

Marquette University

e-Publications@Marquette

Theology Faculty Research and Publications/College of Arts and Science

This paper is NOT THE PUBLISHED VERSION; but the author's final, peer-reviewed manuscript.

The published version may be accessed by following the link in the citation below.

Journal of Medicine and Philosophy, Vol. 34, No. 4 (2009): 384-408. [DOI](#). This article is © Oxford University Press and permission has been granted for this version to appear in [e-Publications@Marquette](#). Oxford University Press does not grant permission for this article to be further copied/distributed or hosted elsewhere without the express permission from Oxford University Press.

Docile Bodies: Transnational Research Ethics as Biopolitics

M. Therese Lysaught

Marquette University, Milwaukee, WI

Abstract

This essay explores the claim that bioethics has become a mode of biopolitics. It seeks to illuminate one of the myriad of ways that bioethics joins other institutionalized discursive practices in the task of producing, organizing, and managing the bodies—of policing and controlling populations—in order to empower larger institutional agents. The focus of this analysis is the contemporary practice of transnational biomedical research. The analysis is catalyzed by the enormous transformation in the political economy of transnational research that has occurred over the past three decades and the accompanying increase in the numbers of human bodies now subjected to research. This essay uses the work of Michel Foucault, particularly his notion of docile bodies, to analyze these changes. Two loci from the bioethics literature are explored—one treating research in the United States and one treating research in developing countries. In the latter, we see a novel dynamic of the new biopolitics: the ways in which bioethics helps to create docile political bodies that will police themselves and who will, in turn, facilitate the production of docile human bodies for research.

Keywords: bioethics, biopolitics, bodies, developing countries, docile bodies, Foucault, resource-limited contexts, transnational research

I. INTRODUCTION

In 1956, Dr. Saul Krugman—with the sanction of the New York State Department of Mental Hygiene, the New York State Department of Health, the Armed Forces Epidemiological Board, and others—began an experiment at the Willowbrook State School, a state-supported institution for mentally handicapped children.¹ This experiment, which ran until 1972, sought to develop a vaccine for hepatitis, outbreaks of which were common at Willowbrook and similar sorts of institutions due to unsanitary conditions. In this study, mentally handicapped children who resided in the facility were intentionally infected, either orally or intravenously, with live hepatitis virus and then monitored to assess the effects of gamma globulin in combating the disease.

At stake was almost every major issue in research ethics: that children were intentionally infected with a pathogen known for high risk of morbidity and mortality; that the children selected were mentally handicapped; that the parental permission letter did not make clear that the children would be intentionally infected; that, due to overcrowding and long waiting lists, parents might have been unduly influenced to enroll their children, as rooms in the experimental wing were readily available; and that many parents who sought placement at the school generally had insufficient resources to keep their children at home or to place them elsewhere.

Although aware of the ethical implications of the study, Krugman countered in his defense that the children would likely be infected with hepatitis naturally from their environment, that they would benefit by being admitted to the experimental wing where care and conditions were better, and that they would likely gain immunity to the virus to which they were exposed. In 1972, the year the study ended, a class action lawsuit was brought against the State of New York for a myriad of violations associated with the school, and Krugman became president of the American Pediatric Association.²

In 1996, forty years after Krugman began his experiments, Pfizer—the world's largest pharmaceutical company—began an experiment at the Infectious Disease Hospital in strife-torn Kano, Nigeria.³ During an outbreak of meningitis, Pfizer researchers selected children from the long lines of ailing people seeking care at the hospital. They treated one hundred with a new antibiotic Trovan, which had never been tested in children, and an additional hundred with ceftriaxone, the gold standard for meningitis treatment, but at a lower than recommended dose. At the same institution, physicians from Doctors Without Borders were providing free treatment with chloramphenicol, a cheaper antibiotic internationally recommended for treating bacterial meningitis. Eleven children in the Trovan study died and an additional 181 suffered injuries including brain damage, partial paralysis, or deafness.

Again, almost every major issue in research ethics emerged: testing two experimental interventions on children when a proven therapy was readily available; whether the parents were informed that intervention was experimental; whether the parents were informed that they were free to choose the free chloramphenicol treatment instead; whether the parents were informed that their children were participating in a research trial rather than simply receiving free treatment from compassionate volunteers; whether Pfizer obtained institutional review board (IRB) approval in advance of the trial; and whether the researchers performed accurate diagnostic tests, provided corollary care for children who did not respond to the Trovan or ceftriaxone or provided follow-up care for children in the study

(Ballantyne, 2008, 188). Lawsuits totaling nearly \$7 billion U.S. were brought by the government of Nigeria and thirty Nigerian families.

In its own defense, Pfizer countered that the children's parents were fully informed and that it proceeded with the approval of the Nigerian government.⁴ They further argued that the trial was, in fact, a philanthropic effort that benefited most of the children enrolled as the number of deaths among those receiving Trovan was less than the overall fatality rate for the meningitis epidemic.⁵ On April 3, 2009, Pfizer settled one of the lawsuits brought by the Kano State of Nigeria. That same day, Pfizer issued a press release announcing that it had become the first pharmaceutical company to be accredited for the protection of human rights in clinical research.⁶

We have, then, two experimental protocols involving children in the context of infectious epidemics—one that infects them with a known pathogen and one that injects them with an experimental agent of unknown efficacy and, as is subsequently discovered, significant toxicity.⁷ On their face, the cases seem quite similar yet admit of important differences, each capturing relevant particulars of biomedical research in their respective eras. Less than a half-century separates them. The time frame they span began at a time of great scandals for research, a time of numerous cries for reform. In response to these cries came a new theory of the moral justification and parameters of medical research. “Modern” codes were drawn up: the Declaration of Helsinki 1964, revised 1983 and 1989; The Belmont Report 1979; the U.S. Federal guidelines on the Protection of Human Subjects (45 CFR 46) 1981; the U.S. Common Rule 1991; and the International Conference on Harmonization (ICH) 1990. It was the new age for research ethics and, subsequently, bioethics.

That we live in the new age of bioethics is signaled by at least one aspect of the foregoing: the presentation and analysis of cases in the ethics of research follow a set narrative.⁸ Like potboilers, bodice rippers, murder mysteries, and Westerns, the narratives of cases in bioethics follow predictable plot lines. Even cases that occurred before bioethics was born, like Willowbrook, are narrated through the lenses of autonomy, beneficence, nonmaleficence, and justice. The inciting force emerges in the relationship of harms to benefits and climaxes in questions of informed consent (or vice versa). In the denouement, justice abridged during the course of the conflict is rectified or so one hopes; in either event, the story closes with lessons to be learned for the future.

The four principles would bring to biomedical research a greater consciousness of the humanity of the substrate upon which such clinical research is conducted. Yet, for all the advances the principles have brought, one change remains below the radar of contemporary bioethics: the transformation in the scope and scale of that very substrate and the sheer number of bodies now subject to research. Perhaps, bioethics considers scandal rather than scope to be its primary concern. Therefore, the fact of increased scope of clinical research passes largely unremarked in bioethics. And in any case, how important is this fact when compared with the sea changes in the practice of biomedical research, the formulation of a set of principles in Belmont and of unified rules of procedures with the Federal Guidelines and ICH, the almost universal adoption of the IRB structure, and the conduct of so much high-quality research? Yet, the fact remains that the numbers of human bodies subjected to transnational biomedical research has become, since 1956, vast and yet remains largely invisible.

To focus on the material reality of bodies, on what happens to them, and to refuse to let one's focus shift away from those bodies is one of the unique insights brought to twentieth-century analytics by philosopher and critical theorist Michel Foucault. By attending carefully to what was happening with the

bodies of the insane, the imprisoned, the sick, and more, Foucault was able to craft a new framework for understanding the dynamics of contemporary culture, a framework he called “biopolitics.” In brief, biopolitics is that social strategy of policing and controlling populations by “increasingly ordering all realms under the guise of improving the welfare of the individual and the population for the purpose of reproducing and furthering the social order” (Dreyfus and Rabinow, 1982, xxvi; Finkelstein, 1990, 15). For Foucault, a vital constituent of biopolitics from the end of the eighteenth century forward was biomedicine.

By focusing on the material reality of bodies and what happens to them Foucault opened a window into the biopolitical function of medicine. But medicine is not alone in this work of biopolitics. Extending Foucault's method uncovers a more recent agent of the work of biopolitics, namely, bioethics.⁹ To see bioethics as a mode of biopolitics is to illuminate the myriad of ways that behind the rhetoric of freedom, empowerment, and improving the welfare of the individual and the population, bioethics functions to produce, organize, and manage the bodies of real, human persons—to police and control populations—toward the ends of larger institutional agents such as the state or, more recently, the biotech industry. To see bioethics as a mode of biopolitics is to raise questions about bioethics’ role in the political economy of biomedicine, particularly when that political economy impinges on human bodies.

This essay, then, seeks to do just this: to explore what it might mean to see bioethics as biopolitics, as an institutionalized set of discursive practices a major purpose of which is to manage and organize the bodies within its purview in order to empower biomedicine and the state. This is certainly a different narrative framework than that of the four canonical principles. Yet, this is certainly not an alternative reading for its own sake. For, I would argue, of the two, only the framework of biopolitics can provide an account of the enormous transformation in the political economy of biomedicine and transnational research that has occurred over the past three decades.

What are some of those changes? Let me briefly note a few here. Marcia Angell (2004) details how a series of legislative and policy changes in the early 1980s—particularly the Bayh-Dole Act and the Hatch-Waxman Act—fueled exponential growth in biomedical research, leading it to become a multibillion dollar global industrial enterprise with unparalleled profitability (Angell, 2004, 6–11).¹⁰ When Trovan was developed in the mid-1990s, for example, Pfizer anticipated that it would prove to be a blockbuster drug, generating up to \$1 billion/year in sales; it garnered \$160 million in sales in 1998, its first year on the market (Lewin, 2001). No such financial windfall could have been anticipated in the Willowbrook case.

Along with these new economic realities have come radical shifts in geography and agency. Behind Krugman stood U.S. governmental agencies; behind Trovan stood a transnational pharmaceutical company.¹¹ By 2001, pharmaceutical research enrolled some 2.3 million subjects in just the United States, in an estimated 80,000 clinical trials, a dramatic increase over the number of people involved in clinical trials in the 1970s (Angell, 2004, 29). And, as the Trovan case makes clear, additional policy changes in the early 1990s opened up new markets in human subjects, shifting the location of biomedical research from the United States and Europe toward developing contexts. Consequently, the number of international human subjects involved in clinical trials grew from 4,000 in 1995 to 400,000 in 1999 just for new drug applications (Petryna, 2006, 47). As of 2000, about 7,500 new clinical projects were being designed for research and development worldwide, a number that had grown to 10,000 by

2001 (Petryna, 2006, 36). With some of these trials enrolling 10,000 people or more, the global scope of human subjects research becomes quickly apparent.

As mentioned earlier, it is this change in the practice of biomedical research—this transformation in the scope and scale of the sheer number of human persons subject to research from Willowbrook to Trovan—that serves as the inciting force of this alternative narrative. The numbers are so vast, yet they are so invisible, both to bioethics and to the general public. Millions of bodies are marshaled in the service of research, yet they are so silent and unobtrusive. They are, in Foucault's terms, “docile.” Millions of bodies voluntarily participate in an orderly fashion in research protocols that do not for the most part further their own ends.

In this essay, I will suggest that one of the main biopolitical functions of bioethics is the creation of docile bodies, in this case, for transnational research. I will not focus on the cases of Willowbrook and Trovan; I open with them because they capture the two loci I will highlight in the following pages: research in the United States and research abroad. In what I know will be a more suggestive than conclusive analysis, I offer two examples of bioethics vis-à-vis transnational research that demonstrate its mission to produce docile bodies for research. These two examples offer snapshots, as it were, of the contemporary conversation on research ethics, a punctilious sampling that might enable us to discern whether a more systematic study is warranted.

The first is a discussion of research ethics in the United States from a recent issue of *The American Journal of Bioethics*. Here, in one of the central professional journals of the discipline, nearly two dozen leading bioethicists consider a novel proposal for rethinking research ethics. The second example draws from the current conversation in bioethics on research ethics in and with resource-limited countries. Here, I will argue, we see a novel dynamic of the new biopolitics: the creation of docile political bodies—docile States—States that will police themselves and who will, in turn, facilitate the production of docile bodies for research. This development takes Foucault's work one-step beyond his own framework, but it is a development consistent with his vision. Before proceeding to the two examples, let us turn briefly to an overview of that vision of Foucault's notion of the disciplinary matrix of bioethics.

II. THE DISCIPLINARY MATRIX OF BIOPOLITICS¹²

Michel Foucault was a prolific writer whose work spanned topics from medicine to sexuality over two decades. Over this period, his critical framework continued to evolve. This section summarizes those aspects of his work most pertinent to understanding bioethics as a mode of biopolitics, particularly his account of the disciplinary matrix of institutionalized discursive practices and the complex interactions between bodies, power, discourses, practices, institutions, and truth.

The focal point of Foucault's analyses—be it of the clinic, the asylum, or the prison—is the material reality of bodies. Foucault is particularly interested in mapping the ways in which bodies within a particular social space are organized and “produced”—shaped, that is, to perceive and behave in particular ways. These mechanisms of organization and production by larger social forces are nothing other than politics, and the organization and production of bodies for social ends is, therefore, biopolitics.

Foucault relentlessly focuses on what happens to bodies, seeing them as the site on which power is contested. Bodies have materiality; sociopolitical institutions do not, at least in the same way. They gain

their reality, their power, from the material reality of human embodiment.¹³ Social theorist Bryan Turner summarizes Foucault's thesis: "The body as an object of power is produced in order to be controlled, identified, and reproduced" (Turner, 1984, 34).

Power, for Foucault, is not negative per se; nor does it follow the binary code of much of liberal political discourse, being either oppressive or liberatory. Rather, it is essentially productive. It is the means whereby all things happen (Giddens, 1982, 219; Finkelstein, 1990, 14). But yet, it is not simply neutral. Joanne Finkelstein captures Foucault's sense of the decentered, circulatory, web-like, nature of power:

Power is a strategy of relations that gives some individuals and groups the ability to act and keep acting for their own advantage. Power is also the ability to bring about a desired situation and to prevent the actions of those who would thwart such desires. (Finkelstein, 14)

Within a biopolitical regime, power will not most often be wielded in an overt, coercive manner. Ideally, individuals come to wield it over themselves. Within a regime of disciplinary power, each person—by internalizing the norms and surveillance of the social order—effectively disciplines herself or himself. As such, this exercise of power can direct individuals to engage in actions that are not necessarily to their advantage. In short, the basic goal of disciplinary power is to produce persons who are docile—persons, in other words, who do not have to be externally policed.¹⁴

But what are the mechanisms of "governmentality," the means by which bodies become docile?¹⁵ Foucault and others identify three necessary elements: discourses, practices, and institutions. Discourses are bodies of concepts, literatures, that define and produce objects of knowledge, governing the ways a topic can be meaningfully talked about and reasoned about. Discourses make possible the appearance of objects at particular historical moments and provide a language for talking about them. Informed consent, for example, did not exist as a primary conceptual object prior to the Nuremberg Code.

Discourses are also deeply allied to bodies. Social theorist Arthur Frank describes discourses as

Cognitive mappings of the body's possibilities and limitations, which bodies experience as already there for their selfunderstanding These mappings form the normative parameters of how the body can understand itself Discourses only exist as they are instantiated in ongoing practice or retained by actors as "memory traces". (Frank, 1991, 42)

One example of such a discourse would be the modern scientific account of anatomy. Arising in part out of the structures of the human body, it equally arranges, depicts, defines, and describes the way in which inhabitants of Western culture literally "map" their bodies; bodies no longer consist of humors or mime the structures of the heavens but instead are composed of organs, systems, tissues, cells, DNA, and so on. Equally, the languages of disease and illness are discourses mapping bodies' self-understandings.

Dorothy Smith refers to discourses as "extralocal texts—texts created elsewhere—that organize action and relationships in local settings by instructing actors in those settings as to what they should do and perhaps proscribing what they cannot do" (Frank, 2001, 356). Frank elaborates on Smith's reading of discourse with the example of diagnostic-related group (DRGs):

In medicine, diagnostic-related groups (DRGs) ... are a prime example of discourse DRGs are written documents, created by a group of specialists working on the basis of individual clinical experience and aggregate data but working apart of any specific scene of clinical practice. These specialists produce a code of diagnosis—all illness must map into DRG categories to be treated—and detailed specifications of what count as reimbursable services for each category. DRGs, as a textual code created elsewhere, thus organize activity in local clinics. People in local settings still make decisions and deliver care, but the text limits and directs what they can do. (Frank, 2001, 357)

A key feature of discourses, as this example suggests, is that the content of the “extralocal text” is understood as technical or formal knowledge, knowledge that is increasingly esoteric, and the purview of specialists and elite professionals.

Discourses, of course, do not simply float free. In order to create docile bodies, they must be incarnated in social practices, in “techniques of discipline.” Discourses and practices stand in reciprocal relationship: discourses define the rules for practices, which in turn enact those discourses vis-à-vis individual bodies.¹⁶ Through the creation of such bodies that then go on to act in the world in self-motivated ways, practices further realize (make real) and reproduce the vision and commitments of the discourses in the world.¹⁷

Discourses are legitimated in part by being embedded in institutions, centralized social spaces that provide spatiotemporal continuity for the punctilious enactments of discursive practices. In doing so, they enable the exponential consolidation of productive power as well as a visible social sanction for the claims put forward in a particular discourse. Further, institutions enable methods of surveillance crucial for the mapping and normalizing of the bodies within their population. Institutionally sanctioned discourses both define the “normal” and, through techniques and practices, encourage individuals to regulate and achieve her or his own conformity with the established rules.¹⁸ Eventually, certain attitudes and practices come to prevail as normal and acceptable. Institutionalization, therefore, has the effect of rendering particular discourses “true”—for you can look around and see that they are telling the truth—and, via their ability to “predict” normalizing outcomes and to produce normal bodies, institutions reinforce the “scientific” character of the discourse's growing body of knowledge.

Disciplinary matrices of discourses, techniques, and institutions are able to exercise power in this decentralized manner insofar as the discourse is able to sustain a regime of truth. “Truth” in this sense points to the creation of knowledge as a function of power. Truth is a product of discursive practices understood to emerge only within a structure of rules, practices, and institutions that control the discourse and collaborate to establish a given claim as true. Knowledge shaped by discourses, empowered by institutions, and wielded through techniques and practices thus has the power to make itself true.

Truth then is embodied and reproduced through “rituals of truth,” practices shaped according to the rules of the discourse which then, not surprisingly, reinforce the truth-claims of the discourse (one might think, e.g., of the truth of the anthropological claim that we are autonomous individuals embodied and reproduced through the practice of advance directives). Through these many factors, the networks of productive power serve to produce, via bodies, particular styles of subjectivity. Under ordinary circumstances, subjects are both produced within discourses and simultaneously subjected to discourses. Such subject production is one component of the process of normalization.

To narrate bioethics as biopolitics will mean to attend to these elements within each of the variety of subissues that make up the discipline. In this particular case, we would ask these questions and look for these dynamics within the complex of transnational research. Where, we would ask, do we find the materiality of human bodies being managed, organized, and produced in particular ways? In what ways is power being exercised vis-à-vis these bodies—what strategy of relations can we identify? To whom among the players in transnational research do these relations give the greater ability to act and to keep acting for their own advantage? How do these strategies enable particular agents to bring about a desired situation and to prevent the actions of others who would thwart such desires? In what ways does the ethical discourse on transnational research forward the conceptual mapping of bodies and actions that enable these strategies? In what practices, techniques, or rituals of truth is this discourse embodied and by what institutions is it made the truth in new locations? How does the discourse do this such that the bodies in question (and their attendant subjectivities) become docile, unaware that they are being produced in particular ways and that they are acting toward others' advantages more than their own? And lastly, how does the rhetoric of the institutionalized discursive practices mask these dynamics, rendering them apolitical, neutral, and objective? For a striking example, let us turn to *The American Journal of Bioethics*.

III. CREATING DOCILE BODIES AT HOME

For Foucault, bodies are the site upon which power is contested; they are equally—as a *sine qua non*—the site upon which clinical research is conducted. At the center of biomedical research is the concrete, material reality of human bodies. In, with, and through these bodies, power is produced and exercised, not primarily by those who inhabit those bodies but by external agents—researchers, physicians, biotech corporations, and national governments. As we have seen, the ability of biomedical research to exercise this power has expanded extensively, particularly since the early 1980s, spreading web like across the globe, encompassing ever greater numbers of human bodies. In this endeavor, the discipline of bioethics has been and remains a key ally, assisting in the production, organization, and management of these bodies.

Conventional wisdom tells a slightly different story. In the received narrative, a series of abuses of human subjects and patients over a 40-year period (1932–1972), often at the hand of U.S. government researchers, led to the founding of the President's Commission on the Protection of Human Subjects (1974), which resulted in the publication of The Belmont Report in 1979. Bioethics thus stands as that agent that corralled potentially dangerous and unregulated scientists, protecting citizens' well-being and autonomy while channeling the outcomes of biomedical research toward the common good.

Working with the same history, sociologist John Evans provides an alternative perspective on the relationship between bioethics and biomedical research. In his book *Playing God: Human Genetic Engineering and the Rationalization of Public Bioethical Debate* (2002)¹⁹, Evans helpfully debunks the dominant myths that shape the recent “histories” of bioethics. His empirical study particularly undermines those accounts that suggest that bioethics is primarily an open, public deliberative practice which involves reasoning with other citizens or a limited set of procedural norms that facilitate the full range of individual value judgments. He challenges accounts that cast bioethics as necessitated by the pluralistic nature of contemporary U.S. society or by expanding commitments to democracy as well as stories that plot such developments as “natural” progressions.

Evans convincingly demonstrates that the growth and institutional embodiment of bioethics in the United States, via government advisory commissions, took shape precisely as a way to circumvent pluralism, to “avoid more direct democratic control” (73). As he demonstrates, the pluralist model of democracy in fact threatened research; it was “unacceptable to the scientists, who feared that an ‘excitable’ public would shut down not only [human genetic engineering] research, but other research in their home jurisdiction that the public did not understand” (36; see also 72 ff.). They were fearful, in other words, of funding cuts (Evans, 76), pointing to the hidden substrate of political economy underlying these discussions.

Bioethics, then, according to Evans's Weberian analysis, emerged not as a mechanism for augmenting freedom or for promoting individual pursuit of self-defined goods and ends; rather, bioethics emerged as a mechanism for shaping and controlling the *hoi polloi* so that the growing Leviathan of biomedical research could quietly continue to pursue its own ends behind the scenes. A first step toward such a goal was to create a discourse and a set of practices—a body of esoteric, technical, and formal knowledge that would be portrayed as inaccessible to the common-person allied to acceptable procedures for decision making housed in the institutional framework of IRBs. The first step, in other words, was to create the new discipline of bioethics.

In more Foucauldian terms, Evans is arguing that one of the first functions and, perhaps, objectives of bioethics—its originating *raison d'être*—was to pacify an outraged and unruly public, transforming them into bodies docile to the research industry. Many examples could be marshaled in support of this argument beyond those included in Evans' own analysis. For our purposes, I would like to highlight a recent exemplar—an exchange on research ethics in *The American Journal of Bioethics*. Although only a punctilious snapshot of the broad and ongoing conversation on the ethics of transnational research, it captures in crystalline clarity the biopolitical essence of bioethics.

Here, in a Target Article, Rosamond Rhodes argues for the “Rethinking of Research Ethics” (Rhodes, 2005). Rhodes is concerned that “current research policies too often limit research,” especially with regard to “vulnerable” populations (7). This concern for vulnerable populations she argues, “set research ethics off in the wrong direction” (7). Consequently, one of the major problems with research ethics is that “the rules give special weight to the protection of the vulnerable” (7). As she notes

Instead of focusing attention broadly on the development of reasonable boundaries for the conduct of human subject research, policies have focused narrowly on the protection of human subjects. Even the titles of oversight policies and agencies reflect this narrow aim. In the U.S., the regulations are called “Policy for the Protection of Human Research Subjects,” and the agency for compliance was first the Office for the Protection from Research Risks (OPRR) and now the Office for Human Research Protection (OHRP). (7)

This focus on protection “wastes opportunities to gather evidence,” and she laments “the contortions imposed on researchers” (9). Human subjects research has, since World War II, contributed to

A dramatic increase in biomedical knowledge and tremendous progress in creating effective treatments We stand [she maintains] on the brink of a cascade of insights into human genetics and the promise of spectacular related advances in biomedical technology Without human subjects research, those treatments are less likely to be available. (15)

Therefore, such an “unjustified inhibition of research” is an “ethical catastrophe” (26). The engine of research must not be stopped.

In light of these problems, Rhodes puts forward what she names a “novel proposal,” one that “society may not yet be ready to embrace” (23). As we saw earlier in Evans’ account of bioethics in the 1970s, Rhodes remains concerned about an excitable public that does not fully understand the importance of biomedical research or the complexities of moral reasoning, but she knows that her audience of fellow bioethicists are professional experts with an “evolving understanding of the moral requirements for the ethical conduct of research” (25). As such, bioethicists should be ready to “reexamine and reassess reigning research dogmas” (25). She proposes a policy of national conscription for biomedical research, a policy of “compulsory research participation” (23). Citizens would have no choice about whether to participate in human subjects research; it would be a duty: “In the same way that we have endorsed laws that require us to pay taxes and to serve on juries, reasonable people should accept an obligation to periodic service as research subjects” (15). Otherwise, they are “taking advantage of the kindness of others,” “being free-rider[s]” and hence being unreasonable and unjust (15). We each need to do our part if we expect to utilize the benefits of medical knowledge.

To be specific, she suggests that “our legislature passes a bill that requires every U.S. resident [note: she does not specify ‘citizen’] to perform some research service every ten years” (16). Even in matters military, we understand the draft to be “selective service,” but not so for Rhodes: from this policy, no one would be exempt, including those without decisional capacity: “Just as other laws apply to those who cannot consent to them, there is no obvious reason why a research participation policy should be different. No group should be exempt from research participation” (17). Of course, autonomy would not be jettisoned. All research participants would have the freedom to choose which protocol they would participate in. Thus, informed consent and autonomy remain respected.

One could not invent a more fitting exemplar of bioethics as biopolitics in action. Rhodes’ proposal is, in essence, a proposal for the wholesale reorganization of the production and management of the bodies of U.S. residents for research. Rhodes’ proposal, if incarnated, would increase the number of persons subject to research in the United States from approximately 2.3 million as noted above, to approximately 35 million per year. This would be a stunning mobilization of human embodiment. It also aims not simply at increasing the number of subjected bodies but as “increasingly ordering” all sectors of the U.S. population, particularly those currently considered vulnerable and therefore protected. Those vulnerable bodies remain unruly—wild and untamed—from the perspective of biopolitics. The vehicle for this shift is the eminently reasonable discourse of bioethics—sufficiently abstract and philosophically esoteric to be largely inaccessible to those whose bodies are under consideration—which is challenged to support a new practice (conscription) embodied in the institutional forms of government and IRB. The professed justification for this radical shift is the improvement of the welfare of the U.S. population (i.e., the common good) as well as the enhancement of the freedom of members of vulnerable groups. The effect, of course, would be to systematically and enormously enhance the power of the transnational research industry.

Rhodes’ proposal was joined in conversation by seventeen respondents in the pages of *The American Journal of Bioethics*, many of whom, like Rhodes, are leading figures in the discipline of bioethics.²⁰ Not all addressed her proposal for conscription. Most found her arguments throughout deeply flawed. Yet by and large, the respondents applauded her proposal as innovative, reformative, provocative,

controversial, courageous, challenging the status quo, and so forth. And almost to a scholar, they are “sympathetic” with her fundamental concern, namely, the way to “engender widespread social support for research as a means of serving the common good” (London, 2005a, 37). As Gavin Hougham notes, Rhodes is not the first to raise concerns about the “unjustified limits on research” (36). Similarly, Howard Trachtman, although rejecting her proposal for universal conscription agrees that we should “compare clinical research to military service [but] in a more expansive manner and view it as national health defense” (2005, W22).

In short—the rhetoric of freedom, public discussion of goods, protecting and advancing pluralism, and being simply about procedures rather than goods notwithstanding—it is clear that the mainstream discipline of bioethics has decided in advance what the good is: as full and active participation by the masses in the ritual practices of biomedical research for the good of society as possible. As in the 1970s, bioethics appears to remain solidly in the employ of the biomedical research establishment: research cannot be hindered; therefore, the task of bioethics is to figure out how to get the masses to agree; and if not, to conscript them to submit their bodies to the biotech industry, while believing that in doing so, they are autonomously choosing their own ends.

Here, with unprecedented transparency, the organization of bodies for research becomes complete. No body escapes, no matter how vulnerable. Resistance and avoidance are no longer possible; all become docile, offering their bodies for the good of the political economy of biotech research. Although Rhodes argues that such conscription advances the interests of each participant, insofar as they or their family members might benefit from the therapeutic fruits of clinical research, it is clear that the immediate and primary beneficiaries will be the agents and institutions conducting the research and making the profits. Here bioethics serves to develop a strategy of relations, a practice, a technique of discipline (conscription), authorized by an institution (federal policy) that will advance the interest of the biotech industry and remove or mitigate those obstacles (difficulties of subject recruitment and national guidelines for the protection of human subjects) that thwart their objectives. Those bodies that might balk at such a blatant move toward production and control are consoled with the fig leaf of autonomous choice; everyone can choose their poison, their protocol. And over time, as those raised under the old regime that understood research participation as an altruistic action of those who sought to give the gift of their participation for the common good die out and the young are raised under the new regime of conscription, universal research service will be understood as the norm, as what everyone does, as what has always been done, for the common good. It will have attained the status of truth.

IV. CREATING DOCILE BODIES ABROAD

If the discipline of bioethics exercises a biopolitical function in the United States, assisting in the creation of docile bodies for research, it is likely that it exercises a similar function with regard to the bodies of populations beyond our own shores. Such a case could certainly be made, for the literature in bioethics on research conducted by first-world agencies on human subjects in developing or resource-limited contexts continues to grow, providing much evidence for this claim. For our purposes, however, I will focus on one particular aspect of this particular literature, as I believe it provides evidence not only of bioethics as biopolitics but also of a potentially new development within Foucault's own framework.

Foucault traces the development of the institutions of disciplinary power during the era of the creation and consolidation of the modern nation-state. His account of institutionalized discursive practices

demonstrates the ways in which such practices mobilize the bodies of citizens to solidify the power of the state. In the contemporary moment, the nature and future of the nation-state is in flux. Only half a century post-colonialism, many states are still “emerging,” trying to craft identities out of arbitrarily rendered geopolitical boundaries. Globalization and neoliberal economics have rendered many transnational corporations larger (economically) than many countries and by their very nature “beyond” national jurisdiction. Consequently, it could be argued that biopolitics now aims to reproduce a different social order than the state. Given the new political economy of globalization, one could argue that, although states remain proximate ends of disciplinary power, a new agent and end of disciplinary power are transnational corporate entities and that individual states now serve as intermediary agents of this power-mobilizing bodies in service of a transnational social order.

Fully establishing such a claim is beyond the scope of this paper, but the literature of bioethics on research in developing contexts provides a provocative piece of evidence. As we saw with the *American Journal of Bioethics* discussion, the discipline of bioethics seeks to produce persons who are docile vis-à-vis the research establishment; as such, research ethics is clearly an exercise of power to direct individuals to engage in actions that are not necessarily to their advantage. Beyond the developed world, however, lies chaos. If vulnerable populations in the United States represent pockets of unruly or untamed bodies from the perspective of first-world researchers, the bodies of persons in resource-limited contexts are a new frontier. How to access and incorporate those bodies into the network of transnational research remains an ongoing challenge, especially when much of this management must be done from a significant geographical distance. A solution to this challenge appears to lie in the creation of docile corporate bodies—docile States—that will police themselves vis-à-vis research ethics, and who will, in turn, facilitate the production of docile human bodies for research.

Most of the literature on the conduct of research in developing contexts follows the standard narrative. The framework for the debate was set in 1988 in two early essays on HIV/AIDS trials in Africa by Nicholas Christakis (1988) and Michele Barry (1988). Barry methodically analyzes HIV/AIDS trials via the subheads of autonomy and informed consent, nonmaleficence and beneficence, and justice with additional commentary on the state of review committees in developing countries. Christakis, after introductory remarks on scientific appropriateness of study populations, structures his analysis within the canon of risk–consent and beneficence.

Subsequent analysis follows this map. Bioethicists tackle challenges presented by developing world contexts to the practice of informed consent, particularly non-Western anthropologies, lack of the concept of choice, lack of basic literacies (cultural, scientific, or otherwise), and alternative notions of the relationships between person and community.²¹ Equally, the literature engages questions of nonmaleficence and beneficence, including not only risk–benefit calculus of immediate and long-term physiological and health ramifications of particular interventions for specific research subjects but equally the kinds and limits of benefits that can enter into the moral calculus as well as questions of who is the proper recipient of benefit—the research subjects, their local community, their country, or some combination thereof.²² Not surprisingly, in considerations of the ethics of transnational research, the debate around beneficence quickly elides into considerations of the principle of justice.²³ Most commentators continue to work with a relatively narrow sense of justice as fairness, where fairness concerns the just distribution of the burdens and benefits of the research (Barry, 1988, 1084–5). Particularly contested is the distinction between “reasonable availability” of benefits versus a more limited notion of “fair benefits.”²⁴ It also includes the controversy over standards of care utilized in

research design.²⁵ This focus on justice stems from a recognition of the power differential and socioeconomic gap between researchers from rich countries and researchers from poor countries; but it is only recently that the conversation has begun to frame the issue as one not primarily of distributive justice but of social justice.²⁶

Beyond the four canonical principles, two additional questions animate this literature. The first, that I will only mention briefly, concerns the ongoing controversy over whether the ethical standards applied when research is conducted by investigators of one country on subjects of another should be internationally universal or context specific. Marcia Angell (1988), for example, argues against ethical relativism, contending that such context specificity with regard to scientific standards would be ruled out of court. If scientific standards are considered absolute, why ought ethical standards be less rigorous? McMillan and Conlon, alternatively, take the opposite position and do so in a particularly illuminating way. Referring to the principle that therapies derived from human subjects research ought to be made “reasonably available” to participant subjects, they argue

Sticking strictly to this principle would stop a significant amount of research The problem is that the Helsinki recommendation is strongly worded and if a treatment is for a chronic illness the cost of having to supply treatment to research participants on an indefinite basis may mean that valuable developing world research is not conducted. (205–6)

Here, as with the *American Journal of Bioethics* conversation and the forebears of bioethics, the expert discourse presumes transnational biomedical research to be an unquestioned good. Insofar as it contributes to the common good, the collective wealth of scientific knowledge and medical treatment, it is increasingly construed as a benefit to which underserved people and populations have a right. As before, behind the rhetoric of autonomy, benefit, and justice lies a commitment that the machinery of the research industry must not be slowed.

The main mechanism for advancing this commitment comprises a final focus of this bioethics literature, namely, the need to establish ethics mechanisms in developing, resource-limited countries.²⁷ A common lament focuses on “the absence and ineffectiveness of ethics review committees in many developing countries” (Anya, 2003) and calls for the enhancing of IRB capacity as well as developing clinical trial capacity in the countries where the research takes place.²⁸ Although even local guidelines may have been crafted, many developing countries lack sufficient bureaucratic infrastructure to implement and regulate them, much less to oversee foreign researchers. A main task of bioethics and transnational research is to create an ethics infrastructure.

Here the biopolitical disciplinary matrix of transnational research ethics becomes clear. Discourses, practices, and institutions come together in a seamless package, whose aim is to reproduce a regime of truth in a new location. Recall Dorothy Smith's notion of discourses as extralocal texts establishing ruling relations through specific practices institutionalized in specific institutional authorities. The change in “geography” in the move from Belmont to Beauchamp and Childress, from the laboratory to the clinic, or from the DRG specialist to clinical practice was relatively subtle. That a “text created elsewhere” was “organiz[ing] action and relationships in local settings by instructing actors in those settings as to what they should do and perhaps proscribing what they cannot do” was easy to miss since the external and local agent share a cultural context.

Such a change in geography is less subtle in the world of transnational research. Here the principles of bioethics, incarnate in the U.S. and international guidelines, function explicitly as extralocal texts. A significant portion of the literature on the ethics of transnational research focuses on steps taken by Western researchers to develop the infrastructure and capacity for ethical oversight in developing countries, the institutions and practices by which these extralocal texts will come to function in an indigenous fashion.

Two examples among many illustrate this initiative. McIntosh et al. provide a detailed overview of the first 18 months of a 5-year National Institutes of Health (NIH)-funded project that was “dedicated to building a sound administrative infrastructure to meet both US and [Dominican Republic] IRB/IEC requirements to assure proper review and oversight of the research study” (418):

In the current study US and DR teams jointly conducted bioethical training for all DR-based project staff that would meet both US and DR requirements, and would also help build ethically sound capacity for tobacco control research in the DR. This training included: (1) the Spanish version Belmont Report with exam; (2) a bioethics course provided by the University of Rochester's IRB (completed by both the US and DR project investigator teams) and (3) in-country training. (418)

Similarly, Lescano et al. (2008) detail steps taken by the U.S. Naval Medical Research Center Detachment (NMRCDC) to create an IRB and attendant infrastructure in Venezuela in 2006. Not only does the NMRCDC take the Venezuelans through a step-by-step development and education process, it has subsequently “maintained close ties, serving in an advisory and mentoring capacity as problems and questions arise” (Lescano et al. 2008, 976). As they note

Training in research bioethics is essential for developing general expertise in the scientific community, and in this case, NMRCDC has been instrumental in engaging our Latin American collaborators in the IRB enterprise In addition to their regular Webcast courses, the National Institutes of Health bioethics team has visited Peru and provided courses in Lima and other cities in Peru since 2005, for the benefit of >500 participants from 13 countries. (977)

In other words, although test balloons of conscription into research service are being floated toward the end of increasing the docility of the bodies of in the U.S. vis-à-vis biotech research, the same bioethics establishment recognizes that a necessary prior step in transnational research is to increase the docility of states, countries, and populations. Such docile political bodies must be created on the way to creating docile bodies for human subjects research within their jurisdiction. Transnational research ethics is equally about remaking the governments of those countries in our own image in order to produce a docility not only of the bodies of individual citizens of countries in the developing world but also of those countries themselves.

That corporate agents are a target is indicated additionally by a unique dimension of the transnational research ethics literature, namely, its attention to communities as agents (Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries, 2004, 18). As mentioned above, in transnational research ethics, the risk–benefit determinations and the interpretation of beneficence do not apply solely to individual research subjects, as is the almost inviolate norm in the United States. Here, communities, populations, or countries are treated as agents. In a significant innovation in research ethics, these corporate bodies are equally deemed the subjects of risks and benefits; they are

the agents of consent. In the case cited at the outset of this essay, for example, Pfizer casts the government in the role traditionally assumed by the human subject: “Pfizer denies any wrongdoing. ‘We continue to maintain—in the strongest terms—that the Nigerian government was fully informed in advance of the clinical study’” (Willyard, 2007, 763)

This concerted effort (funded frequently by the U.S. military or the National Institutes of Health) to ensure the establishment of institutionalized bodies that will enact the discourse of bioethics via practices and techniques such as protocol review and informed consent demonstrates the coextensive nature of discourses, practices, and institutions. As ethics organs are established in each locale, the panoptic grid grows. More and more countries, and thus more and more bodies, come into the official and efficient gaze of biotech research, which can now legitimately extend its power through the materiality of human embodiment. In this way, the discipline of bioethics strategically creates and extends a network of relations that gives transnational biotech research the ability to act and keep acting for its own advantage, to bring about the desired situation of more and more research and more and more profits, and to neutralize those who would thwart such desires. Under the rhetoric of apolitical neutrality and objectivity, bioethics produces particular kinds of embodied subject–citizens that enable the transnational biotech industry to effectively and covertly wield productive power.

V. CONCLUSION

We have before us, then, two examples from the contemporary conversation on transnational research. As in the 1970s, so it is in the new millennium. Bioethics has determined the ends to be chosen—the “good” of biomedical research—and has determined that this is a primary end to be pursued, whether in the U.S. or in developing contexts. This primary good of research has been decided absent an open, public deliberative process by which the citizens of the particular countries in question might identify, prioritize, and choose which goods they deem central to their flourishing as individuals, communities, and nations. This commitment is particularly striking with regard to resource-limited contexts; where most of the population lacks clean water, sanitation, sufficient food, education, and adequate housing, bioethics has staked a firm commitment to pharmaceutical and biotech research as a primary good—perhaps the primary good—to be instantiated. Moreover, it is clear that in the U.S. context we have become sufficiently docile such that Rhodes’ (2005) proposal is not rejected as beyond the pale.

It is my hope that these two examples—the conversation on rethinking research ethics from *The American Journal of Bioethics* and the commitment to advancing ethics mechanisms in resource-limited contexts—are sufficient to suggest that the narrative of biopolitics is a plausible and perhaps a more compelling framework for understanding the function and role of bioethics as it has evolved from the end of the twentieth century in the United States to its more globally expansive role in the new millennium. Certainly, these two examples cannot be more than suggestive, but I hope they are sufficient to invite further exploration into the biopolitical character of research ethics.

Illuminating the biopolitical nature of research ethics is, in fact, critically important to coming to a more accurate and adequate account of bioethics itself. For, as those attuned to history know, the discipline of bioethics is grounded in research ethics. The fundamental groundwork of bioethics was hammered out in the debates around the practice of research. Subsequently, in an almost seamless shift, the principles of research ethics articulated in The Belmont Report became transferred to the clinical context in Beauchamp and Childress’ *Principles of Biomedical Ethics*. In other words, prior to reaching

across international boundaries to function as extralocal texts in resource-limited contexts, once the Belmont principles were established, bioethicists began to apply them and their form of argumentation beyond their original focus in the ethics of human experimentation (Evans, 89–90).²⁹ As David Rothman notes, “the new rules for the laboratory permeated the examining room ... the doctor-patient relationship was modeled on the form of the researcher-subject; in therapy, as in experimentation, formal and informal mechanisms of control and a new language of patients’ rights assumed unprecedented importance” (Evans, 91).

Thus, developments in research ethics retain a critical function vis-à-vis bioethics as a whole. Equally, coming to see the biopolitical dimensions of the ethics of transnational research will facilitate our ability to see how bioethics functions as biopolitics elsewhere. And this is the central question: What is the function of bioethics? What is the role of bioethics in the new political economy of medicine? Is the discipline honest about its relationship to individual freedom and its neutrality regarding the good? Attending to bodies, I believe, is the first and most crucial step in answering that question. Focusing on what happens to the material reality of bodies—and refusing to let our analytic focus shift from those bodies—will indicate whether the rhetoric of freedom and autonomy is sustainable or whether bioethics is in fact yet one more discipline that utilizes strategies of surveillance and control, under appeals to the welfare of individuals and populations, while serving to create docile bodies, bodies both individual and corporate, that will cooperate with the industry of biotech research in ways that do not necessarily further their own good or the good of their citizens, toward reproducing now a transnational economic order.

Notes

- 1 Those familiar with the work of Michel Foucault will recognize the debt of this introduction to the opening of *Discipline and Punish* (Foucault, 1995). The following account of the hepatitis experiments at Willowbrook is drawn primarily from *The Advisory Committee on the Human Radiation Experiments*, 1996, 101–2 and Krugman (1986).
- 2 A Web site of the Frederick L. Erhman Medical Library hosts a biography of Krugman noting his many accolades and making no mention of the concerns raised by the Willowbrook experiments: <http://archives.med.nyu.edu/exhibits/krugman/index.html> (Accessed May 2, 2009). Krugman himself continued to defend the ethics of his experiments at Willowbrook until the end of his life (Krugman, 1986).
- 3 The following account of the Pfizer/Trovan case is drawn primarily from Lewin (2001) unless otherwise noted.
- 4 Deal in Pfizer-Nigerian Drug Suit (BBC, April 3, 2009). Available: <http://news.bbc.co.uk/2/hi/africa/7982236.stm>. (Accessed April 8, 2009).
- 5 Per Pfizer spokesperson, “We continue to maintain—in the strongest terms—that the Nigerian government was fully informed in advance of the clinical study; that the study was conducted appropriately, ethically, and with the best interests of patients in mind; and that it helped save lives” (Willyard, 2007, 763). Pfizer does not state whether this lower mortality rate compares to those children treated with chloramphenicol or those children throughout Nigeria who were unable to receive treatment—effectively, a default placebo control group.
- 6 Press release, “Pfizer Becomes The First Pharmaceutical Company To Be Accredited For Protection Of Human Rights In Clinical Research,” April 3, 2009. Available:

http://www.pfizer.com/news/press_releases/pfizer_press_releases.jsp?rssUrl=http://mediaroom.pfizer.com/portal/site/pfizer/index.jsp?ndmViewId=news_view&ndmConfigId=1016273&newsId=20090403005547&newsLang=en (Accessed April 8, 2009). This accreditation came from the Association for the Accreditation of Human Research Protection Programs and was awarded for its conduct of Phase 1 trials in its clinical research units in New Haven, Connecticut, Brussels, Belgium, and Singapore. Note: this accreditation is only for Phase I trials and only for locations that would not generally be described as “resource limited” or “developing.”

- 7 In 1999, Trovan was discovered to cause liver damage and its use was curtailed by the Food and Drug Administration. It was never approved for use in children (Lewin, 2001).
- 8 In this paper I use the term “transnational” research rather than “international” research. The term international has connotations of mutuality, conjuring images like that of the United Nations where agents meet on equal footing in largely democratic interactions. The term transnational more accurately captures the political economy operative in much of the research currently being conducted both in the U.S. and other developed contexts as well as in resource-limited or developing contexts (which could also be embedded within national contexts not similarly defined). The primary agents of much of the research conducted in the United States or abroad are transnational corporations—primarily pharmaceutical companies but biotechnology firms as well. Whether conducted by a transnational corporation or not, the economic context of research is driven by the philosophy and practices adopted by transnational corporations especially since 1980. Moreover, given the economic relationships that have shaped much NIH and university-based research since the passing of Bayh-Dole in the early 1980s, the characterization of much non-corporate-based research could properly be categorized as transnational. See Kim et al., 2000, 177–243 for further discussion of transnational corporations in general and in relation to health/health care in particular.
- 9 As illuminating as Foucault's work has proven in analyzing the social function of medicine, his work has made few inroads into the literature of bioethics. Those who have brought Foucault's work to bear on the discipline of bioethics include Finkelstein (1990); McKenny (1997); Shuman (2003); Bishop and Jotterand (2006); Lysaught (2006); and Bishop (2008).
- 10 Global pharmaceutical market sales grew from an estimated \$365 billion (U.S.) in 2000 to \$712 billion in 2007. IMS Health, “Global Pharmaceutical Sales 2000–2007,” available: <http://www.imshealth.com>. (Accessed April 10, 2008). The industry is highly profitable, posting profits of nearly 25% of sales in 1990; in 2001, the ten American drug companies in the Fortune 500 earned, as an industry, profits of 18.5% of sales in the same year that the median net return for all other industries in the Fortune 500 (i.e., 490 other companies) was only 3.3% of sales. This was no fluke year; in 2002, Marcia Angell notes, “the combined profits for the ten drug companies in the Fortune 500 (\$35.9 billion) were more than the profits for all the other 490 businesses put together (\$33.7 billion)” (Angell, 2004, 11).
- 11 In addition to corporations, an additional agent plays a significant role in most contemporary research: the contract research organization (CRO). CROs comprise a for-profit industry established in the early 1990s specifically to arrange human subjects research. For-profit companies, they began listing and selling securities on public exchanges in the early 1990s. By 2001, there were roughly one thousand CROs globally with revenues of approximately \$7 billion (Angell, 2004, 29; Petryna, 2006, 37–9).

12 The following section is modified from Lysaught 2006.

13 One of the most compelling accounts of this dynamic is provided by Scarry (1987).

14 Turner suggests that in order to preserve its boundaries and thus reproduce itself, a society must negotiate four tasks: “The reproduction of populations in time, the regulation of bodies in space, the restraint of the ‘interior’ body through disciplines, and the representation of the ‘exterior’ body in social space” (2; see also 91). It would be fruitful to display the many ways in which bioethics is involved with all four of these tasks.

15 Although Foucault uses the word “governmentality,” Dorothy Smith (1999) refers to the mechanisms that connect the local and extralocal with the intriguing phrase “ruling relations.” Governmentality or “ruling relations” does not ascribe agency to a class or any specific individuals, although some individuals and groups clearly benefit from a given system of ruling relations. They are not, per se, intentional, nor directly under control of particular individuals or groups. Rather, their power lies in that they are “pervasive and pervasively interconnected” (Smith, 1999, 49). Ruling relations organize local settings through the medium of discourses and are themselves the effects of that textual organization. Ruling relations make extralocal imperatives appear under such rubrics as rationality, efficiency, and perhaps most relevant to social sciences, objectivity. Cited in Frank, 2001, 357.

16 As Arthur Frank notes, “Theory needs to apprehend the body as both medium and outcome of social ‘body techniques,’ and society as both medium and outcome of the sum of these techniques. Body techniques are socially given—individuals may improvise on them but rarely make up any for themselves—but these techniques are only instantiated in their practical use by bodies, on bodies. Moreover, these techniques are as much resources for bodies as they are constraints on them; constraints enable as much as they restrict People construct and use their bodies, though they do not use them in conditions of their own choosing, and their constructions are overlaid with ideologies” (1991, 48).

17 Bodies, of course, can equally resist, recreate, and transform discourses. My thanks to my reviewer for this reminder.

18 “It is principally through discourse, that is, through the ways in which systems of knowledge are established, expectations of human abilities discussed, and subjects and practices described in the working literature of a professional group, that the ‘normal’ is defined” (Finkelstein, 15).

19 Evans provides one of the most interesting sociological accounts of bioethics. For those interested in Foucault and bioethics, however, Evans’ account needs to be developed in three ways. First, he needs to augment his Weberian reading of bioethics with Foucault, who does not enter into his analysis. Second, possibly related to his reliance on Weber rather than Foucault, Evans does not attend to the obvious relationships between the focus of his study (the human genome project) and the management/production of human bodies, which is evident even from his account. Third, although many of his findings point in this direction, Evans does not display the importance of the relationship between the reconfiguration of bioethics and growth of the biotech industry—i.e., he does not attend to the connections between science and the political economy underlying its growth, especially in the United States, between 1970 and 1995. For example, he is concerned with the reduction of the four principles/ends to one, that of autonomy. He finds this to be a threat to the internal logic of the profession of bioethics and therefore a threat to the profession itself. However, linking bioethics to its economic substrate would clarify for Evans how the move to the single principle

of autonomy actually furthers the internal logic of bioethics, insofar as it is rooted in furthering the economic ends of a state—and the biotech profession—committed to late capitalism: all becomes consumer choice directed toward the end of producing profit. Thus, the profession of bioethics is not threatened by the reduction of all ends to autonomy; it will simply become the profession that ensures that no other ends come into competition with that of autonomy, so as to protect the unbridled operation of the marketplace within the realm of biotech research, application, and health care. These critiques notwithstanding Evans analysis of bioethics is quite compelling.

- 20 This number includes Robert Levine's opening editorial remarks and a subsequent response by Howard Trachtman. Respondents include Ruth Macklin, Tom Beauchamp, Frank Miller, Gavin Hougham, Alex J. London, Richard Sharp, Mark Yarborough, Havvi Morreim, Mary Simmerling, Brian Schwegler, Jeanne Sears, Robert Wachbroit, David Wasserman, Fritz Allhoff, Jeffrey Spike, Justin List, Luis Justo, Amy McGuire, and Laurence B. McCullough.
- 21 See, for example: Angell (1988), Christakis and Fox (1992), Macklin (2000), Farmer (2002), Pace et al. (2005), Pace and Emanuel (2005), Newton and Appiah-Poku (2007), and Bento, Hardy, and Osis (2008).
- 22 See, for example: Angell (1997), Angell (2000), Page (2002), Benatar (2001b), Mfutso-Bengo and Muula (2007), Ballantyne (2008), and Grady et al. (2008).
- 23 See, for example: Benatar (2001a; 2001b) and Hawkins (2006).
- 24 See, for example: Arras (2004), Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries (2004), Pace et al. (2006), Benatar and Fleischer (2007), Upshur et al. (2007) and London and Kimmelman (2008).
- 25 See, for example: Angell (1997), Lurie (1997, 1998, 1999a, 1999b), Lurie and Wolfe (1999), Angell (2000), and McMillan, and Conlon (2004).
- 26 See, for example: Farmer (2002), London (2005a), and London (2005b).
- 27 See, for example: Anya (2003), Gilman and Garcia (2004), Lavery (2004), Lienhardt and Cook (2005), Kennedy et al. (2006), White (2007), Lescano et al. (2008), McIntosh et al. (2008), and Sewankambo and Ijsselmuiden (2008).
- 28 See also Lienhardt and Cook (2005), Benatar and Fleischer (2007), 621; Upshur et al. (2007), Sewankambo and Ijsselmuiden (2008), and Di Tillio-Gonzalez and Fischbach (2008).
- 29 Evans, 2002, 90. For my own analysis of the shift in the form of the principles from Belmont to Beauchamp and Childress, particularly the not-insignificant transformation of the principle of “respect for persons” into the principle of “respect for autonomy,” and the relocation of vulnerable subjects and patients from the principle of respect for persons to the principle of beneficence, see Lysaught (2004).

References

- Advisory Committee on Human Radiation Experiments, *The human radiation experiments: Final report of the President's advisory committee*, 1996 New York Oxford University Press
- Angell M. Ethical imperialism? ethics in international collaborative clinical research, *New England Journal of Medicine*, 1988, vol. 319 (pg. 1081-3)
- The ethics of clinical research in the third world, *New England Journal of Medicine*, 1997, vol. 337 (pg. 847-9)

- Investigators' responsibilities for human subjects in developing countries, *New England Journal of Medicine* , 2000, vol. 342 (pg. 967-9)
- , *The truth about drug companies: How they deceive us and what to do about it* , 2004New YorkRandom House
- Anya I. Ethics and research in developing countries, *Lancet* , 2003, vol. 362 pg. 1419
- Arras JD. Fair benefits in international medical research, *Hastings Center Report* , 2004, vol. 34 pg. 3
- Ballantyne A. Benefits to research subjects in international trials: Do they reduce exploitation or increase undue inducement?, *Developing World Bioethics* , 2008, vol. 8 (pg. 178-91)
- Barry M. Ethical considerations of human investigation in developing countries, *New England Journal of Medicine* , 1988, vol. 319 (pg. 1083-6)
- Benatar SR. Commentary: Justice and medical research: A global perspective, *Bioethics* , 2001, vol. 15 (pg. 333-40)
- Distributive justice and clinical trials in the third world, *Theoretical Medicine and Bioethics* , 2001, vol. 22 (pg. 169-76)
- Benatar SR, Fleischer TE. Ethical issues in research in low-income countries, *International Journal of Tuberculosis and Lung Disease* , 2007, vol. 11 (pg. 617-23)
- Bento SF, Hardy E, Osis MJ. Process for obtaining informed consent: Women's opinions, *Developing World Bioethics* , 2008, vol. 8 (pg. 197-206)
- Bishop JP. Biopolitics, Terri Schiavo, and the sovereign subject of death, *Journal of Medicine and Philosophy* , 2008, vol. 33 (pg. 538-57)
- Bishop JP, Jotterand F. Bioethics as biopolitics, *Journal of Medicine and Philosophy* , 2006, vol. 31 (pg. 205-12)
- Christakis NA. The ethical design of an AIDS vaccine trial in Africa, *Hastings Center Report* , 1988, vol. 18 (pg. 31-7)
- Christakis NA, Fox RC. Informed consent in Africa, *New England Journal of Medicine* , 1992, vol. 327 (pg. 1101-2)
- Di Tillio-Gonzalez D, Fischbach RL. Harmonizing regulations for biomedical research: a critical analysis of the US and Venezuelan systems, *Developing World Bioethics* , 2008, vol. 8 (pg. 167-77)
- Dreyfus HL, Rabinow P. , *Michel Foucault: Beyond structuralism and hermeneutics* , 1982Chicago, ILUniversity of Chicago Press
- Evans JH. , *Playing God: Human genetic engineering and the rationalization of public bioethical debate* , 2002Chicago, ILUniversity of Chicago Press
- Farmer P. Can transnational research be ethical in the developing world?, *Lancet* , 2002, vol. 360 pg. 1266
- Finkelstein J. Biomedicine and technocratic power, *The Hastings Center Report* , 1990, vol. 20 (pg. 13-6)
- Foucault M. , *Discipline and punish* , 1995New YorkVintage
- Frank AW, Featherstone M, Hepworth M, Turner BS. For a sociology of the body: An analytical review, *The body: Social process and cultural theory* , 1991Newbury Park, CASage Publications(pg. 36-102)
- Can we research suffering?, *Qualitative Health Research* , 2001, vol. 11 (pg. 353-62)
- Giddens A. Giddens A. From Marx to Nietzsche? Neoconservatism, Foucault, and problems in contemporary political theory, *Profiles and critiques in social theory* , 1982BerkeleyUniversity of California Press

- Gilman RH, Garcia HH. Ethics review procedures for research in developing countries: A basic presumption of guilt, *CMAJ Canadian Medical Association Journal* , 2004, vol. 171 (pg. 248-9)
- Grady C, Wagman J, Ssekubugu R, Wawer MJ, Serwadda D, Kiddugavu M, Nalugoda F. Research benefits for hypothetical HIV vaccine trials: The views of Ugandans in the Rakai district, *IRB: A Review of Human Subjects Research* , 2008, vol. 30 (pg. 1-7)
- Hawkins JS. Justice and placebo controls, *Social Theory and Practice* , 2006, vol. 32 (pg. 467-96)
- Hougham GW. Waste not, want not: Cognitive impairment should not preclude research participation, *American Journal of Bioethics* , 2005, vol. 5 (pg. 36-7)
- Kennedy SB, Harris AO, Oudemans E, Young L, Kollie J, Nelson ES, Nisbett RA. Developing capacity to protect human research subjects in a post-conflict, resource-constrained setting: Procedures and prospects, *Journal of Medical Ethics* , 2006, vol. 32 (pg. 592-5)
- Kim JY, Millen JV, Irwin A, Gershman J. , *Dying for growth: Global inequality and the health of the poor* , 2000 Monroe, ME Common Courage Press
- Krugman S. The Willowbrook Hepatitis studies revisited: Ethical aspects, *Reviews of Infectious Diseases* , 1986, vol. 8 (pg. 157-62)
- Lavery JV. Putting international research ethics guidelines to work for the benefit of developing countries, *Yale Journal of Health Policy, Law, and Ethics* , 2004, vol. 4 (pg. 319-36)
- Lescano AR, Blazes DL, Montano SM, Kochel T, Moran Z, Lescano AG, Martin GJ. Supporting the creation of new institutional review boards in developing countries: The U.S. naval medical research center detachment experience, *Military Medicine* , 2008, vol. 173 (pg. 975-7)
- Lewin T. Families sue Pfizer on test of antibiotic, *New York Times* , 2001 Aug. 30. Available: <http://www.nytimes.com/2001/08/30/business/families-sue-pfizer-on-test-of-antibiotic.html?pagewanted=1>. (Accessed April 8, 2009)
- Lienhardt C, Cook SV. Conducting clinical trials on tuberculosis in resource-poor countries: Imposed science or equally-shared efforts?, *International Journal of Tuberculosis and Lung Disease* , 2005, vol. 9 pg. 943
- London AJ. Does research ethics rest on a mistake? The common good, reasonable risk and social justice, *American Journal of Bioethics* , 2005, vol. 5 (pg. 37-9)
- Justice and the human development approach to international research, *Hastings Center Report* , 2005, vol. 35 (pg. 24-37)
- London AJ, Kimmelman J. Justice in translation: From bench to bedside in the developing world, *Lancet* , 2008, vol. 372 (pg. 82-5)
- Lurie P. Unethical trials of interventions to reduce perinatal transmission of the human immunodeficiency virus in developing countries, *New England Journal of Medicine* , 1997, vol. 337 (pg. 853-6)
- Lurie P. Ethics of HIV trials, *Lancet* , 1998, vol. 351 pg. 220
- Science, ethics, and future of research into maternal-infant transmission of HIV-1, *Lancet* , 1999, vol. 353 (pg. 1878-9)
- Should research ethics change at the border?, *Medical Journal of Australia* , 1999, vol. 171 (pg. 167-8)
- Lurie P, Wolfe SM. Proposed revisions to the declaration of Helsinki: Paving the way for globalization in research, *Western Journal of Medicine* , 1999, vol. 171 pg. 6
- Lysaught MT. Respect: Or, how respect for persons became respect for autonomy, *Journal of Medicine and Philosophy* , 2004, vol. 29 (pg. 665-80)

- Guinn D. ———And power corrupts...: Religion and the disciplinary matrix of bioethics, *The handbook of bioethics and religion* , 2006 New YorkOxford University Press(pg. 93-124)
- Macklin R. Informed consent for research: International perspectives, *Journal of the American Medical Womens Association* , 2000, vol. 55 (pg. 290-3)
- McIntosh S, Sierra E, Dozier A, Quinones SDZ, Primack A, Chadwick G, Ossip-Klein DJ. Ethical review issues in collaborative research between US and low-middle income country partners: A case example, *Bioethics* , 2008, vol. 22 (pg. 414-22)
- McKenny GP. , *To relieve the human condition: Bioethics, technology, and the body* , 1997New YorkSUNY Press
- McMillan JR, Conlon C. The Bioethics Nuffield CouncilThe ethics of research related to health care in developing countries, *Journal of Medical Ethics* , 2004, vol. 30 (pg. 204-6)
- Mfutso-Bengo JM, Muula AS. Potential benefits and harm of biotechnology in developing countries: The ethics and social dimensions, *African Journal of Medicine and Medical Sciences* , 2007, vol. 36 (Suppl.)(pg. 63-7)
- Newton SK, Appiah-Poku J. The perspectives of researchers on obtaining informed consent in developing countries, *Developing World Bioethics* , 2007, vol. 7 (pg. 19-24)
- Page AK. Prior agreements in international clinical trials: Ensuring the benefits of research to developing countries, *Yale Journal of Health Policy, Law, and Ethics* , 2002, vol. 3 (pg. 35-66)
- Pace C, Emanuel EJ. The ethics of research in developing countries: Assessing voluntariness, *Lancet* , 2005, vol. 365 (pg. 11-2)
- Pace C, Emanuel EJ, Chuenyam T, Duncombe C, Bebchuk JD, Wendler D, Tavel JA. The quality of informed consent in a clinical research study in Thailand, *IRB: A Review of Human Subjects Research* , 2005, vol. 27 (pg. 9-17)
- Pace C, Grady C, Wendler D, Bebchuk JD, Tavel JA, McNay LA, Forster HP, Killen J, Emanuel EJ. Post-trial access to tested interventions: The views of IRB/REC chair, investigators, and research participants in a multinational HIV/AIDS study, *AIDS Research and Human Retroviruses* , 2006, vol. 22 (pg. 837-41)
- Participants in the 2001 Conference on Ethical Aspects of Research in Developing CountriesMoral standards for research in developing countries: From “reasonable availability” to “fair benefits”, *Hastings Center Report* , 2004, vol. 34 (pg. 17-27)
- Petryna A. Petryna A, Lakoff A, Kleinman A. Globalizing human subjects research, *Global pharmaceuticals: Ethics, markets, practices* , 2006Durham, NCDuke University Press(pg. 33-60)
- Rhodes R. Rethinking research ethics, *American Journal of Bioethics* , 2005, vol. 5 (pg. 7-28)
- Scarry E. , *The body in pain: The making and unmaking of the world* , 1987New YorkOxford University Press
- Sewankambo N, Ijsselmuiden C. Responsive research in developing countries, *Lancet* , 2008, vol. 372 (pg. 11-3)
- Shuman J. , *Body of compassion: Ethics, medicine, and the church* , 2003Eugene, ORWipf and Stock Press
- Smith D. , *Reading the social: Critique, theory, and investigations* , 1999TorontoUniversity of Toronto Press
- Trachtman H. Does uncle Sam really want you? A response to “Rethinking research ethics” by Rosamond Rhodes, *American Journal of Bioethics* , 2005, vol. 5 (pg. W22-W23)
- Turner BS. , *The body and society: Explorations in social theory* , 1984New YorkBasil Blackwell

Upshur RE, Lavery JV, Tindana PO. Taking tissue seriously means taking communities seriously, *BMC Medical Ethics* , 2007, vol. 8 pg. 11

White MT. A right to benefit from international research: A new approach to capacity building in less-developed countries, *Accountability in Research* , 2007, vol. 14 (pg. 73-92)

Willyard C. Pfizer lawsuit spotlights ethics of developing world clinical trials, *Nature Medicine* , 2007, vol. 13 pg. 763