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THE PROFESSIONAL GUINEA PIG

Big Pharma and the Risky World of Human Subjects

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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-

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 are 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 individuals 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.

1

GUINEA-PIGGING

The In/Formal Economy of Phase I Clinical Trials in Philadelphia

EXPERIMENTATION

Phase I clinical trials employ healthy human volunteers to test new drugs under development by the pharmaceutical industry, not for therapeutic efficacy but for drug safety. Phase I trials are designed to assess the safety of the drug or compounds being tested, and represent the first time a chemical compound is tested in human beings after having been tested in laboratories and then in animals. After a drug proves its safety in phase I it goes through phases II and III, which involve larger groups of volunteers. While phase II also continues to test the drug for safety, this phase and the next one are intended to test for therapeutic benefits. If the drug proves safe and therapeutically efficacious, it then receives FDA approval and goes on the market.

Phase I clinical trials are designed as controlled experiments that follow an experimental design. The trials are devised to obtain information about how the human body responds to a particular substance, what the levels of toxicity are, and how the drug is absorbed and eliminated. As previously mentioned, this phase is not designed to test therapeutic effects on the volunteers. It is for this reason that the trials have also been described as "non-therapeutic" in contrast to the "therapeutic" trials in phases II and III.

RECRUITMENT, RETENTION, AND PROFESSIONALIZATION OF HUMAN SUBJECTS

Clinical-trial researchers need to recruit volunteers to carry out trials. A healthy population is an indispensable requirement of the experimental

design employed in randomized clinical trials (RCTs) used in phase I clinical-trials research.

A healthy and homogeneous trial population would ensure that all participants have the same condition at the outset, making it easy to attribute the outcome of the experiment to the drug regimes to which the volunteers are exposed. Therefore, the lack of any existing medical condition is an indispensable requirement for the realization of any clinical trial. Phone interviews screen medical histories, as do further screenings to select the candidates and again at the beginning of the trial. A healthy population also contributes to minimize risks among volunteers by eliminating potential drug interactions with existing medical conditions.

Pharmaceutical researchers not only need to recruit a sufficient number of healthy volunteers to conduct trials but need to do so quickly. The more time they expend in finding the volunteers they need, the more they delay their scheduled experiments. Delays are costly and add to overall research expenditures. Obtaining the right number of volunteers but with the wrong qualifications also puts the trial's outcome at risk, seriously compromising the volunteers' health and the validity of the trial. But recruiting the right number and the right kind of volunteers is no easy task. That is why in recent years there has been a shift in the way phase I trials are conducted. While some pharmaceutical companies still run their own trials, most have been outsourced to universities, or to independent contractors known as CROs.

During phase I the professional knowledge required in drug development is mostly supplied by biostatisticians and experts in toxicology. In contrast to later phases in drug research, no specialized knowledge about a particular disease or medical condition is required, making the task of outsourcing easier. Speed, flexibility, and the ability to recruit a large number of volunteers are the usual presentation cards for aspiring CROs. Their functions are broad, from recruiting volunteers and gathering data to ensuring ethical oversight of the trials with the help of a usually friendly ad hoc IRB.

In an open, competitive market, CROs compete among themselves, trying to lure the best research subjects they can find. In recent years increasing competition to attract subjects in high-demand areas has led to a surge in the amounts paid to volunteers. But financial inducements are only part of the package offered to prospective subjects. Instead of the

prisonlike environment offered ten or more years ago, now there are individual suites, Internet access, flat-screen televisions, and even pool tables, among other amenities. Food has also improved, along with a more professional and "respectful" staff. Because of their anti-consumerist tendencies anarchist guinea pigs are not generally appreciative of fancy sites, which usually involve a large number of trial subjects and rotating personnel. Many told me that these sites look like factories, large and impersonal, furthering their sense of alienation. They prefer trials at Jefferson, an academic hospital with a very friendly and stable staff but less glamorous facilities, and some guinea pigs, like Helms, had volunteered only there in recent years. KingLabRat and the Canadian Guinea Pig, in contrast, found large sites like those of GSK very nice and volunteered there quite often. Of course investments in amenities are only made where they are really necessary to attract or retain paid subjects. In remote areas, such as parts of the Midwest, where demand for volunteers is not as strong and paid subjects have fewer choices, trial conditions are not as good.

A glimpse at just a few of the hundreds of advertisements published in weekly newspapers in Philadelphia, or posted at recruitment sites at the major pharmaceutical companies operating in the area, summarizes industry requirements for phase I clinical trials. Subjects must be healthy males eighteen to forty-five years old with flexible schedules. The companies offer "financial compensation for time and travel expenses" or, more directly, invite the volunteer to "make money" by joining a trial. It is not hard to see the gender bias in pharmaceutical research. In phase I clinical trials males have historically been the preferred human subjects and remain so. The gender bias in recruiting volunteers is not lost among paid female volunteers: "When I started doing trials they were not for women at all and I remember that a doctor told me that recently had been a study at that place for a breast cancer medication and the volunteers were all men. I asked why and she said it was because the pharmaceutical industry still thinks of men as normal humans and women as aberrations. Women have abnormal bodies because they are not men, men are the norm. Now most of the trials if you are sterile women can do them, so I think that this is their main concern with it" (Cidar House Girl, 12 June 2004).

Since the level at which an experimental drug becomes toxic is un-

known—that is precisely what a study is to determine—the pharmaceutical industry fears that experimental drugs might affect fertility and pregnancy outcomes in women who volunteer for phase I trials, exposing the industry to lawsuits. Despite this, the pharmaceutical industry has been encouraged in the last decade to incorporate a more diverse population in trials. Still, while women have been included in phase I trials research, they are a very marginal population. Most of the trials enroll only men and just a few recruit both men and women. Trials intended to assess the toxicity of contraceptive drugs or other products devised for women's use employ female volunteers, which is no doubt an advance if we consider—for example—that the birth control pill was originally tested in men.

DEMAND FOR HEALTHY BODIES

Toxicological trials are not seeking just any men but "healthy" men. Again, the recruitment ads give us some clues: "not smoker," "drug-free," "non-congenital conditions," "takes no medication." The pharmaceutical industry goes to great lengths to make sure that the volunteers recruited for phase I trials are "healthy" and thus appropriate research subjects. Phase I trials depend not only on recruitment but also on retention. If someone withdraws from a trial before it is complete for whatever reason, the validity of the trial may be compromised. In sum, market recruitment ensures the availability of the large number of subjects the industry needs to perform phase I clinical trials while also contributing to the correct operation of the trial.

Professional volunteers are aware of the key role that they play in ensuring that clinical trials are run smoothly:

> Well, the biggest thing with a clinical trial is that it's a poker game. The clinical trial wants a specific person with a specific profile that doesn't exist. They know it; guinea pigs know it and people don't talk about it. They want a person that is very healthy, has an open schedule, under a certain weight but does not exercise. A lot of times they ask you not to exercise because that messes up with the trial but then they want you to be under certain weight. The perfect volunteer they require doesn't exist. Everybody lies about complying and that's the biggest thing. I lied about my family medical history, yeah, about drug use, taking medicine. They have a lot of pressure to recruit enough people. The recruiters are under a lot of pressure to recruit, they need people. And also, once they found you too, they want you to continue. Once you showed dependable, you did the study and went through the whole thing, when they need to do a blood draw your veins work, you pee when they tell you to pee, never complain, once they have that they want to keep you. (Spam, 28 July 2004)

Paid volunteers are well aware of the demand for an idealized, perfectly healthy volunteer. They also realize that their body is a valued commodity in clinical trials research. Certainly, as Spam observes, it is not an abstract body that is sought and rewarded in phase I trials, but a well-trained, disciplined, and complying body—or subject.

There is no clear guinea pig career. Some volunteers started their career by selling blood or modeling for art schools, or doing less invasive procedures such as MRIs. Others jumped right into trials. Most guinea pigs have done exclusively trials or moved quickly into trials. This trajectory seems to support the idea that blood, semen, and other body fluids are not as valuable as body as a whole.

Financial compensation plays a central role in recruiting and retaining volunteers. The payment is scheduled to maximize the chances of ensuring compliance with the research protocol among volunteers. Generally it takes at least two or three weeks from the first phone interview to the time a trial begins. It is not until the first leg of the trial is over, or the whole trial if it is a short one, that the volunteer gets paid. Volunteers leaving the trial before the first leg of the trial is completed do not receive any payment, unless they can prove that they are experiencing serious adverse affects as a consequence of their participation. Since the object of the trial is to study the toxicity of the drug, side effects are expected, and therefore volunteers may have a difficult time negotiating their paid discharge with the trial staff. If the volunteers are successful in making their point, then they get paid based on the number of days they stayed in the trial.

There are a number of ways the industry promotes professionalization among human subjects volunteering for their clinical trials. All major research sites in metropolitan Philadelphia have a database of previous volunteers from which they draw when they need to fill a new trial. Potential volunteers regularly receive announcements of forthcoming

trials. Registered volunteers can also check the industry's web site for trial opportunities. Some, like Michael, make occasional phone calls to inquire about possible trials and to let recruiters know about their availability. Most research sites offer financial incentives for referrals, usually from $50 to $100. After a new volunteer finishes a trial successfully the volunteer who referred him gets a check. Eager to fill slots, research sites attempt to recruit volunteers for forthcoming trials even before a clinical trial is over. Currently volunteers are required to wait one month after they have finished a trial before submitting to screening in a new trial, but participants usually receive "invitations" for screenings in future trials once the waiting period is over. This waiting period is intended to "wash out," or eliminate, any trace of a drug from an earlier study. Yet only a few days after a drug has been taken it usually cannot be detected in a blood test. Some people who participated in trials in the early 1980s—when regulations imposing a waiting period between trials were almost nonexistent—remember that even before finishing one trial volunteers were invited to screen for a forthcoming trial and if accepted were enrolled right away.

A PROFESSIONAL GUINEA PIG TRIAL'S JOURNEY

"I needed money and some friends that do trials told me about this one coming. My friend told me that I should sign up because it paid really well for not having to do a lot. It turned out that the drugs weren't too risky and so for the money that you were making it was a pretty safe bet." That's how Michael, my roommate at Fancy House, described how he entered his last trial, just a couple of days after I moved there in early February 2004. He was a twenty-five-year-old white Kansan who had moved to Philadelphia and to Fancy House, one of dozens of radical, anarchist communes in the West section of the city at that time.

Although Michael had a degree in art design and did occasional under-the-table commissions designing jewelry and clothing for some friends in New York, this was not his main source of income. He had been a bike messenger first and later worked in the kitchen of a catering firm. When I met him he had just cut one side of his right thumb while operating a slicing machine. The cut was deep and painful, the kind of wound that made it impossible to stitch. Having no health insurance, Michael dealt with it by washing the site with disinfectants and removing the bandages

from time to time. He missed a couple of days at work and then went back to his catering job, but not for long. He had earlier volunteered for a clinical trial, and two weeks before his accident with the slicing machine he had called one of the oldest medical schools in the city to find out if there were any clinical trials for which he could volunteer. He called not once but twice. As he told me: "You have to keep calling until they know who you are. They have a lot of people interested. I gave them the names of two people that I knew who were regular trial participants there. That helped me out."

The trial comprised two six-day periods with a washout period of ten days in between. For the duration of the trial Michael would need to comply with some restrictions, including prohibitions against drinking grape juice or exercising heavily, because these activities interfere with the drug regime. Michael's trial is a typical double-blind placebo trial, or randomized clinical trial (RCT), in which participants are randomly assigned to different groups that are administered different drug regimes. He had been placed in one of six groups receiving a combination of placebo and different drug regimes varying from 0.4 mg to 10 mg, and he would not know which drug regime he would receive. To test the safety and efficacy of the drug, he would get a tetanus vaccine and then have a biopsy performed to assess the anti-inflammatory response. Michael would have a total of five biopsies during the trial.

After calling a couple of times and naming names Michael was granted a phone interview that lasted about thirty minutes and covered questions about his health history, diet, smoking habits, drinking, and illegal substance consumption habits. As noted above, any congenital disease, mental health problems, or admission of regular use of alcohol or illegal substances is enough to disqualify a potential candidate. In addition, a few extra pounds, low or high blood pressure, or a contaminated urine or blood sample is enough to exclude a prospective volunteer. Some research sites ban prospective volunteers for life if a "toxic" substance is found during the screening process, while others make the ban temporary.

With such requirements, recruiting enough volunteers for toxicological research is not an easy task for the pharmaceutical industry. Since clinical trials use a controlled diet that includes meat, self-identified vegetarians are also banned from clinical trials. Having done clinical trials before, Michael knew that he could not be honest about his vege-

tarian diet. He passed the phone screening and was then called to do an in-person screening for a trial a few days later. Prospective volunteers won't know which trial they will be participating in until they pass the screening process. Michael's screening lasted one hour and involved blood and urine tests, an electrocardiogram, and measurement of his height, weight, and body mass index. Michael had to sign an informed-consent form for the blood draws and other tests. The screening is very demanding, and any minor deviation from the requirements may exclude a volunteer. Luckily for Michael, a few days afterward he received a call from the recruiter informing him that he had passed the screening tests and was accepted.

The next day Michael went back to the hospital, where a nurse practitioner showed him the informed-consent form describing in detail what the study was about, how long it was going to last, the schedule, and financial compensation. He had the opportunity to ask questions about the trial, the drug being tested, and possible risks. He read the informed-consent carefully, asked questions, and then took the twenty-page document home and kept reading it. He wasn't supposed to sign it then but at the beginning of the trial a few days later.

After his screening session Michael received more information about the trial that he would volunteer for. It was an eleven-week, outpatient trial of a new anti-inflammatory drug for which he would receive $1,700. The study was designed to test the safety of the drug. The trial involved three groups of approximately eight volunteers each; a maximum of thirty volunteers would be recruited.

Five days after he qualified, Michael showed up at 7:30 in the morning at Jefferson to start the trial. After signing the informed-consent document he had a new round of checkup tests: "The same thing [as in the screening tests a few days ago], because they wanted to make sure that everything is current," Michael told me. He also had his first biopsy: staff removed skin from his back, with local anesthesia, and then two stitches closed the wound. At 2:00 in the morning he was awakened for additional tests, but was not given any drugs.

He "dosed," that is, took the drug, the following morning at 9:30. "It's just a couple of pills and then we swallow and they check if we swallow them, look into your mouth and into your tongue and everything." Every patient doses at the same time every day. After dosing Michael had his

blood drawn. Staff members use a catheter to draw five or six vials. While Michael was at Jefferson, staff identified him by his tag number, 8246, although informally many nurses would address him by name. Of the seven people in his group Michael knew five. He spent his time at the lounge, watching TV, playing video games, watching movies, and just hanging around. He spent the first night at the hospital, then left the next evening to return the next morning. The days when he just dosed and had blood drawn he spent less time at the hospital than when he underwent biopsies. Six days into the trial he began the ten-day washout period, without any dosing or blood draws. Michael came back at the end of this period for the second part of the trial: another six days of dosing, blood draws, and occasional biopsies. After a few days he felt confident that he would finish the trial and receive the money, so he quit his catering job for good. He received a quarter of the financial compensation after the first phase was over and the remaining amount at the end. Michael didn't seem to worry about the scars left on his back by the biopsies: "I'll carry them for the rest of my life," he told me matter-of-factly.

After cashing his trial's check Michael spent the money on a new, state-of-the-art laptop computer. He was confident about getting into another trial as soon as the thirty-day waiting period between trials expired. He intends to do two more trials to save enough money to be able to live in Spain for a year without the need to have a full-time job there. Broke in the meantime, he distributed lists for a Democratic candidate during a couple of weekends in the neighborhood for $10 an hour and managed to hold on until his next trial with the income he received after a week of showing car models at a horse fair in Pennsylvania.

DEMOGRAPHICS OF THE PROFESSIONAL RESEARCH SUBJECTS

I surveyed eighteen people participating in at least one paid phase I clinical trial in Philadelphia. Their ages ranged from twenty-one to forty-six. Most of the volunteers were in their mid- to late twenties. All but four volunteers were men. Ethnically most volunteers self-identified as white or Caucasian; one volunteer self-identified as Latino.

The volunteers' educational levels covered a wide range: one did not finish high school, four finished high school, six did some undergraduate study, six finished an undergraduate degree, and one was enrolled in doctoral studies. Only three of the volunteers owned their own house, but

in all three cases the owners shared the property communally. The large majority lived in communal houses but did not own them and paid rent. Most did not have any kind of health coverage. Just three had HMO coverage provided by their current employers.

When asked about their motives to enter the trial, volunteers without exception declared that trials were the opportunity to "make easy money," "quick money," "a considerable amount of money in a relatively short amount of time," "a huge sum."

"SOUNDS LIKE A VACATION!"

Survey findings confirm that financial incentives are very important in shaping volunteers' decisions to enroll in phase I clinical trials. Only two volunteers mentioned an altruistic motive along with the financial incentives, and these were volunteers who were not part of the "guinea pigs" community based in West Philly: their social backgrounds were different, and they also differed in their views of the ethics and politics of clinical-trials research.

Financial gain is also reflected in the volunteers' response to a survey question about their main motivation for taking part in the trial. As noted, all the volunteers pointed to financial benefit as their main consideration, but they also noted the duration of the studies and their location. The risk level was mentioned by some as a disincentive, and if a trial was perceived as risky, volunteers said that they would not participate regardless of the financial incentives. I discuss risk perception in depth in chapter 3.

Frank Little, a young volunteer who had done just a couple of trials, sums it up well:

> I was working as a carriage driver for a while downtown and it was OK money but then I saw the paychecks that my friends were doing with the clinical studies. Floyd and Jason told me that they did lots of money. It varies from study to study but it was a significant amount of money for not very much time and what these guys actually had to do for the study is to lie in bed, get one or two pills, watch TV, read, play board games, and periodically have their blood drawn. Periodically they also had to give urine samples and they get this huge chunk of money. I said: "except for the needles and the pills it sounds like a vacation!" The blood draws vary from study to study but, you know, they said frequent blood draws but I didn't care about that, for the amount of money that we are getting in compensation getting my blood drawn a few times is something that I can sacrifice. It's much better than working eight, twelve hours a day just to get my blood drawn five, six times a day [laughs]. (Frank Little, 9 December 2004)

Since money plays such an important role in the volunteers' experience it is not surprising that volunteers should be so candid when they talk about it. Money is one of their main topics of conversation when they talk about trials. Volunteers are always interested in finding new trial opportunities. Usually the conversation focuses on the best forthcoming trials in the area and the financial compensation offered.

When paid volunteers refer to a trial they have completed or one that they might want to join, they always identify the trial by the amount of money offered. Sometimes they also note the duration, whether the trial is inpatient or outpatient, and the drug being tested. Descriptions by sponsors offer information about the physical location of trials. They would say something like this: "A $3,000, two-week, inpatient [or outpatient] trial for a first-in-man drug with such-and-such sponsor." Volunteers are aware of the financial potential of each trial and are able to compare daily and even hourly earnings. Volunteers use these ratios to make decisions among competing trials. All things being equal, the trials that pay more per day or hour are preferred. As a rule, *Guinea Pig Zero*, the zine for professional human subjects edited by Helms and reflecting the views of anarchist volunteers in Philadelphia, advises potential volunteers to turn down any inpatient trial that pays less than $200 a day in the Philadelphia metropolitan area.

Clinical trials for phase I drugs in metropolitan Philadelphia typically offer between $200 and $400 a day to volunteers. Compensation for engagement in a trial might range between $1,200 for three or four days in less intensive trials to $5,000 for three or four weeks in more extended ones; exceptionally a trial might need even more time to be completed.

Volunteers are not compensated for the time they spend in the phone interview, but most of the research sites offer a small amount, $25 or $30, to volunteers for their participation in the screening. Volunteers often receive a voucher for a meal at the hospital cafeteria after the screening and

when they make their occasional follow-up visits to the research site. Volunteers are also compensated for being alternates. Alternates spend the first night of a trial on-site in case any volunteer in the trial cannot continue to participate. Usually the alternate walks away the next morning, having been paid $100 without having taken any drug or undergone any blood draws or intrusive procedures. Alternates are then scheduled to participate in the next cohort of the trial, thus gaining an additional payment.

BETTER THAN A JOB AT MCDONALD'S

Participation in inpatient clinical trials is time-intensive, demanding the volunteer's presence in a particular location for the duration of the trial. Mixed trial regimes that balance inpatient with outpatient visits are less demanding but still limit the volunteer's use of free time during the trial. Volunteers are required to have a flexible job schedule or not work at all at the time of enrollment. As many volunteers admitted, the independence and flexibility, not to mention the income, afforded by participating in clinical trials was much better than a job at McDonald's.

The requirement for a flexible schedule is reflected in the occupational status of the volunteers interviewed. Eleven of the eighteen said that they had worked, in addition to participation in clinical trials research, and seven had trials as their only source of income at the time they were interviewed. Among those who declared they were employed, only three held full-time jobs, while the other eight worked part-time. Of those who held full-time jobs two were labor organizers (one working to organize supermarket workers; the other, janitors) and one held two jobs (repairing bikes at a cooperative bicycle store and selling books at a children's bookstore).

The jobs of the volunteers who worked part-time were diverse. Most were independent, blue-collar jobs such as construction worker, painter, bike messenger, house or office cleaner, housekeeper, and cook. Three volunteers worked part-time at the Wooden Shoe, the oldest anarchist bookstore in the city, which is run as a co-op. The large majority in the sample self-identified as "blue collar" or "working class." Some had working-class parents; others chose typical working-class occupations. No doubt their anarchist ideology, with its emphasis on independent, non-exploitative labor, played a role in their choice of occupation as well as in their class identification.

Professional guinea pigs realize the difficulties they face in depending exclusively on clinical trials for income. While living in the Philadelphia metropolitan area affords a regular supply of opportunities for participation in clinical trials research, the demands of the RCT make eventual enrollment unpredictable and unreliable. Urine and blood samples can be contaminated, not just by illegal substances but by bacteria found in the testing lab. Even if the samples are not contaminated, their values can be too high or too low, thus preventing the candidate from entering the trial. Sometimes a small variation in diet or exercise produces certain enzymes that show up in the samples, disqualifying the candidate. Even high or very low blood pressure can prevent candidates from entering a trial. Certainly there are many other contingencies that conspire against the enrollment of a perspective volunteer and are beyond the volunteer's ability to control. Anticipating rejection, volunteers often screen for two trials simultaneously. Despite their efforts to gain entry, the stringent screening process often bars volunteers for months at a time. Being a full-time guinea pig demands a great deal of energy from volunteers. Scott, an experienced guinea pig, describes his first years working exclusively as a research subject and his later shift between trials and formal employment:

> I just moved to Philadelphia about ten years ago now and I didn't want to go back to a regular job. I traveled that summer, went back to Minnesota and came back here and was looking for a way of making money that was easy and didn't involve a whole lot of work and some guys told me about the trials studies. Went up there to GSK, I don't remember what it was for, something relatively benign. That first study was something like extra-strength Tylenol or something like that. They were looking at how long it would be in your bloodstream or something like that. It was pretty easy and I got paid all that money so I was, wow! I keep doing this, you know. For the first couple of years I don't think that I did any paid work at all. I only did clinical trials alone for two years because it was such a novelty, I could get money taking all these drugs. So, I did this for a couple of years, not doing nothing else, and then I started getting some more paid jobs occasionally but I kept doing the drug studies mostly at Jefferson. (Scott, 26 March 2004)

THE ANARCHIST COMMUNITY IN WEST PHILADELPHIA

The anarchist community in West Philadelphia is concentrated around Baltimore Avenue from 45th Street to 49th and a few lateral streets on both sides of the avenue. It is a buffer zone between the gentrified areas adjacent to the University of Pennsylvania to the south, with remodeled houses and nicely kept apartments, and the dilapidated landscape of a lower-income African American community to the north. The neighborhood houses a vibrant community of immigrants from West Africa with food stores, restaurants, and shops. It also has a significant population of white, working-class and middle-class neighbors and a very vocal liberal community.

The visual signs of radical political activism are hard to miss. At 45th Street the local of the Industrial Workers of the World and the Communist Party league face each other, marking symbolically and physically the entrance into the area. Three blocks up, also on Baltimore and just next to the Dalhak, an Ethiopian bar, stands what local anarchists call "A Space," a hangout and organizing room identified by a big black sign with an encircled white capital "A" in the middle. A few houses away a colorful, hand-painted sign advertises the food co-op Mariposa, where most residents of the radical communal houses buy their food. On the corner of 50th Street and Baltimore stands the Firebird House, also a co-op, which repairs and sell bicycles. Bicycles play an important role in the community, enhancing the self-reliance and autonomy of their residents, who are able to circumvent the system by using a medium that is perceived to be not only cheaper than mass transit but also cleaner. Firebird House is also used by the community as a hangout where residents can exchange gossip and socialize; this is especially true during the summer, but community members ride their bicycles year-round. The Farm Market, next to Firebird House, provides fresh, organic vegetables to a community of politically engaged, hardcore vegans.

Twenty or thirty communal houses foster the anarchist community of the neighborhood. All the houses have names, such as Knot Squat (also known as "Not a Squat," after the occupants managed to buy the house from the city), Cider Garden, the Farm, Rainbow House, and House of the Future. At the corner of 49th Street was Fancy House, were I lived. Most of the houses have a porch filled with plants and sometimes objects

that nobody cared to reclaim or remove. Although some of the fronts are painted, the houses all look somehow deliberately rough and unfinished. On the inside they are roomy, but even Fancy House, one of the best kept, had holes in the kitchen ceiling and the bathroom floor, no doubt a reflection of the owner's punk, hippie, and anarchist aesthetics and preferences. In addition to the residents' rooms, all the houses have a place for bicycles. Most backyards have a very well kept garden.

Fancy House is a good representative of the way the radical community organizes its housing arrangements in West Philadelphia. I moved there in early February 2004 and lived there until late August 2004. Although I knew Julie, its owner, I first had a meeting with the residents, who wanted to know if I could fit into their community. I had the credentials, was socially and politically aware, knew somebody in the house already, and was able to participate in "house meetings" and fulfill my assigned chores, which included emptying in the backyard garden the bucket with organic compost that we had in the kitchen. As in most community housing, residents of Fancy House cooked their meals together and wanted to know if I had a vegetarian diet. I didn't, but after I assured the residents that I was willing to contribute to the food expenses and would not use their pots to cook meat, they let me in. My presence helped to redress the gender imbalance at Fancy House. Finnley, in her mid-twenties, had arrived just a couple of months before I did and worked part-time at a magazine in Delaware. Marisa, also in her mid-twenties, had arrived from Kansas just a few weeks before Finnley and worked as a bike messenger. Asia, in her early thirties, was a close friend of Julie and was in a "sabbatical year" in New York. Asia had lived in the house for almost a year when I moved in and was a very active member of Act-Up. Jamie, in his mid-twenties, was also from Kansas and moved to Philadelphia at the same time Marisa did. He was also a bike messenger.

Michael, also in his twenties and also from Kansas, knew Marisa and Jamie before moving in. He was working in the kitchen of a catering firm when I moved and doing occasional clinical trials. The occupations of the Fancy House are typical of the radical West Philadelphia scene: the residents work in the informal economy, in badly paid jobs that do not have demanding schedules, leaving space for political and social activities. Other community members do paid community work as labor organizers or in community-based organizations such as Act-Up. Some radical com-

munity enterprises like Firehouse, the bicycle repair shop, or Wooden Shoe, the only anarchist library in the Philadelphia area, offer additional job possibilities in a cozy, community environment. At both locations men and women work equally and share profits in a cooperative arrangement, undisturbed by a loyal clientele that is not bothered by their display of long hair, bushy, nineteenth-century beards, tattoos, and piercings.

Living in community housing affords residents cheap rent and low food costs. Rent varied from $190 to $230 a month, depending on the size of the room. Every week $15 for food was deposited in a box kept in the fridge. The residents of Fancy House, like residents of almost all community housing in the neighborhood, shopped at the food co-op Mariposa, where every resident had to work two hours a month. Just a few weeks after I moved back to New York, Michael moved out of Fancy House, and in December, after saving enough "trial money," he flew to Spain.

The geographic mobility and instability among the residents of Fancy House reflect a larger trend among the radical community in West Philadelphia. Community members are always coming and leaving. In such a closely knit community, in which everyone knows everyone else, there is significant potential for disagreements and misunderstandings. This may explain why there is so much gossiping along with discussion of political and social issues. Members sometimes shift their social relationships by changing housing arrangements. If this is not enough, they may leave the city for a while for a similar community somewhere else. Networks connect anarchist communities in Seattle, Vermont, and West Virginia, among others.

"GUINEA-PIGGING" AS A LIFESTYLE

Ideology, community activism, lifestyle preferences, or just plain consumerism can induce volunteers to earn money only by participating in clinical trials, or to move back and forth between clinical trials and informal jobs. Like Scott, many professional guinea pigs feel attached to the novelty of selling their bodies as human subjects for toxicological clinical trials research. One guinea pig, Jennifer, described her year-and-a-half-long spree of participation by saying, "You become addicted to the easy money, you don't want to do anything else."

The paid volunteers whom I interviewed each participated in more than one trial. Some had volunteered for just a few, but most had been

regular trial participants, with seven volunteers having done more than twenty phase I trials. Some remembered having done seventy, eighty, or even more, although they acknowledged losing track after a while. Eight volunteers had done between one and six trials, two volunteers between seven and thirteen, and one between fourteen and nineteen. Most of the volunteers surveyed had done at least one trial during the last year, many between two and five. Three volunteers had stopped participating in trials some years ago. Most of the participation took place in or around metropolitan Philadelphia.

The income derived from clinical trials allowed professional guinea pigs in the West Philly area to buy houses that they later transformed into communal housing, to travel around the world, to buy state-of-the-art computers, and to "chill." As noted above, trials afford volunteers flexible schedules and plenty of time to pursue other interests and occupations. While volunteers in the anarchist community of West Philadelphia pursued a broad range of activities and interests—as might be expected given the anarchist ethos of individuality—some general trends can be traced. For example, Dave Onion arrived in Philadelphia six years ago. A native of Washington State, he had lived as a child in the former Yugoslavia and later in Berlin, from where he traveled to Philadelphia, attracted by the possibility of living in an anarchist environment. There he learned about clinical trials, and after completing a few trials he was able to buy a dilapidated house from the City of Philadelphia for $5,000. Using his background as a construction worker, he rebuilt the property entirely, repairing roofs, refurbishing the kitchen, and installing solar panels to replace electric energy. The house has an unfinished, rough edge—even by community standards—and seems to be always undergoing some repair. The energy from the solar panels is not enough to support central heating or even a fridge, and the rooms have a gloomy, mysterious atmosphere. However, he has devised some ingenious methods to overcome these deficits. A wooden fireplace heats the kitchen, which is the social space of the house, and drinks can be cooled outside by placing them just behind the window in the winter. While Dave Onion's house is an extreme case of self-reliance and autonomy—other paid volunteers have chosen to make the commitment to a place and bought a house—it embodies the communitarian, anarchist ideal of living beyond a commodified, market-driven society.

Dave Onion used a considerable portion of his income to support the construction of a community space nearby. The space, a collective enterprise supported by other individuals and community organizations, was a half-finished building which progressed slowly because of the lack of steady investment. When completed it would accommodate Radio Volta, a community-based station transmitting from one of the communal houses in West Philadelphia. In addition, it will host a popular library (when I was there the books were still stored in boxes in the basement), a software and hardware computer training center for poor, mostly African American women (donated computer carcasses were piled up in a corner), and the office of the *Defenestrator*, an anarchist publication, among other projects.

Although the *Defenestrator* had an editorial board composed of Dave's girlfriend, Mc Mike (a veteran guinea pig and bike repair man at the Firehouse bike shop), and Paul (who also sat on the editorial board of the *Defenestrator*), among other occasional members, the publication was Dave Onion's brainchild. He wrote the majority of the articles, sold advertising space to friendly individuals and organizations, and contributed income from trials if needed. He also took charge of distribution, placing free copies at strategic places in the neighborhood like the A Space, the Food Market, Mariposa, and the Wooden Shoe bookstore. He was also involved in the Industrial Workers of the World (IWW) and helped organize the annual commemoration of Worker's Day each May, usually a gathering in a nearby park accompanied by political discourses related to the occasion, workshops, music, food, and beverages.

The A Space provided a venue for political and community organizing. It was a center of antiwar activities, fundraisers, speeches in favor of the Chiapatistas movement and Guatemalan human rights, screenings of a documentary on worker-run factories in Argentina, and vegetarian dinners. In addition, it was at the A Space that Helms implemented the project "books behind bars," which collected books that he later delivered to prisoners in Pennsylvania. After he left for Paris a friend of his, a fellow professional guinea pig, continues Helms's work.

That anarchist members contributed books for this project reflects not only Helms's standing and reputation in the community but also the privileged position that literacy has among its members. Although their level of formal education is not particularly high, most residents have finished high school and a few others have some years of college or even a diploma, and reading and writing are a significant part of their everyday life. Many communal houses have libraries that include the classics of anarchist literature as well as works by García Márquez, Eduardo Galeano, and Noam Chomsky. Many residents work at the anarchist bookstore and have ready access to books and other printed materials. As noted above, the community has its own periodic publications, the *Defenestrator* and *Guinea Pig Zero*. Quite a few members explore different literary genres. Among volunteers, for example, Spam, an English major, writes short stories. The value accorded to literacy in this community is derived from their anarchist ethos, which accords a privileged position to self-education as a means of developing an alternative class understanding of the world based on the rejection of bourgeois values and practices. In addition, anarchist ideology also values the ability to work with one's own hands. Thus, it should come as no surprise that the anarchist community of West Philadelphia, and in particular its professional guinea pigs, should exhibit an enormous interest in developing some kind of craftsmanship, artisan work, or creative manual activity.

My roommate Michael was a professional jewelry and clothing designer who spent considerable time and effort working on his creations. Another volunteer plays the clarinet on Friday evenings at the local farmer's market. Volunteers at the Farm have converted the basement into a quasi-industrial carpentry site where they have created numerous wooden furniture pieces along with wood and metal sculptures. One of them also brews his own beer, which he stores in the basement.

Trial money also gives volunteers time to do community organizing. "The pharmaceutical industry is financing community activism in Philadelphia," said a close friend of Helms, the editor of *Guinea Pig Zero*. Almost all self-identified anarchist guinea pigs engaged in some kind of community activism, such as organizing International Workers' Day and rallies against the Iraq War, or working with Act-Up and other local community organizations. My fieldwork coincided with the beginning of the Iraq War, and this issue permeated not only my interactions with members of the community but also their everyday lives and organizing efforts. The community is intensely politicized, and local, national, and international politics were topics of animated debate.

Most clinical-trials volunteers are in their twenties and thirties, single, and childless, with flexible schedules and no permanent attachments.

Trial income offers them the opportunities to have fun and travel, and almost every weekend anarchists would hold elaborate parties in community houses that often included DJs and topical costumes. Sometimes they had a political or community fundraising purpose, but birthdays, Halloween, or just the welcome or farewell of a member of the community could serve as an excuse to socialize.

Radical guinea pigs also spend a significant amount of trial income on travel. Most volunteers have alternated periods of trial participation with extensive travel. Dave Onion traveled to Bulgaria, Mexico, and other destinations; Michael lived in Spain before coming to Philadelphia and left for Spain after completing a succession of trials; Spam had embarked on a tour that led him to South Asia and India; Helms had lived in France a few years ago and permanently resettled there a few months after I moved to Philadelphia.

In their spending habits guinea pigs show a clear understanding that their bodies are commodities, almost using their bodies as ATMs to fund their lifestyles. I discuss the commodification of the body in chapter 2.

KINGLABRAT

I met KingLabRat at the downtown youth hostel during my first reconnaissance trip to Philadelphia in the summer of 2002. Of Puerto Rican background, he alternated between Spanish and English while talking to me, mainly about women and sex, his most important concern aside from volunteering. KingLabRat was outspoken and talkative, not shy about being a professional guinea pig, and we readily formed a good bond. In his late thirties he had come from Florida for a trial at Wyeth, and in an effort to save money stayed for a few days at the hostel during the screening process and until he got admitted. Although we shared quite a bit of time together I did not carry out any formal observation then. When I returned to Philadelphia one year later I contacted him, and we made arrangements to meet when he was in the city for another trial. He arrived at the beginning of January from Wisconsin; he had tried to volunteer for a trial there, but things did not go as he had expected. After his arrival KingLabRat learned that the two-week trial, for which he was to be paid $3,000, would not start until one month later. For two weeks he stayed in a homeless shelter downtown, trying to hold out long enough to make it into the trial. KingLabRat explained to me that conditions at the shelter were bad and that he could not "take it anymore." He then traveled to Philadelphia by bus, arrived penniless, and, unable to afford even a cheap hotel, was staying with a Puerto Rican friend. He was hoping to enter a trial at GSK, pay some debts, and pocket some money.

I was able to go with KingLabRat through his trial at GSK. We met regularly before and after his screening, during the trial, and at the end. He was pleased with the attention and happy to help me with the research. When I suggested that he invent a pseudonym to protect himself against possible retaliation from the industry, he performatively chose to identify himself as KingLabRat. It suits him, since he is the most experienced professional guinea pig I have encountered. KingLabRat had been volunteering since he was discharged from the army in his early twenties for allegedly beating a sergeant. In between trials he sold drugs and worked in the morgue in Philadelphia. He had done trials since the mid-1980s at most of the trial facilities in the country from Miami to Texas, including the Midwest, and especially in New Jersey and Philadelphia. KingLabRat embodies—literally, in that his arms were covered by scars left by infinite needle punctures—the emergence of the market-recruited subject in pharmaceutical research. He provides a unique window into the way volunteers become professional guinea pigs.

KingLabRat's motivations to enter the trial are not different from those of the anarchist volunteers: the trials were a business, an opportunity to make money. But KingLabRat, unlike the anarchist volunteers, also believed that the trials offered an opportunity for scientific advancement. He told me: "We're doing something good for the people. Hey, the drug might work!" Whether other volunteers agreed or disagreed with KingLabRat on this score depended on how much credence they gave to the validity of scientific knowledge behind drug development. As we will see in chapters 1, 2, and 3, on major topics such as the social identity of paid subjects, the criteria for selecting trial subjects, and risk assessment and response, KingLabRat's positions do not differ in important aspects from those of the anarchist professional guinea pigs.

KingLabRat knew Helms and other regular anarchist subjects. He had volunteered with Helms at Wyeth a couple of years before, and when I asked about him, KingLabRat readily identified Helms as the "white guy." Racial differences were only part of KingLabRat's estrangement from Helms. KingLabRat was politically conservative, with a libertarian side,

but this did not make him approve of the anarchist group. A devoted Catholic, he used to bring a bible to the trials, usually his only reading. According to him anarchism represented a totalitarian view that "imposed their ways of thinking on you." He elaborated this point: "atheists that shut down when you confront them. They don't like freethinkers." Emphatically, he noted that such an ideology is "wacky and politically wrong." Finally, he suggested that anarchism is "thievery," replacing private property by social property. In his current trial at GSK he had not encountered any anarchists.

During my first visit at the youth hostel I met another professional guinea pig. He was also in his thirties, white, from Canada, and had been living in the United States for a couple of years. Recently he had moved to Tennessee, where he hoped to launch a career as a folksinger, financing himself with the money earned as a volunteer. He encountered KingLabRat and used him to gain knowledge of the local trial scene. By chance, at the end of my fieldwork in July 2004 I stayed for a couple of days at the hostel and I was fortunate to find him again. He had come back to the city for a trial, also at GSK, so I followed him through.

KingLabRat and the Canadian guinea pig represent only a small portion of the universe of paid subjects volunteering in Philadelphia. While they share basic experiences and views with the radical anarchist volunteers, common to all paid subjects, they also have differences. The most important difference—besides the degree of altruism behind their participation—is their geographical mobility. Anarchist volunteers living in the West Philly community sometimes venture to trials in neighboring New Jersey and can eventually volunteer in trials in other areas. However, most of their trials are centered in the metropolitan Philadelphia region. By contrast, other professional guinea pigs—in particular those living outside Philadelphia—have greater mobility. One reason behind this difference is that Philadelphia affords enough trial opportunities to locals who do not need to travel beyond its limits. In addition, familiarity with social networks and trial facilities operates as a powerful incentive to volunteer in the area.

I do not want to overemphasize the lifestyle aspects behind guinea-pigging.

While for anarchists in West Philadelphia guinea pigging seems to be part of their lifestyle, for other groups or individuals beyond this enclave

the aim of supporting a lifestyle may not be as strong, or may not be present at all. For some, joining trials is a way to pay increasing college costs, or gain some extra income in difficult times. But for the anarchists, entering the trial economy seems to be a calculated choice that provides income and the flexibility to pursue other interests. The industry's demands for flexible participants who can accommodate the schedules of clinical trials match the anarchists' desire for independence and autonomy. No wonder that most anarchists in Philadelphia had at one point or another joined the trial economy. They even developed a discourse to rationalize their trial participation. Not having a fixed, eight-hour schedule or a regular boss or employer also allows the anarchists to imagine that they are in some way "outside" the capitalist system. Of course, as I will argue in the Conclusion, they are not: they are a central component of drug development, fueling one of the most lucrative industries, and one with a global reach.