A GUINEA PIG'S WAGE. RISK AND COMMODITIZATION IN PHARMACEUTICAL RESEARCH IN AMERICA.

by

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Abstract

A GUINEA PIG's WAGE: RISK AND COMMODITIZATION IN PHARMACEUTICAL RESEARCH IN AMERICA

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By following the commodity chain from "first in man" phase I trials to phase III trials in a North American city, this dissertation explores the relationship between the increasing commoditization of volunteer's participation in clinical trials and its effects in the way risk is constructed and managed. Fieldwork was conducted between July 2003 and August 2004 in a North American city among a group of mainly anarchist professional "guinea pigs" volunteering as paid subjects for Phase I clinical trials. In addition, research was conducted at a community based organization that performed clinical trial research among mainly poor, African American men and women testing Phase III/IV clinical trials for HIV drugs and drug regimes sponsored either by the pharmaceutical industry on a community site.

The dissertation shows that market recruitment of trial subjects led to a process of professionalization among volunteers signaled by the emergence of a group of professional "guinea pigs" who provided the Pharmaceutical Industry with the regular supply of healthy, disciplined bodies it needed to run an increasing number of trials. The prospect of "easy, quick money" was enough to motivate mainly poor, unemployed working class individuals to become trials subjects to enter into the

"economy of the flesh". While volunteers are deeply aware of the commoditization of their bodies this fact is denied by the pharmaceutical industry and governmental and local regulatory bodies.

The commoditization in clinical trials research and in particular in phase I not only might expose volunteers to new and unexpected risks derived from continuous participation but also challenges major ethical principles and guidelines regulating the protection of human subjects participating in research contained in the Belmont Report. The shift from a captive population to a market-recruited population unfairly targets a particular socioeconomic group of individuals creating thereby a new type of captive and vulnerable population. Paradoxically, this is the situation the Belmont report intended to eliminate when it was formulated.

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A GUINEA PIG'S WAGE: RISK AND COMMODITIZATION IN PHARMACEUTICAL RESEARCH IN AMERICA.

Introduction

On June 16th 2001, the national press first reported the death of a healthy 24-year-old female who volunteered for an asthma study at Johns Hopkins University. The story revealed that a few days into the trial she felt very sick, she was discharged and sent home. Within some hours she checked into the emergency room at a local hospital and fell into a coma. She remained in this state until her death a month later. She had received $ 375.00 for participating in seven to nine sessions as an outpatient in a clinical drug study that resulted in her death[1].

This death touched me deeply, since I had also volunteered as a paid healthy human subject for Phase I trials. During the last months of 1998 while I was pursuing my MA in Quebec City, I volunteered on a couple of occasions as an in-patient for Anapharm, a major CRO (Contract Research Organization) performing Phase I trials for local and international pharmaceutical companies which had their headquarters a few blocks away from my campus at Universite Laval in Saint-Foy. The research facility was a functional, flat, uninviting five stories building no doubt a fine expression of the soviet architecture of the 60's and 70's that also shaped the University campus. Anapharm's staff was organized along a very clear division of labor: women were in charge of "technical" work while, males performed the "research" and "managerial" tasks. Among the volunteers were a mix of unemployed workers, mentally disabled, artists and university students. The research floor was

[1] New York Times. June 16th, 2001.

crowded; dozens of double bunk beds aligned in facing rows. A yellow light went on at night after the regular lights went off. Cash was handed to us in envelopes the last day of the trial on our way out.

The first drug I tested was a new version of a drug to combat heartburn and gastritis that was already on the market. For a five day, in-patient study I received $ 550 Canadian dollars. The second trial was a new drug to increase appetite in terminal patients with HIV or cancer. This experimental drug did not increase my appetite but the trial definitively contributed to raise somewhat my diminished bank account savings by $ 800. I am sure, in retrospect, that the "financial compensation for my time and travel expenses", as the Pharmaceutical Industry regularly frames volunteer's participation in the trials, did not compensate for the risks I faced, the pain of endless blood extractions and the boredom of spending hours doing nothing but watching TV. I volunteered just for the money, and despite some casual observations I did not conduct any systematic research.

The tragic death of a paid volunteer at Johns Hopkins –a very dramatic one, but by no means an exception- elicited various responses from a variety of sources ranging from governmental agencies to self-proclaimed "bioethics experts". The federal government announced 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 their informed consent processes and addressed the claims of the volunteer's relatives with out-of-court legal settlements. Pundits commented on the event extensively in the press, focusing on whether institutional protections for human

subjects volunteering in the trials were effective in protecting volunteers' rights. Some commentators inquired whether the volunteers understood the risks as they were framed in the informed consent form of the study. Others moving beyond issues of form and interpretation adequately pointed to the increasing interrelationship between academic researchers and pharmaceutical companies. Their critiques were centered on issues of conflict of interest inside academic IRB's and the need to further regulate informed consent processes to adequately safe guard volunteer's rights.

While critics made valuable points, I had the feeling that a number of questions regarding risks, commoditization and ethics in relation to biomedical research remain not only unanswered but more importantly, were not formulated. In particular, one major point critics overlooked was the fact that the volunteer was a healthy women who had been paid to join a trial in which, other than the financial compensation, there was no additional therapeutic benefit. Since the use of financial means to entice participant enrollment is currently a significant trend in clinical trials research – in recent years the practice of offering some kind of financial compensation also extended beyond Phase I trials to later phases of drug development- I believe that there is a pressing need to address the consequences brought by the increasing commoditization of the body.

The participation of paid human volunteers in clinical trials research poses new questions in relation to commoditization in trials research, risks and the ethical regulations protecting human subjects participation that have not been analyzed thus far. For example, does monetary compensation distort volunteer's perception of

risks? Or, might it be the case that long-term participation in phase I trials increases risk awareness among professional "guinea pigs"? Which are the effects of commoditization on the ethical regulations protecting human subjects?

By following the commodity chain from "first in man" phase I trials to phase III trials in Northern American city, this dissertation explores the relationship between the increasing commoditization of volunteer's participation in clinical trials and its effects in the way risk is constructed and managed. Fieldwork was conducted between July 2003 and August 2004 among a group of mainly anarchist professional "guinea pigs" volunteering as paid subjects for Phase I clinical trials. In addition, research was conducted at a community based organization that performed clinical trial research among mainly poor, African American men and women testing Phase III/IV clinical trials for HIV drugs and drug regimes sponsored either by the pharmaceutical industry or community sites.

Commoditization in clinical trials research increased significantly with the emergence of Market-recruited patients that substituted "captive" populations in the 80's over concerns that prisoners could not give proper informed consent due to institutional constraints. The use of financial rewards has extended also to later phases of trials research. Market-recruitment of paid volunteers for Phase I clinical trials took off in the early 80's when ethical concerns arose about the ability of captive populations, mainly prisoners, to give proper informed consent. As a result, the industry had to find a new, suitable population to test the safety of the drug, creating in the process a new occupational category: the professional "guinea pig. The prospect of "easy, quick money" was enough to motivate mainly poor, unemployed

working class individuals to become trials subjects to enter into the "economy of the flesh".

In a sense, the emergence of a professional research subject volunteering to test, experimental drugs being developed by the Pharmaceutical Industry brings attention to what Michaela di Leonardo terms the "exotic at home". Professional "guinea pigs" constitute an exotic development of technological and medical culture, with their own ethos, identities and practices. This dissertation is an attempt to further consider Michaela di Leonardo's suggestion to pursue an anthropological examination of phenomena that are "hidden in plain sight around us" (di Leonardo 1998: 10). In so doing, this research calls attention to hidden problems brought by the increasing commoditization 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; Rose 1996).

The shift towards a market-recruited population constitutes just another turn into the increasing commoditization of the body in biomedical research along with an existing market for body organs and parts. Following these developments, there has been a scholarly interest in the commoditization of the body in medicine. This process of commoditization of the body poses new ethical challenges and questions assumptions about the medicalized body, the ownership of the body and the integrity of the self.

This dissertation builds in previous contributions on the anthropology of the commoditization of the body in medicine. Like in other cases in the biomedical realm body commoditization is driven by cultural, economic and technological

processes that transform volunteer's bodies in objects of scientific, medical and corporative desire.

Clinical trials research based on market-recruited subjects is the basis of drug development – and patenting- that has made of the pharmaceutical industry one of the largest and more profitable economic sectors in the American economy. In turn, as this dissertation shows, the commoditization of the body in clinical trials as in other domains in biomedicine, elicits a profound distrust among the public about potential abuses from corporations seeking financial gain in detriment of the well-being of research subjects or the larger consuming public of new drugs. Aware of this potential downfall the pharmaceutical industry uses a number of rhetorical devices like the oxymoron of a "paid volunteer" who is compensated for its "time and efforts" instead of for his/her body to deny that commoditization is taking place.

Professional "guinea pigs" are deeply aware of the fact that their disciplined and compliant bodies constitute valuable commodities for the pharmaceutical industry. Volunteers not only challenge the labels used by the industry but also reaffirm their shared identity, interests and emergent class solidarity prompted by these emergent processes of commoditization. In an attempt to resist the dehumanization and alienation of such medicalized body, volunteers actively seek to disrupt trials in any way they can from tampering with regulations and test outcomes to a successful collective walk out.

Findings suggest that commoditization process shape volunteer's perceptions and responses to risk. More importantly, the reliance of the pharmaceutical industry on a group of professional research subjects might place volunteers to

unforeseen risks like synergistic drug interactions and long-term effects. As this dissertation argues, by exposing a particular socio economic group of volunteers to an undue burden, commoditization in Phase I trials research distorts major ethical principles and guidelines regulating the protection of human subjects participating in research contained in the Belmont report. The shift from a captive population to a market-recruited population unfairly targets a particular socioeconomic group of individuals creating thereby a new type of captive and vulnerable population. Paradoxically, this is the situation the Belmont report intended to eliminate when it was formulated.

Significance

The literature on risk and commoditization has contributed greatly to the understanding of historical, social and cultural processes related to human subjects' participation in biomedical research. Yet, the commoditization process is often more complex and has more consequences than is assumed in the literature.

Subject's bodies play a central role in the commoditization of clinical trials research. By exploring the socio-cultural process that transform bodies into valuable commodities as research subjects, this study attempts to make a contribution to the anthropological study of commoditization of the body. This study also aims to contribute to a broader understanding of the literature on risk in clinical trials research by emphasizing how commoditization processes shape paid human subjects' understandings and responses to risk.

By describing the role paid volunteers, scientific knowledge and ethical

regulations play in the first phases of drug development the dissertation also represents a contribution to the anthropology of commoditization and in particular, to the anthropology of pharmaceuticals.

In addition this research also intends to advance discussions of the ethics of biomedical research, which is now presented mainly in a formal, individualistic, rational and legalistic framework. It seeks to contribute to an approach that incorporates the socio-historical and cultural context in which individuals make their decisions. (Levin 1985; Marshall 1992).

While the focus of this research is centered mainly on subjects volunteering for trials and not on the scientists conducting them, it also intends to be a contribution to the anthropology of science studies. In particularly, it focuses on advancing inquiry into the way that scientific knowledge is produced and organized, and the place of professional beliefs and values in that process (Fox 1974; Latour 1986; Rapp 1999; Franklin 1995).

Finally, this research explores the ethical ramifications of the increasing commoditization of the body in clinical trials research. By describing the articulation of scientific, medical, social and economic practices that make the participation of human subjects in trials research possible this dissertation attempts to contribute to stimulate debate and hopefully transformation of public policies regulating the ethics of human subjects participation in trials research.

Anthropology of risk

Risk society, "reflexive modernity" and governmentality theories on risk

The last two decades the social sciences have seen the emergence of risk studies as a new area of disciplinary interest. Risk has been perceived as an integral part of the a "reflexive modernity" (Beck 1992; 1994, Giddens 1990) in post-industrial societies. Central to Beck's and Giddens writings on risk is the notion that late modernity is characterized by a critique of the processes of modernity, which are no longer unproblematically viewed as producing "goods" but are now seen to produce many of the dangers of "bads" from which we feel threatened. The central institutions of late modernity –government, industry, science- are singled out as the main producers of risks. An emphasis on risk, Beck and Giddens assert, is thus an integral feature of a society that has come to reflect upon and critique itself. An important point made by these authors is that institutions make decisions that place citizens at risk but are not accountable for doing so. Individuals do not seek to live in a world without risk, which according to these authors is impossible but to have a say instead in the type and levels of risk they might be forced to live with.

A similar approach to risk is based on Foucault's writings on govermentality. This approach is not interested in investigating the nature of risk itself, but rather the forms of knowledge, the dominant discourses and expert techniques and institutions that serve to render risk calculable and knowledgeable, bringing it into being. Risk is a way –or rather, a set of different ways- of ordering reality, or rendering it into a calculable form. It is a way of representing events so they might be made governable in particular ways, with particular techniques, and for particular goals. (Dean 1999)

While these risk approaches offer valuable social and political clues to understand how risk is constructed, they have been criticized because they operate at the level of grand theory, with little use of empirical work looking into the ways in which people conceptualize and experience risks as part of their everyday lives. (Lupton 1999). In spite of these critiques, their positions offers valuable insight to understand GPZ as part of the effort of civil society to reflect on the ethics and risks related to the professionalization of "guinea pigs" in clinical trials drug research. In addition, these theories also shed light on the issue of accountability in relation to risk by such powerful institutions such as the Pharmaceutical Industry and the Food and Drug Administration whose risk assessments, technical but also political, place individuals at risks they are not aware of.

A significant event that contributed to the a more empirical understanding of risk in the social sciences was the emergence of AIDS in the 1980's, forcing social scientists to deal with risk issues related to sexual and intravenous drug use practices in an attempt to understand and contribute to more effective solutions. Some of the theorizations on risk presented here are heavily influenced by these efforts and draw their empirical support from AIDS data.

The behavioral approach to risk

The behavioral approach to risk emerged in the 80's heavily influenced by behavioral social psychology. Two of the most used models are the Health Belief Model (Becker and Joseph 1988) and the Theory of Reasoned Action (Ajzen and Fishbein 1980). Here individual behaviors are the only determinants of individual

health. In turn, individual risk behaviors are explained by individuals' risk perceptions. According to these authors, there is a direct relationship between beliefs and practices ensuring that if individuals have the correct information about the risks they face and the ways to avoid them, individuals would rationally choose to change their behavior. In sum, correct information would lead individuals to proper courses of action. Critics have argued that individual beliefs are not the only source responsible for individual practices. Information in and of itself is insufficient to produce risk-reducing behavioral change. Individuals take decisions and act in particular social contexts that cannot be neglected as proposed by such behavioral theories. (Parker 2000). The social context shapes the way risks are perceived and also influences the ways in which individuals respond to them. Furthermore, the context imposes limits on the possible courses of action one individual can choose and implement (Singer 1994; 1998 Clatts 1996).

Professional "guinea pigs" support Parkers' view. They construct a risk hierarchy based on the risk perception that places certain trials like those involving experimental psychiatric drugs at the top, while the testing of drugs already on the market, like pain killers, are low on their scale. My research with paid "guinea pigs" shows that experienced volunteers who had participated in at least one trial they knew presented an unusually high risk level and that they had been enticed by the financial rewards. In this case the social context is represented by particular economic constraints like the need to secure an income to maintain a certain lifestyle, or the addiction to "easy money" might lead volunteers to discount the "correct information" they might have about a particular drug trial. Another social context,

such as the particular biographical and disease experiences shape HIV patients' understanding and response to risk. In this context, patients desperate to hold on to some promise might be encouraged to join a trial that offers very reduced opportunities for therapeutic gain.

All the remaining approaches to the study of risks have some similarities, continuities and contradictions, but they all converge to support the idea that risks cannot be understood unless they are placed in a broader socio-cultural context that surpasses the individual level postulated by the behavioral epidemiological approach.

The cultural approach to risk

The cultural approach to risk is represented by authors like Mary Douglas who stress the cultural determinants of risks in opposition to individual, cognitive and utilitarian approaches emphasized by the behavioral epidemiological and rational choice models. She argues that the concept of risk is not a natural, fixed category but instead has to be understood as culturally, socially and historically constructed. According to Douglas, risks are not individually and subjectively perceived. Every society selects and reacts to a particular set of risks. She notes that the selection and reaction of a particular hazard shows essential features of the social organization of that society (Douglas 1992).

A cultural approach to risk in drug clinical trials helps us to understand why, for example, professional "guinea pigs" place psychiatric drug trials at the top of the risk hierarchy, and how they are considered as dangers to be avoided. This is because they are perceived to "mess up the mind". This perception of risk illustrates the value

professional “guinea pigs” place on the mind and rationality. In addition, the scientific risk assessments and technological understandings of risk dismisses social and political decisions in relation to way risk is dealt with by the scientific and regulatory bodies.

Thus rationality and technology emerge as key contemporary constructions of risk in industrial societies and influences risk understandings among scientists conducting trials and also paid subjects.

The cultural approach illustrates Douglas’ concern for the groups and institutions and by the way in which the response of these communities is functional to the maintenance of a particular form of social organization.

Critics of the cultural approach to risk suggest that is its emphasis on institutions instead of individuals misses a crucial point: not all individuals are equally exposed to risk. As the political economy approach to risk shows, it is usually poor, disenfranchised individuals that are placed disproportionately at risk. This is illustrated by the past use of human subjects in biomedical research taken from “captive” populations such as orphans, mentally feebled, and prisoners, and currently a diverse group of poor, disenfranchised paid volunteers.

Other weakness in this approach is that it emphasizes the normative aspects neglecting, for example, strategic relations among members in the immediate social situation (Bellaby 1990). These points are central to the theorists of the situated rationality approach to risk. An important contribution from these theorists is the realization that social interactions among volunteers shape individual experiences and

understandings of the trials and in particular, the ways in which risk is constructed and dealt with.

Despite these critiques the cultural approach to risk is very significant for the social sciences because it goes beyond a view of risk that a focuses on the individual and her or his psychological or cognitive responses to risk, to an interest in the socio-cultural context in which individuals are situated and in which they make judgments about risk.

The situated rationality approach

The situated rationality theory outlines the situational elements that individuals consider towards adopting a particular behavior (Connors 1996). These authors emphasize the relevance of immediate social and interact ional elements present in the social context in which individuals act and take their decisions about the risks they face. This approach proposes that individuals are influenced by the immediate benefits related to risk behaviors. While inspired by a rational choice approach to risk there are some important differences. Contrary to the rational choice actor the individual here is not an abstract and detached one but instead somebody influenced by the aesthetic, emotional, interact ional elements present in the social context. where he or she acts. As this dissertation shows, volunteers make the decision about entering a trial based overwhelmingly on financial considerations. They calculate hourly income, daily income and total income potentially derived from a possible trial. Volunteers also consider convenience of the location, duration and risk level. But unlike the rational choice subject, volunteers do so in close interaction

with other volunteers. As previously noted, risk assessment is not an individual but a social process. Familiarity with trial sites and the need to enroll with friends or acquaintances volunteering for the same trial are also persuasive facts.

The situated rationality approach is much more interested in explaining its own data than in elaborating a more general theory in relation to risk practices. The emphasis on the immediate benefits of risk behavior, such as financial reward, is also perceived to be an obstacle for a broader application.

The political economy approach to risk

The political economy approach to risk emphasizes social, structural and historical processes reinforcing social inequalities as the main elements to understand the way individuals perceive and deal with risk. Authors like Singer, Clatts, Susser and others discard the cognitive and individual epidemiological approach to risk stressing the ways in which "risky social behavior is shaped by external social and economic context" (Singer 1998). Clatts' study of HIV risks perceptions among intravenous drug users in Harlem shows that experiences such as poverty and social marginalization are linked to the way individuals perceive and deal with the risks. The author suggest that any intervention program should take into consideration the possibilities the individuals have to accomplish the changes required in a behavioral shift, and that any effort that does not take into consideration the underlying social inequalities have a poor chance of success.

The authors that propose apolitical economy approach to risk have also extended their inquiry into health risks in industrial settings (Susser 1988).

Experiences like Love Canal and Three Mile Island in United States and Bhopal in India or Chernobyl in Ukraine among others, have increased awareness of the risks industry poses to workers and residents in areas surrounding factories. The Political economy approach to industrial risk argues that the industry has historically disregarded their workers' health either in an early era characterized by the absence of state regulatory presence or a later period of state regulation. According to Susser, the level and kind of occupational health risks to which workers are exposed is related to the historical development of industry, shifts in worker and management relationship relationships and state regulation. In addition, social movements beyond the workplace also influence working conditions and the existence of industrial hazards and should also be considered in assessing industrial risk.

As previously noted, the political economy approach notes that social inequalities expose certain individuals to a disproportionate number of risk situations. Poor, disenfranchised individuals face risks they might not recognize or are unwilling to address in order to earn a livelihood. Professional "guinea pigs" are one just one of such groups. Their dependence on the income, their mobility and lack of shared experiences at the same work place over a long period of time makes the awareness of long term risk and synergistic interactions harder than in the case of the industrial workers like coal miners or asbestos workers, for example. Governmental regulation did not eliminate risk for volunteers, instead it introduced scientists to assess acceptable risk exposure levels. In turn, neo-liberal governance introduced changes in State's effort to enforce regulations of the pharmaceutical industry introduced during the 70's to protect the public and human subjects participating in clinical trials

research. As a result, critics argue, the regulatory powers of the State have decreased in a context where creating a "good business climate" has replaced previous regulatory concerns with consumers and volunteer's well being (Angell 2004).

While making a valuable contribution by stressing structural inequalities in shaping risk outcomes the authors nevertheless fail to recognize the relevance of symbolic aspects that are also important in the way individuals perceive and deal with risks. An emphasis on structural and historical processes leads to a very structurally deterministic account for human agency. The goal of any risk analysis should account for the material, economic, historical and social constraints without leaving behind the symbolic dimensions of the individual's experiences of risks and the ways in which they can provide agents with power to contest or control their situation more efficiently.

In sum, the behavioral epidemiological model on risk that adopts individualistic, cognitive and utilitarian model neglects the social contexts where individuals live and make decisions about the risks they face. The other perspectives discussed above offer different contributions to the study of risk in clinical trials research, but no single approach can account for the multi-dimensional aspects associated with the way risks are perceived and deal with both by the industry and human volunteers. I wish to stress at this point that there is at the need to go beyond the notion of a universal "risk subject" that tends to appear particularly in the risk society and govern mentality perspectives. Responses to risk may be understood to be aesthetic, affective and hermeneutic phenomena, grounded in everyday experiences and social relationships (Lash 1993). I believe that a better understanding is needed of

how risk logics are produced and operate at the level of situated experience. We need to know more about how the structuring factors of gender, ethnicity, age, social class, and so on, as well as different social contexts such as the different phases and experiences of trials influence risk logics.

Finally, I would address an important point. While all but the behavioral perspectives emphasize the social, cultural and political nature of risk, they offer somewhat differently nuanced approaches to the phenomenon as socially constructed. Indeed, they may be placed at different points along a continuum, with a realist approach of the kind offered in technical-scientific approaches at one pole, and a highly relativist constructionist approach at the other. The question of whether risks are to be understood as constructed or as objective realities is important. My position here is that risks are socially constructed but they are also a significant presence in the lives of any human subject volunteering for any trial. The painful and unnecessary deaths of many human subjects in the last years is a sad remainder of the fact that risks are not merely social constructions but have material and practical consequences as well.

The commoditization of the body in clinical trials drug research

Recent technological advances in transplantation techniques, artificial reproduction and drug development have resulted in the increasing commoditization of the body (Sheper-Huges and Waquant 2003; Sharp 2000). Currently there is a local and international market for major organs like heart, kidney and liver; body tissue; reproductive material such as sperm and eggs; plasma and even hair. The

whole body has also entered this market through the participation of paid research subjects in clinical trials research (Hogshire 1992). According to Hogshire's estimates a volunteer could receive around $100 dollars per day as a research subject. Since then, financial compensation offered to volunteers in America has at least doubled. These are just a few examples of how things become commodified and integrated into a market economy.

In fact, this process of body commoditization is not new in American history where corpses had been sold to dissectionists, anatomists and surgeons. Other forms of commodification include the enslavement of human beings and the current use of reproductively rich products or tissues reaped from the dead (Sharp Forthcoming 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 1967:163). The strangeness of commodities for Marx alludes to the mystification of a commodity's origins where the exploitative labor processes that produced the commodity are obscured. Thus, the commodity appears naturalized, having its own independent life from the social relations that originated it.

Following these developments, there has been a scholarly interest in the commoditization of the body in medicine (Sharp 2000; Scheper-Hughes 2000; Nelkin 2001; Moore 1999). According to Sharp organ transfer –as many new biotechnologies- elicit a powerful social anxiety among the public, which in turn leads to the industry's denial of body commoditization. "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 commoditication of cadaveric donors and its parts. (Sharp Forthcoming 17)

According to Sharp the references to the commoditization of the body is avoided by using the rethorics of the "gift" through which organ transfers is equated with "donating life" and organs with "precious resources" to be "harvested". For Sharp this semantic choices make possible to avoid references to trauma, suffering and death involved in removing organs from the donors. As a result, the language of the gift economy mystifies key aspects or organ transfer.

Not only organ transplant have the capacity to elicit anxiety in American society. Like in many other biotechnological areas, a similar anxiety can be detected in clinical trials research. For example, a popular novel by John Le Carre, The Constant Gardener, later transformed into a movie, describes the abuses of the pharmaceutical industry conducting clinical trials among poor, disenfranchised African residents elicited numerous questions about the ethics of clinical trials in Third World countries. The piece criticized the pharmaceutical industry and also Western Governments and agencies for exploiting the poor for commercial and national gain and denounced the ethical abuses involved in clinical research in developing countries. While usually clinical trials in developed countries do not elicit the same degree of attention or anxiety, recently a very serious episode at a trial sponsored by Parexel in England involving the ADR (Adverse Drug Reaction) to a "first in man" drug trial which caused six volunteers to become seriously ill, brought

up public concerns that the pharmaceutical industry might abuse volunteers in their search for profits.[2]

Like in the area of organ transplantation, pharmaceutical corporations seek to avoid references to commoditization of the body in trials in an attempt to maintain public trust.

In clinical trials research a similar discursive practice to the one observed by Sharp in relation to organ transfer contributes to the Industry's denial of the commoditization of volunteer's bodies. As we will see in Chapter 4, trial subjects are defined by the industry by the oxymoron of "paid volunteer" being compensated not for their labor but by their "time and travel expenses". Chapter 7 in turn shows how the Informed Consent utilizes a language that obscures the risks involved in their participation, for example by using euphemistic terms to avoid references to the possibility of death. As with organ donor kin, Phase I volunteers resent and reject the industry's attempts to label them as volunteers, insisting in their condition of "professional guinea pigs" while resisting the alienation, depersonalization and exploitation brought by the commoditization of their bodies.

Among patients volunteering for HIV trials the commoditization of their bodies is also neglected by portraying them as "altruistic" volunteers contributing for the advancement of scientific research and the public good. As we will see in Chapter 7 neither the industry, nor the government or the IRB's attempt to recognize the commoditization of the body involved in clinical trials research. Doing so would challenge basic ethical assumptions about the ability of certain individuals or groups to proper give informed consent to volunteer in the trials.

[2] The New York Times, Thursday, March 16, 2006.

"Commodities, like persons, have social lives", notes Arjun Appadurai (Appadurai 1986:3) Marx also understood this aspect of commodities prompting us to consider what we might learn if commodities could speak" (Marx 1976:176). The social lives of pharmaceutical drugs has been studied by Geest who covered the social trajectory of western drugs from the production sites to the ways in which it is used by consumers. (Geest et. Alt. 2002). Volunteers in opposition to most commodities and in particular to the drugs they help develop do speak and not just in a metaphorical sense. One of the most important critiques towards the pharmaceutical industry and the commoditization of their bodies in trials research is that this trade not only exploits but also dehumanizes them. As Sharp observes, the dehumanized body is one prerequisite of certain kind of medical interventions like organ transplants and others. The professional "guinea pig" metaphorical identification with an animal species conveys well this notion of disembodied self. In turn, their emergent class solidarity, their identification as professionals, albeit, performing a "weird" type of work, being paid to endure, as Spam notes, and their everyday forms of resistance at work draws attention to their efforts to reassert their human condition.

Methods: Approaching Anarchist "Guinea Pigs" and HIV volunteers

This project focuses on volunteers of pharmaceutical clinical trials in metropolitan Philadelphia where I conducted fieldwork from June 2003 to August 2004. Philadelphia has been historically a major site for pharmaceutical research. The development of the pharmaceutical industry was shaped by its interaction with one of the earlier medical schools in the country (Silverman 1974). This process served as a

model for transformations in the pharmaceutical industry that preceded and shaped larger national and international developments in the field (Libenau 1987). Large Pharmaceutical companies such as Glaxo, Smith and Kline (GSK) and Merck operate in the area. The focus of my dissertation on risk issues serves as a point of entrée to the current social organization of clinical trials as well as to the exploration of the ethics of research and informed consent processes.

When I first arrived in the city I had a very clear idea of my research sites. I would live in the anarchist section of West Philadelphia collecting data among white radical guinea pigs living in the area. In a previous trip I had visited CBTO (Community Based Trial Organization)[3], a community based organization that provides health care services and conducts clinical trials for poor African American men and women living with HIV. At this site I planned to work with scientists conducting the trials only, since financial compensation for patients was not present in some trials and was just "symbolic" in a few others, or so I thought. I envisioned CBTO as a telling example of the last phases of clinical trials in humans, Phases II and III. Additional interviews with a sympathetic researcher at a major Pharmaceutical Company would provide the opportunity to explore scientist's risks understandings from the initial steps or Phase One of clinical trials research. However, it did not play out that way. The informant from the pharmaceutical industry politely disengaged from his previous offer of helping me with my research. On the other hand, more frequent contacts with doctors and staff at CBTO made me

[3] I realize that this research might challenge powerful industrial interests. To protect the people that have contributed with my research and myself, I have chosen not to identify either people or institutional settings in which I have done research. To preserve their anonymity I use generic names or fictitious identifications. CBTO is thus, a fictional name.

question my initial impression that the financial compensation offered to participants at some trials played no role in the patient's motivations to enroll and in the capacity of CBTO to recruit and retain volunteers. Since some kind of financial compensation was involved in some trials conducted at CBTO, I decided to extend my study population to cover not only paid human volunteers for Phase One trials but also patients doing clinical trials to develop drug or test drugs regimes for HIV drugs.

This project thus focuses on two groups of volunteers. One group is constituted by healthy human volunteers that test new drugs being developed by the pharmaceutical industry not for therapeutic efficacy but for drug safety. The human subjects engage in the trials not to seek a therapeutic benefit or for altruistic motives but rather for financial gain (Weinstein 2001). The second groups of volunteers are HIV patients testing new drugs or drug regimes that might help them cope with their disease. While there are many important differences between these two groups of volunteers –the main one being that the Phase I volunteers were healthy while Phase II/III volunteers had a chronic and often life-threatening disease- both received some kind of financial compensation for their participation in clinical trials research. Professional "guinea pigs" as paid volunteers of Phase I trials describe themselves, might receive $ 200 to $400. for a day spent in a trial. Since most of them do more than one trial a year, usually 2 or 3, some even 6 or more, their income can reach thousands of dollars. In contrast, HIV patients usually volunteered for one clinical trial and received between 25 and 50 dollars for a monthly visit.

It should be clear that this sampling of volunteers doing clinical trials research does not intend to be representative of the universe of individuals that

receive some kind of financial compensation for volunteering in clinical trials in America. There are no official statistics about the total number of clinical trials being performed every year in the country or the number of volunteers enrolled in them. 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 in a given year or the number of volunteers enrolled. One study done at a research facility at Pennsylvania University shows that healthy paid volunteers of Phase I clinical trials at that site constituted a very heterogeneous male group that included unemployed workers, part-time workers, students, artists and other social groups mostly of white and African American origin.

I chose to work with a particular sub-population of paid human volunteers in Phase I trials: white, male anarchists from West Philly. I did so not because they are typical in any sense of the volunteer's population in the city, although as professional human subjects they certainly share many experiences and understandings about the trials. This group has been very articulate and vocal about their views concerning issues of commoditization and the ethics of clinical trials and biomedical research helping, to shape what Weinsttein call a public culture of guinea pigs (Weinsttein 2002).

One of the professional "guinea pigs" most articulate and committed members, Grand pa guinea pig, edited a zine, a professional journal of professional human subjects named "Guinea Pig Zero" or GPZ, from 1996 to 2002. Its success led him to publish an Anthology the following year. The author self-identified his project –which received the collaboration of numerous local fellow guinea pigs- 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 political views and practices of this group and their views and experiences of the trials, and in particular about issues of risk and commoditization. Just a few months before I met Grand pa guinea pig, in the early days of my fieldwork, he and two others 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. Bob was very excited about this event when I first met him and he 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 the anarchist volunteers played in it opened up 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 particular group of volunteers, who became the main focus of my research.

At the same time I was aware that while males provide the standard of Phase I clinical trials research, women have some occasions to engage in it as well. I did my best to contact women in this community, trying to asses if gender made any difference in the way trials were experienced, risks were understood and dealt with. Finally, I wanted to have a glimpse into the way other volunteers from different groups might deal with these issues. I knew that many professional volunteers travel across the country looking for trial opportunities, and while they do so they often stay at cheap Youth Hostels. I stayed at the Youth Hostel in downtown Philly for my first month of fieldwork and I met two other guinea pigs. One was a white Canadian man

now living in Tennessee and the other was a First generation American of Puerto Rican descent living in Florida. I lived with them at the hostel, witnessed their preparations for the trials and had the chance to interview them at many key instances throughout their trial participation.

HIV patients volunteering to test new pharmaceutical drugs or novel HIV drug regimes at CBTO were also part of the research. I contacted these patients as they came to the Research Division at CBTO to do check ups, blood draws, or pick up trial medication. I had obtained CBTO's IRB approval for my research that gave me a certain air of legitimacy. My informed consent forms had the institutional CBTO stamp, I used an office located inside the Research Division and 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; a moderate financial compensation was also an incentive for many of those volunteers who contributed with my research.

Physical access to volunteers doing Phase I trials was problematic because this is a highly mobile, scattered population who sometimes live outside Philadelphia. While many lived in the same place or only a few blocks, even houses apart, their busy agendas as social and community activist left little time for me to meet them. If they were not doing political work then they were working in a part-time or even full-time job, or traveling outside Philadelphia. By contrast, volunteers testing HIV drugs were easy to access since they were concentrated in the same place, but their class, race and illness experience made rapport with them potentially more difficult. While I

acknowledge the postmodern emphasis on difference and otherness that radically separates the researcher from the subject; I share the notion of situated knowledge that attempts to build generalizable knowledge while acknowledging social and cultural differences between researcher and participants in the research. I found that the use of medical narratives creates empathy between teller and listener that can contribute to narrowing the distance between researcher and subject.

A semi-structured survey among human subjects was designed to collect data regarding the relationship between the commoditization processes and risk perception among human volunteers. I conducted 18 interviews with volunteers in Phase I clinical trials and 20 survey interviews among CBTO volunteers doing clinical trials. At CBTO I interviewed volunteers for two community-based trials SMART, and Wistar, designed to test new drug regimes, and two "industry" trials testing new drugs, in one case and a new use for a drug already on the market in the other. The first two trials involved a much larger number of volunteers overall and this fact was reflected in the composition of the sample. This "bias" did not bother me since this group received also some kind of financial compensation, precisely one of the factors I wanted to investigate in relation to the way risks were perceived and deal with. While the use of a short survey was useful to inform general views about the ways subjects perceive and deal with risk, it cannot account for individual's experiences of the trials. For this, I conducted 12 life histories selected from among the participants of the survey, based on a combination of the following criteria: length and frequency of participation, types of risks experienced during previous trials, types of trials in which he/she had volunteered. I interviewed twelve volunteers, six from healthy paid

volunteers doing Phase I trials and six from the HIV trials at CBTO. Through these histories I inquired about the volunteer's personal experiences in clinical trials and their understanding of risks involved. I focused in particular on the relationship between the individual's experiences of trials and their possible changes in risk awareness. I also obtained information concerning their views on the commoditization process, in particular the issue of paid volunteer participation. This enabled me to understand better the relationship between personal experiences and the way human volunteers understand and respond to the risks they might encounter in clinical trials. Finally, participant observation of the volunteer's daily lives provided data to further explore issues related to the volunteer's experiences of clinical trials contained in the previous sections. In this way, I was able to observe their daily activities as well as their expectations and anxieties. In relation to the trials, I was able to document the preparations for clinical trials, as well as their responses and experiences in a livelier, more direct way.

Having volunteered as a paid human subject myself for a couple of phase one clinical trials as mentioned earlier, I had a particular insight into the experiences of volunteers in pharmaceutical clinical trials. Our shared experiences and sensibilities allowed other volunteers to interact with me at a common level of understanding and trust. In turn, this rapport with my fellow "guinea pigs" made possible, for example, my residence in a volunteers' communal housing. In so doing, I had a point of entry into their views and feelings not accessible by other research methods, such as questionnaires or semi-structured interviews.

While my ethnography focuses mostly 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 also provided a good starting point to do so. Its principal investigator CBTO's PI is in charge of all the "industry trials" conducted at CBTO and was extremely supportive of my research from the beginning. I conducted extensive interviews with him to explore issues around risk perception, risk management and commoditization in clinical trials to develop new drugs or drug regimes for HIV patients. In addition, since I had to obtain CBTO's IRB approval for my research there I was invited to make my case at their local IRB and got in contact with some of their members. I interviewed some of them to discuss how they saw issues of risks, mechanisms of protections for human subjects and commoditization in relation to the research being conducted at CBTO.

Organization of the Dissertation

The outline of my dissertation follows. Chapter one introduces the aim of my research, the background information, the research problem and question along with relevant theoretical and methodological data.

Chapter 2 describes the history of the development of pharmaceutical clinical trials in America. It documents the role of the State in the shift from an informal social organization of clinical trials prevalent until the pre WWII period to a more formal and institutionalized structure in its aftermath. Finally, this first chapter also explores another turn towards the expansion of commoditization within the existing institutional framework of the previous era around the 70's and unfolding until the present.

In particular, it focuses on two related set of phenomenon. One is the shift from clinical trials in "captive populations" to market based recruited populations. It documents changes in social organization of clinical trials, in particular the emergence of "controlled experiments designs" involving different types of knowledge based in developments in modern statistic techniques, scientific personnel to carry them out and new institutional arrangements to implement them. The second part of the chapter discusses the historical development of the pharmaceutical industry in the city of Philadelphia placing this in the larger context of national and international economic processes. I stress the shift in the city initiated around 1970 and unfolding until the present from an industrial based city to a more service-based economy oriented towards a knowledge based economy stressing biomedical research and medical services. Finally, the chapter documents the effects of these economic processes on the individuals placed on the lower levels of the social structure.

Chapter 3 explores the social organization of clinical trial drug research emphasizing its experimental nature as well as recruitment and retaining mechanisms put in place by the pharmaceutical industry that reinforce professionalization among trial volunteers. The chapter also describes the demographic background of the volunteers and their motives to volunteer in the trial.

Chapter 4 documents how the use of paid volunteers has contributed to shape the social identity of volunteers leading to group solidarity and even class identification. In particular, the chapter analyzes the role played by GPZ in shaping or reflecting the group's identity, as well as their ethical and political stand in relation to the pharmaceutical industry and biomedical research employing human subjects. This

chapter uses the study of the first "guinea pig" strike to explore forms of collective response to the working conditions volunteers face in the trials. Finally, the chapter also covers other forms of resistance used by paid volunteers in clinical trials and explores not only the potential for a sustained collective action among guinea pigs but also obstacles and shortcomings.

Chapter 5 explores the relationship between the commoditization processes in non-therapeutic clinical trials research and the way paid subjects understand and deal with the risks they face. Fieldwork in Philadelphia, among paid, white, male, anarchists volunteering for Phase I trials research reveals how local knowledge shapes the way risk is constructed and managed. Finally, I provide clues to understand why consideration of Long Term Risks is not only neglected by volunteers but also by the pharmaceutical industry and by the FDA in the development of new, experimental drugs.

Chapter 6 describes the social organization of HIV drug trials at CBTO, a community based research organization. It explores the networks, regulations and institutional arrangements that make community based trials and industry trials possible. Life stories and survey data are employed to document the socio-demographic background of the patients volunteering for the trials, their motivations to enroll and their views of the commoditization involved in their participation.

Chapter 7 explores the effects commoditization has on the ethics involved in the use of human subjects in such trials, in particular, in relation to the Informed Consent Process. The chapter describes the ways in which volunteers in therapeutic and non therapeutic drug trials understand the trial's design, goals, risks and potential

benefits, taking into account the patient's motivations for volunteering for the trial, as well as the conditions in which the trial takes place. Finally, the chapter explores the Informed Consent Process at "CBTO".

Chapter 8 revisits the central questions around risk and commoditization in clinical trials research, summarizes findings from ethnographic materials and recapitulates main themes and arguments. In its final part it offers some public policy recommendations to improve the safeguards afforded to professional 'guinea pigs' while inquiring about the convenience of offering more substantive financial compensation to HIV patients volunteering to test drug regimes or new experimental drugs. I also discuss other ways in which this work could be expanded into future directions. While this ethnography dealt mainly with the experiences and perspectives of the paid volunteers in clinical trials, in the future I hope to do research to assess how industry scientists' and government regulatory bodies understand and deal with risks in clinical trials drug research and post marketing exercises.

Chapter 2. From "captive" population to market recruited "human subjects". A brief history of the commoditization of the body in clinical trials drug research.

Introduction

"It is not possible nowadays to do any kind of clinical trial without some kind of financial compensation to volunteers for their participation". (CBTO's Principal Investigator)

Conducting clinical trial drug research in America today involves the financial compensation of human subjects for their participation. The differences regarding subject's financial compensation are striking. In some cases, volunteers get a few hundreds of dollars, in others their compensation might go into the thousands[4].

And it is not only the subjects who are compensated by entering the clinical trial economy. Researchers and research sites receive financial compensation as well. According to Marcia Angell, for example, a medical doctor might receive 7000 thousand dollars for enrollment of a patient to a particular trial and this sum might increase as doctors receive "bonuses" for fulfilling particular quotas. Angell criticizes this aspect of commoditization of clinical trials organization arguing that the practice violates the ethics of clinical trials research, introducing a conflict of interest between doctors or researchers and their patients, while also negatively influencing the outcome of the trials. (Angell 2004).

[4] Differences in financial compensation are explored in chapters 3 and 6

Currently, according to Center Watch, an information services company monitoring clinical research, there were more than 80.000 clinical trials being conducted in 2002 in America alone. Impressive as these figures are, they represent only a fraction of the total number of trials being conducted globally. Since 1980, looking to speed up the drug approval process and in the context of an increasing concentration and internalization of clinical trials drug research, pharmaceutical industries have shipped many clinical trials abroad, mainly to developing countries where ethical regulations are more relaxed, nonexistent or un-enforced, and where trials can find a large population of willing, poor, disenfranchised subjects who enter the trials induced by the prospects of getting access to health care, drugs, medical supervision and financial rewards. (Petryna 2005:193).

This chapter describes some major points leading to the commoditization of human subjects' participation in pharmaceutical clinical trials research in America. In particular, it focuses on two related phenomena. First, the shift from clinical trials in "captive populations" to market recruited populations. This resulted in changes in the social organization of clinical trials particularly the emergence of "controlled experiment designs" involving different types of knowledge based in developments in modern statistic techniques, scientific personnel to carry them out, and new institutional arrangements to implement them.

The second part of the chapter discusses the historical development of the pharmaceutical industry in the city of Philadelphia placing this in the larger context of national and international economic processes. I stress the attempted shift beginning around 1970 and unfolding until the present from an industrial based city to a more

service-based economy oriented towards knowledge requiring biomedical research and medical services. Finally, the chapter documents the effects of these economic processes on the individuals placed at the lower levels of the social structure, which contributed to the creation of a reserve army of human research subjects.

From "captive" populations to "market recruited" research subjects.

Scientific research involving human subjects was conducted until relatively recently in "captive" populations in the absence of formal procedures to regulate the ethics involved in dealing with such groups. Usually, the research subjects came from the lower strata of the society, the poor and the disenfranchised, sometimes recruited from orphanages, mental hospitals or prisons. General hospitals wards often provided unaware, poor, subjects for scientific experimentation. Although the majority of research subjects were underprivileged, sometimes medical students and their teachers volunteered as research subjects as well (Altman 1998).

Although biomedical research involving human subjects did not have clear, formalized ethical guidelines to regulate the conditions and rights of volunteers, this does not mean that it was a free-for-all scenario. According to Lereder, legal regulations, for example, civil law protected human subjects form the results of negligent action that resulted in damage to their physical integrity. On the other hand, medical ethics defined the professional duties of medical doctors in relation to their patients. The Hippocratic Oath, for example, requires physicians not to harm the patients during treatment. In addition, researchers had the responsibility to obtain the consent of their patients before subjecting them to experimental treatments (Lereder

1998). In 1940 the AMA established guidelines to obtain informed consent from patient's volunteering in biomedical research.

Marks points to the same requirement concerning patients participating in clinical trials during the WWII (Marks 1997). However, no formalized procedures to obtain informed consent were established at that time and the request for consent was left at the discretion of the researchers themselves. Until WWII medical researchers claimed their right to self-regulation in their medical practice. Critical issues like the definition of an experiment or the form in which consent had to be obtained were thus unregulated and left to personal and professional interpretation.

This situation led to tragic abuses involving human subjects volunteering in biomedical research. Perhaps, the most recognizable case of abuse happened at Tuskegee, where between 1930' and 1972 a group of 399 poor African-American syphilis patients had their treatment withheld to allow their white, middle class doctors to study the 'natural evolution' of the disease. The research, based on racist assumptions about biological differences between African American and Whites, intended to compare the effects of syphilis among Tuskegee patients with a XIX century study of deceased and untreated syphilis patients in Norway. The study had no scientific value and the experiment provided no therapeutic benefit for the patients who had to cope with the disease without treatment even though Salvarsan –the accepted drug in the early 30's- and then Penicillin in the 1940's had been demonstrated to be effective. Worse, the patients believed they would get medical care by volunteering to collaborate in the research. The experiment continued uninterrupted for more than three decades, involving a large number of researchers,

research centers and regulatory agencies. The results from it were published in medical journals and the study went through numerous reviews by the Public Health Service that had initiated it without major reservations. Ultimately, the case leaked to the press and was cancelled amid an uproar of public indignation and criticism. During Clinton's presidency the last survivors were offered an official apology. A judicial settlement had offered them financial compensation some years earlier.

Tuskegee is a tragic example of how racism, science and state power interacted to shape biomedical research involving human subjects. It also illustrates potential for ethic abuse of patients subjected to experimentation. The abuses resulting from Tuskegee, shockingly as they are do not stand alone. WWII fueled a surge on research involving human subjects. Japan experimented with biological and chemical weapons in Manchuria killing thousands of Chinese citizens; Germany tested depressurization chambers on war prisoners, tested freezing effects, and exposed subjects to chemical and biological agents. The United States also conducted as well their quota of war experiments. For example, following a concern that the use of radiation in weapons led to male infertility among those producing and manipulating atomic bombs, prisoners were exposed to radioactive materials to test its effects on male reproduction (Moreno 2003). This experiment was secret, its documentation was classified, and volunteers were not informed about the particular conditions of the trial they were involved in.

Abuses during WWII led to the need to define a clear set of rules regarding human's subject participation in biomedical research. In 1947 the Nuremberg Code established protective guidelines for the protection of human subjects in clinical trials.

This requires a voluntary declaration of consent by the trial participants, and established the patient's right to receive information on the nature, purpose, risks and benefits of the experiments. According to the code, anticipated benefits should outweigh the risks involved. In addition, it established the patient's right to withdraw from the trial at any time.

Some American scientists argued that this regulation applied to German Scientists only and were not needed for their practice in the US. As they had done in the pre-war period, medical professionals insisted on the benefits of self-regulation. For example, the director of the Public Health Service's division of venereal disease that oversaw the Tuskegee experiment saw no connection between experiments of Jewish concentration camps prisoners and their own research at Tuskegee (Jones 1993).

In 1974 the US Congress passed the National Research Act, which established a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Its recommendations were issued in the Belmont Report in 1979. The report placed America in line with the spirit of the Nuremberg Code that was used explicitly for the guidelines in the Belmont Report. This report, along with the National Research Act, established the institutional requirements designed to protect human subjects involved in biomedical research. One of the central measures was the requirement that scientists receive proper training to conduct the trials. However, the main contribution of the Belmont report was recommendation of need for "Independent" Institutional Review Boards to oversee human subject participation. Board members, both professional and lay, had to guarantee the

conditions regarding the informed consent process. Volunteers needed to be fully informed of the risks and benefits of the trials. The emphasis on free, informed consent presupposes a free individual in the sense that the person is not coerced or constrained to participate in a particular trial. Recognizing that certain groups of individuals do not fulfill this requirement, the Belmont report placed limitations on certain groups of subject populations who could not participate in clinical trials: children, the mentally ill, or institutionalized subjects like prisoners.

The shift from collegial, or professional self regulation to a more formalized, institutionalized regulation of human subject's participation can not be adequately explained as the product of the State's response to scandals and public outcry. Social movements during the 1960's against racial apartheid and in support of civil and human rights provided the context in which demands for ethical treatment of human subjects could be articulated and implemented.

The Belmont Report and subsequent laws resulted in new institutional arrangements to protect human subjects. Institutional Review Boards (IRB's) as well as federal agencies such as the Office for the Protection of Research Subjects became part of the research landscape involving human subjects. The Belmont report's recommendation banning prisoners from clinical trials research had a dramatic effect on the social organization of clinical trials, forcing the Pharmaceutical Industry to devise strategies to find new, suitable research subjects. For example, in 1980, one year after the Belmont Report was issued the FDA banned the participation of prisoners in clinical trials since they were judged unable to give 'informed consent" while living in the institutional constraints of prisons. This regulation signals the end

of the enrollment of institutionalized populations and the shift to a market approach. Until then, prisoners had been the main source of paid human subjects for the pharmaceutical industry, and were the industry's preferred research subjects. An estimated 90% of drugs licensed prior to the 1970 were first tested on prison regulations. (Harkness 1996)

Prisoners were in many senses a perfect population for a controlled experiment. The same living conditions provided good "control groups' for clinical trials while the financial need and the material benefits ensured a large supply of willing and compliant volunteers.

Paid volunteers recruited through market mechanisms were more expensive and demanded new institutional arrangements. Publicity, recruiting centers, screening procedures, and selection guidelines were implemented to reach and recruit a new population of paid subjects. As Chapter 3 shows, the pharmaceutical industry's quest was not just for human volunteers' but for an idealized body, healthy, disciplined and willing. Over time, the professionalization of subjects' participation ensured the pharmaceutical industry with the reliable research population they needed. However, the commoditization of volunteers' participation could not have been possible without another concomitant development: the emergence of the Randomized Clinical Trial (RCT) that took place around the same time and contributed to shape the social organization of clinical trial research.

RCT the "golden standard" of clinical trials research

Randomized Clinical Trials involving paid volunteers recruited by market mechanisms and regulated by the State are a relatively new phenomenon. In 1962 the Kefauver-Harris Drug Amendment act established the need to assess not only the safety of a drug -required by the FDA since 1938- but also its efficacy. In 1938 a drug commercially named Elixir Sulfanilamide containing a powerful, toxic ingredient, (diethyl glycol) went on the market causing 103 deaths before it was withdrawn. As a consequence the FDA demanded that the drug companies provide evidence regarding the safety of all drugs on the market. Until then, a 1906 FDA act had only demanded "truth" from the pharmaceutical companies regarding the accurate labeling of their products and the need to disclose the chemical composition of its formula.

In 1962 following another scandal, the FDA added the requirement of "well controlled clinical investigations" to ensure not only the safety but also the efficacy of drugs. While there was no explicit mention of Randomized Clinical Trials (RCT) these soon became the standard for biomedical research, using statistical models that had been introduced already in agronomy and biology in the Post-War era.

"By 1970, short-term clinical trials were well established as a legal Standard of therapeutic efficacy and as a Standard of excellence in medical research. Although randomized trials were hardly universal in clinical medicine, they were far more common than they have been two decades earlier (Marks 1997:195)

According to Marks, the implementation of RCT demanded and in turn, was pushed by, new forms of specialization and scientific knowledge. Statisticians view

the RCT as the ideal standard of a perfectly controlled experimental design that eliminated the subjective bias of the observer in the interpretation of the outcome. An earlier generations trust in the judgment of experienced researchers was to be replaced by reliance on an experimental method: "The use of properly designed clinical trials permits us to move from an authoritative frame of reference to a scientific one" (Marks 1997: 147)

Most medical researchers agreed. However, not all medical doctors were convinced of the benefits of such methods. Having relied on personal experience as the basis for knowledge many physicians had trouble accepting the idea of randomization and double-blind. Ultimately, the disputes centered on the authority of statistics versus personal experience as a way of producing knowledge. Marks argues that despite these conflicts, the RCT was finally adopted because statisticians emphasis on the need to raise the standards of therapeutic experimentation created an natural alliance with medical reformers who sought to improve the practice of medicine. In so doing, statisticians joined medical reformists as part of a larger self-proclaimed progressive movement. Supporters of the progressive movement came mainly among mainly educated, middle class Americans. This group believed that some level of social reform was necessary and that the best way to achieve social order was through the employment of scientific principles in an organized, modern and systematic fashion. The reform of the American Medical Association, the creation of licensing organizations, stricter professional control, and the restructuring of the medical education are typical Reformer's undertakings. Medical reformists in particular, directed their efforts to regularization and professionalization of medical

practice through "modern" science and rationality. This group made a particular effort to distinguish between professionally trained physicians and alternative practitioners and "quacks" healers. Statistic use was part of the rationalization and scientificity they advocated for medicine and the battle around its implementation in medical practice reflected the conflicting professional and ideological views in a changing field.

If the adoption of RCT was controversial among medical researchers it presented still more problems for the pharmaceutical industry. Although the 1962 FDA act established the need for "well controlled clinical investigations" there was no mention to RCT. The 1962 act was only regulated in 1970. There is no evidence of how the pharmaceutical industry interpreted and reacted to the requirements of the 1962 act[5]. Upjohn goes to the Court to challenge the 1962 act but the Court upheld the enforcement of the 1962 drug effectiveness amendments by ruling that commercial success alone –as proposed by Upjohn- does not constitute substantial evidence of drug safety and efficacy. In other words, this requirement should be provided by well controlled clinical trials.

Currently, double-blind, placebo Randomized clinical trials are now perceived to be the standard in biomedical research and clinical trials drug research. In fact, as discussed in the Chapter 7, the clinical trial design has become so dominant that it took years of concerted efforts of social mobilization from AIDS activist groups to eliminate the placebo requirement arguing that RCT involving a placebo were unethical and were designed exclusively to boost industry claims regarding drug

[5] Studing therapeutic clinical trials in medical settings Marks notes the difficulties of documenting actions and attributing motives to actors in a context in which historical documents are scarce or non-existent 1997:191) the problem is even more acute in relation to pharmaceutical industry trials, industrial secrecy.

efficacy. While there is a big black box in relation to the industry response to the introduction of the RCT in the 1960's, there is no doubt that they have come to embrace it whole heartedly. While it is impossible to document their motives, the notion that RCT helps to support industry claims about the efficacy of the drugs they develop and that their development is not a very risky business.

Clinical trials research and the quest for a "knowledge economy" in de-industrialized Philadelphia.

In the decades following WWII Philadelphia experienced a process of deindustrialization. While this trend followed national and international dynamics, it was particularly strong in Philadelphia due to the nature of its manufacturing base, the extent of sub urbanization and the degree of dependence on state on federal sources (Goode 1994). The city's industrial base relied heavily on the production of non-durable goods. For example, in 1950, 30 percent of Philadelphia's manufacturing jobs were in the non-durable sector while the national average was 19 percent (Summers and Luce 1988)

These industries were more sensitive to labor costs and had less fixed capital than durable goods producers. This condition facilitates restructure to accommodate new production technologies and capital flows trends, in comparison with industries that produce non-durable goods. Philadelphia's dependence on non-durable manufacture exposed the city to the loss of a disproportionate portion of its manufacturing base in comparison to other large cities. One of the most exposed sectors was the production of textiles and apparel, which accounted for twenty-five

percent of the city's total manufacturing employment in 1947. Between 1947 and 1986 this industry lost more than 97,000 jobs, an astonishing 74 percent of all jobs in the sector (Adams et al. 1991: 31) reflecting the impact of deindustrialization on the city. In total, Philadelphia lost nearly three quarters of its manufacturing jobs in the thirty-five year period between 1955 and 1990 (Stull and Madden 1990:22; Admas et al. 1991:30).

The extent of sub urbanization aggravated the effects of de-industrialization in the city. Most of the city's population and jobs had relocated to the surrounding counties that form the metropolitan region. While this pattern is by not means unique, data show that Philadelphia lost more economic activities to the suburbs than forty-two comparable standard metropolitan areas nationwide (Summers and Luce 1988). Between 1970 and 1980 the city lost 11.9 percent of its jobs, while there was an overall gain in the metropolitan area. For central cities nationwide, the average loss was 6.2 percent, which shows the greater impact of sub urbanization in Philadelphia (Goode 1994:30).

Finally, the effects of deindustrialization on the city were increased by the declining tax base coupled with a dramatic reduction of federal funding during the early 80's. In 1979 federal revenues were 25.8 percent of the city tax base; in 1988 they were only 705 percent (Pierce 1990). The fact that the city relied more on its local tax base than any other large city in the country added to its problems. As a result, the city experienced a severe fiscal crisis in 1990.

Impacted by its declining industrial and revenue bases, the city struggled to re-position itself by relying heavily as the service economy, experiencing growth in

finance, insurance, and real state and services the service sectors of business, legal and education during the three last decades.

According to Good, the emphasis the city placed on high technology and the service sector to address the effects of deindustrialization are similar to the policies implemented by other regional cities which are its competitors, which explains the limits of high technology or service restructuring in the city (Good 1994: 31). Good notes that the city was ill prepared to compete with other cities in the Northeast corridor that are economically or politically stronger. New York, Washington, Boston and Baltimore also have competitive advantages in many potential service industries like transportation or tourism. Good shows that where Philadelphia has had some success, as in its high-tech strategy of creating research and development parks like those in Boston or Raleigh-Durham, this has aided the suburbs and not the center city. It has also helped to develop the Princeton corridor and the new industrial parks of Route 202 near King of Prussia, a secondary central business district.

Despite setbacks, Philadelphia remains competitive in the health-care business, higher education and, in particular, biomedical and pharmaceutical research. The city is second only to New York as a location for medical schools, with more than twenty-five hospitals and ancillary institutions. Higher education is also a major industry, Philadelphia hosts two major universities (Good 1994: 36). One of the most successful areas in the shift towards a service economy has involved the location of major pharmaceutical industries that articulate with the research departments of local universities. While this area faces some competition, especially from Baltimore and Boston, its tradition as a major pharmaceutical center gives the city a competitive

advantage in the pursuit of a "knowledge" economy. Currently major international drug companies like Glaxo, Smith and Kline, Wyeth, Merk, Bristol Mayers have their headquarters or conduct clinical trials research in the Philadelphia metropolitan area.

Science, capital and government regulation in the making of the American Pharmaceutical Industry

Philadelphia had been the center of the pharmaceutical Industry in the country since the early XIX century when the first local chemical manufactures were established. Until 1812 America had imported its medicines from Britain but the war distorted this trade and created, in turn, opportunities for local apothecaries. According to Libenau, the laboratories of many pharmacies could expand into laboratories to begin large-scale production with relative ease since the industry was not based on capital investment and only a general knowledge of pharmaceutical practice was required. In turn, the simplicity of the procedures allowed considerable diversification, which facilitated the development of wide markets and the strategic use of particular product lines according to demand. (Liebenau 1987: 12). Foreign-trained pharmacists founded many of the new companies in the second decade of the nineteen-century, and these firms came to dominate the American chemical and pharmaceutical industry into the twentieth century. A good representative was Smith, Kline and French, which had acquired its apothecary license in 1829 and by the middle of the century was already well established. Around this time Philadelphia and New York became the main suppliers of drugs –mainly imported from London- that they distributed through marketing networks reaching urban and rural demand.

The Civil War represented a golden opportunity for the Philadelphia-based industry. The census of manufacturers in the city shows a significant growth between 1860 and 1870. According to Liebenau the number of establishments manufacturing medicines, extracts and drugs rose from 173 to 292, and the number employed in them more than quadrupled, from 1059 to 4729, while capital investment grew even more, from $1,977,385 to $ 12,750,809.

After the war, Powers and Weightman, Rosengarten and Sons, Simth Kline, Whyeth and smaller Philadelphia manufacturers all expanded. By the 1870's the Philadelphia medical manufacturers dominated the region and supplied the bulk of the southern and western markets, aided by developments in communications and transportation.

Fostered by the new opportunities for the exploitation of national markets by 1890, many drug companies grew substantially, displacing less successful competitors. In Philadelphia, Smith Kline grew, to the detriment of Wyeth and other large businesses, to became the city's most important dealer. Other regional players also gained considerable local and national muscle. Squibb and Merck in New York and Oarke Davis, Lilly and Upjohn extended also their markets.

As some companies grew they started to employ in their laboratories scientists as they began to emerge from medical schools that had adopted scientific-based knowledge about bacteriological and biochemical processes. Philadelphia's position as an outstanding medical center played an important role in bringing medical science to the attention of the pharmaceutical industry. However, the companies did not start immediately to produce drugs based on scientific principles and methodologies.

Instead, the companies assumed “more of the veneer than the substance of scientific medicine”. (Liebeneau 1987: 41) Usually, the pharmaceutical industry’s claims to science did not led to the installation of science-based laboratories. Despite the industry’s scientific pretensions, their labs did not resemble the research centers of their European counterparts based in Germany.

From the beginning the industry in the United States was a mixture of science and big business. (Balis 2000) In Germany its development was based on different premises. Organic chemistry began in the 1860’s when the molecular structure of basic carbon compounds as deciphered. In the second half of XIX century Germany expanded and improved its training of chemists. It was these scientists who founded an organic chemistry industry. Their research into coal-tar products, led after 1880 to a synthetic drug industry.

Aspirin was among the first and most successful of these German pharmaceutical products. From a similar research lines came Erlich’s development of Salvarsan, an efficacious drug for treating syphilis.

The German industry retained its connection to its scientific roots and was controlled by a technically trained directorate until the 1910’s. The link between academic training and industry remained strong. Germany dominated the international chemical market and was almost exclusive worldwide producer of coal-tartar based dyes, and other drugs until the First World War.

With such an industry and relatively unsophisticated technological origins, there was not the same impetus in the United States for a strong connection between

the academic training of chemists and the new chemical industry[6]. This was critical to the way in which the pharmaceutical industry developed in the United States.

For many firms, the use of science meant merely an effort to increase drug standardization

Two directories were published to inform doctors about drugs. One was the United States Pharmacopoeia, published every ten years listing drugs and preparations. The other was the National Formulary, which contained pharmaceutical formulas in current use.

In the course of their efforts to reform medicine, the American Medical Association established the Council on Pharmacy and Chemistry in 1905. The purpose of the Council was to encourage doctors to move against the forces that resisted the advancement of "rational therapy". It was also intended to discourage the use of patented drugs by physicians. The Council provided the standards that would allow physicians to prescribe ethical drugs with confidence. It was also an attempt on the part of the AMA to gain some degree of disciplinary control over the pharmaceutical industry. In 1906 the AMA established its own chemical laboratory with the cooperation of the American Pharmaceutical Association. It established its own definitions of acceptable drugs, as well as appropriate drug analysis and standards. Only those drugs that had been accepted for inclusion could be advertised in professional medical journals. With the passage of the 1906 Act the standards of the Pharmacopoeia and the National Formulary took on the force of law.

[6] For a more complete description of the relationship between academic and industrial pharmacology, see Swann, Academic Scientists and the Pharmaceutical Industry.

According to Liebenau, standardization, the employment of scientists, or even a small laboratory, did not necessarily imply a significant shift in a company's outlook during the last decades of the nineteenth century. (Liebenau 1987: 46) The author argues that the pharmaceutical industry held an ambivalent attitude towards science, it used science in its commercially as a promotional and marketing device but the scientific knowledge was not incorporated into the drug development process.

However, Libenau argues that by the first decade of the twentieth century many American pharmaceutical companies had adopted science not only at the rhetorical level but also in their production lines. Many of their products emerged from the laboratories, emphasizing their scientific qualities; science was now used to define whether a company had attained standards of quality. (Liebenau 1987: 79). Science-based laboratories helped to increase drug standardization, which in turn appealed to physicians giving the companies a competitive advantage. Also the use of science in pharmaceutical laboratories helped the industry to differentiate from "quack" proprietary drugs, enhancing the "modern", scientific image of the company.

The 1906 FDA act regulating drug production had demanded 'truth" in labeling. To comply with the law the drug had to be accurately assayed and labeled to identity contents. This requirement made the equipment of laboratories a necessary expense for all ethical drug companies. They accepted the necessity as a way for them to distinguish themselves from the manufacturers of patent medicines. Drugs were divided into categories, ethical and proprietary drugs. Proprietary drugs were patented substances. Their formulas were kept secret and they were advertised to the general public. Ethical drugs were those that were advertised only to the medical profession

and their ingredients and patent information were disclosed. Only patented medicines were prepackaged. In the case of ethical drugs, the pharmacist of physician prepared the prescription. There were however, no stipulations attached to the prescription. The druggies could make up enough for a whole family or package and sell the doctor's prescription to the general public (unless it contained opium).

Legislation was a response to the demand that state regulation be standardized, along with interest group pressures in such large pharmaceutical manufacturers as Smith Kline and French. The company wished to exploit their near monopoly on certain markets and the facilities of their laboratories, and to reduce competition by driving smaller producers out (Liebenau 1997).

Liebenau argues that the 1906 FDA legislation served to "rationalize" the industry, forcing out of business the small producers, mainly proprietary drug producers, who could not afford to equip themselves properly. The large pharmaceutical industries insisted on a high standard of purity that could not be met by small operations. As a result of this legislation, the number of companies competing in the marketplace declined while large companies with analytical laboratories continued to thrive.

An alliance between ethical drug firms and medicine was being forged in the name of science, and in opposition to proprietary medicines. The analytical laboratory was already well equipped by the turn of the century. The labs performed two functions: protected the company from purchases of inferior raw materials and standardized its finished products.

Pharmaceutical industry thus advanced aided by technological advancements, scientific ambitions and governmental regulations. The First World War provided a political incentive for the American Government to suspend German patents, allowing American companies to further accumulate capital by producing previously German-patented drugs. We witness here the complex interactions among capital development, government regulation, science and medicine.

With the beginning of First World War, supplies from Germany became unreliable further forcing America to produce its own chemicals and medicinals. While drug producers used patriotic rhetoric to abrogate German patents, used thus German technology to develop an American chemical industry (Balis 2000), only large companies benefited from this development, since the industry had become technically sophisticated, requiring considerable equipment, and investments in fixed capital.

The pharmaceutical industry emerged from the First World War stronger than before. Large government contracts and the acquisition of patents provided the bases for growth[7]. Industrial applications of organic chemistry in the United States became important only after bureaucratic and industrial structures had developed, and after a class of industrial management appeared. (Balis 2000:34). Mergers and takeovers within the chemical industry in the 20's led to stronger managerial structures an as well as scientific expansion. (Liebenau 1987). The business of pharmaceuticals

[7] Help by significant resources from the acquisition of German patents in 20's drug companies began to build solid research facilities. G.D Searle opened a lab in 1924, Smith Kline and French in 1925, Burroghs Wellcome (USA) in 1928. Other companies with minimal research staff expanded them in the late 20's and 1930's. Merk opened its Institute for Therapeutic research in 1933, Eli Lilly opened a research laboratory in 1934, Squibb opened the Institute for Medical Research in 1938, the same year the Abbot Research Lab opened its doors. (Swann, "The Evolution of the American Pharmaceutical Industry", Pharmacy in History, 37 (1995), 81

evolved within the context of the changing nature of American capitalism, but it was also shaped by the rapidly developing scientific discipline of pharmacology, which emerged as an important academic discipline during the end of the nineteenth and the beginning of the twentieth centuries. Furthermore, the relationship between academic and industrial pharmacology changed significantly in the interwar years, which had a profound effect on the shape of the emerging drug business.

The pharmaceutical industry used the language of science to legitimize itself. For many drug companies the rhetoric of science was important, as a way of redefining pharmaceuticals, and repositioning and legitimizing many pharmaceutical companies. This reflected a change in marketing strategy as well as changes in the product. In this context, it is perhaps understandable that academic pharmacologists in the United States distanced themselves from the pharmaceutical industry, fearing commercial exploitation. Over time, the need for funding, combined with assiduous courtship from the industry, broke their resistance (Swann 1994)

The industry experienced a period not only of growth but also specialization along particular product lines. Large producers that before the war had offered thousands of products centered their efforts on just a few. Small businesses that wanted to thrive had a strong incentive to merge with larger companies if they wanted to keep producing ethical drugs.

Although WWII with its demands for penicillin and antibiotics speeded up the organization of the pharmaceutical business, furthering research and product development on an unprecedented scale, Libenau argues that the new structures involving marketing as well as research and the relationship with academic scientists

and medical doctors had been built during the years preceding the Great Depression. (Liebenau 1987: 134).

The service economy and the emergence of the professional research subject.

The shift towards a service economy in Philadelphia had –as in many other large urban areas- dramatic effects not only at the top of the social scale but also, at its bottom. If for well-educated, entrepreneurial professionals in the "FIRE" sectors, biomedical research and education the new economy provided opportunities the same is not true occupations at the lower level.

While 75 percent of the metropolitan Philadelphia workforce is employed in non-manufacturing activities in the service sector, the shift to a service sector has not fully compensated for manufacturing job losses. As has been previously documented, the service economy provides employment with few, or no retirement benefits or health care, and lower wages. At the same time it produces a de-skilling in their workforce, making professional or learning through experience and apprenticeship industrial jobs something of the past. As a result, workers in the service economy move from one job to the next without acquiring any new skills that can lead to their upward mobility.

One of the most distressing effects of the shift from an industrial to a service economy in Philadelphia has been the emergence of a mass of vulnerable, unemployed or poorly employed workers. This group, along with others from around the country contributes to fill the slots in the emergent clinical trials industry. This process has been documented abroad by Rajan, which describes the inclusion of

unemployed workers into the trials economy who become subjected to speculative regimes of scientific research and capital accumulation in India.

"Just so, in Mumbai, one can see how forced deproletarization, as a consequence of a shift in modes of production from manufacturing to commercial capitalism, leads to the virtual death of an entire industry and to the creation of a new population of subjects who are retrenched workers and subjects of experimental therapeutic intervention". (Rajan 2005: 26).

In conclusion, this chapter describes some processes leading towards the commoditization of paid human subjects who volunteer for clinical trials research in America. Ethical regulations formalized after WWII established the need to select a population free of constraints and able to give "proper informed consent" to volunteer in the trials. Unable to keep employing "captive populations", as trial subjects, the pharmaceutical industry turned to a market recruited population.

This shift in the volunteer's composition happened at the same time that government regulation forced the industry to show not only that the drugs were safe but also therapeutically beneficial. Despite its initial opposition, the industry finally adopted RCT's as the "golden rule" in clinical research. As it had done in with the 1906 FDA drug act and the 1938 FDA legislation the industry managed to foster processes of concentration and centralization when it used it at its advantage. The adoption of RCT can be seen as the culmination in a process that turned the XIX century cottage laboratories into major bureaucratic institutions involving thousands of employees in multiple locations, carrying a variety of specialized managerial and scientific endeavors.

Industry growth was also due to technological and scientific innovation couched by direct government intervention, as in the case of Salvarsan and other German patents confiscated during WWI war.

The pharmaceutical industry in Philadelphia from the beginning was a significant player in the field and like many others pharmaceutical industries beyond Philadelphia, profited immensely from the State regulatory efforts. As Philadelphia experienced a profound shift from an industrial economy to a service oriented one, the industry would play a major role in boosting the city's pretensions to become a center player in the "knowledge economy" based on medical services and clinical trials research. While this process attracted a wave of upper-middle class professionals to run the more dynamic sectors of the service economy in the city, it also produced a significant number of unemployed or precarious workers with fewer possibilities for upward mobility, fewer benefits, and less pay than was the case in the old industrial economy. It is from these individuals willing to sell their bodies as commodities in the trials economy that the pharmaceutical recruits its subjects.

Chapter 3

"The biggest thing with a clinical trial is that it's a poker game."

The Social Organization of Clinical trials drug research in Philadelphia.

This chapter explores the social organization of clinical trial drug research, emphasizing its experimental nature as well as recruitment and retaining mechanisms put in place by the pharmaceutical industry that reinforce professionalization among trial volunteers. The chapter also describes the demographic background of the volunteers and their motives to volunteer in the trial.

The experimental nature of Phase I clinical trials and the use of Randomized Clinical Trial designs (RCT)

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 is 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, then 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 to be safe and therapeutically useful, it then receives FDA approval and goes on the market.

Phase I trials are conducted either at pharmaceutical industry research sites, at

contracted sites in University settings, or at sites held by independent contractors named Contract Research Organizations (CRO's). At this stage the professional knowledge involved 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.

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 "therapeutic" [8]trials in Phases II and III.

Recruitment, retention and professionalization of human volunteers in Phase I clinical trials.

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 or (RTC) used in Phase I clinical trials research.

A healthy and homogeneous trial population would ensure that all participants

[8] The notion of clinical trials research as being of therapeutic value has been challenged in recent years by authors who point out that the goal of drug research is not therapeutic but to produce knowledge. However, the emergence of HIV drug trials adds to the complexity of the discussion. I will deal with this issue at a later chapter.

have the same starting condition making it easy to attribute the outcome of the experiment to the various drug regimes to which volunteers were exposed. Therefore, the lack of any preexisting medical condition is an indispensable requirement for the realization of any clinical trial. Phone interviews screen medical histories, and screenings to select the candidates and again at the beginning of the trial serve the same purpose. A healthy population also contributes to minimize risks among volunteers by eliminating potential drug interactions with pre-existing medical conditions.

Pharmaceutical researchers not only need to recruit sufficient numbers of healthy volunteers to conduct trials but they need to do it 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 volunteers they need too early, but with unqualified candidates, would also put the trials outcome at risk, seriously compromising the volunteers' health and the trials validity. Thus, the ability to recruit the right number and quality of volunteers is critical for the organization of clinical trial research.

A glimpse at just a few advertisements of the hundreds 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 between 18 to 45 years old with flexible schedules. In exchange, the industry offers "financial compensation for time and travel expenses" or, more directly, invites 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 been historically and still remain the preferred human subject. The gender bias in recruiting volunteers is not lost among paid male 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". (Shon 6/12/2004)

Since toxic levels of experimental drugs are unknown –that is precisely what the study intends to determine -the pharmaceutical industry fears that experimental drugs might affect fertility and pregnancy outcomes in women volunteering in Phase I trials, exposing them to lawsuits. Despite this, the pharmaceutical industry has been encouraged in the last decade to incorporate a more diverse population in their 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 toxicology 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 pill was originally tested in men.

The demand for an idealized perfectly healthy volunteer

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 volunteers they recruit for their Phase I trials are "healthy" and

thus appropriate research subjects. Phase I trials depend not only on the recruitment but also on the capacity to retain volunteers. If someone, for whatever reason, withdraws from a trial before it is complete, the validity of the trial might be compromised. In sum, market recruitment ensures the availability of the large numbers 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 they play to ensure that clinical trials can be 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 7/28/2004)"

The demand for an idealized perfectly healthy volunteer is not lost on human volunteers. Paid volunteers 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 after and rewarded in Phase I trials, but a well-trained, disciplined and complying body –or subject- that the recruiters are seeking and rewarding.

There is not a clear guinea pig career. Some volunteers started selling blood or modeling for art schools, or doing less invasive procedures such as MRI's. Others

jumped right into trials. Most guinea pigs have done exclusively trials or moved quickly into trials. Idea that blood, semen 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 two or three weeks, at least, from the first phone interview to the time the trial actually begins. It is not until the first leg of the trial is over, or the whole trial -if it is a short trial with just one leg- that the volunteer gets paid.

When approximately half of the trial has been completed, volunteers receive a "check" for one fourth or one third of the total amount of the trial. The remaining amount is granted after the trial ends. In addition, a patient might receive a "bonus" at the end of the trial for the successful completion of the trial schedule. This discretionary sum usually ranges from a few hundred dollars to thousands in the most extensive trials, and while volunteers don't count on them, it certainly is a welcome addition to the "financial compensation". 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 might 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.[9]

[9] The pharmaceutical industry uses financial compensation either in the form of "bonus" for completion or the scheuled payment with the bulk of the compensation being perceived at the completion of the trial to

There are a number of ways in which 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 incoming 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", that is, older volunteers bringing new volunteers to a trial, usually from fifty to one hundred dollars, After a new volunteer finishes a trial successfully the volunteer who "referred" him gets a check in his mailbox. Anxious to fill slots, research sites attempt to recruit new volunteers for incoming trials even before a clinical trial is over. Participants usually receive "invitations" for screenings in future trials once the 30-day period between trials is over. Currently, volunteers are required to wait one month after they have finished a trial before submitting to screening in a new trial. This waiting period is implemented to 'wash out' or to eliminate any trace of the drug in the body. Usually a few days after a drug has been taken it cannot be detected in a blood test. Some people who participated in trials in the early 80's -when regulations regarding the need for a waiting period in between trials were almost nonexistent- remember that even before finishing one trial, volunteers were invited to screen for an incoming trial and if accepted, were enrolled right away.

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ensure compliance from subjects. This constitute an open violation to the Belmont Report and current ethic regulations that forbid the use of any means that might constrain the will of the volunteer to enter and remain in a trial. Decisions about participation should be free and voluntary. I discuss this issue further in Chapter 7.

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 new roommate at Fancy House, described how he entered his last trial, just a couple of days after I moved there in early February 2003. He was a 25-year-old white Kansan that 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 he 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 he 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 he could volunteer in. Actually, he called them not once but twice. 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 which included, for example, the prohibition to drink grape juice or to exercise heavily, because these activities interfere with the drug regime. Michael's trial is a typical double-blind placebo, or RCT, in which individuals are randomly assigned to different groups involving different drug regimes. He would not know which drug regime he would receive. He had been randomly assigned into one of six different groups receiving a combination of placebo and different drug regimes varying from 0.4 mg. to 10 mg. To test the safety and efficacy of the drug, he will get a tetanus vaccine and then a biopsy will be 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, the 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 are 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 trial participation. Having done clinical trials before, Michael knew he could not be honest about his vegetarian life-style. He passed the phone screening and was then called to do the 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. The screening lasted one hour and involved blood and urine tests, EKG (Electrocardiogram), BMI (Body Mass Index) measuring the ratio of fat on the body, weight and height measurements. Michael had to sign informed consent forms for the blood draws and other tests. The screening is very demanding and any minor deviation from requirements might exclude a volunteer from joining. Luckily for Michael, a few days afterwards 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 of the trial 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 involved. He read the Informed Consent Form 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 he would volunteer for. It was an eleven-week, outpatient trial of a new, anti-inflammatory drug for which he would receive $1700. The study was designed to test the safety of the drug. The trial involved three groups of approximately 8 volunteers;

a maximum of 30 volunteers would be recruited.

Five days after he qualified, Michael showed up at seven thirty in the morning at Jefferson to start the trial. After signing the Informed Consent Form, he had a new round of check-up 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 two o’clock in the morning he was awakened for additional tests, but was not given any drugs.

He “dosed”, that is he 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 doing it at five-minute intervals. 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. Out of eight 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 slept one night at the hospital, the first one. He left the same evening to return the next morning. The days in which he just “dosed” and had blood drawn he spent less time there than when he underwent biopsies. Six days into the trial he had a 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 he would finish the trial and receive the money, and 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 as a matter of fact.

After cashing his trial's check he spent it on a brand 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 ten dollars 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.

Demographic data of volunteers of Phase I clinical Trials in Philadelphia

I surveyed 18 people participating in at least one paid phase I clinical trial in Philadelphia. Their ages range from 21 to 46. Most of the volunteers are in their mid twenties to late twenties. All but four volunteers are men. Ethnically, the large majority of volunteers self-identified as white-Caucasian, one volunteer self-identified as Latino.

The volunteer's educational levels ranges from unfinished high school to Post-graduate student, however, the large majority of volunteers concentrate in three categories: finished high school (4), unfinished undergraduate degrees (6) and finished undergraduate degrees (6). One volunteer did not finish high school and one

was doing doctoral studies. Only three of them owned their own house, but in all three cases the owners shared the property communally. The large majority lived also in communal houses but did not own them and paid rent. In relation to their health coverage, the vast majority of volunteers do not have any kind of HMO or health coverage plan. Just three volunteers 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".

"Except for the needles and the pills it sounds like a vacation!"

Survey findings confirm that financial incentives are very important in shaping volunteer's decisions to enroll in Phase I clinical trials. Data analysis shows a striking unanimity in the volunteer's responses. All pointed to financial gain as their main, and in almost all cases, only motive to volunteer. Only two individuals mentioned an altruistic motive along with the inducements of financial incentives. However, it should be noted that in this case the responses belong to volunteers who were not part of the ""guinea pigs" community based in West Philly[10].

[10] In part these two professional volunteers have a different social background reflecting the heterogeneity of the larger paid human subject population in the country. While they share similar experiences as paid volunteers with the anarchist population, they also diverge in significant ways regarding issues of social identity and in particular their views of the ethics and politics of clinical trials research. I discuss these issues in Chapter 4. I included them to gain a comparative perspective and the limited representation of this group in my sample makes any generalization very risky and highly exploratory.

This attitude is also reflected in the volunteer's response to another survey question inquiring about their main consideration to enter the trial. All the volunteers pointed to financial benefit as their main consideration regarding whether they would enter a trial or not. In addition, volunteers noted that the duration of the studies and location were also important considerations. The risk level was mentioned by some but the underlying assumption was that trials in general do not pose big risks for volunteers. If a particular trial was perceived as risky, volunteers said that they would not participate in it regardless of the financial incentives involved. I discuss the issue of risk perception in depth in Chapter 5.

Nathaniel, a young volunteer having 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 these guys what 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 varies 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).' (Nathaniel 12/9/2004)

Since money plays such a relevant role in the volunteer's experience it is not surprising that volunteers are 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 incoming trials in the area and about the financial compensation offered.

When paid volunteers refer to a trial they completed or one they might want to join they always identify the trial by the amount of money offered. Sometimes this information is accompanied by the duration, type of trial, that is, in-patient or outpatient, and the drug being tested. Finally, the sponsor of the trial offers information about the physical location of the trial. They would say something like this: “A $ 3000, two week, in-patient (or out-patient sometimes) trial for XXX drug with such and such sponsor”. Volunteers are not only aware of the financial potential of a particular trial but they also compare the potential for daily and even hourly earnings. Volunteers use these ratios to make decisions among competing trials. All things being equal, the trials that pay a higher ratio per day/hour are preferred. As a general rule, Guinea Pig Zero, the Human Subjects Zine for professional human subjects edited by Grand pa guinea pig and reflecting the views of anarchist volunteers in Philadelphia, advises potential volunteers to turn down any trial that pays less than $ 200 a day for an in-patient study in the Philadelphia metropolitan area.

Clinical trials for Phase I drugs around the metropolitan Philadelphia area typically offer between $ 200 and $ 400 per day to volunteers. Compensation for engagement in a trial might range between $ 1200 for three or four days in less intensive trials to $ 5000 for volunteering three or four weeks in more extended ones; exceptionally a trial might need 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 in their occasional visits to the research site to follow up with the trial schedule. Volunteers are also compensated for being "alternates" in a particular trial. Alternates stay the first night of a trial as a potential replacement for any volunteer in the trial in case he or she cannot participate. Usually, the alternate walks away the next morning with $ 100 without having taken any drug or undergoing any blood draws or intrusive procedures. "Alternates" are scheduled to participate in the next cohort of the trial, thus gaining an additional sum to the total trial payment.

"Better than a Mc Donald's Job"

Participation in in-patient 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 in-patient with out-patient 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 to work at all at the time of the enrolment. As many volunteers admitted, the independence and flexibility, not to mention the income, allowed by participating in clinical trials was "much better than a Mc Donald's job".

The requirement for a "flexible" schedule is reflected in the occupational structure of the volunteers interviewed. Eleven declared 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, but the vast majority (8) had part-time positions. Of those who held full time jobs two were labor organizers, one helped to

organize supermarket workers, and the other was working to organize janitors in the city. The remaining volunteer working full-time and held two jobs, one repairing bikes at a cooperative bicycle store, and the other selling books at a children's bookstore.

Among volunteers who held part-time jobs their employment represented a diverse scope of jobs and trades. Most of the jobs were independent, blue-collar types of occupations such as construction work, painter, bike messenger, house or office cleaner, housekeeper or cook. Three volunteers worked part time at "The Wooden Shoe", the oldest anarchist bookstore in the city that is run as a co-op. The large majority in the sample self-identified as "blue collar" or "working class" background. 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 their participation in 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 the eventual enrolment unpredictable and in volunteer's terms, un-reliable. Urine and blood samples might be contaminated and not just by the use of illegal substances, but by bacteria found in the testing lab. Even if the samples are not contaminated, their values might be too high or too low to prevent 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

prevents candidates from entering the trial. Certainly, there are many other contingencies that conspire against the enrollment of a perspective volunteer that 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. In this context, volunteers sometimes rely on a part time or even full time job seeking a more steady source of income.

Scott's trial experience reflects well the shift between informal jobs and clinical trial participation.

> "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 XXX and 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 blood stream or something like that. It was pretty easy and I got paid all that money so I was, wough! 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 job occasionally but I kept doing the drug studies mostly at YYY" (Scott 6/3/2004)

Professional "guinea pigs" at the anarchist community in West Philadelphia

The anarchist community in West Philadelphia concentrates 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 Pennsylvania University

campus with its remodeled houses and nicely kept apartments to the south 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 their typical food stores, restaurants and shops. It also hosts 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 the local of the International 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 anarchist call the "A space" a hang out and organizing room identified by a big black sign with an encircled white a in the middle. A few houses away a colorful, hand painted sign advertises the Food Coop "Mariposa" where most of the radical communal houses buy their food. On the corner of 50th street and Baltimore stands the "Firebird House" also a coop, which repairs and sell bicycles. Bicycles play an important role in the community enhancing the self-reliance and autonomy of their residents, which in a literal sense, run "outside of the system" by using a medium that is perceived to be not only cheaper than mass transit but also cleaner. The place is also used by the community especially during the summer when is wormer, as a "hang out" space, to exchange gossip and meet people but community members ride their bicycles all year round. The Farm Market at its side provides fresh, organic vegetables to a community of politically correct hard core "veggans".

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 their occupants managed to buy it from the city, Cider Garden, The Farm, Rainbow House, House of the future. At the corner of 49th was Fancy House were I lived. Most of the houses have a porch filled with plants and sometimes objects nobody cared to reclaim or to remove. Although the front might be painted, they 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 their owner's punk, hippie and anarchist aesthetics and preferences. All the houses have, in addition to the resident's room a place destined for their bicycles, indexing the place bicycles have in their everyday lives. The back yard usually has a very well kept garden.

Fancy house is a good representative of the way the radical community organizes their 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 had a meeting with the residents who were interested seeing if I could fit into their community. I had the credentials, was social and politically aware, knew somebody in the house already, and was able to participate in "house meetings" and fulfill my assigned chores that included emptying the bucket with organic compost we had in the kitchen in the backyard garden. Like most community housing, Fancy house residents cooked their meals together and wanted to know if I had a vegetarian diet. I didn't, but after I assured them I was willing to contribute to the food expenses and that I wouldn't use their pots to cook meat, they let me in. My presence helped balance the gender balance at Fancy House. Finnley in her mid 20's, had arrived just

a couple of months before I did and worked part time at a magazine in Delaware. Marisa, also in her mid 20's arrived just a few weeks before Finnley from Kansas and worked as a bike messenger. Asia in her early 30's 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 and was a very active member of Act Up. Jamie, in his mid 20's, was also from Kansas and moved to Philadelphia at the same time Marisa did. He was also a bike messenger.

Michael also in his 20's from Kansas, knew Marisa and Jamie before moving there. 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 also representative of the larger radical West Philadelphia scene, involved in the informal economy, in badly paid jobs that don't 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 as Act Up. Some radical community 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, XIX century beards, tattoos and piercing.

Living in a community housing affords residents a cheap rent and low food costs. Rent varied in relation to the size of the room, larger rooms paid slightly higher rents, from $190 to $ 230 a month. Fifteen dollars for "Food money" was deposited in a box kept in the fridge every week. Fancy house, like almost all

community hosing in the neighborhood, bought the food at the food co-op "Mariposa". In exchange, every resident had to work two hours a month in the co-op. 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 Fancy House residents reflects a larger trend among the radical community in West Philadelphia. Community members are always coming and leaving. Being such a closely-knit community where everybody knows everybody, there is a significant potential for disagreements and personal misunderstandings. This perhaps explains the fact that gossip is one of the most frequent topics of conversation along with political and social issues. Members sometimes shift their social relationships by changing housing arrangements. If this is not enough, they might leave the city for a while for a similar community somewhere else. Networks connect anarchist communities in Seattle, Vermont and West Virginia among others.

"Guineapigguing" as lifestyle

Ideology, community activism, life-style issues or just plain high tech consummerism push volunteers not only to move back and forth between informal jobs and volunteering in clinical trials, but also moves them to participate exclusively in clinical trials. Like Scott, many professional guinea pigs feel attatched to the "novelty"of selling their bodies as human subjects for toxicological clinical trials research. As Jennifer, one female guinea pigs described her year-and-a-half spree of

clinicals trials participation by saying, “you become addicted to the easy money, you don’t want to do anything else”.

Paid volunteers interviewed participated in more than one trial. Some of them have volunteered in just a few, but most of them have been regular trial participants. For example, seven volunteers have done more than 20 or more phase I trials. Some remember having done 30 or 40 or even more, although they recognize they don’t keep track after a while. Eight volunteers have 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 to five. Three volunteers had stopped participating in trials some years ago. Most of their trial’s participation takes place in or around the metropolitan Philadelphia.

The income derived from clinical trials participation allowed “professional guinea pigs” in the West Philly area to buy huses they later transformed into communal housing, to travel around the world, buy state-of-the-art computers and “chill”. As noted above, trials afford volunteers flexible schedules and “free time” leaving plenty of room to pursue other interests and occupations. A glimpse into some volunteer’s interests as well as to the ways in which they spend the trial obtained in the trials provide a good indication of their every day activities and routines.

While volunteers in the anarchist community of West Philadelphia pursue a broad range of everyday activities and interests –indexing the anarchist ethos of individuality and pursuit of individual interests – some general trends can be traced.

For example, Dave Onion arrived in Philadelphia six years ago. A native from 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. It is here that he learned about the clinical trials, and after completing a few trials he was able to buy a dilapidated house from the City of Philadelphia for $5000. Using his background as a construction worker, he rebuild the property entirely, repairning roofs, setting the kitechen, and even installing solar pannels to replace electric energy. The house has an unfisished, rough finnish –even by community standards- and seems to be always in repair or undergoing some reform project. The energy provided by the solar pannels is not enough to support central heating or even a fridge, and the rooms have a gloomy, mysterious atmosphere . However, Dave 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's house is an extreme case of self-reliance and autonomy –few 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 commoditized, market-driven society.

Trial money also gives volunteers time to do community organizing activities. "The pharmaceutical industry is financing community activism in Philadelphia" said a close friend of Grand pa guinea pig, the editor of Guinea Pig Zero . Almost all self-identified anarchist guinea pigs engaged in some kind of community activism such as organizing rallies against the Iraq War, International Worker's day, Act Up, and work

with many other local community organizations and causes. My fieldwork coincided with the beginning of the Iraq War and this issue permeated not only my interactions with them but also their every day lives and organizing efforts. A very politizised community, International and local politics were current topics of debate and animated most of our as well their conversations.

For example, Dave 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 due to the lack of steady investment. When completed it would accommodate Radio Volta, -a community-based radio transmitting from one of the communal houses in West Philadelphia. In addition, it will host a popular library –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 carcases were piled up in a corner- and the office of the Defenestrator, an anarchist periodic publication among other projects.

Although the Defenestrator had an editorial board composed by Dave's girlfriend, Mc Mike, a vetern "guinea pig"and bike repair man at the Firehouse bike shop, along with Pau,l who also sitted in the committee, among other ocassional members, the publication was the braichild of Dave. He wrote the majority of the articles, collected advertisement funding from friendly individuals or organizations and contributed with income from trials if needed. He also made the distribution, placing numbers to be picked freely at strategic places in the nighborhood like the A space, the Food Market, Mariposa and also at the dowtown's Wooden Shoe anarchist

bookstore. Dave also was involved with the International Workers of the World (IWW) and helped organize the commemoration of May I, Worker's Day usually a gathering in a nearby park accompaied by political discourses related to the occasion, workshops, music, food and beverages.

The A Space, provided a venue for political and community organizing. The A Space was the center of activities against the War and in particular helped coordinate the community's participation in Anti-War rallies. It also hosted numerous fundraisng events, not only related to the mobilization against the war, but also featuring an invited speaker from the Chiapatistas movement, for Guatemalan human rights, a documentary movie on factories being run by workers in post-neoliberal Argentina or a vegetarian dinner.

In addition, Grand pa guinea pig implemented at the A Space the project "books behind bars", collecting books which he latter delivered to prisoners in the state of Pennsylvania. After he left for Paris, a friend of his, a fellow professional "guinea pig", continues Bob's work. The fact that anarchist members contributed with books for this project, relfects not only Bob's standing and reputation in the community, but also the privileged position literacy has among its members. Although the 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 is a significant part of their everyday life. Many communal houses have libraries with readings that include from the classics of anarchist litterature, to authors like Garcia Marquez, Eduardo Galeano and Noam Chomsky. Many residents work at the anarchist bookstore and have ready access to books and

other printed materials. The community has its own peridic publication, The Defenestrator (as mentioned above) and Guinea Pig Zero, a zine for Human subjects. Quite a few explore different literature genres. Among volunteers, for example, Spam –a major in English- writes short stories. The value accorded to literacy in this community is derived from their anarchist ethos which also accords a privileged position to "self-education" as a means of developing an alternative class understanding of the world, based on the rejection to bourgeois values and parctices. In addition, part of anarchist ideology also values a working ethic based on manual labor and the hability to "work with one's own hands". Thus, it should come to no suprise that the anarchist community of West Philladelphia, and in particular, its professional "guinea pigs" exhibit an enormous interest in developing some kind of craftmanship, artisan work or creative manual activity.

My roommate Michael was a professional jewelry and clothing designer and used a considerable amount of time and effort working on his creations. Another volunteer plays the clarinet on Friday's evenings at the local Farm Market. Volunteers at "the Farm" have converted the basement into an industrial-like carpentry site. They have created numerous wooden furniture pieces along with wood and metal sculptures. One of them also fabricates his own brew of home made beer, which he also stores in the basement to let it 'sit'.

Most volunteers are around their 20's and 30's. Mostly of them are single and childless with flexible schedules and no permanent attachments, and trial income offers them the opportunities to have fun and travel. Anarchists held elaborate parties that often included DJs and topic customs in community houses almost every

weekend. Sometimes they had a political or community fundraising purpose, but birthdays, Halloween, or just the welcome or farewell of a member of the community 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 arrangements. Dave travelled to Bulgaria and Mexico as well as to other destinations, Michael lived in Spain before comming to Philadelphia and left to Spain after completing a sucession of trials. Spam had embarked in a tour that led him to know South Asia and India. Bob had lived in France a few years ago and permanently resettled there a few months after I moved to Philadelphia.

In addition to the travels, trial income also serves to purchase of expensive commodities, such as laptop computers. Showing a clear understanding that their bodies are also commodies, guinea pigs would often enroll in a trial as part of his or her arrangements to travel, get a new computer I deal with the issue of the commoditization of the body in Chapter 4.

King Lab Rat: a window into the professional "guinea pig" outside the anarchist West Philly community

I met Denny at the downtown Youth Hostel during my first "reconnaissance" trip to Philadelphia in the summer of 2002. A first generation American from Puerto Rican background he alternated Spanish and English while talking to me, mainly about women and sex, his most important concern aside from volunteering. Outspoken and talkative he was not shy about being a professional "guinea pig" and

we readily made a good bond. In his late thirties he had come from Florida for a trial at Whyeth and trying to save money, stayed a few days at the hotel 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 came back to Philadelphia one year later, I contacted him and we made arrangements to meet once he had the opportunity to come back to the city for another trial. He arrived at the beginning of January from Wisconsin where he had tried to volunteer for a trial but things did not go as he had expected. After his arrival, Denny learned that the two week trial for which he will get $3000 would not start until one month later. For two weeks he stayed in a homeless shelter in the downtown area trying to hold out long enough to make it into the trial. Denny explained to me that conditions at the shelter were bad and that he could not "take it anymore". He traveled to Philadelphia by bus, arrived penniless, and unable to even afford a cheap hotel was staying with a Puerto Rican friend. He was hoping to enter a trial at XYZ, pay some debts and pocket some money.

I was able to go with him through his trial at XYZ. We met regularly before and after his screening sections and also in between the trial and at the end. Denny was pleased with the attention and happy to help me with the research. At my suggestion that he invent a pseudonym to protect himself against possible retaliation from the industry, he performatively chose to identify himself as King Lab Rat. It suits him fine since he is the most experienced professional "guinea pig" I have encountered. Denny had been volunteering since he was discharged from the army in his early twenties for allegedly beating a sergeant. In between trials he also sold drugs

and also worked in the Philadelphia Morgue. He had done trials since the mid 80's at most trial facilities in the country from Miami to Texas, including the mid west, and especially in New Jersey and Philadelphia. Despite a tendency to idealize the past, as a supposedly familiar environment where everybody knew everybody, were trial opportunities were plenty and working conditions were better, Denny embodies – literally, 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 became professional "guinea pigs".

His motivations to enter the trial are not different from those of the anarchist volunteers. For Denny the trials are a business, an opportunity to make money. However, in this respect Denny introduces an additional motivation absent from anarchist volunteers. He believes that trials could also represent an opportunity for scientific advancement. He told me: "We're doing something good for the people. Hey, the drug might work!" Discrepancies on this point are related to their different positions in relation to the validity of scientific knowledge behind drug development.

As we will see in Chapters 4 and 5, on major topics such as social identity as paid subject, criteria to select the trials and risk assessment and response, Denny's positions do not differ in important aspects from those of the anarchist "professional guinea pigs", contributing to create a "guinea pig" culture.

Denny knew Grand pa guinea pig and other regular anarchist subjects. He had volunteered with Bob at Wyeth a couple of years before, and when I asked about him, Denny readily identified Bob as the "white guy". Racial differences were only part of Denny's estrangement from Bob. Denny 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 free thinkers". To Denny such ideology is "wacky and politically wrong". Finally, he also suggested that anarchism is "thievery", replacing private property by social property. In his trial at XYZ he had not encountered any anarchists.

During my first visit at the Youth Hostel I met also another professional "guinea pig". He was also in his thirties, white, from Canada, had been living in the country for a couple of years. Recently he had moved to Tennessee where he hoped to launch a career as a folk singer financing himself with the money earned as a volunteer. He encountered Denny and used him to gain knowledge on 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 XYZ, so I followed him through.

King Lab Rat 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 –beside the altruism behind their participation- is their geographical mobility. Anarchist volunteers living in the West Philly community venture sometimes to trials in neighboring New Jersey and can eventually volunteer in trials in other areas. However, most of their trials are centered in or around the metropolitan Philadelphia

region. By contrast, other professional "guinea pigs" –in particular, living outside Philadelphia- exhibit larger geographical mobility. One reason behind this difference is that Philadelphia affords enough trial opportunities to local who do not need to travel beyond its limits. In addition, the familiarity with social networks and trial facilities operates as a powerful incentive to volunteer in the area.

In conclusion, this chapter shows that the professional "guinea pig" plays a major role in the social organization of clinical trials. Without their participation the pharmaceutical industry would have significant trouble running an increasingly higher number of clinical trials, compromising drug development and thus, their entire business model. Dependable, trained and disciplined bodies are essential to the trial economy and the industry offers them good financial incentives to keep them as volunteers. In fact as this chapter shows, financial gain is the only motive shared by all subjects. Professional guinea pigs in the anarchist community join the trials exclusively for the "easy money" which offers them the income and the flexibility they want to pursue their anarchist lifestyle based on community living arrangements, social and political activism and healthy doses of travel and leisure time. Dependence on the income derived from their clinical trials participation shapes their perception of, and willingness to, engage in risks related to clinical trials research.

Chapter IV

"They don't pick you for your mind, they want you for your body". Commoditization, class formation and resistance among "professional guinea pigs".

Introduction

This chapter documents how the use of paid volunteers has contributed to shape the social identity of volunteers leading to group solidarity and even class identification. In particular, the chapter analyzes the role played by GPZ in shaping or reflecting the group's identity as well as their ethical and political stand in relation to the pharmaceutical industry and biomedical research employing human subjects. This chapter uses the study of the first "guinea pig" strike to explore forms of collective response to the working conditions volunteers face in the trials. Finally, the chapter also covers other forms of resistance used by paid volunteers in clinical trials and explores not only the potential for a sustained collective action among guinea pigs but also its obstacles and shortcomings.

"The rent-use of your body and the inside operating fluids"

When asked about what they think they are being compensated for as participants in a trial, volunteers do not hesitate. King Lab Rat, a 39 yeas old Latino volunteer that has travel to almost every trial facility in the country since his early 20's and defines himself as a "professional lab rat", offers one of the most comprehensive answers: "It's for the rent-use of your body and the inside operating fluids, that's it pretty much in a nutshell". Paid volunteers understand that their body

is a commodity and that is for their body, "fluids therein" that they are being "compensated" by the pharmaceutical industry. Hinting at the alienation produced by volunteering in paid clinical trials research Grand pa guinea pig noted that "They don't care about your mind, they want you for your body".

As seen in the previous chapter, volunteers strategize their participation in trials to supplement or gain income to support themselves or their life styles. Volunteers' clear understanding of their bodies as a commodity stands in opposition to industry's denial that commoditization is taking place. The industry uses a series of rhetorical moves to move away from their reliance on commoditized bodies. One semantic turn is the pharmaceutical industry's definition of volunteers' participation in trials. Institutional recruitment advertisements for Phase I clinical trials research seek to enroll "paid volunteers" in exchange for "financial compensation of time and travel expenses". It is hard not to note the oxymoron behind being called a "paid volunteer" for clinical trials research. How can somebody be simultaneously paid to do something voluntarily and free of constraints?

Also the suggestion that time and travel expenses is what volunteers are being compensated for is revealing. It suggests that the pharmaceutical industry intends to compensate volunteers for the income they failed to generate or lost by engaging in a trial and for the costs incurred by joining the trial. In turn, this form of financial compensation would be "an exchange" for the willingness of a "paid volunteer" to join a particular trial. What this language intends to mask is the fact that volunteers are not "paid volunteers" but workers placing their bodies and not just their time at the service of the pharmaceutical industry. The industry's attempt to deny that labor is

being extracted intends to place the "exchange" beyond the regulation of labor laws. The industry's denial of commoditization has a schizophrenic character. On one hand, the industry ignores commoditization through a language that stresses voluntariness, and avoids references to labor, pain and suffering. On the other, it contradicts itself by offering "easy money" in exchange of participation and the continuous references to financial inducements in order to recruit volunteers that otherwise have no other motivation to participate.

In response to the industry's characterization, volunteers are quick to note the cynicism of such an approach. Contesting the oxymoronic label of "Paid Volunteers" they realize that their participation is not free of constraints, and that it is not free will but money that brings them to participate in research trials. This point will be further explored in Chapter 7 in relation to volunteers' perception of the Informed Consent Process.

Professional "guinea pigs" understand that when they volunteer in a trial they are entering a business relationship, a contractual arrangement. Some volunteers explicitly defined their work status as "short term contractors", having signed a contract, the Informed Consent Form with specific duties, responsibilities and rights, and even paying taxes, although this is a mere normative requirement since most volunteers never consider doing so.

"The mild torture economy: you are not asked to produce or to do something anymore, you are being asked to endure something".

Volunteers understand their participation as trial subjects as a particular type

of work not based on physical labor –the traditional image of work and workers, influenced by their anarchist and working class background. Professional "guinea pigs" have the sense that while volunteering for a trial " You don't do much" " Jut lay there" or as Nathaniel put it in the previous chapter, "except for the needles and the pills it sounds like a vacation ". Most guinea pigs would agree with Chris who taking this fact into consideration classified the trials as "A weird type of work".

> "I don't know, another thing kind of funny too is that the manufacturing has been taken off, outside the country, so you are not allowed to do things any more. They call it the new economy, the informational economy. And the other side of this informational economy is the mild torture economy, you are not asked to produce or to do something anymore, you are being asked to endure something. So, if you are a guinea pig you are enduring something, people are doing things to you and you are just enduring it, you are not actually producing something. I feel that I am a worker but it is not work, it's like a security guard that does not produce nothing, just watches stuff. A security guard just gets paid to be bored, it's about how much can you deal with being bored, that's the real hard part of it, the time and discomfort of being there. But it's different when you are in a cleaning job, I am doing something but being a guinea pig is just being paid to endure something that happens to me, which is weird. It's a different type of activity, I still feel that there is some work in it but the nature of work has changed. And I am letting people pay me in exchange to the control they have over me. (Spam 7/28/2004).

This quote is particularly insightful in describing the nature of the guinea pig's work: being paid not to produce but to endure something, or in other words, to be a subject to regimes of science and capital accumulation.

Most of the time volunteers spend as inpatients is filled with dead periods when they are just laying in bed, waiting to do a blood draw, or just hanging around chatting, watching TV, playing games or reading. Like the security guard from Spam's example, volunteers are bored most of the time and this is one of their main complains about the experience of being a "guinea pig". In addition, volunteering

might be painful, in particular if the blood draws are not performed skillfully or if there is trouble to "find a vein" which are common occurrences. King Lab Rat adopted a "macho" approach to pain and suffering and boasted about his capacity to tolerate pain which he saw as a clear sign of masculinity. He also confided to me how he dealt with the discomforts of being a research subject. He said that he focuses not in his body and what is going on. Instead, he thinks about the things he is going to do with the money he will receive. [fieldwork notes]. The detachment between the mind and the body experiences and the emphasis on material gains and in planning is similar to strategies adopted by sexual workers during sexual encounters.

The understanding that their body is a commodity and that they are entering a market transaction also shapes volunteers understandings of the activity they are engaging in, but also their social identity. Instead of viewing themselves as "paid volunteers" they see themselves as workers and also "guinea pigs". In fact, veteran volunteers or volunteers who derive their main income from their participation in clinical trials usually identify themselves as "Professional Guinea Pigs". Volunteers even came up with a verb "guinea pigging" to define their professional activity.

> "Well, not patient because this would imply that they are doing something to improve your health. Kind of worker, although such of strange kind of work, definitely guinea pig. Well, I think that it's both, worker and guinea pig because you are paid to take this risk and also for this kind of weird dehumanization. It's funny, what it gets me the most is getting EKG's I guess. And it's funny because it's for my safety and it is not invasive, has no side effects, but I take my cloths and these people start putting things over my naked chest and then is when I feel like a guinea pig more than a worker. It's so much like sex work, like been exposed to a dominatrix out there, it's so demanding. It's something that most people wouldn't get through. The guinea pig part is also because they pay you just to demean you to animal status, you are just letting yourself be measured by the functions of your organs and stuff, something that most people wouldn't agree with (Shon 6/12/2004)"

It is clear that human volunteers are "guinea pigs" only in a figurative, metaphorical sense. The analysis of these metaphors is important it because sheds light on the relationship between paid volunteers and the pharmaceutical industry. They are also key to understand social identity among guinea pigs, and the relationship they enter into when they volunteer for a trial.

The metaphor of a "Professional Guinea Pig" encapsulates at the same time their identity of workers, somebody who holds a profession or trade, and somebody who is paid to take risks and to be dehumanized. Shon's definition of guinea pig covers two intertwined meanings. One relates to the animal, the species traditionally used in biomedical research. This image evokes notions of passivity, objectification, and ultimately alienation. His comparison with sexual workers further reaffirms this dimension of the guinea pig experience. In fact, the association between "guinea pigging" and sexual workers comes frequently among professional "guinea pigs". Echoing Chris' idea that volunteers are paid to "endure something" in a "mild torture" economy Helms, elaborates the relation between both:

> "There are similarities with sex work because you get penetrated, you get needles, you get the tubes, whatever. They are penetrating your body. You really get penetrated. It is not an illusion; it is not a figurative thing. That's one similarity with the sex work. Another thing is that you are renting up your body and they don't care about what you are thinking and they don't want to be talked about, they just want your body to do something and react to the drug so they can watch it" (Helms 1/15/05)

There is another meaning associated with the term guinea pig and it expresses a metaphor for somebody who takes risks in an experimental context where the outcomes are uncertain. The way it is used by volunteers, to be a "guinea pig", or a professional one, is to be paid not only to be dehumanized but also to take risks, to

face uncertain outcomes. Volunteers are aware of the history of ethical violations, human rights abuses, and even some horrors involved in biomedical research. How much do they know about the risks they face and how they respond to them will be the topic of the next chapter. “Professional Guinea Pigs”, unlike other workers, do not sell their labor power every day in a continuous relationship. Instead, a Guinea pig does it in a discrete way based on fragmented trial participation. Their “Contractor” image defines this characteristic well. Paid volunteers shift from one trial to another, alternating with periods of other informal jobs or just unemployment.

In their view, the payment received is not for abstract “time’ as presented by the pharmaceutical industry, but instead, time filled by the boredom and the discomfort experienced during the trial. The industry might be recognizing this fact since the amount of money volunteers receive is in direct relation to the discomfort of the procedures, such as the number of blood extractions, or the need for intubations or more invasive procedures, as well as the time spent in the trials. Professional guinea pigs are well aware of these criteria, and even experienced guinea pigs boast that they can predict the amount of money they would receive for a trial based on the trial schedule where the time and procedures are specified.

The short-term nature of their engagement with a research site has serious consequences for the way they see long-term risks. Once the trial is over volunteers tend to think that the risk is also over. Unlike workers in the coal and mining sectors, or asbestos or other cases of industrial pollution, the lack of continuity in their trial participation disrupts the social networks and shared experiences that would allow “Professional Guinea Pigs” to focus on long term risks. While anarchist volunteers

form a more stable and closely-knit community than the rest of the paid subjects in the country, the previous observation also holds here. I will develop these issues in my discussion of risk in next chapter.

Guinea Pig Zero and the making of a "guinea pigs" class.

As E.P Thompson has shown in The Making of the English Working Class, the production of print materials played a relevant role in shaping the class identity of the XVIII century English working class. In this classic masterpiece, Thompson demonstrates how through the production, distribution and discussion of journals, pamphlets and other documents, industrial workers come to reflect and shape their own identity as a different group of people with similar interests, and in turn, not only different but also people with opposed class interests in relation to the capitalist class.

In a context marked by the existence of a professional, market-recruited population for clinical trials research, guinea pigs also employed journals to nurture forms of class identification and solidarity. Social class can be defined in many ways and none of them are free of debate and contestation. While some definitions stress life styles and subjective self-identification as indexes of class position, others emphasize, for example, the objective relationship with the means of production. In this classic formulation, according to Marx, those dispossessed of the means of production need to sell labor to earn subsistence. Critics point out that changes in the capitalist mode of production relativizes the utility of this definition because almost everybody is in the same position.

Despite these observations, I want to retain the notion that the relationship

with the means of production shapes group identities in terms of shared interests and experiences. In the case of "Professional Guinea Pigs", for example, they share a similar social identity based on their trade and their experiences and views about the organization of the trials and their participation. "Professional Guinea Pigs" also have similar forms of knowledge that include medical lingo and even similar forms of humor. They also share not only working class identification but also most professional guinea pigs hold working class jobs.

"Guinea Pig Zero: A Journal for human research subjects" was edited in Philadelphia by Grand pa guinea pig from 1996 to 2000. During this period eight numbers were published. The first numbers were sold for $ 2 although later numbers which included more pages were sold for slightly more. Old numbers could also be purchased for $ 4. Estimates about readership are hard to make because the editor kept printing and selling old numbers by request along with recent numbers, but he places its reach between 500 and 1000. In 2001, after discontinuing the zine, the editor decided to publish an anthology of "Guinea Pig Zero". Both the zine and the anthology gave Bob some publicity and made him known to a larger public.

Although Helms was the editor and writer of the majority of the contents of the zine, he saw Guinea Pig Zero as the product of the collective efforts of professional guinea pigs across the country. "I tried to portray the experiences not only of myself but other guinea pigs I knew and knew about GPZ. In particular places I also give my own opinion but it was me based on a group of people who had done it. It wasn't just based on my own experience and nothing else". The zine, according

to his editor, was a forum to voice the "perspective of the guinea pigs and that's all it ever tried to be. The company can go to hell. They are not writing this magazine".

Helms decided to publish a zine just a few months after he started doing clinical trials. Before entering trials he majored in literature at Temple University where he also participated in student protests in support of the striking faculty. Later he took a job as a field organizer for the Hospital Worker's Union. From 1991 to 1994 he spent time campaigning with Human Service workers. After he left his last job he worked at painting, carpentering and construction jobs in Philadelphia. While he entered his first trial in the mid nineties and kept volunteering until he left to France in 2003, he also kept doing some work on the side to supplement his trial income. He does not remember how many trials he has done, but has done at least forty, all at XXX, the only place that allowed him to do trials after he became well known for editing GPZ.

He based his journal on earlier zine models like Dishwasher and Temp Slave! Both belong to a sub-zine genre, the jobzine which according to Helms "treated unglamorous jobs as the platforms of culture" (Helms 2001). In a personal interview he expanded his understanding of the genre.

> "[A jobzine] it is a zine about what people would consider a crummy job, not a career goal and not having a career goal that necessary goes farther than that. In other words, you had a life but your life was not around working for somebody else, your psychology was not sold out, you had your own identity. Your world did not include what your boss said your world was. Your work was just your work, you were yourself, your own person and your goal was not to kiss your boss' ass. Labor movement kind of idea, job zine with emphasis in a particular trade and also the idea of freedom from industry. I never took an aid." (Helms 1/15/05)

The first number was published in May 1, 1996. The 32 page issue was printed only employing black and white colors and inaugurating what would become a tradition, its cover portrayed a guinea pig wearing a hat and a tie. Later issues would portray guinea pigs in different postures, being attached to medical instruments, dead, or standing on a bowl supposedly containing Paxil, a psychiatric drug, and others.

The date chosen, celebrating a major landmark in labor organizing and identity, was deliberate although the number does not make any explicit reference to it. While Helms did not hide his anarchist beliefs either he also opted not to make his political ideology the center of the zine although the zine was clearly focused on labor issues and working class, or "guinea pig" identity and solidarity.

The editorial for the first number introducing Guinea Pig Zero to the reader presents the zine as a space to discuss their experiences from a guinea pig's perspective. The main point made in the presentation is that in contrast to the objectifying, alienating treatment they receive as research subjects, guinea pigs are mindful subjects with shared trajectories and interests.

> "They [scientists] want us to tell them how we're feeling, and whether our minds and bodies are coming apart, and then to leave it at that. But every guinea pig discovers, after a short period of time with the species, that we constantly tell each other what's on our minds. In fact, we have a little society of our own, with folklore, our own strange humor, special cares and most importantly, a commonality of interests" (Helms 1996).

The publication attempts to make clear to their readers not only that guinea pigs have common interests, but also that these interests are in opposition to those of the scientific establishment and, in particular, the pharmaceutical industry. According to Helm's editorial, it is "unnatural for a guinea pig to let the scientists know what he's thinking".

One of the goals of Guinea Pig Zero is to rescue the value of the contribution human subjects have made to further biomedical research. While volunteering for a trial might be alienating and dehumanizing, according to Helms "on the other hand it takes the human research subject to the level of civilization when he or she looks in the mirror and sees the face of a specialized worker, whose craft has its own wondrous history, its own jargon and its own little culture" (Helms 2001). This proud identification with their work among guinea pigs no doubt echoes the way in which workers have spoken about themselves since the beginning of the industrial revolution.

The organization and contents of Guinea Pig zero reflect their concerns and interests. The first number provides a good glimpse into "guinea pig" culture. One of the main issues for the zine is the radical re-appropriation of the history of human subjects in experimental research that puts the subject not at the center of the process. Instead their experiences and contributions are contained in a narrative that places biomedical science at the center with volunteers at the margin. The first article in the zine, "The treadmill of History", explores the history of participation of human subjects in biomedical experimentation stressing, on one hand, the contributions made by volunteers, and the ethical violations of their rights on the other. The zine also presents sections about guinea pig humor, home remedies offering help "for clean, fresh blood", and a book review section on "The double blind", a 1960's novel involving clinical trials research by the author John Rowan Wilson.

A quick reading of the contents of this zine number indexes the concern with revalorizing the contribution of human subjects to biomedical research throughout

history as well as the attempts to foster a guinea pig "culture" with its shared meanings, interpretations and particular forms of humor. A later number, for example, offer humorous hints on "How you will know that's He's a Pro: The signs of a Bona Fide Guinea Pig". Among the clues are: wearing clothing or accessories printed with the research unit's logos; knowing more about blood chemistry than a second-year medical student; interrogating waitresses about poppy seed content of bread products; references to one's anticubital vein as a "financial pipeline". It's easy to see the proudness behind being a "professional guinea pig" in these jokes. Other jokes I heard during my fieldwork make the same point by stressing and ridiculing the differences between a professional guinea pig and an inexperienced, paid human subject.

The second number introduces the report cards, a central concern of Guinea Pig Zero with the working conditions faced by professional guinea pigs. Here fellow guinea pig members evaluate clinical facilities in the country giving them grades for items such as: amount of financial compensation on average per study, quality of the facilities and the food provided during the trials, professionalism and skills of the staff, their capacity to avoid unnecessary procedures during the screening process or changes in the schedule. Since evaluations depend on individual guinea pig accounts, some are more detailed than others, although all of them cover these points that are perceived as instrumental in choosing a research facility. In addition, other reports also evaluate more subjective topics such as the "environment", or the "atmosphere" of the facility.

The report cards were one of the more popular sections of the zine and represented Helm's attempt to stress shared material interests among professional guinea pigs. While other sections of the zine challenged dominant representations of guinea pigs among the biomedical sector, the report cards signaled a more direct threat that could interfere with the capacity of such places to recruit new human subjects. If the facility was a Contract Research Organization (CRO) hired by a pharmaceutical company to conduct trials, a bad grade could also alert the sponsor of the trial to review the contract with the organization. It is not surprising then that after Harper's published one of the report cards in which Guinea Pig Zero had evaluated and reported the failures of a clinical trial research facility by Helms he was sued for "libel".

Although the case was dismissed after Harper rejected Guinea Pigs claims as unfounded, the emotional drain of facing a trial and what Helms interpreted to be a "cowardice act at my expense" from Harper's later apology left him wary. Entering the debate about the libel lawsuit, Philadelphia Magazine confirmed independently that the report card issued by Guinea Pig Zero was accurate. Helms covered his libel trial in one number of Guinea Pig Zero, providing a class analysis to explain how Harper's Publisher, the grand son of the billionaire philanthropist MacArthur sided with the interests of the industry and against Guinea Pig Zero. As I mentioned in the introduction, this episode also served as a cautionary tale for me by alerting me to the potential conflicts that might arise from the critique of a very powerful industry.

The "Guinea Pigs" revolt.

In December 2002 a group of guinea pigs volunteering for a study at XXX successfully challenged a major pharmaceutical company and obtained a significant concession by threatening to "walk out" in the middle of the trial. When I met Grand pa guinea pig a few months later, one of the first things he asked me was if I was familiar with the strike at XXX. I was. Dave, a close friend of Bob, and also a veteran guinea pig living in West Philly, had joined the same trial and gave his version of the event in the Defenestrator, a periodic publication that represents the views of the anarchist community in Philadelphia. Bob, in turn also wrote a piece for the International Workers of the World (IWW), an anarcho-syndicalist union. Every guinea pig in West Philly was familiar in one way or another with the walk out at XXX and offered me their candid perspectives on it. Even "guinea pigs" who were not in the area at the time and who moved into the city later on, soon became "socialized" into the master strike narrative. Part of their excitement comes, no doubt, from the fact that the guinea pigs were successful in challenging a powerful company they have "no sympathy for". In addition, the event represented the first time guinea pigs in the West-Philadelphia radical scene had successfully used the threat of a "walk out" to press the Pharmaceutical Industry to accept their demands.

The trial started in early December at the facilities of XXX a research hospital of one of the oldest and more traditional medical schools in the city. Volunteers tested a low dose of an anti-anxiety drug -"enough to cause some drowsiness but too low for a mood change" according to Bob- for a major Pharmaceutical company that regularly carries out its Phase I clinical trials at this facility. The trial with its pre-

screenings and follow-up appointments lasted seven weeks. According to the schedule the trial would have five sections in which volunteers were supposed to stay in the hospital for four days with releases in between each of these stays for 36-hour periods, except for a break during Christmas and New Year. As it is the case in extended trials involving invasive or unusual procedures, the recruiters selected experienced, reliable guinea pigs. Among the volunteers there was a slight majority of African Americans, followed by White volunteers, all between the ages of 18 and 45, the usual age range in Phase I clinical trials research. Three volunteers were from the radical West Philadelphia scene and most of them knew each other from earlier studies.

As part of the trial schedule volunteers had to defecate in a container so that the staff could search for the remains of the drug tablet. Along with this procedure, a catheter was inserted and fifteen blood samples were collected during each period. The diet was regulated so that all volunteers would get the same meals. For the duration of the trial volunteers were required to abstain from drinking alcohol or using any other drug, including aspirin or vitamins.

Volunteers were to receive $3350 for the completion of the study. Before the first segment of the study was, over everybody agreed that the pay was too low for the inconveniences caused by the trial's schedule. Guinea Pigs were talking about leaving for better paying trials in the area and complaining about the conditions of the trial. In particular, the impossibility of drinking alcohol during the Christmas break caused major worries among volunteers. Dave, a 32-year old volunteer, and an experienced guinea pig and editor of the Defenestrator, summarized their mood well:

> "I think that it was really a collective thing. And it is not always that people start talking about leaving. There were many folks saying: "I'm getting the fuck out of here and I am gonna screen for this other study". Especially because it was Christmas it was a lot of people willing to lose the $ 1000 they would get for finishing the second part of the trial, you know. And also, it was such a pain in the ass to do the study: it was not like you could go, sit down and read a book or anything. You were constantly being demanded to do something else every twenty minutes or something. It just like made sense to us to do something like that". (Dave Onion 5/18/2004)

Within a few days into the study volunteers charged Grand pa guinea pig to write a one-page memorandum that "respectfully" asked for a re-negotiation raising the financial compensation for their participation to $ 4.500. Bob was well known both to volunteers and to XXX staff, which he had earlier evaluated for Guinea Pig Zero, giving them credit for decent pay and professional staff. However, Bob took care not to appear to be the organizer of the event. When gathering signatures for the memorandum he was careful to show that the argument was not coming mainly from him. "Another guinea pig walked the paper around the ward in plain view of the staff and I signed my name in the middle of the list rather than first" Bob confided. Within a day volunteers managed to secure the signatures of all but one volunteer. However, some peer pressure made him sign after the list was completed, and he asked the management to let him sign it too. Six volunteers met the staff at XXX to formally deliver their memorandum with their claims.

To influence the management, volunteers kept talking among themselves about leaving the study in the middle for other studies which would have caused a major financial set back for the sponsor since all data collected at to that time would become useless. On the other hand, quitting a trial after the first half is over only deprives a volunteer of half of his income, which is prorated in relation to the days in

the study. Bob also suggested that the volunteers ingest flexible vinyl propaganda scraps, so that the staff would find little notes reading “more money” in their feces but his idea was rejected.

After delivering their note, the volunteers were promised an answer before the holiday break. XXX clinical trial managers informally assured the volunteers that they understood and agreed with their request. The final decision though rested with the Pharmaceutical Industry that sponsored, and paid for the trial expenses. On the evening before the group was about to leave for the holiday break they had not heard from management and were increasingly anxious about their demands. Just a few hours before their release, the unit director summoned all volunteers to the lounge for a brief announcement. XXX had gotten the authorization from the sponsor to raise the financial compensation volunteers would receive for participation in the trial. Instead of the sum required in their memo guinea pigs received a $ 800 increase, which was still “plenty of money”. We all “cheered and thanked them profusely” Bob wrote. For their part, before the meeting broke, the nurse “emphatically stated” that what happened should not set a precedent and that volunteers can not “band together” to put pressure on sponsor in the middle of a trial. She assumed that this was an unusual case where the special trial requirements had not been adequately incorporated into the financial compensation.

According to Bob and Dave’s written and oral testimonies of the successful walk out at XXX, the event had erupted almost spontaneously without major organizational work. While anarchist guinea pigs certainly played a role in the events, they are quick to emphasize that they were not instrumental in leading it. “Some

people had some union background and I was surprised how easy it was. I know some union organizers and just watching them trying to organize people even on a small scale it's not easy for them. For us it was just little effort, like two people needed some work but everybody else was on board from the beginning" (Dave Onion 5/18/04)

While the walk out was a collective enterprise this should not obscure the role played by more radical guinea pigs in articulating their demands and presenting them to the staff. Grand pa guinea pig, with his experience as labor organizer and his familiarity with XXX staff, played a key role in his efforts to mobilize guinea pigs. This was also his last trial. He was soon about to reach 45 years of age, the age limit imposed on Phase I volunteers. The unrest among volunteers facing what they thought were unfair clinical trial conditions might have provided Bob with an opportunity to finally fight the Pharmaceutical Industry.

The confluence of radical labor organizers and a population of professional guinea pigs volunteering for a trial under unfair or tough labor conditions has no doubt presented itself before, if not in other cities, at least in the Philadelphia metropolitan area. Why did it take so long to successfully launch a concerted collective effort to address them? And what does this successful attempt mean both for the guinea pigs and the pharmaceutical industry conducting clinical trials in the region?

While open conflict between volunteers and staff are rare, the potential for open or more veiled forms of conflict between staff and volunteers is embedded in the social organization of the trial. Members of the staff such as nurses, technicians and

lower ranking administrators and recruiters, are the first to mediate between management and volunteers. This buffer position exposes them to demands, concerns and anxieties of the volunteers. Male anarchists tend to be more sympathetic toward nurses than other volunteers. Anarchist volunteers tend to see Registered Nurses, phlebotomists and other technicians on the staff as occupying low paying jobs which are also exploited forms of labor. Certainly this sympathy does not prevent them for complaining specially in the cases where lack of skills are involved. In particular, poor blood extraction techniques have painful consequences for volunteers which sometimes are not shy about it.

Changes in schedule cause major inconveniences for guinea pigs by altering their schedules and compromising their ability to carry out other activities such as work or political and social activism as well as disrupting to social life.

African American and Latino volunteers might also experience discriminatory treatment. Denny felt clearly race was an issue in the way staff related to him and others, an impression that I was in position to confirm by talking with radical white male volunteers. Since I was unable to observe directly relationships between staff and volunteers, or among volunteers themselves, I had to rely on indirect accounts through the narratives the volunteers.

In addition to these structural sources of conflict, the walk out threat was a collective response prompted by what volunteers perceived to be unfair and unusual working conditions. While bad or just plain hospital foods or excessive blood draws are presents in many clinical trials, the need to preserve the feces is not a usual arrangement. According to Bob, volunteers were unhappy about the odors and the

discomfort caused by the procedure. Still, what gave them the sense that the trial conditions were too hard or intolerable for the amount of money they would receive was the fact that the trial schedule had been changed since it had been signed by volunteers, and it was so compressed that as Helms put it: “practically you had no wash out periods [the break between the legs of the study], you were always in the trial”.

As a result of the changes, the trial, which was supposed to be conducted over the Fall, was pushed up to the last weeks of the year, going over New Years Eve. When the volunteers started the trial they soon realized that they would need to come back after the Christmas break for the last part of the trial. This realization, along with the organizational efforts of savvy anarchist organizers among them, who rallied volunteers to sign the memo, might have been enough to successfully launch the walk off threat.

According to Helms and Dave one of the conditions that made the event a success was that all of the volunteers were “Professional guinea pigs” who knew each other form the trial scene. Two central conditions were thus instrumental in launching the “walk out threat”. Being professional volunteers, members had a shared understanding of what it is possible to accomplish in the context of a clinical trial. They knew that their numbers and the structure of the trial divided into many legs afforded them a relatively powerful position to support their claims. If the trial could not be continued the sponsor would both lose all the data and compromise seriously their research schedule. A professional body of volunteers also ensured according the necessary degree of mutual trust needed to engage in such event. As Helms told me

"nobody is gonna risk their money for somebody they don't know and that they don't trust".

Another strength of the effort was its focus on a single, central and immediate demand focused on the amount of money they would receive for their clinical trial participation. The guinea pigs collective action did not attempt to change working conditions at XXX on a permanent basis, or to address larger issues related to the way clinical trials are organized and conducted by the pharmaceutical industry. The volunteers were clear in delimitating their grievances and claims to this particular trial and its special circumstances. Despite the differences among volunteers, they all shared the same interest, maximizing the income they obtained through from the trials. Although this contributed to their success here, it does not provide the grounds for extending forms of collective action that go beyond such immediate material concerns.

> I also think that what happened at XXX was in part, a unique situation. I think that it will be difficult to organize GP, also because so many people are coming and going, there is a lot of instability with people that are guinea pigs too. Half of the people are just doing it for once or twice and it would be difficult to make them take a bit of a risk. They just want to get some easy dollars and don't think about it again. I think that there might be easier to get people together around other issues around safety, accountability and health kind of stuff. I think that's what worries people more. (Dave Onion 5/18/04)

According to Bob and Dave, but also many other guinea pigs I interviewed, working conditions are usually good at XXX. As mentioned earlier, Bob gave XXX unusual high grades in his ranking of clinical trial research sites. Also he noted earlier, the staff is professional and the pay scale is the standard for the industry.

Given the comparatively high income afforded by volunteering in clinical trials, individuals have few incentives to challenge the industry.

Another factor that might explain the difficulty in organizing guinea pigs is not only that they are usually well paid and they don't have many incentives to risk their source of income, but they are a very mobile and unstable population. Some guinea pigs travel across the country seeking the most profitable trial opportunities. Others, like the anarchist community in West Philadelphia, only volunteer for trials in the metropolitan area. In addition, volunteers move in and out of clinical trials alternating between a number of informal and formal occupations and activities. To complicate things more, clinical trials seldom last more than a few weeks. Certain trials can be done in just two or three in-patient days, while others need a little more than a month to be completed. After the trial the volunteers might not see each other for a long time, if they ever meet again. Finally, for many guinea pigs doing trials is not part of their social identity and therefore they do not have a large degree of investment in improving trial conditions, the ethics or regulations of the trials. All the informants I talked to about the possibilities for an organized guinea pig action suggested that it was very unlikely to happen under the current circumstances. Many things needed to change before we can see a union of guinea pigs they noted, pointing to the need to change the capitalist system first. In any case, the conservative and antiunion atmosphere in the country makes it hard to discuss these issues. Still, there are other, more subtle ways in which the guinea pigs resist the conditions they face as clinical trial subjects.

The awareness of the limits for any kind of sustained organizational work among guinea pigs nuanced their excitement about the success obtained during the walk out at XXX. Grand pa guinea pig edited an anthology of Guinea Pig Zero in a Popular Press and discontinued its production. Just a few months after his last trial participation at XXX he moved to France where he lived in a working class neighborhood in the suburbs of Paris. He gained his living by doing some painting and construction jobs, although his difficulty with the French language made things hard for him. He was considering doing some clinical trials in Paris as well.

It is also difficult to forecast how the successful walk out success might shape the organization of future clinical trials in the area. After participating in the XXX events Dave did a couple of trials, although not at this facility. He was unsure about how the Pharmaceutical Industry might respond to the walk-out, but hinted at the possibility that they might end up moving south where labor costs and organized opposition were lower.

> "I am sure Merck thought about it too but I am not totally sure which effect it had in reality. I think that a lot of studies are apparently moving south. I think that Merck or some big pharmaceutical company just opened a place in the South. The North people are paid a lot more than in the South. I've heard about some places in the South that you get paid $ 100 a day or $ 150 a day. Compare that to BM [Bristol Meyers], which for some studies is paying $ 400 a day. I think that for the pharmaceutical industry, companies like Merck that should sound a red light in the sense that they have to improve things if they don't want to lose trials patients to the South or whatever. I don't know it's hard to tell really" (Dave Onion 5/18/2004)

The landscape of the Pharmaceutical Industry in Philadelphia changed dramatically almost two years after the events of December 2002. The major pharmaceutical giant that sponsored clinical trial research at XXX ran into serious trouble after its billion-dollar blockbuster drug Vioxx was retired from the market

when the FDA announced it presented an unacceptable risk for patients. While there are still trials being conducted at XXX, its future as a CRO seems to be linked to the resolution of the problems at the Pharmaceutical Industry giant that sponsors its trials there. In addition, GSK another international pharmaceutical company based in the city announced recently that it has stopped its recruitment of Phase I volunteers. Certainly, I am not suggesting that these developments are related in any form to the successful walk out threat at XXX. They seem to be fueled by international, national and also local considerations. What is certain, however, is that these events have the potential to alter radically the livelihoods of hundreds or even thousands of people that in one way or another relied on the income provided by their participation in clinical trials.

"It's a pretty common thing that people are always bringing things in and it really fucks up the data"

While organized forms of collective action against pharmaceutical industry interests are rare among volunteers, individual acts of resistance, or what De Certau called "resistance of the weak' (de Certau 1982) plague the routine development of clinical trials. Professional "guinea pigs" have a number of ways of resisting or challenging the authority and power embedded in the organization of trials obliquely and indirectly.

Professional "guinea pigs" for example, consciously and deliberately disrupt the way clinical trials are organized. Usually the food provided during in-patient trials is at best, 'institutional food", homogeneous and not very tasty. This circumstance

provides the guinea pigs with a good excuse to supplement their diet as in-patient volunteers with food sneaked in from outside. Clinical trial settings vary in the extent to which regulations and procedures are standardized and enforced. Most research sites in the Philadelphia metropolitan area do not search volunteers when they enter the research facility as trial subjects. This lack of institutional zeal affords opportunities to bring in diverse products to supplement an anticipated poor or restrictive diet. Seeds, peanuts and fruit are preferred items among professional "guinea pigs". Most volunteers are not vegetarians, a requirement for clinical trial participation, but those who lie to be admitted, find it hard to follow the meat based diet. Except for the few trials where the staff closely monitors volunteers in their diet intake, undercover veggies "trade" food with others, exchanging meat for vegetables.

Avoiding the trial's drug is not possible for in-patient volunteers who are closely monitored, but out-patient trials are less strict and have less possibilities to ensure compliance. Occasionally outpatient "guinea pigs" succeed in avoiding the trial's medication. During fieldwork I met some out-patient volunteers who avoided taking part of the drug or drug regime. In some cases volunteers coordinated between themselves to avoid taking the drug or part of it. In other cases these were just individual decisions. While in some cases volunteers who disrupted the diet or drug regimes were only taking advantage of lax or nonexistent controls, these can become rebellious acts. This is particularly evident among anarchist professional guinea pigs who hold a clear anti-industry stand. Shon an anarchist volunteer with an experience of more than ten years of paid clinical trials is not shy in explaining the ways in which he attempts to resist and subvert the everyday routines as a human subject.

> "I even try to sabotage the results now and then. I am pretty cynical and don't think that the trials result in much medical benefit and most of the guinea pigs feel just the same way. So we bring in snacks when we are supposed to be fasting. I do it consciously to screw them, but other people do it because they are veggies and are hungry and in part to screw them and take their dignity back. It's a pretty common thing that people are always bringing things in and it really fucks up the data, you know. If you are going to do a blood test and you just had a candy bar before, that would bust your sugar levels a lot. But, so, I don't have any bad conscience about perpetuating capitalism by being exploited by the pharmaceutical industry (Shon 6/12/2004)".

As Shon recognizes, cynicism is associated with these acts of resistance in clinical trials. In particular, anarchist volunteers do not have faith in the clinical trials research and the pharmaceutical industry. As previously mentioned, volunteers note that the demands for a perfectly healthy volunteer can not be met. In spite of this, the volunteers, the industry and goverment agencies pretend that this is not the case. In addition, anarchist subjects' observations about the exclusion of women and minorities from the clinical trials and the possible effects of this on the outcome, also adds to their cynicism.

But acts of resistance are not only explained by the lack of belief in the promises of science but also by the shared opposition to a process that exploits and dehumanizes volunteers. These small acts of resistance are a way in which they recover their sense of humanity and agency while faced with a powerful institution also indexes a social system that they oppose.

Mindful of these acts of resistance clinical trials are carved out in a controlled setting with heavy surveillance of volunteer's bodies, checking dose intake, diet and other critical issues. I believe that if there is an element conspiring against the validity of clinical trials research it is not to be found in the limited attempts through wich volunteers try to disrupt the process, but more importantly in

the trial's lack of representation of women and other demograhic groups in their population. In addition, as I will argue later, the main problem with clinical trials is not their validity but their lack of innovation, since most of them are trials for me-too drugs, re-runs of drugs that are already in the market but where the companies feel they can still find a niche in the market by marketing a new brand of the same thing.

Anarchist volunteers have not only a cynical view of the pharmaceutical industry but also a traditional hostility towards them. Having this in mind, how do they explain to themselves their engagement as clinical trial subjects which, if successful, would benefit the industry they despise?. Radical male professional "guinea pigs" do not see their participation in a trial as a contradiction. They have thought about this issue and their narrative on this topic is very uniform and carefully laid out. They are quick to point out that both the pharmaceutical industry and themselves intend to make money performing clinical trials research. According to their view, exploitation is inalienable in the capitalist society and dependent labor relationships are prone to be exploitative as long as they remain in this framework. The pharmaceutical industry is exploitative but they point out that the same was true of other forms of paid labor they held in the past, as truck drivers, burger king employees, or UPS conveyor belt workers. "Guinea pigs" recognize they are helping the industry make profits, but this was also the case in other paid labor positions.

Anarchist female paid subjects: their views on the commoditization of their bodies in clinical trials

While I met fewer anarchist women in my fieldwork I can not avoid noting that those I met seem to be as critical of the pharmaceutical industry as their male counterparts, but also, seemed to be more troubled by their role as subjects. Farmgirl in her mid 20's, had moved from Chicago to Philadelphia less than two years earlier, lived in a couple of houses in the West Philly community and earned her income alternating between trials research and a part time job as an office cleaner. She sold her blood for $70 on a regular basis until she learned about the possibility of volunteering for the more lucrative in-patient trials. She had done five trials, almost exclusively at XXX.[11] Farmgirl who does not take medicines in her everyday life and also has actively participated in campaigns against pharmaceutical companies, is troubled by her role as subject:

> "Definitely it actually makes me sick that they [the pharmaceutical companies] rub the money in front of my face and I take it and support something that I don't support in any other way and don't want to support. It is also something that is kind of easy to justify. When I did the first study it was just because I didn't had any money. And I justified it like: this is a part of society I don't believe in and do not want to be a part of, and here I am, and poor me. Of course, I take money from the drug companies because they suck, I take their money. But now I have more money and feel that I cannot do it any more, at all. May be I take a break but then they call you and tell you "just come for five minutes and get $1000000". And once you do them it is kind of addictive, you just keep doing it. But I definitely hate these companies. I have spent time boycotting Proctor and Gamble and other companies and then these pharmaceuticals offer you all this money and here I am, back again. I hate

[11] Farmgirl is concerned about long term risks and had not volunteer in trials that involve new, "first in man" drugs which she perceives as high risk. Ironically, she had volunteered for a trial involving Vioxx, sponsored by Merck which she thought at that time to be low risk. It was a drug already on the market and even her granmma used it. A few months after our interview the FDA withrew the drug from the market because it presented unacceptable risk levels of heart failure episodes among users.

> them, really hate them. It is something I definitively struggle with. (Farmgirl 6/1/2004)

Women, like their anarchist male counterparts, are quick to express their antipathy and distrust of the Pharmaceutical Industry and the State. But anarchist women make no detours to say that they see their participation in clinical trials research as a contradiction, not only because it helps the pharmaceutical industry profits but also because it represents a biomedical model based on treatment rather than prevention, of which they are also very critical.

The critique of the biomedical model by anarchist women represents an important distinction in relation to male volunteers' perceptions. Although male "professional guinea pigs" are very critical of the ethics of biomedical research they are less vocal about the science behind the trials. This fact has a direct relevance to the way "professional guinea pigs" understand and deal with the risks they face in volunteering as clinical trial subjects. This will be the topic of my next chapter.

As mentioned earlier, women have less opportunities to participate in trials and they usually do not rely on them as their main source of income. Anarchist women have only sporadic possibilities to enter the trial economy and therefore are freer than their male counterparts to take a tougher stand towards the pharmaceutical industry and the social organization of trials research.

In conclusion, professional "guinea pigs" are aware of the value of their bodies as commodities in the "economy of the flesh", as Grand pa guinea pig put it. This view contrasts with Industry efforts to deny the fact that "paid volunteers" are in fact not voluntering but are working, and are not being compensated for their "time and efforts" but for their labor. As professional volunteers recognize, they do a

"wierd kind of work" since they perceive themsleves as being paid not to do something but do endure something, that is, to be a subject. This fact is conveyed by their methaphorical use and indentification with, the image of the guinea pig. The image conveys ideas of passivity, subjectivity, objectification and ultimately alienation which makes some of them compare their situation with that of sexual workers.

Professional "guinea pigs" and in particular anarchist subjects have created a strong working class identity based on their common experiences and interests that lead them to reclaim the dignity of human subjects in biomedical research.

Opposition to the pharmaceutical industry takes many forms, usually small acts of sabotage, introducing forbiden food into the facility, purposedly altering blood or urine results, and other minor acts through which subjects express their identity and humanity in conditons that commoditizes and alienates them. This chapter has explored everyday acts of resistance, but it also describes a major collective event in which professional "guinea pigs" mobilized to achieve better working conditons. The analysis of this event sheds light on their identity, ideology and working experiences, but it also reveals the possibilities and the limits for collective action. While the presence of a strong sense of group solidarity and shared interest might favor engagement in forms of collective action, the uniqueness as well as the conditions that made for its success reveal also its limitations. The relatively high income volunteers derive from their participation and the fluidity and mobility of this population make forms of organizing extremely difficult.

Chapter 5

The Construction of Local Knowledge and risk management among professional "guinea pigs" in phase I clinical trials in the United States.

> "So you know, when you start doing studies you start meeting the regulars that have been doing trials frequently, may be ten years if not longer, and they are fine. You hear from time to time some horror stories but they seem to be such an exception. So when I talk with people that have been doing it for a very long time I think that trials are really very low risk compared to these other occupations I was talking about. But there are a few things that make me wonder. I've noticed that people sometimes, maybe because they are scared to think about it, don't really recall risks once they are over. I remember a guy was saying he never had side effects and that he was fine and then we were talking about things and he said that that had done an HIV trial for a medication and he had jaundice because it stayed in his liver. He didn't think of it as a side effect, he probably didn't like to think about the whole instance. So, I think that it is pretty rare, pretty extreme, but I wonder how much of this tendency comes out. They want to make their money, they don't want to think about the humiliations and the risks they had been through and maybe they end up being a little dishonest about the risk with themselves. So, taking that into account I am not sure about how to go about risks" (Shon 6/2/2004).

Introduction

There is no Phase I clinical trial research without risk. The trial is designed as a controlled experiment that intends to produce knowledge on basic aspects related to the safety of the drug. Since the drug has until then only been tested in animal species, a number of questions remain in relation to how the chemical compound would behave in a human organism. The only way to answer these questions entails a certain degree of risk for volunteers.

While in the past these trials have been conducted in "captive" populations, the use of market-recruited, professional "guinea pigs" as research subjects pose a

number of questions concerning the way risk is understood and dealt with by this population.

In Shon's account, risk perception at first seems very straightforward and unproblematic. Experienced "guinea pigs" in general have not encountered major adverse effects while volunteering in the trials. This fact along with the realization that, when compared to other professions held by guinea pigs, trials are believed to have a "low risk", this eases their concern regarding risk exposure. But then Shon admits that volunteers sometimes do not want to think about risks once the trial is over. He insinuates that the need to keep doing trials might lead volunteers to overlook particular risks they might face in trials. As a result of this realization, he seems much less certain about risk perception among volunteers and unable to offer a definite statement. While Shon's first approach to risks faced in trials is shared by most volunteers, the ambiguity about the risk assessment is fairly uncommon among professional volunteers.

Professional "guinea pigs" tend to define risks in much more certain terms, corresponding to the way Shon started to comment upon his risk perception. Even when most experienced "guinea pigs" have encountered adverse effects, they are extremely rare and, in any case are not as relevant as the dangers they faced in other work environments. Veteran "guinea pigs" tend to focus on present risks without giving major consideration to long-term risk that might be derived from their trial participation.

Shon's account reveals not only the complexity and nuanced texture of the way professional subjects perceive and deal with risk in trials research, but for me, his

insightful recognition about the guinea pig's denial of LTR (Long Term Risk) was also the first evidence I had showing not only the veteran's concerns with LTR but also something about its denial. His recognition came to me almost at the end of my fieldwork, and provided a new lens through which I could look at issues of risk perception and management among professional "guinea pigs". Before this moment, and along with my numerous encounters with the anarchist community of paid "guinea pigs", as well as with non-anarchist guinea pigs, I had inquired in many ways about their concern with LTR always coming up with the same answer: "the drug in the blood "washes away" a few days after the trial is over and does not appear either in blood or urine tests." In addition, more inexperienced volunteers would add that they did not plan to depend on the trials income forever, and that they had better plans in their future than following a "guinea pig" career.

It thus seemed as if the concerns I had about LTR were not shared by anybody else in the "guinea pig" community. But this was not true. In such a close-knit community I got to know some of my informant's female friends as well, and some of them confided to me that they had a great deal of concern not only about LTR faced by volunteers, but also the immediate effects of their trial participation. One friend told me that her partner was "catching every virus around because his immune system is weakened by the trials". She said "he is always sick", and mentioned that she had asked him many times to "leave the trials and get a regular eight-dollars job", but that he doesn't stop doing trials because of the income and also because "he thinks it is cool because it is supposed to be alternative, contra-cultural stuff and all that".

The professionalization of Phase I clinical subjects led to the formation of a

steady market-recruited group of individuals being employed regularly as human subjects. One of the most pressing issues in relation to their participation is the relation between risks and these commoditization processes.

This chapter explores the relationship between commoditization processes in non-therapeutic clinical trials research and the way paid subjects understand and deal with the risks they face. Fieldwork was conducted in Philadelphia, a major pharmaceutical research site among a group of paid, white, male, anarchists volunteering for Phase I trials research. The chapter describes how local knowledge shapes the way risk is constructed and managed by volunteers. Finally, I also provide clues to understand why consideration of Long Term Risks is not only neglected by volunteers but also by the pharmaceutical industry and the FDA regulating the development of new, experimental drugs in the country.

As Mary Douglas reminds us, risks are individually perceived but socially constructed. Risk in the context of clinical trials research is understood by disciplines such as medicine, epidemiology and pharmacology as a quantitative, bounded and discrete phenomenon that can be objectively measured and dealt with. In this techno-scientific perspective risks can be expressed statistically, providing the basis for neutral decisions about causation, safety and dosage. However, social scientists have shown that assessing risk in clinical trials research is a contingent social process.

Focusing on the way scientists detect adverse drug reactions at the trials and in post-marketing phases, Corrigan argues that scientific knowledge and practices are shaped by epistemological, political and institutional arrangements to produce the scientists' risk assessments. Although scientists present their findings as "ready-

made", that is, finished and stable, risks assessments are fluid and dependent upon a kind of knowledge that is always in the making. In turn, Abraham argues that adverse drug reactions are not neutrally assessed as the scientists claim. Instead, this author shows how the scientific assessment of some drug trials has been influenced by pharmaceutical companies financial interests, which play a significant role by ignoring, dismissing or obfuscating unfavorable results.

Human subject's understanding of risk in phase I research has not been studied. However, there are some studies of individuals volunteering for later phases of the drug development. These studies are centered in particular on the informed consent processes focusing, for example, on lay perceptions of risk in opposition to professional understandings, the role conflicts of interests might play in the way risks are communicated to the volunteers, and the influence of biographical and illness trajectories in patient's decisions about risk taking.

Risk perception among professional "guinea pigs" is shaped by their clinical trial experiences and interactions with other volunteers. In this sense, risk perception is thus closely related to the socialization into being or becoming a professional "guinea pig".

Paid subjects share narratives of which kind of trials represent risk and which ones do not, and also how to deal with these situations. Local knowledge shapes the social construction of risk and the strategies volunteers chose to implement to cope with the risks they perceive. A quick reference to "guinea pig" jokes around risk would provide clues into the socially constructed character of risk in this population.

Humorous tales describing bizarre experiments, or risky situations, form part of the guinea pig folklore. For example, some jokes depict an operation to remove and re-install the pinky toe for $ 5000, or to remove the heart and "put it back" for $ 10.000. These jokes, which according to Guinea Pig Zero, the zine for human research subjects edited by Grand pa guinea pig an anarchist guinea pig in west Philadelphia, were first launched by the head researchers at XXX, and quickly picked up among professional "guinea pigs". The popularity of the jokes reflects not only paid subject's awareness about commoditization of their own bodies but also their anxieties around the risks they might face as paid subjects.

Volunteers not only share jokes around risks but more importantly they also exchange information about risks they might face in trials and how to deal with them. In particular, professional "guinea pigs" have numerous instances in which they do so. It is not unusual for volunteers in the West Philly community to consult each other about potential risks they might face in a prospective trial, especially if the drug is not a marketed drug, and thus has not been tested yet in humans. In addition, volunteers might search the Internet and sometimes reach individuals with medical training if they have doubts about the drug being tested.

The required signature of the Informed Consent Form at the beginning of the trial provides the most relevant institutional opportunity to discuss risks volunteers might encounter. This document details the design, procedures, risks and benefits of the study and is perceived by volunteers to be the main source of information about the trial.

The informed consent process, the screening, and the lengthy in-patient trials, offer opportunities for close interaction among volunteers. The latter especially provides less experienced members an opportunity to expand their understanding of the way trials are organized, which risks they might face and how to deal with them.

The social construction of risk among professional "guinea pigs" is based on two different but complementary classifications. On the on hand, risk is constructed along a temporal dimension that differentiates between short-term risks and long-term risks. On the other hand, risk is placed along a hierarchy from low risk, to medium to high risk.

Paid subjects' concerns are located in the present and are related to the trial they are currently volunteering for and the consideration only of its short-term effects. Grand pa guinea pig, who has done more than 40 trials over a five-year period, elaborates on the perception of risks as related to the conditions of a given trial.

> "Nobody thinks a lot about Long Term Risks. It is like getting a job in a restaurant; the neighborhood with a lot of crime, a far away train, whatever. You are thinking about a short-term problem, you are not thinking about what it is going to bother you five years from now. You are thinking how are am I gonna get to this job and now I am getting my weekly paycheck for this job. And with a trial is the same thing. You are not thinking that these things are going to give you cancer five years from know, or that you might have a high level or radiation in your body. (Grand pa guinea pig 1/05/2005)

As Helms observes, volunteers are not thinking that they might become ill years after the trial. Instead, they are worried about short term considerations such as acceptance into the trial, and then focusing on the schedule in order to receive the financial compensation for doing so.

In addition to a temporal ordering of risk, volunteers implicitly operate with a hierarchy of risk that places certain risks they face. While influenced by scientific constructions of risk, professional "guinea pigs" understandings of risk are shaped by their experience and knowledge gained through their participation as paid subjects.

Low risk studies are considered to be those that involve drugs that are already in the market and present few or no side effects, even at the high doses administered during the trial. A new brand of Tylenol, or a similar "pain medication" would be placed in this category and would constitute the most popular trial choice among professional guinea pigs.

Paid subjects perceive most clinical trials as presenting a moderate risk level. This evaluation is based on two elements. First, their views of the trials as "a carefully controlled situation", an assessment that is based on the scientific design of the trial and the ethical regulations about the use of human subjects which, in their view, contributes to limit risk levels. The second element shaping the volunteer's perception of a moderate risk level in trials is their conviction that serious adverse effects or dangerous situations are exceptional in their trial experiences as paid "guinea pigs".

While most volunteers do not experience serious adverse effects, the uncertainties derived from the experimental nature of the trial introduce a degree of caution in the volunteers' risk perception. Professional guinea pigs recognize that scientists do not know everything about the drug, its risks and side effects. Thus in my survey of guinea pigs' risk perception when asked about risk levels involved in trials, volunteers indicated the risk level as moderate instead of low.

This characterization contrasts with risk assessment among non-volunteers and the general public who, feeding on past and present abuses in biomedical and in clinical trials research, perceive trials as being more risky.

While the majority of the trials are placed in the medium risk category by volunteers, some trials are perceived as presenting a high risk. New experimental drugs, and in particular, those that change the inmunological system, or psychiatric drugs that alter the chemical structure of the brain are considered to be high-risk. Experimental studies involving genetic drug testing and sleep deprivation studies are also a source of major concern. Volunteers rank experimental drugs as riskier than marketed drugs. Their assumption is that a marketed drug has already been tested in healthy volunteers in Phase I, but also in later phases, and by a much larger population after it has reached the market. In contrast, an experimental drug, or "first in man", as it is called by volunteers, does not offer this safeguard.

> "I definitively prefer to do drugs studies with drugs that are already in the market and sometimes I took experimental drugs. But again, there is that thing where a marketed HIV or psych drug might have a lot more risk than an investigational drug that is only a blood thinner. What I would ask when I was in a study is: what would this drug do to me chemically? If it thins or straightens my blood I am not that worried about it. But if it does affects my mind or significantly affects the chemistry of my body, that's more of a risk than a blood thinner or a bone strengthener". (Spam 7/28/2004)

Experimental drugs, are believed to present a higher risk than non-experimental drugs, but this assessment is relative and rests upon such factors as their chemical composition and established side effects. It is in this sense then that research subjects perceive an experimental drug that acts as a of blood thinner or a bone strengthener, as less risky than a marketed drug for psychiatric medications or HIV – which are believed to be very toxic, based on the side effects listed in the Informed

Consent forms. While some volunteer's views that experimental drugs present a higher risk than experimental drugs is also shared by scientists, the way volunteers understand and deal with the risks they face is heavily influenced by local knowledge about their bodies and biological processes.

Guinea Pig Zero provides a series of "horror" stories depicting volunteers' experiences in such trials. In such stories, psychiatric drugs stand at the top of their risk hierarchy, eliciting a very strong negative response. Drug trials involving psychological drugs that change the chemistry of the brain stand at the top of their risk hierarchy.

> "A drug has to stay in your body to interact with another drug but it washes out in a few days. It is gone so it is not going to interact with something that you are going to take later. Think of this, if you smoke half a pack of cigarettes a day and a couple of beers a day you are way ahead, miles and miles ahead of me than doing a guinea pig study on carefully controlled situations, very clear dosages. If it is one of these high-risk studies like studying a new kind of Paxil, Prozac or something, then you are really in the Wild West. You are taking a ridiculous risk and it is too bad that some people go for it –a lot of people are- it is even worse that people are sponsoring studies and try to make money on garbage that is dangerous and it doesn't help anybody". (Bob 1/15/2004)

Here, as Bob suggest, volunteers enter uncharted territory. Bob elaborates why these trials are perceived to be high risk and something to be avoided at all cost.

> "Psychiatric trials are for a couple of reasons very different from trials of non-psychotropic drugs because they involve your mind. You are renting your mind and your body at the same time instead of just your body. It is a completely different economic deal. Secondly, in the psychotropic drug trials, people are writing diseases into existence. You cannot fake fast heartbeat into existence; you cannot make people believe that the heart is beating faster. I put a stethoscope into your chest and check your fucking heartbeat, that's simple. They cannot invent your blood pressure but they can invent your depression, they can invent your mood. And they can change the interpretation of what you say according to what the drug market wants. The marketing department writes the label of the drug, not the fucking doctors, the scientists. It is the

> marketing department. And they also write the disclaimers, CBTO the lawsuits. Blame the disease, not the drug. Like, he is getting into middle age, a lot of time on its hands and is getting a little raunchy goes into the psychiatrist for a little talk, gets put on Prozac and two weeks later he slaughters the whole family with a rifle and blows his own brain out. Tell me it is not the fucking Prozac! That is what I think, fuck you, fuck you. And it happens over and over again and the lawsuits get buried by companies that put a lot of money to quiet people down".

Bob's strong opinion about clinical trials involving psychiatric drugs echoes professional "guinea pigs" concerns with these trials, and offers a powerful contrast to the usual, more neutral, way in which they talk about risks they face in clinical trials. Following a long established western tradition, the mind is perceived as separated from the body, a locus of reason and rationality, giving the mind a privileged position vis a vis other body organs.

In addition, the wariness and even hostility the anarchist community has towards psychiatric drugs is based on their critical view of the role of the industry in developing new drugs. Psychiatric drugs indexes the abuses of the pharmaceutical industry that constructs mental diseases and therapeutics "writing diseases into existence" placing both volunteers and patients at risk in their search for profits. In addition, for the anarchist "guinea pigs" community of West Philadelphia these trials have also more direct and personal connotations. A former professional "guinea pig", an experienced volunteer and well-known local activist, enrolled in such trials with tragic results.

This event caused such an impact on the community that Grand pa guinea pig used it as the key evidence to issue a report card for the research site where the trial took place. The headline reads: "Brain-sluts, look no further: XXX Corporate Control

in All of its Glory". The top corner displays the grade given to the site. GPZ gave the facility a "dirty" D, noting that while the pay level was good and trial duration was generally short, "the catch is that your mental health is not very important to these researchers". It is to document this statement that GPZ reminds the reader of the case of "one experienced guinea pig" enrolled for a study at the facility. The trial, according to GPZ, was conducted in December 1995 and involved the antidepressant Paxil with the antihistamine Seldane. As a result, he "emerged with $ 7000 in his pocket but his mind in Planet Zork". According to the zine, the trial site was not concerned about this "life-changing mental breakdown" experienced by the volunteer. The GPZ outrage comes not only from this neglect but also from the fact that the facility enrolled the volunteer in a new experimental trial in June of the same year, just a few months after the first trial ended.

As a consequence of this trial participation, his fellow professional "guinea pigs" remember him as being "delusional", hallucinating, paranoid, and clearly losing touch with reality. For example, he insisted that the movie twelve monkeys conveyed a militant message to the radical community of anarchists in West Philly to organize to overthrow the US government using bacteriological and chemical weapons. Nobody took his suggestion seriously. In another episode, he tried to buy a dilapidated house to start a new community, but he falsified transaction documents and in the end his friends had to bail him out with money from their own pockets. These events, along with his mood swings, anxieties and anti-social behavior ended up by alienating him from his best friends, forcing him to abandon the West Philly anarchist community. Some former friends believe he is in Italy, others think he

might be in Australia. The story was relevant enough to the West Philly anarchist community for it to be published in GPZ. Anarchist "guinea pigs" who knew him personally all mentioned the case to me. Even some volunteers who came later to the area referred to the case to make a point about the danger of this type of trials.

The persistence of the social memory of this single event many years later suggests that the story has some iconic value. I suggest that this narrative operates as a cautionary tale among the community of anarchist professional "guinea pigs" about the abuses of the industry and the risks involved in volunteering for trials that "mess up your mind".

Risk, commoditization and the professionalization of the "guinea pig" subject

Their identity as workers and the definition of "guinea pigging" as work, which they acknowledge, shapes the volunteer's identities, especially, those in the anarchist community of West Philadelphia although the same is true for some other self defined "professional guinea pigs" as well. The commoditization of clinical trials research has in turn, shaped a group of reliable, knowledgeable and willing individuals who depend or rely on such participation to support themselves. Rajan describes a similar process among unemployed textile workers in Mumbai earning their livelihood as experimental subjects for genetic trials. He argues that as experimental subjects they enter into systems of capital as a source of value creation as well as a source of scientific knowledge production. (Rajan 2005).

In order to become a professional research subject in this double sense, subjected to capital as well as to science- the volunteer has to remain for some time in the trial economy. A one-time participation does not constitute professional guinea

pigging. As shown earlier, the disciplined body is an indispensable requirement of the professional research subject, and it is for this reason that professional participants are being sought and rewarded by the industry. But there is another element that also plays a central role in the transition from volunteer to professional "guinea pig".

Volunteers with just a few trials seem to show some concern about the risk faced in trials and also mention possible Long Term Effects (LTE). Routinization, however, leads to diminished concern on both counts. Dependency on trial income, trial experiences that have not exposed them to side effects, along with interactions with more experienced volunteers convinces newcomers that risks are not to fear. Also, as volunteers move along in their careers as "guinea pigs" their experiences contribute not only to their risk perception, but also to a shared narrative about risks.

> "I don't think I did many studies that might have LTE. I didn't do studies that had a pretty bad LTE in my body chemistry. So, I am not that worried about it. No. Also, it's hard to tell too but there is so much fucking toxic stuff around, at work, I lived around Oil refineries, I lived in an old house, I used to work with this chemical, I used to work with that chemical. I don't know if a LTE shows up I would be able to tell where it came from. No, I am not that worried". (Spam 7/28/2004)

Such perceptions influence practices and in turn, practices also shape guinea pig perceptions. The notion that some trials are risky might lead volunteers not to join a particular trial. In turn, the continuous participation in trials can produce changes in perceptions. A trial previously thought to be dangerous or risky might be conceptualized as presenting lower risk if it follows experience with a similar situation. The reverse situation is also possible.

> "I am definitely concerned about different things than I was before. I did this one study at Jefferson that was an anti-anxiety medication and it was messing people a lot and people were leaving the study really fast, you know. The

> nurses encouraged you to report adverse effects and I was feeling kind of dizzy and my head was kind of swollen. So the nurses talked and said: "he has to go" and the guy from Merck come and see me and the doctor basically told me that I could walk myself out of the study but I would forfeit $ 300 if I walked away out of the study and I didn't know if it would get worse or not. And then the nurses basically fought, argued with this guy and told him that they should release me. That was a big eye opener for me. I think that different places have different policies about it too. In that sense, I realize at a personal, experience level how far drug companies –I mean, I knew that basically- are willing to push things on and if anything happens it's basically your fault because you choose to stay in the trial or whatever. So, in that sense, yeah, that changed like a little bit. (Dave Onion 5/18/04)

As we see, as they become more engaged and dependent on the trial economy, volunteers' understandings of the trial and the risks they face also change. Beginners are more worried than professionals about risks they might face. Maybe this reflects the general population's anxieties about biomedical research involving well-publicized abuses. Volunteer's initial uneasiness focuses around the unknown effects of the drugs, but also reflects a discomfort with a procedure they do not yet fully understand. In addition, volunteers are concerned about potential long-term risks. Some volunteers mentioned that they were somewhat concerned about the possibilities of developing cancer in the future.

As the volunteer becomes socialized as a professional "guinea pig" and interacts with more experienced workers, and as their own experience involves no serious Adverse Drug Reactions (ADR's), less experienced volunteers adopt the common professional narrative about how to understand and deal with risk. They begin to think about risks more as professional "guinea pigs". Their risk sensibilities are more focused on particular trials, such as trials involving psychiatric medication,

genetic drugs and sleep deprivation studies. At the same time, routinization leads them to minimize or even deny long-term risks.

As we have seen, risk assessments are compared to risks the guinea pig have faced or would face in industrial or service jobs, in chemicals or industrial accidents, or accidents with heavy machinery. Also, risks volunteers might face as professional "guinea pigs" are contrasted with risks the general public face when taking drugs. This evaluation by the anarchist volunteers reflects their ethical views rather than those of the pharmaceutical industry. According to professional "guinea pigs", patients taking marketed drugs are "unaware", and are in fact un-paid guinea pigs, since the drug might present adverse side effects not detected in experimental phases due to their small numbers. Vioxx and many other drugs that have been retired from the market due to unacceptable risk levels for patients gives some credence to this belief.

Risk management strategies among professional "guinea pigs".

Professional "guinea pigs" believe that risk can be known, and then managed. While this perspective is based on their particular trial experiences and understandings, it also helps volunteers sustain their confidence and keeps them volunteering. Local knowledge influences not only the way risk is constructed, but also the ways in which they attempt to manage the risks they face.

The local classification of risk hierarchies is a way in which volunteers deal with anxiety and attempt to manage it. In addition, the strategies professional "guinea

pigs" implement lead them to avoid trials they place at the top of their risk hierarchy, even quitting the trial if risks were not foreseen.

If a trial is perceived as being very high risk, volunteers might avoid the trial altogether. The prospect of financial compensation and their dependency on the trial income might lead volunteers to do trials they would not otherwise be inclined to do. Most experienced "guinea pigs" have done at least one trial they perceived as "too risky", enticed by the promise of substantial financial gain. At the same time, experienced volunteers say that they have at least once turned down a trial because they felt it presented risks that were not acceptable.

For the anarchist professional "guinea pig" community some of these concerns are less acute than for paid subjects that come from elsewhere. Volunteers from outside the city face traveling and housing expenses –usually in cheap places like the Youth Hostels, where I met Denny and the Canadian "guinea pig", and they face living costs without knowing if they will be accepted into the trial. Once they are accepted, the in-patient trial regime covers most of their material needs, but also influences their capacity to decide whether they want to stay in the trial if something does not go the way they expected. Until they get the check "they [the pharmaceutical company sponsoring the trial] have you by the balls', as the Canadian volunteer told me. By contrast, the anarchist "guinea pigs" are single, with no children, have their own living arrangements, and face less pressure to undertake risks or trial conditions they feel are not acceptable.

A more extreme version of risk management is to abandon the trial. This is a very rare and extreme measure, and professional "guinea pigs" use it at a last resort.

Sometimes the drug has secondary effects that are harder than the volunteers had anticipated. If the volunteer manages to show that these effects are the direct result of the trial, then he or she might be able to leave the trial, sometimes receiving payment for the full amount, sometimes a "pro-rated" portion of the participation in the trial. While there is no penalty involved in leaving the trial in such circumstances, making the case is not easy, and failure to do so can be financially costly for participants.

Finally, some professional "guinea pigs" believe that certain substances help them to "clean the blood" and to "detoxify" the body of the chemicals they absorbed during the trial. They assume that the chemical substances are only contained in the blood and urine. If a few days after the drug intake is finished the drug remains cannot be found in tests, then volunteers consider that none remains in their bodies. This assumption is shared by most professional "guinea pigs" which in turn, helps to explain why they do not give a lot of attention to their "cleansing" practices other than drinking water, a standard procedure suggested usually by the nurses or doctors conducting the trials.

Volunteers do resort to other cleansing methods on special occasions, for example, after a very long and demanding trial when they fear that the drug administered had a particular toxicity, or if they are planning to do another trial soon after finishing the first. Cleansing practices are also based on local knowledge about their bodies and the interaction with the substances they encounters as volunteers.

Scott, an experienced volunteer living in anarchist community explains some of his methods:

> "There are a couple of times where I didn't wait what it was supposed to wait. Like I did one two weeks after the other or something. I make sure to drink a

> lot of water and actually took some herbs in those cases. One of the best ways to clean up your system is lots of water, of course, and then golden seal and then non-sugar cranberry juice. The combination of that stuff would wash you out. So, I did that and I thought that I was reasonably safe doing that. I don't remember what the drugs were but they didn't seem risky". (Scott 6/3/2004)

Unsweetened cranberry juice, is a standard drink for professional "guinea pigs" and is believed to help absorb, metabolize and eliminate toxic trial substances. In addition, the use of herbs like Goldenseal or Marigold flowers is suggested by GPZ, which recommends them as ways of "keeping the blood fresh and clean". Goldenseal according to the zine is "said to have a dramatic cleansing power, and is recommended by herbalists for removing the toxins related to alcohol, coffee, nicotine and other substances from blood".

A small group of volunteers in the anarchist community sometimes attempt to implement diets by eating only eat apples for some days, or yogurt, in the belief that this also helps "clean" their bodies. The use of herbs and organic methods of cleansing is preferred in the anarchist community. Although anarchist volunteers usually eat meat in the trials, mainly due to their lack of choice, they place a high value on vegetables, organic diets and healing practices. Professional subjects not affiliated with the anarchist group prefer instead a chemical approach, using blood supplements that contain iron, which helps rebuild the blood supply. King Lab Rat, a 40 years Latino volunteer commuting from Florida, and with more than 20 years of experience as paid volunteer offers almost an "infomercial" for iron supplements which he uses extensively to cleanse his blood in order to be able to volunteer for the another trial as soon as possible.

> " If you volunteer in another trial before time they might find out, they might know but sometimes you can pull it off. When they do the blood work, urine work, they'll know because if your system is not properly flushed it will be in your system. So you have to wait seven to ten days to have your drug flushed out. If you are physically fit and you take care of your blood work you could jump into another study seven to ten days after you finish one. We have stuff on the market that works, replenishes your blood, iron supplements. I take it specially when I come out of a long trial where I had a lot of blood drawn. This thing really guarantees to build up your red blood cells. Everything in your body is being taken care of by fluids. The fluids are the only thing that gets into every micro-cell of your body. This Elixir takes care of anything at the micro-cell level in your body, even into your bones. So take that, put it into a shoot glass before a meal and it'll do the trick. You will feel it working. A lot of people is taking this, they dropped the pills and got the bottle.
> I am satisfied with myself because I accomplished what many people cannot get: I managed to live comfortably." (King Lab Rat 2/16/2004)

Although King Lab Rat makes some radical claims embedded in techno-scientific jargon "Everything is your body is being take care of by fluids. The fluids are the only thing that gets into every micro-cell of your body", his knowledge about drug work and bodily processes does not differ greatly from the local knowledge held by professional anarchists. His preference for chemical supplements rather than an organic approach might be a cultural difference.

Despite their attempts to manage risk, professional "guinea pigs" are placed at considerable risk given the fact that many remain in trials for many years, exposing themselves to potential synergistic drug interactions and long-term effects.

The social organization of the clinical trials and the "guinea pigs" lifestyle makes it more difficult for them to become aware of these interactions and effects that might appear sometimes many years after a trial is completed. While volunteers maintain close interaction during the trials, which might last from a few days up to a few weeks, once the trial is over volunteers usually do not remain in contact. Some

leave for other cities looking for new trial opportunities. Even the more stable community of professional anarchist "guinea pigs" in Philadelphia is highly mobile and in constant flux.

This fact contrasts with the stability of other categories of workers performing toxic or dangerous trades such as coal miners, or those exposed to asbestos or other industrial pollutants. It was only over extended periods of sharing experiences that these workers developed an awareness of risk in contrast to that offered by the Industry. In the case of professional "guinea pigs" their mobility and the relative anonymity conspire against this possibility. The fluidity and instability of the "guinea pig" work place resembles those of migrant agricultural workers who face similar problems associated with toxic substances.

The lack of a centralized register of human subjects volunteering for Phase I trials might also obscure the existence of the problem for the Pharmaceutical Industry and regulatory agencies like the FDA. In addition, conspiring against the recognition of the need to study long-term risk, is the fact that the pharmaceutical industry has no incentive to invest in such a research.

In conclusion, my research suggests that professional "guinea pigs" might be more knowledgeable about risks in ways that captive, institutionalized populations have never dreamed of. In turn, their continuous participation in clinical trials might expose them to risks they are not only not willing to think about, but also are also unable to recognize.

I have thus argued that risks are socially constructed, and have shown how local knowledge shapes the way in which professional "guinea pigs" define and deal

with the risks they face. Risk classification allows volunteers to bring some order and sense of control to a situation of uncertainty they depend upon to sustain their livelihood. Their anxiety about psychiatric drug trials reflects not only the privileged value they place on "the mind" but also their critical stance towards the commoditization of the body in clinical trials, as well as the abuses of the pharmaceutical industry. Local knowledge of the body and bodily processes shape their perception of risk and the strategies they put in place manage them. Risk classification, risk avoidance and cleansing are the main ways in which volunteers try to limit the risks they face.

Despite their efforts, the market recruitment of paid volunteers for phase I research places subjects at risks they are unable or unwilling to recognize. As someone put it: "you become addicted to the trials, to the easy money". In a context where opportunities afforded by industrial or well-paying service jobs have vanished, the lack of choice and the need to secure an income leads some volunteers to underestimate long term risks. To make matters worse, albeit for different reasons, the pharmaceutical industry and governmental bodies are not willing to tackle the problem.

Chapter 6. Social organization of HIV clinical trials research at a Community Based Clinical Trial Organization "CBTO".

Introduction

This chapter describes the social organization of HIV drug trials at CBTO, a community based research organization. In particular it explores the networks, regulations and institutional arrangements that make community based trials and industry trials possible. Life stories and survey data are employed to document the socio-demographic background of the patients volunteering for the trials, their motivations to enroll and their views of the commoditization involved in their participation.

CBTO

CBTO occupies a five story, terracotta building in the downtown area. The street, filled with nicely kept colonial houses, is close to the historical district and like the surrounding neighborhood it has undergone through an intense process of gentrification since the mid 90's. Still, its central location is perfect to serve their "customers", mostly poor African American HIV patients. CBTO is a large community based center for AIDS research also providing health care for poor HIV patients, education and advocacy.

As the HIV epidemic grew it also generated a powerful social response that led community members to organize to fight against the disease inspired by the conviction that progress against AIDS could not be made if efforts to develop

effective drugs and vaccines were left to the pharmaceutical industry alone. Community based trials of which CBTO was part of a larger national network would engage in trials the industry was perceived as not interested in pursuing due to their lack of immediate profitability. In addition, Act Up, a social movement to support the cause of AIDS established an informal but close relation to CBTO when one of its members joined its educational section. In turn, CBTO is also the result of a neo-liberal management of the epidemics at a local level that resulted in States and Cities transferring resources and responsibilities in addressing the epidemics to community organizations.

The spatial changes at CBTO offer a glimpse into its transformation from an activist managed community research site occupying a small room at the Graduate Hospital in the late 80's to its current location at Locust Street, providing health care, HIV research and advocacy. These changing roles for CBTO index also the need to balance activism with the rhetoric and practices of a service organization devoted to the "consumers'" well being.

CBTO started as part of the Community Research Initiative that in 1987 obtained a grant from the American Fund to support community based AIDS research. The grant was requested by Dr. John Turner a gay endocrinologist treating AIDS patients with the belief that without community involvement, therapeutic advances in drug research would be much harder to achieve. CBTO joined the Community Research Initiative effort in 1990, occupying a small office space at the Graduate Hospital of the University of Pennsylvania in downtown Philadelphia.

For the first four years CBTO did only community-based research as part of the Community Research Initiative network but in 1995 a grant from CPCRA allowed them to do further community based research. Its staff grew from 4 to 10 including its director, one administrative position, and seven members of the research team. The grant also allowed CBTO to move to half of the fifth floor at its current location and it also provided funds to hire a community activist for Teach, an education and advocacy program for patients living with HIV.

In 1996 John Lax, CBTO's board president died donating funds for the opening of a Treatment Center which opened the following year filling the space contiguous to the research area. In 2000 a grant from the Robert Woods Johnson Foundation made it possible to hire CBTO's PI as its full time medical director. Around the same time the research lab that was crowding the fifth floor along with the treatment center moved to a new space in the first floor.

While during CBTO's first years its Board was composed of doctors, currently there are no doctors on the Board. According CBTO's director and a board member the composition of the Board reflects the institution's role as a minority provider. The majority of the board are people of African American descent and may be, one third to almost half are living with HIV. The director of CBTO summarizes the Board's composition well: " Lots of different people. We just don't have a lot of rich people".

HIV clinical trial research

Clinical trials are conducted at CBTO's research department. The facility is located in the first floor and it is identified by a notice posted on its glass door. The lobby accommodates a copy machine, a couple of seats, and a desk sometimes

occupied by a secretary. Note pads and pens displaying different HIV drug logos are used by patients to fill out a sign-in sheet. One wall has a Viracept clock and close to it a poster announces the SMART study, with an invitation to "Joining a Global, AIDS effort". Patients wait in the lobby until it is time for their appointment. Usually there are no more than a few patients visiting the facility every day. Then they ring a bell on an interior door and usually Grace, the head nurse, Susan, a nurse, or Tori, the phlebotomist come to the door and let them in. Sometimes there are one or two patients waiting at the waiting room, most of the time patients come to their scheduled appointments in time and do not have to wait. After walking through, a room filled with cabinets and CPCRA files used only occasionally for NIH and Industry monitors, patients are ushered to a room to be interviewed and usually to have their blood taken. Although the research department houses three exam rooms staff regularly uses only one that has a CPR, for cardiac monitoring delivering a chart indicating the cardiac rhythm. In addition to a stretcher, all exam rooms have cabinets filled with needles, cotton and supplies. The lab counts with a centrifuge to separate blood components, which are usually sent outside for processing. The research space also uses two rooms as office space.

Staff greets their patients by their names and can identify which trial they are in, even if they are not one of their patients. In addition, the stability of the staff and the continuous interaction with their patients which in certain trials might cover from 48 up to 96 weeks also builds personal relationships. Currently there are 128 patients involved in HIV trials research at CBTO.

There are two different types of trials being conducted at CBTO: "community" trials and "industry" trials. As a community based research site it is involved in the CPCRA network, which administers among other trials the SMART trial. CBTO also serves as a research site for other community trials such as Wistar, a trial conducted by the University of Pennsylvania. Finally, CBTO also does "Industry trials" to test new drug regimes being developed by the Pharmaceutical Industry.

Industry Trials

CBTO's Principal Investigator oversees the care of the patients that come to the Jonathan Lax Center. In addition, as Principal Investigator for Industry trials he is in charge of almost all the Industry Trials that are going on at the present time at CBTO. An infectious disease doctor before coming to CBTO in 2001 he was a junior attending at Cooper Hospital in Philadelphia. During his experience at Cooper he used to be a co-investigator for HIV trials.

The majority of the HIV trials conducted at CBTO are phases III or IV, that is, involving drugs that are already approved by the FDA or in the verge of being approved. Most of the studies performed at CBTO test different combinations of drugs already approved by the FDA. Other trials involve testing drugs on the verge of being approved and placed in expanded access programs.

While CBTO's PI notes that experimental drug trials are "a little of concern to me because we don't have a clear idea about how are they going to interact with the host" he acknowledges that the main reason why these studies are not conducted at CBTO is lack of infrastructure. In particular, some of these studies demand that these

patients stay overnight and there are no facilities to accommodate these needs available at CBTO.

Since 2000 twelve industry trials have been conducted at CBTO. If in 2000 only two trials were conducted currently five or six are scheduled. CBTO's PI summarizes the reasons for this growth: "there are more opportunities and our comfort level has increased, the comfort levels of our staffing during these trials has increased as well. There are more combinations of drugs being tested out there and the level of competition among pharmaceutical companies is big". The emergence of protease inhibitor drugs in the mid nineties opened up significant opportunities for drug development as well as for therapeutic interventions. While in the mid nineties there were only a couple of protease inhibitor drugs, currently there are more than 20 AIDS drugs available and many more in the "pipeline". More drugs also mean more possibilities of drug combinations, which in turn have to be also tested. CBTO's PI also suggest an additional reason for the emergence of HIV drug trials: "everyone wants to show that their drug is the preferred one, so there is a lot of competition, so there are more trials".

CPCRA trials.

One of the most important trials being performed at CBTO as part of the CPCRA network is the SMART trial. It is coordinated by Grace the head nurse of the Research Department. It is a long-term study, meaning six to nine years intended to assess whether HIV patients can interrupt their treatments over extended periods of time without compromising their health status. CBTO is one part of an international

network of research sites in North America, Europe, Asia and South America that involves many other research centers and more than 1500 volunteers. The study attempts to enroll nearly 6000 volunteers in the incoming years.

Grace came to CBTO as a Clinical Research Coordinator in May 2001. Before this, she had worked at the HIV unit of the University of Pennsylvania's Graduate Hospital since 1992. In addition to taking care of the patients, she also engaged in clinical trials at the facility testing among other drugs, protease inhibitors. Her interest in trial research increased after the completion of her master's degree. Coming to CBTO's research department offered her an opportunity to further her research interests while still being able to work with HIV patients in an environment she described as "family".

She is the project coordinator for the SMART study. This involves supervision, quality assurance, budget preparation, the liaison between the CBTO's office and the network, which is in Washington, organizing group meetings, and organizing conferences calls.

Institutional Review Boards.

Before a trial can be conducted at CBTO it must be reviewed by its IRB. Until 1997, CBTO had been sending their protocols to big university hospitals in the city, which resulted sometimes in considerable delays so that CBTO's patients lost important research opportunities. To solve this problem, and also keeping pace with the demands of growing research activities, CBTO decided to form its own in house IRB. A lawyer from a community-based organization that provides legal advice and

services to AIDS patients was named its chair. In addition, currently the board has six additional members, three community representatives and three medical doctors from local university hospitals.

The IRB discusses the goals and design of the study emphasizing in particular the risks and benefits for the volunteers. It also makes sure that the Informed Consent Form adequately conveys this information to the volunteers in lay, non-technical language. Chapter 8 explores the role of CBTO's IRB in as part of the Informed Consent Process along with its views about issues of commoditization in HIV trials research.

When a Pharmaceutical company approaches CBTO about conducting a trial there, it submits the research protocol with a detailed description of the goals and design of the study and in particular the risks and benefits that can be anticipated to the Principal Investigator which in turn, submits it to the local IRB for its approval. In the case of Industry trials, the study must be also be submitted to the central IRB of the company that promotes the trial. Each trial has it own Data Safety Monitoring Board (DSMB) that reviews the data that is being collected and is in charge of raising any potential problems that might arise in relation to the trial. Every adverse event is reported to our IRB by the DSMB to be reviewed.

> "There is no way in which you can anticipate and predict a bad outcome but is very important to have a system in place that is efficient and that it could eventually monitor the progress of the trial and that's what Data Safety Monitoring Board is meant for. To be able to monitor the safety closely of these patients and make sure that if there any pattern, out there, that look suspicious so this Data Safety Monitoring Board to be able to unveil this pattern and try to address the issues and if they believe that the risks outnumber the benefits then they should stop the trial. That's what they do usually. It all depends on how vigilant we are, how good the system that we

> have in place is able to determine these risky patterns and unveil them". (CBTO's PI 4/27/2004)

In addition, the industry trials being conducted at CBTO received monitors from the pharmaceutical industry. Monitors come to CBTO on a periodic basis, usually 12 weeks scrutinizing the research protocol to assess that there are not 'inconsistencies" in the data.

According to the Principal Investigator no significant problems had been reported by industry monitors in relation to trials being conducted at CBTO, except, some patient's records not showing in the charts. "But you know, we haven't had any major problems. The only problem we have is patients fell through the cracks and not showing to the charts but we have not had any major adverse event".

Recruitment

Volunteers for trials conducted at CBTO are recruited in a number of ways. Most of them belong to the Jonathan Lax Center. In addition to patients coming from its own Clinic, CBTO also obtains some of its volunteers from Presbyterian Hospital at University of Pennsylvania. Others are referred to CBTO by infectious disease doctors, like Dr. Watkins across the street, who have patients that meet the criteria for its trials. Doctors refer patients to CBTO because they can benefit from the study. While most of the patients live in Philadelphia, the institution has been able to attract patients from New Jersey, Altoona Pennsylvania and even one from Florida.

In general, CBTO's trials volunteers reflect the demographics of the population they serve: a majority of poor African-American men and women, but

there are also Latino and white volunteers. This composition is unusual in terms of national trends of HIV clinical trials research, which has been conducted mostly on white males. CBTO's PI outlines the relevance of such sample for HIV drug research and treatment:

> "It's important to study drugs and regiments in these patients because [they] respond to these drugs differently. So a regime that would be preferred in a Caucasian male might not be the best regime for an African American male. And there is also the gender issue; we know that for certain drugs females tend to have more side effects than males; so also gender plays a role. Usually if you look at studies comparing regimes among themselves you have 70 to 80% males 15 to 20% female. And usually you have 65 to 70% Caucasian and the rest are African American, Hispanics and other minority groups. At CBTO we have 70% men and 30% in women. That's good, we are reporting high on both.
> We are very appealing because we have more minorities willing to enroll. And again, there is an element of financial gain in patients doing clinical trials and unfortunately African American and Hispanic are poorer than the Caucasian population in general".

As is the case in Phase I trials, later phases of drug development also need to recruit subjects to participate in the trials. Sites with a potentially large body of volunteers are as CBTO's PI recognizes, very appealing for the Pharmaceutical Industry, which needs to find thousands of patients to complete its drug trials. Usually large university research hospital has both accesses to large number of volunteers and to the scientific expertise to conduct the trials. Smaller, specialized sites such as CBTO might also enter the network of HIV clinical trials research inserted in particular drug niches.

> "Well, the pharmaceutical companies decide who they want to choose in terms of sites, the way they wanted. Sometimes in considering the type of populations and also in terms of how they rate the site according to past experience, the credibility of the site, and the reputation of the site. So, they might come to us with a first class study or a third class study. Clearly the importance of these trials is ranked differently and the sites that are picked up

> to do these trials are ranked differently as well. A first rate study picks first-rate sites to do it. We have been approached by all kinds of studies. I would rate them as first rate, second rate and even sometimes third rate studies and you know, it's up to us to decide if we are going to do the study or not but it's not up to us to decide if we are going to be picked up. Really, each study differs from the other and the pharmaceutical companies pick their sites based on who they believe it's gonna deliver and who's not gonna deliver. And if they have a study that it is too little they want to pick up small sites that they think they can deliver. I tell you, if I had to rate my site I think that it's very competitive because we have the experience, we see a lot of patients in terms of HIV –obviously- and we have a record and a history of research. So they would want to work with us and that leads to novel therapies and novel strategies". (CBTO's PI 4/27/2004)

HIV trials and financial compensation

CBTO receives financial compensation for their enrollment in Industry trials. According to CBTO's Principal Investigator the resources paid from the pharmaceutical industry to research sites such as CBTO are intended to compensate for the time researchers spend in dealing with the paperwork, follow up calls, and patients visits. In addition, it also intends to cover direct costs like lab tests.

> There are two major categories, if you want, the researcher, the time that you are expending, the time that your staff is spending dealing with the situation and you have also costs of the blood work that you are doing. We take blood and many times instead of sending it to the Central lab where the pharmaceutical company wants us to send it to, we do it in our lab instead. And this is costly and sometimes we need to do an X ray too. Then, there are direct and indirect costs. And then, there is the effort of the researcher, researchers, in a sense. Our effort is based on the phone calls, the physics that we do with the patient, encounters that we have with these patients.
> The data belong to the industry that is doing the trial, so all that we do is provide them with the data and they analyze the data. So, we are compensated by the work that we are doing but I don't necessarily see this as a lucrative thing for us because if we think about it, I think that it is money losing. (CBTO's PI 4/27/2004)

CBTO's PI and I had developed a close relationship over time and he was grateful to have the opportunity to present his point of view on an a controversial issue related to the conflict of interests that might arise when the position of doctor conflates with the condition of researcher as well. He provided a very open disclosure revealing details of its operational budget to show that CBTO made no profit and probably lost money doing industry trials. CBTO gets around $5000 dollars per patient enrolled in trial, which might last between, which might last between 48 and 96 weeks. The amount of revenue CBTO receives from its industry trials is placed by CBTO's PI around a figure of less than 10%, probably close to 7%. CBTO's PI estimates that hiring a full time nurse will cost between her salary and fringe benefits $70,000 dollars a year. He continued:

> "Once you add the direct and indirect costs of the study you probably need to generate $100.000 to cover this costs which at $5000 per patient means that you need to enroll 20 patients. We average 2 to 3 patients a study. So you have to have probably 8 to 10 studies, so your nurse will be involved in 8 to 10 trials to generate her salary and we are not talking about benefits to CBTO. And 8 to 10 studies, 2 or 3 patients each…again, you have to understand that is hard to enroll in these studies, so there is not much of leverage. It's a hard business. So, our studies, the studies we are doing at CBTO are not self sufficient so the personal involved to do this studies we have to pay them from other resources beside the resources we are generating from industry trials". (CBTO's PI 4/27/204)

According to CBTO's PI the main reason that CBTO is involved in trials is that they are bringing a new agent or a new modality to patients that are in bad need of this treatment modality, or they are asking a very important question. "Let me give you an example, the SMART studies is asking this very important question: once that we start patients on treatment should we treat them for life or can we treat them as needed? And that is an important question."

The comoditization of volunteers in HIV clinical drug trials.

Not only does CBTO receive financial compensation for its participation in the trials but the volunteers themselves are often compensated for their enrollment. This is true not only for the Industry trials but also for the community-based research developed through the CPCRA. In contrast to Phase I trials where subjects are paid hundreds or even thousands of dollars to join a trial, Phases II, III and IV offer considerably lower amounts in compensation. For example, at CBTO SMART volunteers received $20 every four months. Industry trials offer similar financial benefits. In addition CBTO's patients might also receive tokens or money to cover their parking expenses. According to CBTO's PI financial compensation has become an integral part of clinical trials research for clinical trials involving HIV drugs.

> "Let me tell you one thing that unfortunately is reality. We cannot and unfortunately we will never be able to do [trials research] if the patient is not compensated to do these trials, unfortunately. Now, the problem we have, unless the trial is bringing something revolutionary to the table, patients are not very motivated, they have other choices, other therapeutic choices. Let's say you are trying to compare two regimes where the drugs have been FDA approved. The patient can get any of these drugs without having to participate in the trial. If it is a new drug that is on the verge of being approved by the FDA and the patient feels that they might need this drug to survive then, they might do the study. So, it all depends on the need to do the trial. And even if there is a need to do the trial patients are not very motivated because they are taking time away from their work and spend a couple of hours every month or every two months and they need time for their travel, their parking and sometimes need to be compensated by their time away from work. So compensation is becoming very important, it's a good incentive" (CBTO's PI 4/27/2004)

CBTO's PI seems to believe that willing HIV volunteers for drug trials have become a scare resource, one that needs to be lured back with financial incentives in order to be able to conduct industry trials. May be scarcity of volunteers is more

apparent than it looks to CBTO's PI. During the last ten years drug trials for HIV had multiplied to an unprecedented level while the HIV population has remained steady or had just a small growth in the country. Other factor that can contribute to the idea of low demand for trials is the fact that nationwide white males continue to be the standard for HIV trials despite NIH efforts to incorporate minorities from other demographic groups such as women and African American and Latinos. On the other hand, CBTO's PI is right in pointing out that many patients now have fewer incentives to join trials than in the past. Thanks to community mobilization and the collective action of AIDS organizations, HIV patients have now access to health coverage that provides them with a wide range of therapeutic opportunities that were not simply there just ten years ago. This fact helps explain why unless it is a life of death issue, or a very promising drug volunteers might hesitate to enter a trial and just wait until the trial is completed and the drug available on the market.

The PI at CBTO believes that the need to offer financial incentives to patients who join HIV trials presents an unintended consequence. He notes that patients who are supposed to enter the trial for altruistic reasons, or to help find a cure or improve a therapeutic option end up joining the trial influenced by the financial rewards they might get. Financial compensation thus would introduce a bias in ethical standards that mandate that patients are enrolled only if they understand the risks and benefits of the study and also in a situation free of constrains might be violated. I will discuss the relationship between comoditization in HIV trials research and research ethics in the next chapter.

> " Ideally the patient should not be paid, and motivation should be the only reason to participate in a trial because you wanna answer the question, it's a scientific question that you want to answer, you understand the risks, you understand the benefits and you are not doing it for the money. Money might be a bias in a sense but I think that we are not compensating them with money to save their lives, we are compensating them for parking. We compensate them from the toll they pay to cross the bridge. So, the compensation is symbolic, it's not gonna make them rich. Unfortunately some patients see it as a way of generate money and sometimes they get involved in trials they shouldn't be involved in –not in our site- but I read of patients doing things that they really shouldn't be doing". (CBTO's PI 4/27/2004)

Demographics of HIV patients doing clinical trials at CBTO

This section present the life stories of John, Michael and Geraldine, 3 patients volunteering for HIV trials at CBTO. Michael is the only one volunteering in an "industry" trial, Boeringher Ingelham, testing the efficacy of the drug Tipranavir which is in the latest stages of development along with another drug from the same laboratory that was already approved. John and Geraldine were volunteering for a "community" trial, Wistar, although different versions of it. The trial did not involve drugs but intended to asses the progress of the virus in certain patients. Since every trial offered financial compensation, I used these cases to explore issues of commoditization in relation to volunteers' participation in the trials.

The demographic and social backgrounds of John, Michael and Geraldine reflect the age, gender, race and class background of the larger population of trial participants volunteering for HIV trials at CBTO. Like the majority of CBTO's volunteers, John, Michael and Geraldine are in their mid 40's. The gender composition of the sample, two males for every female not only reflects the ratio at CBTO but moreover, the epidemiological trends in the US.

John and Geraldine are African American, Michael is white. This ratio reflects also the particular composition of CBTO patients, more minority oriented and, in particular, African American. Also, Michael has a middle class background while John and Geraldine, like the majority of CBTO's population come from poorer families.

The use of narratives allows us to place volunteer's decisions to join the trial not in an abstract rationality but instead in the context of their living conditions, past and present. In particular, the narratives illustrate how major biographical events in their lives as well as current and past circumstances shape how volunteers make sense of, and deal with, their current situation. In particular, this section explores volunteer's motivations to join the trials and the issue of financial compensation, placing the decision in the context of the volunteer's past and everyday life experiences in coping with HIV.

When I met John he came into my office with a kid's bike he found on the street on his way to CBTO. He was very happy about his find and hoped that although the bike was not in very good shape, he could still sell it and "make a buck". He had been living in a shelter and just recently managed to move to a rented room and live independently. John had been coming to CBTO for years as a volunteer for the Wistar trial.

He was born in Augusta in 1947, Georgia and came to Philadelphia when he was 18 years old. John's father died when he was ten and he lived with his mom, older brother and sister. He remembers that at school he always got good grades until sixth grade, when he stopped because he was doing a lot of drinking and drugs and

got kicked back to grammar school. He regrets that he never learned to read. John started working very early in his life.

His father had a wood business, and when he died a friend of his bought the truck and the coal and everything else and John and his brother started working with him. This was his first job, out of necessity. " I've been always a survivor, you know what I mean? My mother didn't have enough money after my father died and she had to work and I had to learn how to cook at an early age if I wanted to eat. And back then you could sell soda bottles –they ain't got here not more-, I used to plug soda bottles to have extra money to go to the movies, to go to the football games on the weekends, it was a kind of hard struggle".

At 16 John left Augusta to try his luck in Philadelphia where her sister where living. He explained to me:

> "But for me, being the baby of the family, I was always experimenting and always kind of adventurous. I always wanted to try something new.
> Like I said, I left Augusta at 16, quit the school and got a job because I was curious, adventurous and you know, Augusta is really small: at ten o'clock the bus stops running. If you live outside the city that means that you need a car. My sister, my older sister lived in Philadelphia and she used to come down every Christmas and visit. So she said: "when do you come to Philadelphia?'. Oh, yeah! I am wild anyway, you know what I mean. So I went, moved to Philadelphia in 1976, Ringle Street. I got a job later on that year at a restaurant called Geno's, I was 18. They sold burgers and they also sold Kentucky fried chicken, it was like two restaurants in one. So that was my first job here and I was cooking chicken. I cached real fast and the manager who hired me got real close.
> When I came to Philadelphia I was just smoking weed but when I got here I got introduced to speed. I was doing speed on the job, me and my manager, I told him about it and he said: "bring me some in". He had never tried, he liked it and we got real close. (John 7/30/2004)

When John was working at the restaurant he met his future wife who was also working there.

> I met my wife in the same restaurant, we got a place together. I am still getting high, doing a lot of drugs, she was not but she didn't say anything because she was in love with me. We stayed together for two and a half years. I am working, she was working, but I would never stay home. She got pregnant and still I wouldn't be home but I was bringing money.

When something disappeared from the restaurant where he was working his friend and manager fired him. It was then that John, unemployed, starts a career dealing drugs.

> Then, I had a cousin that lived in Atlanta, whom I never met, and he started coming here bringing me pounds of weed. Now I am selling weed. I was walking around with $2000 per day. He was coming like twice a week bringing me weed. I am the king of the neighborhood now because you know, back then weed was the real thing, like it is crack now but back then it was weed. I was living the life of Reilly, everybody in the neighborhood giving me and my wife respect.

It is around this time that he also started shooting speed. "I started using needles. One night I was with a couple of friends and they told me that I should try to shoot it and my being curious, adventurous, I did it. I couldn't hit myself so they did it and I tried and I liked it, so I started shooting it"

In 1979 he left his wife and started a relationship with a woman that was living across the street from his sister. After leaving his wife with two kids, he we went back to Atlanta, Georgia. "My girl started tricking for money, you know. When I moved back to Atlanta I had another connection and I was selling weed. And this went on for years". After having two tickets for driving under the influence (DUI) he decides that is time to go back to Philadelphia. They moved with her mother, his girlfriend went back to "tricking" and John found job in a factory. "We were still doing our stuff" John told me, alluding to his drug habit but then his girlfriend "OD [Overdosed] on me. I was scared to shit. I put her in the bathtub in cold water and she

came back". Although John was very concerned with the risks of overdose in relation to his intravenous drug use he was not aware of the risks of AIDS transmission.

> Me and my girl we shared needles, sure, I wasn't never too particular about it. I didn't hear about AIDS until the 90's. I was having sex wild, no condoms, nothing. So I was sharing needles a lot and sometimes they tell you that you need alcohol and bleach to clean it. But sometimes I just wait to whoever was taking the needles outside and run some water through it and dump it, but you can still see a little blood on the thing. That happened, I got HIV. I think that's the way I've got it because I know a lot of people with HIV now that I shared needles with. I could also have gotten it from unprotected sex because I never used condoms either. I still don't like them but I use them because they say that you can get locked up from spreading this shit. So, I don't like them but I use them, now.

After his girlfriend's last OD she stopped using drugs and she wanted him to stop.

> I said: "why should I stop? I never OD". But she wanted me to stop and then I went to Eagleville and had a seven-day blank. I got some pills, got caught and was kicked out. When my girlfriend saw me she told me "what are you doing here? I thought you wanted to stop?' So, she kicked me out right away". Then, John came back to Georgia and stayed at his mother's house in Augusta. He landed a lob at a steel factory "a damn good job, the highest paying job I ever had". He worked there for two years but lost his job because of his drug use. "I was getting high too much, I couldn't get my ass to work. I got a job at another factory but that job man, that job sucked. It was an animal food factory and the flies and the shit around sucked. All they do is to change the name in the bag".

John was working when he learned that his mother had passed away. He then moved back with his older sister to Philadelphia. Shortly after returning to the city, John went to jail upon committing a crime to pay a drug-related debt, where he learned of that he of his HIV status. "And when I got locked up they do the test on me and that's how I knew I had HIV, 1998. I said: "why not do the test" but I never thought I might have it. Before I knew I had it, I thought I would spread the shit then,

then they will find a cure. But after I got it I changed my mind: no, I am not going to spread this shit, you know what I mean?"

Michael

I met Michael when he came to CBTO for a routine follow up on an 'industry trial'. After living with HIV since the late 80's, he was running out of therapeutic options and hoped this new trial would give him new possibilities.

Michael was born in 1961 in Philadelphia. He had a middle class upbringing.

> Mother, father, one older sister. My dad was a chemist and my mom was a house maker and a part-time worker. My childhood was somewhat dysfunctional. My father was an alcoholic so that created a lot of distress in the family. I guess early childhood was ok. I wasn't a very happy child through my high school. I was questioning things in my teens and in high school, I was very uncomfortable and that led when I was 15 or 16 to a lot of marijuana usage. I think I was just trying to get away from a lot of stuff. That marijuana usage stopped after I flunked two years in high school, I had to do summer school, I quit smoking pot. I did well in high school. (Michael 7/30/2004)

After finishing high school Michael found a job in a restaurant in downtown Philadelphia. He frequented gay places downtown but struggled still with issues related to his sexual identity.

> "I am in a struggle there because, as I said, I am almost 18 and I still haven't quite figured this out. I never had a sexual experience until downtown. I associate being homosexual with failure, that is what I was told. Failure in not fitting in, in being different. I was very concerned about it in my job. I've worked with a lot of gay individuals and I loved them all, very much, I wasn't ready to come out yet.
> Early on there was a lot of you know, sitting on the fence for fear. I associate success with being straight".

At twenty and wanting to 'fit in' he left the restaurant business and went to work in the credit department of a bank while still doing part-time courses to get an accountant degree. He engaged heavily in anonymous sex and 'binge drinking'.

> "I wanted a "regular job". I stayed there. Now, my drinking is escalating a lot with a lot of binge drinking. I was coming downtown –still living in Northeast- and a lot of, you know, the cinema…I wasn't going a lot to gay bars. I was just doing a lot of anonymous sex. That lasted for a while and then finally I met a guy and I guess I felt in love and I was still living at home but things were securing up with my mom and then I thought that it was time to leave. I was 23. It was right on the 80's, 83, 84, that time. At that time I still had a boyfriend downtown. He was 15 years older than I was, very nice. He was doing fine but he hadn't come out either. Even I came out before he did. In our relationship he was not out in public. By the time I was 24 I had finally done that.
> I also decided that I wanted to cook. I loved the bank but I decided that it was time to pursue a cooking career. If I was going to do it at any time, it was there. I went to the Restaurant School here in Philadelphia and I embarked on that. So, I am in a new apartment alone, totally new job –I went to work to the Fish Market Restaurant- and I worked full time night and I went to school full time day. I was really burning up fast. Between that year and the drinking I know I killed myself.
> Things were going very well, working, studying, living alone but it was a year of madness, very lonely, very lonely. I had no connections with downtown. Even when I met people I knew from the bars I was really at a loss. And with all the sex that had been going on, all this madness".

By the mid 80's, the HIV epidemic was already under way and Michael could not avoid taking note.

> "I remember watching the TV one time and Channel 4 had this thing and it really hit me. I guess it was 1987 by now, it was a special and it had two guys talking on the phone. It was a play focused on AIDS and it was a presentation of an off Broadway show that ran in New York. So I remember watching it, I focus on these two guys talking on the phone, very sad, back and forth talking about a friend. And you hear that and you know what it's happening around here and in San Francisco and it was like the second or third time that I ask myself this question. I wonder I hadn't done anything wrong, but I knew I had. I knew it was a problem. But when I saw the TV piece I thought, I wish I hadn't done anything, poured another drink and thought: "well, let's see what happens". I wonder if I had met anybody in the restaurant business with

> AIDS. I definitely heard of people passing away but I was trying to shut it off".

Despite Michael's efforts to "shut off" the risk of HIV transmission, two years later he was forced to deal with his own status as HIV positive.

> "So, I came down with Hepatitis B. This might have been early 89. Mid 89 I was sick as a dog. I was so sick and I had no health insurance, I had no doctor –I was working but with no health insurance- and really blind to gay man's disease. Except for the usual sexual diseases I was ignorant of all that. I was not even dressing things and it was crazy. I am paying for it dearly now. I called my sister and she called Jefferson. And the nurse-administrator set me up with the doctor. The guy was a very nice guy, probably the greatest guy in the world. So, he needs to see me. I go back that same day and he was waiting for me. I could barely walk, I was so sick. He laid me down and told me that they were doing the blood work and that they would call me as soon they came in. I had the idea that I might have HIV in the back of my mind but not really.
>
> He suggests an HIV test and I thought "ok, you have to do what you have to do". He brings me back and then he gives me my HIV diagnosis so now I am really like a wreck. Everything was a mess. I thought my life was over. I was only 28 years old and I thought that I was just gonna die. He told me: "you are gonna go five years". My doctor said: "this is what we do for this, this is how we treat this. You feel very sick now. It's probable that the Hepatitis. I've seen your counts and based on this you probably had this for two years because your counts are at 300. That means that you have this for a while. I am gonna give you five years. You are gonna have five years".

Geraldine

Geraldine was introduced to me by Grace, the head nurse in the research department at CBTO. Geraldine had been coming to CBTO as a patient first, then engaged in weekly women's support groups and finally ended up working at CBTO as a peer-educator coordinator. In her mid 40's, she was born in Hawaii but did not stay there for long. Her father was in the navy, which forced the family to move frequently, until their parents got divorced and she moved with her mother and brothers to Delaware.

> " I had two brothers one younger and one older than me. I was seven and I was in Delaware until I was seventeen years old. I went to kindergarten and first grade in California, second grade in Delaware and I graduated from high school there.
> While I was in high school I started doing marihuana and doing drugs and drinking, you know, the high school kid kind of stuff. So then, I moved on to doing cocaine when I was in my twenties. In 1983 I had one child, I graduated when he was six months.
> I was living with my son's father for a little while and he didn't want to support us. I had a little job here and there. I was 17. I worked at Campbell's soup factory and then I worked in King Cole, another factory. At Campbell's I was sorting vegetables all day and King Cole was the same way but it was a clam factory and I had to sort the clams from the shells, I liked that job. It's just a small, little piece that you pull out, with your fingers. It came already open. Then I worked at Thompson, which is a Chicken factory, but I just lasted thirty days. In the chicken factory I had to grab the chicken's kidney and stuff and all up to here [the arm] my wrist would be so sore after the day because I had to grab it and you had to do like two at a time. So I didn't last that job too long. Then I tried to do some job training but didn't work. And then I started using drugs heavily and then at twenty-three, twenty-four I moved to Wilmington, Delaware. I just moved there because I went to jail for shoplifting in Dover so I spend there like six months and then they put me on work release and I had a little job doing janitorial work. (Geraldine 8/2/2004)

After being released from jail, Geraldine stopped using drugs for a while until she started using drugs again while engaging in prostitution to afford the drugs and shelter. It is then that she is arrested for prostitution by an undercover police officer and went back to jail for six months. Some time after she was released Geraldine came back to jail once more, also on prostitution charges. It is around this time that she finds out about her HIV status.

> "Somewhere in between I found out I was HIV positive, it was 1989 when I was diagnosed. I just had a cold that I could not get rid off and it was this time of year, August and I couldn't shake this cold. So I went to the doctor and he said that he would treat me for the cold but that he wanted to do an HIV test. And me: "sure, go ahead, if you have to take it, you have to take it. Do it". Not thinking that it would come out positive. I never thought about it. Even when I was sharing needles and stuff I never thought about it because I was trying to get high. And also they didn't have much education at Wilmington, they only had bleach kits and condoms, that was the outreach. And that's as far as the

> street outreach went. They didn't say that you constantly do these things that you always have to have bleach kits and all the stuff, they never said that. They just gave us a bleach kid and condoms and that was it. They never sit down with us and explain things to us. I never knew anybody with HIV, nothing, nobody. I never asked, and back then you couldn't tell because you didn't look like you had HIV. So when I found out I was upset, I was four months clean and I started using again because the doctor said: "you have AIDS and you are gonna die". He didn't say go to this place to get medical care, or there are these help groups, no."

Coping with HIV

Once he learned about his HIV status, John equated his diagnosis with a death sentence, an assumption made by many health workers, patients and public alike in the 80's. However, a few years later, his contact with Action AIDS, a community based organization, led him to re-evaluate his situation.

> "I didn't know that much about it and I thought: "damn I am dying". I know that they have no cure, then I am dying. But after I thought a little more about it if you take your medication you can live a normal life. My case manager told me these things. Because when I was in jail Action Aids comes to jail, so I had a case manager. And they put me in another cell with other people with HIV, everybody in the house was HIV. And they had a lot of meetings, told me about HIV, that it's not a killer, that having HIV is not AIDS, well, I got educated. Still not sinking in: I got HIV, how the hell I did that? I should have been more careful but I didn't give a fuck.
> When I learned that I had HIV then, a couple of friends of mine which were shooting drugs told me they were HIV. I never told nobody. The only people I told I was HIV is my family.

John not only received information about HIV and became more confident about the outcomes but also managed to receive treatment from a top medical doctor and researcher from a local university.

> The doctor I am hooked up now, I've been with him for four years. He worked at Temple and he moved to Presbyterian, he is the chief of the infectious disease department. So, I have one of the top doctors in the country. He goes all over the country giving presentations and stuff. I just stick with him and I stopped using drugs for a while. I stopped using drugs about one year and a

> half because I am still trying to figure this shit out. I am going to tell people about my HIV or not? I am going to tell a girl I am with that I am HIV even when I am using a condom? Why should I tell her?

John kept going to Action Aids on a regular basis and this past year he started working with them doing outreach among male shelter residents.

> "I meet my case manager every week at Action Aids. Now I am a volunteer. They have this new program and I have my little cards I pass out. I've been working for over a month now and I gave out more than 400 cards in shelters, drop in centers where people came from all over the country and they have nowhere to go. I give them cards to go and get tested for AIDS. They get counseling and shelter, the same thing I got. What we are trying to do is to have them to come in. The cards have my last four digits of my social security card and last week just eight people showed up, so I know it was me. I want to spread the world that you can get tested and still have a normal life before it is too late. Well, no, I wouldn't say a normal life because I feel different now. My life changed because you know, I heard people talking about other people who got HIV and it's like they got plague or something. Like, if I touch you, you might get HIV; they don't know but that's what they think. I hear people talking about people who I know they have HIV and I don't want them to talk about me like that. And I just got out of a relationship with this girl –she got HIV and she was my first HIV partner- and she told me right away. I didn't told her that I had it: she read it on my medication. She was kind of calm about it. I came late that night and she said: "why didn't you tell me that you had HIV?" and I: "uh? How do you know?". She said: "Why are you taking these medication? I've seen your medicine". "So, I got it too. OK, all right" This is recent, this is like, two weeks she stayed with me."

John is currently taking HIV medication and is doing fine. He told me that since he cannot read the drug names he knows which ones to take looking at their colors. The system works fine for him, he hasn't missed a dose.

> I saw my doctor and he said that I don't need to start taking medication right away. Like I said, I have a top doctor in the field then I said: "well doctor it's up to you" and he said: "right now everything is cool". Then I said: "ok, let's start taking the medication".
> I started talking with Teri (CBTO's phlebotomist) and she knows I am taking my medication because every time she do my blood draw everything is undetected, I have no problem taking my medication. I get my pills once a month and I am getting them religiously, you know what I mean? I don't miss a dose, I take them twice a day. I haven't miss a dose in four years.

After being diagnosed Michael learned that he had five years more to live. He started taking AZT, the only drug available at that time, kept working and stepped up his alcohol consumption.

> "You probably are gonna get sick during these five years and we are gonna take care the best we can. But I cannot guarantee you a comfortable life after five years. He said: think about that". I am 28 so this is not good. He said that he would keep me as comfortable as possible and that I would be under his care, don't worry about anything. And he started me on AZT. Then he stopped it because my counts had gone up and then he tried again with AZT when the count went down. And that began the process. That was the initial drug.
> I went back to work. I was determined. I just forgot about the five-year plan, I blocked it out. I took the AZT I drunk more vodka and I got another job. I had a new job and then I had to address the HPB so I had to go into a surgery for that. So I took care of that and I was like in a lot of pain for that and I thought: "What have I done? I was a wreck. I was really a train wreck. I just still worked hard and I just kept going."

Around that time Michael also met somebody, started a relationship and moved together with him. He also kept working in the restaurant business.

> "I met a guy –in one of these obscure places- but I liked the guy and he was older than me, divorced. And the thing was that he accepted me for what I had. Because I had a lot of rejection, even in a few months I was not having…so, we went into a relationship very early on. We were happy initially. I entered for all the wrong reasons: for acceptance because I felt that I couldn't do any better. So, we got together, it should be 1990 then, I moved him in and I continued to work."

At work and outside his close circle Michael attempted to hide his HIV diagnosis.

> "Remind, people were dying by then. I am noticing it, my eyes were just more open to the whole idea. Not really friends but I see co-workers I am noticing this rumor, and this and that, a lot of gossip and rumor and crap. Because I was trying to hide my diagnosis so I was trying to hide the pills and stuff, you know.
> I still worked –I don't know how, it's just amazing- my T cell count was 180 so there was always back and forth to the doctors. I had lung problems but I would just keep going. That's what I did. I just keep running back and forth between doctors and they keep treating me. It was either false alarm or if they got it, they got it and then I came back to do my things."

Michael continues taking AZT, holds on, keeps working and also becomes more knowledgeable about resources for HIV patients. He also keeps fighting opportunistic infections and his long time alcohol habit.

> "At that point I was still managing, right now we are at the point where it is AZT and d4T. There aren't a lot of drugs out there, 91-92 it was right at that point where if you didn't catch the proteases you would die. So I hang on for a while with that and then I went to…it's kind of a blur because I am such an alcoholic mess at that time. I went back to work at that time and I was just trying to keep my head above water, to maintain financial independence, things like that, pay the health insurance, the AZT was covered by the State of Pennsylvania and what have you. So I was also getting knowledgeable about drugs and the SPBP and all the good stuff but I was always in state of high anxiety with the whole thing. At around that time, in 93 I got another job with a big catering service and I worked for them, it was good, it was a good thing. But at this point I am not feeling well, I had another herpes outbreak. My boss protected me, I think that she knew what was going on. I cannot remember if I told her or not. I probably did and I have a feeling that she didn't care, she was ok with it. I kept working, 93, and then I started to have a breakdown. Checked myself in an institution to come off of the alcohol but that was unsuccessful –stayed for a while but I even got drunk inside-. I went back to work but fell on the stairs. They gave me unemployment and vacation time: " when you are ready to come back, you come back". They were so nice. I was less healthy. I couldn't get into a clinical trial for protease inhibitors because my T cells count was too low, my doctor was very concern and I sort of started to give up."

With his health deteriorating Michael decides to retire from the restaurant business and files for disability.

> "So, I filed for disability in 1994 –I regret that now- it was advised at that point. I just had three hearings, no attorney, I did everything on my own on my home, did everything I had to do and they granted it.
> So, I stayed home, went to volunteer at Jefferson, I drank heavily and I kind of existed for a number of years under that. I had a pair of little jobs doing catering, nothing so steady. It was a life of just decadence and debauchery. No stable relationship, just myself and the house and I moved a roommate in. We existed for a while, didn't work so he left, I brought another in and for a period of 93 to 95 I stayed in the house with roommates."

Around the mid 90's the first protease inhibitors become available through expanded access programs and Michael does not miss the opportunity.

> "At that point Crixivan had just arrived, or Fortovase? -the first one-. So then, I quickly went to expanded access and started it right away. I didn't do the trials, my T cell counts were too low to do the trials. They wanted people with higher counts. But this drug was available and before it was in Pharmacies I was getting it. So I started on a protease inhibitor as soon as it came out. I was probably on AZT, Epivir, DdI, there wasn't a whole lot. I was on a combination and I made it over the hump. I wasn't feeling good, the drugs were like the worst. Also what happens is that I was getting sick from liver disease now because of my alcoholism. I had complicated everything with my alcoholism, so I had a bad liver and my doctors were very, very concerned. And about 1994 I had extended liver damage, my T cells were dropping like crazy, I was even trying not to drink for periods of time. I knew about AA but I wasn't even to go there because I wanted to drink. So, I kept that way, I finally lost the house because I couldn't keep up with the payment so I moved from there to a little apartment across the street where I am right now. That was 1995. I was still seeing David occasionally, he would come by, we had sex sometimes –behind his boyfriend's back-, typical madness.
> And all this time I had been case managed through Jefferson and also Action Aids. All the expanded program access I did it on my own. My doctor and myself did it. I felt like I had all the time in the world to do paperwork so I did."

In Spring of 96' Michael tries for first time to stop drinking by enrolling in the Alcoholic Anonymous program. Although he doesn't stay in the program for long and despite the effects of alcoholism on his health that aggravates existing HIV opportunistic infections, ten years after first diagnosed Michael starts to realize that he might "make it over the hump".

> "I didn't stay in that AA meeting. I moved into the apartment in 95, I went to the first AA meeting on my own in Spring of 96. At this point the alcohol had destroyed my hip, had destroyed my liver, my count was low, I couldn't walk, I needed to use a cane, it just had gotten ridiculous. So, I went, stayed ten, fifteen days, drunk again, but I was tempting.
> I filed for bankruptcy in 97, tried to clean some of the wreckage. I was always seeking the new drugs that were coming up, I was always seeking into whatever was happening. I was still being taken care by the doctors over Jefferson. I was always coming with infections and stuff and they did a fantastic job. Everything that seemed to come out of me they seemed to treat. I was always getting one fucking thing after another and I was always sick. This

> was 10 years after I was diagnosed, pretty amazing, absolutely! The sprinkles were one of the worst because they were all over your face and people could see it, I was thinking: "this is not happening to me". But the doctors took great care of me.
> I had a specialty HIV care at Jeff, not a particular doctor yet, we switched over. More of the protease drugs started coming on the market at that point, 97 –I am not sure-. I started Crixovan right away and I started thinking that may be I would make it over the hump here. I started thinking that I could do it, that I would get through this mess. But now, I was a full-blown up alcoholic and I had been for a long time."

That year Michael also tried again to curb his alcohol habit and came back to AA. This time he succeeded.

> " I started to go to AA and I stayed. 1997 to mid 98, that year was not nice. Not real wreckage. In that year I got more time sober than I ever did and then in 99 I just stopped. I stayed in AA and became part of it, I broke off with everybody from outside, all ties. So, now is what I do. I focus my life on that. I will be sober six years in January this year. I had the five-year coin. So what I do is that I spend a lot of time on that, I volunteer in the community center so I am back more in gay life than I have ever been –than I was when I was drinking-. I am more involved in the community, instead of just a bar. I volunteered in Washington West project which is an HIV testing site, on Locust, right on the block. I've volunteered for two or three years and that was a very good experience for me. So I guess it's pretty much it. I guess I am happier, not dating right now but I still struggle around being with guys that are positive, I am not sure whether I am gonna go with that. I met a couple of guys at AA but I am hesitant, I don't want to destroy that thing, you know? He is negative, I am positive but also he is recently ill. I think that may be it is too much too soon. It's crazy out there, there always coming a couple of guys to the meetings recently diagnosed."

When Geraldine learned about her HIV status she had been in and out of jail and also in and out of rehabilitation programs for her drug addiction. She tried to ignore her HIV status and did not change her life style for some time. Then, she found a support group for people living with HIV.

> " I found out about this support through my addiction because I went to a rehab for drugs and alcohol and my counselor told me about support groups for people living with HIV. But I still wanted to get high, so I went to that group but they knew that when I didn't come was because I was getting high and they would come for me and they would miss me for two or five minutes

> but they still would come for me because, you know, it was that kind of support group. No, I never thought about becoming HIV positive. Why I was trying to get clean for? So I thought that I was enjoying by myself –that's what I thought I was doing, enjoying by myself- kept doing the same stuff, no protection, nothing. I kept doing that until I was pregnant with my daughter and then I didn't know who the father was because I was still tricking and all that stuff. I had unprotected sex, of course, and I didn't believe in abortions –I never had and I never had an abortion- so had her and she's been blessed because she is not HIV positive. I was more concern about her than myself because they re-tested me again, but this time when I got the results I was at the doctor's office at an infectious disease clinic. They sat me down and explained to me everything. They told me that I should go there for my medical care, they just came out with AZT so there was more hope from the first diagnosis when they told me that in a couple of years I was gonna die. Which back then, it was true, I guess but I am still here. When I went out I started tricking and stuff and my daughter ended up in foster care in Delaware. Then, when I really realized that I really wasn't going to die it's when I decided to change. Around late 92, I was still doing drugs and stuff but I was still here. So I thought, they told me two years and I am still here, they lied to me. So when I realized that I was still here I thought that I had to do something because I had two children already."

It is then that Geraldine decides that she wants to stop using drugs but she needs to enroll in a rehab drug program.

> "So what I did is that I saw my counselor and we did another assessment for me to go inpatient. So three months later my counselor calls me. I am still getting high but the last day was May 15, tried to get high but didn't have more money and instead of going out I stayed in bed. The next day my counselor calls me saying I had a bed. I was ready for it. I stayed in the program for one year and then outpatient for another year."

Free of her drug habit, Geraldine turns for support among the HIV women's support group managed by Action AIDS.

> "Then I started going to HIV support groups. I got hooked up with Action Aids, they had a women's support group then I went to another support group in Dinn Street, that was for everybody, that was co-ed and then I started getting educated about the disease and then I started peer education. 95 or 96 is when I did my first presentation to children about HIV/AIDS in a community center and I was explaining about AZT and everything related to drugs. It was fun and they got a lot of information from me. Then I started doing more presentations through the speakers of Action Aids. Then at Action Aids we did a program called Woman-to-Woman program then I started the

> Project Teach at CBTO in 97. Then I got offered a position here, at CBTO in 2000 as assistant case manager. March 2001 they asked me if I wanted the position of outreach person, by March of the following year they asked me to be case manager assistant. I am also studying but it is frustrating. I didn't even had time to do my financial aid for the fall semester yet, so I am trying to get that done. But I didn't had time because my husband has mental health issues. We are getting away for this weekend so we don't have to do anything.
> I started taking medication for AIDS in July 97. My first cocktail was Sequanavir, AZT, D50 and Napavir. That lasted until October 97 and then it was Crixovan, Epivir and Zerit I took that for like, seven years. Now I am on Ziagen, Viramune and Viread."

Community activism as a shift in their experiences living with HIV

What I want to stress in this section is the fact that one of the things in common, besides their initial denial of HIV, and their struggles with drug and alcohol addiction, and precarious life-styles is their encounter with AIDS community organizations that gave them new insight on the meaning and perspectives of being HIV. Through this interaction they gained valuable information about the disease, their prognosis and possible treatments –which also increased during the nineties, in particular after 1995-. This participation "empowered" them to keep fighting and gave them new spaces to find support they needed. As a result all three got 'educated' not only about the disease but also learned about networks of support and institutional help. All them got involved in community based organizations, participated in meetings and in their organizational or outreach activities. John even managed to get some financial support doing 'outreach' work and Geraldine became a professional HIV peer educator.

HIV trials and the Fight for their lives

John's contact with CBTO was initially through a study he was doing sponsored by Presbyterian, the hospital of the University of Pennsylvania. Although John is not sure what the trial is designed for, he knows that he can monitor his viral load and have access to valuable information about the workings of the virus. Being on a fixed income, the financial compensation received also helps him have ends met.

> "My doctor at Presbyterian introduced me to somebody –it wasn't Teri then- it was somebody at Presbyterian but it was done here at CBTO. Before I dealt with Teri I meet three or more people but Teri is the nicest one.
> I don't know exactly what are they looking for when they draw the blood but the only thing I know is that I have to have my blood drawn anyway to see my viral load and stuff. So, they was giving money to draw my blood, why not take it? I am on a fixed income, you know what I mean? My case manager just did a money budget for me, what I pay and what I am getting. I came $200 over what I get because I smoke cigarettes. Cigarettes is 5$, five times thirty, that's a lot of money. I have to pay for my room and I don't get food stamps so I have to buy my food and I like to eat; food ain't cheap. With HIV you have to try to maintain a diet, you have to eat vegetables and stuff. So, it's kind of rough to survive, man, but I am a survivor. I was a survivor since I was 16. I'm on my own.
> I get a check from disability, four hundred and eighty something and I am getting a check from the flyers of $124 once a month. Together that's 611$, that ain't nothing. Then, occasionally, my sister has a neighbor and if I wash up her car, that's $ 20. And sometimes I do odd jobs, a neighbor wants me to go to the store. It's rough but I am going to make it. I do whatever to survive."

John receives a check for disability and uses welfare programs for access to medication and health care.

> "I am still on welfare for the medication, I have insurance. I have all the medicine I need for free, that's one good thing about them. Not in all the United States, but in Philadelphia they see that you get your medication but it's different for different states. Like, in Georgia a man cannot get on welfare, only a woman and she has to got kids. If you cannot make it in Philadelphia you cannot make it nowhere because there are so many places with benefits, all you need to do is walk a little to get it but it's worth it. And I am independent guy, I am on my own. While I did the shelter thing, I don't like nobody telling me what to do, when to go to sleep. So, I told to myself, the

> money I was fucking up doing drugs and shit: that's the place to stay. So I quit. I said, I take that money and put it in a place to stay. So for the last two years I've been on my own, out of drugs and I have my own place, you know what I mean? I am paying bills again –I haven't been paying bills for so long- I am gonna get telephone bills, I am paying light bills, water bills. I need a phone, you know, in case something might happen at night and my sister be worry about me and shit. She comes twice a month, unless something happens. I know I should visit her more. Yes, I need a phone. I am gonna get a phone next week."

After being diagnosed as HIV positive in the mid 80's Michael had been under medical treatment since and as a result he has almost exhausted almost all drug regimes. He came to CBTO a few months ago to enroll in a trial hoping it could bring new therapeutic options for him.

> "I decided to do this trial at CBTO because we sort of run out of options because I always have this high resistant type because I did so many things and some of them are cousins of cousins. My doctor said: "you are doing ok but I don't have anything else to give you". He is at Jefferson but he knew about Zanavir so he set me up with Mark Walkings because he had early access but he pulled a genotype out of me and said: "don't even bother to take it, it will fail, fail, fail" and we believed him in the end. So between him and my doc we moved into other options. What about a T20 trial coming into place? But I missed it because the T cell count was different. They wanted 50 and under and I was above that, so I missed it. So then they wanted to send me to Belleview because they didn't have anything left. He said: "I can run just one more oral with you and then we are out of options. We need to find some options to back you up for these five more years". My doctor called me and said: "you know I really want you to consider CBTO". He really had wanted to consider CBTO a long time ago but now he said it was the time: "it's here, it's coming, you have to go" and I said ok. That's how I appeared here. And at the same time I started looking at T20. We got expanded access for that. Now I am taking T20, Tipranavir, Norvir, Tricevir, Viriad. Basically four drugs in the same class and then T20 –his own- and then Tipranavir and Norvir is part of the clinical trial. So you have all the classes covered, except for the middle class, which I am done with that. Previously I've tried a drug with my doctor by Giulliard called Previard. It was supposed to be another nuke but it was a failure.

This trial seems to be working for Michael helping him to cope better. The trial along with the medication he is receiving "creates a better life" for him.

> "I feel very happy with this trial. I have some problems with the orals now, it's has been a while but I have some stomach distress lately and I have to address that. Also, the needle was ok but there wasn't a lot of fat that I had, so right now I am concentrating the needles on the belly, so 99% of my needles go in here. It's hard to push the needle but it gets in there.
> For Tipranavir and T 20 I get expanded access. As long the drug doesn't kill anybody I think they are gonna keep it in expanded access. For all purposes I plan to stay on T20, Norvir and Tipranavir for as long as I can take them. My numbers are much better now. I never had a viral load under one or two million. The lowest I had was 60.000 and now it is undetectable. This is the first time in my life. One little, tiny time I had it with Crixivan but it lasted a month and then it falled apart. If the viral load comes down, the pain goes down, it's weird. I used to wake up in the morning and I couldn't move, the overall physical pain had gotten really bad and it's funny how that has changed. That's one thing researchers should start asking and researching about. So it does create a better life."

Dependent on a disability check his financial situation is tight but he manages with the help of his supporting family. Feeling better and more confident he intends to find a part time administrative job.

> "I go over my budget nearly 75 dollars a month. I am going over 1000$ in debt a year. It's not bad. My family is generous but not wealthy. My mom helps me out, a fifty, a hundred here, Christmas time. So it's good, I have a supporting family, they love me, if I ever go into financial trouble they bail me out but I always try to live within these 800$ a month. I'm feeling it's time to get a legal part time job, like receptionist, similar to what I do in the community center, I answer phones, etc."

Geraldine has been coming to CBTO for years now first as a patient and now as a worker as a peer educator outreach person. She entered the Wistar trial in December. The trial does not involve any drug test, but rather assessing viral load variations.

> "I am doing the Wistar trial here and I am still on medication. The first part of the study was that they were drawing blood every month and when I became undetectable they would draw blood for like two more times and they would, after 8, 16, no 32 weeks would draw your blood for the last time but they still would see you. My next time I will have my blood draw will be September. I

> am not getting any new medication in this trial, I take my own meds. I started it in December. I wanted to help other people not just me.
> I am getting my medication through SPBP a State program developed through the Department of Public Welfare for people who work whose income is not over 30.000$ a year. If you work and have a higher income you then have other options. Medicines are high. In 97 I was getting my medication through medical assistance. But as I started working more hours I lost that and I got this one last year. If you are not working you can apply for SPBP but you can also apply for medical assistance."

Currently Geraldine is not only working and trying to finish an Associated Degree in drug counseling but also divides her time taking care of his three children and her ailing husband.

> "Right now I am living with my husband and three of my children. After I entered my last rehab program I found I was pregnant with my last child. They had AZT for the mother, monitored the baby and that's was it. But they kept me on my medicines until I entered labor. They gave me a cesarean. This is April 1993 and the doctor says: "if he is not breathing I am not trying to save him", "how can he say something like that –he is an African doctor-?" I said to myself, I am not going to worry about that. When I saw him breathing, ah, ah, ah, that's it! Henry is like his father. He's a miracle, he shouldn't be here. My thirteen years old daughter came home April fourth, on her birthday [from foster care] nine years ago. And then my baby son is six. All different personalities, my personality, their personalities, oh my goodness!
> I think that I had more money before I started working. I am broke just a few days after payday and I didn't use to be broke a few days after payday. Now I have to pay all this bills, we have to buy our food because we don't get food stamps because we are getting too much money. I am not getting a check from disability because I work. Before I had received checks but now I don't because I work. My husband gets disability. He has arthritis in both ankles. He cannot walk outside the house.
> I think that it's good that other people that are HIV positive to look at life a little bit different and know that just because they have HIV that doesn't mean that they cannot work, they cannot do things for themselves because they can. I am struggling sometimes but it can be done."

[This weekend she was going away with her husband to a hotel, they told their kids they were going to Jamaica but didn't expect the older ones to believe that. Pay baby-sitting]

A common theme in their narratives: being a survivor.

Despite their differences regarding gender, class, racial or sexual orientation, the life stories of John, Michael and Geraldine reveal similar trajectories. Their awareness and proudness of their ability to hold on, to struggle, to survive, to make it, in very difficult circumstances is hard to miss in their accounts. The notion of "struggling" and their perceptions as "survivors" structures not only their accounts but also shapes their sense of self, their identity, allowing them to make sense not only of their past but also their present as HIV patients and trial participants.

For all of them the trial is one more strategy they have in coping with the disease. In Michael's case it offers the possibility to test new drugs in their last stages of development that have not been introduced to the market yet, expanding his already limited therapeutic options.

For John and Geraldine, doing better with their HIV condition, the trial is not a life and death matter but instead it offers them the possibility to contribute to the development of scientific knowledge while also gaining valuable information about their health condition and the workings of the virus. It is clear that for these patients trials offer certain "empowerment" by making them active participants in their struggle against AIDS. Knowing viral loads, or how the body responds to the virus offers a sense of agency and control. But there seems to be an additional gain in their trials participation. Geraldine, John and Michael seem to have experienced an improvement in their quality of life associated with their clinical trial participation.

This perception is confirmed by CBTO's PI who suggests that patients that are enrolled in trials tend to do better than those than did not:

> "It's my impression that patients that are involved in trials tend to do better than patients that are not involved in trials, in general. And the reason is that being involved in trials, they are monitored very closely, they have more support, they are closely monitored, there is that accountability that goes on, the regular visits, and every time a patients shows up into his visits he is reminded that it is extremely important that he takes the medication, getting five, six calls in between visits from the study coordinating to see how he is doing, reminding him to take his medication, stuff like that. And for definition, when somebody gets involved in a trial, understanding what the commitment is, he has to really make to be in a trial, that tells you something about the background of the patient. These are usually who care, who are very obsessive, they want to really do everything right. But nevertheless, being in studies is important because it really keeps the patient involved. We still have problems of adherence. Sometimes we have people that come with the bottle half-full. And we tell them, why are not taking your medication? But again, the fact that they are coming regularly to see their doctor is helpful. The number of visits in a trial is more common than non-trial patients. We see our patients usually four times a year. If they are in a trial they have to come eight to nine times a year."

Finally, in addition to the empowerment gained through the enrollment in HIV trials, and the possible benefits in terms of their quality of life, for some patients there an additional gain: financial. Financial compensation plays also a role in John's and Geraldine motives to enter the trial, even if it is not their main motivation. Michael is also in need but with a larger support network due to family help financial compensation is not relevant. Also, his higher stakes in the outcomes of the trial makes the financial issue much less relevant for him.

Geraldine, John and Michael's attitude towards financial compensation reflect similar views among the larger population of patients enrolled in HIV trials at CBTO. For example, in a semi-structured survey I have done among some volunteers when asked about their motives to join the trial, two thirds mention help science find a cure or improve treatment options as their only motive. Despite the general formulation of the question, some also expressed their hope that the trial would also benefit them

therapeutically as well. In addition, besides their intention to contribute to scientific advancement, for one third of the volunteers surveyed, financial compensation is also a factor in their decision to volunteer for the trials. As some put it "money is always good" and 'even a little money helps".

However, it is clear that while financial incentives might have played a role in the volunteer's decision to join the trial it is not the main consideration. The fact that financial compensation is important to some of them might be explained in part for their financial need. In a radical break with professional "guinea pig" in earlier phases of drug development volunteers for HIV trials at CBTO do not perceive themselves as a commodity, trading their body for financial gain as it was the case among the professional 'guinea pigs" in Phase I drug trials. Instead, HIV trial volunteers see themselves as patients and are in turn, treated as such by the researchers and staff at CBTO.

In conclusion, this chapter shows that while less central than in Phase I research, financial compensation also plays a role in the social organization of HIV trials at CBTO. While according to its Principal Investigator the financial resources the institution receives from the "industry" trials is just a minimal portion of its operating budget, financial compensation plays an important role in recruiting volunteers for HIV trials.

Narrative analysis of three CBTO volunteers illustrates that they perceive themselves as being "survivors" against very difficult circumstances. It is their struggle to live and survive that pushed them to "get educated" about their disease, adopting an active role against it that included community participation in AIDS

organizations, the active search of medical resources among which they count their decision to join the HIV trials. Although for some of them being in poverty “some money helps” financial motivations are not their main motivation to enter the trial. Instead, like for all the volunteers at CBTO, they see the trials as an opportunity to empower themselves in their fight against the disease, gaining knowledge about the viral loads and defense mechanisms. For some, like Michael, which had almost exhausted his therapeutic options after many years living with the disease, a trial represent a welcome opportunity to expand his drug repertoire.

Chapter 7

Informed Consent Processes, Ethics and Commoditization in clinical trials research.

Introduction

As mentioned in Chapter 2 the participation of human subjects in biomedical research was not regulated until the institutionalization of Institutional Review Boards (IRB's) in the 1970's as part of the Informed Consent process, to ensure adequate volunteers' protection. Most of the literature on ethics in clinical trials surged as a response to the atrocities committed under the Nazi regime leading to the Nuremberg Code in 1948. This literature illustrates ethical abuses in the use of human subjects participating in biomedical research (Annas 1992; Katz 1984; Altman 1998; Moreno 2000; Kauffman 2000; Mayers 1991; Rothman 2000). A particular area of ethical concern focuses on the institutional mechanisms that safeguard human participants (Barber 1980; Gray 1975; Fox 1974, 1989). Examining clinical trials in the 70's, just as the process of bureaucratization of clinical trials research was being consolidated, Barber and Gray focus on the impact of new mechanisms such as the Institutional Review Boards (IRB's) on research ethics, and the potential for these mechanisms to prevent further abuses. Barber notes that professional norms do not stress enough the value of informed consent, and that the institutional pressure particularly on young researchers to achieve or consolidate their positions, may put their subjects at risk.

These authors make a valuable contribution by providing systematic data about the social organization of medical research and, in particular, the mechanisms

of human subject protections in academic settings. However, a limitation of this literature is that the authors fail to acknowledge the relationships between academic and industrial settings, as well as the role of the pharmaceutical industry in shaping governmental regulation of clinical trials, which was a central part of the process of commoditization of medical research taking shape at the time (Hornblum 1998). Hornblum studied the newly formed partnership between the pharmaceutical industry and Pennsylvania University conducting research involving prisoners in Pennsylvania from the WWII until the 1960's. He argues that financial compensation for a vulnerable and captive population led to unethical research practices. Prisoners perceived the trials as risky and dangerous, he notes, but could not avoid participating in them due to their willingness to improve their material conditions.

More contemporary attempts to address the relationship between ethics and commoditization focus on professional understandings and regulation of risks in pharmacological clinical trials (Abraham 1995; 1997; 2002; Corrigan 2002). Abraham has pointed to the political and economic elements shaping governmental regulation of new drugs both in the US and the UK. He argues that neoliberal policies weakened the regulatory powers of the state in both countries, leaving the pharmaceutical companies in a better position to influence regulations. The author suggests that this outcome compromises public safety and calls for active public control and citizens' participation to ensure stricter drug regulation procedures. Despite the contributions of the literature on ethics and commoditization to the understanding of historical, social and cultural processes related to human subjects' participation in biomedical research, a number of questions remain. For example, how

financial compensation shapes patients' understanding and disposition to take risks. How do scientists understand the relationship between commoditization and risk involved in clinical trials? And finally, how IRBs understand and deal with the relationship between commoditization in clinical trials and informed consent processes.

This chapter explores the effects of commoditization in clinical trials on the ethics involved in the use of human subjects, in particular, in relation to the Informed Consent Process. The chapter describes the ways in which volunteers in therapeutic and non-therapeutic trials understand the design, goals, risks and potential benefits, taking into account the patient's motivations to volunteer, as well as the conditions in which the trial takes place. Finally, the chapter explores the Informed Consent Process at "CBTO".

" I know what it does to rats" Informed Consent understanding among professional "guinea pigs".

As we have seen in Chapter 3, the Informed Consent Form is the most important source of information about the trial for Phase I. This document details the design, purpose, procedures, risks and benefits involved for human subjects.
As mentioned in Chapter 5 volunteers perceived themselves as informed or very informed about the risks involved in the trials they have joined. A review of a semi-structured survey I conducted among 18 professional 'guinea pigs' confirms this perception. A majority of those who had volunteered in the last six months to a year,

two thirds of respondents remembered the sponsor of the trial, the drug or drugs being tested, the goal and the main risks mentioned in the informed consent form.

During my fieldwork I also had the opportunity to follow numerous professional "guinea pigs" volunteering in diverse settings. I questioned them after they had received the Informed Consent Form after qualifying for the trial and again after they signed it following enrollment. Michael, whose case was introduced in Chapter 3, offers a good example of the way volunteers' understand and respond to the Informed Consent Form. He was first exposed to the form once he was selected to enter the trial. At this point he had an interview with a registered nurse who explained to him the basic components of the trial. A few days later he entered the in-patient trial at XXX and on his first day he, along with the other volunteers, had the opportunity to ask questions about the Informed Consent before signing it. I met him after he had received the form. He told me he had trouble going through it. It was thick, he said. He had asked no questions of the nurse who had handed it to him. He knew who the sponsor was, but could not tell what was the purpose of the study. And while he recognized that the trial involved a CRT (Controlled Randomized Trial) – most trials are randomized trials- he was confused about the complex design involving different drug dosages and control groups. While reviewing the form he noticed that the drug had been tested before on dogs and rats. While nothing happened with rats, one dog had died. I asked him about this. Was he concerned? No, he wasn't, he told me. He just pointed out the fact to me, he said, not knowing what to make of it. It was a much larger dose than the one he would get, he said.

Finally, he could not describe the schedule that included a number of days as in-patient, with a wash out period in between, and then another period as an in-patient. What Michael remembered very well was that it was a two-week, in-patient study at XXX, and that he would pocket $2700 at completion.

After Michael had his first break from the XXX trial, I met him again and we talked about the trial's Informed Consent Form. This was just two weeks after he first received the Informed Consent Form and a few days after he had entered the trial, and this time Michael had a much better idea of the trial goals, design and risks. I asked him if he felt he understood the trial better as the trial progressed. He said he did. As we have seen in Chapter 3, the interaction with other professional 'guinea pigs' before and during the trial plays a crucial role in shaping volunteers' understanding, not only of the risks involved, but also the way the trial is designed, its schedule and organization.

Also, time is an important factor in shaping volunteer's understanding of the trial. As Michael shows, his knowledge increased over time. The first time he was handed the Informed Consent after being accepted but before volunteering, he understood very little. After signing and volunteering, he understood more. By the end of the trial he was able to recite every minor detail concerning the goal of the trial, the drug being tested, the schedule and the risks involved.

During the trial the informed consent had also changed. For example, after the trial started XXX handed another copy of the Informed Consent to Michael announcing some changes to the protocol. Fifteen new members had been added to the study, and following legal requirements, the sponsor had to inform volunteers of

any modifications. Michael was not concerned by this change. However, another change did affect him. He received a $ 700 bonus for his trial participation. He told me he was happy about the money, but he also wondered "why are they giving you extra money? Is there something risky or nasty about the trial? Not that he was very worried. "Easy money" he told me.

The Informed Consent form elicits a number of responses, associations, anxieties and demands among professional "guinea pigs". Some of their anxieties are the product of incomplete or misleading information about design and risks associated with the trial. One source of concerns as we have seen with Michael is the changes introduced to the Informed Consent Form once the trial has started. A Canadian "guinea pig" with a few trials behind him in the US perceives himself as very informed about risks he might face, but changes in the form also give him some pause. I asked him about his self-perception in relation to his degree of information in relation the risks and benefits of the trials.

"Usually very informed. Sometimes the form is not very clear. Most of the time it is because they write procedures out and then they add things later at the last minute, and they change the Informed Consent. Sometimes it happens when the study is about to start and sometimes it happens when the study has already started and that pisses a lot of people off. (Canadian Guinea Pig 7/4/2004).

Another source of concern for professional 'guinea pigs' is the elusive, scientific jargon embedded in the form.

"They have to tell you everything that ever happened, but they say, for example: a large percentage of this population. They tell anything that ever happened when the

drug was tested and then they say this stuff probably won't happen to you. A lot of people have this problem with the Informed Consent. I think that my fear in relation to risk is not so much what they know and are not telling you. It's what they don't know". (Spam 7/28/2004)

Chris's concern is not with the fact that scientists might not willingly disclose information they have about risks but instead, the fact that the uncertainties of the research context make risk assessment uncertain. One of the main unknowns of Phase I studies, as mentioned in chapter 3, is the extrapolation of toxicological results from animals to humans. The fact that a substance has not proven to be toxic for animals does not mean that it is not toxic for humans, which is precisely what the Phase I trial is designed to prove. These kinds of risks are embedded in the structural design of the trials. This element disturbs not only Chris but also other "guinea pigs" as well. Dave, commenting on this issue told me: "I know what it does in rats".

Professional 'guinea pigs" responses to the Informed Consent process reflects their uneasiness and anxiety about the commoditization of the clinical trials in general. As I have shown in previous chapters, it is not scientific advancement or altruism that motivate them to volunteer. With "no illusions" about the Pharmaceutical Industry's intentions in drug research, volunteers only engage in the trial economy for financial gain. They are very aware of the commoditization of their bodies and, as we have seen, resent the dehumanizing treatment they receive as "research subjects". While they self-define themselves as workers in a contractual relationship, they also see the exploitative, coercive elements involved.

> "I was saying it's a fundamentally coercive relationship but any time money is being exchanged for a service –even if this service is consensual- the person

> needs the money to survive, I mean, it's a coercive relationship, there's no way around it. So, because of that, you know, it's a coercive relationship so, I am consenting to participate, I am not being forced to but I need the money and I know that and they know that. It's a business relationship. It's a contractual relationship, I am not certainly doing it out of the goodness of my heart and they are not paying me out of the goodness of their heart, they are paying me because they know this is the only way they are going to get people to do the studies. There are not a lot of people that are out there that want to put experimental medication in their body for the hell of it. So, I think that the big thing they are paying people for is, because there is a lot of people that are out there and this is an easy way to make money taking experimental medication. So, the pharmaceutical companies that are doing this, they are exploiting that, they are exploiting the need that people have for money." (Nathaniel 9/12/2004).

Nathaniel's statement illustrates the group's position concerning the ethics involved in Phase I clinical trial drug trials. One of the most distinctive elements of this group also is their strong stand in relation to the way commoditization affects the ethics of the research process.

"An antipileptic reaction is when your heart stops beating and your lung stops breathing": Commoditization and ethics in trials research among professional guinea pigs

In Chapter 1 I argued that the pharmaceutical industry denies the commoditization of the body in clinical trials research by employing a number of semantic turns that mask the origin of the bodies that feed their trial wards. Professional research subjects become thus, "paid volunteers" being compensated for their "time and efforts". This operation continues in the wording of the Informed Consent Process where a hyper-technical language is employed to avoid references to risks, suffering and death.

Scott, a close friend and collaborator of Grand pa guinea pig who has been

doing clinical trials in Philadelphia for more than ten years explains his anxiety over this point.

> "You have to go to them [doctors and staff] with demands, I am not saying you should do it in a confrontational way but you have to go with the mindset that these people are over here and you are down here, you have to make sure that your communication is appropriate for that kind of relationship. It doesn't mean that you are going to scream at them but you go and say: "ok, I am not going to do the study until you explain what antiepileptic reaction is". This is an example for a study I did once. They were reading down the Informed Consent and they were going like, this is a Phase 1 study. First time in man, we did it with animals already and she is saying that the dose, 20 times over the normal rate, would produce an antipileptic reaction in 60% of the animals. And I was like: "what is an antipileptic reaction?' she paused, "well, is when your heart stops beating and your lung stops breathing", then I said: "that means that you are dead?" and she replied: 'as long as it doesn't start again, yes". That's good to know. People has to be in the right mind set to deal with the authority figures. You cannot be in the mind-set that you are going to CBTO them in everything. You have to be in the mind set that you are not going to trust them for everything too, and that you are going to take care of yourself. So, who is going to help you with that? The people that are at your level, so I think that this is the kind of thing that people in any job had understood. They know how the hierarchy breaks down, how the people in your level in the hierarchy work together to make sure that your rights are being respected. (Scott 6/3/2004)

Challenging the wording of Informed Consent Forms, demanding a less technical and more understandable language to refer to the procedures and risks they face and by reclaiming the dignity and value of the work they do as professional "guinea pigs" volunteers bring commoditization to the forefront of phase I clinical trials research. The group's recognition of the commodization of their bodies also leds to their challenge of the ethics of clinical trials research under the current institutional arrangements. As I have shown in Chapter 4, Guinea Pig Zero (GPZ) attempts to provide a narrative of the history and present circumstances of human subjects in biomedical research from the point of view, and in defense of, the interests

of the human “guinea pigs”. Thus, one of the key issues for the zine was the advocacy of an ethical standard that reflects volunteers’ concerns instead of those of the industrial, professional or institutional groups. Grand pa guinea pig, the editor, covered a number of historical cases of abuse involving human subjects. The zine also gave attention to the Informed Consent process, making it one of the most important issues in delivering the ‘report cards’ of different research sites. Helms noted that laws and regulations cannot adequately protect volunteers. Affirming his anarchist identity, which was shared by most of the professional “guinea pigs” in West Philadelphia, Helms relies not on institutions but in the possibilities of individual and collective organized action.

> “The courts are not going to protect you, the government is not going to protect you. Take advantage of the numbers, take advantage of getting together when the management does not expect you to get together, be very careful, avoid situations like serotonin drug trials, avoid psychiatrists like the plague. In other words, the authorities, the regulators, the courts they are not there to protect you if you are a working class or guinea pig, anybody in the low end of the totem pole. Your brains, your strategy and your getting together and above all, never believing in them, never believing in authorities, you believe in yourself and what it is real about yourself. (Grand pa guinea pig 1/15/2005)”.

Despite the ideological cohesion among the anarchist and other radical volunteers, some members have slightly different views about the role law and regulatory bodies play in safeguarding the well-being and ethical treatment of human subjects involved in research. While sharing the same identity as ‘guinea pigs’, experiences, and views of commoditization in phase I research, some members have expressed a pragmatic conviction that institutions can play a positive role in protecting them.

> "Of course that in a lot of levels I don't trust them. In the bottom line they are making the money. But at the same time, because their bottom line is making the money, at a certain level I don't think they are going to be honest with me out of the goodness of their hearts but I think that they are going to be honest with me because they want to protect their backs. So in this sense I trust that the information they give me about secondary effects and so forth is very accurate because they don't want to be hit with a big lawsuit. So, in this sense, I trust them but it's not, as I said, because these altruistic companies that are out there to do good, it's because they want to protect their own interests, which is not to be hit with a big lawsuit". (Nathaniel 9/12/2004).

Shon, another volunteer, expresses the same conviction about the positive influence of State regulation in protecting human subjects.

> "I think that there is an interesting question you raised about State regulation. While I was working in the truck driving in California I noticed that the regulation on truck driving was much more lax that other kinds of driving regulations so I wanted to do something about it in that context of deaths on the job and also as an anti-status. The thing is that biomedical research is much more regulated and I am happy that it is regulated to the degree it is now, specially compared to the research previously done on prisoners, the Tuskegee experiment, syphilis. Compared to that history I am very happy for the State intervention on that. I can also imagine a society where the regulation would be done by the social and not by the State, through the participation of interested citizens and independent boards." (Shon 6/2/2004).

Nathaniel and Shon's views of governmental regulation are not totally at odds with their radical beliefs. Perhaps their positions might be viewed as tactical differences, the recognition that sometimes the system provides pathways that can be used as a protection against the worst abuses in research. As Shon also recognizes, ethical protection for human subjects have evolved in the last decades, offering levels of protection not afforded to previous generations.

Informed Consent understanding among HIV volunteers at CBTO.

Like the professional "guinea pigs", HIV patients volunteering at CBTO also relied on the Informed Consent Form as a means of acquiring information about the trial design, goals, risks and benefits. In addition, patients at CBTO also consulted with their personal doctors and CBTO staff in charge of their trials before making a decision. This fact reflects an important difference between these two groups. As we have seen in previous chapters, while professional "guinea pigs" do not trust the scientists or the pharmaceutical industry, CBTO volunteers have a trusting relationship with their doctors and CBTO researchers.

However, in some cases their trust should be relativized. A small group, a minority of African American volunteers, have shown concerns about the ethics of trials, mentioning past abuses involving African American populations, and in particular Tuskegee. These patients trust their doctors but also feel that there is something they are not telling them about risks. They expressed their belief that if researchers tell volunteers everything they know about trial then volunteers would not volunteer.

When I began my fieldwork at CBTO in spring 2004, all the volunteers had been enrolled in their trials, some for years. Unfortunately, this prevented me from observing how they understood the Informed Consent Form at the moment of signing. As a result, I could not make the same kind of 'follow up" I had done with professional "guinea pigs" volunteering for Phase I trials. However, data from a survey I administered to this population sheds some light about their knowledge of the trial they were in, its goals, design, risks, and benefits.

The majority of 20 patients interviewed at CBTO declared that they perceived themselves as informed or very informed about the risks they faced when they became volunteers. Most of patients were able to correctly identify the trial they were in, its goals, the drug or drugs involved –if any-, as well as the main risks and benefits. Some patients had trouble identifying the sponsor of the trial. Instead of naming the institution that supported the study, they would name their doctor at CBTO, or the name of the principal investigator of the study, or more frequently the name of the staff member they see on regular bases when they come to do something related to the study. This confusion has no practical consequences and might reflect the complex social organization of trials at CBTO where "industry" trials are held together with "community" trials.

This level of understanding is not surprising, given the fact that as we have seen in Chapter 6, CBTO volunteers actively engage in the trials as part of their strategy to cope with their disease. In addition, trials represent an opportunity to get access to drugs, get better health care and help science advance in the understanding and treatment of the virus. As mentioned in the previous chapter, many volunteers have experienced strong community participation that "empowered" them as a "consumers" of health care services. As a result, they have developed an active role in their health care. Some had, for instance, gone through community based educational programs, at CBTO and elsewhere, that have a section on the ethics of biomedical research in HIV trials.

CBTO's IRB makes the Informed Consent Process one of their most important concerns. This care is, in turn, reflected in the way Informed Consent is sought in the institution. A description of Informed Consent Processes follows in next section.

It is not possible to establish a comparison of the effects of commoditization on Informed Consent Processes among Phase I professional "guinea pigs" and CBTO's HIV trial volunteers. As mentioned, all HIV trial volunteers were enrolled in trials when interviewed, while some professional "guinea pigs" had undergone some trial months, even years earlier. The difference in time shapes the way individuals remembered their trial experiences and their recollections regarding Informed Consent Process. Furthermore, differences in trial design exist not only between groups, but also among HIV volunteers at CBTO. While some trials like Wistar involved no more than the collection of blood samples to monitor viral loads, other trials involved complex drug regimes trials (SMART) or experimental drug trials (Tipranavir).

However, while I am not attempting to do a rigorous comparison of the two groups, some general themes emerge in relation to Informed Consent and ethics. Perhaps the most relevant coincidence between both groups in relation to the Informed Consent Process is the denial of the Pharmaceutical Industry, the IRBs and the scientists involved in trials research of the commoditization of the body involved in such research. As noted earlier, terms as "paid volunteers" being rewarded for their "time and efforts" in the case of Phase I professional "guinea pigs" and the references to "altruistic" volunteers for HIV drugs trials in later drug research are routinarily employed to mask references to a commodified body. Two related sets of reasons

explain this attitude. On the one hand, commoditization in phase I trials involving a group of individuals that regularly volunteer enticed by financial rewards contradicts major ethical principles that guide the Informed Consent Process. The Belmont report clearly establishes that a social and economic vulnerable group is not free to consent and cannot be allowed to volunteer in such trials. This is the reason "captive" populations such as prisoners were banned from trials research. As I will argue in the last section of this chapter it seems that commoditization of clinical trials research has managed to substitute a group of captive volunteers for a marketed recruited group of volunteers constrained by their socio economic status.

While commoditization forces are not so prevalent among volunteers for later phases of drug research and in particular HIV trials some financial compensation for volunteers is usually in place. The denial of commoditization among this population is explained by concerns around the potential for abuse introduced by the fact that volunteers would do so not on the basis of purely altruistic or scientific motives but also their own financial convenience as well compromising thus the principle of autonomy of the person established also in the Belmont Report.

The different degree in which volunteer's bodies are commoditized in their participation as trial volunteers also explains their contrasting attitudes towards the ethics of trials research and the Informed Consent Process. Professional 'guinea pigs" are very concerned in relation to the Informed Consent and ethics. In contrast, apart from some members who had some anxiety over past research abuses, CBTO volunteers were generally unconcerned about this aspect. They trusted their doctors, the institution and hoped that the trial would benefit them, or help scientific

advancement, or both. As we have seen in the previous chapter, financial compensation played a role in the motivation of one third of the volunteers at CBTO, but was not the main impetus, and did not shape their identity or attitude towards the trials.

Ethics, commoditization and the Informed Consent process at CBTO

As noted in the previous chapter, CBTO's IRB oversees clinical patient's rights, making sure the Informed Consent Process is followed. First, the IRB should decide whether a proposed trial involving HIV patients can be conducted. Once a trial is approved, the IRB has to ensure that informed consent is secured from the volunteers before they join the trial. This section explores how the ongoing commoditization of HIV trials shapes the way CBTO approaches the Informed Consent Process.

CBTO's IRB places a high value on research, but some members are suspicious of the pharmaceutical industry's motives for conducting HIV trials.

> "I haven't been involved with any regulatory bodies before but I have a big belief in the value of research. And while I may be always skeptical of the motives of the pharmaceutical companies, and I am concerned about pharmaceutical companies making an inappropriate amount of money while rationing out an important product. I do think that research is fundamentally important in contributing to make a dent into the epidemic. (IRB's Chair 8/17/2004)

IRB's chair's endorsement of research echoes CBTO's commitment to research since its foundation when a group of HIV doctors and activists founded CBTO in the belief that without community involvement in research, progress would be much more slow to come. On the other hand, as a Community AIDS lawyer and

activist, the chair's concern with the profit-driven pharmaceutical industry echoes similar views from AIDS organizations that denounced market driven HIV research that makes access to promising drugs difficult for poor patients both at home and abroad.

The Principal Investigator and liaison with the Pharmaceutical Industry trials conducted at CBTO, while strongly endorsing the pharmaceutical industry contributions, also has a nuanced view of this relationship.

> "Clearly, in HIV the patient's interest is the heart here and what we really care is for our patients in a sense. As you know, HIV advancement has been industry driven. All of the advances made in HIV have been made thanks to the efforts of the pharmaceutical industry. All the drugs that have been manufactured for HIV that are live-saving are not manufactured by NIH or federal organizations. All the tests, resistance testing, viral load test, were manufactured by industry companies. So, unfortunately we are obliged to collaborate with industry because they are the main players in this field. And if we want to be an entity involved in cutting-edge research there's no escape but to collaborate with the industry and that's what's happening. Unlike the CDC and vaccines, for example, or epidemiological studies where the CDC is very strong and you would want to collaborate with the government, in HIV if you don't have a good relationship in collaborating with industry companies you're nobody.
> The people doing clinical trials for the industry are researchers, and we deal with the scientific part more than with the marketing part. When we do the trials we are not collaborating with the marketing people. We are dealing with the scientific liaison in the pharmaceutical company and the scientists are scientists wherever they are they are scientists. They are very objective, they are very decent –their integrity is unquestionable- and we don't deal with marketing, we don't have anything to do with marketing. It's mainly the scientific committee of the company we are dealing with". (CBTO's PI 4/27/2004)

As an HIV researcher and doctor, I could sense CBTO's PI's excitement for recent developments in pharmaceutical research involving HIV drugs. As a doctor – very respected and loved by his patients- new drugs offered him the possibility of improving the therapeutic chances of his patients, making them live longer or

improving their quality of life. He seems to endorse the pharmaceutical industry without reservations. All the HIV drugs that are life saving have been developed by the pharmaceutical industry. The CDC or the NIH had not made a significant contribution. Scientists working for the pharmaceutical industry are perceived by CBTO's PI as being objective, their integrity, unquestionable. CBTO's PI's rhetoric is very influenced by scientific discourses that stress the value of neutrality, objectivity and progress.

HIV community activists have challenged this view, arguing that science, ideology and politics played a significant role in HIV drugs research. In particular, community advocates denounced the contributions federal government made in basic research through the CDC and the NIH which, in turn, were later appropriated by the pharmaceutical industry. In this view, the public sector heavily subsidized the pharmaceutical industry by funding expensive and basic research that was the basis of drug development by the private sector. HIV community movements denounced also racial, class and gender biases in clinical trials research for HIV drugs conducted by the industry. For example, initially the pharmaceutical industry used a placebo in their HIV trials. The practice was abandoned only when HIV activists denounced the practice as unethical since it would withdraw therapy from somebody in need and when existing therapies were available.

Due to this activist movement the industry was also forced to change the design of their HIV trials in the mid 90's testing an experimental drug against an existing HIV therapy instead of a placebo. Social pressure from HIV advocates also forced the industry and the government to acknowledge the fact that HIV trials need

to accommodate a broader racial and gender demographic, reflecting the development of the epidemic. As a result, African Americans and women have been progressively incorporated into HIV research.

Despite CBTO's PI endorsement of the pharmaceutical industry he is not signing a blank check to the industry. He recognizes that "unfortunately we are obliged to collaborate with industry companies because they are the main players in this field" and sees the industry at the forefront of "cutting edge" research from which CBTO can benefit.

Echoing a major critique from community advocates, the Principal Investigator's concern is that industry trials are frequently designed to maximize commercial claims instead of producing new knowledge.

> RA: My question was focusing on the following. On one study you have Tipranavir and another drug, Norvir. Are they from the same company?
> PI: No, Tipranavir is from BI [Boer Ingenham] and Norvir is from Abbott. It is not necessary that the two drugs belong to the same company. In the majority of the trials they do not, except in regimen trials. Comparing two regimens among themselves, usually the drugs that you are comparing in the regimen tend to come from the company that design the trial. So the trial tries to use as many drugs as possible in this trial that are manufactured by the company. Most of the drugs are like these. For example, we are doing a trial for GSK comparing Kaletra to Lexiva. The backbone is Abacavir and 3TC, which are two drugs manufactured by GSK, it is not Tupanavir and 3TC, which is manufactured by another company. So the company that designs the trial tends to pick up the backbone based on the drug that the company manufactures.
> That's the whole idea, to compare a drug against a preferred regimen to see if it does well or not. But the backbone, meaning the other two drugs in the regimen –usually comparing two drugs involve the same drugs in both arms- might not be the best option for the patient. [in the case they are from the same company].
> . If you had a chance to design the trial sometimes you wonder if that's the best thing for the patient, now that we know what's preferred and what's alternative. But again, it's always learning. Every time you are doing a trial you are learning more things about the combinations.

As we can see, CBTO is ambivalent about industry trials. The institution recognizes the benefits that can derive from its relationship with the industry, but at the same time it fears different aspects related to the commoditization involved in the research. These anxieties are reflected particularly in their views of the Informed Consent Process. Decisions such as which trials should be accepted and which not show some of the tensions that exist between the desire for scientific and therapeutic advancement, and the protection of volunteers from the effects of commoditization.

CBTO's IRB and commoditization of Pharmaceutical Industry trials

The local IRB at CBTO is concerned also about the effects of the increasing commoditization via financial incentives to recruit patients for their trials. Although minimal at CBTO, the increasing presence of material rewards is perceived as an "undue influence" which constitutes a potential threat to the integrity of the Informed Consent where individuals are supposed to be able to evaluate risks and benefits with independence of any other consideration.

> Well, I am always concerned about the influence that pharmaceutical companies can buy because they have a lot of money. The idea of patient compensation is a tricky one because why are you giving a patient twenty dollars if you stand to make millions. On the other hand, I want participants to balance risks and benefits by themselves, I don't want to see that balance unduly influenced by money. My concern is that if you offer me a lot of money instead of a little bit of money I might be more willing to overlook the risks and I am very concerned about that. I don't want to see participants overlook the risks, it should be a fully informed consent. (CBTO's IRB Chair 8/17/2004)

Risk and benefit analysis is the standard way in which human subject participation in biomedical research is evaluated by prospective volunteers and by local IRB's while deciding on the merits of a particular trial involving human subjects. This criteria, first established in the Nuremberg Code in 1948, has since been incorporated as a key element to judge the ethics of trials. Benefits anticipated from the trial should outweigh the risks to volunteers. This criteria has been criticized by social scientists because it involves a very abstract rationality, detached from the particular contexts in which volunteers weigh the decision to enter the trial. CBTO's IRB considers the relationship between risk and benefits as the basis for their decision, but first, members consider whether the research question has any validity.

> "We think about it in terms of analysis: first, we assess if there is a valid scientific question. Then we go on to the analysis of the risk and benefits of the study. Just to digress with that, if you look at Tuskegee, was that a valid scientific question? Well, I don't know if the question itself was invalid but then when you go to the risks and benefits, then we are off the table. So I think that is always the question of whether the research question is valid. If you look at the experiments during the WWII, were they asking valid questions? The research was all over the place and there were no controls, maybe there was not even a valid question. I think that Tuskegee gives us a lot to think about in terms of interesting questions, maybe, maybe not.
> But the point is that once that you start getting to the risks and benefits analysis then it becomes an absolute no-no". (IRB's Chair 8/17/2004)

As shown in Chapter 2, there was no science behind Tuskegee. However, Ronda's point illustrates how the CBTO's IRB approaches the issue. If the research question has no validity then the analysis of risks and benefits becomes irrelevant, and it becomes unethical to expose human subjects to prove a meaningless point.

Deciding whether a question has scientific value presents problems for a body that is composed of professional and lay members.

> RA: I went to one IRB meeting and was surprised by the quality of the discussion, everybody was so engaged. You are a lawyer, how do you evaluate scientific claims?
> IRB Chair: It is very difficult. We are fortunate to have very knowledgeable doctors and very knowledgeable consumer representation. Because I am obviously not a medical person my role is to break things down even more basically. So, explain it to me very clearly, what would they show? How would it help and in the primary analysis if the help is for the pharmaceutical companies and not the patients then there is something that we are unlikely to approve.

In assessing the validity of the question one major consideration for CBTO's IRB is that the trial is designed to answer a scientific question and not to produce a marketing claim for the pharmaceutical industry. However every research protocol submitted for IRB approval is analyzed also in light of the industry's desire to market the drug.

> Some [were] too risky but most protocols we have rejected are similar to one we had just reviewed. The idea is this; we are looking at the question that is being asked. Is this a valid question, or is this a question that is really designed to give the pharmaceutical companies better marketing –well, not marketing but better claims about their drugs. Is the trials structured in such way that the results can only give favorable results. Geez! Taking two of our drugs in combination is better than taking only one of our drugs. So, now can sell two of their drugs. We are concerned when we see protocols that are more designed to enhance the reputation of the drug, a particular company, rather than to benefit the participant.
> RA: What about the Tipranavir-Norvir trial? How do you see this trial in particular?
> IRB Chair: We looked at those trials and we see that although the trial might generate good marketing claims there is still a valid scientific question. When we have the discussion about approving [a drug] we always try to go back to our basic mission: is there a valid scientific question being asked? And if we cannot go beyond that question then we are done. (IRB's Chair 8/17/2004)

While CBTO's IRB has rejected numerous "industry" trials in recent years because they failed to prove scientific or therapeutic merit, the question of whether a drug trial has scientific merit or is driven by marketing claims does not provide such a clear cut answer. Decisions are reached through a process of discussion and negotiation that involves competing claims and interests of scientific, political, economic, institutional, and local communities.

When CBTO's PI receives a study from the pharmaceutical companies that he feels is not suitable to be conducted at CBTO, he does not return it to the company. Instead, he sends it to the IRB and in this way he can "kill" the project without loosing face with the pharmaceutical industry.

> " Yes, we bring the protocol to the IRB meeting. It is a fair way. When you want to kill a project we are successful doing it at the IRB meeting. But sometimes I wanted to carry a project and the IRB killed. It happened to me. And I tell you; the IRB perceives new drugs as high-risk studies. And this was a new drug and they wanted to [the PI], you know, start looking to the safety profile of this drug and trying to determine the right dosing, so this was like a phase II and the IRB didn't like the idea. They didn't like the idea that the pharmaceutical company wanted to know about the pharmacokinetics of the drug and this was shut down by the IRB." (CBTO's PI 4/27/2004)

According to CBTO's PI, Figth's IRB is so jealous in safeguarding the well being of their patients that sometimes they "kill" trials he thought had merit. Trials that involve experimental drugs pose also a concern for the IRB. Most of the trials conducted at CBTO are of drugs that are in the latest stages of development, or drugs that are already in the market but that are being tested for a different application.

What seems unusual in CBTO's IRB workings is that unlike other IRB's that had been criticized for following a formalistic, almost legal approach to Informed Consent processes, members at CBTO engage in a discussion that goes beyond the

formal issues. As IRB's Chair's testimony illustrates lay and professional members alike engage in a discussion about the validity of the trial, attempting to distinguish between scientific merit and marketing claims. Nevertheless, CBTO's IRB approach to the Informed Consent by volunteers for HIV trials seems static. It assumes that once the Informed Consent Form is signed the individual has fully grasped its content. Certainly, the IRB's approach to the Informed Consent Process reflects a standard practice among such boards both at home and abroad.

> "You know, there is an updated Informed Consent Form if things should change but from a legal stand point the problem of that [informed consent process as not just an instance but as process] the problem with that is that if you say after you are in a trial "I understand it better now" then there is some suggestion that you understood it less before and then if you were understanding less, were you understanding so much less than you shouldn't have signed it to begin with. If so, all of the trial was unauthorized and that leaves you to the presence of liability. You have a mark in time, I see the liability from this moment forward. If you come back later and say: "ok, now I really understood" the first time was then unauthorized? And then it brings a lot of liability questions that make it crazy.
> I think that the Informed Consent Form is totally a legal document. The point of the informed consent is to be clear that there is a moment where you were given the option, yes, no, and you stated which your wishes are". (IRB's Chair 8/17/2004)

Social scientists' criticism of such an approach points to the fact that it considers the Informed Consent part of a process and not just a single event. CBTO's IRB chair thus proposes that the legal character of the Informed Consent Form does not have a negative impact on volunteer's participation in the trials. On the contrary, she perceives its legal character to operate as a protection against human subject's rights, since violations to the Informed Consent Process can lead to stiff penalties and lawsuits against violators. In her view, the legal force of the Informed Consent Form might then help prevent abuses from the pharmaceutical industry.

"If in my desire, me meaning my pharmaceutical hat, if my desire to protect myself has the incidental benefit of making sure that you understand it, because if the only way that I get to be protected is if I explained it clearly to you, then good, everybody is happy". (IRB's Chair 8/17/2004)

In addition, CBTO's IRB chair proposes that the absence of conflict of interests among its members ensures its independence of industry pressures.

> "We are a completely un-conflicted IRB. We are not benefiting from the research dollars given to CBTO. One member works for the AIDS library, which is a member of CBTO, but her salary and her position is not dependant upon CBTO getting research. As for the rest of us we are separately employed, individual members of the community and thus we are not influenced by pharmaceutical dollars. In fact, my law firm does not accept pharmaceutical money. We don't solicit it, we don't accept it and so we try to be as –I don't want to say pure because then you have an indication that if you accept it you are not pure- but unbiased as possible".
> I think that if you compare us to other institutions' IRB's where all the members are employed by the agency and where is a direct correlation between the money in their pockets and the research they approve, compare that with our IRB where none of the members has a financial motivation to be on that board. You know, if CBTOs stops doing research tomorrow, while it will be unfortunate for the community, it wouldn't affect me or anybody else on the board at all. And I think that the greatest protection for the patient comes from having a board that is completely conflict free. So in this sense, we have been always conflict free, we have been always mindful of having consumer participation, making sure that consumers on the board have an equal opportunity to evaluate risks and benefits".

Informed Consent Form

As mentioned, as part of the Informed Consent Process the IRB's has to ensure that human subjects volunteering for a trial give proper informed consent. CBTO's IRB role is to make sure that the Informed Consent Form follows standard guidelines for the protection of human subjects. The Form should describe in lay terminology the trial design, goals and nature. In addition, risks and benefits should

be clearly established. It should be clear for the prospective volunteer that he or she can decline to participate or leave the trial at any time. Furthermore, alternative treatment options should be provided in case a volunteer decides not to join a particular trial.

The local IRB at CBTO goes to great lengths to ensure that these requirements are met in every informed consent form submitted as part of the application for a new trial. However, the IRB board does not directly oversee the signing of informed consent by patients. IRB's are not supposed to get involved in the administration of Informed Consent Forms. The oversight of the informed consent signing is not made by the IRB, but is responsibility of the Principal Investigator of the study. At CBTO the Principal Investigator or the Head Nurse of the study is usually in charge to make sure that the procedures are followed.

For example, Grace, the head nurse in charge of the SMART trial, one of the largest trials at CBTO, explains how she obtains the Informed Consent from her patients.

> "As far as my patients go, every visit I go over the informed Consent Form before the study begins reminding them what the study is about, reminding them what arm they were randomized to. I ask them if they have any questions. I tell them all the time that this is voluntary and I think that the patients in the SMART trial, anyway, they have a good understanding of it, as far as I know." (Grace 8/25/2004)

Although the structure of the Inform Consent Form follows certain legal standards some trials have a more complex design than others and this fact is reflected in the trial's Informed Consent Form. The SMART trial for instance, involves the randomization of its population into two groups, one receiving their usual HIV medication while the other arm does not receive any medication unless

their HIV defenses drop below certain pre-established levels. Grace, takes great care in making sure that the patients enrolled in the trial understand abstract concepts like randomization, a key in the design of the trial.

> "They might not understand that word, that's why I use "the flip of a coin". They flip a coin and you can either get heads or tails and they I tell them what they mean. One is green, one is red, green means you go and red means that you stop, I try to make it in a language that they can understand. Plus we have a SMART media outlet that is very patient friendly and has a good description of the Informed Consent Process, what the study is about, how long. They interview actual patients that have questions and then you can see on the tape, really nice". (Grace 8/25/2004)

As a result of the efforts put in place to properly obtain informed consent CBTO staff seem confident that for the most part patients are aware of the trial design, goals, risks and benefits. CBTO's PI summarizes this perspective:

"The majority of patients that we had in trials understood what they were getting into. Some patients might have a slightly little understanding of what you would wish them to have, and usually you try to clarify that before they enter the trial, but I never encountered a patient that had an opposite understanding, or different understanding to the point they say: "you know what, that is not what I thought it is". I personally never had that experience, but it happens. I've heard that it happens."

As previously mentioned, the understanding of informed consent depends upon additional things such as the complexity of the trial design, and understanding increases with time as volunteers remain engaged in the trial, which explains some differences in the understanding of informed consent among CBTO volunteers, who have the same demographic background.

The commoditization of the body and the ethics of clinical trials research in America.

As mentioned in the introduction, the commoditization of the body has become an increasing presence in biomedicine. Clinical trials offer an additional venue for commoditization of the body and body parts. "Captive" bodies in prisons provided the bulk of the subjects for trials research until they were banned in 1980. Since then, an expanding pharmaceutical industry relied on market-recruited paid subjects to fill their needs. This shift led to the emergence of a new class of professional "guinea pig" subjects. In turn, commoditization trends expanded their reach into later phases of clinical trials research with volunteers and research sites being financially compensated for their participation. While volunteers are aware of the commoditization of their bodies in trials research –particularly in phase I trials- pharmaceutical companies, governmental regulatory bodies and local IRB's use a language that attempts to mask this reality. As noted earlier, studying organ transplant in America Sharp suggests that the denial of the commoditization of the body in this realm attempts to ease social anxieties in relation to abuse by powerful industry interests. Certainly, the same kind of concern might be behind the pharmaceutical industry's denial of commoditization in relation to clinical trials. But how do we account for the same denial among governmental bodies like the FDA and the NIH and local IRB's?

As this dissertation shows commoditization of the body in clinical trials has produced a body of professional research subjects in earlier phases of trials research and an increasing dependence of financial rewards to lure volunteers into later phases

of research. My argument is that commoditization subverts basic ethical principles and guidelines regulating the participation of human subjects in research. In particular, commoditization trends challenge the Belmont Report, which was formulated in the mid 70's to protect human subjects, and sets the foundation of the architecture of the Informed Consent process and current ethic regulations protecting the participation of volunteers.

On July 12, 1974 the National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report summarizes the basic ethical principles identified by the Commission in the course of its deliberations and was issued in April 18, 1979. The document begins with a brief introduction of ethical principles and guidelines for research involving human subjects followed by a section setting the boundaries between practice and research. The following section outlines the main ethical principles: respect for the persons, beneficence and Justice. The final section outlines the application of these principles in relation to the informed consent, the assessment of risk and benefit and the selection of subjects.

The existence of market-recruited subjects in Phase I clinical trials defy the principle of Justice. According to the document an injustice occurs when "some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly" (1979:5) The case used to exemplify this principle in the text is the Tuskegee syphilis study where poor rural back men were denied existing treatment in order not to interrupt the research project. It is a good example since the withdrawal of existing therapy illustrates both the denial of a benefit to which patients

were entitled and also the imposition of an undue burden on this population. The document argues that conceptions of justice in this historical background can be extended to research involving human subjects. “The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulation, rather for reason directly related to the problem being studied. (1979:6). The section of the report that illustrates the application of the principle of justice to the selection of subjects provides further evidence of the articulation of the principle with the practice. According to the text, the principle of justice while applied to the selection of subjects needs to accommodate two levels: the social and he individual. Individual justice requires that researchers exhibit fairness in the selection of the subjects. Social justice establishes the need to distinguish between “classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear the burdens and on the appropriateness of placing further burdens on already burdened persons” (1979:9). The document notes that “some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research” (1979:9)

This is a revelatory statement on the philosophy behind the formulation of this document. The Belmont Report imbued in a progressive ideology of human rights

and the protection of vulnerable groups seeks to protect particular groups from possible abuses in research. Drawing from past abuses where institutionalized populations of orphan children, mentally ill and prisoners had been exploited as subjects the documents intends to set standards to prevent this from happening again, particularly when there is no therapeutic gain involved. While the document makes no mention of Phase I trials it is possible that this situation was in the author's minds since a number of abuses had been reported in prisoner populations volunteering for such trials and this population was regarded in the document as unable to give proper, "free" informed consent. The question remains, which would be the "other less burdened classes of persons should be called upon first to accept these risks of research". The document is silent on this issue as well, but since institutionalized populations could not be employed as suitable research subjects it is safe to assume that market-recruited populations would fill the void. Would this procedure ensure proper, egalitarian subject recruitment? Again, there is no direct reference to this question. However, the authors caution against the effects of economic disadvantage on the unfair recruitment of vulnerable research subjects:

"One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for

administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition" (1979:10)

It seems that current market-recruitment for phase I trials research constitute a direct challenge to the Belmont Report. Many paid subjects for non-therapeutic trials research are poor and constitute clearly the "economically disadvantaged" the report was concerned about. Glaxo, Smith and Kline has its clinical trials research facility at the campus at Pennsylvania University, bordering a dilapidated neighborhood mostly African American from which they draw some of their volunteers. Other universities, like Johns Hopkins in Baltimore are also build in the middle of deprived, impoverish areas whose residents volunteer regularly in the trial opportunities afforded in the campus. It is possible to think endless situations around the country. Not all volunteers are poor however. While they are not certainly rich, this research has show that for other volunteers it exist a life style associated with being a professional "guinea pig".

It is clear however, that the transition from an institutionalized to a market recruited population has produced a group of professional subjects that depend upon the continuous participation in the trials, which in turn relies on their continuous participation to operate correctly. In this sense, this shift towards a paid research subject has produced a new group of "captive" volunteers subjected to the risks and hazards of clinical trials research by regimes of science, capital investment and socio-economic factors such as the emergence of a service economy unable to provide the secure and well paying jobs of an industrial economy, higher rent costs brought from gentrification in certain areas and the increase of tuition for students among others.

Commoditization in Phase I trials research might also place a heavy burden on this population that has no other reason to volunteer in the trials than financial gain. One year after the Belmont Report was issued it led to the suppression of phase I trials among prisoners and signaled the emergence of a market-recruited trials population. It was hard to anticipate then the effects of this change on the new emergent population of professional "guinea pigs". As mentioned in chapter 5 continuous trial participation might expose volunteers to long term effects and synergistic interactions, which can burden the lives of paid volunteers. The recognition of this fact from the pharmaceutical industry, governmental regulatory agencies and local IRB's would challenge the current organization of Phase I clinical trials research and might explain why the problem has not been addressed yet.

However, there is an additional reason. Paid volunteers are considered to be free of the constrains of previous institutionalized populations, and in position to give proper consent to become research subjects. The market-recruitment is part of a contractual arrangement between two individual parties in which subjects, the legitimate owners of their bodies decide to volunteer in exchange of financial compensation. Commenting on organ transplant and ideas of body ownership in America Sharp notes that the belief in the body as private property is broadly shared in America while it is challenged in Sweden where a socialized view is preferred. American's view of the body as personal property is rooted in what Macpherson termed "Possessive Individualism" a bourgeois notion of the individual and property rights (Macpherson 1961). In this sense, the notion that our body is our own private property and that we can dispose of it as we please in the context of a contract among

free, consenting individuals forms the basis of American ethos. It is this notion that explains why market-recruitment of volunteers is perceived as an ethical practice.

In conclusion, this chapter describes the effects of commoditization on the Informed Consent process in clinical trials research. It analyzes how volunteer's and institutional responses to the Informed Consent Form elicits particular concerns about their engagement in an increasingly commoditized field. Paradoxically, one effect of the commoditization of clinical trials research is that the denial of the Pharmaceutical Industry, the IRBs and the scientists involved in trials research of the commoditization of the body involved in such research. The Informed Consent Form becomes such a site of denial and contestation as volunteers, in particular, phase I volunteers which are more exposed and aware of the commoditization of their bodies, attempt to challenge industry's definitions.

Professional "guinea pigs" attitude to the Informed Consent show their anxiety derived from the fact that as "contract workers" they are exposed to a dehumanized situation that leaves them vulnerable and uncertain about the dangers they might face. For anarchist subjects in particular, informed consent also evokes an ethical response in which they claim not just the right to be informed about the risks they might face, as they also engage in an active search for information, which advocates the humanity and dignity of paid volunteer work. While paid volunteers response to Informed Consent processes reveal a profound dissatisfaction with central aspects of the commoditization of clinical trials, HIV volunteers views of the Informed Consent processes shows not distrust nor opposition but trust in medical doctors and institutions. HIV volunteers at CBTO see the Informed Consent form as a

requirement for entering the trial and as a source of information. Aside from a marginal number of African American patients who expressed some reservations about the motivations of the researchers conducting the trial, most of them had no doubts regarding medical researchers' intentions, the trial design or the ethics of HIV trials research. This different responses between both groups might be explained by fact that although the financial compensation played a role in the motivation of one third of the volunteers at CBTO, it was not their main motivation to enroll, and did not shape their identity and experience of the trials.

For CBTO, Informed Consent Processes nevertheless elicited some anxiety and tension about what trials to approve and how to properly inform subjects about trial conditions. This reflects the way HIV trials are organized and conducted at CBTO. A major theme for CBTO's IRB concerns the dilemma between conducting HIV trials with the industry to attract promising drugs or drug regimes on one hand, and their wariness about the ethics of such trials on the other. CBTO's PI, for example, does not question the "scientific integrity" of the researchers in the industry, but is critical of certain trial designs that compare drugs from the same company that seems to serve industry interests rather than those of the patients'.

In turn, while proclaiming the need to do scientific research to advance in the control of the disease, CBTO's IRB has shown apprehension about the industry motivations behind sponsoring certain trials that would enhance the companies marketing claims instead of scientific and therapeutic advances. Its members also fear that the economic power of pharmaceutical industries might abuse poor, desperate patients involved in HIV trials research.

CBTO's IRB, unlike similar institutions that have been criticized for having a purely formalistic approach to the Informed Consent Processes, has engaged with both formal and substantive issues related to the trial, posing such relevant questions as the relationship between commercialism and marketing in clinical trials research and its design and goals. In a sense, this recognition of the presence and effects of commoditization in trial research at CBTO's IRB is exceptional. Industry and governmental bodies deny that commoditization of the body occurs at all in trials research. Recognizing the commoditization in phase I trials contradicts the spirit of the Belmont Report and current institutional arrangements to deal with protections of human subjects in research. The shift from a captive population to a market-market recruited population unfairly targets a particular socioeconomic group of individuals creating thus a new type of captive and vulnerable population. This contradiction with ethical norms and regulations is masked though by existing notions about an autonomous, free and consensual individual able to "contract" in a way previous groups of captive populations were not. This legalistic view of the encounter between the paid subject and the industry is incorporated into the Informed Consent Form, which has become a legal document legitimizing the contract between two parties.

Conclusion.

By following the commodity chain from "first in man" phase I trials to phase III trials this dissertation explores the relationship between the increasing commoditization of volunteer's participation in clinical trials and its effects in the way risk is constructed and managed. The dissertation shows that market recruitment of trial subjects led to a process of professionalization among volunteers signaled by the emergence of a group of professional "guinea pigs" who provided the Pharmaceutical Industry with the regular supply of healthy, disciplined bodies it needed to run an increasing number of trials. The prospect of "easy, quick money" was enough to motivate mainly poor, unemployed working class individuals to become trials subjects to enter into the "economy of the flesh". This constitutes just another turn into the increasing commoditization of the body in biomedical research along with an existing market for body organs and parts. While volunteers are deeply aware of the commoditization of their bodies this fact is denied by the pharmaceutical industry and governmental and local regulatory bodies.

Commoditization is denied by the Pharmaceutical Industry by a series of semantic turns that portraits subjects as "paid volunteers" being compensated by their "time and effort". However, paid subjects became aware of their status not as volunteers but as workers, and developed a shared identity based on common experiences and interests. In turn, professional "guinea pigs" developed ways to express their opposition to the commoditization of their bodies that exposed them to conditions that dehumanized, alienated and exploited them. Everyday forms of

resistance like their refusal to follow diet regimes, or their attempts to disrupt trial results constitute venues to express group solidarity and affirmation. The analysis of their successful strike at XXX shows not only the potential for collective action but also the limits imposed by their mobility and fragmentation.

The commoditization of their bodies involves the continuous participation in trials research, which in turn, exposes professional "guinea pigs" to risks they might be unable or unwilling to recognize. Commoditization shapes not only the subjects' understanding of risk but also their responses to it. Their perception that they were "contractors" being hired for individual trials made them consider the risks in the trials they were joining, but they did not consider the cumulative result of synergistic drug interactions resulting from years of trial participation. Furthermore, the prospects of financial gain upon which they depended to sustain their lifestyles seemed to predispose them to neglect the effects of long-term participation in clinical trials. To complicate their situation, when evaluating risk volunteers constructed a scale that placed certain trials, like those involving psychiatric drugs and other drugs perceived to be especially dangerous at the top of the scale, but in practice financial inducements still leads them to volunteer in trials they considered to be high risk.

Volunteers risk management strategies were also closely related to the commoditization of their bodies in clinical trials research. If professional "guinea pigs" perceived the trial to be high risk they might skip the trial altogether, or might drop out in the middle if adverse effects were severe or unexpected. However, doing so involved the loss of financial gain and therefore this was not a common practice. In addition, some volunteers might attempt "cleansing practices" based on their local

knowledge of their bodily responses to the trial drugs if they feared that the drug course had been very toxic or if they planed to enroll soon in another trial.

Unlike coal miners, asbestos workers or other employees working in toxic environments, their mobility and the seasonal character of their participation tended to obscure the problem of side effects, and in particular, the long-term effects associated with their trial participation. Finally, another element that might obscure their recognition of the problem was that neither the Pharmaceutical Industry nor the FDA keep careful records of the frequency and type of trials involved in trials research.

While financial compensation as also offered to patients at CBTO volunteering to test HIV drugs, this reward cannot be compared to the sums received in Phase I research. At CBTO some volunteers admitted that "some money helps", but financial inducements did not constitute their main motivation and did not shape their identities or their experiences of the trial. The narratives of John, Geraldine and Michael show that the decision to volunteer for HIV trials should be seen in the context of their struggle against the disease. The trial offered them the opportunity to gain valuable knowledge about the workings of the virus, their health status, and for Michael, an opportunity to expand therapies after years of dealing with the disease.

Chapter 7 shows that commoditization shapes the way professional "guinea pigs" perceive and respond to the Informed Consent Form. For this group, the Informed Consent Form elicited anxieties about the exploitation and dehumanization they experienced as paid human subjects. In particular, the anarchist "professional guinea pigs" demonstrated the presence of a research ethic that differed from that

held by the scientific community. In addition, as a result of their hostility towards the Pharmaceutical Industry, they felt the need to become active agents in the evaluation of the information contained in the Informed Consent Form. Based on their own history as research subjects they also felt that they had something to contribute to the role of human subjects in drug research.

For HIV patient's at CBTO the Informed Consent Form elicited a response characterized not by distrust to the scientific establishment but by their confidence and trust in doctors. The form did not produce any alternative ethical views or responses. Finally, for CBTO's IRB and for their scientific staff, the possibility to conduct "industry" trials (in contrast to "community trials") represented both an opportunity and a danger. Industry trials might contribute to the development of much-needed new drug therapies that could improve the quality of life for patients. On the other hand, as a community based organization, the presence of industrial financial interests also elicited anxieties concerning the capacity of CBTO to deal with the pressures that marketing and commercial interests can exert on the Informed Consent Process. A "totally un-conflicted IRB" was perceived to be a safeguard against undue pressures from industry. In addition, lay and professional members alike engaged in formal discussions in relation to the Informed Consent Process, concerning the validity of the trial design. They were suspicious of any trial that was only intended to advance "marketing claims". However, the tensions between the demands of the "industry" trials and CBTO's commitment to HIV patients remained as the number of Pharmaceutical trials increased.

The commoditization in clinical trials research and in particular in phase I not only exposes volunteers to new and unexpected risks derived from continuous participation but also challenges major ethical principles and guidelines regulating the protection of human subjects participating in research. The shift from a captive population to a market-market recruited population unfairly targets a particular socioeconomic group of individuals creating thus a new type of captive and vulnerable population. This contradiction with ethical norms and regulations is masked by existing notions about an autonomous, free individual able to "contract" in a way previous groups of captive populations were not. This legalistic view of the encounter between the paid subject and the industry is incorporated into the Informed Consent Form, which has become a legal document that confuses and alienates research subjects.

The emergence of a group of professional "guinea pigs" in phase I trials research in The United States parallels the emergence of a globalized and flexible model of capital accumulation over the last two decades. Political theorists like Nikolas Rose (1996) in particular, and Graham Burchell (1996) show how these new regimes of capital accumulation have emerged in conjunction with new –neoliberal rationalities of rule that transform citizens subjectivities in various ways. Rose illustrates the "enhancement of the powers of the client as customer-consumer of health services, of education, of training etc. which specifies the subjects of rule in a new way: as active subjects individuals seeking to "enterprise themselves", to maximize their quality of live through choice, according their life a meaning and value to the extent that it can be rationalized as the outcomes of the choices made"

(1996:57). According to Rose, "this notion of the neo-liberal governance requiring that the goals of the state and individuals being the same, assumes that people make a role in "enterprising" themselves, in the name of personal freedom and freedom of choice" (Rose 1996). This new, entrepreneurial self becomes thus, functional to the interests of the neo-liberal state which can now rely on economizing to serve the interests of global capital.

Professional "guinea pigs" embody the new subjectivity required by neo-liberal governamentality. Their flexible bodies (Martin 1994), disciplined, compliant, yet with open schedules and high geographical mobility come handy and "ready made" to serve the needs of a regional and global economy. Their desire for this kind of work and life-style make of these subjects the most flexible workers imaginable, constituting the prototypical "footsoldiers of global capital" (Mitchell 2003). This might be the ultimate irony, in particular, in relation to the anarchist research subjects. Their "entrepreneurialization", as "self-contractors" constitutes not a withdrawal from a system they despise but a fundamental goal of neo-liberal governamentality. While they think they are "opting out" of the system by becoming "guinea pigs", they don't realize that their ability to do so depends on a neo-liberal economy that has set up the playfield in such a way that a group of such "entrepreneurial selves" can be entrepreneurial and feel they are making their own choices. (Lindenbaum 2006 personal communication). Instead of resisting the forces of capitalism they are being seduced and used by it. By becoming "active individuals who enterprise themselves to maximize their quality of life" (Rose 1996:57) research subjects fill a particular niche in the local and global economy. In at almost schizophrenic move, "Guinea

Pigs" both rationalize their actions in ways that reflect and counter hegemonic neo-liberal imperatives.

One of such imperatives is the need for individuals to take responsibility for their own actions and in particular, behaviors that might place them at risk. As this dissertation has shown, Informed Consent Forms responsibilizes research subjects for their own decisions while obscuring possible risks by semantic turns and technical language. I believe in the need to move beyond neoliberal frameworks that emphasize individual responsibility for risks and replace it for a deeper understanding of how corporate desires, technological advances and neoliberal regimes of governance place certain groups of individuals at risk as research subjects. It becomes imperative that anthropological research explores the ethical ramifications of the increasing commoditization of the body in clinical trials research. By describing the articulation of scientific, medical, social and economic practices that make the participation of human subjects in trials research possible this dissertation attempts to contribute to stimulate debate and hopefully transformation of public policies regulating the ethics of human subjects participation in trials research .

Some Public Policy recommendations.

Risk is embedded in the structure of clinical trials involving human subjects. Producing knowledge about new potential drugs and drug regimes involves dealing with unknown or unforeseen outcomes. As in the past, it is the vulnerable, the desperate or the poor that bear the burden in trials research, at home and abroad. Market recruitment is perceived as a legitimate mechanism of risk allocation, where

individuals freely consent to place their bodies at risk in exchange for financial rewards. However, the reliance on such recruitment mechanisms should not validate the current social organization of trials, especially the risks level subjects are exposed to today. As I mentioned, I do not suggest that all risks can be eliminated. What as a society we can do is at least to make clear the level of risk we are willing to accept. Placing individuals at risk for the benefit of the common good is a social decision. Thus we can decide who will suffer the risk burden, establish conditions to minimize risk exposure, and maximize benefits for trial participants and the society as a whole. The following suggestions point to a more equitable distribution of risk in the management of trials.

1) The need to keep detailed records documenting the participation of paid volunteers in trials research. Of particular relevance is information related to who volunteers, how often, where, and in which trials.

2) Scientific, impartial studies of possible drug interactions in the short term, but also over extended periods of time attempting to prevent long term toxicity and synergistic effects.

3) Restriction of the number of trials, diminishing thereby diminishing drug exposure and potential adverse effects. Since this would change some aspects of the market-based organization of trials research, it would encounter stiff resistance from the pharmaceutical Industry. However, from the point of view of larger social interests, there is no harm involved in this measure. Most trials are conducted on “me too drugs” versions of drugs that are already in the market. This increases the industry’s profits, allowing them to capture or expand market share, while exposing

volunteers to risk with no scientific advancement. Fiscal incentives could be offered to companies that did trials that involved the development of innovative drugs. For example, the so called "Orphan drugs" that is, drugs that target a condition so rare that research costs might not be recovered, are a good area for implementing public subsidies.

4) Recognition of volunteers' participation as labor along with better working conditions and proper compensation. We should recognize that paid subjects place their bodies at the service of scientific research and are not just contributing their "time and effort", albeit as they note, it is a "weird" type of work. Acceptance of this point should improve their contractual relationship, affording labor protections guaranteed to other workers in risky environments.

5) Finally, as this research documents, commoditization in Phase I clinical trials research creates a new population of "captive" market –recruited paid research subjects challenging basic ethical assumptions orienting the protection of human subjects in research. The pharmaceutical industry, scientists and governmental regulatory bodies should consider how this new development in brought by commoditization affects the ethical protections for human subjects.

The current corporatization of the FDA along with a pervasive neo-liberal ethos that assumes that what is good for business is good for public administration, tends more towards facilitating a good business climate than to public intervention, and is not adequate to implement any of these recommendations. These recommendations also challenge the industry's and governmental agencies denial of commoditization in Phase I trials research. Thus implementing these

recommendations might need a concerted effort on the part of civil society to re-discuss issues of commoditization, risk and ethics in trials research. In the meantime, social movements and patient's rights advocates have been making demands and suggesting possibilities. These actions have already resulted in a number of successful lawsuits that challenge the conflicts of interest in IRB's and the failure to adequately disclose risks and procedures in Informed Consent Forms.

Another related issue is the question of financial compensation for Phase II and III HIV trials. HIV trials constitute an exception to the general trend in research, which usually involves poor, disenfranchised populations. Despite recent efforts by NIH to increase the participation of these groups who are poorly represented in HIV trials, racial anxieties, and the memory of past abuses in African American population are perceived to explain their under-representation. HIV trials have been conducted in general on white, middle class men. In this respect, CBTO volunteers constitute an unusual demographic group reflecting the current epidemiological trend of the disease, which affects increasingly poor, African American and Latino men and especially women. While volunteers receive small amounts as financial compensation, and financial gain is not their central motive to participate, many admit that money helps. A more substantial compensation could help volunteers improve their quality of life and in so doing, increase their adherence to medications. I realize that this suggestion raises fears that a substantial financial arrangement might coerce individuals into volunteering for trials. On the other hand, poverty, difficulty to access drugs and their illness trajectories condition volunteers' decisions to join trials. Individuals are never totally free to consent as the formalistic approach to Informed

Consent makes us believe. I do not have the solution to this problem but I think that it is important to at least formulate the question.

Future Research Directions.

CBTO's PI's collaboration afforded a glimpse into the relationship between a community-based organization conducting "industry trials" and the pharmaceutical industry. I intend to extend my study to understanding how scientists perceive and manage risk in research trials conducted by the Pharmaceutical Industry.

The Vioxx lawsuits, for example, constitute a unique opportunity to analyze how risk is constructed by industry scientists and by administrators at the FDA. Vioxx represents just the last case in regulatory failure, and points to the need to continue to address issues of commoditization and regulation in the United States.

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