter existing structures of healthcare financing, requiring governments to reduce public health expenditures and/or replace once reliable public expenditures with fluctuating inflows of foreign aid. These changes in state investment then reduce the quality and general provision of healthcare services – e.g., the number of healthcare facilities, the number of medical personnel, the training of these personnel, etc. (Mladovsky et al.

2012; Reeves et al. 2013; McCoy et al. 2005; Stuckler and Basu, 2009). Stabilization measures also dictate drastic cuts to social program spending (e.g., systems of welfare, health insurance, social security, etc.), which reduces the state's capacity to ensure a baseline of public health, thereby further straining already disinvested healthcare facilities. In Greece, for example, rates of HIV infection increased by 52% between January and May of 2011 as the newly, IMF adjusted government was forced to slash spending on its needle-exchange program for substance abusers (Stuckler and Basu, 2013). And indeed, research shows that cuts in social spending are associated with SAP implementation across all low-income democracies outside of Sub-Saharan Africa (Kentikelenis et al. 2015b; Nooruddin and Simmons 2006; Noy 2011).

Second, the medical workforce within LDCs is significantly and negatively affected by austerity measures that result in hiring freezes, wage cuts, and the implementation of "wage bill ceilings" (i.e., a state-imposed limit on wage expenditures) (Kentikelenis et al. 2014b; Stubbs et al. 2017). These SAP-induced outcomes not only diminish the recruiting, training, and thus number of available medical personnel, they are also key drivers of medical "brain drain," or the increasing out-migration of medical professionals from less-to-more developed nations. (Lefrançois 2010; Kentikelenis et al. 2016). As Heimer (2007) observes of Africa, "…the research is unequivocal: doctors, nurses, pharmacists, and other skilled personnel, already in short supply, are moving in droves to jobs in developed countries, hoping to find better managed health-care facilities, chances for further education, better working conditions, and higher pay" (563-564). This medical brain drain is all the more concerning given that the World Health Organization (WHO) argues that at least 20 doctors per 100,000 people are needed to maintain minimum public health standards within any given nation. And yet, 31 out of 54 African nations

fell well below this standard as of 2003, with Liberia, for instance, having 2.3 doctors per 100,000 in 1997 and 3.8 per 100,000 in 2015 (The Global Health Observatory; Heimer 2007).

Third, the introduction of "user fees" (i.e., fees-for-medical services) and other revenue-raising measures for the repayment of debt, such as co-payments for medications, have been a common feature of SAP conditionality (Thomsons, et al. 2017; Mladovsky et al., 2012; Labonté and Schrecker 2007). According to Kentikelenis (2017: 298), "the rationale for applying such fees was generating additional resources, improving efficiency, and increasing access. Yet, they failed to live up to their promise and have been linked to reduced access for the poor, high administration costs, and bureaucratic inefficiencies." Using data from 47 African nations, for example, Anyanwu and Erhijakpor (2009) find that a World Bank directive to implement a $0.33 user fee for access to outpatient health centers resulted in an astonishing 52% reduction in healthcare visits, which was then followed by a 41% recovery upon the directive's suspension. Similarly, a simulation model of 20 African nations found that the implementation of healthcare user fees resulted in an estimated 233,000 under-5 deaths per year, or a 6.3% increase in such childhood deaths annually (Morris and Taylor 2005; Thomsons et al. 2017).

Fourth, SAP-imposed deregulation measures greatly impact the public-private ratio of health service provision, resulting in private (i.e., for-profit) companies assuming far greater control over systems of national health (Homedes and Ugalde, 2005; Thomsons 2017). This, of course, increases access to medical care and broadens the array of medical services available to the middle and upper classes, while severely limiting such access and availability for the poor and working classes, the latter of which occurs via increasing medical costs and the simultaneous "rollback" of public healthcare provision.

Fifth, and largely as a result of austerity, retreating state services, and the increasing prominence of for-profit healthcare models, SAPs promote a general decentralization of healthcare systems (i.e., the transfer of financial, organizational, and operational decision-making to subnational authorities) (Homedes and Ugalde 2005; Stubbs et al. 2017). This decentralization of once public (i.e., state-managed) health care responsibilities is hypothesized to decrease bureaucratic inefficiencies while increasing the cogency of regional governments in responding to locally determined health needs. Though these outcomes might hold true for some of the best managed and best funded districts, research shows that decentralization most often "…produce[s] a more fractious and unequal implementation of services—including those for child and maternal health—nationally" (Thomson 2017: 11; Djibuti et al. 2007). In addition, decentralized systems have proven profoundly inadequate when disease outbreaks, natural disasters, and/or civil unrest require the coordination of healthcare resources for the general population, which is to say nothing of the budget execution, financial mismanagement, and corruption problems that plague such systems (Djibuti et al 2007; Kentikelenis 2015; Thomson 2017).

*Changes to Health and Healthcare Systems via Indirect Effects of SAPs*

In addition to the above specified *direct effects* of World Bank and IMF macroeconomic policy, the four "…ations" of structural adjustment impose many *indirect effects* on LDC health and healthcare systems. For example, a key component of SAP stabilization is the intentional devaluation of national currencies. This measure is ostensibly designed to promote the international competitiveness of LDC economies by reducing the costs of export goods for consumption abroad (Downey 2015; Sernau 2009; Labonté and Schrecker 2007). However,

weak national currencies increase the real cost of imported goods, including the pharmaceuticals, medical equipment, and medical supplies that disproportionally sustain LDC healthcare systems (Breman and Shelton 2006; Pandelfelli et al. 2014).

In addition, liberalization measures, such as the removal of tariffs, customs, capital account controls, and other import-export restrictions, lift barriers to international trade and encourage inflows of investment capital from wealthy nations in the core (Downey 2015). In doing so, however, trade-based tax revenues within LDCs are significantly reduced, which in turn undermines the financial resource base that sustains healthcare policy and its implementation (Baunsgaard and Keen 2010). Moreover, such liberalization measures have been shown to increase LDC's vulnerability to global economic fluctuations, to retard the development of infant industries, and to increase LDC dependence on externally produced goods and services, all of which further hinders the capacity of LDC governments to develop and effectively finance healthcare systems (Kanji et al. 1991; Ikamari 2004; Shandra et al. 2011; Thomsons 2017; Kentikelenis 2017).

Finally, and apart from the public-to-private transition of healthcare systems outlined above, SAP-imposed privatization of state-owned industries, enterprises, and natural resources dually impacts LDC health and healthcare systems. These measures are advocated as a source of revenue raising for cash-strapped governments to service external debt. This economic growth is alleged to occur via the selling off of state-owned enterprises to foreign interests and the subsequent long-term revenue streams that will follow the more efficient operational management of these enterprises (Babb 2009; Spronk and Webber 2007; Labonté and Schrecker 2007).

And indeed, the initial sale of state-owned assets often results in short-term financial gains. In the medium- and long-term, however, these gains quickly dissipate, as the state's most profitable sources of revenue become sequestered by multinational corporations who repatriate, rather than reinvest, the majority share of LDC derived profits (Thomson et al. 2017; Downey 2015; Labonté and Schrecker 2007). In this way, SAP host nations lose their most significant and reliable sources of medium- and long-term revenue streams, which are essential elements to the sufficient financing and thus proper functioning of any national healthcare system (King et al. 2009; Shandra 2012; Kentikelenis 2017). Lastly, mass privatization has been shown to substantially increase unemployment rates (especially among adult males), which reduces access to healthcare through (i) the withdraw of healthcare coverage often provided by state-owned industries and (ii) a loss of wages and thus ability of former state employees to afford increasingly privatized healthcare services (Stuckler and Basu 2013; Stuckler et al. 2009).

*Changes to Health via SAP Effects on Social Determinants*

Broadly defined, the social determinants of health (SDH) refer to the social, economic, and environmental conditions in which people live, learn, work, and age, and thus the conditions that either block or facilitate opportunities for health (Labonté and Schrecker 2007; Simons et al. 2018). The four "…ations" of structural adjustment, therefore, exert profound influence over public health outcomes in that they often disrupt and restructure these social determinants.

First, structural adjustment can significantly worsen the social conditions that promote positive health practices, thereby exacerbating the direct and indirect effects that these policies have on public health outcomes. For instance, increasing unemployment due to mass privatization, coupled with the rollback of social services due to austerity measures, have been

shown to increase levels of chronic stress among impacted populations, which is relevant to population health for two important reasons. On the one hand, chronic stress is known to impair memory, increase the risk of depression, elevate blood pressure, increase the risk for cardiovascular disease, lower immune responses, and affect hormonal systems (Sapolsky 2005; Pickett and Wilkinson 2015). On the other hand, chronic stress has been shown to intensify secondary practices of self-medication – e.g., drug, alcohol, and tobacco use – as coping strategies, which are causally associated with a host of negative health outcomes throughout the life course (Stuckler et al., 2009). And unlike the direct and indirect effects that SAPs impose on systems of health, which are more rapidly reflected in public health outcomes, the consequences of disrupting SDH often take decades to become apparent. This point is made clear when considering Bank and Fund deregulation and liberalization measures that have facilitated the mass rise of tobacco consumption in low- and middle-income nations (Gilmore et al., 2009), which result in poor health and novel disease burdens after a period of significant delay (Kentikelenis 2017).

Second, the four "…ations" of structural adjustment have been consistently linked to increasing levels of socio-economic inequality, which – beyond the immediate effects of material deprivation and poverty on collective wellbeing – negatively impacts public health in a number of important ways (Downey 2015; Oberdabernig 2013; Babb 2009; Dreher 2006; Ram 2006; Vreeland 2007; 2002). For instance, increasing levels of income inequality intensify systems of social stratification and hierarchy, accentuating class and status differences that degrade the socio-cultural fabric of societies. The result is a general breakdown in social cohesion, trust, community involvement, ethnic harmony, and increasing levels of violence (Pickett and Wilkinson 2015). And as research shows, measures of social cohesion, such as friendships,

community engagement, and social networks, are as protective of health as tobacco use is harmful (Holt-Lunstad et al., 2010). While diminished social cohesion is but one of *many* casual mechanism that mediate the relationship between rising inequality and poor health, it is worth noting the most recent review of the relevant literature, which reports that 94% of peer-reviewed studies find at least one statistically significant association between increasing inequality and worsening health (Pickett and Wilkinson 2015) Indeed, this inequality-health association is all the more concerning given the World Bank's own projections, which estimate that 86% of the global South's total population will continue to experience rising levels of economic inequality until at least the year 2030, despite its original and optimistic predictions for an expanding, global middle class (2007).

Third, education is a crucial social determinant of health, impacting health over the life course in two important ways. On the one hand, education directly informs and increases individuals' knowledge about health, how to access health, and how to effectively communicate and interact with healthcare providers (i.e., cultural health capital) (Shim 2010). On the other hand, education is the single strongest predictor of socio-economic mobility, which improves access to a host of societal opportunities, all of which feed back into other determinants of health (e.g., residency and its environmental conditions, social networks, employment, education, healthcare services, health-promoting practices, etc.) (Kentikelenis 2017; Jamison et al. 2013). However, and as previously addressed, SAPs have been shown to drastically reduce educational quality and attainment opportunities within many developing nations. These impediments to education occur not only because of SAP-mandated reductions to education expenditure and declining tax revenues, but also because of Bank and Fund imposed user fees for primary education, which severely limit educational access for the poor and working classes (Babb

2005). Compounding these deleterious effects, Daoud et al. (2017) find that SAPs also reduce the protective benefits of parents' educational attainment for the general health of children.

Fourth, and as delineated in the previous section, SAPs have a profoundly negative effect on the environment and the capacity of state authorities to enact and enforce environmental regulations (Downey 2015). For example, SAPs have prompted intense processes of agrarian and forest conversion that favor cash crop, mineral, and exotic timber production and thus the export-oriented model of economic development – as opposed to import substitution policies that better serve the interests of subsistence farmers and industrial laborers. The result is an immediate loss of livelihoods and reduced access to ecosystem services (e.g., food, clean air, freshwater, disease regulation functionality, etc.) both of which are essential determinants of health (Labonté and Schrecker 2007; Pacheco 2006). Loss of wages and/or employment, for instance, result in economic insecurity and material deprivation which, in turn, engender long-term unmet medical needs and/or disastrous, emergency healthcare expenses that often impact familial households at the intergenerational level (McIntyre et al. 2006).

In addition, land transition for cash crop, timber, and mineral export – combined with lax environmental regulations that inhibit state oversight of production processes – result in severe ecological degradation, which disproportionately impacts the health of structurally disadvantaged populations less able to avoid exposure to hazardous environmental conditions (Labonté and Schrecker 2007). Similarly, SAP-induced deregulation of state regulatory capacities facilitates the migration of core-based "dirty industries" to periphery nations, notably to export processing zones (EPZs), which provide industrial "pollution havens" for the cheap extraction of ecological carrying capacity that would otherwise be realized in the core (Jorgenson 2012; Rice 2009; Labonté and Schrecker 2007). However, this practice too leaves poor and working-class

populations asymmetrically vulnerable to the adverse health effects of hazardous waste exposure which include, but are not limited to, a wide range of cancers; asthma and other respiratory diseases; neurological diseases such as Parkinson's, multiple sclerosis, and Alzheimer's disease; as well as developmental disabilities such as cerebral palsy and (likely) autism (Centers for Disease Control 2018).

Finally, the very same land conversion processes, and associated rural pollution and labor-subsistence implications, have dramatically altered the degree, mode, and pace of modern-day urbanization, which has proven to produce a host of vulnerabilities to various municipal health hazards (Davis 2006; Kentikelenis 2017). In particular, mass waves of rural-to-urban migration have resulted in the proliferation of large-scale urban slums or informal settlements, with the number and population of such slums increasing dramatically since the 1980s. Throughout this decade, for instance, many LDC cities witnessed a 12% or more annual growth rate of such settlements, which was more than twice that of the average annual growth rate of LDC cities as a whole (Davis 2006). Thus, by the year 2000, the number of LDC slum occupants had surged to an estimated 850 million, with approximately 43% of middle-income nation urbanites and 78% of lowest-income nation urbanites categorized as living in slum settlements (UN-Habitat 2003). In the year 2020, this number increased still further, reaching over 1 billion, or one-seventh of the total global population, with the number of slum residents projected to double by the year 2030 (UN-Habitat 2020; 2007; Davis 2006).

These massive waves of LDC urbanization, in turn, leave hundreds of millions of people to contend with the deplorable conditions of slum life, which is typified by "non-durable housing, inadequate sanitation, unsafe water, insufficient living space, and insecure tenure" (UN-Habitat 2016). And as is well established in the social-epidemiological literature, the conditions

of deprivation ubiquitous to slum settlements dramatically increase the risk for poor health and a broad range of disease states among the populations that live therein (Sverdlik 2011; Ezeh et al. 2017; Lilford 2017). For example, slum residents are known to suffer from elevated rates of *communicable diseases* (e.g., hepatitis, tuberculosis, diarrhea, HIV, etc.); *non-communicable disease*s (e.g., diabetes, cardiovascular disease, cancers, and neurological diseases); *psychological diseases* (e.g., depression, psychoses, suicidal ideation, mourning, etc.) *malnutrition* (e.g., wasting, stunting, undernutrition, and the many diet-related diseases that follow); and *poor infant and maternal health outcomes* (Friesen et al. 2020; Olusoji et al. 2013; Gruebner et al. 2012). These effects on the social determinates of health are then exacerbated by the deregulation and subsequent privatization of water and sanitation services, which allows for-profit companies to introduce user fees for such services (Thomson 2017), thereby imposing an additional financial barrier to both (i) those attempting to exit slum settlements and (ii) those attempting to avoid their entrance.

*Discussion*

In sum, this section has provided a broad overview of the various pathways through which structural adjustment polices affect public health and healthcare systems in many developing nations across the global South. Although non-exhaustive in its presentation, the above findings demonstrate a clear causal association between SAP implementation and declining public health and healthcare infrastructure. Thus, just as SAPs effectuate a general "opening up" of LDC economies – institutionalizing the continuation of colonial-like exchange relations that extract uneven flows of natural and human capital from the periphery – they also effectuate a general opening up of new *structurally produced*, human environments via the

*underdevelopment of health*, which is itself a direct consequence of the core's historical and ongoing depletion of this natural and human capital (Waitzkin and Jasso-Aguilar 2015). Put differently, SAP-imposed structural disadvantage (i.e., declining healthcare provision, worsening and/or unaddressed disease states, growing inequality, unemployment, rampant poverty, treatment naivete, etc.) produces the exact human environments (read resources) that attract the mass outsourcing of bio-pharmaceutical R&D to LDCs, thereby allowing the industry to displace its own internal crisis (i.e., the exhaustion and/or contamination of domestic bodies) via the incorporation of new international body stores as sources of commodifiable value.

SAPs, therefore, serve a key institutional function in the outsourcing of pharmaceutical and biotechnological R&D to developing nations, ultimately paving the way for clinical trial outsourcing and the systems of unequal ecological exchange that characterize it. They do this by creating the conditions of nontraditional research areas or "frontier zones," which are central in attracting the operations of contract research organizations (CROs) and their industry sponsors. The most pronounced of these pull conditions were addressed in chapter 5 and include lower operating and production costs, looser ethical regulations, quick subject recruitment times, and unfettered access to treatment naïve body supplies – all of which are clearly causally linked to SAP implementation. However, and directly associated with these four conditions, SAPs further result in the decline of public healthcare infrastructure, unprecedented medical brain drain to the North, and to the public-to-private transition of healthcare provision. These factors, in turn, allow drug development outsourcing to be construed and increasingly integrated as a necessary component of (still existing) healthcare delivery systems. That is, the *direct* and *indirect* effects of SAPs on LDC health – which are mediated through the social, economic, and environmental inequalities delineated above – ultimately legitimize the outsourcing of human-based

experimentation and bioproduction processes as a vital *public good,* as an important source of health and international investment for which developing nations should be grateful.

As observed by Petryna (2009), the pharmaceutical industry is now actively "co-opting the activist role," adopting the human rights and social justice frameworks in its marketing of outsourced R&D as a public health good. To do this, it underscores the medical access gap between more and less developed countries and "enter[s] into new partnerships with development agencies, national health ministries, philanthropic institutions, multilateral agencies, and nongovernmental organization to address…and fill public health voids in places where national systems and markets have failed or have been absent altogether" (Petryna 2009: 192). Simultaneously, industry sponsored CROs provide eyes and ears on the ground of these so-called "rescue countries," identifying and marketing specific regions and regional populations as prime experimental environments for the generation of human-derived value. Upon securing pharmaceutical contracts to mobilize the most lucrative of these environments, CROs proceed to (i) secure the necessary infrastructure to conduct medical research, (ii) insert the required medical personnel to perform, monitor, and record its execution, and (iii) recruit experimental subjects from some of the most poverty-stricken and medically deprived regions in the world. In this way, the outsourcing of medical R&D is said to absorb many of the social and economic shocks of SAP-induced state withdrawal – ostensibly filling the void of public health needs by providing the desperately sought mechanism of access to "treatment" (Petryna 2009; Li et al. 2015). This access, however, is inextricably tied to medical experimentation. Thus, experimentation-as-healthcare becomes increasingly normalized within regional delivery systems (Li et al. 2015), thereby allowing the pharmaceutical industry to tout its international activities as a civically virtues public good.

Finally, frontier zones are typified by highly flexible regulatory environments that arise as a direct consequence of SAP-induced state withdrawal, with these environments representing yet another central pull factor attracting pharmaceutical investment (Nahavandi 2016). As noted by Shah (2006: 112):

> The modern hunt for bodies leads drugmakers to places almost entirely short of such [regulatory] oversight. Such is the case in India, where a one billion body bounty entices industry investigators.

This level of flexibility goes beyond that of the ethical variability addressed in chapter 5 in the context of ICH-GCP synchronization and subsequent trial design variation between more and less developed countries (see chapter 5). Indeed, the weak or withdrawn political and legal institutions that follow state deregulation and austerity measures produce regulatory environments that exist in a state of flux, resulting in a clinical trials marketplace that is largely self-regulated (Shah 2006; Petryna 2009; Prasad 2009; Goldstein 2012; Li et al. 2015). And although – in the narrative context of experimentation-as-healthcare – CROs claim to maintain rigor, safety, and accountability in the medical research they conduct, providing access to otherwise inaccessible physician-patient care along the way, deep regulatory voids mean that traditional physician-patient relations are reconfigured and made subordinate to the interests of value generation. As one CRO physician-investigator observes:

> Our mission is not about treating the patient. This is not a primary objective, and somehow this is explicitly forbidden. Investigators can recruit only eligible patients. It's the physician's decision as to who will be participating. But maybe this patient has a more severe disease; that's a secondary consideration. Patients must meet the inclusion/exclusion criteria first. Other factors are informal, whether he [a doctor] wants to help this or that patient. But this decision has to be guided by the [trial design] protocol. *We don't see patients, we see data* (Petryna 2009: 101).

Having extracted these data (i.e., products) from experimental bodies, continued access to the experimental drug is at the full discretion pharmaceutical companies, with the most fortunate of

test subjects granted continuity of treatment for a period of time via “extended-access” or “compassionate-use programs” (Petryna 2009).

Taken together, the SAP-induced conditions of frontier zones represent the primary set of pull factors that entice biopharmaceutical outsourcing to low- and-middle income nations, with this geographical displacement serving as a spatial fix to the industry’s latest accumulation crisis. Indeed, the above specified conditions are critical in that they attract, guide, remove barriers to, and thus protect otherwise over-accumulated R&D capital, thereby ensuring continued investment flows into the South, which in turn ensures continued outflows of human-derived biological value to the North. Thus, the export-oriented model of economic development persists in the context of life science bioproduction. In this model, pharmaceutical and biotechnological firms are free to exploit and commodify the bodily value of populations in the periphery, with LDCs having few alternatives but to make their diseased, impoverished, and treatment naive populations available for Western-based research and development. In this context, however, the bodies of structurally disadvantaged populations take on new value and worth. Having once been considered as nothing more than a hindrance to economic development, these populations are now actively marketed as national assets – as new, structurally produced human environments – that attract novel inflows of investment capital and new strategies of human-directed economic development that necessitate the marketing and use of structurally disadvantaged human bodies as sources of commodifiable value.

**Conclusion:**

Beyond providing additional support for the majority of theoretical predictions outlined in table 1 (see pages 45-46), the above findings are consistent with prediction 10, which expects

that the outsourcing of life science research and development will be highly dependent on the implementation of World Bank and IMF policies. More specifically, this prediction expects that SAP host countries will suffer from a variety of negative social, economic, and environmental outcomes that result in the underdevelopment of health and healthcare systems. It further expects that these declining structural conditions will encourage the outsourcing of biopharmaceutical R&D because such circumstances will produce a surplus pool of inexpensive experimental bodies that are diseased, impoverished, treatment naïve, and thus easily mobilized for use in clinical trials research. As demonstrated in the previous section, structural adjustment clearly imposes many negative effects on the health and healthcare systems of LDCs, thereby engendering the very human environments that attract pharmaceutical and biotech investment to underdeveloped nations.

In addition to establishing empirical consistency with prediction 10, this chapter has served to identify several gaps within leading sociological theories of the environment. These gaps include: (i) often inadequate analytical attention paid to IFIs and the macroeconomic policies they implement, (ii) a failure to recognize the bioeconomy and its reorganization of human bodies as a sources of commodifiable value, (iii) a failure to recognize how this reorganization provides capitalists with a new set of human environments and production strategies for the absorption of surplus capital, (iv) a failure to recognize the implications of these processes for the disproportionate exploitation of populations in the periphery and thus the unequal extraction of bodily value by the core.

In the following and final chapter, I provide a general summary of my research findings and discuss the implications of these findings for a reevaluation of the proposed environmental and resource-based limits that are theorized to eventually halt the perpetual expansion of capital

and therefore the economic system of capitalism itself. Here, it will be further established that leading sociological theories of the environment have failed to account for newly emerging, bioeconomic markets and modalities of capitalist expansion, which increasingly subsume the human body as a primary site and resource in the production of economic value, thereby providing otherwise over-accumulated capital with an entirely new set of human-based environments and production strategies in which to invest and thus achieve continued rounds of accumulation.

# Chapter 7

# CONCLUSION: BIOECONOMIC PRODUCTION AND THE "LIMITS" OF CAPITALISM

It is clear that clinical trial research is an essential aspect of biopharmaceutical production and its increasing globalization. Less evident to most people, however, are the kinds of clinical trials that are being conducted, the organizations and institutions involved in their execution, the populations disproportionately utilized in these experiments, and the structural and historical processes that drive their transnational expansion. Even less apparent are the various ways in which biopharmaceutical and broader bioeconomic modes of production come to exploit and commodify the human body as a novel form of natural capital.

To better illuminate these points, I have established a working definition of the body's ecological commodification, which designates three human-directed processes as unique to the process of bodily commodification as nature. These processes include: (i) the enactment of waged, human labor on its own species (i.e., waged labor performed on the would-be laborer), (ii) the targeting, technological manipulation, and extractive valorization of the body's internal, "naturally" occurring materials, capacities, and functions, and (iii) the consequent production and commercialization of human derived biocommodities that are bought and sold as any other goods derived from nature. Using this definition, I then established how contemporary modes of bioeconomic production diverge from historical instances of bodily commodification that incorporated the body's reproductive and generative capacities. This divergence, I argued, is marked by the bioeconomy's functioning, which requires that the production process be relocated *inside* the human body, thereby "enrolling" its internal value potential (i.e., its in vivo processes, materials, and/or services) in novel forms of bio-social commodity production. In this

way, the body's internal ecology is made the immediate target of human labor power which, through the process of technological intervention, renders a human-derived product that is produced by the productive labor (i.e., work) of an external other.

Subsequently, I provided a detailed description of the biopharmaceutical production process, paying specific attention to the nature of bodily utilization within clinical trials research and to the manufacturing and testing of human therapeutic biologics. By way of this description, I showed how the most central components of biopharmaceutical R&D are dependent on the exploitation of human biological materials, information, and in vivo processes as sources of commodifiable value. This, in turn, allowed me to further establish how the extraction and valorization of the body's value potential is achieved via the capacity of human beings to enact labor *on* and *within* their own species. Therefrom, I argued that experimental subjects – and others from whom biological value is extracted – cannot be understood to engage in any meaningful form of self- or object-directed labor, but rather constitute the very objects upon which others' exploited labor is enacted.

To provide additional support for the above claim, I first conducted content analysis of a popular online information and discussion portal (*Just Another Lab Rat*) that is often used by members of the professional clinical trials community. By way of this analysis, I was able to assess the interpersonal communications of research participants, which allowed me to determine how research subjects, themselves, understand the processes of clinical experimentation and whether they understand their role within clinical research to be that of laborer or resource. My findings show that experimental subjects commonly experience and construe clinical trials research as a source of "easy money" devoid of "real work" at a "real job," as a period of vacation during which one is paid 24 hours a day – while sleeping, while eating, while watching

television. To bolster these findings, I then established that the overwhelming majority of clinical trial participants (particularly in the international context) suffer from a structurally induced deficit of human capital, which – in conjunction with opportunity deficits to use what little human capital they do possess – blocks their participation in the formal labor market. Thus, outside of drug testing and development, experimental subjects generally constitute nonproductive assets in the creation of economic value. However, and as demonstrated in chapters 4 and 5, it is exactly this deficit of human capital that purifies the body – from a drug testing standpoint – thereby transforming otherwise economically nonproductive populations into coveted sources of value creation.

In addition, I have argued that if the biopharmaceutical industry does in fact exploit the human body as natural capital than its historical development should follow a theoretically predictable set of patterns. To demonstrate that it does follow these patterns and thus that the body is sometimes commodified as natural capital, I established a set of expectations drawn from leading sociological theories of the environment. I then tested these expectations against the industry's developmental trajectory since the early 1970s. In establishing empirical consistency with these theoretical predictions, I have shown that the industry has experienced *three ecologically unique crises* of overaccumulation. I have further shown that industry efforts to resolve these crises have culminated in a series of spatial fixes, each of which has intensified the practice of clinical trial outsourcing to underdeveloped nations.

The first of these crises was a direct consequence of changing ethical standards in U.S. medical research, which blocked the industry's continued use of prison populations in clinical trial research. To circumvent this crisis, the industry pursued geographic expansion from U.S. prison systems into mainstream U.S., and to a far lesser degree Western European, academic

research centers. This spatial fix provided the industry with adequate access to experimental bodies throughout much of the 1980s. Later in the decade, however, the industry experienced a second accumulation crisis resulting from the drug pipeline explosion, which exhausted the body supply capacity of newly exploited academic research centers. To resolve this crisis, the industry once again pursed a spatial fix via the ICH-GCP, which allowed pharmaceutical companies to intensify the expansion of clinical trial research into a relatively small number of predominantly developed nations around the world.[24]

The industry's third accumulation crisis was directly associated with the 1997 FDA Modernization Act, which from a drug testing standpoint led to the mass contamination of U.S. bodies, thereby producing a profound ecological crisis for the industry. As previously demonstrated, this third accumulation crisis was unique in that the industry was *not* deprived of adequate access to experimental bodies (i.e., resources), *but of adequate access to clean or treatment naïve bodies* (i.e., uncontaminated resources). In order to resolve this crisis, the industry has dramatically intensified the practice of clinical trial offshoring. However, unlike previous rounds of transnational expansion, the industry now exports a highly disproportionate percentage of its clinical experiments to developing nations in the global South. Within these nations the industry is free to exploit lower operating and production costs, looser ethical regulations, quick subject recruitment times, and unfettered access to treatment naïve body supplies, all of which facilitate an uneven extraction of bodily (i.e., ecological) value from populations in the periphery.

In this globalized context of clinical trial experimentation, I further illustrated the body's ecological commodification by analyzing the various ways in which contract research

[24] The ICH-GCP is the International Conference on Harmonization and Good Clinical Practice guidelines (see chapter 5).

organizations (CROs) market developing nation body supplies to pharmaceutical firms. Their advertisements, as demonstrated in chapter 5, in no way attempt to market human bodies as sources of labor. For example, these ads do not showcase increasing levels of human capital, low wages, and/or pliant workforces. In contrast, clinical trial body supplies are advertised as diseased and treatment naïve and thus, from a drug testing standpoint, as pristine and untapped ecological resources from which commodifiable value can be extracted.

Upon confirming the increasing significance and degree to which life science firms export human-directed research and development (R&D) to low- and middle-income nations, I identified the World Bank and IMF as playing crucially important policy roles in the execution of this North-to-South outsourcing. To make this determination, I analyzed the macroeconomic policies these institutions formulate and implement in developing nations, the socio-economic and environmental pathways by which these polices shape the underdevelopment of health and healthcare systems within these nations, and how this underdevelopment aids pharmaceutical and biotech firms by enhancing their ability to access and exploit new, structurally produced human environments abroad. Through this analysis I identified three general pathways through which Bank and Fund structural adjustment policies negatively impact public health outcomes. These include policies that *directly* affect health and healthcare systems, polices that *indirectly* affect health and healthcare systems, and polices that affect *the social determinants of health.*

These direct and indirect effects on LDC health – which are mediated through the social, economic, and environmental inequalities imposed by Structural Adjustment Programs (SAPs) – were then shown to be causally associated with the declining conditions in nontraditional research areas or "frontier zones," which are central in attracting the operations of CROs and their life science sponsors. These conditions, as demonstrated in chapter 6, are a direct

consequence of SAP-induced state withdrawal, which forces LDCs to contend with a number of deepening public health voids that the biopharmaceutical industry claims to address and fill via outsourced R&D projects to the South. Thus, experimentation-as-healthcare becomes increasingly integrated and normalized within regional systems of healthcare delivery – a process that reduces diseased, impoverished, and treatment naïve populations to new, structurally produced human environments that are marketed, exploited, and commodified as such.

These findings suggest that the SAP-facilitated outsourcing of life science bioproduction represents little more than a continuation of the export-oriented model of economic development, which is typified by colonial-like exchange relations between the global North and South. In this model, pharmaceutical and biotechnological firms are free to exploit and commodify the bodily value of populations in the periphery – populations that suffer from a host of structurally imposed conditions that ultimately attract and benefit life science firms in the core. Through this novel and exploitative system of outsourcing, the industry ostensibly executes a civically virtuous public good via injections of otherwise overaccumulated R&D capital into the global South. In reality, however, these inflows of investment capital function to ensure continued outflows of human-derived biological value to the North, which allows the biopharmaceutical industry to overcome its own internal crisis (i.e., the exhaustion and/or contamination of domestic bodies) via the displacement of market contradictions abroad.

Having summarized my research findings, I now provide a brief discussion of the contributions this dissertation makes to the relevant sociological and non-sociological literatures. Here, I outline and consider some of the most important social and theoretical implications of the research. I then conclude the chapter with a brief overview of this study's most pronounced limitations.

*Contributions to Sociological and Non-Sociological Knowledge*

The findings of this study provide broad empirical support for the ten theoretical predications highlighted in this dissertation, thus drawing attention to the various ways in which the life science industry exploits and commodifies the human body as natural capital. This dissertation therefore makes a unique contribution to a small, but growing body of literature that challenges social scientists to rethink society's relationship to the natural world and to reconsider the body's role within contemporary capitalism. The theoretical importance of this reorientation is clear. As rapid new scientific advances in the fields of biotechnology, biomedical, and biogenetic research continue, so too will opportunities for the human body to be seized upon by new bio-exploitative modes of capitalist production. This, of course, is not to say that the body's ecological commodification is or necessarily will be a ubiquitous aspect of everyday economic production or that bodily commodification as labor is no longer important. It is to say, however, that the body's traditional and theoretically accepted role in economic production – as producer and consumer of goods and services – is undergoing an historically unprecedented transformation consequent to rapid technological innovation and development. It is therefore essential that social science scholars begin to grapple, both substantively and theoretically, with the various ways in which the human body is and will continue to be incorporated into newly emerging projects of capital accumulation.

In what is perhaps the most significant contribution to this new line of inquiry, Cooper and Waldby (2014) argue forcefully for the theoretical model of "clinical labor." In this model the bioeconomy is understood to diminish the traditionally held demarcation between productive labor (human work) and reproductive labor (human life). It does this by internalizing the

production process within bodily space, incorporating the body's productive and regenerative capacities into novel forms of bio-social commodity production. This process of bodily relocation, incorporation, and production, they argue, constitutes a novel form of bio-social labor relation. In this labor relation, the "laborer" enters a bio-specific market to sell the body's in vivo biological processes and/or services (i.e., the work of human ecology), as they would otherwise sell their labor-power in any traditional (i.e., non-bioeconomic) market. However, this dissertation has demonstrated that bioeconomic or "clinical laborers" do not apply any meaningful form of productive labor (i.e., work) on nature/matter/object to produce the commodity, good, or service in question. Rather, clinical laborers simply provide access to the body's normal biological elements and functions. In providing this access, Cooper and Waldby argue, clinical laborers "engage in a peculiar kind of risk-bearing labor" in which they "truly labor only inasmuch as they subject themselves to the possibility of metabolic transformation" (2014: 137).

Regardless of these assertions and the overall brilliance of Cooper's and Waldby's work, risk is not constitutive of labor, and the ability to bear risk (while intrinsic to the process of valorization) is not the primary productive force in the clinical research industry. Rather, and as demonstrated throughout this study, it is the waged and exploited labor of scientists and medical professionals, consciously enacted *on* and *within* the bodies of experimental subjects, that is productive of human-derived biological value. In underscoring this, and several other key points regarding the supposed "labor" of clinical labor, I have suggested that the work of Cooper and Waldby is held captive by age-old anthropocentric prejudices[25] that cause them to misdiagnose

[25] It is clear, for example, that in the context of dominant Anglo-European society, the wealthy have been understood as better than and above the poor, men as better than and above women, Whites as better than and above non-Whites, *humans as better than and above nature.* We, as a globalized human society, have evolved to the point of acknowledging and openly challenging the first of these three sharp and highly stratified distinctions. The latter,

what is now the body's *ecological* exploitation as a novel form *labor* exploitation. They therefore mischaracterize the true nature of the bioeconomic revolution and the new structural position of many human beings within this revolutionized economy, thereby also misapprehending human being's relationship to each other and to the natural world. It would seem, therefore, that additional contributions are required, for theoretical models are useful only to the degree that they accurately explain empirical reality (Fligstein 2001).

I contribute to this new theoretical project by highlighting key gaps within leading sociological theories of the environment. These gaps include: (i) often inadequate analytical attention paid to international financial institutions (IFIs), the macroeconomic policies they implement, and the implications of the policies for the social, economic, and environmental outcomes these theories postulate (ii) a failure to recognize the bioeconomy and its reorganization of human bodies as a sources of commodifiable value, (iii) a failure to recognize how this reorganization provides capitalists with an entirely new set of human environments and production strategies for the absorption of surplus capital and thus its continued accumulation, and (iv) a failure to recognize the implications of these processes for the disproportionate exploitation of populations in the periphery, which occurs via the unequal ecological extraction of bodily value by the core.

In underscoring and attempting to fill these gaps, I have endeavored to provide a novel and environmentally unique perspective through which to analyze processes of bodily commodification. I have further qualified the merit of this perspective by demonstrating several overarching points: First, the body, like nature, possesses inherent value potential. Second, the body, like nature, can be an object of labor enactment. Third, the body's value potential, like that

however, remains socially embedded and pervasive to currents of intellectual thought, thereby obstructing the unobstructed pursuit of scientific knowledge.

possessed by nature, can be extracted and commodified. Fourth, once commodified human bio-products enter a globalized market in which they are bought and sold like any other good derived from nature.

These empirical findings are highly significant in that they force environmental and bioeconomic scholars, along with social scientists in general, to reconsider the theoretical heritage that has historically served to extract humanity from the realm of nature. In particular, these findings challenge a key set of principles that guide contemporary socio-environmental theory – principles rooted in the human-nature division solidified by Marx. This dualism, as previously noted, is fundamentally based in the unique and inimitable capacity of human beings to perform labor which, for Marx, is the sole medium through which humans (i) exercise an elevated state of consciousness, thereby expressing that which makes them human and (ii) create economic value via the usurpation, manipulation, and transformation of nature. Thus, under capitalism, labor is the principal characteristic that separates humanity from the natural world as well as that which mediates society's estranged relationship to this world (Foster 1999).

Although so ingrained as to be most often implicit, this human-nature dualism is the cornerstone of virtually all socio-environmental theory. Environmental scholarship is therefore constrained by a theoretical tradition that blocks the conceptualization of human bodies as natural capital or the ways in which this capital is now incorporated directly into the production process. However, when human biological materials, information, and in vivo processes become sources of commodifiable value, when bodies are transformed into objects of labor enactment, and when human-sourced bio-products are bought and sold as any other commodity derived from nature, we are forced to rethink this thesis, thereby reconsidering humanity's position within the natural world and its increasing vulnerability to the exploits of capital.

I have contributed to this theoretical reassessment by reconceptualizing the human body as natural capital and arguing for the scholarly application of this conceptualization – both theoretically and empirically – when situationally appropriate. Using this reconceptualization, environmental scholars and social scientists in general will possess a new and ecologically unique perspective through which to analyze (i) the rise and/or intensification of human-based bioproduction, (ii) the structural forces driving its geographic expansion, and (iii) the processes of bodily commodification that sustain it, and (iv) the social, environmental, and theoretical consequences of this expansion. Of equal importance, this reconceptualization will allow social scientists to better understand capitalism's tendency to come full circle (i.e., exploit and commodify even that which created it) and to better predict the very real human consequences that are sure to follow. In other words, it is clear that human bodies are now involved in capitalism in ways that go far beyond their traditional and theoretically accepted role as producers and consumers in market exchange (Guthman 2011). As such, capitalism, once understood to be that which separated humanity from the natural world, now exhibits the capacity and need to subsume human beings as nothing more than that which is ecological. In this way, capitalism once again expands the limits of traditionally understood resource systems. As observed by Simon (1996):

> Each epoch has seen a shift in the bounds of the relevant resource system. Each time, the old ideas about 'limits,' and the calculation of 'finite resources' within the bounds, were thereby falsified. Now we have begun to explore the sea, which contains amounts of metallic and perhaps energy resources that dwarf the deposits we know about on land. And we have begun to explore the moon. Why shouldn't the boundaries of the system from which we derive resources continue to expand in such directions, just as they have expanded in the past?

It has been my contention throughout this study that modern society's biotechnological turn signals the arrival of one such epoch. In this bioeconomic context, the bounds of finite

resources systems are reconfigured and relocated *within* human beings, a process that transforms the body's internal ecology into a site of production that is made equally as vulnerable to patterns of overuse, contamination, and disequilibrium as is the "natural" environment itself. In this way, capitalism now functions as a great equalizer – reinserting that which it once extracted and elevated above nature back into the natural world.

*Limitations of Research Presented*

As described in chapter 3, this dissertation utilizes a case study approach – based on both primary and secondary data – to (i) determine if and the degree to which life science firms come to exploit and commodify the human body as natural capital, (ii) identify the various causal mechanisms that initiate and intensify processes of bodily commodification by these firms, (iii) document the degree to which macroeconomic policies imposed by IFIs facilitate the expansion of bodily commodification processes from more-to-less developed nations, and (iv) test the explanatory power and thus applicability of leading sociological theories of the environment to bioeconomic modes of production.

Certainly, case study methodologies are an appropriate way, if not the only practical means, to track the developmental history and production strategies of a specific economic sector and to evaluate the potential value or inadequacies of existing theoretical models in explaining this history and such strategies. Nevertheless, the case study approach has several noteworthy limitations. First, and in the context of determining how the biopharmaceutical industry, itself, views, understands, and acts upon its international body supplies, I was limited to publicly available industry documents, CRO advertisements, and academic publications. This is an important limitation because as life science firms have intensified and deepened their

commodification of LDC bodies, they have likewise fallen under increasing public and academic scrutiny and criticism.[26] These criticisms have resulted in what many observe to be an industry wide effort to "clean up" its imagine and whitewash its international activities. There is little doubt, for example, that such efforts contribute greatly to the pharmaceutical industry's increasing use of human rights and social justice rhetoric in framing outsourced R&D as a public health good. And having analyzed a significant number of CRO advertisements that date from the early 2000s to the present, I can personally attest to a general shift from the use of market-oriented language to describe vulnerable populations – e.g., test subjects become "patients," experimental agents become "treatment," medical research becomes "medical care," etc. All this is to say that I lacked access to the industry's internal documents, communications, and administrative personnel, which – even in the context of an industry wide cleanup effort – would have shed a great deal of additional light on the research at hand, especially in regard to the industry's understanding and use of human bodies as ecologically exploitable goods.

Similarly, in conducting content analysis of the *Just Another Lab Rat* portal, I was limited to assessing the communications that portal members wanted in the public domain. On more than several occasions my observations were disrupted when relevant discussion threads went private (i.e., moved to private discussion boards) to avoid self-incrimination and/or the public discussion of industry-specific criticisms that were deemed to be potentially problematic. The reasons for this often-noteworthy degree of secrecy seemed twofold. First, the portals creator (David Gray) was observed to censor (i.e., remove) posts that too blatantly opposed the endorsed standards of clinical research (e.g., not washing out). Gray was also observed to ban "rats" (as they would

[26] This is especially true in the context of life science firms' subcontracting human-directed R&D to international CROs; the market-oriented language often used to describe structurally disadvantaged populations in CRO advertisements; the lack of access to post-trial treatment for experimental subjects; accusations of exploitation, malfeasance, unethical clinical practices, etc. (Li et al. 2015; BD 2013; Prasad 2009).

often self-identify) from the portal entirely, which was at times a point of contention and resentment that portal members would openly express. Second, before going private, a number of portal members expressed anxiety about industry representatives possibly observing their discussions, which were principally industry critical. From this, I can only hypothesize that portal members feared being industry blacklisted – i.e., flagged as behaviorally problematic test subjects whose bodies would yield low quality data. As for the legitimacy of this fear, and the exact behaviors and discussions deemed necessary to hide, I can only speculate.

Finally, while the case study approach provides an effective tool to test and evaluate the potential value or inadequacies of existing theoretical models, it cannot be used to definitively demonstrate the validity of any such theoretical explanations. What it can do is provide strong evidence that demonstrates the various weaknesses of existing theories, and strong evidence for the strengths and explanatory power of others. This, too, is an important limitation of the research presented (albeit one shared by virtually all research methodologies). Thus, while I believe this study provides strong empirical support for the body's ecological commodification under systems of life science bioproduction and thus strong support for the overall applicability of sociological theories of the environment to the bioeconomy and its functioning, I cannot definitively prove the validity of these claims. What I can do, and did, however, is (i) point out multiple instances in which the body's use, exploitation, and commodification diverged from historical instances of bodily utilization, (ii) underscore the historically unprecedented technological developments that made such instances possible, (iii) test a set of theoretically informed predictions against the social, economic, and environmental outcomes of the bioeconomy's historical development, and (iv) demonstrate consistency or inconsistency with the theoretical expectations of these predictions. In doing these things, it is hoped that this

research contributes to an intellectually conducive space in which future researchers can consider and debate the validity and explanatory power of each theoretical model as they pertain to modern society's biotechnological turn.

## REFERENCES


Anyanwu, John and Andrew Erhijakpor. 2009. "Health expenditures and health outcomes in Africa. *African Development Review*. 21(2): 400-433.

Avorn, Jerry. Ameet Sarpatwari, and Aaron S. Kesselheim. 2015. "Forbidden and Permitted Statements about Medications – Loosening the Rules." *The New England Journal of Medicine*. 373 (10): 967-972.

Babb, Sarah. 2009. *Behind the Development Banks: Washington Politics, World Poverty, and the Wealth of Nations*. Chicago: University of Chicago Press.

Babb, Sarah and Ariel Buira. 2005 "Mission Creep, Mission Push, and Discretion: The Case of IMF Conditionality." In *The IMF and the World Bank at Sixty,* ed Ariel Buira. London: Anthem.

Baunsgaard, Thomas and Michael Keen. 2010. "Tax Revenue and (or?) Trade Liberalization." *Journal of Public Economics*. 94(9-10): 563-577

B.D. (Berne Declaration) Magazine. 2013. "Human Guinea-pigs: Clinical Trials on the Cheap." *Berne Declaration.* Special Edition.

Berg, Bruce L. 2009. Qualitative Research Methods for the Social Sciences. Boston: Allyn & Bacon.

Becker, Gary. 1964. *Human Capital*, New York: Columbia University Press.

Becker, Gary. 2002. "The age of human capital." Education in the Twenty-First Century. Retrieved from: http://economics.dlut.edu.cn/uploadfiles/20081106200614853.pdf, accessed 11 August 2020.

Bello, Walden F., Shea Cunningham, and Bill Rau. 1999. *Dark Victory: The United States and Global Poverty*. Oakland, CA: Pluto.

Birch, Kean and David Tyfield. 2012. "Theorizing the Bioeconomy: Biovalue, Biocapital, Bioeconomics or…What?" *Science, Technology, & Human Values.* 38(3) 299-327.

Bonds, Eric. 2016. "Losing the Artic: The U.S. Corporate Community, the National-Security State and Climate Change. *Environmental Sociology.*

--- Eric. 2011. *Hegemony and the Humanitarian Challenge: The United States' Legitimation of Contested Violence.* Dissertation Thesis. University of Colorado-Boulder.

Breske, Ashleigh. 2018. "Biocolonialism: Examining Biopiracy, Inequality, and Power." *Global Politics and Societies, Hollins University.*

Breman, A., Shelton, C., 2006. Structural adjustment programs and health. In: Kawachi, I., Wamala, S. (Eds.), *Globalization and Health*. Oxford University Press, Oxford.

Bunker, S.G. (2005) 'How Ecologically Uneven Development Put the Spin on the Treadmill of Production', *Organization & Environment* 18(1): 38–54.

Cardao-Pito, Tiago. 2016. "A Law for the Social Sciences Regarding Us Human Beings." *Journal of Interdisciplinary Economics* 28(2): 202-229.

Caufield, Catherine. 1996. *Masters of Illusion: The World Bank and the Poverty of Nations*. New York: Henry Holt.

Campbell, Eric G. 2007. "Doctors and Drug Companies – Scrutinizing Influential Relationships." *The New England Journal of Medicine.* 357(18): 1796-1797.

Chang, Ha-Joon. 2008. *Bad Samaritans: The Myth of Free Trade and the Secret History of Capitalism*. New York: Bloomsbury.

Chadwick, Rachelle. 2018. *Bodies that Birth: Vitalizing Birth Politics.* New York, NY. Routledge.

Chossudovsky, M. 2003. *The Globalization of Poverty and the New World Order*. Pincourt, Quebec: Global Research, Center for Research on Globalization (CRG).

Chew, Lisa., Theresa S. O'Young, Thomas K. Hazlet, Katharine A. Bradley, Charles Maynard, and Daniel S. Lessler. 2000. "A Physician Survey of the Effect of Drug Sample Availability on Physicians' Behavior." *J GEN INTERN MED.*15: 478–483.

Clearly, Krystal. 2016. "Feminist Theories of the Body." *The Wiley Blackwell Encyclopedia of Gender and Sexuality Studies*. 1st ed. Edited by Nancy A. Naples. 2016 John Wiley & Sons, Ltd. Published 2016 by John Wiley & Sons, Ltd.

Cohen, G. A. 1979. "The Labor Theory of Value and the Concept of Exploitation." *Philosophy & Public Affairs*. 8(4). 338-360.

Collier, David. 2011. "Understanding Process Tracing." *Political Science and Politics.* 44(4): 823-830.

Conrad, Peter. 2007. *The Medicalization of Society: On the Transformation of Human Conditions into Treatable Disorders.* The John Hopkins University Press. Baltimore.

Cooper, Melinda. 2008. *Life as Surplus*. Seattle: University of Washington Press.

Cooper, Melinda., and Catherine Waldby. 2014. *Tissue Donors and Research Subjects in the Global Bioeconomy*. Duke University Press.

Daugherty, Christopher. 2000. “Quantitative Analysis of Ethical Issues in Phase I Trials: A Survey Interview Study of 144 Advanced Cancer Patients.” *Ethics & Human Research*. 22(3): 6-14.

Davis, Mike. 2006. *Planet of Slums*. London, New York: Verso.

Daoud, A., Nosrati, E., Kentikelenis, A.E., Reinsberg, B., Stubbs, T.H., King, L.P., 2017. Born Into Adjustment: Child Health, Parental Education and the International Monetary Fund. Mimeo. University of Cambridge.

Dickenson, Donna. 2017. *Property in the Body: Feminist Perspectives*. Cambridge University Press.

Dickens, Peter. 2001. “Linking the Social and Natural Sciences: Is Capital Modifying Human Biology in its own Image?” *Sociology*. 35(1): 93-110.

Djibuti, Mamuka., NatiaRukhadze, David R. Hotchkiss, Thomas P.Eisele, and Eva A.Silvestre. 2007. “Health Systems Barriers to Effective use of Infectious Disease Surveillance Data in the Context of Decentralization in Georgia: A qualitative study.” *Health Policy*. 83, (2-3): 323-331.

Downey, Liam. 2015. *Inequality, Democracy and the Environment.* New York: New York University Press.

Downey, Liam. Eric Bonds and Katherine Clark. 2010. “Natural Resource Extraction, Armed Violence, and Environmental Degradation. *Organization & Environment.* 23(4). 417-445.

Domhoff, G. William. 1990. *The Power Elite and the State: How Policy Is Made in America*. New York: Aldine de Gruyter.

Domino, Marisa and Marvin Swartz. 2008. “Who are the new users of antipsychotic medications?” *Psychiatric Services* 59:507-514.

Donohue, Julie. 2006. “The History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection.” *The Milbank Quarterly.* 84(4): 659-699.

Dreher, Axel. 2006. “IMF and economic growth: The effects of programs, loans, and compliance with conditionality.” *World Development*. 34(5): 769-788.

Dunbar-Ortiz, Roxanne. 2014. *An Indigenous Peoples’ History of the United States.* Boston: Beacon Press.

Dumit, Joseph. 2012. *Drugs For Life: How Pharmaceutical Companies Define Our Health.* Durham and London. Duke University Press.

Ebeling, Mary. 2011. “‘Get with the Program!’: Pharmaceutical marketing, symptom checklists

and self-diagnosis." *Social Science & Medicine.* 73: 825-832.

Elliott, Carl. 2007. "Guinea-pigging: Healthy human subjects for drug-safety trials are in demand. But is it a living?" *The New Yorker.*

---. 2014. "The Best-Selling, Billion-Dollar Pills Tested on Homeless People: How the destitute and the mentally ill are being used as human lab rats." Matter.

Epstein, Stephen. 2007. *New Handbook of Science and Technology Studies.* MIT Press 2007.

Ezeh, A.; Oyebode, O.; Satterthwaite, D.; Chen, Y.F.; Ndugwa, R.; Sartori, J.; Mberu, B.; Melendez-Torres, G.J.; Haregu, T.;Watson, S.I.; et al. 2017. "The history, geography, and sociology of slums and the health problems of people who live in slums." *Lancet* 389, 547–558.

Fisher, Jill and Corey Kalbaugh. 2011. "Challenging Assumptions About Minority Participation in US Clinical Research." 101(12): 2217-2222

Fisher, Jill. 2015. "Feeding and bleeding: The Institutional Banalization of Risk to Healthy Volunteers in Phase I Pharmaceutical Clinical Trials." *Science, Technology and Human Values*. 40:199–226.

---. 2009. *Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials*. New Brunswick, NJ: Rutgers University Press.

Fligstein, Neil. 2001. *The Architecture of Markets An Economic Sociology of Twenty-First-Century Capitalist Societies*. Princeton, NJ: Princeton Univ. Press.

Flyvbjerg, Bent. 2001. *Making Social Science Matter: Why Social Inquiry Fails and How it can Succeed.* Cambridge: Cambridge University Press.

Foucault, Michel. 1979. *Discipline and punish: The birth of the prison*. Harmondsworth: Penguin Books (original work published 1975).

---. 1978. *The history of sexuality, Vol. 1: An introduction*. Trans. Robert Hurley. New York. Random House.

Fortune Business Insights. 2022. Retrieved on April 4 2022 from: https://www.fortunebusinessinsights.com/industry-reports/contract-research-organization-cro-services-market-100864

Foster, John and Hannah Holleman. 2014. "The theory of unequal ecological exchange: a Marx-Odum dialectic." *The Journal of Peasant Studies*. 41(2): 199-233.

Foster, John. 1999. "Marx's Theory of Metabolic Rift: Classical Foundation for Environmental Sociology." *The American Journal of Sociology.* 105(2): 366-405.

---. 2005. “The Treadmill of Accumulation: Schnaiberg’s Environment and Marxian Political Economy.” *Organization & Environment.* 18(1): 7-18.

Franklin, Sarah. 2007. *Dolly Mixtures: The Remaking of Genealogy*. Durham: Duke University Press.

Frank, Richard and Rena Conti. 2005. “Mental Health Policy and Psychotropic Drugs.” *Milbank Quarterly.* 83(2): 271–98.

Frank Richard., Rena Conti, Goldman H. 2005. “Mental Health Policy and Psychotropic Drugs.” *Milbank Quarterly*. 83(2): 271-298.

Friesen, John., Victoria Friesen, Ingo Dietrich, and Peter F. Pelz. 2020. “Slums, Space, and State of Health—A Link between Settlement Morphology and Health Data.” *Int. J. Environ. Res. Public Health.* 1-28.

Frey, Scott. 2003. “The Transfer of Core-based Hazardous Production Processes to the Export Processing Zones of the Periphery: The Maquiladora Centers of Northern Mexico.” *Journal of World-Systems Research.* 9(2): 317-354.

Galeano, Eduardo. 1997 (first published in 1973). *Open Veins of Latin America: Five Centuries of The Pillage of a Continent*. Isabel Allende. New York: Monthly Review Press.

George, Alexander L. and Andrew Bennett. 2005. *Case Studies and Theory Development in the Social Sciences*. Cambridge: MIT Press.

Gellad, Ziad and Kenneth W. Lyles. 2007. “Direct-to-Consumer Advertising of Pharmaceuticals.” *The American Journal of Medicine.* 120. 475-480.

Glickman, Seth. John G. McHutchison, Eric D. Peterson, Charles B. Cairns, Robert A. Harrington, Robert M. Califf, and Kevin A. Schulman. 2009. “Ethical and Scientific Implications of the Globalization of Clinical Research.” *The New England Journal of Medicine.* 360(8): 816-23.

Goldstein, Donna. 2012. “Experimentalité: Pharmaceutical Insights into Anthropology's Epistemologically Fractured Self.” In book: *Medicine and the Politics of Knowledge*. (pp.118-151). 1st Edition. Publisher: HSRC Press

Gould, Kenneth. A., David Pellow, and Allan Schnaiberg. 2004. “Interrogating the Treadmill of Production: Everything You Wanted to Know About the Treadmill but Were Afraid to Ask.” *Organization & Environment.* 17(3). 296-316.

Gould, K.A., Pellow, D.N. and Schnaiberg, A. (2008) *The Treadmill of Production: Injustice & Unsustainability in the Global Economy*. Boulder, CO: Paradigm Publishers.

Gould, K.A., Weinberg, A. and Schnaiberg, A. (1995) 'Natural Resource Use in a Transnational Treadmill: International Agreements, National Citizenship Practices, and Sustainable Development', *Humboldt Journal of Social Relations* 21(1): 61–93.

Goldman, Michael. *Imperial Nature: The World Bank and Struggles for Social Justice in the Age of Globalization.* Yale Agrarian Studies Series. New Haven, CT: Yale University Press.

Government Accountability Office (GAO). 2002. "Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations." *Report to Congressional Requesters*

Government Accountability Office (GAO). 2017. "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals." Retrieved on March 10 2021, from: https://www.gao.gov/products/gao-18-40

Gruebner, Oliver., Mobarak Khan, Sven Lautenbach, Daniel Müller, Alexander Krämer, Tobia Lakes, and Patrick Hostert 2012. "Mental health in the slums of Dhaka - a geoepidemiological study." *BMC Public Health*. 12(177): 1-14.

Grady. Christine., Gabriella Bedarida, Ninet Sinaii, Mark Anthony Gregorio, and Ezekiel J Emanuel. 2018. "Motivations, enrollment decisions, and socio-demographic characteristics of healthy volunteers in phase 1 research." *Clinical Trials*. 14(5) 526–536.

Grosz, Elizabeth. 1994. *Volatile Bodies: Toward a Corporeal Feminism*. Bloomington: Indiana University Press.

Guerrini, Anita. 2003. *Experimenting with Humans and Animals: From Galen to Animal Rights.* Baltimore: Johns Hopkins University Press.

Guthman, Julie. 2011. *Weighing In: Obesity, Food Justice, and the Limits of Capitalism.* Berkley. University of California Press.

Harkness, Jon M. 1996. "Research behind Bars: A History of Nontherapeutic Research on American Prisoners." Ph.D. diss., University of Wisconsin, Madison.

Hall, Peter A. 2003. "Aligning Ontology and Methodology in Comparative Research." In *Comparative Historical Analysis in the Social Sciences*, ed. James Mahoney and Dietrich Rueschemeyer, 373–404. New York: Cambridge University Press.

Harvey. David. 1982. *Limits to Capital.* Chicago: University of Chicago Press.

---. 1989. *The Condition of Postmodernity.* Cambridge, MA: Blackwell.

---. 2010. *The Enigma of Capital and the Crises of Capitalism*. London: Profile Books.

Haraway, Donna. 2007. *When Species Meet. Minneapolis: University of Minnesota Press.*

Harris, Gardiner. 2009. “Drug makers are advocacy group’s biggest donors.” New York Times. October 21, 2009: A23. Available at: http://www.nytimes.com/2009/10/22/health/22nami.html. Accessed January 15, 2017.

Hawthorne, Susan. 2007. “Comparative Perspectives Symposium: Bioprospecting/Biopiracy. Land, Bodies, and Knowledge: Biocolonialism of Plants, Indigenous Peoples, Women, and People with Disabilities.” *Signs: Journal of Women in Culture and Society*. 32(2): 3202-0003.

Healy, Kieran. *Last Best Gifts.* 2006. *Altruism and the Market for Human Blood and Organs.* Chicago university Press, Chicago.

Helmreich, Stefan. 2008. “Species of Biocapital.” *Science and Culture.* 17(4). 463-478.

--- 2007. ‘‘Blue-green Capital, Biotechnological Circulation and an Oceanic Imaginary: A Critique of Biopolitical Economy.’’ BioSocieties 2(3). 287-302.

Heimer, Carol. 2007. “Old Inequalities, New Disease: HIV/AIDS in Sub-Saharan Africa. *Annual Review of Sociology.* 33: 551–77.

Henderson, Diedtra. 2007. “Drug firms’ funding of advocates often escapes government scrutiny.” Boston Globe. March 18, 2007. Available at: http://www.boston.com/business/globe/articles/2007/03/18/drug_firms_funding_of_advocates_often_escapes_government_scrutiny. Accessed January 15, 2017.

Horwitz, Allan. 2007. “The ‘DSM’ and the Outcomes of Stressful Social Arrangements.” *Journal of Health and Social Behavior.* 48: 3. 211-222.

Holt-Lunstad, Julianne., Timothy Smith, and Bradley Layton. 2010. “Social Relationships and Mortality Risk: A Meta-analytic Review.” *Plos Medicine.* 7(7): 1000316.

Homedes, Núria and AntonioUgalde. 2005. “Why neoliberal health reforms have failed in Latin America.” *Health Policy*. 71(1): 83-96

Hsieh, Hsiu-Fang, and Sarah Shannon. 2005. “Three approaches to qualitative content analysis. Qualitative Health Research.” 15(9):1277–1288.

Hurt, Stephen R. "Third World debt". *Encyclopedia Britannica*, 28 Sep. 2018, https://www.britannica.com/topic/Third-World-debt. Accessed 17 June 2021.

Humphrey, Margaret. 2003.Whose body? Which disease? Studying malaria while treating neurosyphilis. In: Goodman J (ed.) *Useful Bodies. Humans in the Service of Medical Science in the Twentieth Century*. Baltimore: John Hopkins University Press, 53–77.

Huskamp, Haiden, Marcela Horvitz-Lennon, Ernst R. Berndt, Sharon-Lise T. Normand, and Julie M. Donohue. 2016. “Patterns of Antipsychotic Prescribing by Physicians

to Young Children." *Psychiatric Services in Advance*. 10(1176): 1-8

ICH Harmonized Tripartite Guideline. 1996. "International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. *ICH Expert Working Group.*

IFPMA (International Federation of Pharmaceutical Manufacturers & Associations). 2017. "The Pharmaceutical Industry and Global Health. *IFPMA.*

Ikamari, Lawrence. 2004. "An upsurge in early childhood mortality in Kenya: a search for explanations." Afr J Health Sci. 11: (9-20): 9-20.

International Labor Organization. Labor and Social Issues Relating to Export Processing Zones. *International Labor Office*. Geneva, 1998.

Jafar, Tazeen. 2009. "Organ Trafficking: Global Solutions for a Global Problem." *American Journal of Kidney Diseases.* 54: 1145-1157

Jamison, D.T., Summers, L.H., et al., 2013. *Global health 2035: A World Converging within a Generation*. Lancet 382, 1898-1955.

Jacobson, Michael F. 2005. "Lifting the Veil of Secrecy from Industry Funding of Nonprofit Health Organizations." *Int J Occup Environ Health.* 11: 349-355.

Jorgensen, Paul D. 2013. Pharmaceuticals, Political Money, and Public Policy: A Theoretical and Empirical Agenda." *Journal of Law, Medicine & Ethics.* Symposium. 561-569.

Jorgenson, Andrew and Brett Clark. 2012. "Are the Economy and the Environment Decoupling? A Comparative International Study, 1960–2005." *American Journal of Sociology*. 118(1-44.

Jorgenson, A. & Clark, B. 2009. "The economy, Military, and Ecologically Unequal Relationships in Comparative Perspective: A Panel Study of the Ecological Footprints of Nations, 1975-2000." *Social Problems.* 56. 621-646.

---. 2009. "The Sociology of Unequal Exchange in Ecological Context: A Panel Study of Lower-Income Countries, 1975–2000." Sociological Forum 24:22–46.

*Just Another Lab Rat* (*JALR*). Retrieved from: https://jalr.org/

Kaushik Sunder Rajan. Kaushik. 2006. *Biocapital: The Constitution of Postgenomic Life.* Durham: Duke University Press.

Kanji Najmi., Nazneen Kanji, and FirozeManji. 1991. "From development to sustained crisis: Structural adjustment, equity and health." Social Science & Medicine. 33(9): 985-993.

Kentikelenis, Alexander. 2017. "Structural adjustment and health: A conceptual framework and evidence on pathways." *Social Science & Medicine.* 187: 296-305.

Kentikelenis, Alexander., Thomas H Tubbs, and Lawrence P. King. 2015. "Structural adjustment and public spending on health: Evidence from IMF programs in low-income countries." Social Science & Medicine. 126: 169-176.

Kentikelenis, Alexander., Lawrence King, Martin McKee, and David Stuckler. 2014. "The International Monetary Fund and the Ebola outbreak." *Lancet Glob Health*. 3: 69–70.

Kerbo, Harold. 2005. "Foreign Investment and Disparities in Economic Development and Poverty Reduction A Comparative-Historical Analysis of the Buddhist Countries of Southeast Asia. *International Journal of Comparative Sociology* 46(5-6): 425-459.

Kharas, Homi. 2020. "What to do about the coming debt crisis in developing countries." *Brookings Institute*. Retrieved from: https://www.brookings.edu/blog/future-development/2020/04/13/what-to-do-about-the-coming-debt-crisis-in-developing-countries/

Kidd, Dan. 1996. "The International Conference on Harmonization of Pharmaceutical Regulations, the European Medicines Evaluation Agency, and the FDA: Who's Zooming Who?" *Indiana Journal of Global Legal Studies.* 4(1): 183-206.

King, Lawrence., Patrick Hamm, and David Stuckler. 2009. "Rapid Large-Scale Privatization and Death Rates in Ex-Communist Countries: An Analysis of Stress-Related and Health System Mechanisms." *International Journal of Health Services.* 39(3): 461-489.

Kirsch, Irving. 2009. *The Emperor's New Drug: Exploding the Antidepressant Myth.* The Bodley Head. London.

Kierans, Ciara. 2015. "Biopolitics and Capital: Poverty, Mobility and the Body-in-transplantation in Mexico." *Body & Society.* 21(3): 42-65.

Kowal, Emma and Jenny Reardon. 2013. "Indigenous body parts, mutating temporalities, and the half-lives of postcolonial technoscience." *Social Studies of Science* 43(4): 465–483

Kornfield, Rachel, Julie Donohue, Ernst Berndt, and G. Caleb Alexander. 2013. "Promotion of Prescription Drugs to Consumers and Providers, 2001–2010." *PLOS ONE.* 8(3): 1-7.

Kway, Edda. 2014. "Backward Linkages of Firms Under Export Processing Zone Authority in Tanzania. *International Journal of Education and Research* 2(7): 63-76.

Law, Jacky. 2006. *Big Pharma: Exposing the Global Healthcare Agenda.* New York. Carroll & Graf Publishers.

Labonté, Ronald and Ted Schrecker. 2007. "Globalization and Social Determinants of Health: The role of the Global Marketplace (part 2 of 3)." *Globalization and Health*. 3(6): 1-17.

Langan, M. 2018. *Neo-colonialism and the Poverty of 'Development' in Africa.* Cham: Palgrave Macmillan.

Larkin I, Ang D, Avorn J, Kesselheim AS. 2012. "Restrictions on pharmaceutical detailing reduced off-label prescribing of antidepressants and antipsychotics in children." *Health Aff (Millwood)* 33: 1014-23.

Lee, Allison and Alex Doukas. 2017. "Cross Purposes: After Paris, Multilateral Development Banks Still Funding Billions in Fossil Fuels." *Oil Change International.*

Lefrançois, F. 2010. The IMF, the Global Crisis & Human Resources for Health: Still Constraining Policy Space. *London: UK Consortium on AIDS & International Development and Action for Global Health UK.*

Lilford, R.J.; Oyebode, O.; Satterthwaite, D.; Melendez-Torres, G.J.; Chen, Y.F.; Mberu, B.; Watson, S.I.; Sartori, J.; Ndugwa, R.; Caiaffa, W.; et al. 2017. "Improving the health and welfare of people who live in slums." *Lancet* 389, 559–570.

Li, Rebecca., Mark Barnes, Carmen Aldinger, and Barbara Bierer. 2015. "Global Clinical Trials: Ethics, Harmonization and Commitments to Transparency." Harvard Public Health Review. 6: 1-7.

Marx, Karl. 1976. *Capital, Vol 1*. New York: Vintage.

Marrow, Thomas. 2004. "Defining the Difference: What Makes Biologics Unique." *Biotechnology Healthcare.* 24-29.

Mayring, Philipp. 2000. "Qualitative Content Analysis. *Qualitative Social Research*. 1(2).

Mann, Michael. 1986. *The Source of Social Power Volume 1: A History of Power from the Beginning to A.D. 1760.* Cambridge: Cambridge University Press.

Mahoney, James. 2000. "Strategies of Causal Inference in Small-N Analysis." *Sociological Methods & Research* 28: 387-424.

Mayo Clinic. 2021. "Gastroesophageal reflux disease (GERD)." Retrieved on March 11 2022 from: https://www.mayoclinic.org/diseases-conditions/gerd/diagnosis-treatment/drc-20361959#:~:text=Your%20doctor%20inserts%20a%20thin,(esophagitis)%20or%20other%20complications.

McMichael, Phillip. 2004. *Development and Social Change: A Global Perspective*, 3rd ed. Thousand Oaks, CA: Pine Forge Press.

McNamara, Courtney. 2016. “Trade liberalization and social determinants of health: A state of the literature review.” *Social Science & Medicine*. 176: 1-13.

McIntyre, Diane., Michael Thiede, Göran Dahlgren, and Margaret Whitehead. 2006. “What are the economic consequences for households of illness and of paying for health care in low- and middle-income country contexts?” *Social Science & Medicine*. 62(4): 858-865

McCoy, David., Mickey Chopra, Rene Loewenson, Jean-Marion Aitken, Thabale Ngulube, Adamson Muula, Sunanda Ray, Tendayi Kureyi, Petrida Ijumba, and Mike Rowson. 2005. “Expanding Access to Antiretroviral Therapy in Sub-Saharan Africa: Avoiding the Pitfalls and Dangers, Capitalizing on the Opportunities.” *American Journal of Public Health.* 95: 18-22.

Mitford, Jessica. 1973a. “Experiments behind Bars: Doctors, Drug Companies, And Prisoners.” *Atlantic Monthly.* 23: 64-73.

---. 1973b. *Kind and Usual Treatment: The Prison Business.* New York: Knopf.

Mladovsky, Philipa., Divya Srivastava, Jonathan Cylus, Marina Karanikolos, Tamás Evetovits, Sarah Thomson, and Martin McKee. 2012. “Health Policy Responses to the Financial Crisis in Europe. WHO Policy Summary 5.”

Morris, Saul and Regina Keith. 2005. “Impact on child mortality of removing user fees: simulation model.” *British Medical Journal*. 331(7519): 747-749.

Moore J (2015) Capitalism in the Web of Life. New York: Verso.

Nahavandi, Firouzeh. 2016. *Commodification of Body Parts in the Global South: Transnational Inequalities and Development Challenges.* Palgrave Macmillan.

Nilsson, Jakob and Sven-Olov Wallenstein. 2013. *Foucault, Biopolitics, and Governmentality*. Södertörn Philosophical Studies.

Nooruddin, Irfan and Joel W. Simmons. 2006. “The Politics of Hard Choices: IMF Programs and Government Spending.” *Cambridge University Press.* 60(4): 1001-1033.

Noy, Shiri. 2011. “New contexts, different patterns? A comparative analysis of social spending and government health expenditure in Latin America and the OECD.” *International Journal of Comparative Sociology*. 52: 215-244.

Nundy, S. and C.M. Gulhati. 2005. “A New Colonialism? Conducting Clinical Trials in India.” *New England Journal of Medicine.* 352(16): 1633-6.

Oberdabernig, Doris. 2013. “Revisiting the Effects of IMF Programs on Poverty and Inequality.” *World Development*. 46: 113-142.

O'Connor, James. 1996. "The Second Contradiction of Capitalism." In *The Greening of Marxism,* edited by Ted Benton, 197–221. New York: Guilford.
---. 1989. "Capitalism, Nature, Socialism: A Theoretical Introduction." *Capitalism, Nature, Socialism.* I. 11-38

---. 1973b. *Kind and Usual Treatment: The Prison Business.* New York: Knopf.

Ojakangas, Mika. 2005. "Impossible Dialogue on Bio-power: Agamben and Foucault." Foucault Studies. 2: 5-28

Osabu-Kle, D.T. 2000. "The Politics of One-Sided Adjustment in Africa." *Journal of Black Studies*, (4), 515.

Pandolfelli LE, Shandra J, Tyagi J. 2014. "The international monetary fund, structural adjustment, and women's health: a cross-national analysis of maternal mortality in Sub-Saharan Africa." Sociol Q. 2014; 55:119–42.

Patton, Michael. 2002. *Qualitative research and evaluation methods* (3rd ed.). Thousand Oaks, CA: Sage.

Pacheco, Pablo. 2006. "Agricultural expansion and deforestation in lowland Bolivia: the import substitution versus the structural adjustment model." *Land Use Policy.* 23(3): 205-225.

Palsson, Gisli., 2009. "Biosocial Relations of Production." *Comparative Studies in Society and History.* 51(2): 288-313.

Petryna, A., Lakoff, A. and Kleinman, A. (2006) "Global Pharmaceuticals: Ethics, Markets, Practices." Durham: Duke University Press.

Peet, Richard. 2003. *Unholy Trinity: The IMF, World Bank, and WTO*. New York: Zed Books.

Pellow, David. 2007. *Resisting Global Toxics: Transnational Movements for Environmental Justice.* Cambridge: MIT Press.

Pellow, David and Robert Brulle. 2005 *Power, justice, and the environment: A critical appraisal of the environmental justice movement*, ed. by David Pellow and Robert Brulle, MIT Press.

Petryna, Adriana. 2011. "The Competitive Logic of Global Clinical Trials." *Social Research.* 78(3): 949-974.

---. 2009. *When Experiments Travel: Clinical Trials and the Global Search for Human Subjects.* Princeton University Press.

---. 2007. "Clinical Trials Offshored: On Private Sector Science and Public Health. *Biosocieties.* 2: 21-40

---. 2005. “Drug Development and the Ethics of the Globalized Clinical Trial.” Paper Number 22.

Pfeiffer, J., Chapman, R., 2010. “Anthropological perspectives on structural adjustment and public health.” *Annu. Rev. Anthropol*. 39: 149-165.

Pickett, Kate and Richard Wilkinson. 2015. “Income inequality and health: A causal review Author links open overlay panel.” Social Science & Medicine. 128: 316-326.

Poitras, Geoffrey and Lindsay Meredith. 2008. “Ethical Transparency and Economic Medicalization.” *Journal of Business Ethics.*

Prell, C., Feng, K., Sun, L., Geores, M., & Hubacek, K. 2014. “The Economic Gains and Environmental Losses of US Consumption: A World-Systems and Input-Output Approach.” Social Forces 93(1):405-428.

Prasad, Amit. 2009. “Capitalizing Disease: Biopolitics of Drug Trials in India.” *Theory Culture & Society.* 26(5): 1-29.

Pulido, Laura. 2017. “Geographies of race and ethnicity II: Environmental racism, racial capitalism, and state-sanctioned violence.” *Progress in Human Geography* 41(4): 524-533.

Radley, D., S Finkelsteein and R. Stafford: 2006, “Off-Label Prescribing Among Office Based Physicians.” *Archives of Internal Medicine.* 166. 1021-1026.

Relman, Arnold, and Marcia Angell. 2002. “How the Drug Industry Distorts Medicine and Politics: America’s Other Drug Problem.” *New Republic,* December 16, 27-41.

Reeves, Aaron., Martin McKee, Sanjay Basu, and David Stuckler. 2013. “The political economy of austerity and healthcare: cross-national analysis of expenditure changes in 27 European nations 1995-2011.” Health policy 115(1): 1-8.

Rice, James. 2009. “The Transnational Organization of Production and Uneven Environmental Degradation and Change in the World Economy.” *International Journal of Comparative Sociology.* 50(3-4). 215-236.

Robbins, Paul and Alistair Fraser. 2003. “A Forest of Contradictions: Producing the Landscapes of the Scottish Highlands.” *Antipode.* Blackwell Publishing, Oxford.

Robbins, Richard H. 1999. *Global Problems and the Culture of Capitalism.*Sarah Kelbaugh. Boston: Allyn and Bacon.

Rose, Nikolas. 2007. “The Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century.” Princeton: Princeton University Press.

Rothman, Shelia M., Victoria H. Raveis, Anne Friedman, and David J. Rothman. 2011. "Health Advocacy Organizations and the Pharmaceutical Industry: An Analysis of Disclosure Practices." *American Journal of Public Health*. 101(4): 602-609.

Sah, Sunita and Adriane Fugh-Berman. 2013. "Physicians under the Influence: Social Psychology and Industry Marketing Strategies." *Journal of Law, Medicine & Ethics.* Symposium. 665-672.

SAPRIN. 2004. Structural Adjustment: The SAPRI Report (The Policy Roots of Economic Crisis, Poverty, and Inequality). New York: Zed Books.

Sapolsky, R., 2005. Sick of Poverty. *Scientific American*. 293: 92-99.

Schipper, Irene and Francis Weyzig. 2008. "Ethics for Drug Testing in Low and Middle Income Countries: Considerations for European Market Authorisation." *SOMO.*

Schjelderup, Guttorm and Raymond W. Baker. 2015. "Financial Flows and Tax Havens: Combining to Limit the Lives of Billions of People." *Global Financial Integrity.*

Schnaiberg, Allan. 1980. *The Environment: From Surplus to Scarcity.* New York: Oxford UP.

Scheper-Hughes, Nancy and Loic Wacquant (Editors). 2002. *Commodifying Bodies.* Published in association with *Theory, Culture & Society.*

Sernau, Scott. 2009. *Global Problems: The Search for Equity, Peace, and Sustainability.* Karen Hanson Boston: Pearson Education.

Shah, Sonia. 2006. *The Body Hunters: Testing New Drugs on the World's Poorest Patients.* New York: W.W. Norton & Company.

Shandra, Carrie., John M. Shandra, Bruce London. 2011. "World Bank Structural Adjustment, Water, and Sanitation: A Cross-National Analysis of Child Mortality in Sub-Saharan Africa. *Organizations and Environment.* 24(2): 107-129.

Shim, Janet K. 2010. "Cultural Health Capital: A Theoretical Approach to Understanding Health Care Interactions and the Dynamics of Unequal Treatment." *Journal of Health and Social Behavior*. 51(1): 1–15.

Shiva, Vandana. 1997. *Biopiracy: The Plunder of Nature and Knowledge*. New York: Zed Books.

Simon, Julian L. 1996. *The Ultimate Resource 2*. Princeton, N.J.: Princeton. University Press.

Simons, Ronald L., Man-Kit Lei, Steven RH Beach, Ashley B. Barr, Leslie G. Simons, Frederick X. Gibbons, and Robert A. Philibert. 2018. "Discrimination, Segregation, and Chronic

Inflammation: Testing the weathering explanation for the poor health of black americans." *Developmental Psychology* 54(10): 1993-2006.

Sismondo, Sergio. 2009. “Ghosts in the Machine: Publication Planning in the Medical Sciences.” *Social Studies of Science.* 39(2): 171-198.

---. 2007. “Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?” *PLoS Med.* 4(9): 1429-1433.

Skocpol, Theda. 1979. *States of Social Revolution: A Comparative Analysis of France, Russia, and China.* London: Cambridge University Press.

Smith, Sarah. 2012. “Intimate geopolitics: Religion, marriage, and reproductive bodies in Leh, Ladakh.” *Annals of the Association of American Geographers* 102(6):1511-1528

Smith, Linda. 2008. *Decolonizing Methodologies Research and Indigenous Peoples.* Zed Books Ltd. New York.

Social Watch. “Sustainable Development: The Right to a Future.” Retrieved December 2021, from: https://www.socialwatch.org/report2012

Spronk, Susan and Jeffery R. Webber. 2007. “Struggles against Accumulation by Dispossession in Bolivia: The Political Economy of Natural Resource Contention.” *Latin American Perspectives.* 34(2): 31-47.

Stuckler, D., Basu, S., 2013. *The Body Economic: Why Austerity Kills*. Basic Books, New York.

Statista. 2021. “Top 10 pharmaceutical companies based on R&D spending as revenue share in 2019 and 2026.” Retrieved on March 11 2022 from: https://www.statista.com/statistics/309471/randd-spending-share-of-top-pharmaceutical-companies/#:~:text=Global%20R%26D%20spending,over%20230%20billion%20U.S.%20dollars.

Steinmetz, George. 2004. “Odious Comparisons: Incommensurability, the Case Study, and ‘Small N’s’ in Sociology.” *Sociological Theory.* 22(3): 371-99.

Steedman, Ian et al. 1981. *The Value Controversy*. London: Verso/New Left Books.

Stubbs, Thomas., Alexander Kentikelenis, David Stuckler, Martin McKeee, and Lawrence King. 2017. “The impact of IMF conditionality on government health expenditure: A cross-national analysis of 16 West African nations.” *Social Science & Medicine.* 174: 220-227.

Summers, L.H., Pritchett, L.H., 1993. The structural-adjustment debate. Am. Econ. Rev. 83, 383e389.

Subrhmanian K. and Mohanan Paillai. 1988. “Multinational Firms and Export Processing Zones.” *Economic and Political Weekly*. 13(34): 1473-1477.

Sunder Rajan; Kaushik. 2006. *Biocapital: The Constitution of Postgenomic Life.* Durham: Duke University Press.

Sverdlik, Alice. 2011. “Ill-health and poverty: a literature review on health in informal settlements.” *Environment and Urbanization*. 23(1): 123-155.

Temple, Robert. 2002. “Placebo-Controlled Trials and Active Controlled Trials: Ethics and Inference.” In *The Science of the Placebo: Toward an Interdisciplinary Research Agenda.* London: BMJ Books.

Thomas, Cindy., Peter Conrad, Rosemary Casler, and Elizabeth Goodman. 2006. “Trends in the Use of Psychotropic Medications Among Adolescents, 1994 to 2001.” *Psychiatric Services*. 57(1): 63-69.

The Global Health Observatory. Accessible at: https://www.who.int/data/gho

Toulmin, Stephen. 1987. “National Commission on Human Experimentation: Procedures and Outcomes.” In *Scientific Controversies: Case Studies in the Resolution and Closure of Disputes in Science and Technology.* Cambridge University Press. 599-615.

Toussaint, Eric. 2005. *Your Money [or] Your Life: The Tyranny of Global Finance*. Translated by V. B. Manus, R. Krishnan, and G. Roche. Chicago: Haymarket Books.

Thomson, Michael., Alexander Kentikelenis, and Thomas Stubbs. 2017. “Structural adjustment programmes adversely affect vulnerable populations: a systematic-narrative review of their effect on child and maternal health.” *Public Health Reviews*. 38(13): 1-18.

Trusheim, Mark. Murrary L. Aitken, and Ernst R. Berndt. 2010. “Characterizing Markets for Biopharmaceutical Innovations: Do Biologics Differ From Small Molecules?” *National Bureau of Economic Research: NBER Working Paper Series.*

Tremain, Shelley. 2010. “Biopower, Styles of Reasoning, and What’s Still Missing from the Stem Cell Debates.” Hypatia. 25(3): 577-609.

Tsing, Anna. 2015. *The Mushroom at the End of the World: On the Possibility of Life in Capitalist Ruins.* Princeton University Press. Oxford.

Tucker, Robert. C., Editor. 1979. *The Marx and Engels Reader 2nd Edition.* W.W. Norton & Company. New York.

United Nations. *Urbanization and Development: Emerging Futures. World Cities Report;* United Nations Publication: New York, NY, USA, 2016.

---. 2007. Twenty First Session of the Governing Council. Retrieved on February 20, 2022, from: https://www.preventionweb.net/files/1713_463146759GC202120Slum20dwellers20to20double.pdf

---. 2020. "World Cities Report 2020: The Value of Sustainable Urbanization." Retrieved on March 7 2022 from: https://unhabitat.org/World%20Cities%20Report%202020

---.2003. "The Challenge of Slums - Global Report on Human Settlements 2003." Retrieved on March 7 2022 from: https://unhabitat.org/the-challenge-of-slums-global-report-on-human-settlements-2003

U.S. Food & Drug Administration. 2015 Available At: https://www. fda.gov/ About FDA/ CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm Accessed May 15 2017.

Vasudevan, Pavithra., "An Intimate Inventory of Race and Waste." *Antipode* 0(0): 1–21

Vallette, Jim, Daphne Wysham, and Nadia Martínez. 2004. "A Wrong Turn from Rio: The World Bank's Road to Climate Catastrophe." Washington, DC: Sustainable Energy and Economy Network, Institute for Policy Studies.

Vreeland, James. 2007. *The International Monetary Fund: Politics of Conditional Lending*. New York: Routledge.

Waldby, Catherine. 2002. ''Stem Cells, Tissue Cultures and the Production of Biovalue.'' Health: An Interdisciplinary Journal 6(3): 305-23.

Waitzkin, Howard and Rebeca Jasso-Aguilar. 2015. "Empire, Health, and Health Care: Perspectives at the End of Empire as We Have Known It." *Annual Review of Sociology*. 41:271–90.

Wallach, Lori, and Patrick Woodall. 2004. Whose Trade Organization? A Comprehensive Guide to the WTO. New York: New Press.

Wacquant, Loci. 2001. "Whores, Slaves and Stallions: Languages of Exploitation and Accommodation among Boxers." *Body & Society*. 7(2-3): 181-194.

Walker, Rebecca., Marci D. Cottingham, and Jill Fisher. 2018. "Serial Participation and the Ethics of Phase 1 Healthy Volunteer Research." *Journal of Medicine and Philosophy*. 43: 83–114.

Wallace, Charles Z. 2018. "The Value of the Dead: The Commodification of Corpses in Western Culture." *Spectrum*: 7(1): 1-7.

Whitt, Laurelyn. 2009. *Science, Colonialism, and Indigenous Peoples*. Cambridge: Cambridge University Press.

Wilson, Ara. 2011. “Foreign Bodies and National Scales: Medical Tourism in Thailand.” *Body and Society.* 17(2-3): 121–137.

---. 2004. *The Intimate Economies of Bangkok: Tomboys, Tycoons and Avon Ladies in the Global City*. University of California Press.

Woods, Ngaireand and Demenico Lombardi. 2006. “Uneven Patterns of Governance: How Developing Countries are Represented in the IMF.” *Review of International Political Economy* 13(3): 480-515.

World Bank: Global Economic Prospects 2007: Managing the Next Wave of Globalization Washington, DC: World Bank; 2007.

World Bank. 2020. Retrieved December 2021, from: https://www.worldbank.org/en/news/press-release/2019/10/02/debt-stocks-of-developing-countries-rose-to-78-trillion-in-2018-world-bank-international-debt-statistics#:~:text=WASHINGTON%2C%20Oct.,International%20Debt%20Statistics%202020%20shows.

Wright, Patrick and Gary McMahan. 2011. “Exploring human capital: putting ‘human’ back into strategic human resource management.” *Human Resource Management Journal*. 21(2): 93-104.

Yin, Robert K. 2009. *Case Study Research: Design and Methods*. Thousand Oaks, CA: Sage Publications.

Yu, Yang., Kuishuang Feng, and Klaus Hubacek. 2014. “China’s unequal ecological exchange.” *Ecological Indicators*. 47:156-163

Zavestoski, Stephen., Rachel Morello-Frosch, Phil Brown, Brian Mayer, Sabrina McCormick and Rebecca Gasior Altman. 2004. “Embodied Health Movements and Challenges to the Dominant Epidemiological Paradigm,” in D. J. Myers & D. M. Cress (eds), *Authority in Contention: Research in Social Movements, Conflicts and Change* 25: 253–78