Image from the exhibition *Subtle Thresholds*, reproduced with permission of the artist, Fritha Langerman.

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>
> Boring (1954: 581)

6

Experimentalité: Pharmaceutical insights into anthropology's epistemologically fractured self

Donna Goldstein

> *The problem was that the anthros (and the médicos), reductionist to the core, conceived the object of their study not as a people but as a population. The Yanomami, who indeed had the requisite sorts of brains, eyes, and fingers, were a control group in an inquiry centered elsewhere.*
> (Geertz 2001: 21)

IN HIS REVIEW OF Patrick Tierney's (2000) *Darkness in El Dorado*, Clifford Geertz (2001) reflects on the research behaviour of anthropologists. At the time of Geertz's review, Tierney's passionate book had already sparked an explosive debate, among anthropologists and the public at large. Geertz's insight that anthropologists conceptualise their objects of study as populations instead of people continues to fuel tensions not only between sub-disciplines, but also between anthropology and other medical and science-oriented professions. Geertz's accusation builds on a perception of anthropology as situated within the natural sciences, but also hints that this positioning might be problematic.

Geertz points out that the researchers who had worked on the now infamous case of the Yanomami, James V Neel and Napoleon Chagnon, saw the Yanomami as pivotal links in a Darwinian chain. Specifically, Neel and Chagnon's culturally based genetic research was designed to test the Darwinian conjecture that 'masculinity, violence, domination, and the appropriation of women are selectively linked in tribal society…and thus that warfare and inequality were driving forces in the separation of Homo sapiens from other primates' (Geertz 2001). Geertz is here alluding to the ways in which the Yanomami, a tribe known for its late 'contact' with Western civilisation due to its isolation deep in the Amazon, has been endlessly appropriated by anthropologists as representative of our earliest and most pristine Homo sapiens selves. Even the interpretive turn that Geertz himself initiated in the mid-1980s to question just this sort of appropriation has had little effect on the way certain anthropologists look to small-scale or non-state tribes such as the Yanomami

for evidence of a distant past. Indeed, Tierney asserts that Neel initially became interested in the Yanomami for their potential to serve as a pristine radiation-free control group for the atomic bomb radiation studies that he had begun conducting on the Japanese after the conclusion of the Second World War (Tierney 2000).

We do not have to look to isolated tribes to find the thorny issues that surround control groups and populations. Global clinical research trials are prime sites for exactly the problem that Geertz describes, where populations are overlooked as people and are seen instead as a source of data for clarifying experimental work. In this chapter, I review the controversies that surround the use of control groups in pharmaceutical science as a means of illuminating the epistemological divisions that frame our own field of anthropology. What pharmaceutical scientists and certain anthropologists have in common is an experimental emphasis on highly specific methods that require, among other attributes of rigour, a human control group,[1] which shares vital characteristics with the experimental group but does not receive the treatment being tested. It is the population that is held constant, the unmanipulated and unadulterated point of reference that proves the significance of the characteristic it is missing. Without it, contemporary science, as we know it, would fail. In the pages that follow, I use the word *experimentalité* to capture the ways in which scientific subjectivity relies on the control group as fundamental to reliable results. My work builds on Adriana Petryna's notion of experimentality. Petryna (2009) rightly locates experimentality as part of the new geography of pharmaceutical capital and power. *Experimentalité,* as I discuss it here, helps to locate the now global and corporate standard discussed by Petryna in the formation of our earliest and most esteemed scientists. Quite simply, I use the term *experimentalité* to capture the mentality that accompanies experimentation, the thinking that goes into scientific design and method, the mindset through which scientists technologise, specify and professionalise the quest for truth. By interrogating the scientific process as it unwittingly tangles with biopolitics and bioethics, I join a number of other scholars and anthropologists exploring similar issues (e.g. Biehl 2005, 2007; Hayden 2007; Lakoff 2004; Petryna 2005, 2006, 2007, 2009; Petryna, Lakoff & Kleinman 2006).

I provide here three accounts of pharmaceutical politics that take place in distinct socio-historical time periods and draw from different kinds of evidence. Each of these accounts reveals how *experimentalité* motivates scientists working with human experiments to seek human control populations that are purified of qualities that would confound the experiment. The first account analyses the climax of a novel that is now hailed for introducing the dilemmas associated with control-group science to an early twentieth-century audience, Sinclair Lewis's 1925 *Arrowsmith*. The second account focuses on the methodological orientations that led to Tierney's allegations against Neel in *Darkness in El Dorado*. The third account draws from my ongoing research on pharmaceutical production and distribution in contemporary

(neoliberal) Latin America. All three cases pivot around a specific and contextualised understanding of the control group, and each is embedded within *pharmaceutical politics,* the politics of the production, consumption, marketing, sale and/or laboratory and human testing of pharmaceutical products. In each case, while members of the scientific community conceptualise the control group as fundamental to their particular scientific research process, individuals outside this community see the use of the control group as reductionist and potentially dehumanising.

My primary aim is to relate these ethical debates to the epistemological dilemmas that continue to fracture anthropology. In the final section of the chapter, I bring these three divergent accounts of pharmaceutical politics into dialogue with one another in the hope of illuminating the ambiguities that remain in anthropology's bioethical domain in spite of our repeated attempts to ignore them. In particular, I seek to link the human experimentation that takes place in global clinical trials (see, for example, Petryna 2009) to the human experimentation that takes place within anthropology, as exemplified, albeit in somewhat dramatic fashion, by Neel's research on the Yanomami. Anthropology as a discipline still honours a holistic Boasian ideal, even when members of its four traditional subfields cohabit with vastly different methodologies and epistemologies. By contextualising the field's internal disagreements socio-historically as part of a much broader debate over experimentalité, I hope to illustrate why it is becoming at once increasingly necessary and increasingly difficult for anthropology to forge a unified bioethical future.

Cultural anthropologists working in science studies have for some time been interested in the idea that scientific facts emerge as part of a social process and that an important element of scientific training involves learning how to sort through data and interpret which data are meaningful. Latour and Woolgar's (1986) ethnographic investigation of the neuroendocrinology laboratory within the Salk Institute inspired a generation of scholars to examine the socially constructed aspects of the scientific process. The field has grown immensely in the last three decades, with many anthropologists writing about the effects of capitalism (and neoliberalism) on various aspects of the scientific process and on biomedicine more specifically. As an extension of Michel Foucault's notion of the *biopolitical* (see Lemke 2001), the concept of *biocapitalism* has emerged to capture how a broad array of biomaterial (e.g. cells, molecules, genes, genomes and pharmaceuticals) produces value in the marketplace (see Sunder Rajan 2006; Rose 2006). Global clinical drug trials and the ethical problems they entail have become central in this discussion, as is evidenced by a recent volume on global pharmaceuticals edited by Petryna et al. (2006) and a recent ethnography by Petryna (2009) on drug developers' search for global human subjects in clinical trials research. In particular, Petryna (2009: 36) notes that the evolution of ethical standards in human research has local instantiations: 'In zones of crisis, protection and safety considerations are at times weighed against immediate

health benefits or the scientific knowledge to be gained. Ethics and method are thus modified to fit the local context and experimental data required.' (2009: 36)

Petryna's ethnographic project shows clearly how ethical standards are applied differentially to different populations, a practice that likewise explains the differential ethical treatment suffered by the very 'darlings' of the anthropological gaze, the Yanomami. There is an important, if uncomfortable, overlap between Petryna's pharmaceutical subjects and Neel's anthropological subjects. The question of informed consent among impoverished populations is just one of the many ethical questions that anthropological and pharmaceutical researchers share. Yet, while these kinds of ethical questions are deeply embedded within anthropology, they are also differently positioned within the field's sub-disciplines. This divergence is a product of our different epistemological understandings of the world and of the nature of knowledge production. Some anthropologists would argue that human experimentation, even if it does not produce any known benefit to the individuals involved, is worthwhile in that it produces knowledge that contributes to the understanding of humanity, whether such knowledge provides theoretical information on human origins or practical information on curing disease. Other anthropologists would argue that human experimentation is problematic if its research design puts the well-being of current populations at risk through either methodological attention or methodological neglect. What is worthy of recognition is that this epistemological distinction appears not only within anthropology but also in the ever-enlarging interdisciplinary field of bioethics.

When Tierney's book first shook up our field, my department staged a debate and discussion in which I participated. In spite of all the information that has been provided in the ten years since then, I would argue that neither my colleagues nor I have changed our positions. Some of us were and are more sympathetic to Tierney's allegations of misconduct by Chagnon and Neel, some of us less so. In particular, anthropologists who were familiar with Neel and his distinguished career forcefully defended his reputation. Chagnon was perhaps less easy to defend because of a number of coinciding claims about unethical behaviour in a range of situations. Yet, even now, one of my colleagues recently distributed to his fellow faculty members a photocopy of a short article titled 'Chagnon critics overstepped bounds, historian says', recently published in the journal *Science* (Mann 2009). My colleague's decision to deliver a copy of the article to each faculty mailbox, with the title prominently highlighted, suggests that the dispute survives. I hope that by writing about these issues one decade later, after my own deeper immersion within similar epistemological controversies that frame clinical trials research in Mexico and Argentina, I can shed new light on what the Neel case tells us not only about scientific research and human experimentation, but also about past, present and future divisions within anthropology.

This chapter broadly shares Petryna's concerns about the differential values placed on distinct populations in human clinical drug trials. I add to her collected set of portraits of scientists within the pharmaceutical industry and focus ever more closely on what these scientists are telling us about *methodological rigour*, here defined as the drive to produce credible scientific evidence. Throughout the chapter, I point to the ways in which the human control group has been a consistent actor in pharmaceutical and other scientific research involving human experimentation. The chapter, thus, explores the controversial space of a scientific method that itself produces the need to value populations differently.

The first account focuses on the actions of Martin Arrowsmith, the fictional medical doctor turned research clinician depicted in Sinclair Lewis's Pulitzer Prize-winning novel *Arrowsmith*,[2] and the ways in which Arrowsmith's actions have been interpreted by literary critics and scientists. The novel's climactic ending pits the biologist's devotion to scientific rigour against the humanist's desire to abandon controlled placebo research in a human population as it becomes apparent that the potential cure being tested against a deadly plague is actually working. The second account examines the scientific conduct of geneticist James V Neel, one member of the multidisciplinary research team working in Yanomami territory in Venezuela and Brazil during the measles epidemic of 1968, focusing particularly on the methodological rigour that Neel sought in this version of human experimentation. The third account is drawn from my current ethnographic field research project in Argentina and Mexico. I present a close-up portrait of Dr Victor Hernandez,[3] who had recently moved away from his public sector work and had accepted a position as clinical research director for a global 'Big Pharma' corporation, citing his professional interest in carrying out 'good science' as a key factor in his decision.

These protagonists, all devoted to carrying out good and methodologically rigorous science, share a deep belief in the integrity and solidity of control group research. Each of them takes a separate route to solving problems of scientific rigour: Martin Arrowsmith eventually retreats to become a purer laboratory scientist in an isolated setting in Vermont; James V Neel changes research direction to study what he believes to be a pristine tribe in the Amazon; and Dr Hernandez enters the belly of the beast, a global pharmaceutical corporation. Their careers move in and out of industry and the academy, always sharing an interest in the pursuit of reliable scientific results.

The control group

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> (Boring 1954: 581)

In *The Progress of Experiment: Science and Therapeutic Reform in the United States, 1900–1990*, historian Harry M Marks (1997: 2) describes the rise of statistical practice and reasoning within medical research and among a group of therapeutic reformers who 'sought to use the science of controlled experiments to direct medical practice'. Marks traces the history of these reformers through the century as they arrive at a standard of scientific integrity, namely the double-blind, randomised, controlled trial (RCT), which became accepted among medical practitioners and by the United Sates Food and Drug Administration (FDA) in the 1980s.[4] According to Marks, the reformers' trust in science went hand in hand with a suspicion of the motives of corporations and of business. He characterises the present moment as one in which the therapeutic reformers have, to some extent, 'won'. However, contrary to the reformers' hopes and dreams, it seems that corporate control over science has gained financial traction and has manipulated scientific talent in a variety of ways. Many observers, including Marks, would agree that there are still methodological flaws and underestimation of risk in human experimentation, whether carried out by industrial or academic scientists.

One area highlighted by Petryna (2009) that remains controversial among pharmaceutical scientists and others concerns the use of placebos. While placebo experiments maintain an aura of respect within the FDA, they present a series of ethical dilemmas for scientists testing new drugs, particularly if a standard treatment already exists.[5] Recently, some clinical research scientists have taken the position that placebo-controlled trials are unethical when effective therapy is available for a condition being studied. This position emerged most vociferously in the aftermath of the 1994 azidothymidine (AZT) trials in Africa, which involved testing minimal and simplified dosage levels of AZT to prevent vertical transmission among impoverished people, who, before these trials, had no formal treatment available to them. At the very heart of the debate, of course, is the fact of the differential between the existence of a treatment and that treatment's availability to a particular population.

Petryna (2006, 2009) examines the logic of the AZT trials and the ensuing debates in the context of the global clinical trials industry, which is forever seeking treatment-naïve populations around the globe for study. Scientists in favour of

placebo trials usually invoke methodological rigour, arguing that the only way to know whether a pharmaceutical product works is to view its effects against an unmanipulated control group. Indeed, the 1994 AZT trials were a sort of litmus test for clinical trial ethics, in that placebo trials were rationalised by some scientists who pointed both to the methodological need for control and to the impoverished medical condition of the original study population. Many bioethicists likewise referred to the medical deprivation experienced by these populations, arguing that no one would be worse off as a result of such trials. Petryna notes, in particular, that Dr Robert Temple, associate director of medical policy at the Center for Drug Evaluation in the United States, ultimately used the notion of context to throw his support behind placebo advocates and to challenge the 2000 revisions made to the Helsinki Declaration,[6] which opposed the use of placebo controls in cases where known therapeutic treatment is available. Temple successfully challenged the Helsinki revision by pointing to the International Conference on Harmonisation (ICH) guidelines, an alternative ethics document that defined placebo controlled trials of a new agent as a decision that ought to be subject to context and made by researcher, subject and institutional review board (IRB), and might differ by ICH region (Petryna 2006, citing Temple 2002). Petryna suggests, in addition, that those in the medical community who favour placebo control trials are guided seemingly by their desire for high-quality scientific data (that is, for what they perceive to be methodological rigour).

A second issue is the extent to which research is embedded in capitalist processes that affect the nature of the science. Medical research journals have amply recognised ways in which the profit-seeking interests of pharmaceutical companies have infiltrated the scientific process, including the ghostwriting of studies, where doctors are employed as authors by companies needing experts to support their products (see, for example, Ross et al. 2008; Moffat & Elliott 2007), and the cherry-picking of data results, as in the Vioxx case (see Zwillich 2005; Krumholz et al. 2007).[7] Research scientists and medical doctors alike have begun to recognise that market forces often lead to a lack of regulation and oversight, internal design flaws and corruption of many varieties. The quest for populations who have never been treated for a particular illness – often more easily procured outside of the comparatively wealthy and healthy Western countries – can be traced, in part, to the uncomfortable fact that the effects of new drug treatments can be more clearly established by the reaction of 'virgin' or 'naïve to treatment' bodies (Petryna 2006, 2007, 2009). Thus, the impoverished and marginalised populations that are likely to remain untreated for treatable illnesses are the same populations sought after for high-quality placebo control global clinical trials. In such contexts, administering a placebo treatment appears reasonable, since it leaves the populations in the same state they were found in (or an arguably no-worse state); at least, this is the

rationale of scientists who openly defend placebo control studies, no matter what the known treatment.

There appears to be a convergence between two seemingly disparate desires among scientists: first, the desire for a particular kind of methodological rigour conferred by greater numbers of participants and credible statistical significance, as in the case of RCTs; and, second, the desire to minimise any additional risk to these selfsame participants (Petryna 2009). This convergence, I argue, ultimately promotes the use of human control group research, including placebo control studies. However, the call for methodological rigour can take shape among a range of scientists working in different kinds of institutions and can hide some of the biases of those very same institutions. By examining the meaning of the human control group to the scientists who are the protagonists in the accounts below, I hope to highlight the importance of the control group to the production of scientific knowledge, while exposing its potential dangers in the context of human experimentation.

Doctor and research scientist: Martin Arrowsmith

The Western literary community received *Arrowsmith* as the first serious analysis of the tensions between research scientists and medical doctors. Lewis was perhaps the first American novelist to collaborate with an expert from a prestigious research institute in order to frame the scientific context of a piece of fiction; he was also one of the first novelists to provide a substantial description of the tensions between 'science pure' and 'science commercialised'. The novel is a haunting fictional (yet plausible) depiction of human control group experimentation in the early 20th century during a deadly human epidemic in a distant land. Lewis clearly displays some of the assumptions of imperial medicine at that time, with white First World scientists saving lives as well as negotiating the treatment of black Third World natives as control group subjects whose lives would provide a new methodological certainty to laboratory findings.

Arrowsmith is the story of a young man of humble Midwestern origins whose life is traced from his early training in medicine (circa 1904) and bacteriology, through his rise to a position in a prestigious research institute, to his final embrace of pure scientific laboratory research approximately 20 years later. It is also a sophisticated tale about science politics and divisions involving medical doctors, laboratory scientists, public health specialists, science institutions and commercial interests. Martin Arrowsmith rejects various forms of what the novel depicts as tainted or commercialised science: first, the dead-end and anti-intellectual nature of small-town medical practice; then, the absorption of the medical profession into a form of public health quackery complete with dysfunctional regulatory mechanisms

and corrupt interpretation of scientific findings; and, finally, in the last pages of the novel, the pressures for discovery imposed by the commercial (capitalist) interests that insert themselves into the bosom of credible science institutions. The novel exposes the struggle of scientific research to maintain its honesty, method and rigour in spite of human ignorance, the emerging profession of public health and the commercialising interests of the pharmaceutical industry, all of which are shown as corrupt yet bolstered by purported humanitarian interests. It is reasonable to claim that the novel also outlines the complex morality tale of how the control group evolved inside early 20th-century science institutions in North America and among individual scientists struggling with the defence of scientific rigour within the confines of human experimentation.

Arrowsmith (1925) opens with a dedication page in the form of a thank-you note to the real-life physician and bacteriologist Paul De Kruif (1890–1971), who worked closely with Sinclair Lewis as a scientific expert and collaborator over a period of two years. De Kruif, who at the time of his collaboration with Lewis was in the process of writing *Microbe Hunters,*[8] had been dismissed from employment at the Rockefeller Institute in New York for publishing popular articles that were interpreted as critical of the Institute.[9] De Kruif advised Lewis throughout the writing of *Arrowsmith*[10] and is generally credited with mentoring Lewis on the technical debates and social tensions that characterised medical and clinical science research communities in the early 1900s. According to literary critic James Hutchisson, De Kruif's professional science background and philosophy were critical to Lewis's novel. De Kruif and Lewis were jointly given a monetary advance and a book contract from Harcourt, Brace & Company, which enabled them to 'set out on an extended tour of the West Indies in order to gather material for the climax of the novel, the plague on St. Hubert which brings the novel to its climax when Martin Arrowsmith's scientific scruples come up against his medical ethics' (Hutchisson 1992: 51).

Like Martin Arrowsmith, De Kruif hailed from the Midwest and attended medical school there, eventually falling under the spell of the renowned German-born American biologist Jacques Loeb,[11] who is believed to have been the main inspiration for one of the key characters in the novel, Dr Max Gottlieb. Gottlieb, one of the more complex characters in the novel, is at once a trained German scientist, 'a Jewish outsider', and a man who thinks little of anything but his own work. HM Fangerau (2006: 83) describes Gottlieb as the character personifying a 'radically reductionist' research philosophy, 'a strict mechanist' who pursues meticulousness and whose ultimate goal is the acquisition of quantifiable results.

In the last hundred pages of Lewis's novel, Gottlieb, now at the helm of the McGurk Institute (recognised by *Arrowsmith* scholars as modelled on the Rockefeller Institute for Medical Research in New York City), insists that Arrowsmith, who has

found a serum that he believes will cure the bubonic plague, maintain a control group of individuals to be denied the serum, in a human experiment in the West Indies. In earlier parts of the novel, Gottlieb is richly portrayed as the righteous, rigorous and anti-commercial scientist, the professorial figure defending against both the slipshod nature of American science and the invasion of commercial interests into the medical profession. His passion for what he understands to be real scientific findings – or final truths – provides a refuge for Martin Arrowsmith, enabling him to find his way out of the clutches of corporate science and quackery and into the safe environs of a seemingly more sane, rational and pure (that is, not commercialised) laboratory (not human) science. Yet, Gottlieb's stubborn insistence that Arrowsmith maintain a human control group in the midst of a deadly epidemic gives the reader a refined insight into the debatable tension between scientific research for the (future) good of all humankind and the good of live human beings who are expected to sacrifice for that future.

In the final section of the book, Lewis describes Gottlieb as inured to the suffering of humankind, a man who 'lived to study the methods of immunizing mankind against disease', but who 'had little interest in actually using those methods'. Early literary critics of *Arrowsmith* write about Gottlieb's parallels with the actual science heroes of that time, among them Jacques Loeb, and emphasise Lewis's intention to stay true to De Kruif's disaffection for corporate science interests. But Lewis's characters are not allegorical. Gottlieb, a man perceived as easily through his virtues as through his flaws, has been of interest to both literary critics and readers far beyond the time frame within which the novel was written.

The early 20th century marks the beginning of the commercialisation and corporatisation of basic science laboratory findings for medical/humanitarian ends as well as for profit-making, an explosive period that incubated the embryonic versions of today's pharmaceutical corporations. According to science historian Charles Rosenberg, who wrote about *Arrowsmith* in 1968:

> The genuine scientists in *Arrowsmith*, Gottlieb, Terry Wickett, and Arrowsmith himself, all share the same conception of truth. It is knowledge obtained in rigidly controlled experiments, knowledge analyzed and expressed in quantitative terms. There is only one assurance in life, Gottlieb warns the youthful Arrowsmith: 'in this vale of tears there is nothing certain but the quantitative method'.
> (Rosenberg 1968/1963: 52)

Throughout the novel, barriers to scientific research – namely, the odious commercialism associated with emerging forms of scientific knowledge and the humanitarian possibilities of applied science (including pharmaceutical discovery and public health/disease control) – are irredeemably paired and, in turn, contrasted

with the strict and rigorous pure science model and method that Gottlieb offers. It is this juxtaposition of idealism with implied human imperfection that is the genius of the novel: Lewis allows for an ethical interpretation in which Gottlieb's zeal for real scientific discovery is both celebrated and questioned. While administering his serum on St Hubert, Martin Arrowsmith's devoted wife Leora and much-loved friend Sondelius both die, and it is at this climactic moment that Arrowsmith finds he can no longer abide by his promise to Gottlieb to maintain a control group (in this case, a placebo group) of untreated patients. In his grief, he begins inoculating everyone on the island, damning his study and producing inconclusive results. By the time he returns to the McGurk Institute, he is spared Gottlieb's harsh judgment, as Gottlieb himself is near death. Yet, Arrowsmith has come to the self-recognition that he is a failed scientist, and, in the final pages of the novel, he retreats to his own monastic laboratory in rural Vermont (with a like-minded fellow scientist) to carry out unadulterated science experiments devoid of humans and their corrupting institutions. For historians and anthropologists of science, Lewis's novel not only predicts and narrates some of the bioethical issues and tensions involved in scientific research on humans, but also opens an ideological space to view his hero with a critical eye.[12]

While the control group in the context of human experimentation has necessarily evolved conceptually and historically in a broadly global context, it has remained the unspoken gold standard of excellent research design.[13] In *'Arrowsmith and The Last Adam'*, one of the essays chosen to appear in a volume of reviews of the celebrated novel (Griffin 1968), Dr William B Ober MD critiques the novel in the strongest of terms for the way it suggests that Martin Arrowsmith's abandonment of the control group dictum could be perceived as a humanitarian gesture, or at least leaves this open to interpretation:

> This well-trained scientist from the McGurk Institute actually administers the treatment to the control group as well as the experimental group…Far from being a credible or creditable hero, he behaves like a fool, yet we are supposed to clasp his image to our bosoms and morally profit from his example. George the Third may profit from his example, but I doubt that any embryonic doctors or researchers can. Martin Arrowsmith's scope may have sufficed for the 1920s, but it is ill-equipped for the more complex world of the 1960s.
> (Ober 1968/1963: 58–59)

Ober's impassioned critique captures a major trend within scientific research circles that finds the humanitarian dilemma posed by Lewis to be, in a word, ludicrous. Even today, it stands in firm opposition to my own cultural anthropology-inflected reading of the novel in 2010. While I am prepared to interpret

Gottlieb's fanatical insistence on control group experimentation in the context of a live human epidemic as questionable, Dr Ober is not. Ober's interpretation of Lewis's storyline, reprinted in the very same year as Dr James V Neel's excursion to the Amazon, opens up new possibilities for understanding 'the more complex world of the 1960s', to borrow Ober's own turn of phrase. Ober's objection is at least twofold: first, he finds it inconsistent that a novel so intent on realism depicts a well-trained scientist as choosing such an unscientific solution; and, second, he takes issue with the novel's implication that the unscientific solution may be morally superior. As I argue in the following two sections of this chapter, the control group experimentation dilemmas depicted in *Arrowsmith* and debated within early 20th-century scientific communities have not been put to rest, either within the reflexive in-house anthropological debates regarding the ethics of Neel's 1968 measles vaccination campaign in the Yanomami territory or within the contemporary framing of global clinical research trials of new pharmaceutical products.

Doctor and geneticist: Dr James V Neel

In 1968, James V Neel (eventually, a National Academy of Sciences geneticist) and Napoleon Chagnon (eventually, one of anthropology's most famous cultural anthropologists and best-selling authors) led a team to the Amazon to research a number of issues related to the Yanomami Indians. Their research trip, funded by the Atomic Energy Commission (AEC), was to include the collection of blood samples, tests to examine glucose tolerance and parasite burden, the collection of oral histories that specified genealogies from Yanomami villagers, and (possibly) the observation of reactions to the Edmonston B measles vaccine among the Yanomami. When Tierney (2000) reflected on this expedition 30 years later in his controversial *Darkness in El Dorado*, he raised a number of questions surrounding Neel's behaviour in a measles epidemic that swept through the villages of his Yanomami research subjects (see Borofsky 2005). Had Neel carried the measles vaccine with him to the Amazon as part of a research plan or as treatment for a potential epidemic? Why did Neel bring with him what appeared to be an outdated form of the vaccine? Why did Neel's actions in the field overwhelmingly focus on administering the vaccine rather than on providing care to the sick? Tierney also claimed that the Yanomami had been used as a control population for the atomic bomb radiation studies of the 1950s that Neel remained invested in. Since Tierney's understanding of Neel hinged on his connection to the atomic bomb radiation studies, the discussion below returns to a few milestones in Neel's professional career and biography.

Because the Yanomami suffered from severe anaemia and had never been exposed to either wild measles or the measles vaccine, researchers in 1968 knew little about how they would react to a vaccine or an epidemic. Yet, there was a consensus among a broad range of evolutionary and genetic scientists that Amerindians historically had lacked immune or genetic resistance to epidemics such as measles, a position stated repeatedly in explanations for their high mortality rate after the European conquest. Neel, however, had been sceptical of the genetic and immune system data supporting this position. Rather, he turned to the Yanomami as offering a rare opportunity to study a number of unsolved puzzles regarding immune system reactions and genetic mutations, as well as early forms of social organisation. As he asserts in his 1994 memoir, *Physician to the Gene Pool*:

> WE BELIEVE THAT IN MANY DETAILS OF THEIR MATERIAL CULTURE AND SOCIAL ORGANIZATION, THE YANOMAMA ARE PROBABLY AS CLOSE TO THE SOCIETIES OF EARLY, EVOLVING HUMANS AS CAN BE FOUND TODAY.
> (Neel 1994: 139, original upper case)

Neel had established in an earlier (1966) field trip that the Yanomami had never been exposed to measles and, thus, constituted a 'virgin soil' population – one susceptible to particular diseases because of lack of exposure and the presence of other diseases that weaken the immune system. In the same memoir, Neel (1994: 161) states that he knew of the measles outbreak among the Brazilian Yanomami before leaving for the field and so planned to bring with him 2 000 doses of measles vaccine to set up a 'fire break' at the disease's portals of entry.

As had been proposed in the research protocol, Neel and his team moved through the area vaccinating villagers (something he had not necessarily planned on doing himself) and collecting blood samples. One of the problems for those thinking about the ethical aspects of his behaviour is whether Neel acted correctly in moving so quickly through the villages, keeping to his research agenda and perhaps curtailing the time that could have been spent in each location caring for the sick. The question arises in this case only because Neel had earned a medical degree on his way to becoming a geneticist, a trajectory common for serious scientists of his generation. Yet, Neel's own memoir suggests that, at best, humanitarian considerations were only part of the equation (Neel 1994). It is clear that the James Neel writing in his memoir is a scientist interested in the broader implications of the measles epidemic among the Yanomami – specifically, whether they had the same capacity to develop antibody titres as did Caucasians. He ultimately found that they did, thus challenging the assumption that these groups suffered from higher death rates due to an innate susceptibility. Certainly, Neel knew that he was in a unique position to watch an extraordinary event unfold, an epidemic

among a 'virgin soil' population. However, even in his memoir, Neel (1994: 165) seems disappointed that 'experiments of nature always lack the control of laboratory experiments', a disappointment I suggest we keep in mind as we look backward through his career.

The groundwork for Neel's later mindset – that treatment and research were two wholly separate intellectual projects – may have been prepared in the 1940s by his experience within the Atomic Bomb Casualty Commission (ABCC), whose purpose was to determine the long-term genetic effects of the atomic bomb on Hiroshima and Nagasaki survivors. In 1947, Neel became interim director of the ABCC, and throughout his career he maintained a devotion to the genetics portion of this project. While he was not by any means individually responsible for the 'no medical treatment' policy – the policy stating that because the ABCC was a research and not a treatment project, American medical doctors were prohibited from treating Japanese victims of the bomb – he had participated in the early discussions of the policy that led to its primacy in the structuring of the ABCC.

The ABCC expected that the Japanese would carry out the medical treatment programme prohibited for Americans, an assumption that was never 'officially' adopted as a policy (although it did seem to work in practice). M Susan Lindee (1994) explains in *Suffering Made Real: American Science and the Survivors at Hiroshima* that the most important barrier to establishing medical treatment within the ABCC itself was the desire to avoid appearing to accept American moral responsibility for the suffering caused by the atomic bomb. Regarding the no-treatment policy, Neel wrote in his memoir that medical care was indeed provided by Japanese physicians on the ground and argues that except for a few, the Japanese were largely content:

> One of the most frequent Japanese complaints has been that we (the ABCC) only examined them (like guinea pigs), but did not offer treatment in the event of findings of medical significance. The fact is that the terms under which the ABCC operated did not permit treatment, but any finding, whether on a child or an adult, was not only explained carefully to the patient (or parents), with the recommendation to see his/her physician, but also the patient's personal physician received a detailed letter describing the findings. The amazing cooperation which all the programs of the ABCC have enjoyed down through the years suggests that the complaints concerning the ABCC emanated more from a politically oriented, vociferous few than from the 'silent majority'. (Neel 1994: 85)

Neel also found himself at the centre of highly contentious scientific debates regarding the accuracy and the interpretation of the collected ABCC genetics data.

Lindee, who came to Neel's defence on several occasions in the aftermath of the Tierney accusations, states that the genetics data collected and analysed in aggregate form seemed to reveal very little effect of exposure to radiation on human genetics (Lindee 1994: 194). At the time, however, scientists debated fiercely how the categories of 'exposed' and 'control' population data were defined, given meaning and interpreted, as well as how long-term genetic effects were to be identified. As Lindee explains, some of the problems involved the interpretive nature of self-report data from atomic bomb victims who reported their exposure to radiation. Further, the genetic studies data were plagued with methodological issues of comparability that involved defining who was to be considered a control population and who an exposed population.

Changes in method were introduced over time because of improvements in infrastructure, and Neel was frustrated by his inability to control some of these changes:

> Once a procedure is introduced into a study such as the genetics program, it should remain the same, otherwise the early data will not be comparable with the later data. This was especially important in this study, since the proportion of all births to relatively heavily exposed parents was decreasing year by year. To study the later births with better procedures than were available for the earlier births would be to introduce a possible bias. I well remember discovering on one of my periodic trips to Japan that the current director, a pediatrician by training, now that improved facilities were available, had, with the best of intentions, just introduced a series of radiological examinations into our 'standard' nine-months check to facilitate the detection of skeletal abnormalities. When I pointed out the potential for bias and requested that the procedures be discontinued, there ensued a somewhat spirited exchange. His final comment was, 'alright, if you want *inferior* examinations I'll see that you get them', to which I replied, 'yes, but *uniformly inferior*, please'.
>
> (Neel 1994: 89, original italics)

For Neel, ensuring the uniform collection of data was paramount to the integrity of his study and was the only way to ensure its comparability with data collected earlier. To this end, he was willing to sacrifice improvement in the technology that might have provided a more precise detection of skeletal abnormalities.

Additionally, Lindee notes that the AEC exerted generalised political pressure for scientists to minimise any findings that would suggest serious long-term radiation effects on human populations. While Lindee grapples with this issue in her book and does not clearly resolve it, Neel writes more securely of the triumph of science over politics:

> Not unexpectedly, the funding of the follow-up studies in Japan by the Atomic Energy Commission has on occasion led to charges that our activities and writings were slanted by association with an organization devoted to the development of atomic energy, an organization that might be expected to take steps to minimize reports of the unfavorable consequences of exposure to radiation. I myself feel that on several occasions, spokespersons for the AEC have been less than candid on some of the health issues stemming from the AEC's activities. Such obfuscations as have occurred (concerning, for example, fall-out at weapons testing sites) have emanated largely from the Weapons Division of the AEC; the Division of Biology and Medicine, through which the follow-up studies in Japan were funded, has been much more forthcoming. The National Academy of Sciences, keenly aware of the delicacy of these studies, has been almost paranoid in sniffing out efforts to influence its direction of these activities. I can state categorically that at no time over the past 48 years have I been aware of any improper pressures with regard to the content or analysis of the genetic studies. Exchanges with the AEC concerning the program there were, but it was science, not politics, that prevailed.
> (Neel 1994: 89)

Neel was clearly comfortable in his role as research scientist, and, as with so many of the ABCC participants of that generation, he viewed science as something apart from everyday political jockeying. In short, Neel's career is marked by his insistence on a devotion to rigorous methodology, an acceptance of the division between treatment and research, and a belief in the separation of science and politics.

To return to the subject of Neel's later research in the Amazon, it seems that the Yanomami may very well have played a role in the AEC research as a kind of control population for measuring naturally occurring genetic mutations, since it was assumed that they would have one of the world's lowest radiation rates by virtue of their position deep in the Amazon, away from the radiation effects of large cities. In an otherwise heavily footnoted chapter and book, Tierney (2000) states that he obtained information that the Yanomami were used as a control for the atomic bomb radiation studies through the Freedom of Information Act and that this was the Department of Energy's explanation, yet he fails to substantiate this claim with any additional references. It is worth noting that in 1958, Marcel Roche, another member of Neel's 1968 research team, had carried out an iodine metabolism study for the AEC using radioactive iodine tracers. In this study, the Yanomami functioned as a kind of control group for other populations who suffered from goitre and reacted differently to iodine. These 'tracer studies' were later deemed unethical by the Department of Energy because they lacked informed consent. As Tierney

(2000) points out, other scientists found these studies potentially harmful to the Yanomami, since iodine 131 is considered a toxic substance.[14]

In one of his entries in his 1994 memoir, Neel reflects on his own life trajectory and career choices. He began his studies in 1931 at the age of 16 in general biology at the College of Wooster, Ohio, where he studied under Warren P Spencer in his Drosophila laboratory, subsequently entering graduate studies with geneticist Curt Stern (1902–1981) at the University of Rochester. Stern was a German Jewish scientist who emigrated from his native Germany in 1924 and trained an entire generation of young geneticists in the United States. He was one of many German Jewish émigrés who were perceived as methodologically rigorous and scientifically sound, much like Jacques Loeb, the model for Gottlieb in *Arrowsmith*. In 1942, Neel made the decision to enter medical school as part of his scientific training, but he quickly returned to genetics. In a section of his memoir titled 'Retreat from Clinical Medicine', Neel reveals some of his frustration with clinical medicine:

> I enjoyed clinical medicine, both for the diagnostic challenge and the satisfaction in relieving suffering, and hope I was a competent and compassionate physician. But increasingly, as the genetic side of my career unfolded, I was impressed by the amount of physician effort which, often at great and ever increasing expense, was devoted simply to prolonging a human life whose mission was clearly accomplished, often under circumstances for which the patient had no great enthusiasm. Do not misunderstand: There is no more worthy and noble effort than to bring relief to a suffering patient. But the geneticist in me was gradually getting the upper hand.
> (Neel 1994: 31)

Like Martin Arrowsmith, Neel found medical training interesting but not nearly as intellectually challenging as a research career in genetics. For Neel, the field of human population genetics offered potential answers to some of the most pressing questions of all time.

Tierney's representation of Neel's career in *Darkness in El Dorado* is worth keeping in mind because it reveals the scientific mindset and concern with methodological rigour that was formative of Neel's professional identity, as well as the pre-regulatory milieu in which this professional identity was structured. Seeing himself as a scientist foremost, Neel never fully defined himself as a medical doctor grappling with the potential moral issues that might have irritated others in the same position. His scientific cohort was seemingly concerned more with the future good that scientific findings would produce for humanity than with more immediate human rights such as informed consent, beneficence and justice, rights that indeed were far from the public conscience at that time. In the concluding section of this chapter, I return to Tierney's criticism and, in particular, to the

divergent reactions to his criticism within anthropology, to see what these discussions tell us about the methodological and epistemological orientations that divide our subfields and threaten a unified bioethical future.

Doctor and clinical research scientist: Dr Victor Hernandez

> *I have never obtained any ethical values from my scientific work.*
> (Albert Einstein)

In 2005 and 2006, I interviewed more than 20 members of the broadly defined HIV/AIDS health community in Mexico City, including activists, medical doctors, research scientists and government officials, as part of a larger research project concerned with pharmaceutical politics in Latin America. All of the people I interviewed pointed me in the direction of Dr Victor Hernandez, widely known as one of the most respected infectious disease physicians in the country and also widely beloved by HIV/AIDS activists, not only for his devotion to the public health sector (which still treats the poorest sectors of society), but also for his thoughtful positions with regard to clinical trials research among people living with HIV. Dr Hernandez is by all accounts one of the best and brightest medical doctors and clinical researchers in Mexico City, and he is, additionally, a moral compass respected within the country for protecting patients from poorly designed clinical research protocols that do not hold the patient's interests as primary. At the time of my interview with him, he had already held either successively or simultaneously a number of positions, including chief investigator at a major government institution (and chief of hospital epidemiology and quality control at the same institution) and adjunct professor at one of the leading medical schools in Mexico City. He was trained in internal medicine, surgery, infectious disease control and epidemiology by the finest programmes in Mexico and abroad, and he was lead author or co-author on an impressive number of books, book chapters and professional journal articles. Dr Hernandez was suggested by many members of the HIV/AIDS health community as the person to interview because he was outspoken about the questionable clinical research protocols proposed by large pharmaceutical corporations, and also because in 2006 he had accepted a position as chief of clinical trials research at one of the major US pharmaceutical corporations with an important headquarters in Mexico. Everyone was dying to know why this respected activist doctor had decided to work for 'Big Pharma'. In his positions in private clinics and public hospitals, he had been an important intermediary between HIV and AIDS patients interested in new treatments and companies seeking to carry out phase-3 clinical trials research in Mexico.

Phase 3 global clinical trials of HIV and AIDS treatments, which are common in Argentina and Mexico, typically compare a new treatment with the best currently available treatment (i.e. 'standard' treatment) or different doses of a standard treatment. Unlike the AZT trials carried out in Africa in the early 1990s, phase-3 clinical trials in this context do not involve placebo studies of populations without access to drugs. Importantly, they attempt to capture individuals who have not started treatment yet, and thus enable researchers to track the effects of the new treatment on less- or non-pharmaceuticalised bodies.

I made contact with Dr Hernandez through a mutual friend and set up an appointment with him in his office at AMBA Pharmaceuticals (my pseudonym for this US-based global pharmaceutical corporation). AMBA Pharmaceuticals became a corporation at the beginning of the 20th century and was transformed into a major global corporation by mid-century. The company has a distinguished history in the production of important anti-cancer drugs and drugs used in the treatment of HIV infection. Generally speaking, it has a better reputation among consumer and activist groups than do other corporations of similar stature.

In the course of the interview, Dr Hernandez explained that many pharmaceutical companies working in Mexico design clinical research protocols that are ethically questionable in terms of the scientific questions they hope to answer. As he described a number of specific cases to me, he jotted down diagrams and typical HIV and AIDS cocktail combinations in my notebook. Some clinical research protocols that he had been asked to judge, he insisted, were designed not to ask significant scientific questions but instead to keep a company's product actively generating profits. Such protocols created a (global) demand for patients who either had never before received treatment (i.e. naïve patients) or had had limited treatment options. The protocols would start their subjects on medications that already were considered obsolete in other locations, he continued, leaving the individual patient open to negative outcomes such as drug resistance. According to Dr Hernandez, it is not the use of naïve populations per se that is problematic; rather, it is the tendency to use these populations to carry out 'bad science'. His concern was that under certain kinds of corporate control – combined with corruption in Mexican government institutions and a lack of expertise – science was being perverted for the sole purpose of producing profit. Doctors were rewarded with incentives to accept the premises of these protocols – as if they were indeed methodologically rigorous and good science – and were paid by the pharmaceutical company to enter patients into the study. Through this kind of manipulation, the company in question could increase the sales of pharmaceutical products that otherwise might have been phased out of use.

Dr Hernandez repeatedly asserted during our interview that this scenario was not unique to HIV and AIDS-related pharmaceuticals. He criticised the loose and unregulated structure of local IRBs in Mexico, which, he said, were poorly managed,

lack expertise and were overworked. Dr Hernandez advocated more regulation, citing the new US requirement that companies announce on a public website when protocols have been approved, when they will begin and at which location.[15]

When Dr Hernandez accepted his position at AMBA Pharmaceuticals, his friends and colleagues in the broader HIV/AIDS medical, research and activist community were shocked. Yet, Dr Hernandez believed that AMBA Pharmaceuticals was ethically superior to other Big Pharma companies working in Mexico, and he had faith that the regulatory environment in the US would guarantee the company's integrity. Most notably, he felt that AMBA Pharmaceuticals was one of the few environments that remained untainted by the corruption plaguing Mexican institutions on the receiving end of these studies, a fact that would ultimately enable him to perform better science:

> When they invited me to come and work here, everything was 100% regulated. There wasn't going to be any type of poor business dealings – no one would offer someone money or do things that were against my principles. For that I wanted to come. I talked about this in my interview. These are the ideas of this company anyway … There is a line here that I can call if I find out that someone is doing that [something corrupt]. There is a director here who just came in heading up what is called the Area of Compliance. Its function is to make sure there is integrity within the company. This doesn't happen in every company – I think it is starting to happen. But it's very difficult.
>
> (Taped interview translated from Spanish, Dr Hernandez, 2006)

In the end, Dr Hernandez found that he could exercise his commitment to science more easily inside AMBA Pharmaceuticals than inside the Mexican government institution that he had led for many years. The paradox of his professional choice was not entirely lost on me. In the context of neoliberal deregulation in Mexico during the previous three decades, the specific corporate regulatory environment of AMBA Pharmaceuticals offered a kind of refuge.

Global pharmaceutical corporations are successful in recruiting talented science professionals under conditions of neoliberal governmentality, in large part precisely because of the allure of 'good science', or at least a better science than is possible beyond the walls of the corporation. More regulated than local institutions, they also have better funding and infrastructure. In the wake of drastic neoliberal reforms, public institutions that were once robust now lack fundamental resources, and the system has been so fully decentralised at the national level as to be without proper local regulatory structures. The pharmaceutical industry and the contract research organisations they hire as intermediaries to oversee and conduct research, therefore, speak to the scientific community

of professionals by offering not just monetary incentives (as Petryna 2009 and others suggest), but also the promise of good science, often performed via large-scale controlled global clinical research trials.

Some of Dr Hernandez's peers abroad have defended the use of placebo controls among impoverished populations, seeing these populations as necessary to methodological rigour and emphasising the need for controls so that a clear scientific understanding can be reached about how new drugs work on an untreated body (e.g. Temple & Ellenberg 2000; Temple 2002). Dr Hernandez agrees that control group populations are necessary to the production of good science, even though his position is mitigated by a firm belief that research protocols should guarantee patient access to the full range of successful treatments both during the study itself and once the study has ended.

Dr Hernandez also recognises that ambiguity is often buried deep within the details of particular clinical research protocols, and that the entire system relies on a dependable system of oversight and regulation at a number of technical levels. Global clinical research protocols depend on having local professionals who can judge the logic and benefit of the research protocol as it applies to local populations, a widespread problem that Dr Hernandez spoke of at length during his interview with me. Given the shortage of local expertise, it is often the very same doctors who are both judging protocols as members of IRBs and benefiting professionally and financially from securing approval.

In the course of my research, I began to understand how HIV/AIDS medical professionals like Dr Hernandez, oriented to the basic sanctity and centrality of the control group, wholeheartedly support the idea of using treatment-naïve populations for research. Such populations, as many medical anthropologists have argued, are important precisely because they act as a human control group for the highly medicated and treated populations of higher income countries. However, science professionals in their local contexts, among them Dr Hernandez, generally do not criticise the use of these same populations by the global pharmaceutical industry, instead reserving their condemnation for protocols that test a product or set of products solely for a particular company's financial gain. Because it has now become the responsibility of medical and clinical research professionals on local IRB committees to make sure the protocols are designed with the local population's interests in mind, conscientious doctors like Dr Hernandez want stricter regulation of research protocols so that the scientific questions being asked are 'real' rather than manufactured for the sake of a particular company's profit margin. Still, in spite of his heightened awareness of the potential for the capitalist perversion of science, Dr Hernandez was less concerned with the global risks that human experimentation within today's capitalist system could imply.

In sum, while Dr Hernandez would be the first to demand regulation that would encourage corporations to follow up with patients and provide successful treatment for participants beyond the end-date of the protocol, he knew that this sort of regulation was not entirely achievable within the Mexican context. As a scientist concerned with scientific rigour, he instead chose to focus his ethical gate-keeping on something much more achievable: making sure that clinical trials are held to the standard of good science. In his position as chief of clinical trials research, he was able to influence the trajectory of pharmaceutical research by rejecting protocols that were of questionable scientific value. His experience with resource-poor public hospitals and inept government bureaucracies had taught him that science was potentially corruptible for a price. If he were the designer, he figured, his own personal dilemmas in the face of this putrefying system would be potentially mitigated.

Experimentalité, epistemology and anthropological bioethics

Martin Arrowsmith, James Neel and Victor Hernandez each faced serious ethical questions when the methodological demands of their scientific profession conflicted with the humanitarian demands associated with their training as physicians. Martin Arrowsmith could not continue with human experimentation after he endured the death of his wife, friend and countless members of the native population who did not receive his treatment. At the end of the novel, he retreats to a scientific laboratory in Vermont that is devoid of humans and the dilemmas of human experimentation. James Neel's research among the Yanomami was probably not anticipated as an ethical challenge that would involve a deadly epidemic and a vaccine, but it turned into exactly that. In Japan, he had conducted research on the victims of atomic bomb radiation and experienced the methodological difficulties that accompany comparative human radiation studies (see, for example, Johnston 1994, 2001; Welsome 1999). Although we will probably never know what kind of influence this early research had on his decision to go to the Amazon, we do know that to the scientists of Neel's generation, the Yanomami represented one of the last human virgin soil populations. Victor Heranandez's career, likewise, is faced with human treatment and experimental dilemmas, although his work is situated in a contemporary setting that is burdened by pharmaceutical politics. As a medical doctor working on the frontlines of HIV/AIDS treatments in a developing country, he is hyper-aware of the ways in which all of his patients are potential human experimental material. The same methodological demands that drove Arrowsmith to his monastic laboratory and Neel to an encounter with what he believed to be our 'early evolving' and as yet unadulterated social and biological human selves,

prompted Hernandez to retreat to a large pharmaceutical corporation where he could exercise better scientific control over human experimentation.

All of these professional scientists shared in the *experimentalité* of their scientific milieux. In the 1920s, Arrowsmith tried to maintain the control group that was becoming increasingly central to modern scientific methodology, even when confronted with a deadly human epidemic. In the 1950s, Neel insisted on collecting his Japanese skeletal data according to the original procedure so as to maintain the methodological rigour and continuity of the experiment, in spite of advances in technology that would have enabled more accurate measurements. In the first decade of the new millennium, Hernandez, who is otherwise an outspoken patient advocate, remains neutral regarding the use of certain populations in Mexico as control groups for human experimentation in inquiries centred elsewhere. He is unable to question the methodological obsession with control groups as integral to scientific discovery, even when he knows that some populations are differentially advantaged and others differentially disadvantaged by them.

Global ethical guidelines that protect human subjects in the context of research are continually developing. A rich history for human subjects research has evolved in a number of codes over time, including the Nuremburg Code of 1947, the Helsinki Declaration of 1964 and the 1971 guidelines (codified into federal regulations in 1974) issued by the Department of Health, Education and Welfare. The Belmont Report of 1979 attempts to summarise these codes and essentially lays out three ethical pillars for human subjects research: respect for persons (informed consent), beneficence (the idea that the research subject should not be harmed and that research should maximise possible benefits and minimise possible risks) and justice (fair distribution of costs and benefits). The Belmont Report clearly warns against the use of human subjects for research that may not ultimately benefit the study subjects, and additionally warns of the ethical issues that might arise in proposed research on children. Scientists working with human populations necessarily must orient to these global guidelines, while simultaneously remaining true to discipline-specific intellectual guidelines established in their own fields of inquiry.

This brings me back to anthropologists' divergent responses to the Neel controversy. I want to suggest here that the fractious debate regarding whether Neel acted ethically in the field is better seen as a debate over the ethics of control group science. That is, the reason that anthropologists are unable to agree on this particular case is profoundly related to the divergent epistemological and methodological assumptions that undergird our research practices. What Neel did in the field had less to do with Neel as a person than with his orientation to the control group, a fact that gets lost in the in-house debates I examine below. In short, Neel's orientation

to the control group as the gold standard of good science is an orientation that is not equally embraced across subfields.

The major anthropological sources that have sought to assess Neel's career through the lens of the Yanomami episode have been unable to reach consensus regarding his motives and intentions in the context of his personal research agenda. The American Anthropological Association's *El Dorado Task Force Papers* (AAA 2002), for instance, noted that while task force members shared many points of agreement, they held contradictory interpretations regarding Neel's research agenda and his behaviour in the field. Anthropologist Linda Rabben (2004: 135–136), in *Brazil's Indians and the Onslaught of Civilization*, notes that people examining exactly the same materials reached sharply different conclusions: 'Scholars with sharply opposed views went to his papers and field notes, kept at the American Philosophical Society, and unsurprisingly came up with differing interpretations of Neel's actions and motives.' As recently as 2005, an edited volume titled *Yanomami: The Fierce Controversy and What We Can Learn from It* (Borofsky 2005) continued to raise questions about the fine line defining research as opposed to humanitarian interests. The seven experts convened to produce this volume were unable to agree on whether Neel 'focus[ed] sufficiently on the Yanomami and their health needs or [gave] greater priority to his own personal research at the expense of the Yanomami' (Borofsky 2005: 293). Was the Edmonston B measles vaccination part of Neel's original research protocol? Was the vaccination campaign, in the words of the AAA El Dorado Task Force, 'organized for research, as a humanitarian program, or both?' (AAA 2002(1): 1:25)

Why can't the anthropologists agree among themselves as to what Neel's motives and intentions were? What exactly is at stake here? Why bring us back to this sensitive and seemingly irresolvable issue? I am convinced that the Neel case holds a key insight for anthropologists as we seek to forge a common future, one that envisions some basic level of communication about bioethics as they differentially take place within and between the sub-disciplines. This case, and those I have shown here in parallel to this case, point to the multiple epistemological distinctions that divide us and cause us to understand things differently.

Earlier in this chapter, I attempted to move the question away from solely an individualised interpretation of Neel's motivations and actions in the Amazon during 1968 and, instead, to frame the development of Neel's career and professional affiliations in the context of his own biography, subjectivity and professional training as a world-class geneticist. Specifically, I have suggested that Neel's behaviour reflected the professional training he received in the early 20th century among a group of emerging scientists concerned with a particular epistemological grounding in the world – one concerned with scientific rigour, methodology, quantifiable results and controlled experimentation, and somewhat naïve with

regard to ethical issues concerning human subjects. Like other serious scientists of this time frame, Neel was more interested in carrying out research that pursued 'broader' scientific questions regarding human health rather than engaging in humanitarian efforts targeted towards individuals and communities in the present. The limitations of Neel's training, forged at the crosswinds of medical and genetics research, would have made the abandonment of his research agenda nothing short of extraordinary, even in the context of a serious and fatal human epidemic. Dr Ober's critique of *Arrowsmith* gives us a context for how a measles vaccination programme among an Amazon population might have been perceived among the medical and genetics research community of Neel and his peers. Had Neel simply carried out the vaccination as a 'public health' or 'humanitarian' effort, he would almost certainly have ended by condemning himself as a Martin Arrowsmith; in Dr Ober's incisive words, as one who 'fails as a scientist even as he fails as a man' (1968/1963: 59). Both Neel and Ober came of professional age before the Belmont Report, before medical schools required ethical training, before informed consent became normative. Informed consent was not established as the precept within human subjects research that it is today.

However, there is more to my claim here than the obvious fact that Neel was trained before the introduction of a series of ethical codes that we today take for granted. Indeed, the concept of informed consent itself is currently being hotly debated in medical and clinical research communities. For the purposes of understanding how these issues affect our own anthropological discipline, I turn now to our own present and the relevance of these issues to the discipline of anthropology. In the 19 February 2009 issue of the *New England Journal of Medicine,* a team of Duke University researchers (Glickman et al. 2009) questions the growing trend of carrying out clinical trials offshore, claiming that informed consent might be unduly influenced by economic considerations. It would seem that some scientific communities have been rather slow to acknowledge this point.[16] Anthropologists currently working in the area of global clinical trials (e.g. Petryna 2009; Sunder Rajan 2006) are pointing beyond issues of informed consent to another problem – new forms of capital that seek human populations for their experimental value may lose sight of the human needs of these same populations (see, for example, Goldstein 2007) in purporting to answer broader scientific questions, and may also neglect the broader political economic policies that create decrepit public health systems and the pharmaceuticalisation of individual bodies (see, for example, Biehl 2007).

Anthropologists and other critics of neoliberal globalisation have understandably been more cautious in their assessment of the futures of scientific breakthroughs (see, for example, Rose 2006). Adriana Petryna (2009) convinces me, however, that the complicated bioethical dilemmas faced by scientists working

within the global clinical trials industry are worth considering from a number of different perspectives, including those perspectives that might make us anxious about the future. Petryna hints at the dizzying array of bioethical issues involved in the global clinical trials industry, beyond those covered by the standard and procedural adherence to contemporary human subjects research protocols. She cites the philosopher Hans Jonas, who in 1968, the year of the Neel expedition, expressed concern about our narrow interpretation of informed consent and scepticism about human experimentation as an imperative for progress (Petryna 2009). Jonas seemed to advocate a form of consent that would recognise the ways in which political economy and the social necessarily complicate our understanding of consent. Petryna ultimately cautions her readers that while traditional modes of patient protection are being challenged, experiments themselves are being touted as global health goods. She writes, 'The scientific integrity of this experimentality is *not* a given', and notes that scientists both within industry and in academic settings:

> testify to the pitfalls and question the public value and safety of the resulting medical commodities. Ultimately, this experimentality underwrites a research agenda that does not necessarily provide the most valid and relevant medical outcomes, and it introduces added risks … they reaffirm the critical need for a more socially responsible and scientifically rigorous approach that can value patients and make globalization 'good for world health'.
> (Pogge in Petryna 2009: 194)

This caution might be extended to anthropology's own connections to human experimentality, including the work of James V Neel.

Many of the same contemporary scholars who have claimed that the sole purpose of Neel's use of the vaccine was humanitarian have also, in other instances of the larger debate about research ethics, acknowledged the possibility that research and treatment are often intertwined in complex ways. Kim Hill, a biological anthropologist and expert on native tropical South Americans, argues that Neel would havebeen 'irresponsible' not to collect data about the vaccination programme that could later be used for broader humanitarian purposes. He formulates this argument in part as an addendum to Ryk Ward's assertion (see AAA 2002(1): 26) that 'Neel had planned a public-health campaign and … had decided on the Edmonston B vaccine because they believed that it gave longer immunity than the Schwarz vaccine'. Yet, Hill (in Borofsky 2005: 127–128) also writes that Neel's desire to use the vaccine and research its effects is 'standard practice in all of modern medicine'. Tierney's controversial book suggests that Neel ought to have suspended his research among the Yanomami and that this would have been, and remains, a reasonable ethical expectation. Yet, this expectation is not universally recognised, let alone codified, as Hill makes clear when he concludes that 'this combination

of treatment and research is not remotely unethical'. After all, it was only in the aftermath of Tierney's more serious but questionable accusations – most notably, the idea that Neel actually had a hand in initiating the epidemic by introducing the vaccine – that Neel's behaviour in the field even came under scrutiny.

To me, it is not so important whether Neel prioritised his research over caring for sick Yanomami – as I believe he did – as it is that we, as anthropologists, try to help build a code of bioethics for future research that considers how we search for and design rigorously controlled forms of experimentation, especially when we are acting upon human 'populations' in some particular way. What does it mean when researchers collect data among naïve populations with the intent of benefiting 'the whole of humankind', but not the naïve population itself? Or, as in the ABCC studies in Japan, of benefitting the future of the human race, yet not assuming moral responsibility for the suffering provoked directly by the use of atomic weaponry? From my perspective as a cultural anthropologist, I can appreciate Neel as a scientist who achieved a broader understanding of the genetic and immune system responses of the Yanomami, and I acknowledge that this understanding was contingent upon his ongoing collection of blood samples in the midst and aftermath of a life-threatening epidemic. By observing the Yanomami febrile response to the epidemic in behavioural terms (for instance, his discovery that the posture in which villagers lay advanced the disease) and in genetic terms (revealed through the titres of blood that he procured while the epidemic raged around him), Neel was able to conclude that the Edmonston B vaccine produced the same immunity in Yanomami Indians as did live measles. However, the scientific information gained from this undertaking does not erase my feeling that Neel, even while succeeding as a geneticist and a scientist, failed personally as a humanitarian. I began this chapter with Clifford Geertz's recognition that in the Yanomami expedition, the anthropologists and the doctors – reductionist to the core – had started to conceive of the object of their study not as a people but as a population. The doctors are currently questioning that conceptualisation, as the Glickman et al. (2009) article attests. The issues and proposed solutions raised in this article, among them the argument that industry sponsors, contract research organisations and the academic community should assume greater responsibility for ethical conduct and for quality oversight of clinical research in developing countries, are sure to inspire further discussion among clinical researchers and doctors. It will be interesting to see how these debates unfold in a community of medical doctors who are highly embedded in a number of interlocking institutions, both industrial and academic, and who are only now beginning to come to grips with the concrete ways in which scientific research is influenced and structured by forces beyond the science itself, namely the global economic system and a host of local factors. But how will we, the anthropologists, deal with these very same issues?

The days are long past, one would hope, when simply adhering to methodological rigour is enough, as Martin Arrowsmith hoped to do on St Hubert Island in order to meet the requirements of control group research and the expectations of Dr Gottlieb. Yet, the professional decisions of Dr Hernandez bring us full circle. While Arrowsmith's mentor Gottlieb is portrayed as methodologically obsessed in his impulse to maintain the control group at all costs, he is also held up throughout the novel as the heroic scientist who remained steadfast against the commercialisation of science and capitalism's intrusion into the scientific process. Dr Hernandez cannot inhabit this position, as we have already seemingly moved past the point of return to a pre-capitalist science. The unfolding pharmaceutical politics now situates research and treatment as friendly bedfellows in settings with declining public health sectors. While these settings contain populations attractive to the global pharmaceutical corporations that are now tasked with conducting scientific research, they also call up bioethical concerns regarding the nature of informed consent and the use of control groups for inquiries centred elsewhere. By suggesting that the field of anthropology is similarly situated across an epistemological divide regarding the uses and design of human experimentation, I hope to provoke more discussion regarding the ways in which a methodologically diverse anthropology can forge a shared bioethical future, if indeed this is possible.

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Endnotes

1 For three fascinating and distinct histories of the control group, see Boring (1954), Kaptchuk (1998) and Dehue (2005).

2 Sinclair Lewis declined the Pulitzer Prize. Several sources state that he refused it because the Pulitzer was meant for books that celebrated American wholesomeness, and his novels, which he considered critical of this quality, should not be awarded a prize with this expectation attached to it.

3 Dr Victor Hernandez is a pseudonym.

4 See also Epstein (2007) for another perspective on 1980 reforms and their drive toward what he calls an 'inclusion-and-difference' paradigm that invented a kind of biomulticulturalism.

5 In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

6 The Helsinki Declaration (original 1964) is one of the cornerstones for ethical procedure in human research and was written by the World Medical Association. In spite of its worldwide recognition, it is not binding by international law. It has been revised several times, including in 1975, 1983, 1989, 1996, 2000 and 2008.

7 Vioxx was withdrawn from the market by Merck & Co. in 2004 after studies showed that it elevated the risk of heart problems. The FDA had initially approved its safety. It later was revealed that some of the studies that gave Vioxx entry into the marketplace had either suppressed or fabricated data.

8 *Microbe Hunters* (1926) features an accessible set of biographies of medical heroes and is considered a classic among physicians and scientists. De Kruif's book contains an important chapter on the army doctor and medical researcher Walter Reed ('Walter Reed: In the Interest of Science and for Humanity!'), who was responsible for determining that yellow fever was transmitted by mosquitoes and not by clothing and bedding soiled by body fluids and excrement. Reed is widely recognised as having provided convincing arguments (in 1900) that risky research on human subjects was morally permissible if the individual had provided (informed) consent. The yellow fever experiments performed by Reed and his associates are widely recognised today as having been the precursors to a more fully defined debate on the nature of informed consent with human subjects.

9 Fangerau (2006) notes that De Kruif had published on some of *Arrowsmith*'s themes in *The Century Magazine*, in Stearn's *Civilization in the United States* and in *Harper's Magazine*.

According to Robin Marantz Henig (2002), De Kruif's anonymous chapter in Stearns's *Civilization* described American medicine as lacking a scientific approach to disease prevention and treatment and filled with commercial cunning. Henig also notes that while the chapter criticised American medical doctors for not behaving enough like the Rockefeller scientists, the head of the Rockefeller Institute nevertheless called for De Kruif's resignation the day after its publication (1 September 1922).

10 There are differing accounts as to what the expectations for collaboration were. In his memoir, De Kruif (1962) explains that he initially believed he would be a co-author and was disappointed when it became clear that he would not be given any authorial credit beyond a note of gratitude.

11 Jacques Loeb (1859–1924) was a German-born (Jewish) American biologist noted for his work on parthenogenesis. In 1910, he became a member of the Rockefeller Institute for Medical Research (now Rockefeller University), New York City, a position he held until his death. De Kruif idolised Loeb, and a series of letters exists between them that began shortly after De Kruif's dismissal from the Institute. See Fangerau (2006) for more on the relationship between the two.

12 By 1925, Sinclair Lewis had already established his fame through his satirical depiction of the culture of capitalism in other realms, most notably in *Babbitt* (1922), which won the Nobel Prize for literature (1930).

13 See, for example, Kaptchuk (1998).

14 In addition, Tierney positions Neel as having been involved professionally with other scientists who had been key players in some of the most unethical experiments of the Cold War period. For instance, Tierney provides a professional genealogy of Neel's contact with members of the famed Manhattan Project, precursors to the AEC, who were involved in a series of ethically questionable experiments involving plutonium injections into humans. One of the major figures believed to have been involved in this experiment, Colonel Stafford Warren, is credited by Neel with having sponsored his promotion to the directorship of the ABCC. Lieutenant William Valentine, believed to have served as 'the injector', worked with Neel from 1942 to 1945 in the study of inherited anaemia, thalassemia.

15 The US regulation Dr Hernandez is referring to calls for an announcement of any new drug trial on the website of the Federal Institute for Public Information (Mexico).

16 In the light of Melinda Cooper's (2008) thesis that the delirium of late capitalism gets translated directly into the day-to-day infrastructures of government and science, the *NEJM* article seems naïve. If we take Cooper seriously, we might consider that these populations were indeed targeted for their impoverished state.

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