Introduction

# A GUINEA PIG'S WAGE

*Risk, Body Commodification, and the Ethics of Pharmaceutical Research in America*



## PROFESSIONAL RESEARCH SUBJECTS AND THE NEW "ECONOMIES OF TORTURE"

On 16 June 2001 the national press first reported the death of Ellen Roche, a healthy twenty-four-year-old who had volunteered for an asthma study at Johns Hopkins University. The story revealed that a few days into the trial she felt very sick and was discharged and sent home. Within some hours she checked into the emergency room at a local hospital and fell into a coma. Ellen remained in this state until her death a month later. She had received $375 for participating in seven to nine sessions as an outpatient in a clinical drug study that resulted in her death (Altman 2001).

This tragic death—a dramatic one, but by no means unique—elicited responses from a variety of sources ranging from governmental agencies to self-proclaimed "bioethics experts." The federal government announced that it would interrupt all federal funding for biomedical research employing human subjects at Johns Hopkins until the university improved the protections for human subjects in research. In turn, Johns Hopkins agreed to review its informed-consent processes and addressed the claims of Ellen's relatives with out-of-court legal settlements. Commentators wrote about the event extensively in the press, focusing on whether institutional protections for human subjects volunteering in the trials were effective in protecting the volunteers' rights. Some inquired whether the volunteers understood the risks as they were framed in the informed-consent form. Others pointed to the increasing interrelationship between academic re-

searchers and pharmaceutical companies. Their critiques were centered on conflicts of interest inside academic institutional review boards (IRBs) and the need to further regulate informed-consent processes to adequately safeguard volunteers' rights.

While critics made valuable remarks, one major point that they overlooked was that the volunteer was a healthy woman who had been paid to join a trial in which, apart from the monetary gain, there was no therapeutic benefit. Since the use of financial incentives to boost participants' enrollment is currently a significant trend in clinical trials research—in recent years the practice of offering some kind of financial compensation has been extended beyond phase I trials to later phases of drug development—I believe that there is a pressing need to address the consequences of increasing financial compensation for trial volunteers.

In fact, as this book will illustrate, being paid to test drug safety has become an essential part of the clinical drug trial enterprise in America. Pharmaceutical companies depend upon paid subjects to test an ever increasing number of drugs coming out of their "pipelines," and subjects see their participation not as an altruistic gesture but as their job, a particular kind of trade with some resemblance to a mild torture economy in which bodily pain, boredom, and compliance are exchanged for money (see the discussion of body commodification below). Spam, a resident of West Philadelphia in his early thirties and an experienced "guinea pig" who since quitting the trials has been working as a union organizer for janitors, offers his insight into what is it is like to participate in what he calls the torture economy as a paid subject:

> I don't know, another thing kind of funny too is that the manufacturing has been taken off, outside the country, so you are not allowed to do things any more. They call it the new economy, the informational economy. And the other side of this informational economy is the mild torture economy, you are not asked to produce or to do something anymore, you are being asked to endure something. So, if you are a guinea pig you are enduring something, people are doing things to you and you are just enduring it, you are not actually producing something. I feel that I am a worker but it is not work, it's like a security guard that does not produce nothing, just watches stuff. A security guard just gets paid to be bored, it's about how much can you deal with being bored,

> that's the real hard part of it, the time and discomfort of being there. But it's different when you are in a cleaning job, I am doing something but being a guinea pig is just being paid to endure something that happens to me, which is weird. It's a different type of activity, I still feel that there is some work in it but the nature of work has changed. And I am letting people pay me in exchange for the control they have over me. (28 July 2004)

The participation of paid human volunteers in clinical trials research poses new problems that have not been analyzed thus far regarding financial compensation in trials research, risks, and the ethical regulations protecting human subjects. For example, does monetary compensation affect the way volunteers think about risks and benefits, placing volunteers at risk? Or might long-term participation in phase I trials increase risk awareness among professional guinea pigs? Are existing ethical frameworks enough to protect paid subjects, especially during the phase I trials? Finally, even if subjects are aware of the risks they face and even if their rights as subjects are ensured, are they not being exploited anyway as the weak link in the trial economy?

To answer these questions I conducted ethnographic research of paid research subjects in clinical trials conducted between July 2003 and December 2004 in Philadelphia. Its core was a group of self-defined professional guinea pigs who earned their livelihoods as research subjects testing the safety of drugs developed by the pharmaceutical industry. My work illuminates the professionalization of research subjects, the experiences and meanings associated with being a paid subject, the effects of financial compensation on the way volunteers understand and deal with risk, and the ethics of protecting human subjects in biomedical research. In addition, for comparative purposes I extended my research to a group of poor, mainly African American and Latino men and women testing HIV drugs and drug regimes for phases II and III at the Community-Based Trial Organization (CBTO).

New drug compounds are first tested in animals, usually dogs or rats—because the animals are cheap—and if the substance shows low toxicity it is then tested in phase I trials involving a small group of thirty to a hundred healthy human subjects. If the drug proves to be safe in phase I it then advances to phases II and III, which usually involve a much larger

group of patients—sometimes in the thousands—who have the condition that the drug is supposed to improve. The compound continues to be tested for safety while its therapeutic value is assessed. Most compounds are abandoned during phase I because of their toxicity, and only a handful of drugs make it through all the research phases. The process of moving a drug from the lab to the public usually takes twelve to fifteen years. Making an accurate assessment of costs is more difficult, and the task has become deeply politicized amid efforts by the pharmaceutical industry to justify increasing drug prices: the industry routinely states that developing a new drug costs close to a billion dollars, whereas critics argue that costs are much lower and that significant amounts are spent not in research and development but on marketing exercises (see Angell 2004). In any case it is clear that after research and development are complete the costs of production are low, and that drugs that have made it into the market more than compensate the pharmaceutical industry for its research and development expenses, making it one of the most profitable industries in the country.

Payment to recruit healthy research subjects in America is a relatively new phenomenon. Until the mid-1970s phase I trials were conducted on prisoners, who in many ways were the ideal research subjects: captive, compliant, and readily available, with the prison setting providing an almost perfect controlled environment. But confinement, stigmatization, and financial need placed prisoners in a vulnerable position as research subjects (see chapter 6). Eventually abuses and renewed ethical concerns over the capacity of prisoners to give proper, uncoerced consent brought the practice to a halt.

The pharmaceutical industry was then forced to find a new population for an increasing number of drug trials. Paying healthy volunteers to test their drugs was the way to replenish the pool of research subjects. Initially students, artists, the unemployed, and other groups explored this new source of income. Some welcomed the opportunity and continued volunteering regularly. Not only did subjects become dependent upon the trial income but the drug companies increasingly appreciated having experienced trial subjects who were knowledgeable about the procedures and tolerated the depersonalization, pain, and boredom that so often accompany the trial experience. The pharmaceutical industry started luring these new subjects with even larger payments, mailings, and ads.

As a result, a new occupational category was developed: the professional guinea pig.

During my research I learned that in most cases the prospect of financial compensation is the guinea pigs' only motivation to participate in the trial economy. Drugs being tested range from compounds never tried before in men—"first-in-man" drugs, usually known to volunteers by a series of numbers and letters—to bioequivalence trials for drugs already on the market, like painkillers or psychiatric and other riskier drugs. According to Hogshire's estimates, in the early 1990s a volunteer could receive around $100 dollars a day as a research subject. Since then, financial compensation offered to volunteers in America has at least doubled (Hogshire 1992). In Philadelphia, a hotbed for clinical trials research, payment might range from $1,200 for three or four days in less intensive trials to $5,000 for three or four weeks in more extended ones; on occasion a trial might need even more time to be completed, with even higher payments going to volunteers. Trials that involve unusual and uncomfortable procedures or that test psychiatric drugs tend to pay more, in an attempt to attract reluctant research subjects.

Sometimes volunteers shift between their trial participation and low-paying jobs as cooks, construction workers, housepainters, or bike messengers. But for many participants trials become their full-time job: full-time volunteers might enroll in five to eight trials a year, deriving a total estimated income of $15,000 to $20,000 in exceptionally good years. Some experienced research subjects I met had participated in seventy, eighty, or even more phase I trials over the course of a few years. As one experienced professional guinea pig admitted, "You became addicted to the trials, to the easy money." This group, as this book illustrates, constitutes the backbone of phase I clinical trials in America and should be distinguished from other volunteers such as those affected by particular diseases or conditions, their kin, or even disease activists who volunteer only occasionally, motivated not by financial gain but altruistic, personal, or even political goals.

The trajectories of professional guinea pigs also contrast with those of HIV patients volunteering for later phases in clinical trials research. While for Michael, John, and Geraldine, poor patients enrolled in HIV trials at CBTO, "money helps"—although their participation does not command large sums of money like participation in phase I trials—but their motiva-

tion is not financial. As these histories illustrate, these volunteers hope to gain access to better heath care and expect the drug or regimes to offer them new therapeutic options while they learn more about their bodily responses to the virus. Their trial participation reveals itself as part of a larger strategy to control the disease that also involves an active role in managing their condition, "getting educated" about the virus, and having and open relationship with those who treat them. Volunteering in these trials is an additional resource in the fight for their lives, a powerful demonstration of the patients' will to live (Biehl 2007).

Paying healthy people to test for drugs that they don't need is another step toward commodifying the body in biomedicine. But unlike those who sell a kidney or plasma, professional guinea pigs see their whole bodies become the commodity. Trial subjects are well aware of how valuable their bodies are, despite the protestations of the pharmaceutical industry that subjects are volunteers being compensated just for their time. They see themselves as workers, entering a professional and contractual relationship with the industry. Trials are their business, a way of making quick, easy money.

Yet while dependent on the income, research subjects are generally distrustful of the pharmaceutical industry and resentful of the depersonalized, humiliating, and alienating treatment they often receive. Like workers in similar subaltern positions, professional guinea pigs both comply with the trial demands and resist them whenever they can, for example by introducing forbidden food or attempting to disrupt trial regimens. The industry counters these efforts by using financial inducements to recruit, retain, and control trial subjects. All volunteers in phase I trials whom I interviewed admitted that they had reservations about certain trials, such as those testing psychotropic drugs or drugs that alter sleep patterns or the immunological system—and for good reason—but they ended up volunteering anyway, swayed by the financial incentives. And once volunteers enter a trial, money is doled out strategically to ensure compliance: the largest sum is given after the trial is over, often with a bonus as an incentive for completion.

As my work illustrates, the prospect of financial gain shapes the way risk is understood and dealt with by professional guinea pigs. Paid subjects believe that most trials pose only a moderate risk. This perception is based on their personal experience as trial subjects and the rarity of serious

adverse drug reactions (ADRs), but it is also influenced by their need to keep doing trials. I argue that social inequalities expose certain subjects to a disproportionate risk. Poor, disenfranchised volunteers face risks that they are unable or unwilling to recognize because of their need to earn a livelihood. This situation can be considered exploitative and directly challenges existing ethical regulations established to protect human subjects in biomedical research (Elliott 2008; Elliott and Abadie 2008). In a paradoxical turn, the prohibition against using prisoners in clinical trials created a new group of poor, vulnerable, and exploited population of healthy, paid subjects, this time a population created by the market. (As I will show in chapter 7, the creation of a professional class of paid healthy subjects recruited to test drug safety in phase I clinical trials challenges ethical arrangements established by the Helsinki Declaration of 1964 and the Belmont Report, issued in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.) At the same time, neoliberal governance diminished the state's ability to protect the public and human subjects participating in clinical trials research by de-regulating the pharmaceutical industry. At least since the 1980s, the perceived need to create a "good business climate" has trumped previous regulatory concerns with consumers' and volunteers' well-being (Angell 2004).

The attempts of professional guinea pigs to manage risk are not completely successful. Many remain in trials for years, exposing themselves to potentially dangerous drug interactions and long-term effects. The organization of clinical trials and the lifestyle that guinea pigs lead make it difficult for them to become aware of these interactions and effects, which sometimes appear long after a trial is completed (Abadie 2009). In this respect guinea pigs differ from other workers in dangerous trades, such as coal miners and those exposed to asbestos or other industrial pollutants: although these workers were at first uninformed, after extended periods of sharing experiences they did become aware of the risks they faced, and of how these risks had been understated by the industry that employed them. (See Rosner and Markowitz 1988, which describes how silicosis emerged as an occupational disease in the early twentieth century after mining workers challenged industry and state-appointed experts.)

In the case of the professional guinea pigs, their mobility and relative

anonymity conspire against this possibility. The fluidity and instability of the guinea pig workplace bring to mind the world of migrant agricultural workers, who face similar dangers caused by toxic substances. The lack of a centralized registry of human subjects who volunteer for phase I trials may also obscure the existence of problems for the pharmaceutical industry and regulatory agencies like the Food and Drug Administration (FDA). In addition, the pharmaceutical industry has no incentive to invest in research into long-term clinical-trials risks.

## THE COMMODIFICATION OF THE BODY IN CLINICAL-TRIALS DRUG RESEARCH

Recent technological advances in transplantation techniques, artificial reproduction, and drug development have resulted in the increasing commodification of the body (Scheper-Huges and Wacquant eds. 2002; Sharp 2000). Currently there is a local and international market for major organs like the heart, kidney, and liver, body tissue, reproductive material such as sperm and eggs, plasma, and even hair. As noted above, the whole body has also entered this market through the participation of paid research subjects in clinical-trials research. These are just a few examples of how bodies become commodified and integrated into a market economy.

In fact, as the anthropologist Leslie Sharp reminds us, this process of body commodification is not new in America, where corpses were long sold to dissectionists, anatomists, and surgeons. Other forms of commodification include the enslavement of human beings and the current use of reproductively rich products and tissues reaped from the dead (Sharp 2007, 42). One of the first to call attention to this issue was Karl Marx, who wrote, "A commodity appears at first sight an extremely obvious, trivial thing. But its analysis brings out that it is a very strange thing" (Marx 1976 [1867], 163). What Marx found strange is the obscuring of the exploitative labor processes that produced the commodity, making the commodity appear naturalized, with its own life independent from the social relations that originated it.

There has been recent scholarly interest in the commodification of the body in medicine (Sharp 2000; Scheper-Hughes 2000; Andrews and Nelkin 2001; Moore and Schmidt 1999). According to Sharp, organ transfer—like many new biotechnologies—elicits a powerful social anxiety

among the public, which in turn leads to the industry's denial of body commodification. "Body commoditization—especially within the highly celebrated arena of organ transplantation—quickly erodes an already shaky public investment in medical trust. In response to such deep concerns, the transplant industry has generated an array of powerful euphemistic devices that obscure the commodification of cadaveric donors and its parts" (Sharp 2007, 17). Sharp notes that references to the commodification of the body are avoided by using the rhetorics of the "gift," through which organ transfers are equated with "donating life" and organs are "precious resources" to be "harvested." For Sharp these semantic choices make it possible to avoid referring to the trauma, suffering, and death involved in removing organs from donors. The language of the gift economy mystifies key aspects of organ transfer.

It is not only organ transplants that trouble American society. A similar anxiety can be detected in clinical-trials research. A popular novel by John Le Carré, *The Constant Gardener*, which describes the abuses of the pharmaceutical industry in conducting clinical trials among poor, disenfranchised African residents, raised numerous questions about the ethics of clinical trials in third world countries. The author criticized the pharmaceutical industry and also western governments and agencies for exploiting the poor for commercial and national gain and denounced the ethical abuses associated with clinical research in developing countries. While usually clinical trials in developed countries do not draw as much attention or provoke as much anxiety, concerns that the pharmaceutical industry might abuse volunteers in its search for profits were again brought to the fore by a recent "first-in-man" drug trial sponsored by Parexel in England in which six volunteers became seriously ill (Associated Press 2006).

As with organ transplantation, pharmaceutical corporations that conduct trials avoid referring to the commodification of the body in an attempt to maintain public trust. In clinical-trials research a discursive practice similar to the one observed by Sharp in connection with organ transfer contributes to the industry's denial of the commodification of volunteer's bodies. As we will see in chapter 2, the industry refers to trial subjects with the oxymoron "paid volunteer," the pretense being that they are compensated not for their labor but for their "time and travel expenses." Chapter 7 shows how language of informed consent obscures the risks of participation, for example by using euphemisms for death. Like

the kin of organ donors, phase I volunteers resent and reject the industry's attempts to label them volunteers, insisting that they are professional guinea pigs.

"Commodities, like persons, have social lives," notes Arjun Appadurai (Appadurai 1986, 3). Marx understood this aspect of commodities, prompting us to consider what we might learn "if commodities could speak" (Marx 1976 [1867], 176). Professional guinea pigs, in opposition to most commodities and in particular to the drugs that they help to develop, do speak, and not just in a metaphorical sense. Volunteers' bodies become the site where the social and cultural processes that produced the emergence of professional subjects are articulated and displayed. As some authors have shown, embodiment adopts very particular forms (Csordas 1994; Lock and Farquhar eds. 2007). Many professional guinea pigs whom I met show some "battle scars." I was much impressed by KingLabRat's needle scars in both arms. Born to Puerto Rican parents and raised in Florida, he was a former soldier, drug dealer, and morgue worker in his late thirties who had been doing trials since his early twenties, touring the country in search of good trial opportunities. His pseudo-royal nickname mockingly referred to his years of trial participation. KingLabRat got his scars in the 1980s, a time when the use of catheters was discouraged to prevent the possibility of injury or infection, subjecting volunteers to innumerable needle punctures. Michael, my roommate, who started volunteering much later and had no needle marks in his arms, once showed me the scars on his back, product of a trial that required a biopsy. Pointing to them dismissively, he said: "I'll carry them forever. That's why [the pharmaceutical industry] pays so well." Although his scars were no bigger than an inch square, they reminded me of the cover of Allen Hornbum's book *Acres of Skin*, about experiments conducted on prisoners at Holmesburg Prison from the postwar era until the 1970s. In it a black man showed his back covered by large, decolorated skin patches, the product of a dermatological substance tested by a famous scientist from the University of Pennsylvania (Hornblum 1998).

But paid research subjects display more than their scars. As mindful bodies (Lock and Scheper-Hughes 1987), volunteers themselves offer accounts about what it means to be a professional guinea pig. One of the most important critiques of the pharmaceutical industry and the commodification of bodies in trials research is that the process not only

exploits but dehumanizes research subjects. The tendency of research subjects to identify themselves with guinea pigs conveys well this notion of disembodied self. It is also not rare for volunteers to resort to images of torture, sex work, or prostitution when describing their activities. And their emergent solidarity as professionals—albeit professionals who perform a weird type of work, being paid to endure, as Spam notes—and their everyday forms of resistance at work draw attention to their efforts to reassert their human condition.

## APPROACHING ANARCHIST GUINEA PIGS AND HIV VOLUNTEERS

I carried out eighteen months of ethnographic research in Philadelphia among research subjects volunteering in clinical drug trials. Philadelphia has historically been a major site for pharmaceutical research. The development of the pharmaceutical industry was shaped by its interaction with one of the earliest medical schools in the country (Silverman and Lee 1974), a process that provided a model for national and international developments in the field (Liebenau 1987). Large pharmaceutical companies such as GlaxoSmithKline (GSK), Wyeth, Bristol-Myers Squibb, and Merck began to operate and conduct research in the area. The city and its metropolitan area provide exceptional opportunities for enterprising professional subjects.

This ethnography focuses on a group of self-defined professional guinea pigs, all white males, who live in West Philadelphia in a community that could best be described as anarchist and volunteer mainly in the metropolitan area for phase I trials. Members of this community are articulate and vocal about their participation as trial subjects, the practices of the pharmaceutical industry, and the regulation of clinical trials, and their outspokenness helps to shape what Weinstein calls a public culture of guinea pigs (Weinstein 2001). They strongly object to the abuse and exploitation of clinical subjects in biomedical research but are also proud of the subjects' historical contribution to scientific progress.

One of the professional guinea pigs most experienced, articulate, and committed members, Robert Helms, had participated in more than eighty trials, mostly in the metropolitan area of Philadelphia, before being forced to stop a few years ago because of an imposed age limit of forty-five. A graduate in classical studies from Temple University and a former labor organizer in the health care sector, he edited *Guinea Pig Zero*, a zine

dedicated to the experiences of professional human subjects, from 1996 to 2002. Its success led him to publish an anthology in 2002. Helms saw the publication, on which numerous local fellow guinea pigs collaborated, as an anarchist project intended to give voice to the experiences and concerns of professional human subjects in clinical-trials research. I was interested in the relationship between the clinical-trials experiences of this group of subjects and their views on social identity, risk, and body commodification. Just a few months before I met Helms, in the early days of my fieldwork, he and two other radical guinea pigs had played a key role in the first known strike at a phase I clinical trial at Jefferson Hospital, a research site that does clinical trials for the Merck pharmaceutical company. Helms was excited about this event when I first met him and asked me about it. The strike had been discussed in one number of *GPZ* and I was somewhat familiar with it. I realized that the strike and the role that the anarchist volunteers played in it opened an opportunity to explore not only issues related to their experiences of the trial but also their responses to some of the conditions they faced. This event reaffirmed my choice to study this group of volunteers, who became the main focus of my research.

It should be clear that this sampling of volunteers doing clinical trials research is not intended to be representative of the universe of those who participate in phase I research. The FDA publishes a list of all the drugs that received approval in a given year, but the pharmaceutical companies do not disclose the number of trials being performed or the number of volunteers enrolled. There is also no reliable information on the demographics of this population, and, as I have already mentioned, no centralized register of trial participants. Subjects remain essentially invisible, hidden.

While there are no demographic statistics about research subjects in phase I trials, most volunteers regularly enrolled in trials in the metropolitan area of Philadelphia are poor, relatively uneducated, and African American or Latino. In some trials white anarchists are a marginal presence, while in other trials they are not present at all. This overrepresentation of African Americans happens despite their historical misgivings about biomedical research and negative experiences dating back to the Tuskegee experiment (Jones 1981; Reverby ed. 2000). Anxieties among African Americans about participating in clinical research continue until

the present, for example in connection with AIDS research (Jones 1981; Reverby ed. 2000; Epstein 1996).

While all professional volunteers share experiences and interests, racial and ethnic differences shape the way they understand and deal with risk, a topic that I wished to explore. I knew that many professional subjects travel across the country looking for trial opportunities, and while they do so they often stay at cheap hostels. I stayed at the youth hostel on Baker Street in downtown Philadelphia for my first month of fieldwork. There I met KingLabRat, with whom I lived at the hostel while witnessing his preparations for the trial. I sought any chance to interview him at key instances, from his initial trial screening to his discharge once the trial was over. We kept in touch, and I was able to join him months later when he came back to the city to enroll in a new trial. This case study offers a window into how race and ethnicity shape the experiences of professional guinea pigs outside the anarchist community of West Philadelphia. At the same time, I was aware that while males provide the standard of phase I clinical trials research, women have some occasions to participate as well. I also contacted women in this community, to assess if gender made any difference in the way they experienced their trial engagements.

Despite my focus on paid phase I subjects, I also studied HIV patients who volunteered in later phases of trial research to assess the safety and efficacy of pharmaceuticals or novel HIV drug regimes at CBTO. Since financial compensation has increasingly been extended to participants in the later phases of drug development, for comparative purposes I also extended the study to a group of HIV patients volunteering for phases II and III. Comparison between these participants and the phase I group illustrates the extent of body commodification in trials research and the particular problems of professionalizing the first phase of drug development. There are many important differences between these two groups of volunteers, the main one being that the phase I volunteers were healthy while volunteers for phases II and III had chronic and often life-threatening diseases. Members of both groups received some financial compensation for taking part in clinical trials. Professional guinea pigs in phase I trials might receive $200 to $400 for a day spent in a trial. Since most volunteers do two or three trials a year and some do six or more, their

income can reach thousands of dollars. In contrast, HIV patients usually volunteer for one clinical trial and receive between $25 and $50 for a monthly visit in a trial that can last many years.

I contacted these patients as they came to the Research Division at CBTO for checkups, to have blood drawn, or to pick up trial medication. I had obtained approval from their local institutional review board for my research, which gave me a certain legitimacy. My informed consent forms had the institutional CBTO stamp, I used an office located inside the Research Division, and I was introduced by CBTO staff to incoming volunteers as a researcher doing a survey among patients volunteering at the facility. I have no doubt that while this institutional support helped me recruit many trial volunteers, modest financial compensation was also an incentive for many of those volunteers who contributed to my research.

I used various methods to collect and analyze data. I gathered data through a combination of participant observation and formal and informal interviews. My analysis relies on all sorts of data. In typical ethnographic fashion, eliciting my informants' comments on events and observing volunteers as they moved in and out of the trials and into their everyday lives was a central aspect of my research. I was precluded from volunteering as a subject myself by concerns for my well-being—strongly expressed by Shirley Lindenbaum, then my advisor, and many other faculty members—and by legal and regulatory constraints, which also prevented me from observing the routines, interactions, and activities of the clinical trials. In retrospect, choosing not to volunteer in trials as part as my data collection strategy proved to be the right decision, because I was able to retain some analytical and emotional distance while also being stimulated to think about additional sources of data with which to answer my research questions. So rather than firsthand knowledge, I relied on my observation of the professional guinea pigs' activities outside the trial locations. I was able to live with a group of them for more than a year in a very tight-knit community of professional research subjects and had ample opportunities to document in a lively and direct way their preparations for the trials, as well as their expectations, anxieties, and views. I followed prospective healthy subjects to their screening appointments, interviewed them after they had completed the first portion of the trial—usually after a week or so, usually as inpatients—and again at the end of the trial. The goals, risks, and benefits of a trial are typically

disclosed to participants mainly in the consent form that they sign after enrollment. Discussing the information contained in these documents in a naturalistic setting, soon after the volunteers had signed them, afforded a unique window into their perspectives on risk and how it relates to financial compensation.

In addition to participant observation, I conducted more than forty semi-structured interviews, approximately half with self-defined professional guinea pigs volunteering in phase I trials and half with HIV patients in the community site. This technique allowed me to explore the topics of financial compensation, risk perception, and risk management. While this method was useful for capturing general views about the ways risks are perceived and dealt with by subjects, it cannot account for individuals' experiences of the trials and how they change over time. For this I conducted twelve life stories, having chosen from among the participants according to the following criteria: length and frequency of participation, types of trials in which the participant had volunteered, and risks experienced during previous trials, if any. I inquired about the participants' personal experiences in clinical trials and their understanding of risks, focusing on the relationship between the participants' experiences of trials, their possible changes in risk awareness and risk management, and their expectation of financial gain.

My fieldwork was facilitated by my experience as a guinea pig. Although I did not take part in clinical trials during my research in Philadelphia, during the last months of 1998, while I was pursuing my MA in anthropology at the Université Laval in Quebec City, I volunteered on a couple of occasions for a major contract research organization (CRO) that conducted phase I trials for several local and international pharmaceutical companies which had their headquarters a few blocks away from my campus. At that time I never imagined that this could be a topic of academic interest and I volunteered only for the money. I found out about the trials from radio and newspaper ads that invited healthy young males with free time to make "quick, easy money" by becoming paid volunteers for clinical drug research. Since kindergarten I had always been wary of needles, and the idea of selling my body to the pharmaceutical industry gave me pause. However, unable to work in a foreign country and in need of cash, I ended up accepting the invitation.

The research facility was a functional, flat, uninviting five-story build-

ing, no doubt a fine expression of the Soviet architecture of the 1960s and 1970s that also shaped the university campus. The research floor was crowded; dozens of double bunk beds were aligned in facing rows. A yellow light went on at night after the regular lights went off. I couldn't avoid noticing the resemblance to a prison cell. For a minute I was reminded of abuses involving prisoners and other vulnerable populations used as research subjects in the past. However, I decided not to focus on the risks involved in becoming a trial subject and thought instead of the money I would get. The ad line "quick, easy money" still resonated in my mind.

Most paid subjects whom I met were frequent trial participants who defined themselves as "professionals." Volunteers were a mix of mentally disabled persons trying to supplement their governmental disability checks, university students after tuition money, artists buying some creative time, and generally unemployed or unemployable subjects who would waste no time putting the cash to good use. In a way that resembled the mob practices depicted in *The Sopranos* more than the careful accounting of a research institution, cash was handed to us on the last day, at discharge, in yellow envelopes. (More than a decade later, the conditions at clinical trials sites in Canada seemed not to have changed that much. See Martin Patriquin 2009.)

The first drug I tested was a new version of a drug already on the market that combats heartburn and gastritis. I learned later that the drugs tested in these trials are called "me too drugs" and are preferred by paid subjects because the drug has already been tested in research and used by patients, providing additional security. For a five-day inpatient study I received $550 Canadian. The second trial was a new drug to increase appetite in terminal patients with HIV or cancer. This experimental drug was a "first-in-man" because it was the first time the compound was tested in human beings, having been tested for safety in dogs and rats. It did not increase my appetite, but the trial definitely contributed to augmenting my diminished bank account by $800. I am sure in retrospect that the "financial compensation for my time and travel" did not fully compensate for the risks I faced, the pain of endless blood extractions, and the boredom of spending hours doing nothing but watching TV.

Having volunteered as a paid human subject for a couple of phase I clinical trials, I had a particular insight into the lives of volunteers. Our

shared experiences and sensibilities allowed other volunteers to interact with me at a common level of understanding and trust. I had a point of entry into their views and feelings not accessible by other research methods, such as questionnaires and semi-structured interviews.

While my ethnography focuses on paid human volunteers in clinical-trials research, I also intended to grasp the scientist's understanding of and dealings with risks and ethics in a context of increasing commoditization. CBTO provided a good starting point. Its principal investigator is in charge of all trials sponsored by the pharmaceutical industry and was extremely supportive of my research from the beginning. I conducted extensive interviews with him to explore risk perception, risk management, and commodification in clinical trials used to develop new drugs and drug regimes for HIV patients. In addition, since I had to obtain approval for my research from CBTO's institutional review board, I was invited to make my case to the board and interviewed the IRB's chair and other members to discuss how they saw issues of risks, the protection of human subjects, and commodification in relation to the research being conducted at this community-based trial site.

## ANTHROPOLOGICAL CONTRIBUTIONS

The emergence of professional research subjects who volunteer to test experimental drugs are an example of what Michaela di Leonardo terms the "exotic at home." Professional guinea pigs are an exotic development of technological and medical culture, with their own ethos, identities, and practices. This book is an attempt to further consider di Leonardo's call for an anthropological examination of phenomena that are "hidden in plain sight around us" (di Leonardo 1998, 10). My research calls attention to hidden problems brought about by the increasing commodification of the body in clinical trials, in the context of an emerging professional subjectivity created by new regimes of techno-science and capital accumulation (Rajan 2005; Rajan 2006; Rose 1996; Rose 2006). Thus far this topic has failed to capture the imagination of anthropologists. My research is the first ethnographic description of the experiences of healthy paid subjects in the United States, or anywhere.

Even so, pharmaceuticals in general have not escaped the notice of anthropologists, who have explored the commodity chain from production sites to the uses of pharmaceuticals by consumers (Petryna, Lakoff,

and Kleinman 2006). They have also looked at marketing practices, the role of drug representatives in shaping doctors' prescription practices (Oldani 2004), and the cultural, economic, and political determinants of drug consumption (Abraham 1994; Biehl 2007; Farmer 2002). And although anthropologists have paid little attention to the first phase of clinical drug trials (Whyte, vand der Geest, and Hardon 1996; Whyte, vand der Geest, and Hardon 2002), they have studied the pharmaceutical industry's increasing reliance on CROs to run the daily operations of trial sites, including the recruitment of volunteers and the hiring of friendly IRBs to speed up drug development in the United States (Fisher 2009) and abroad, mainly in third world countries, where regulations are few or unenforced (Petryna 2006; Petryna 2009). Documenting the professionalization of clinical-trials subjects in the first phase of drug development represents a contribution to the emergent field of the anthropology of pharmaceuticals.

This book is based on classic ethnographic research, documenting the discourses and practices in the particular historical and sociocultural context in which research subjects live and make decisions about trials, money, risks, and benefits. Its situated knowledge is one of the strengths of anthropological inquiry, offering a description of the forces leading to the professionalization of trial subjects in phase I clinical research as well as the meanings, emotions, and everyday struggles involved in guinea-pigging. By exploring the sociocultural processes that transform bodies into valuable commodities as research subjects, this ethnography directly contributes to the anthropological study of the body (Lock 1992; Lock and Scheper-Hughes 1987; Lock and Farquhar eds. 2007; Martin 1994) and body commodification (Sharp 2000; Sharp 2007; Scheper-Hughes 1996; Scheper-Hughes and Wacquant eds. 2004). It also furthers the literature on risk by emphasizing how commodification processes shape professional subjects' understandings and responses to risk. The richness of ethnographic data also illuminates current debates on biocitizenship (Petryna 2002; Rose 2006) and the ethics of protecting human subjects in clinical trials and more broadly in biomedical research. My aim is to advance ethical discussions which are often presented in a largely formal, individualistic, rational, and legalistic framework, and it seeks to contribute to an approach that incorporates the cultural context in which indi-

viduals make decisions about risks and benefits (Levin 1985; Marshall 1992; Marshall and Koenig 2004).

Finally, while conducting normative analysis and formulating policy recommendations are not the main foci of my work, I engage in some of each here in the hope of stimulating public debate, with the goal of transforming public policies to ensure the ethical and safe engagement of paid subjects in trials research.

The reader will come to understand the experiences of a group of self-defined professional guinea pigs who earn their livelihoods as research subjects for phase I clinical trials by testing drugs being developed by the pharmaceutical industry. By following research subjects as they volunteer, the book illustrates the social organization of clinical trials, the role of financial compensation, and its effects on the ethical arrangements intended to protect human subjects in biomedical research.

The Introduction presents the aim of my research, the research problem and question, and relevant theoretical and methodological data. Chapter 1 explores the social organization of clinical-trials drug research and describes how increasingly large payments to subjects reinforce professionalization among trial volunteers. Chapter 2 deals with the identity, ideology, compliance, and resistance of trial subjects. Chapter 3 illustrates the way paid subjects understand and deal with the risks involved in being a professional guinea pig. Chapter 4 provides a counterpoint to previous chapters by describing the social organization of phase II and III trials for HIV pharmaceuticals at a community-based research organization. Chapter 5 portrays the life stories of Michael, John, and Geraldine, illustrating the struggles and aspirations of poor HIV patients enrolled in trials at a community-based research organization. Chapter 6 describes the history of the development of pharmaceutical clinical trials in America. Chapter 7 revisits the central questions about paying subjects to volunteer in clinical-trials research. Chapter 8 summarizes research findings and offers public policy recommendations to improve the safeguards afforded to professional guinea pigs.