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Diagnosing Exploitation: Justice and Human Subjects Research

by

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ABSTRACT

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In our effort to protect the human subject of medical research we have failed to ensure that the subject will be treated justly, specifically, we have failed to ensure that the subject will not be exploited. I argue that we fail in this regard because we do not understand the concept of exploitation well enough to identify and address all instances of the problem. This dissertation builds a model of exploitation, complete with a principle of justice in transactions, and applies this model to human subjects research.

The model of exploitation shows that A exploits B just in case A gains through his transaction with B, and A’s gain is unjust with respect to B. Drawing from both economic theory and social and political philosophy I show that A’s gain is unjust with respect to B just in case A’s gain is larger than the fair market price and A can make no entitlement claim to the difference.

Applying this model to human subjects research shows that whether a subject is exploited depends on a number of variables, including what the subject can offer to the researcher, what the subject seeks to gain through his participation, and the alternative
ways in which the subject can pursue his desired goods. Each variable can be instantiated in a number of ways, and various combinations of these instantiations can characterize several different subject populations. For each population we can construct a “fair research protocol” and determine whether a given clinical trial is exploitative to subjects recruited from this population. Using this method I show that at least three current research practices, namely, offering money for participation according to an expense-reimbursement model, recruiting from the clinic, and advertising clinical trials as treatment options, are exploitative to at least some patient populations. I also show that these cases of exploitation, and all other cases of exploitation in human subjects research, can be prevented in three ways: first, by modifying protocols to exclude exploitative elements; second, by changing recruiting methods to exclude subject populations vulnerable to exploitation; and, finally, by prohibiting the research.
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Introduction

In the field of research ethics much attention has been paid to protecting the human subject of medical research. To this end we require that subjects consent to participation in research, and we require that the research present an appropriate risk-benefit ratio. I argue that these requirements have failed in their goal to protect the human subject because they fail to ensure that the subject is treated justly, in particular, they fail to ensure that the subject is not exploited.

The requirements fail in this respect for a number of reasons. First, problems of confusion and occlusion have often caused problems of exploitation to go undetected. When multiple moral wrongs occur simultaneously it often happens that only one of the wrong is identified and addressed. In this way problems of exploitation are often confused with and occluded by problems of nonconsensual or harmful experimentation. Second, even when we do recognize a potential problem we do not understand the concept of exploitation well enough to correctly identify and address the problem. In recent years bioethicists have published articles addressing questions of exploitation in such practices as commercial surrogacy, markets in human organs, placebo controlled clinical trials in third world countries, and placebo controlled research within our own borders. These articles, however, have made little progress toward resolving the issues
they seek to address. In all of these articles the authors attempt to apply a poorly defined concept to a concrete problem and this results in poorly supported conclusions. They use the term exploitation as if its meaning, truth conditions, and moral force were self-evident when they are not. There is no complete model of exploitation, and thus no necessary and sufficient conditions for truth in exploitation claims. We do not know with certainty when exploitation occurs, therefore we do not know how to prevent exploitation, and we do not know whether we should prevent exploitation because we do not know the moral weight and moral force exploitation claims carry.

This thesis will build a complete model of exploitation and determine whether exploitation occurs in human subjects research, how we can prevent it, and whether we should prevent it. In this chapter I discuss the history and current state of the regulations and practices by which we protect human subjects of research. I show the ways in which we protect human subjects of medical research and I show the way in which we fail to protect the human subject of medical research. In the next chapter I turn to problems of confusion and occlusion, and in later chapters I develop a model of exploitation and apply it to human subjects research.

**History of the Protection of Research Subjects**

Prior to the mid-twentieth century there was little ethical reflection on using human subjects in medical research. This was, for the most part, due to the fact that there were few practices that we would classify as medical research. Scientific methods and statistical analysis had not yet been developed, and most of the practices that deviated
from what was then the standard of care would be classified as innovative therapy rather than experimentation.

The beginning of the nineteenth century saw the development of statistical analysis, and as scientific methods grew more sophisticated physicians began to perform experiments that could be classified as non-therapeutic medical research.¹ For example, William Beaumont conducted a decade-long experiment on Alexis St. Martin, whose partly healed gunshot wound opened a window into his stomach. Martin allowed Beaumont to drop various items into the hydrochloric acid of his stomach, and in 1833, Beaumont published a book entitled *Experiments and Observations on the Gastric Juice and the Physiology of Digestion.*² By the turn of the twentieth century an “experimental spirit” had changed the face of medicine and this soon gave rise to concerns over the role of the patient as subject and the dangers posed by particular research protocols.³ A roughly defined ethic emerged wherein physician researchers acknowledged that they could not use their patients to test methods or drugs that had no relation to the patient’s illness or condition. They also agreed on the need to use freely consenting volunteers instead of patients for dangerous experiments. Additionally, the researcher usually demonstrated that the experiment did not pose an inordinate amount of risk by making himself the first volunteer.⁴

For the first half of the twentieth century the research community seemed to believe that the conscience and integrity of the researcher was sufficient protection for the subjects of experiments. Physician researchers were considered to be “among the more high minded of the profession,” and many thought their character was such that they would always protect the interests of their patient. The research community was
content to let individual researchers self-regulate and developed no formal guidelines or
regulations for conducting research on human subjects. They maintained this position
despite evidence that researchers were sometimes experimenting on unconsenting
patients and sometimes imposing inordinate risks. In 1947, however, the news of the
Doctor’s Trial at Nuremberg drew the attention of the world to the ethical issues in
medical research and things began to change.

In 1946, twenty doctors and three administrators, many holding prominent
positions within the Third Reich, were tried at the war crimes tribunal at Nuremberg for
medical experiments conducted during World War II.5 The doctors had used
unconsenting concentration camp prisoners as subjects for experiments. These were
experiments “conducted with unnecessary suffering and injury ... in which [the subjects]
experienced extreme pain or torture, and in most of them they suffered permanent injury,
mutilation, or death.”6 The twenty-three defendants were charged with “murders,
tortures, and other atrocities committed in the name of medical science,” and sixteen
were convicted. Nine of the sixteen were sentenced to long prison terms and seven were
sentenced to death by hanging.

Although Germany, unlike the United States and most other countries, actually
had sound and adequate regulations for biomedical research, the doctors were judging
according to an ethical code of conduct that was created specifically for the purpose of
their prosecution. Rarely are ex post facto norms used in adjudicating legal or other
issues, but in the case of the Nuremberg trials “the prosecutors and the judges believed
that, far from being ex post facto, these standards expressed moral imperatives that
should be known to all civilized humans.”7 The code of conduct consisted of a list of ten
principles “that must be observed in order to satisfy moral, ethical, and legal concepts” in the conduct of human subjects research. These ten principles emphasize and delineate the requirements for informed and voluntary consent and the requirements for appropriate risk and benefit. The ten principles constitute the first formal ethical code for biomedical research, the “Nuremberg Code”.

The atrocities revealed during the “Doctors’ Trial” at Nuremberg threatened both the effectiveness of the protections for human subjects of research and the reputation and integrity of the biomedical research community. Partially in response to this, the World Medical Association (WMA) drafted its own code for ethical research. The code was proposed and adopted at a meeting in Helsinki in 1964, and has since come to be known as the Declaration of Helsinki. Like the Nuremberg Code, the Declaration emphasizes the need for informed and voluntary consent, but also differentiates therapeutic from non-therapeutic research and stresses the scientific standards that should govern good research.

More than a decade later the place of codes, guidelines, and regulations in biomedical research was still uncertain. There seemed to be an undercurrent of resistance to moving from guidelines to regulations, and even into the mid 1960’s the research community had yet to establish any formal regulations. Researchers still thought that the conscience and integrity of the investigators were enough to ensure ethical conduct in research, and apparently the Nazi experiments were not seen as evidence to the contrary. The Nazi doctors were not physicians lacking integrity and conducting research in bad conscience, rather they were seen as physicians who had been corrupted by the Nazi ideology and as such had developed a general disregard for the
value of all human life. So it was not the physician as researcher who lacked integrity and good conscience, but rather the Nazi as physician and researcher who could not be trusted to conduct research appropriately. So researchers elsewhere, not subjected to the social context of the Third Reich, were still thought to be capable of respecting and protecting their subjects. Even though everyone agreed with the guidelines of the Nuremberg Code and the Declaration of Helsinki, most thought that regulations were not needed.

The ability of the research community to self-regulate was drawn into question during the following decade when several incidents of egregiously inappropriate conduct in medical research were made public. The first of these revelations was Henry K. Beecher’s article, “Ethics and Clinical Research.” His article was published in the highly respected New England Journal of Medicine, and it listed 22 examples of published studies which, at their inception, would have satisfied neither the Nuremberg Code nor The Declaration of Helsinki. These 22 studies, he claimed, represented only a small sample of the research that was being conducted without the consent of the subject, had an inappropriate risk benefit ratio, or both.

Human experimentation ... has created some difficult problems with the increasing employment of patients as experimental subjects when it must be apparent that they would not have been available if they had been truly aware of the uses that would be made of them. Evidence is at hand that many of the patients in the examples to follow never had the risk satisfactorily explained to them, and it seems obvious that further hundreds have not known that they were the subjects of an experiment.

Among the 22 examples he discussed was the Jewish Chronic Disease Hospital (JCDH) study, which later generated much more public scrutiny and a response from the National Institute of Health. Shortly after the JCDH controversy news broke of the Tuskegee syphilis study. These events launched the discussion about the ethical issues in
biomedical research into the public sphere and there was renewed concern over the use of
human subjects. From this soon followed new legislation, codes, and concrete guidelines
and regulation for human experimentation.

In 1963, Dr. Chester Southam was working at the Jewish Chronic Disease
Hospital and wanted to study the role of the body’s immune system in defense against
cancer.\textsuperscript{13} He persuaded the medical director of the hospital, Dr. Emmanuel Mandel, to
allow him to experiment on the patients at that hospital. There he injected live cancer
cells under the skin of elderly patients in order to study their immunological response,
specifically, the rate at which they rejected the cells. None of the patients gave consent
for the live cancer cells to be injected into their body, and in most cases, neither the
patients nor their families ever knew they were participating in an experiment.
Colleagues of the physicians objected to the experimental methods, and news of
experiment went public when an enraged board member wanted to investigate the matter
and sued the hospital for access to the relevant patient records. Ultimately, Dr. Southam
and Dr. Mandel were censured and their licenses to practice were suspended for a year
(but the suspension was stayed).

In 1964, partially in response to the JCDH case, the National Institute of Health
(NIH) appointed an internal committee, known by the name of its chairman, Robert
Livingston, to review issues in human experimentation. The Livingston committee came
to a conclusion that was, for its time, remarkable:

... in the setting in which the patient is involved in an experimental effort, the
judgment of the investigator is not sufficient as a basis for reaching a conclusion
concerning the ethical and moral set of questions in that relationship.\textsuperscript{14}

This statement is remarkable because it repudiates the idea that the conscience of the
investigator is adequate to ensure that an experiment will be ethical. For more than half a
century it had been custom to leave judgments about the appropriateness of an experiment up to the researcher alone, and now researchers and administrators were doubting whether this practice was sufficient for protecting the subject. They were beginning to recognize that there is an intrinsic conflict of interest between the physician as caregiver and the physician as researcher. As caregiver, the physician enters into a relationship with a patient to help the patient by whatever means available. The physician and the patient share a mutual goal of health for the patient, and this is best realized when physicians and patients cultivate close relationships with each other. As researcher, the physician enters into a relationship with a patient not to help, but to confirm or disprove some scientific principle. The rigors of good science require that this relationship be impersonal and objective, and that the investigator not be biased in any way by concern for a patient. Furthermore, the professional goals of a researcher are not furthered by fostering good relationships and healing patients, but rather by procuring research funds and publishing the results of successful experiments. Physicians, researchers, administrators, and other health professionals began to realize that the physician as caregiver might have been a good advocate for the interests, rights, and welfare of the subject, but the physician as investigator is especially ill-suited for the task of protecting subjects because it conflicts with his interests. Relying on investigator integrity was not only naïve but perhaps counterproductive to ensuring the protection of subjects.

The JCDH case showed that investigators were not adhering to guidelines stated in the Nuremberg Code and the Declaration of Helsinki, and the practice of self-regulation was not enough to ensure the consent of the subject and the appropriateness of
risks and benefits. So then NIH director James Shannon determined that the process of judging the appropriateness of an experiment needed to be unbiased, and the only way this could be achieved was to institute a process of peer review. No longer would the investigator get to determine whether his study was ethical, instead, other professionals in the field would review the protocol to ensure that it complied with the guidelines regarding informed and voluntary consent and appropriate risks and benefits. A Policy and Procedure order was issued to research institutions in early 1966 requiring that they establish such an independent review body (IRB) to review all experimental protocols before the experiment begins.

The discussion on guidelines and regulations did not end with the institution of the IRB by the NIH, for soon after that policy was set, news broke of yet another unethical experiment that seemed to call for more stringent protection of human subjects. In 1972 the New York Times published a front page article describing what has come to be known as the Tuskegee syphilis study.\textsuperscript{15} For more than 40 years, about 600 black men, most of whom were poor and uneducated, had been denied the standard care for syphilis in a Public Health Service (PHS) study designed to determine the natural course of the disease. In 1932 PHS physicians in Tuskegee, Alabama, began to trace the pathological evolution of syphilis in approximately 400 black males, and another 200 without syphilis served as controls.\textsuperscript{16} The subjects were not told anything about their disease, or even the name of their disease, instead, physicians simply told them they had “bad blood”. The men were promised free transportation to and from hospitals, free hot lunches, free medical care, and a free burial after autopsies were performed. The PHS physicians did not administer arsenical and mercurial medications, the then standard
treatment for syphilis, and took steps to make sure no other providers prescribed syphilitic treatments. Later, physicians withheld penicillin when it became the proven method of treatment for syphilis. The men were also subjected to inconvenient and sometimes painful procedures, such as spinal taps, that were medically unnecessary but provided useful information for the study. Furthermore, the entire study was being conducted without the consent of the subjects, for none had even been asked if they wanted to participate.

It is unclear how many people in the Department of Health and Human Services (DHHS) supported, or even knew about, the study. But when the study was publicized by the national media the Assistant Secretary for Health announced that he was “shocked and horrified.”17 He appointed the Tuskegee Syphilis Study Ad Hoc Panel to determine among other things, whether the study was ever justified, either at its inception or after penicillin became available, and whether the rights of patients participating in research sponsored by the Department of Health, Education and Welfare were adequately protected. The panel found the Tuskegee syphilis study to be unethical both at its inception and in its continuation, and called for establishment of a national human investigation board with authority to regulate all federally supported research with human subjects.18

In 1974 Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and charged it with the task of recommending to the Department of Health, Education and Welfare regulations to protect the rights and welfare of human subjects of research.19 In 1979, the Commission produced the Belmont Report in which it identified the basic ethical principles that
should underlie research on human subjects. It stated that respect for persons, beneficence, and justice should guide all conduct in biomedical research. The Commission also wrote 17 reports suggesting the ways in which these principles should be applied to the problematic issues in research.

The Belmont Report, with its accompanying reports, was an advancement over the previous codes in a number of ways. All three documents were concerned with the conditions under which subjects should participate in research, and they all state that these conditions are at least two: a subject can participate in research (1) only if he has given informed consent, and (2) only if there is an appropriate ratio between the risks to the subjects and the expected benefits of the research. The Belmont Report, however, went beyond the two guidelines in that it elevated these conditions from pro-forma requirements to applications of basic moral principles, the principles of respect for persons and beneficence. In applying these principles the authors were able to address many of the more problematic issues, for example, conducting research on persons with diminished capacity for consent.

The most significant way in which the Belmont Report differed from the previous two codes is that it proposed a third type of consideration for protecting human subjects: justice in the selection of research subjects. Considerations of justice were needed to prevent researchers from taking advantage of vulnerable groups. Thus the Belmont Report proposed that ethical reflection in research should not be concerned with only the conditions under which subjects can participate in biomedical research, but also with the question of who should be a research subject. It states that justice should be a
requirement in the selection of research subjects in order to ensure that researchers will not take advantage of vulnerable groups.

The guidelines and recommendations put forth in the Belmont Report and its accompanying publications were adopted by both the Food and Drug Administration (FDA) and the NIH and incorporated into parallel regulations in 1981. Ten years later the regulations were adopted by 15 other agencies as common federal rule (CFR). Currently all research done in institutions that receive federal funds and all research submitted to the FDA for approval of a new drug or device must comply with the regulations stated in the CFR.

The Problem

Since the publication of the Belmont Report there has been substantial discussion and progress on the principles of respect for persons and beneficence, and the issues of informed consent and risk-benefit ratio. The principles enjoy sound philosophical grounding, and there is general consensus, at least to a point, on how to apply them and the conditions under which informed consent and an appropriate risk-benefit ratio are achieved. These requirements are present, in one form or another, in all of the major policies governing research on human subjects.

Unlike respect for persons and beneficence, however, there has been relatively little progress on the role of justice in research on human subjects. To be sure, the problems of nonconsensual and harmful experimentation were the dominating concerns of early ethical reflection in biomedical research. But once these problems were
addressed, and, for the most part, remedied, problems of injustice in the treatment of subjects have become more evident. There is little consensus, however, on the concept of justice to which we should appeal when contemplating issues in biomedical research. There is also uncertainty regarding the scope that any conception of justice would have when applied to biomedical research. Consequently, justice as a principle of research ethics does not enjoy a solid philosophical foundation, and there are few requirements in current guidelines and regulations that ensure justice in medical research.

The little work that has been done on justice in research has focused on the protection of vulnerable groups. History has shown that certain disadvantaged groups have received an unjustly large share of the burdens of research, and, in some cases, an unjustly small share of the benefits. Certain vulnerable populations, for example, prisoners and the mentally incompetent, have been the victims of unjust treatment because they have often been the subjects of research that does not directly benefit them as a group. Researchers have recruited from these populations because of the convenience they offered, even when the research question was not, in any way, uniquely related to this subject population. When one population bears the burden of being a research subject, and additional populations enjoy the benefits of the research, then it could be the case that the subjects, as a population, are treated unjustly. The history of human subjects research shows egregious examples of this kind of abuse. In an effort to protect certain vulnerable groups from bearing an unjust share of the burden of medical research, stringent criteria have been adopted for the conduct of research in these populations. Currently, special regulations exist for research with children, prisoners and
other captive populations, pregnant women, human fetuses, and neonates involved in research.  

The protection of these particular groups, however, falls short of the goal of ensuring justice in the selection of all research subjects. Unlike respect for persons and beneficence, the principle of justice in the context of human subjects research does not have sound philosophical grounding, therefore we have no working conception of justice. We do not know what constitutes justice in the research transaction, so we do not know how to ensure that research subjects are treated justly. This is not to say that the special requirements instituted for children, cognitively impaired, prisoners and other captive populations, pregnant women, and fetuses fail to prevent injustices in these populations. In all likelihood these regulations do ensure that these groups are treated justly. It is possible, however, that these regulations are too restrictive regarding some populations, and not restrictive enough regarding other populations. These regulations focus on populations defined by reference to a single characteristic, and they fail to recognize that individuals within this population can differ in a number of ways. If these differences are relevant to the requirements for just treatment, then the requirements for just treatment will differ among individuals in the same population, and the current regulations may be too restrictive. If indeed this is the case then the current regulations are problematic in only a minor way because, one might argue, it is better to err on the side of caution. The current regulations, however, might be problematic in a more major way if they are not restrictive enough with respect to certain populations. The special requirements ensure just treatment for the specified populations, but they would ensure justice for all research subjects only if these populations represent a comprehensive list of the groups vulnerable
to injustice, and it is not clear that this list is comprehensive. Without a working
conception of justice we do not know which features make an individual vulnerable to
injustice, so we can not identify those who are vulnerable, and we cannot be sure that all
vulnerable populations and individuals are protected from unjust treatment.

In this dissertation I advance the thesis that the regulations and guidelines are not
restrictive enough because they are currently based a list of vulnerable populations that is
incomplete. In particular, they fail to recognize and protect individuals who are seek
money but are vulnerable because of their socio-economic circumstances, and individuals
who seek medical treatment are vulnerable either because of their socio-economic
circumstances or because they suffer from a poor understanding of the purpose and likely
results of the clinical trial. My model of justice in research transactions produces the
requirements for justice for each of these three subject populations and I show that the
current regulations and guidelines fail to enforce these requirements. In fact, some of the
current guidelines and practices allow and, in some cases, even encourage researchers to
act exploitatively towards these vulnerable subjects.

The emphasis currently placed on respect for persons and informed consent, for
example, allows, and sometimes invites, exploitative behavior. Respecting a person’s
autonomy requires that researchers secure informed and voluntary consent from every
subject. Inducements can threaten the voluntariness of consent if they are excessive, so
the guidelines prohibit excessive, or undue, inducements. It is difficult, however, to
determine when an inducement is so great that it is excessive and hence problematic, so
most researchers and IRBs take a conservative position and allow only minimal
inducements, or disallow inducements altogether. This obviously preserves the
voluntariness of consent, but this also results in a situation wherein the subject may not be receiving all that he should for his participation. Research participants often incur a cost for participation: they give their time, endure other inconveniences, and sometimes pay money for things such as parking. They do all of this and often get little or no direct benefit from the research. To expect and ask this from the research subject without giving anything in return may be denying him his due and treating him unjustly. Respecting autonomy, therefore, does not ensure that justice will obtain in human subjects research, and the emphasis on ensuring autonomy and informed consent can encourage potentially exploitative behavior.

Many people fail to appreciate that exploitation is a moral wrong that is different moral wrong of seduction, and many people fail to appreciate that these two moral wrongs occur under different conditions such that preventing one does not necessarily prevent the other. Indeed, preventing seduction can sometimes create exploitation. It is dangerous to prevent seduction at the expense of exploitation without first determining their relative moral force. It is possible that exploitation is worse than seduction and thus we should tolerate seduction rather than exploitation. Or, it is possible that exploitation and seduction carry equal moral force, and, if one can be prevented only at the expense of the other, then the research simply shouldn’t be conducted.

Consider the following two cases:

**Case 1:** Having been recently laid off, Adam reads the classifieds in search of work. As he nears the end of the section he becomes more and more despondent over the dearth of employment opportunities, until he sees an advertisement offering $75 for participation in a drug study. His excitement overwhelms him and he immediately calls the information line where he learns that the study needs healthy volunteers to test a new delivery method for a common, over-the-counter pain killer. They pay him $10 for a screening visit, where they take his medical history, draw blood for lab-work, and run other non-invasive tests. A week later a
nurse-coordinator calls to tell him he is eligible and she offers to pay him $65 to participate in a study that will require a 2 night stay in a phase 1 facility. Because Adam still has not found employment, he accepts and reports to the phase 1 facility the following Friday evening. The study starts Saturday morning at 6am when they draw blood for baseline values and then administer the experimental nasal spray. Over the next 24 hours they draw blood eleven more times. At 6am on Sunday morning the study concludes and Adam goes home with $65 in his pocket. Adam regards his participation in this study as a job, an opportunity to make money, but he will be paid only $75 for the two visits, totaling 33 hours of work, which include a two-night stay at a phase 1 facility and 13 blood draws.

**Case 2:** Bob is a day laborer who gets only occasional work. Currently Bob is not working at all because he suffers from a painful sinus infection. His low income qualifies him for Medicaid, so he makes an appointment to see his primary care physician to get medication for his sinusitis. During the exam the physician confirms his diagnosis with an x-ray, offers to write Bob a prescription that will be covered by Medicaid, and the physician also tells Bob that she is running a clinical trial for a new treatment for sinusitis. If Bob would like to enroll she will pay him $75 for his participation, but the protocol requires 4 office visits, 4 blood draws, 2 sinus taps, and, if he enrolls, there is a 50% chance he will get a placebo rather than the experimental medication. If he gets the placebo his body will eventually heal itself, but this will take longer and be more painful than if he simply filled his prescription for the antibiotic. Bob considers his options: he could secure medication that will treat his sinusitis at no cost to him, or, he could enroll in a trial which would include inconvenience, painful procedures, the additional risk of the pain associated with untreated sinusitis, and a payment of $75. He decides that money is more important to him than comfort, so he agrees to participate in the study. Bob regards his participation as a job, an opportunity to make money, but he will be paid only $75 for 6 hours of work, which includes 4 office visits, 4 blood draws, 2 painful sinus taps, and a 50% chance that his sinusitis will not be treated.

Both of these cases satisfy the current regulations and guidelines in that the subjects were properly informed and there is an appropriate ratio between the risks to the subject and the benefits to the subject and society. Nevertheless, both cases make us uncomfortable. If these cases satisfy the current requirements, yet still make us uncomfortable, then the current requirements might not be sufficient to ensure that research subjects are treated justly.

In a similar way, requiring an appropriate risk-benefit ratio also fails to prevent exploitative behavior towards the subject. The risk-benefit requirement prevents
unnecessary harms, minimizes the risks to the subject, and ensures that the risks are proportional to the anticipated benefits of the research. But the risk-benefit assessment that is suggested by the guidelines and currently used by researchers and IRBs takes into account risk to patient, benefit to patient, and benefit to groups of people or society on the whole. So the current standards allow social benefit to counterbalance risk to the subject. As such, it prevents only useless or inefficient experiments, that is, experiments that promise little benefit or those that present an inordinate amount of risk to the subject. The requirements do not prevent experiments in which the subject bears risks and anticipates no benefit. This allows for the possibility of the subject giving a great deal and receiving little or nothing in return, which, under some circumstances, could be unjust.

Requiring an appropriate risk-benefit ratio would not invite problems of exploitation if subjects volunteered for altruistic reasons. If we knew that subjects wanted to help others, then we would not be concerned about the fact that they give so much and receive so little in return. There is, however, good evidence that the subject’s primary motivation for participation in research is not, in most cases, a desire to help others, but rather a desire for direct therapeutic benefit, or, in some cases, a desire for material gain. In fact, researchers often engage in practices designed to recruit subjects who act according to non-altruistic motives. For example, they advertise their study as a new treatment option, or they promise money for participation. Rarely do researchers recruit subjects by appealing to their desire to help others. When subjects desire therapeutic benefit, it is possible that a study that satisfies the current risk/benefit ratio requirements will offer a level of benefit that is unjustly low. Thus the current risk-
benefit ratio requirement and guidelines allow researchers to offer a risk-benefit ratio that might be unjust and exploitative for subjects who are motivated by therapeutic benefit.

Consider the following two cases:

Case 3: Catherine is experiencing a frequent urge to urinate and pain with urination, so she makes an appointment with her family physician. A working mother of two young children, Catherine is fortunate to have insurance, but she is a busy woman and often has difficulty finding time to see the doctor. In order to see the doctor for this complaint she has two cancel 2 business appointments. During her visit the doctor quickly diagnoses Catherine with a urinary tract infection and he offers to write her a prescription, but he also tells her that she is eligible to participate in a clinical trial testing a new treatment regimen for urinary tract infections. The doctor explains to her that the trial is testing a shortened course of treatment for an antibiotic that has already been approved for marketing, and the trial will require three additional office visits, 3 blood draws, and 2 EKGs, and, if she participates, he will pay her $75 dollars. Catherine came to the clinic seeking only treatment for her condition, so she is not interested in the money, nor is she interested in participating in the trial for altruistic reasons. She wants only to get better; and to this end she is intrigued by the possibility of getting a newer or better treatment. Catherine does not understand that the trial is testing a shortened course of treatment against a standard course of treatment for an antibiotic that has already been approved for marketing, and therefore available to her by prescription. So Catherine does not understand that the trial will not offer her any health-related benefit that she could not secure for herself simply by filling her prescription. Instead, Catherine trusts that her physician will act only in her best interest, and she thinks that he would offer her participation in the trial only if he thinks it would be best for her. Catherine wants to get better, and she mistakenly regards participation in the study as the best way to get better, so she volunteers for the study, and she endures the unnecessary inconveniences, and in this way gains access to a drug that she could have obtained by simply making a trip to the pharmacy.

Case 4: Deborah is self-employed without a great deal of disposable income, she is uninsured, and she suffers from urinary incontinence. She knows that there are effective treatments for her condition, but she also knows that a 30 day supply of the medication will cost $100, which is more than she can afford. Currently she manages her incontinence with adult diapers, but these are inconvenient and sometimes cause urinary tract infections, so she is ecstatic when she sees a television advertisement recruiting subjects for a clinical trial of a “new treatment method” for urinary incontinence. When she calls the toll-free information number the call-person quickly screens Deborah for eligibility and explains to her that the study is a placebo controlled trial for the transdermal delivery of an already approved and effective medication. Deborah is disappointed to hear that the study is placebo controlled, but, as she has no other options, she listens on. The call-person explains that participation in the study will require 4 office visits
over the course of 12 weeks, 4 blood draws, and EKG, and daily entries into an electronic journal to record the number and frequency of her episodes of incontinence. For her participation Deborah will be paid $100. Deborah is indignant over the terms of the study because she is contributing a lot of time and effort to help the researcher and the pharmaceutical company gather the information they need to assess the efficacy of the product, and in return they offer her only a 50% chance of getting treatment for her condition. Deborah knows that the pharmaceutical company could run the study with an active control, in which case she could offer her a 100% chance of receiving a treatment for her condition. Deborah, however, has no other options. So she enrolls in the study because she wants the treatment for her condition, and even though she has only a 50% chance of receiving this treatment, a 50% chance is better than no chance.

Both of these cases satisfy the current regulations and guidelines regarding consent and appropriate risk-benefit ratio. Though Catherine suffers from a misunderstanding of her physician’s intentions and the purpose of the study, given the minimal risk involved she is competent to make a decision about participation. Both Catherine and Deborah give valid consent, and in both cases the risk to the subject is minimal and there is potential benefit to society so there is an appropriate risk-benefit ratio. Nevertheless, both cases make us uncomfortable. If these cases satisfy the current requirements, yet still make us uncomfortable, then the current requirements might not be sufficient to ensure that research subjects are treated justly.

Without a working conception of justice we cannot be sure what justice requires in the context of human subjects research. We do not know the conditions under which research subjects are treated justly, and we do not know the conditions under which they are treated unjustly and exploited. This uncertainty makes it difficult to develop regulations and guidelines that will ensure justice in the selection of subjects and prevent exploitation. The regulations and guidelines do protect some subject populations, but there is good reason to believe that many more are vulnerable and currently unprotected.
In this dissertation I develop a model of exploitation and a working conception of justice for interpersonal transactions which provide, among other things, the criteria for justice in subject selection. This allows us to identify the conditions under which researchers treat subjects justly and, alternatively, the conditions under which researchers treat subjects unjustly and therefore act exploitatively towards subjects. Once these conditions become clear it will be easy to identify which subject populations are vulnerable, and what, if anything, can be done to prevent the exploitation of subjects from these populations.

I begin this dissertation by introducing exploitation as a concept distinct from the moral wrongs with which it is usually confused, namely, coercion, seduction, and comodification. In the following two chapters I construct a model of exploitation by first identifying the necessary and sufficient conditions for exploitation claims, and then articulating these conditions with a concept of justice in interpersonal transactions. In chapter 5, I examine the nature of research transactions and identify the goods and services exchanged, and in Chapter 6, I apply the conditions of justice to determine the just research protocol. In the final chapter I examine current research practices and I identify both vulnerable groups and individuals who are currently not protected from exploitation. I show how the current regulations, guidelines, and practices allow researchers to act exploitatively towards these subjects, and I suggest ways in which such exploitation could be prevented.
Exploitation is sometimes confused with, and often occluded by, other moral problems. When a proposal appears to be problematic people seem to reach for any term that represents a moral wrong and apply it to the problematic proposal. They then assume that all the moral work is done, that other people will understand that the proposal is problematic and other people will know what should be done about it. Coercion, exploitation, seduction, and comodification are often used in this indiscriminate manner. Perhaps in an effort to make the proposal appear even more problematic these terms are sometimes applied two at a time, and this happens even when the case in question does not display the necessary conditions for either term.

Confusion among moral terms is a problem because one can prevent a moral wrong only if one knows it is likely to occur. Each moral term refers to a particular moral wrong that carries a unique moral weight and force, and when the terms are confused and used indiscriminately their meaning is lost and we cannot know for sure why a given proposal is problematic. More importantly, we cannot know for sure what we should do about it. Confusion among moral terms is a problem that must be corrected in order to make progress in identifying and resolving the types of moral wrongs that occur in human subjects research and any other field of human activity.
Occlusion among moral terms is also a problem because, again, one can prevent a moral wrong only if one knows it is likely to occur. One moral harm occludes another when the first gathers attention in such a way as to prevent the second from being seen. One moral wrong is more likely to occlude another we do not clearly understand the nature of the second moral wrong or the conditions under which it occurs. When we cannot see a moral wrong we do not know when it is likely to occur, and, more importantly, we cannot prevent its occurrence. Furthermore, in cases where multiple wrongs are likely to occur, and one moral wrong occludes another, it might happen that correcting the harm we can see exacerbates the harm we can not see. Correcting one wrong at the expense of another is a dangerous practice, especially when their comparative moral weights are not fully understood.

For these reasons it will be useful to work through these problems of confusion and occlusion and establish exploitation as a moral concept distinct from other moral wrongs such as coercion, seduction, and commodification. In this chapter I present accounts of coercion, seduction, and commodification. I identify the locus of the moral wrong for each concept, and show that exploitation refers to a moral wrong that is conceptually different from each of these three. In the following chapter I begin to develop an account of exploitation.

**Coercion**

The dominant philosophical and legal position is that the distinction between coercive and non-coercive proposals mirrors the distinction between threats and offers. That is, threats coerce whereas offers do not.¹ Alan Wertheimer offers what, on first
glance, appears to be a simple yet discerning way in which to distinguish threats from offers and thus coercive from non-coercive proposals:

A threatens B by proposing to make B worse off relative to some baseline; A makes an offer to B by proposing to make B better off relative to some baseline.\(^2\) Whether a proposal is a coercive threat, according to Wertheimer, can be determined by whether that proposal makes the recipient worse-off. The simplicity of this account, however, is misleading because without further specification and modification it is overly inclusive and hence inaccurate.

The distinction between coercive and non-coercive proposals does not entirely mirror difference between threats and offers because not all threats are coercive. A simple threat, one that merely contains a promise of harm, indeed promises to make its recipient worse off, but this does not entail that the threat is coercive. To promise and deliver harm is simply to harm another person, not force or coerce. A threat is coercive only if it contains a conditional promise of harm. In a coercive threat, the intention to inflict harm is presented as a non-compliance cost for a demand. Thus, all coercive threats have two features: a demand and a cost for non-compliance (NC-cost). Consider the classic case of a coercive proposal, the highway gunman’s threat: “Your money or your life.” Here the demand is to hand over the wallet, and the cost to the victim for not complying with the demand is to be shot.

Wertheimer’s account shows that both the demand and the NC-cost must, individually, make the recipient worse off. Insofar as a threat is a promise of harm, the non-compliance cost of a coercive threat would make a victim worse off. The demand component of coercive threat must also make a person worse-off. A “rich uncle” might threaten but does not coerce his niece with the following proposal:
Take this thousand dollars or I will not give you any more money. The demand must require an unwelcome task in order for a threat to be coercive, and all things being equal, accepting money is not an unwelcome task.

A third feature must also be present in order for a conditional threat to make a person worse off. The demand and the NC-cost must be presented as exclusive alternatives. A victim's consent is coerced only when she agrees to satisfy the demand, and she is unlikely to make such an agreement unless she is forced to choose between the demand and non-compliance cost. For example, if the highway gunman's victim knows that a pane of bullet-proof glass separates her from the gunman, she is likely to drive off and choose the option in which she neither satisfies his demand nor pays his cost for non-compliance. The victim of the threat must be forced to choose one or the other, and the only way this force can be effected is if the coercer blocks her option to do neither and thus presents her with an exclusive choice between the demand and the cost for non-compliance.

An account of coercion that contains only these three features would be incomplete because it would incorrectly determine the following proposal to be coercive.

A psychopathic person breaks into a couple's house and instead of killing either the husband or the wife, finds more pleasure in the prospect of watching the husband kill his own wife. So he issues the following threat to the husband: "Kill your wife or I will break your arm."

This threat contains a demand and a non-compliance cost that both promise to make the recipient worse off, and the would be murderer presents these as exclusive options. Thus, according to Wertheimer's account, the threat is coercive. Coercion, however, is a type of force and a coercive threat must have the effect of forcing the victim to satisfy the demand. Given that the non-compliance cost to the husband is so much less than the cost
of satisfying the demand, he is not forced to kill his wife. Indeed, we would hardly allow this threat to constitute either a moral or legal excuse if the husband did kill his wife. In order for a threat to be coercive, the victim must be forced to satisfy the demand, and this happens only when there is sufficient distance between the cost of non-compliance and the cost of the demand. If there is not sufficient distance, and the recipient chooses to pay the cost of non-compliance, the would-be coercer’s activity then becomes one of simply harming the victim.

A coercive proposal is thus a threat that satisfies four criteria: (1) it must contain a demand that makes the recipient worse-off; (2) it must contain an NC-cost that makes her worse-off; (3) these must be presented as exclusive options; and (4) the NC-cost must be significantly worse than the cost of satisfying the demand. Coercion is a defect in consent, and this defect follows from the fact that the victim’s act of consent is, in some sense, forced and thus involuntary. The voluntariness of the victim’s act is compromised in two ways. First, the coercer restricts the freedom of the victim by removing one of her options. Prior to the coercive threat she enjoyed the option of neither satisfying his demand nor paying his cost for non-compliance. The coercer blocks this option with his threat of harm and thus forces her into a choice situation in which she must choose to either satisfying his demand or pay his cost for non-compliance. The coercer compromises her voluntariness in a second way by manipulating her new choice situation and creating sufficient distance between the two options such that she has “no choice” but to satisfy his demand. When he is responsible for the fact that she is in a dichotomous choice situation, and he responsible for the fact, that she effectively has no choice but to
satisfy his demand, he undermines her voluntariness and forces her to choose a particular option and thus creates a defect in her consent.

People often claim that offers to participate in research are coercive, especially when the offer includes a promise of money or other reward. They claim that offers like those presented to Adam, Bob, Cathy, and Deborah are coercive because the reward might make the potential subject feel like he or she is forced to participate in the study. According to this account of coercion, however, none of the offers in any of these examples is coercive because these offers do not include coercive threats. Even if one interprets the offer to participate as a demand to participate, there is no non-compliance cost for not participating, and the option to not participate in the trial remains open to the subject. These offers thus lack at least two of the necessary criteria for a coercive threat, and it would seem that none of the potential subjects are coerced into participation.

There is, however, another way in which one might argue that researchers do coerce their subjects into participating in medical research in cases like Adam, Bob, and Deborah. The offer the researcher makes to Adam and Bob could be construed as a conditional threat if one takes a non-conventional approach in determining whether a person is “worse-off”. Inasmuch as Adam and Bob are likely to experience some harm through participation, afterall, they will experience inconvenience, discomfort, and risk to their well-being, it might be true that their participation in the study will make them worse-off. If one can show that Adam and Bob will be worse-off if they don’t participate in the study then the offer to participate will be a coercive threat in disguise. The offer will place both Adam and Bob in a situation where they must choose between two options, both of which will make them worse-off. Showing that Adam and Bob will bw
worse off if they do not participate, however, is a difficult task because neither Adam nor Bob had $75 before the offer, and neither will have $75 after the offer if they do not participate, so it would seem that their level of well-being has not changed. Some might argue, though, that it is a mistake to compare Adam and Bob’s well-being post-transaction to their pre-transaction baseline because their pre-transaction baseline is not where they should be. Neither Adam nor Bob should be in a position where they have no money to feed their families. Even though there was no change in their status, there should have been a change in their status, and the denial of this change effectively makes them worse off than they should be.

This type of reasoning is easier to grasp in Deborah’s case. Recall from Chapter 1 that Deborah has no health insurance and has limited financial means, so she lacks access to health care. Many people argue that individuals like Deborah, and the many other uninsured Americans, should have access to needed health care. Like Adam and Bob, it would seem that Deborah has the option of walking away from the offer to participate in medical research without falling below her pre-transaction situation. If, however, Deborah should have access to health care, and we measure her well-being against what should be the case, rather than what is the case, then Deborah is worse-off when she does not get the needed medical care.

Initially this argument might seem unreasonable, but it illustrates a problem in the foregoing account of coercion: it can sometimes be difficult to determine whether a given proposal is coercive because it can sometimes be difficult to determine whether the proposal makes a person worse-off. In order to determine whether a person is “worse-off” one needs a baseline position against which to measure the projected consequences
of the proposal. A person’s baseline, generally speaking, is what would have been the case in the in the normal or natural or expected course of events. However, ambiguity in the interpretation of “expected” can give rise to two different types of baselines. As Robert Nozick notes,

The term expected is meant to shift between or straddle the predicted and morally required.\(^4\)

The predicted course of events constitutes a descriptive baseline, whereas the morally required course of events constitutes a normative baseline. Sometimes these two baselines will be similar enough to agree on whether a person is worse-off, but in some cases they will be so different that a person is worse-off relative to one but not worse-off relative to the other. In these cases it is difficult to determine whether a person is, all things considered, worse-off because it can be difficult to determine which baseline position is the more appropriate standard for comparison.

In the case of the highway robber, for example, the descriptive and normative baselines are similar enough to agree that the threat is coercive. The predicted and normal course of events is roughly the same as the morally required course of events. What usually happens and what ought to happen during an encounter between two parties is that they do not interfere with one another’s interests. In both baseline positions she would have continued to enjoy both her money and her life, and the demand and the NC-cost of the gunman’s proposal take her below both of these baselines and the proposal is clearly a threat.

When the descriptive and normative baselines are significantly different, however, it is not so easy to determine whether a proposal is an offer or a threat. Robert Nozick provides an excellent example of this problem with the following “slave case”: 
A beats B, his slave, each morning for reasons unconnected with B’s behavior. A proposes not to beat B the next morning if and only if B does X.\(^5\)

Here the demand is to do X (and not be beaten), and the NC-cost is to be beaten as usual. In this situation the descriptive baseline for the slave, the predicted course of events, is that he will be beaten the following morning. Against this baseline, A’s proposal to not beat B does not make B worse-off because, regardless of whether the demand takes B below his baseline, the NC-cost does not. Thus, A’s proposal is not a threat when measured against the descriptive baseline. The slave’s normative baseline, however, is significantly different. Regardless of whether B should be enslaved, A clearly should not beat B. Thus, B’s normative baseline, the behavior that B can morally require of others, is that he not be beaten. The NC-cost, the prospect of being beaten the following morning, takes B below his baseline. Assuming X is an unwelcome task, both the demand and the NC-cost make B worse-off when measured against the normative baseline, and A’s proposal is a threat. Therefore, when measured against the descriptive baseline A’s proposal is an offer, and when measured against the normative baseline it is a threat.

Determining whether a threat is coercive, then, is difficult in the few cases in which the baselines yield conflicting results. The problem lies in determining which of the two baselines one should use as a standard of measurement. Most philosophers concede that it is impossible to establish the primacy of one baseline over the other such that one would be appropriate baseline for all cases. The question they attempt to answer is how to determine the appropriate baseline for any given case. In the remainder of this paper I describe two such solutions, those proposed by Nozick and Wertheimer, and show that their proposals are flawed. The reason their solutions are incorrect leads me to
believe that one can categorically solve the problem of baselines, and I propose a new version of the normative baseline as the appropriate baseline for all cases.

The baseline problem is typically seen as unsolvable on a theoretical level because counter-examples exist for both the descriptive and the normative baselines. Nozick’s slave case shows that the descriptive baseline is inappropriate in at least one case, and thus cannot serve as the standard of measurement for all cases. The following case provides a counter-example to the normative baseline.

Smith, a burglar, is currently in possession of ten thousand dollars that he recently stole from a bank. When a fellow burglar, Jones, finds out that Smith has this money, he then holds him up, and says, “Give me the money or I’ll shoot you.”

In this case, Smith’s descriptive baseline is one in which he enjoys possession of the money. Since Smith has stolen the money, and hence has no right to it, his moral baseline is one in which he does not have the money. The demand Jones issues to Smith, “Give me the money,” does not take him below the normative baseline, and thus does not constitute a coercive threat. Jones, however, is clearly coercing Smith into giving him the money. The normative baseline thus seems to be inappropriate for at least this case, and perhaps for all cases in which the descriptive baseline sets a higher standard that the normative baseline. If, as these counter-examples indicate, it is truly impossible to establish the primacy of one baseline for all cases, then one is left with the problem of resolving conflicting baselines on a case by case basis.

Nozick proposes to solve the problem by allowing contextual features to determine the appropriate baseline. He claims that in any situation where the baselines diverge, one should assess a coercion claim against the baseline that the recipient would prefer.
It may be that when the normal and morally expected courses of events diverge, the one of these which is to be used in deciding whether a conditional announcement of an action constitutes a threat or an offer is the course of events that the recipient of the action prefers.\textsuperscript{6}

When the two baselines differed in the slave case, for example, the appropriate one to use is the one that the slave would prefer. This would clearly be the normative baseline, the course of events in which he is not beaten. When they differed in the bank robber case, it appropriate one to use is the baseline Smith would prefer, which would obviously be the course of events in which he continues to enjoy possession of the money. In both cases, the baselines correctly yield a determination of coercion.

Wertheimer proposes a different approach to the problem of baselines by refusing to establish the primacy of one over the other in all cases or even a given case.

There is no single right answer to the coercion question when the results of the nonmoral and moral tests diverge. Each test supports a defensible or plausible coercion claim.\textsuperscript{7}

Instead of choosing either a descriptive or normative baseline, he uses both at the same time, and if either baseline shows that the recipient will be worse-off then the proposal is a threat. According to Wertheimer, conflicting baselines do not affect whether a given proposal is a threat, but the fact that they conflict does affect the moral weight of the coercion claim that results. A threat that makes one worse-off relative to both the normative and descriptive baselines will carry more weight than a threat that makes the victim worse-off when measured against only one baseline.

Both Nozick’s and Wertheimer’s approaches are flawed because they incorrectly categorize the following proposal as coercive.

Every year for the past ten years John’s employer, Mr. Q, has given John a handsome Christmas bonus. This year Mr. Q tells John that he does not intend to give Christmas bonuses, but will offer overtime to those who would like to supplement their December income.
Here the normative and the descriptive baselines differ in that the Mr. Q is not morally required to give Christmas bonuses (this is not part of the pay schedule), but, given their history, John could reasonable predict that Mr. Q would give bonuses. When measured against the descriptive baseline, the proposal promises to make John worse off because either he must work overtime or forego his supplemental income in the month of December. The normative baseline, however, is a position in which John does not enjoy the bonus, so Mr. Q does not make him worse off by withholding it. Thus, it is not clear whether Mr. Q’s proposal coerces John into working overtime.

Both Nozick and Wertheimer would consider the proposal to be coercive, but their conclusions would be incorrect because Mr. Q’s proposal does not, in fact, satisfy the criteria for a coercive threat. Nozick would use the descriptive baseline because, all things being equal, John would clearly prefer the course of events in which he receives a Christmas bonus. Relative to this baseline the proposal promises to make John worse off so the proposal would be a coercive threat. Wertheimer would also consider the proposal coercive because at least one of the baselines yields this result. This proposal is not a case of coercion, however, because it fails to satisfy two of the necessary criteria.

In order for a proposal to be coercive, the coicer must present a threat of harm to the victim and he must manipulate the victim’s options such that the victim will choose to comply because the cost of non-compliance is much worse than the demand. Mr. Q’s proposal to John does promise harm, but this is not a harm for which Mr. Q is responsible. John may have already made promises or commitments expecting a Christmas bonus, and now that he will not get one he is faced with either failing to meet his commitments or working overtime. If John fails to satisfy Mr. Q’s demand to work
overtime then he suffers the cost of broken promises, but this cost is created by John’s actions, it is not imposed on John by Mr. Q. The cost of non-compliance that John experiences is thus self-imposed. Therefore, it is not a feature of the proposal that Mr. Q makes to John, and the proposal fails to satisfy one of the criteria.

The proposal also fails to satisfy a second criterion in that it does not establish distance between cost of the demand and the cost for non-compliance. The actual cost of non-compliance is determined by John. Depending on the promises and commitments he may or may not have made, the cost could be great or small. If he needs the money to cover a bet he placed with his bookie, then indeed the cost is high and he has no choice but to work overtime. On the other hand, if he is a fiscally responsible person and does not spend money until he has received it, then the cost of not working overtime may be small. We cannot hold that Mr. Q coerces John because the harm that may befall John and the feelings of no choice that he may experience result from John’s actions, they are not features of the proposal.

A solution to the problem of baselines must provide guidance for all cases in which the baselines diverge, and there are two ways in which baselines can diverge. The first is when the descriptive baseline sets a higher standard than the normative baseline, and the second is when the normative sets a higher standard than the descriptive. I propose that in both cases a modified version of normative baseline is the appropriate standard for comparison.

When the descriptive baseline sets a higher standard than the normative the normative baseline will always be the appropriate standard for comparison. Descriptive baselines indicate the normal and expected course of events and they are comprised, in
part, of regular and predictable behavior. Altering regular behavior may result in harm to others because people might expect it to continue and make certain arrangements such that they will be harmed if the pattern is interrupted, changed, or stopped. In this way a change in one's behavior can threaten harm to another and, in some cases, force the other into a "no choice" situation wherein they must comply with a demand or else suffer a more costly consequence. The harms that are created by altering expected behavior, however, are not features of the proposal, but instead these harms are created by the actions of the proposal's recipient. The harms that constitute the NC-Cost are not features of the proposal but rather features of the situation that were created by the recipient, so the proposal is not coercive. Therefore, when the baselines differ, and the descriptive baseline is higher, it will never provide a reliable standard of measurement for coercion claims.

The counter example of the thief and his blackmailing friend challenges this position. In this case, the descriptive baseline sets a higher standard than the normative because Smith is in possession of money to which he has no right. So Jones' threat to take the money harms him when measured against the descriptive baseline, but not when measured against the normative baseline. Insofar as our intuitions tell us that this is a case of coercion, it would seem that the descriptive baseline is the appropriate standard of measurement because it yields the correct result. The analysis of this case, however, does not serve as a counter-example to the normative baseline because it erroneously determines the baselines to be diverging.

In this case the baselines appear to be diverging, but the analysis relies on an incorrect interpretation of the normative baseline. If the correct specification of the
normative baseline is used, the baselines do not actually diverge, and both yield a determination of coercion. The baseline that is being used is Smith's normative baseline vis-à-vis the party from whom he stole. With respect to this party, he has no right to the money. If they demanded their money back or threatened to call the police, their threat would be justified and their proposal would not be coercive. Smith's normative baseline vis-à-vis Jones, however, is one in which Smith is in possession of goods to which Jones has no claim. Jones' demand to hand over the money brings Smith below this baseline and, when combined with the other features of the proposal, constitutes a coercive threat. When the "coercer specific" baseline is used, this case does not provide a counter-example to normative baseline for scenarios in which the descriptive baseline sets a higher standard.

The "coercer specific" normative baseline is also the appropriate standard for cases in which the descriptive baseline is lower than the normative baseline. This type of difference can occur when a person has a right that certain interests not be frustrated, but these interests are, for whatever reason, already set back. Consider the following case of coercion.

A and B enter into a contract that promises payment for services rendered, and A performs the agreed upon services. B, however, has another job that he would like A to perform, and decides to use the money he owes A as leverage. B then says to A, "Do this other job or I will not give you the money."

A's descriptive baseline is his actual position, one in which he does not have, and can no longer reasonably expect to get, the money. His normative baseline is one in which he has the money because this is the morally required course of events. When measured against the descriptive baseline this proposal does not coerce because A is not made worse off, thus this baseline line is inappropriate for this case. Only when measured
against the normative baseline is A coerced. Even though A may not be in possession of the money, B threatens a wrongful harm when he indicates that he will not pay what he owes, and thus B issues a coercive threat to A.

A descriptive baseline that is lower than the normative indicates that a person is in a position wherein he can make moral claims on others. Perhaps he was unjustly pushed into the situation, in which case he can demand what he is owed or reparations. Alternatively, misfortune could have put him in the situation and he might have a moral claim against others for aid. Regardless of how he got there, if he can make moral claims against others, failure on their to discharge moral obligations towards him creates a wrongful harm. However, a person wrongfully harms another in this way only we he has a specific and assignable obligation to the recipient of the proposal. If the recipient has a moral claim against the state or against other people, these claims would not affect the moral status of the person’s actions towards the recipient. For example, if another party, C, unaware of the arrangement and default between A and B, offers A a job, he would not be issuing a coercive threat because C does not owe A any money.

The coercer-specific normative baseline allows us to see that the researchers who offer participation to Adam, Bob, and Deborah do not coerce their subjects. The only baseline against which the offers to Adam and Bob would be coercive is a normative baseline in which Adam and Bob are owed welfare assistance. Whether Adam and Bob are indeed owed welfare assistance is an open question, but even if they were, they could make such claims only against their community, state, or other collective group to which they belong. Only in special circumstances could they make such claims against individuals, and, absent those circumstances, their coercer-specific normative baseline
does not render them worse-off for rejecting the offer. Similar reasoning shows that the offer researchers make to Deborah is not coercive. If Deborah is owed access to needed medical care, only in special circumstances can she can make this claim against an individual health care provider, and absent those circumstances her coercer-specific normative baseline does not render her worse-off for rejecting the offer to participate in the study. Unless one is forced to choose between two options that will both render one worse-off one is not coerced. Adam, Bob, and Deborah each have the option to not participate in the study, and none of them will be worse-off for choosing this option, so none of them is coerced.

Even though the subjects of these cases are not coerced, these cases still make us uncomfortable. Coercion is not the only way in which researchers can act wrongly towards subjects, so if we have ruled out coercion, and their behavior still makes us uncomfortable, they must be engaging is a different type of morally wrong activity. These cases make us uncomfortable because the subjects each have a vulnerability that the researcher uses to his advantage. Both Adam and Bob are vulnerable because they need money, and the researcher uses this vulnerability to his advantage when he offers money and entices them to enroll in his study when they might not have done so otherwise because the pay is so low. Deborah is vulnerable because she is sick and in need of health care which she cannot secure on her own. The researcher uses this vulnerability to his advantage when he recruits her with the promise of treatment and entices her to enroll when she might not have done so otherwise because the trial is too inconvenient. In each case it is unlikely that the patient would have participated in research, but he does because he is vulnerable and the researcher uses this vulnerability to
his advantage. In this dissertation I argue that these cases make us uncomfortable because the researcher exploits the research subject.

Knowing that the coicer-specific normative baseline is the appropriate standard of comparison helps in understanding that exploitation can occur in non-coercive conditions. Consensual exploitation can occur only when a person exhibits a particular vulnerability because a person will be unlikely to consent to a transaction in which he is treated unjustly if each enjoys ideal circumstances. Only when a person is situated in conditions that are less than ideal, and is in need of something, would he consider a transaction in which he is treated unjustly but gains access to some amount the desired good. In some cases the vulnerability will arise through misfortune, in other cases the vulnerability will arise through the fault of the exploitee, and in other cases the vulnerability will arise through the fault of the exploiter. The coicer-specific baseline shows us that only when the vulnerability is wrongfully imposed by the exploiter is the exploitation coercive, in all other cases the exploitation is non-coercive.

This analysis shows that coercion and exploitation are distinct moral concepts and each refers to a unique moral harm. Coercion is a wrongful reduction in freedom and exertion of force, whereas exploitation is wrongful advantageous use. Coercion claims will often entail exploitation claims insofar as the coicer often wrongfully gains from his use of the coercee. When this happens it is important that problems of coercion do not occlude problems of exploitation, otherwise we run the risk that problems of exploitation will not be addressed. Coercion can also happen in the absence of exploitation, and, more importantly, exploitation can happen in the absence of coercion. When coercion and exploitation occur separately it is important that we do not confuse the two because
each refers to a different moral wrong, each carries a different moral weight and force, and each is addressed in a different way.

**Seduction**

Seduction occurs when a person is presented with an offer that contains a reward so appealing that it distorts the person’s appreciation of the risks involved in the transaction. Insofar as exploitative offers usually contain rewards as well, many people seem to confuse exploitation and seduction and regard them as synonyms for problematic offers. If an inducive offer is problematic in any way, they believe, this problem can be generally described as seductive, exploitative, or both, without any change in the meaning or moral wrong referenced. Indeed, some people even like to throw coercion into this confusion of moral terms, and the result is that all three moral terms are used indiscriminately to refer to any and every problem presented by an inducive offer. In this section I argue that offers cannot be coercive, and I argue that exploitation and seduction are not synonyms because the two terms refer to distinct moral wrongs.

An inducement is a motive or consideration that leads one to action, and it often comes in the form of a reward for acting in a certain way. Inducive offers are proposals that contain both a demand and a reward, where the reward is intended to motivate the recipient to accept the offer and satisfy the demand. A makes and inducive offer to B when B would not have satisfied the demand, when B would not have acted in a certain way, but for the reward attached. Inducements can come in different levels and they can range from merely attractive to extremely attractive, and when the offer is extremely attractive it can be problematic. Some argue that while offers, in general, cannot coerce,
extremely attractive offers are different. These offers, they claim, can be so attractive that they effectively coerce.\textsuperscript{8} I argue that extremely attractive offers cannot coerce, but they can be problematic when they are either seductive, exploitative, or both.

An offer is a proposal that increases a person’s open options in that it presents the recipient with one more option than she previously enjoyed. An offer can be either simple or complex.\textsuperscript{9} An offer is simple if something is unconditionally presented for acceptance or rejection. For example, “I will give you my pen.” Alternatively, an offer is complex if presents something with added conditions. For example, “I will give you my pen if you give me two dollars.” Complex offers can contain demands as a condition for the reward, and this has lead some philosophers to think that offers can be coercive. Despite the fact that conditional offers contain demands, these offers cannot be coercive for the following reasons. Coercion is a defect in consent that is created by the process in which the consent is sought. A coercer forces a victim into a particular course of action by reducing her freedom and forcing her into a dichotomous choice situation. A coercer also introduces a cost for non-compliance, and thus manipulates her two remaining options to the effect that she will choose the one he wants her to choose. Offers, in contrast, are proposals that effect a net increase in a person’s open options, giving her at least one choice not previously available. Offers never decrease the number of options available to a recipient, and, more importantly, offers never contain costs for non-compliance. Thus, when presented with the offer of a new possibility, a person is not forced into a dichotomous choice situation, and without an NC-cost, she is not forced to select the option the coercer wants her to choose. She remains free to refuse the offer,
and will not be harmed in doing so. Offers, therefore, cannot be coercive because they cannot, by their very nature, exert any force.

Despite the foregoing argument Joel Feinberg argues that offers can be coercive because they can force a person into a particular course of action. Feinberg gives an account of force in which A forces B just in case A is effective in getting B to opt for the alternative A wants B to choose.\textsuperscript{10} A can force B in many ways, one of which is to issue a threat. However, A can also effectively force B when he makes an offer in which he has manipulated the options available to her in such a way that B has no choice but to choose the option A wants her to select. A can manipulate B’s options by making a conditional offer. He can offer something that B wants badly, but attach to it something that A wants from B. To illustrate this conception of force Feinberg offers the case of “The Lecherous Millionaire”:

B’s child will die unless he receives expensive surgery for which the state will not pay. A, a millionaire, proposes to pay for the surgery if B will agree to become his mistress.\textsuperscript{11}

Here A makes an offer to B which Feinberg thinks is forceful and thus coercive. A makes an offer in that he increases B’s open options: all options B had prior to A’s offer are still open, and she now enjoys one more, namely, the course of action in which A pays for her child’s surgery and she becomes his mistress. A, however, has manipulated B’s options in that he has attached a demand to something B wants badly. B now faces a situation in which

\ldots the only alternatives to the projected consequences of the favored alternative [are] too costly to be eligible for B’s choice.\textsuperscript{12}

B wants the surgery for her child so badly that all of her alternatives are “too costly to be eligible for choice.” A has rearranged B’s options in such a way that she has “no choice”
but to comply with his demand or else suffer an undesirable consequence.\textsuperscript{13} Therefore, according to Feinberg, A has forced and thus coerced B into becoming his mistress.

Feinberg’s analysis of the millionaire’s offer, however, fails to show that this case in particular, or offers in general, can coerce. The millionaire does not force the woman to consent to his intimacies, instead, his offer simply pushes her into a “no choice” situation. This type of choice situation does not, in itself, force a person into a particular course of action. The millionaire’s offer places the woman in a choice situation in which, given her values and goals, one option is much more attractive to her than alternative options. The offer does include an undesirable feature, namely, becoming the mistress of the millionaire, but so does the alternative of watching her child die. Even when she takes the cost of the demand into account, the cost/benefit ratio of the offer is still much more attractive than her other option. Indeed, the distance between the value she associates with the millionaire’s offer and the value she associates with her other option is so great that she has “no choice” but to accept, it would be irrational for her to do otherwise. The unfortunate woman, however, is not, as Feinberg believes, “forced” into making this decision. She is simply behaving rationally given her chosen goals and her understanding of the means by which to achieve these goals. Such behavior is not forced.

The fault in Feinberg’s argument for coercive offers lies in his conception of “force”. According to him, force is a feature of the consequences, and a sufficient condition for A forcing B is that A gets B to opt for the alternative A wants B to choose.\textsuperscript{14} This is significantly different from a traditional account of force. Most accounts are process oriented such that B is forced if there is a defect in the process by which she makes her choice. A consequential account of force is problematic because it fails to
distinguish among the many ways in which A can get B to make a particular choice. It
does not seem to matter to Feinberg how A gets B to choose the desired course of action.
A can use influence, reasoning, or threats of harm, and he would still claim that A forces
B. Inducements, reasoning, and threats of harm, however, carry different moral weights,
and a conception of force that fails to differentiate among them is unsatisfactory.
Feinberg’s conception fails to differentiate between the cases in which a person’s choice
is the result of rational deliberation and cases in which a person’s choice is the result of a
combination of wrongful harms and rational choice. Feinberg thus fails to show that
offers can force and therefore fails to show that offers can be coercive.

I disagree with Feinberg that extremely attractive offers can be coercive, but I am
sympathetic to Feinberg’s idea that extremely attractive offers can make a person feel
forced to choose a particular option. Inducements can cause a shift in the cost/benefit
ratio a person associates with a particular offer such that even if the person would not
have pursued a particular course of action, X, on its own, an inducement, Y, can cause
the cost-benefit ratio to change such that the person genuinely desires to pursue the
combination of X and Y. Indeed, if a person has a strong desire for Y, and has a mild
aversion to X, then it would be irrational for her not to pursue the combination of X and
Y. In this sense the force is not a structural feature of the choice situation, and it does not
come by an outside hand, but instead the force is generated by the person’s own
preference schedule.

It would seem, however, that this type of force does not produce any moral force.
People who make decisions under these conditions act with full understanding, and
though they may feel their voluntariness is compromised, this, in itself, is not enough to
produce exculpatory force. Force can carry exculpatory force only against the person who exerts it, and if there is no outside person exerting the force, then there is no person from whom the agent could be released from involuntarily assumed obligations. In short, though a person may feel forced in these situations, this type of force does not affect the validity of the commitments they make to others. The force they feel, however, can certainly elicit empathy, even sympathy, from others. Though we might not exonerate a person from the choices they make, we might understand why she made the particular choice and judge her less harshly for her actions.

Inducements thus are not coercive, and when they function in a way that shifts the cost-benefit ratio associated with an option they do not compromise a person’s consent. It would seem, then, that inducements are appropriate unless they compromise a person’s consent in another way. There is indeed a second way in which inducements can affect a person’s decision making process. Sometimes an inducement can be so great that it is seductive and when an inducement affects a person’s decision making process in that way it compromises consent. An extremely attractive offer becomes seductive when it contains a reward that is so irresistible the recipient is unable to fully appreciate the costs associated with the transaction. These offers can sometimes promise benefits that are so appealing that they effectively blind a person, so to speak, to the costs associated with the proposal, and when this happens the person makes a decision on an erroneous, cost/benefit analysis. When an inducement merely shifts the cost/benefit ratio associated with an offer the inducement does not compromise consent, but when an inducement causes an erroneous cost/benefit ratio it does compromise consent. An erroneous cost/benefit calculation is a false belief, and a person who makes a decision based on a
false belief fails to satisfy the necessary conditions for valid consent. Valid consent requires that a person act with intentionality, understanding, and voluntariness, and when a person acts according to a false belief she fails to fully satisfy the condition of understanding.\textsuperscript{15}

Extremely attractive offers are problematic when they cause this effect, but it is difficult, in a practical sense, to determine if and when a proposal compromises a person's decision making process in this way. The value associated with certain incentives is subjective, and thus may be different for different people. Moreover, different people may have different thresholds for when a good is so appealing that it distorts judgment. It is nearly impossible prospectively, or even retrospectively, to determine whether a particular inducement will have this effect on any given person. Perhaps the best we can do is institute a reasonable person standard. A reasonable person standard could provide objective thresholds, beyond which an inducement would be problematic for the average, reasonable person.

Even if we can resolve the difficulty in determining when an offer is seductive by appealing to a reasonable person standard, we will still have difficulty determining the moral force of seduction claims. Seduction compromises a person's consent by inhibiting her understanding of her choice situation, but not all compromised consent is invalid consent. Competence to consent is often thought to be a concept that admits of degrees rather than thresholds. It is very difficult to establish a threshold of competence above which we say all people are competent for all decisions, and below which we say that people are incompetent for all decisions. We rarely determine a person to be categorically competent or incompetent, and instead we often determine a person to be
more, or less, competent as the case may be, and competent to make some decisions and not others. For example, an elderly patient suffering from dementia might be competent to a lesser degree than others. This patient might be incompetent to make treatment decisions, but he might be competent to make a decision regarding what he will eat for supper. Our requirements for valid consent slide along a scale that reflects the risk associated the options open to a person. We value autonomy and believe it is important that people make their own decisions when they so desire. Using a risk-relative notion of competence allows us to err on the side of autonomy in the cases where it is difficult to determine whether a person is competent to make their own decisions. When there is little at stake, there is little reason to override a person’s desire to be autonomous, but when there is more at stake, and a person may experience harm if she makes a poor decision, then we are more rigorous when determining her competence to decide for herself. Seduction compromises a person’s understanding of her situation, and thus compromises her competence, but whether the compromised consent is invalid consent will depend on the risk associated with the choice at hand. In high risk scenarios seduction can be problematic, and perhaps should not be tolerated, but in minimal risk scenarios seduction poses less of a problem.

In three of the four sample cases the offer to participate in research is an inducive offer because it contains a reward, but I argue that these inducements are not seductive and thus these inducements are not problematic. Researchers offer money as an inducement to both Adam and Bob, but the amount they offer is so paltry it would fail to seduce the reasonable person. Indeed, the reason these two cases make us uncomfortable is not that amount of money is problematically high, instead, these cases make us
uncomfortable because the amount of money is problematically low. $75 is paltry compensation for the inconvenience and discomfort Adam and Bob will experience while participating in the trial. In Deborah's case the researcher offers her the possibility of a health related benefit, and, because Deborah is sick, the possibility of treatment is an inducement for her. Deborah's condition, however, is not severe, and a 50% chance at free treatment is attractive, but not extremely attractive, and this inducement is not seductive. As in the cases of Adam and Bob, Deborah's case makes us uncomfortable not because the reward is problematically high, instead, it makes us uncomfortable because the reward is problematically low. The researchers entice her with the promise of free treatment, but offer only a 50% chance of receiving effective therapy when they could have designed the protocol differently and offered her a 100% chance of receiving effective therapy. In all three of these cases the offer to participate in research contains an inducement, but these inducements are not so high that they would cause a reasonable person to misappreciate the risks associated with the research. In these cases none of the offers to participate in research is seductive, and the fact that these cases make us uncomfortable indicates that the offers are morally problematic for a reason other than seduction.

Seduction refers to a particular moral wrong wherein one party solicits consent from another in a way that is likely to compromise the validity of the consent and whatever transaction follows might be non-consensual for the victim of the seduction. Exploitation refers to wrongful advantageous use, which may or may not be consensual, and when exploitation is non-consensual the defect in the consent of the expolitee might be caused by coercion, seduction, or any other factor that compromises a person’s
intentionality, understanding, or voluntariness. As happens with coercion, seduction will often entail exploitation because the person who seduces usually takes advantage of the person who is seduced. It is possible, however, for seduction to happen in the absence of exploitation, and it is possible for exploitation to happen in the absence of seduction. Seduction and exploitation both represent ways in which offers can be problematic, but each refers to a different moral wrong, with a different moral weight and force, and different corrective measures must be taken for each. Therefore it is important to correctly identify any and all moral wrongs associated with an offer or transaction, and it is important to avoid problems of confusion and occlusion among moral wrongs.

Commodification

When money is offered for participation in research, the research subject, or some part of him, is commodified, and some people think this is problematic. When money is offered for participation in research the offer to participate can also be exploitative, and, because both commodification and exploitation can refer to the problems associated with offering money, these terms are often confused. In this section I describe the process of commodification and discuss the ways in which commodification can be problematic. I show that not all cases of commodification are morally problematic, but when they are, the moral wrong is different from exploitation.

A commodity can be anything, from orange juice to athletic skill, which is recognized to be valuable and made available for exchange on an open market. Commodities have three important features: (1) they are proprietary, (2) their value is instrumental and completely reducible to their price, and (3) they are fungible. A commodity is proprietary in that it is owned: it is something that belongs to a party, and
this party can keep it or sell it as they choose. The value of a commodity consists entirely of its exchange value, or price, and this is determined by the amount a buyer will give in order to acquire it and the amount a seller will accept in order to part with it. As a commodity, a good has no value except its exchange value, and this is comprised entirely of its usefulness to a buyer and seller. In this way commodities are fungible, meaning they are interchangeable with other goods that promise the same usefulness. As Cathleen Kaveny writes, “One widget is a good as any other.”17

Some goods come into existence as commodities, and others have become commodities over time. For example, automobiles came into existence because they were useful to people; but gold and silver, though they have been in existence for perhaps millennia, became commodities only when man discovered their beauty. Commodification is the social process by which something previously in existence comes to be perceived as a commodity, as well as the state of affairs once that process has taken place.18 We tolerate and even encourage the commodification of many goods because commodification does have benefits. Introducing a good into the stream of commerce allows the market to guide research, development, and production and marketing, and this often results in higher quality and lower cost. We contest, however, the commodification of certain goods when we are personally or socially troubled with the good being valued and traded as a commodity.

Microorganisms, transgenic animals, human gene sequences, human ova and sperm, and surrogate motherhood have all been contested commodities.19 Transplantable organs have not yet been commodified, but the recent debates among philosophers and bioethicists suggest that their commodification would be contested as well.20 Critics of
the commodification of these things argue that it is inappropriate to view them as commodities, and their arguments typically take any of four forms. First, critics try to show that the good simply does not meet the first criterion for a commodity because it is not proprietary. For example, some claim that microorganisms, transgenic animals, and gene sequences are neither created nor legitimately acquired by those who claim to own them, and thus cannot be proprietary goods. Second, critics of commodification try to show that it is inappropriate to view these goods as having value that is only instrumental and reducible to a price. To view a good, such as a transplantable organ, in this way reduces something that is integral to our personhood to a price, and this materialistic reductionism is problematic because it is incompatible with the intrinsic value that we ascribe to all persons. Third, some people contest the commodification of goods such as transplantable organs because it transforms what should be a process of gift-giving into a market transaction. Finally, some people think that commodification of goods such as surrogate motherhood and transplantable organs is problematic because it leads to certain untoward consequences, in particular, exploitation.

These are, in brief, the types of arguments through which the commodification of living organisms and their parts has been contested. These arguments indicate the types of moral problems that commodification can pose, and they are all quite different from problems of exploitation. Concerns about improper commodification are concerns about property claims in non-proprietary goods, instrumental valuation of goods with intrinsic value, and gift giving versus economic transactions. It is not clear, however, that these concerns are applicable to human subjects research. I argue that the only legitimate concern about commodification in human subject research is the concern that it will lead
to exploitation, and this does not indicate a problem of commodification, instead, it indicates a problem of exploitation.

It is becoming increasingly common for researchers to offer money to research subjects. Sometimes the money is meant to reimburse them for their expenses, which could include their actual expenses and their time away from work. Sometimes, however, the money is meant to be a recruitment incentive for studies that might otherwise have difficulty enrolling, and in these cases the money is offered simply for participation. When money is exchanged for participation in a clinical trial, some aspect of the human research subject becomes a commodity. The easiest way to identify this feature is to examine what the subject gives to researchers and the research.

First, and most obviously, he gives time and endures inconveniences. He shows up for appointments, he might keep a diary recording certain events in his daily life, or he might be otherwise inconvenienced by following a particular diet, or taking medications according to a specific schedule. If he is being paid for his participation, and his participation consists of giving time and enduring inconveniences, then his time and convenience are the goods that are commodified. The practice of giving time and enduring inconveniences such as these, however, could be easily seen as unskilled labor. Indeed, many jobs do not require more work or skill than is involved in these tasks. If this is true, then the unskilled labor of the research subject is the feature that is becoming a commodity. Labor, however, is a generally accepted commodity and such commodification would be unproblematic. Insofar as the research subject is being compensated only for his labor, one is not likely to object to commodification. The question remains, however, whether he is being compensated for other things.
A second thing the research subject offers to the researchers is an assumption of risks. In agreeing to participate, the research subject volunteers to assume the risks of an unproven therapy. These risks may be somewhat benign, or they may be more serious in nature. In any case, if the subject is being compensated for participation, and participation entails an assumption of risks, then he is being compensated for his assumption of risk. His risk assumption, then, is a commodity. Once again, though, risk assumption is a generally tolerated commodity. Underwater welders, workers on off-shore oil rigs, expatriates stationed in dangerous locations, and others who work dangerous jobs often receive pay set at a level that compensates them for the risks they assume. Indeed, the U.S. Department of State thinks that employees who work in dangerous places should receive an additional payment of 25 percent of their normal salary.\(^2\) (This is in addition to compensation for an actual harm should it occur.) If labor and risk assumption are the only features of the human research subject that are commodified, then such commodification should not be contested. They are not, however, because the human research subject is compensated for at least one other thing.

The most important thing a research subject gives is the use of his body as a laboratory. Researchers need to know how a disease progresses, how a particular drug acts in the human body, or whether a certain condition responds to an experimental therapy. Animals can provide some data, but ultimately researchers need a human body to gather the data necessary to determine whether a therapy is safe and effective for people. In this sense, the research subject gives researchers the use of his anatomy, and his physiological, biochemical, and neurological processes, and other general and basic features of the human body when he lets them observe, and even alter, the workings of
his body. When the human research subject is paid to participate, he is thus compensated, at least in part, for the use of his body as a laboratory. The use of a person’s body is not a generally tolerated commodity, so there is no easy answer as to whether this commodity should be contested. Indeed, there is no easy answer as to whether the use of a person’s body can even function as a commodity. In the following section I will examine whether the use of a person’s body is a good that can satisfy the criteria for a commodity, and, if so, whether commodification of this good is appropriate.

As an autonomous being a person owns himself, and this ownership extends to all parts of the body. People own their bodies as a whole, the parts internal to them, and the parts of them that can be removed. Insofar as researchers use all or some of these parts of a person, the research subject owns what the researcher uses. Ownership of a body or parts integral to its functioning, however, cannot be proprietary in that a person cannot sell these and still remain a living person. When a subject sells the use of his body to a researcher, the “sale” is not a transaction in which ownership is transferred. Instead, when he offers his body to researchers he is merely letting them use his body for a while. He is, in a sense, renting it to them while still using it himself: he retains primary use of his body, and offers them secondary use. This use is similar in kind to the commodity a fashion model might sell, namely, the use of her looks. She retains ownership and primary use of her appearance, but also sells her appearance to others. In some cases the secondary sale may alter her primary use, for example, a client might ask her to change some feature of her appearance, but secondary use need not affect primary use. For both the model and the human research subject, it is possible to offer a secondary use that does not in any way affect the primary use of the good by the owner. Secondary use of the
research subject’s body is a commodity that is owned and traded in a biomedical experiment, therefore, the any argument that attempts to show that the commodity is not proprietary fails in this case.

One might contest this commodification with the second type of argument.25 Human beings, as autonomous agents, have unconditional value that deserves categorical respect. This value extents to our body, and the parts integral to it, because they are both physically necessary for, and intimately connected to, our personhood and existence as an autonomous agent. When a research subject sells the use of his body as a commodity, his body is valued at its market price and only for its usefulness. When his body is valued only instrumentally, it cannot, at the same time, be valued intrinsically. Thus, valuing his body for its usefulness is incompatible with the unconditional value he deserves as a human being. Therefore, commodification of his body is inappropriate and should be contested.

This argument fails to show that the research subject should be a not be commodified for at least two reasons. First, the feature of the human research subject that is commodified is neither physically necessary for, nor integral to, his personhood, and thus not something that holds derivative intrinsic value. Second, commodification of this good in particular, and all goods in general, does not necessarily lead to the good being valued only instrumentally. It is possible for some goods to simultaneously hold both instrumental and intrinsic value.

An autonomous agent’s unconditional worth extends to those parts of him that are physically necessary for, or intimately connected to, his individuality and personhood. Secondary use of our body is not a feature of us that is physically necessary to our
existence. The primary use of our body is necessary to sustain our existence as an autonomous agent, and the primary use thus has derivative intrinsic value. The secondary use of our body, however, is not vital and thus cannot derive intrinsic value in this way. Neither is it intimately connected to our identity or personhood. The features connected to our personhood are those things that make us people, as distinct from all other species, and those things that make us individuals, as distinct from all other persons. It would be difficult to make a comprehensive determination of all features that have derivative intrinsic value and all features that have only instrumental worth in this way. Nevertheless, some things are clearly one or the other. Our minds are integral to our identities as individuals and our identity as a species distinct from all others species. A woman’s reproductive organs might be integral to her personal identity and her identity as a member of her gender. Both of these might carry derivative intrinsic value. Our toenails, however, are not intimately connected to our personhood, and thus have no derivative intrinsic value. Our body, in its most general form, is not something that differentiates us in any meaningful way from one another, and it is not something that significantly differentiates us from other species. Our anatomy, and physiological, biochemical, and neurological processes, and so on, are not special features of our bodies to which we are intimately connected. Indeed, we often do not even think of these aspects of our being except when they malfunction, when they present themselves as a nuisance. Individual parts of our bodies might be more intimately connected with our sense of identity, for example, a woman’s reproductive organs, sometimes even her breasts. When research involves a specific and more intimate part of the body, this argument may not apply. But research that involves a general use of the body, such as
observation of neurological processes, or pharmacokinetic testing, the aspect of the body that is being used is not something with which we have an intimate connection and thus not a feature of us that carries derivative intrinsic value.

Even if our bodies do carry intrinsic value, it does not follow that the commodification of the human research subject would be incompatible with regarding him as an autonomous agent with intrinsic value. This argument assumes that we cannot simultaneously regard something as having both market value and intrinsic value. However, from the fact that a thing might be intimately connected to our identity and personhood, it does not follow that it cannot, at the same time, be valued instrumentally. There are several practices that indicate otherwise. Our identities as individuals are, in part, based on our mind and our knowledge base, but the nature of many professions requires that we regularly share these things for money. Our personalities are another feature of us that are intimately connected with our personhood and individuality. But radio disc jockeys and television hosts regularly sell their personalities, indeed the National Broadcasting Company (NBC) currently values Katie Couric’s personality at thirteen million dollars per year.

The notion that we cannot simultaneously recognize a good’s market value and its intrinsic worth is unnecessarily reductionistic. This view relies on what Margaret Jane Radin terms “the commodified theory of human nature,” which she explains as the belief that market understandings are more powerful than their possible alternatives, such that we will always value a good in market terms, even to the exclusion of other forms of valuing. Radin rejects this theory as both untenable and unrealistic. Indeed, when we watch Katie Couric on *The Today Show*, we enjoy her as host of the show, but at the
same time still recognize her as a person, as a being with intrinsic, non-market value. It is possible and not inappropriate to value a feature of a person instrumentally, while still recognizing that the person has unconditional value as an autonomous agent. This involves what Radin calls “incomplete commodification”, the coexistence of market and non-market understandings of a good. It is also possible, and not inappropriate, to view the human research subject as a good that has been incompletely commodified. Thus, absent an argument showing that commodification of a feature necessarily leads to this good being valued only instrumentally, this argument fails to show that commodification of the human research subject, or any other body part, is inappropriate.

The third argument against the commodification of body parts, indeed, the commodification of the research process itself, is that the exchange of money for participation in research transforms what should be an altruistic enterprise into an economic transaction. On the one hand, body parts should be transferred from donors to recipients as gifts, and subjects should participate in research for altruistic reasons rather than personal gain. On the other hand, researchers should not have to pay subjects for participation, and furthermore, researcher should not turn a profit on their data, because the research enterprise should be motivated by altruism and concern for the welfare of our fellow man. The commodification of body parts, and the commodification of the research process itself, undermine and, critics claim, eventually destroy the gift giving and altruistic nature of the endeavor. The donation of body parts, participation in research, and the pursuit of medical knowledge would no longer be gift exchanges and altruistic endeavors, but would instead become monetary transactions.
This argument is unconvincing for two reasons. First, it fails to show why body parts in particular, and the research enterprise in general, should be gifts rather than commodities and for-profit ventures. Second, such commodification does not preclude altruism. Even if subjects are compensated, it does not follow that only subjects who are seeking compensation will enroll. Some subjects might still enroll for altruistic reasons, so the gift relationship may continue to exist. Likewise, even if researchers and medical personnel are engaged in a for-profit venture, it does not follow that only researchers and medical personnel who are seeking profit will participate. The real fear motivating proponents of this argument is that subjects and researchers might participate for non-altruistic reasons, and for some reason, they do not want the activity of human subjects research to be transformed in this way. They want all participation in research to be altruistic.

The problem with limiting research to subjects who want to make a gift of their time and body is that researchers often recruit, either by necessity or accidentally, from populations of people who are particularly ill-suited to be making gifts. Researchers sometimes need subjects who suffer from a particular medical condition, indeed, in some cases they would be asking those who have been ravaged by a disease to make gifts of their body and time. Researchers working in public hospitals often recruit subjects from lower socio-economic classes, and these are hardly people who can afford to make gifts of their time. The ideally suited person for gift giving is the person who is fortunate enough to have things to give, and rarely does a candidate subject satisfy this condition.

Likewise, the problem with limiting research to only those researchers who would make gifts of their time and ability is that few researchers would initiate clinical trials. In
an ideal world, we would all give whatever time, money, and other resources we could spare as social gifts: we would participate in community service, medical research, and any other worthy cause. But most of us do not have much spare time or many spare resources, and thus do not make many gifts. If research relied on only altruistic motives, many experiments would either fail in their inception or fail to meet their enrollment goals.

A productive research community requires researchers need to be pursuing something worthwhile for themselves, and in order to fill their trials, researchers need to enroll people who are pursuing something worthwhile for themselves. Those who want to prevent the commodification of the human research subject and promote research as an altruistic and gift giving activity must realize that their goals are mutually exclusive with progress in medical research. Given that the argument for this position is weak, and the consequences of adopting such a position are severe, there is good reason to not oppose the commodification of the human research subject or the research process in general.

The most compelling argument for opposing the commodification of the human research subject is the concern about untoward consequences. Many people fear that if we offer money for participation in research then only those who need money will volunteer for participation, and this will create a situation in which medical research is conducted mostly on people from lower socio-economic classes. In this way commodification will lead to advantageous use of those who are socially and economically vulnerable and this is morally wrong. This is a compelling argument, and a reasonable concern, but this is not a concern about commodification. This is not a concern about trading body parts for money, this is a concern about exploitation.
Our reaction to the cases of Adam and Bob illustrates that our concerns are about exploitation and not commodification. Recall that Adam and Bob were both offered $75 to participate in research, so in both cases their time, effort, and use of their bodies were exchanged for money and thus commodified. These cases make us uncomfortable, but we are not concerned about whether Adam and Bob can claim ownership rights to their bodies, whether their intrinsic value is inappropriately reduced to materialistic terms, or whether they should be donating their time and bodies for free. Adam and Bob seek research studies as employment opportunities, and we can respect and understand the activity in this way. We are concerned, however, with the fact that they are paid so little, and the fact that researchers can pay them so little because they are both economically vulnerable. Our real concern is exploitation.

In this sense concerns about the commodification of the human subject of medical research are often statements in which commodification is confused with exploitation. Commodification and exploitation are distinct moral problems. The commodification of the human research subject is not in itself problematic, but when it leads to problems of exploitation, and this problem cannot be avoided, then the problem of exploitation might provide a compelling reason to oppose commodification. The two remain, however, distinct moral concepts, each with its own moral weight and moral force.

Conclusion

Exploitation is a moral wrong that is different from the moral wrongs of coercion, seduction, and commodification, but we need to know more about the conditions under which exploitation occurs in order to determine the truth of exploitation claims in the
context of human subjects research. We need to identify the necessary and sufficient
conditions for exploitation, and we need to determine whether all exploitation is morally
wrong. If there are some cases of exploitation that carry no moral weight, then we need
to identify the features that separate pejorative from non-pejorative exploitation. In the
next chapter I begin to develop a model of pejorative exploitation, and in the following
chapter I complete this model. In the later chapters I apply the model to human subjects
research. I show that some of the current practices are indeed exploitative, and I show
the ways in which we can prevent the exploitation of human subjects of medical research.
Three

A Model of Exploitation

The American Heritage Dictionary provides the following definitions for "exploitation":

1. the act of employing to the greatest possible advantage;
2. utilization of another person or group selfishly or unethically.¹

The first definition captures the benign use of the term, for example, when a person exploits her talents, or a company exploits its resources. The second definition captures the morally charged use of the term, a use that both recognizes and passes judgment on a state of affairs. For example, when we say that prostitution is bad because it exploits women, we are simultaneously recognizing that some person or group of people are using these women to their advantage, and we are making the moral judgment that this use is inappropriate or otherwise wrong. Under both definitions a person exploits someone or something when he uses it to his advantage, but, depending on the circumstances of the case, this exploitation can carry either a non-pejorative or a pejorative connotation. That is, some cases of exploitation are morally neutral, and some cases are morally wrong. It is often easy enough to determine when one is using someone or something to one's advantage, but it is not so easy to determine when this utilization is morally wrong.

In this chapter I will identify the features that make an act of exploitation morally wrong. This normative model of exploitation will provide both the necessary and
sufficient conditions for pejorative exploitation, and will thus determine whether any given case of utilization is morally neutral or morally wrongful exploitation. I begin by identifying the three normative uses of exploitation and explore the underlying models for each. Some people think that we must either accept pluralism and the conflicting conclusions that will follow, or reject all but one model, but I argue these models are all variations of a similar theme and all can be true without producing conflicting conclusions. I show that all theories of exploitation can be expressed by a single model with two necessary and jointly sufficient criteria. The first criterion, that the exploiter gains, is relatively straightforward, and it will be easy to see the circumstances under which this condition is satisfied. The second criterion, that this gain is unjust with respect to the exploitee, is more difficult to articulate and will require more analysis. In the next chapter I develop a principle of justice in transaction to complete the model. In the following chapters I apply this model to medical research and discuss the moral weight and moral force of the exploitation claims that result.

Models of exploitation

A survey of the use of exploitation, both in the literature and common parlance, produces as least three accounts: Marxist exploitation, feminist exploitation, and contemporary analytic exploitation. The first and perhaps most classic use of the term refers to the Marxist complaint that capitalistic economies are unjust. Marxist exploitation describes the way in which the capitalist class, the “bourgeoisie”, wrongfully gain at the expense of the worker, the “proletariat”. Marxists argue that exploitation is an inevitable consequence of capitalistic societies, and since exploitation is morally wrong,
this constitutes a good enough reason to move away from capitalism as a structure for social organization and move towards socialism and eventually communism. This type of exploitation refers to specific type of mistreatment, of a particular party by a particular party, and this mistreatment happens only in a certain setting. Thus any use of exploitation that does not refer an unequal exchange, between the workers an capitalist, in a capitalistic economy, refers to a type of exploitation that differs from Marxist exploitation.

In the literature and common parlance we also see a second use of exploitation, one that differs from Marxist exploitation, and instead refers to a specific class of wrongs that women suffer in a male dominated society. Feminists use exploitation to describe the inappropriate advantageous use of women made possible through the vulnerabilities created by their oppression in a male dominated society. This differs from Marxist exploitation because the perpetrator of the wrong is men as a class, including both property owners and workers, and the victim is women as a class, regardless of whether they own property. Also, feminist exploitation is not limited to capitalistic economies because it can occur under any form of social organization as long as there is inequality between men and women. The feminist present a second model of exploitation, one that is quite different from Marxist exploitation, and one that refers to a specific moral wrong under specific circumstances.

We also see a third use of exploitation, one that differs from both Marxist and feminist exploitation, and refers instead to a range of injustices that occur in a variety of settings. This uses includes the concern about our treatment of student athletes, the uneasiness that surrounds markets in human organs and gametes, and the complaint that
vendors take advantage of consumers when they engage in price-gouging practices in times of need. These are not concerns limited to a specific population, such as women or those who own no capital, and they refer to a notion of exploitation that is independent of setting. Moreover, the exploitation claims generated by these concerns can be true and meaningful without reference to a larger moral program. These exploitation claims are quite different from the Marxist complaint against capitalistic social structures, or the feminist complaint against the injustices in a male dominated society, and they constitute a third type of exploitation. I will call this the contemporary analytic model of exploitation because this type of exploitation has only recently been explored and modeled.

In this section I present detailed analysis of each of these three models, and I identify the necessary and sufficient conditions for each type of exploitation claim. In the next section I address and resolve the problem presented by these multiple and competing models of exploitation.

Marxist exploitation

In recent years interest in Marx's theory of exploitation has experienced a significant resurgence, particularly at the hands of analytic philosophers who are questioning both its coherency and moral force. This challenge has divided Marxist theorist into two camps: the traditional Marxists who propose a historically accurate interpretation of Marx's theory exploitation, and contemporary, or analytical, Marxist who propose a revised and augmented account Marx's theory of exploitation. In the following section I will present both the traditional Marxist and the analytical Marxist
definitions of exploitation, and comment briefly on the differences, strengths, and weaknesses of each definition. I do not attempt to resolve the issue of which definition is better, instead, I am content to recognize both as independently viable definitions of exploitation.

Jeffrey Reiman is perhaps the most vocal and prolific defender of the traditional Marxist definition of exploitation. According to Reiman, the Marxist definition of exploitation is, and should be, as follows:

A society is exploitative when its social structure is organized so that unpaid labor is systematically forced out of one class and put at the disposal of another.\(^3\)

To thoroughly understand the nature and significance of Marxist exploitation it will be useful to examine more closely the two most important features of this definition: first, that (some) labor is unpaid, and second, that this unpaid labor is forced.

Central to the traditional Marxist definition of exploitation is the belief that some of the labor the worker gives to the capitalist in exchange for wages is unpaid labor. To understand why Marx believes the labor is unpaid one first needs to understand his labor theory of value and his concept of surplus value. According to the labor theory of value, the value of any particular commodity is determined by the amount of labor necessary to produce it.\(^4\) Marx deliberately ignores the effect of all production costs except labor, and the value of a commodity can be captured, without remainder, by the labor-time required to manufacture the good. Regardless of whether this simple model accurately reflects the value assigned to the commodity in the real world, and John Roemer, for one, thinks it does not, as a heuristic device this model enables us to appreciate an essential and socially important feature of commodity production. It also helps us understand the way in which a capitalist economy functions.\(^5\)
In a capitalist economy, those who own the means of production, “the capitalists” or “the bourgeoisie”, will hire workers to produce commodities and pay them wages for their labor. The capitalists will then sell the commodities for more money than the wages they paid for the production of the commodity. The value, or price, assigned to the good is higher than the wages paid for the labor required to produce it, and Marx calls this difference, this additional value, “surplus value”. The worker, then, cannot purchase the good he made with the amount he received in wages. Assuming similar mark-ups will occur with all commodities, the worker cannot purchase any good that required the same amount of labor time. With his wages a worker can only purchase goods whose production required less labor than the amount of time he spent laboring for his wages. In effect, the worker gives more labor than he receives, thus, he gives some labor for free.

Marxists hold that workers in capitalism work more hours for their bosses than the number of hours of work it takes to produce the real equivalent of the wages their bosses given them in return, and thus that they work in part without pay. According to the purchasing power of the wages the worker receives, he is not paid the full amount his labor is worth for all of the hours that he works. Instead, he is paid only a portion of that amount, which means that only the proportional number of labor hours are paid, and the remaining labor hours he works for free.

This idea of unpaid labor is an important feature of Marxist exploitation, but perhaps even more important, at least to Rieman, is the belief that this unpaid labor is somehow forced. In a capitalist economy the capitalists own the means of production, and they also command the purchasing power, or money, which workers need in order to live in a society in which money is traded for goods and services. Workers own little except their capacity to labor, so the only way they can make a living is to sell their labor. Only the capitalists will be interested in purchasing the labor because they own the means
of production, and only the capitalists will be able to trade the money the workers so badly need for labor. Thus, ownership of the means of production and command of purchasing power gives the capitalist class a significant bargaining advantage over the working class. The result is that the worker, for fear of being offered no work at all, will work for wages that are less than his labor is worth. The worker will feel forced to agree to an unequal exchange because he has no other open options.

The traditional Marxist model of exploitation has two necessary and jointly sufficient conditions: (1) workers are forced to transact with the capitalists, and (2) the exchange between the worker and capitalist is unequal with the worker receiving less than he gives. Exploitation occurs whenever these criteria are met, and the Marxists believe that conditions in a capitalist economy will always meet these criteria. Marxists also believe that the exploitative conditions of this type of economy serve as the basis for at least three normative conclusions. First, exploitation is an indication of the domination of workers by capitalists, and domination is an evil. That one class of people is forced into an unequal exchange by another is a sign of subordination and a failure to recognize the inherent equality of persons. Second, exploitation is a measure of the degree to which people are alienated under capitalism. In a capitalist economy workers are alienated from themselves because “their life-activity takes an alien, inhuman form.” The structure of such a society creates and perpetuates

... social relationships in which the life-activity of the laboring majority is increasingly stunted, reduced to meaningless physical activity which, far from developing and exercising their humanity, reduces them to abstract organs of a lifeless mechanism. Their products belong to a non-worker, the capitalist, to whom they must sell their activity for a wage which suffices only to keep them alive so that they may sustain the whole absurd cycle of their lives.
The third normative conclusion Marxists draw from the fact that workers are exploited is that the worker's labor is wrongfully taken from them. Reimer, Roemer, and others describe exploitation as expropriation, and Marx himself describes the capitalist-worker relationship using terms such as embezzlement, theft, and robbery. For these three reasons, and perhaps others, Marxists believe that exploitation embodies all the evils of a capitalist society and carries enough moral force to support, even mandate, a move from capitalism to socialism.

In recent years a group of contemporary Marxist theorists, known as the Analytical Marxists, has challenged this traditional definition of Marxist exploitation and the normative conclusions that it supports. John Roemer, a prominent member of this group, argues that the model of exploitation that traditional Marxist use is not normatively interesting because it is not, in any necessary way, linked to the evils Marxists associate with a capitalist economy and therefore cannot be the basis for the conclusion that capitalism is bad.

According to Roemer, traditional Marxist find their definition interesting and useful because they believe it is an indicator for, or measure of, the presence of the moral wrongs of domination, alienation, and expropriation. They believe that exploitation is an inescapable feature of a capitalist economy, and exploitation indicates a morally bad state of affairs, so exploitation supports an argument against capitalism. Roemer, however, argues that this model of exploitation is neither a necessary nor sufficient condition for the evils of domination, alienation, and expropriation because, "inequality is not necessarily co-extensive with surplus value." These evils of capitalism can exist in absence of exploitation so defined. Therefore, if the surplus value definition of
exploitation is an unreliable indicator of the reasons Marxists believe capitalism is unjust, then the surplus value definition of exploitation refers to a concept that is morally uninteresting.

After rejecting this "surplus value definition" of exploitation, Roemer proposes a new model of exploitation, the "property relations definition," which, he believes, captures the underlying reason why Marxists think capitalism is unjust. According to the property relations definition of exploitation, a coalition S' capitalistically exploits its counterpart, S, if the following three conditions hold:

If S were to withdraw from the society, endowed with its per capita share of society's alienable property (that is, produced and nonproduced good), and with its own labor and skills, then S would be worse off (in terms of income and leisure) than it is at the present allocation.

If S' were to withdraw under the same conditions, the S' would be worse off (in terms of income and leisure) than it is at present;

If S were to withdraw from society with its own endowments (not its per capita share), then S' would be worse off than at present.15

Roemer believes that a group of people, S, is exploited if they would be better off, and their counterparts would be worse off, if alienable assets were redistributed in such a way that every person gets an equal share. In other words, workers are exploited when they are economically disadvantaged as a result of an unequal distribution of property.

Based on Roemer's interpretation of the traditional Marxist model of exploitation, we see that both the surplus value definition and the property relations definition are distributive definitions of exploitation, and they differ only in terms of where they locate the source of the injustice. On the one hand, the surplus value definition locates the injustice in the actual transaction between the workers and capitalist class, where there is an unequal exchange of labor for wages. On the other hand, the property relations
definition admits that there is an unequal exchange at the point of the transaction, but focuses on the source of this injustice, which lies further back in the inequality of the initial distribution of alienable resources. Roemer thinks the property relations definition of exploitation is better than the surplus value definition, and should be of more interest to Marxists in their struggle against the capitalist economy because it captures the causes of domination, alienation, and expropriation, namely, “differential ownership of the means of production.”  

There is an ongoing debate between the traditional Marxists and the analytical Marxists over which definition more accurately describes Marx’s theory of exploitation and his objections to capitalism. Traditional Marxists argue that Marx never intended to include a concession to a principle of distributive justice, and because Roemer appeals to such a principle in his definition exploitation the definition is fundamentally a-Marxist. Reiman also charges that Roemer’s definition is a-Marxists because it contains no reference to force, a notion he thinks is of central importance in Marx’s objections to capitalism. Indeed, some traditional Marxist claim that Roemer strays so far from traditional conceptions of Marxism that he should no longer even be considered a Marxist theorist. Roemer, however, argues that traditional interpretations of Marxism are morally uninteresting and the Marxist theory of exploitation is revitalized and more useful to the Marxists when augmented with his notion of distributive justice.

For the purposes of this dissertation it will not be necessary to resolve the debate between the traditional and analytical Marxist. My thesis in this chapter is that all competing definitions of exploitation can be expressed by a single model, and I can avoid the difficult task of resolving this dispute by showing that both the traditional Marxist
definition and the analytical Marxist definition can be expressed, without remainder, by the conditions presented in the contemporary analytical model.

**Feminist exploitation**

The feminist theory of exploitation is similar to the Marxist theory of exploitation in that both theories are concerned with the oppression of one class by another, and both theories are concerned with the subsequent advantageous use of the oppressed by the oppressor. Marxists claim that the capitalist class oppresses the working class and then uses the workers advantageously by trading unequal amounts of wages for labor. Feminists claim that the male class oppresses the female class and then uses the vulnerabilities created by this oppression to their advantage. The two theories share a second similarity in that both suffer from internal disagreements over the source of the oppression and the way in which the oppressive force creates exploitative conditions. Marxists disagree whether the source of oppression and subsequent exploitation is, on the one hand, the coercive conditions created by the fact that the workers do not own property, or, on the other hand, an unequal initial distribution of the means of production. Feminists also disagree about the source of oppression, but there are more than two competing sides on this issue. Indeed, there are many different, and sometimes conflicting, approaches to a feminist theory of exploitation.

Although there is a great deal of variation between different feminist schools of thought, feminists as a whole are committed to the belief that there are injustices against women.\(^{19}\) Their program requires determining how women ought to be treated, identifying how women are, as a matter of fact, viewed and treated, and demonstrating
that they are not being treated in accordance with the standards of justice or morality.\textsuperscript{20}

This common program, however, seems to signify the extent of the similarity among the various schools thought.

Feminism is grounded on the belief that women are oppressed or disadvantaged by comparison with men, and that their oppression is in some way illegitimate or unjustified. Under the umbrella of this general characterization, there are, however, many interpretations of women and their oppression, so that it is a mistake to think of feminism as a single philosophical doctrine, or as implying an agreed political program.\textsuperscript{21}

Indeed, interpretations of women and the oppression they experience in a male dominated society vary dramatically. Some feminists argue that the source of women's subordination is their role in the family or their biological role in reproduction, others claim it is their role in the labor market, still others claim the problem stems from males' tendencies to sexual violence.\textsuperscript{22} Different types of oppression create different types of vulnerabilities, and different types of vulnerabilities allow different types of advantageous use. Therefore women can be exploited in many ways, and these many types of exploitation will all fall under the heading of a feminist theory of exploitation.

Despite the apparent variability, there is a common model that underlies the many types of feminist exploitation. All schools of thought within feminist philosophy are committed to the same program, so they all try to formulate the same complaint against society, namely, that society oppresses and then exploits women. They argue that society's oppression of women, whatever its source, creates in women certain vulnerabilities. When others prey on these vulnerabilities and use women to their advantage they do more than merely oppress, they exploit. Thus, according to feminists, the exploitation of women is advantageous use made possible by the creation of vulnerabilities through oppression. This model of exploitation has three necessary and
jointly sufficient conditions: (1) X causes women to be oppressed, (2) oppression because of X creates certain vulnerabilities, Y; (3) others in society use women advantageously because of Y. The different types of exploitation that occur within the feminist theory all use this same model, and they all argue that these three conditions are satisfied, but they differ in the way they instantiate the variables and satisfy the conditions.

The liberal feminists offer one such version of exploitation. The liberal feminist holds that the genesis of female subordination is:

... a set of restraints that block women's entrance to and/or success in the public world. Excluded from places such as the academy, the forum, the marketplace, and the operating room, the true potential of many women goes unfulfilled.²³

Women thus suffer from lack of opportunity and this makes them vulnerable to occupational exploitation. Society exploits women when it directs them towards careers, such as school teaching, that are socially necessary but offer less professional potential than the careers typically open to their male counterparts. Though women may be just as capable as men, they cannot achieve the success they may desire because they are socially limited to certain occupational fields. This is advantageous use made possible by oppression, and therefore this is feminist exploitation.

Cultural feminists offer a different version of exploitation because they locate the root of female subordination in the tendency of a patriarchal society to push women towards roles of care and nurturance.²⁴ This leads women to value their ability to help others, perhaps even feel obligated to help others, and this creates a vulnerability to exploitation insofar as women enter into relationships where others typically benefit more than her. Henrik Jorgensen argues that this particular motivational structure makes surrogacy arrangements exploitative to women.²⁵
Studies have uncovered many different, and sometimes conflicting, motivations for surrogates, but one almost always is mentioned, namely altruism. The surrogate mother simply wants to do something for the future social parents and finds that which she can get out of the arrangement herself to be of limited importance.26

Emphasizing and reinforcing women’s social and biological role as caregivers oppresses women because they do not realize the other ways in which they could make valuable contributions to other individuals and society, and likewise, they do not realize the other ways in which they could create value for themselves. This type of oppression creates a vulnerability in women because it shapes women’s desires in such a way that women want well-being and happiness for others, and only the satisfaction in helping others for themselves. This vulnerability, this desire to nurture and give to others, allows others to use women in an advantageous manner because they can get more from their interaction with women and give less in return.

The altruistic surrogate mother is less well-off in comparison with the adoptive parents than the commercial surrogate. After all, the latter is paid a small amount of money for her efforts.

This is advantageous use because the person with whom the woman interacts gets what he wants, while giving the woman less in return compared to what she would demand were she acting according to alternative preferences. When women act according to this motivational structure they engage in transactions that are less profitable for them than alternative transactions; indeed, in cases where women are compelled to act in self-sacrificing ways for the sake of others, the transaction is harmful to them.

Though the different schools within feminist thought will produce many different types of exploitation, it is easy to see that a common model underlies them all. This model is advantageous use made possible by the creation of vulnerabilities through male-dominated oppression. This model constitutes the feminist theory of exploitation.
Contemporary analytic exploitation

The contemporary analytic theory of exploitation is described in the more recent body of literature that breaks from the Marxist tradition and the feminist tradition and analyzes exploitation as a concept independent from capitalism or men’s oppression of women. The contemporary analytic model of exploitation can be seen in its most evolved form in the works of Joel Feinberg and Alan Wertheimer, who agree on the substance of the model, but disagree on certain details. In the following section I present the model of exploitation that can be drawn from the work of both philosophers, focusing on the similarities and noting the differences. I begin with the model presented by Joel Feinberg, not because his is better or worse, but simply because his appeared first.

Joel Feinberg believes that the crucial feature in distinguishing pejorative from non-pejorative exploitation in all settings is the appearance of an independent element of wrongfulness.

A may simply utilize some traits or circumstances of B’s for his own purposes without wrong or harm to B or anyone else. Sometimes this is called “exploiting” the other’s traits or circumstances, but in this sense “exploits” is non-pejorative, and is just another way of saying “puts to use”. Not all use is ill use. … In some examples, on the other hand, A, by wrongfully extracting advantage from B’s traits or circumstances, can be said to have exploited those traits or circumstances in the full-blown pejorative sense of “exploit”.

Feinberg thinks the essential element of undifferentiated exploitation is simply that A gains through his use of B, whereas the essential elements of pejorative exploitation are:

1. A gains through his use of B, and
2. A’s gain is wrongful to B. All instances of pejorative exploitation will be similar in that they include these two elements, but instances of exploitation can differ dramatically in the way in which they satisfy these conditions.
With regard to the first condition, the way in which A uses B can vary according to two dimensions. First, A can enlist B’s cooperation in one of two ways: coercively or non-coercively. That is, B’s cooperation in the social endeavor can be either voluntary or involuntary, either consensual or non-consensual.

1. A’s act can be exploitative and coercive, as when his proposal effectively forces B to act in a way that benefits A.\textsuperscript{29}

2. A’s act can be exploitative and noncoercive, as when he takes advantage of B’s traits or circumstances to make a profit for himself either with B’s consent or without the mediation of B’s choice at all.\textsuperscript{30}

If A’s use of B is non-coercive, then B must have some exploitable feature that will allow A to use B to his advantage. When A plays to this exploitable trait, this vulnerability, B will agree to cooperate, so an exploitable trait is an essential feature of non-coercive exploitation. So, we see a second way in which A’s use of B can vary: the almost infinite number of vulnerabilities that will allow A to non-coercively exploit B. According to Feinberg, virtually any trait or circumstance is, in principle, exploitable provided it is causally relevant to the exploiter’s goals.\textsuperscript{31} Virtues and vices, a vulnerability to force or deception, an underlying disposition, or an “unhappy circumstance” are all exploitable traits.

A can exploit such character flaws in B as recklessness, cockiness, or intemperance, as well as other-regarding flaws like greed, vindictiveness, or enviousness. A can even exploit B’s self-regarding virtues, for example, taking advantage of his cautious prudence by a bluff … Indeed, [an exploitable trait is] any trait or circumstance that makes B reasonably predictable, and it is precisely in his predictability to one who has studied him closely that he becomes vulnerable. By capitalizing on his knowledge of B’s character and his present circumstances, A gets B to respond in the desired manner without using any force or deception whatever.

Depending on how A uses B, that is, how A secures B’s cooperation, exploitation can be either coercive or non-coercive, and, because there are an almost infinite number of ways
in which B could be vulnerable to non-coercive exploitation, there are an almost infinite number of ways in which A can non-coercively exploit B.

Instances of exploitation can also differ along a third dimension which is the way in which the benefits and burdens of social cooperation are distributed between A and B. A’s pay-off admits to little variance in that A must gain through his transaction with B in order for “advantageous use” to transpire. There are a variety of ways in which A can behave wrongly towards B, but if there is no gain for A, there is no exploitation. If A harms B but receives no gain, then A might be blameworthy for abuse, assault, discrimination, oppression, or any one of several moral wrongs. Exploitation, however, refers to a particular moral harm, namely, using another to one’s advantage, and this can happen only when one gains some advantage through his use of B. Where we see the variance in pay-off schedules is in the effect social cooperation can have on B’s interest, and B’s interests can be affected in at least two ways: B can experience a net loss or B can experience a net gain.

We would not normally speak of exploitation ... when B himself gains from the use to which A puts him. B’s not gaining, however, may also be too strong a requirement. B could gain from his own exploitation, I suppose, but be badly used because A gained disproportionately. For exploitation to occur it is not necessary that the exploiter always gain and the expolitee always lose, rather, all that is required is that A gains, and that A’s pay-off stand in a certain relation to B’s pay-off. When referring to this relation, Feinberg sometimes describes it as “disproportional”, “asymmetrical”, “wrongful”, and finally he settles on “unjust”.

[Exploitation] produces a form of unjust gain that offends the moral sense of the observer in a way similar to that of genuinely unfair freeloading.
Along with variation in terms of coerciveness and vulnerability, exploitation can also vary in terms of the outcome to B. B can be coerced, or suffer from any number of vulnerabilities, and B can suffer a set-back to his interests or have them furthered, and still be exploited by A. The result of variation along these three dimensions is an almost infinite number of exploitation types.

Alan Wertheimer presents a model of exploitation that is similar to Feinberg's in that both list two necessary conditions, namely, that A gain, and that A's gain is unjust with respect to B. Like Feinberg, Wertheimer thinks these two conditions are jointly sufficient and any case that satisfies these two criteria is an instance of exploitation. Both are reluctant to set any criteria for the pay-off to B because whether B gains or loses does not determine whether exploitation occurs, it merely determines the type of exploitation that occurs.

An exploitative transaction is one in which A takes unfair advantage of B. A engages in harmful exploitation when A gains by an action or transaction that is harmful to B where we define harm in relation to some appropriate baseline. A engages in mutually advantageous exploitation when, in relation to the same baseline, A gains unfairly or excessively by an action or transaction that is beneficial to B.34

Similarly, both are reluctant to establish any necessary criteria regarding B’s consent. As Wertheimer writes, “A defect in consent is not a necessary condition of exploitation.”35 Whether B’s participation in the transaction is coercive or non-coercive, voluntary or involuntary, does not determine whether exploitation occurs, it merely determines the type of exploitation that occurs. So the two agree that there are at least these two dimensions of variability in the types of exploitation, because both recognize that exploitation can be either harmful or mutually advantageous, and either consensual or non-consensual. Wertheimer and Feinberg disagree, however, on at least two points:
first, whether these two dimensions capture all of the morally interesting ways in which instances of exploitation can vary; and second, whether consensual and non-consensual exploitation should carry they same moral force.

Wertheimer thinks that distinguishing between harmful and mutually advantageous exploitation on the one hand, and consensual and non-consensual exploitation on the other, can generate a two-by-two matrix that captures all of the morally interesting features of exploitation.

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According to Wertheimer, each type of exploitation has a different moral weight and moral force, but all instances of the same type of exploitation have the same moral weight and force. Feinberg, however, disagrees because he thinks there are other morally interesting ways in which exploitation of the same type can differ. The moral weight and moral force of any given exploitation claim, according to Feinberg, can vary according to the trait, feature, or circumstance one exploits. Indeed, Feinberg believes it is worse to exploit some traits than others.

Wertheimer and Feinberg also disagree on the moral weight and force that accompanies consensual exploitation. Wertheimer regards exploitation as a moralized concept, and he believes that all four types of exploitation constitute the same type of moral wrong. Nonconsensual exploitation may be worse than consensual exploitation, it may carry more moral weight, but both types constitute the same kind of moral wrong;
and this wrong is a wrong to the exploitee that gives the exploitee license to complain. Feinberg, however, thinks that consensual and nonconsensual exploitation present moral wrongs that differ not only in moral weight but moral kind. He agrees with Wertheimer that nonconsensual wrongs are wrongs to the victim, but he refuses to recognize consensual wrongs as wrongs to the victim. Instead, he believes such wrongs are "free-floating evils."

... a little-noticed feature of exploitation is that it can occur in morally unsavory forms without harming the exploitee's interests and, in some cases, despite the exploitee's full voluntary consent to the exploitative behavior. In these cases, there is no wrongful loss for the exploitee, who can himself have no grievance. If the exploitation in these cases is, as it seems to be, a moral evil, then it is a free-floating one.  

According to Feinberg, consensual mutually advantageous exploitation is such a "free floating evil," and, though he never specifically addresses the issue, we can assume that he would hold the same for consensual harmful exploitation. Elsewhere in his writings Feinberg supports "The Volenti Maxim," which states that a person can never be wronged by conduct to which he has fully consented. It would follow then that the "free-floating" nature of the evil is not limited to consensual mutually advantageous exploitation, but would apply to consensual harmful exploitation as well.

Though Feinberg and Wertheimer disagree on the moral weight, the moral force, and the moral wrong associated with some types of exploitation, these disagreements do not jeopardize the fact that they agree on the general characterization of exploitation, and the necessary and sufficient conditions to determine truth in exploitation claims. "At the most general level, A exploits B when A takes unfair advantage of B." If A gains, and A's gain is unjust or unfair to B, then both Feinberg and Wertheimer agree that A exploits B. Similarly, if either condition fails to obtain, then both agree that A does not
exploit B. Furthermore, they both agree that the following four criteria are each sufficient to categorize an exploitation claims into any of one of four types. First, if B experiences harm as a result of her interaction with A, and B does not consent to this interaction, the A exploits B in a non-consensual and harmful way. Second, if B experiences a gain as a result of her interaction with A, but B does not consent, then A exploits B in a non-consensual but mutually advantageous way. Third, if B experiences harm as a result of her interaction with A, and B does consent to this interaction, the A exploits B in a consensual and harmful way. Fourth, if B experiences a gain as a result of her interaction with A, and B does consent, then A exploits B in a consensual and mutually advantageous way.

The points on which Wertherimer and Feingberg disagree, namely, the moral weight, force, and type of moral wrong contained in these four types of exploitation are important issues when considering what to do about exploitation claims, but not important when determining when, and under what circumstances exploitation occurs. For the purposes of this chapter it is enough to determine the necessary and sufficient conditions for exploitation, later in the thesis we will discuss the moral weight and moral force of exploitation claims.

Conflict and resolution

These three models are clearly and significantly different from one another, yet each claims to be a theory of exploitation. So what are we to do with three different theories when each claims to provide an explanation for the phenomenon of exploitation? The usual response is to entertain the following dichotomy: either admit to pluralism in
theories of exploitation, regard each as true, and find some way to balance and negotiate the conflicting conclusions that will inevitably follow, or, argue that one is correct to the exclusion of all others. For obvious reasons, the latter is an unappealing choice. The thought of rejecting, for example, the feminist complaint that women are treated unjustly is unappealing; and recognizing the complaint but refusing to acknowledge that it is exploitation is not much better. Inasmuch as this is an example of inappropriate advantageous use, it should be called exploitation.

This type of reasoning leads most scholars to adopt an approach much like the first, wherein they recognize pluralism in theories of exploitation and accept the conflicting conclusions that pluralism will sometimes produce. But this also leads to a less than ideal state of affairs. Consider the difficulty Nancy Jecker experienced when trying to analyze random controlled trials according to the thesis that research is permissible provided the subjects are not exploited (the Exploitation Thesis). In the course of her article she refers to at least three different types of exploitation, and shows that the practice in question exploits subjects according to two of the models, but not the third. In the face of these conflicting conclusions she writes:

More reflection on the myriad of ways of using people unfairly is needed to state the Exploitation Thesis in its fullest form. Under the pluralism approach we can expect conflicting conclusions about whether a state of affairs is exploitative. It might happen that according to one model a transaction is exploitative, but according to another it is not, and these conflicting conclusions are uninformative and unhelpful in determining whether a moral wrong is occurring and whether we should do anything about it.
I argue that this dichotomy between pluralism and exclusion is a false dichotomy. Our options are not limited to rejecting two or accepting all three as different but true, instead, we should regard two of the models as instantiations of the third model. If both Marxist exploitation and feminist exploitation can be explained by the conditions presented in the contemporary analytic model of exploitation, then we will have a single model through which to evaluate exploitation claims, and this model will simultaneously recognize Marxist exploitation, feminist exploitation, and exploitation in a variety of other settings. More importantly, when a given state of affairs satisfies the contemporary analytic model, but not, for example, the feminist model, then discrepancy will indicate a difference in circumstance rather than challenge the truth of the exploitation claim. In the following section I show that the Marxist and feminist models of exploitation can be expressed, without remainder, to the contemporary analytic model of exploitation.

The Contemporary Analytic model of exploitation shows that exploitation occurs if, and only if, A gains through his use of B, and A’s gain is unjust with respect to B. Within this model there are at least four types of exploitation: consensual and non-consensual harmful exploitation, and consensual and nonconsensual mutually advantageous exploitation. The non-consensual types can vary in the way that A secures B’s cooperation in that B could be forced or otherwise coerced into participating, or B’s consent to participate could be defective in some other way. Consensual types of exploitation can also vary in the way that A secures B’s cooperation, because A must play to a particular vulnerability in order for B to agree to an unjust transaction, and B can suffer from any number of vulnerabilities. Harmful and mutually advantageous exploitation can also vary in the type and degree of harm or gain that B experiences.
Given all the ways in which the contemporary analytic model can vary, it should come as no surprise that it can capture the way in which capitalists exploit the workers in Marxist exploitation. The traditional Marxists complain that the capitalists systematically force unpaid labor out of the workers for their own gain.\textsuperscript{41} The labor is unpaid because the exchange of labor for wages is unequal, and the amount of labor embodied in the goods which the worker can purchase with his income is less than the amount of labor he expended to earn that income. This unpaid labor is forced because the worker, since he owns no property, feels forced to work for these low wages for fear of being offered no work at all.

In traditional Marxist exploitation the capitalists gain through their use of the workers, so it is clear that the first condition is met. Inasmuch as this exchange is unequal, the second condition is also met. Though inequality is not a synonym for injustice, Marxist claim that capitalist economies are unjust because they inevitably lead to these unequal exchanges. This implies that Marxists equate injustice with inequality, and, according to them, an unequal exchange is an unjust exchange. So the second criterion, that A’s gain is unjust to B, is satisfied in Marxist exploitation. The contemporary analytic model supports the complaint that capitalist exploit the workers in a capitalistic society.

Not only does the contemporary analytical model support the exploitation claim, but the model captures the two most important features of the way in which capitalists wrongly treat the workers. If the capitalists didn’t gain through their use of the workers, that is, if the capitalists were no better off, or even worse off, when they forced unpaid labor out of the workers then there would be no justifiable exploitation claim. The
capitalist advantageously use the workers only when they gain from forcing workers to work for low wages. Furthermore, the only reason the capitalist gain is wrongful is because it is unjust. If both the capitalist and the worker gain, and both gain a just or equal amount, then there would be no charge of pejorative exploitation. Only when the capitalists gain an unjust amount do we consider their gain inappropriate, and their use of the worker wrong, and the working arrangements in a capitalistic economy exploitative.

The additional criteria for determining the type of exploitation also capture the other morally interesting features of the Marxist complaint. Reimer thinks that one of the more important elements of Marxist exploitation is the coercive power the capitalist have over the workers because of their monopoly on the means of production and the way in which they wield this power to force to workers to work for free. The coercive or forceful nature of the exchange is easily captured by classifying the exploitation as non-consensual. When we classify the tradition Marxist definition of exploitation as non-consensual but mutually beneficial exploitation in the contemporary analytic model we can describe Marxist exploitation in a way that losses nothing of moral interest. Therefore, traditional Marxist exploitation can be adequately explained through the contemporary analytical model.

In a similar way, the analytical Marxist definition of exploitation can be explained through the contemporary analytical model. The analytical Marxist claim that workers are exploited when they are economically disadvantaged as a result of an unequal distribution of property. Recall that both the traditional Marxist and the analytical Marxist think the workers are treated unjustly in the unequal exchange of labor for wages, but they differ in terms of where they locate the source of the injustice.
Traditional Marxists locate the source in the coercive conditions of the individual transactions, whereas the analytical Marxists locate the source further back, in the inequality of the initial distribution of alienable resources. This difference is important for the purposes of devising strategies to rectify the injustice, but for the purposes judging the behavior of one group towards another we should focus on the inequality in the transactions that happen between two individuals, or more generally, between two classes of people.

The analytical Marxist account of exploitation will satisfy the two necessary and jointly sufficient conditions for contemporary analytic exploitation in the same way as the traditional Marxist account. The capitalists gain through their use of the workers, so the first criterion is satisfied. Similarly, the unequal exchange of labor for wages is an unjust exchange, so the second criterion is satisfied. Unlike traditional Marxist exploitation, however, the analytical Marxist do not merely equate inequality with injustice, instead, they think this exchange is unjust for a slightly different reason. The analytical Marxist would claim that this gain is unjust because the capitalist started with an unjust advantage, namely, a larger than equal initial distribution of alienable resources.

It is not clear whether the analytical Marxist believe that the capitalists coerce the workers into these unjust transactions, so it is not clear whether analytical Marxist exploitation would satisfy the criteria for non-consensual exploitation. If we assume that it would not, then the analytical Marxist definition of exploitation can be adequately explained through the contemporary analytical model of mutually advantageous exploitation.
The feminist theory of exploitation is, in many significant ways, different from the Marxist theory of exploitation, but it too can be captured without moral remainder by the contemporary analytic model of exploitation. The feminists claim that women are exploited when they are oppressed by a male dominated society, this oppression creates vulnerabilities, and others prey on these vulnerabilities and advantageously use women. This type of exploitation would clearly satisfy the first criterion on the contemporary analytic account because others always gain through their use of women. Again, if others fail to gain through this use then they do indeed commit a moral wrong against women in general, and the particular woman with whom they interact, but we would be reluctant to classify this wrong as exploitation. Similarly, this gain is unjust with respect to women, for if it were just then one would not need to prey on a vulnerability to secure a woman’s cooperation, and if it were just it is not clear that the treatment would be inappropriate or wrong. For example, in Henrik Jorgensen’s example if the contract parents paid the surrogate mother a just wage for her services, regardless of whether her desire to serve as a surrogate mother was determined by genuine or socially imposed preferences, the contract parents would not exploit the surrogate mother.

Different versions of feminist exploitation will satisfy the remaining criteria in different ways depending on the proposed source of oppression and the vulnerabilities it creates. For example, the liberal feminists believe that women are oppressed because their opportunities in the public world are circumscribed, and this oppression makes them vulnerable to occupational exploitation. So others gain at her expense when a woman is directed towards, for instance, school teaching, when she may have preferred a career with more professional potential. Though her options may have been circumscribed she
was not forced to enter the public world and she would have some choices among
occupations, so it would be a stretch to say that she was coerced or otherwise acted in an
involuntary manner. Furthermore, because the woman does gain through these
interactions, just not as much as she could have, or should have, were other career options
available to her, this type of feminist exploitation would qualify as consensual mutually
beneficial exploitation.

Cultural feminist present a theory of exploitation that would be categorized as
nonconsensual, though any given instance may qualify as either harmful or mutually
advantageous. Their theory argues that women are oppressed when a patriarchal society
pushes them towards roles of care and nurturance, and this type of oppression creates a
vulnerability in women because it shapes their desires in such a way that women want
well-being and happiness for others, and want little for themselves except the satisfaction
in helping others. They believe that preferences formed under these conditions are not
genuine, and behavior conducted according to this preference schedule is not fully
autonomous and therefore not fully consensual. The cultural feminists leave open the
possibility that transactions could either harm or benefit the women in that both
sacrificial and beneficial behavior would be consistent with this motivational structure. If
the woman engages in sacrificial behavior then she will clearly experience a material
harm, and since her preferences are not genuine, she will not experience any gain in the
form of preference satisfaction. Even if the woman experiences some benefit, she likely
will not experience as much as she would have if acting according to a different
preference schedule, so the transaction could be exploitative in a mutually beneficial way.
The moral wrongs contained in the cultural feminist’s theory of exploitation are all captured by one of the four types of contemporary analytic exploitation.

In conclusion, the Marxist model of exploitation, in both its forms, and the feminist model of exploitation can be expressed by the contemporary analytic model of exploitation. The contemporary analytic account not only preserves the truth conditions of these exploitation claims, but it captures and explains the special and different aspects of each type without moral remainder. Therefore, we can say that there is a single model for determining truth in exploitation claims. This model has two necessary and jointly sufficient conditions for truth in the claim that A exploits B: first, A must gain through his use of B, and second, A’s gain is must be unjust with respect to B.

The necessary and sufficient conditions for exploitation

Exploitation has two necessary and jointly sufficient criteria: first, A must gain through his use of B, and second, A’s gain must be unjust with respect to B. In many cases it will be easy enough to determine when these criteria are satisfied, but there are a variety of circumstances that can, in fact, make such determinations more difficult. It will be useful to briefly explore the way in which A can gain and the ways in which A’s gain can be unjust with respect to B.

In order to determine whether and in what ways A can satisfy the first criterion we first need an account of gain. That is, we need an account that will determine when and how much a person gains. Typically defined, a person gains if and only if her interests are promoted, but, depending on how one defines interests, there are at least two different accounts of gain. According to the first, a person’s interests are desire based
and determined by her subjective preferences. On this account a person gains when she satisfies her desires, whatever the object of her desire may be. On the second account, a person gains only when her objective interests are promoted. That is, when she attains something that is objectively good for her. One’s objective interests can overlap with one’s subjective interests, insofar as the one can sometimes have a preference for things that are objectively good for that person. But one can have an objective interests in an end for which one has no desire. For example, Aristotle holds that wisdom is an objective good for all people, but any given person may or may not have a subjective desire for knowledge. Likewise, one can have a subjective preference for something that is not objectively good for her. For example, many people have a desire for unhealthy food.

While both the objective theory and the subjective theory can support a determination of gain, and both the objective theory and the subjective theory can support a determination of wrongfulness, only the subjective theory of preference can support a determination that a gain is unjust with respect to another party. As we will see in the following chapters, the motivations of the parties to a transaction play a large role in determining justice in transactions. Justice in transactions is concerned with the distribution of the benefits that parties seek to gain and the costs that parties seek to avoid. Insofar as parties seek to gain only those things that they desire, and they seek to avoid only those things that they desire not to have, only the subjective preference theory can identify the type of gain that may or may not be unfair. For example, if a child wants a candy bar, and a shop keeper wants money, justice in this transaction will concern the terms on which money is exchanged for the candy bar. If we determine that the just
transaction terms require the child and the shopkeeper to trade fifty cents for the candy bar, and they do so, then we say that the transaction is just and non-exploitative. This is not to say, however, that the child is not wronged in any other way. Indeed, if the candy bar is harmful to the child’s health, and therefore presents a set-back to the child’s objective interests, then despite the fact that the child wants the candy bar, one could say that the shopkeeper and the manufacturer of the candy bar wrongfully harm the child in supplying him with an unhealthy product. This wrong, however, is a different than the wrong involved in injustice and exploitation. Only subjectively defined interests will provide an account of gain that can support judgments of injustice and exploitation, therefore only subjectively defined gains will be of interest to us in evaluating exploitation claims. A person will satisfy the first condition for exploitation if, and only if, his subjectively defined preferences are satisfied.

A needs to gain through his interaction with B, but this gain need not be of any particular size or type. A’s gain need not be particularly large, more interestingly, A’s gain need not be larger than B’s gain, it just needs to be unjust with respect to B. For example, a lawyer whose net gain is less than his client’s may still exploit the client if the lawyer’s gain constitutes an unjust portion of a settlement. Similarly, A’s gain need not be of any particular type. Oftentimes it will be monetary, or material, as when as receives some valuable good, but it need not be limited to this form for exploitation to occur. Even if A receives no monetary or material gain he can still gain if other of his preferences are satisfied. If A has a preference for entertainment, sexual pleasure, sympathy, or anything else, and through his interaction with B he gets to enjoy the object
of his desire, then A has gained and it is possible for A to gain in a way that is unjust to B.

It is also important to note that in order for this condition to be satisfied, A's gain must be a net gain rather than gross gain. A may gain through an interaction with B, but if A pays a cost, either to B or to another party, this cost can offset his gain such that he does not exploit B. If A gains some, but loses more, through his interaction with B, then A does not exploit B. Measuring a net gain can sometimes be difficult because one must establish a time period for making the relevant assessments. If A's gain is immediately offset by a cost, then his net gain is obviously nil. But the cases in which A enjoys a gain, and, after a period of time, encounters a related cost, present a problem. For example, a rapist may derive immediate sexual pleasure from his victim, but later discover that during this encounter he contracted a sexually transmitted disease. If the window of measurement is small, the rapist gained at the expense of his victim and thus exploited her. If the window is large, this gain would be offset by the harm of hepatitis. Just how big the window ought to be is difficult to say, and any stated length of time runs the risk of arbitrariness. It does seem, however, that if A has time enough to enjoy his gain, then it should count as a gain.

The cases in which A intends to gain, but in the end experiences a net loss, are interesting cases. If A intends to gain through his use of B, but, by accident, fails to gain, then it is questionable whether, in fact, he exploits B. Both Feinberg and Wertheimer present exploitation as a consequential concept. A can exploit B, they claim, even if A does not intend to because he thinks the terms of the transaction are just. Alternatively, though A seeks to gain from a transaction, he does not exploit B unless he actually gains
from the interaction. Thus, the relevant measurement for exploitation claims is not A’s intent to gain, or his potential gain, but rather A’s actual gain. This does not mean that accidents can exonerate A from all moral blameworthiness, and both Feinberg and Wertheimer agree that A should bear some moral blameworthiness for his intent to exploit.

We should distinguish between the case in which A unsuccessfully seeks to gain from a transaction (as in an attempted theft) in which case A acts exploitatively but does not exploit, … distinctions between (1) A gains, (2) A unsuccessfully seeks to gain.42

Here we see that intent to exploit is a sufficient condition for acting exploitatively, but intent is neither a necessary nor sufficient condition for exploitation. In order for exploitation to occur, A must actually gain through his use of B, and A’s gain must be unjust with respect to B.

There are a number of factors that can make it difficult to determine whether A gains, for example, whether the gain is net or gross, and whether this gain is potential or actual, but it can be even more difficult to determine whether A’s gain is unjust with respect to B. When A gains and B is harmed, it is often easy to see that the outcome is unjust with respect to B and thus easy to tell when this condition is satisfied. But in the cases where both A and B gain it is more difficult to determine whether any given outcome is unjust. Though Marxists like to focus on equality as a condition for justice, we quickly see that injustice does not always require gross inequality, nor does inequality, in itself, constitute justice. An outcome can be unjust even if the benefits are distributed equally among the parties to the transaction. For example, if A and B are building a house together, and they do the same kind of work, but A puts in many more hours than B, then an equal sharing of the profits would be unjust with respect to A. This
example also shows that not all unequal outcomes are unjust. In this case, an outcome in which A enjoys a larger share of the profits than B would, in fact, be just. When both A and B gain, it seems that the outcome is unjust only if B also has a claim to some or all of the benefit that A enjoys. Neither Feinberg nor Wertheimer, however, state the conditions under which B can make a legitimate claim to A’s benefits. In order to apply the contemporary analytic model of exploitation, one needs a principle of justice in transactions.

Conclusion

Exploitation refers to a variety of acts, in a variety of settings, some of which are morally permissible and some are morally wrong. Despite the multiple uses, and the multiple theories explaining these uses, there is a single model of exploitation that underlies all uses and explains all theories. The model of exploitation developed in this chapter provides the two necessary and jointly sufficient conditions for pejorative exploitation. The first criterion, that the exploiter gains, is relatively straightforward, and in most cases it will be easy to determine whether this condition is satisfied. The second criterion, that this gain is unjust with respect to the exploitee, is more difficult to articulate and will require more analysis. In the next chapter I develop a principle of justice in transactions to complete the model. In the following chapters I apply this model to medical research and discuss the moral weight and moral force of the exploitation claims that result.
Four

A Model of Justice for Interpersonal Transactions

In Chapter 3 I developed a model of exploitation that provides two necessary and jointly sufficient conditions for truth in exploitation claims. This model shows that a transaction between A and B is exploitative just in case A gains and A’s gain is unjust with respect to B. In Chapter 3 I determined the conditions under which A gains, in this chapter I will determine the conditions under which A’s gain is unjust with respect to B.

Generally speaking, justice requires equitable and appropriate treatment in light of what is due or owed to persons.\(^1\) Justice obtains when rewards and punishments are distributed to those who deserve them, or, in the absence of legitimate desert claims, when rewards and punishments are distributed equally to all. Justice requires that all who are equal in terms of their desert claims be treated equally, and all who are unequal in terms of their desert claims be treated unequally. The difficulty that arises in most problems of justice is determining the ways in which people are equal, or unequal as the case may be, and the way in which these equal or unequal making features can determine what is due or owed. It can be very difficult, for example, to determine who ought to be treated equally when distributing grades. Should students who put forward equal amounts of effort get the same grade? Or only those who give the same performance? If grades are distributed according to, say, performance, then it follows that all students who
perform the same should get the same grade. It is not clear, however, that performance, or effort, is the appropriate equal making feature. Perhaps it should be some combination of the two? Even if we were able to resolve this issue and determine the basis upon which students come to deserve grades, we would then be faced with another difficult issue, namely, determining which grade a given amount of effort or a certain performance deserves. Should the standards be objective such that a student merits an “A” only when she writes a professional quality paper? Or should the standards be relative such that a student deserves an “A” when she writes the best paper in the class? Indeed, there are several features and several scales according to which one can distribute grades, and each instructor might have his own solution to this distributional problem, but from the fact that students often complain that their grade is “unjust” we can see that not all people agree on a single solution, and grade distribution remains a problem of justice.

Problems of justice are not limited to the classroom setting, indeed, they arise in almost every setting where goods or rewards are distributed. For example, we encounter similar difficulties when we try to determine the appropriate distributional scheme for health care. Currently health care is distributed according to ability to pay in that a person receives health care if she is able to pay for the care or if she has arranged for a third party to pay for the care (e.g. a private insurer or a government program). However, there are many people who claim that such a distributional scheme is unjust. A just distributional scheme, they argue, would be one in which health care is distributed according to need. In the debate over which feature is relevant to the distribution of health care, ability to pay or need, we again see the difficulty in identifying the appropriate equal making feature for matters of justice.
This difficulty in identifying the appropriate feature and establishing what is due or owed is particularly problematic when determining what is just for the purpose of evaluating exploitation claims. When individuals engage in transactions with another party sometimes goods are exchanged, sometimes goods are created, and, as we will see later, sometimes a good is created in the course of an exchange. When goods are created through mutual cooperation it can be difficult to determine the basis on which this created good should be distributed among the parties to the transaction. Likewise, when goods are exchanged it can be equally difficult to determine how much of a particular good one party should give in exchange for the good he receives. In the absence of fraud, deceit, and the like, it is not easy to determine what is due or owed to a person when, for example, he sells his house. Should the seller be paid according to amount of effort he put into his house? His performance in owning and maintaining the house? His needs when selling the house? Should he be paid according to the buyer’s ability to pay? Does he deserve to benefit from external conditions, for instance, a housing shortage created by a recent flood?

In this chapter I examine the problem of justice that arises in interpersonal transactions. To begin, I describe interpersonal transactions and identify the benefits and burdens to be distributed among the parties to the transaction. Then I examine whether the appropriate distribution of these benefits and burdens will reflect the amount of effort contributed by each party, or whether the appropriate distribution will reflect unconditional equality. Ultimately I reject distributions based on either effort or equality, and I introduce Alan Wertheimer’s proposal for solving this problem of justice. He believes that the ideal market and the “fair market price” are promising as a model of
justice for interpersonal transactions, and I develop this idea more thoroughly. I show that ideal markets do produce interpersonal transaction terms that are just, and, more importantly, I show that real markets can do the same thing. I conclude this chapter by presenting a hybrid model of justice that will produce the just terms for any given interpersonal transaction and will thus provide a standard against which we can evaluate exploitation claims.

**Interpersonal Transactions**

The injustice in exploitation occurs when one party takes advantage of another. When A gains at the expense of B, or, more specifically, when A takes an unjust portion of the goods created through the mutual cooperation of A and B, we say that A exploits B. The problem of justice in exploitation concerns the distribution of what is sometimes referred to as the "social surplus" of the transaction.\(^3\) The social surplus of a transaction is not the entire product of the transaction, but only that portion of the product that constitutes the bargaining range between the two parties, and this, in turn, is determined by their respective reservation prices. The reservation price is the value a party must receive for a good or service before he will agree to transact.\(^4\) For example, imagine that Eric is selling his house and Paul wants to buy it. Eric has listed the house for $175,000 and Paul is willing to pay this much. Secretly, however, Eric will accept a bid as low as $150,000. In this scenario Eric will refuse to transact for a price below $150,000, so this value represents his reservation price, and Paul will refuse to transact for a price above $175,000, so this value represents his reservation price. In some cases the reservation prices will be the same, but when they differ, as in the case of Eric and Paul, the space
between them constitutes a “bargaining range” or a “zone of agreement.” For Eric and Paul, all points between $150,000 and $175,000 represent mutually agreeable terms for the transaction, and both parties will agree to transact at any point within this zone of agreement. This bargaining range constitutes the social surplus of the transaction because each of the two parties will transact for their reservation price, leaving the difference, which is $25,000 in the case of Eric and Paul, as unclaimed surplus. It is this social surplus that needs to be distributed in a manner that is just.5

It is difficult to determine what would constitute a just or unjust distribution of the social surplus in these settings because it is difficult to determine what is due or owed a person when he or she engages in an interpersonal transaction. Classical principles of distributive justice will look for features that are in some way relevant to the good when determining what is due a person, and usually these are features such as effort, performance, contribution, need, and the like. If there are no features that are relevant to the good, then there is no way in which the parties to the transaction can make different desert claims, and all parties must be treated equally in the distribution. Interpersonal transactions present a particularly difficult problem of justice because there seems to be no single feature according to which parties to the transaction should be treated unequally, but, at least in some cases, it also seems inappropriate to treat them equally. In the following section I show that effort and contribution are inappropriate features, and I show that equality is inappropriate as well. I conclude that interpersonal transactions do not neatly fit into the paradigm of classical justice and I present Alan Wertheimer’s proposal as a much more promising solution to this problem of justice.
Among the classical desert bases the most promising choice for the distribution of the benefits of interpersonal transactions is effort or contribution to the cooperative venture. Intuitively, effort and contribution are appealing as the bases for desert claims because most of us think that through hard work a person somehow earns or deserves what he creates. The degree of effort or contribution put forth seems a reasonable way to differentiate among people because those who work harder or contribute more ought to receive a larger portion of the goods created through the cooperative venture. In order for effort and contribution to serve as criteria for justice in transactions, however, one must show that they are both morally sound and feasible in this context. I argue that they are neither sound nor feasible, and thus dismiss them as a criterion for justice in transactions.

Many object to theories of justice based on effort and contribution because they rely on features that are themselves morally arbitrary. Hard work, effort, and contribution are often stipulated as the bases of such desert claims, but many argue that character traits such as the propensity to work hard, expend effort towards a goal, or contribute to a joint venture are themselves gifts of nature, unearned and undeserved. John Rawls makes a particularly compelling argument on this point.

No one deserves his place in the distribution of native endowments, any more than one deserves one’s initial starting place in society. The assertion that a man deserves the superior character trait that enables him to make the effort to cultivate his abilities is equally problematic; for his character depends in large part upon fortunate family and social circumstances for which he can claim no credit. The notion of desert seems not to apply to these cases.6

One does not deserve one’s social background or natural talents, nor the behavior they produce, like one’s productivity, therefore, Rawls argues, one cannot claim to deserve rewards for the behavior. Effort and contribution are therefore theoretically unsound as the focal points for just distributions.
Even if effort and contribution were sound bases for a justice, such distributional principles would be impractical in the context of markets and other types of interpersonal transactions for at least two reasons. First, desert claims are claims that are categorical, and the fluctuating conditions of the marketplace and other transaction settings make it impossible to satisfy the categorical nature of desert claims. A desert claim is a claim that some person or thing deserves some occurrence or mode of treatment in virtue of some fact about him or it. These claims are always of the form “M deserves X for A,” where M is the bearer of the desert claim, A is the factor that is said to create the desert, and X is what the bearer deserves. Desert claims are categorical because once a desert basis is linked to a reward, that reward should follow every time a person exhibits the specified desert basis.

The fluctuating conditions of interpersonal transactions create a setting in which effort and contribution sometimes produce wealth and sometimes produce nothing. Whether effort and contribution produce wealth or other rewards, and the amount of wealth, or the size and type of rewards, often depends on luck and other outside factors. For example, people’s desires can fluctuate, as can their ability to pay, so external circumstances like market demand and economic climate can affect whether a given endeavor will succeed regardless of the amount of effort and contributions made by the parties to the transaction. If desert claims were based on effort or contribution, and parties to a transaction invested significant amounts of effort and contributions, then the parties would deserve rewards. If a party can state a desert claim, and if the party exhibits the specified behavior, then we say that he or she ought to have the reward, and a situation is unjust if he or she does not receive it. If luck or other external circumstances
cause this cooperative venture to fail, then the parties to the transaction would not get their deserved reward, and the resulting situation would be unjust. All things being equal, however, most would regard this situation as merely unfortunate rather than unjust.

If desert claims allow matters of luck to determine matters of justice, if they render an unfortunate situation unjust, then they are clearly inappropriate for interpersonal transactions.

Effort and contribution are impractical as criteria for justice in interpersonal transactions for a second reason, namely, the difficulty involved in determining legitimate desert claims. When cooperative ventures employ varied resources and highly integrated means of production it can be difficult, perhaps even impossible, to accurately measure the productivity or contribution of an individual party. Wertheimer complains of this problem when he writes,

... the measurement of a [party’s] contributions will be so difficult that they do not provide a reasonable basis for regulating transactions.\(^8\)

Thus, effort and contribution as the focal features for a principle of distributive justice in interpersonal transaction are neither morally sound nor feasible.

In the absence of a suitable principle that can differentiate among people on the basis of features that are relevant to the good one might look to a principle of equality. However, equality as a principle of distribution in interpersonal transactions immediately runs into both theoretical and practical difficulties. The heterogeneity in the goods exchanged and produced in any given transaction leads to practical problems because one needs a common unit of measurement to accurately assess the value associated with the components in the transaction. It is impossible to determine whether any given exchange
is equal without a way to measure and compare the value of the goods. For example, what would constitute an equal exchange when a house is traded for money?

In interpersonal transactions the most feasible notion of equality is equality of gain, where justice would obtain when parties to the transaction experience an equal net gain. Though such a principle of distribution would be appealing when the social surplus appears “ex nihilo,” such as when two parties must split “manna from heaven,” in all other cases we find equality of gain to be problematic.\textsuperscript{9} We seem to find utility of gain intuitively unappealing, and thus theoretically suspect, and this is evident in our aversion to practices such as price discrimination.

That we do not equate a fair transaction with equal gain is particularly well exemplified by a common and negative reaction to price discrimination, in which the seller varies the price of a product in accordance with its value to the buyer. We think that an auto garage should charge the same price for a battery, whether it is being installed under routine maintenance (generating moderate utility gain to the buyer) or because the car has broken down (generating a high utility gain to the buyer.) … Our general aversion to price discrimination suggest that we cannot easily appeal to a principle of equality of utility gain as a criterion for a fair transaction.\textsuperscript{10}

Thus neither effort or contribution nor equality seem to be suitable criterion of justice in voluntary transactions.

\textbf{Wertheimer's Proposal and the Ideal Market}

Alan Wertheimer believes that our intuitions regarding price discrimination lead us to a notion of justice in which differences in need and utility schedules play no part. We think it is unjust to be charged more for a product or service simply because we will benefit from it more than others. The corollary shows that justice obtains when all buyers are treated equally, when all buyers are offered the same terms regardless of the utility they may gain from the transaction. Equal treatment for all buyers is a feature of
perfectly competitive markets, and Wertheimer believes that the "fair market price" determined by these "hypothetical" or "ideal" markets might provide a solution to the problem of justice in voluntary transactions. In this section I present Wertheimer's rather inchoate proposal of the ideal market as a standard for justice, and in the following sections I expand on his idea of the ideal market as a model of justice.

The "hypothetical" or "ideal" market is a theoretical construct that simulates a perfectly competitive market and produces the "fair market value" for any good traded in a market setting. The ideal market consists of five assumptions that characterize the market, buyers and sellers, products and services, the state of competition, and the way in which these features will interact to produce standardized transaction terms. The first assumption is that the means of production are privately owned and each individual enters the market with his "initial factor endowment" which includes ownership of his person, his labor, his skills, and whatever additional resources and means of production he may have. Second, both buyers and sellers in the ideal market are fully informed about the products and services available to them. They are knowledgeable about the performance and quality of the products, including the costs of all alternative ways of producing or acquiring them. Third, buyers and sellers behave rationally in that they seek their own gain and are not moved by concern for the welfare of others. Their preferences are ordered and transitive and they select appropriate means toward their chosen ends. Fourth, both buyers and sellers are motivated to transact.

The fifth assumption is that the products and services offered for exchange in the ideal market are fungible and there are enough suppliers and enough buyers to create competition on both sides of the transaction. Products that are fungible are
interchangeable with like products and services so that buyers cannot distinguish among the products offered by various sellers and sellers cannot distinguish among the payments offered by potential buyers. When there are enough buyers and sellers to create competition then all participants in these idealized transactions will be “price-takers” as none can be “price-setters.” In such a state of perfect competition no buyer or seller can influence prices by his own independent actions.\(^\text{14}\) No vendor can charge a higher price, and no buyer can offer less because competitors will offer better terms. Competition among vendors and competition among buyers will keep the price of goods and services at the point where they approximate production costs.

The price that the ideal market determines for any given product or service is called the “fair market price.” It represents the price that an informed, unpressured, and motivated seller would get from an informed, unpressured, and motivated buyer in a perfectly competitive market. If there were a bargaining range between the parties to the transaction, that is, if the buyer would have paid more or the seller would have accepted less, the ideal market divides and distributes this social surplus according to the current market value of the goods or services being exchanged.

If the “fair market price” price does, as Wertheimer believes, represent the just terms for transactions then we have a solution to our problem of dividing the social surplus and we should be able to resolve all questions of exploitation. It is not clear, however, why we should regard the fair market price as providing a criterion of justice. Moreover, even if the fair market price does represent a price that is just, it is not clear how this fair market price, a hypothetical price produced by a theoretical construct, can provide a determinate answer to all division problems that we may face in real
transactions. Wertheimer addresses both of these questions but ultimately leaves both unanswered.

In the following discussion I present both of Wertheimer's arguments that the fair market price is just, and also the guidance he provides on its scope and applicability. I show that his first argument for justice fails outright, and his second argument fails to convince. Furthermore, the guidance he provides on the scope of the fair market price is confusing and renders the criterion inapplicable in all but the clearest cases. Then I present an argument for the fair market price as a criterion of justice in transactions, and I define the scope and procedure through which one can apply the fair market price to transactions in real markets.

Wertheimer begins his defense of the hypothetical market with the following disclaimer which indicates that he does not intend for his arguments to be complete.

A full defense of a hypothetical market price as a principle of fairness would need to be worked out in much greater detail, as would a defense of any principle of fairness.\textsuperscript{15} Nevertheless, he firmly believes that the fair market price shows promise as a criterion of justice for a "certain range of cases," and he thinks this for two reasons. Wertheimer's first argument is that the fair market price matches our intuitions regarding the injustice of price discrimination.

The competitive market price is a price at which neither party takes special unfair advantage of particular defects in the other party's decision-making capacity or special vulnerabilities in the other party's situation. ... it may not be a "just price," all things considered, but it may well be a nonexploitative price, for neither party takes unfair advantage of the other party.\textsuperscript{16} The notion of equal treatment is deeply seated in our intuitions regarding justice, and if we are unable to determine a "just price," equal treatment regarding prices may well be sufficient for justice. For example, even if I do not know how much the parts and labor
for a new battery should cost, as long as I am charged no more than others for this service
I cannot complain that I have been treated unjustly. The hypothetical market guarantees
equal treatment in this respect because no sellers and no buyers can be "price setters," no
person can alter the price of a particular good or service to take advantage of another's
circumstances. If a person tries to charge more, or offer less, for a particular good or
service their offer will be rejected because the competition will offer more attractive
terms. Thus, in a hypothetical market all buyers and all sellers will be treated equally
regarding the prices for particular goods and services, and, according to Wertheimer, this
equal treatment matches our notions of justice so buyers and sellers are treated justly in
the hypothetical market and the fair market price really is just.

This first argument is not merely incomplete but destined for failure because a
closer examination reveals that the conception of justice on which it is based actually
fails to match our intuitions. Equal treatment, without an external reference point on
what that treatment should be, does not provide a good criterion of justice because it is
not the case that equal treatment always implies just treatment. For example, in an effort
to sell my house I get an appraisal, and then list the house for twice the appraised value.
This price is considerably more than the house is worth, but I do treat all buyers equally
in the sense that I quote the same price to any and all buyers. We would hardly think that
this exorbitant price is a just price, and the fact that I treat all potential buyers equally
does not make the price any more just. This example shows that it is possible to treat
people equally but unjustly. To be fair, Wertheimer does supply an external reference
point, namely the fair market price. But he argues that the fair market price is just
because people are treated equally in the perfectly competitive market. Thus without an
external reference point for prices in the competitive market, his reasoning is circular and the argument fails.

Wertheimer's second argument for the justice of the fair market price is, quite simply, that it is appealing. The fact that a concept or principle is appealing carries some weight within the contractarian tradition because, according to the contractarian approach to morality, one should accept a principle of justice if, and only if, the principle furthers one's interests. Given the obstacles to collective action, rational bargaining theory shows that principles will be accepted by communities of moral agents only if they can be shown to be mutually advantageous to all parties. Wertheimer thinks that the fair market price is appealing in a way that would speak to all, and, because it is appealing, it would be adopted by all persons in a position to choose the principles that will govern their personal transactions.

If the basic structure [of society] includes a competitive market for many goods, as it probably will, the market will take care of the transaction price in those contexts. But the parties will also understand that situations will arise in which there is no competitive market and will want to have principles to regulate their transactions in those context as well. Given the desire to settle on such a principle, parties in the original position may well settle on such a hypothetical market price or something like it.17

Wertheimer may be correct that this principle is appealing, but simple appeal does not suffice for a contractarian justification for a principle of justice. Even if agents do select competitive markets for the distribution of many goods, as Rawls believes they will, it is not clear that they would also select the fair market price as the criterion for justice in all non-competitive contexts. Depending on the priorities of the agents, they may, or may not, select the fair market price as a way to order personal transactions. A contractarian justification requires, among other things, a statement of the priorities of the agents and their rational bargaining strategy, and an argument that shows these will necessarily lead
to the selection of a particular principle. Wertheimer’s contractarian justification may be promising, but it is promising at best. Absent these important features there is no reason to believe that the fair market price would be chosen as a principle of justice in transactions.

Finally, when addressing the feasibility of the fair market price as a criterion of justice, Wertheimer admits it is workable in only a limited number of cases for two reasons. First, the fair market price can provide a criterion of justice only when a perfectly competitive market can be easily imagined.

Some transactions may involve goods that are so rare that it strains the imagination to posit a hypothetical market price.\(^{18}\) Second, the fair market price seems to be unworkable in cases where there are market imperfections of certain kinds. For example, if A has invested resources and developed proprietary information that is not available to B, say, A has good reason to believe that there is a valuable deposit of minerals on land owned by B, then A and B will transact under non-ideal conditions.\(^{19}\) If we allow the fair market price to set the standard for justice, A would treat B unjustly if he did not share his information, or at least transact on the terms that would occur if B was privy to A’s information. But this is surely absurd, or so Wertheimer thinks, and he concludes the fair market price simply does not provide a workable conception of justice when the asymmetries of information or bargaining power are not unjust.

[when] there are important but not unjust asymmetries of information ... What would be a fair transaction under these circumstances? ... In the final analysis, this may be a case in which there is no stable or applicable principle to which we can appeal.\(^{20}\)

Whether the market imperfection is just or unjust, however, is an unreliable indicator of whether the fair market price is appropriate as a criterion of unjust. The asymmetry of
information in the preceding case is certainly not unjust, but what about the asymmetry of bargaining power that results from unlucky, but not unjust, circumstances? For example, it is not unjust that after a particularly bad snowstorm A, the proprietor of a hardware store, is the only one in town who can offer snow shovels for sale. It would, however, seem strange to say because A’s holding are not unjust the fair market price does not apply and he can charge whatever he wants. On the contrary, this is exactly the type of exploitation Wertheimer is trying to capture. As Wertheimer describes it, the scope of the fair market price is so limited and confusing that the criterion is inapplicable in all but the most clear cases.

Ultimately, Wertheimer merely waves his hands at the fair market price and states that it looks promising as a criterion of justice for personal transactions. He hints at ways in which it might be justified and the ways in which it could be helpful in resolving issues of exploitation. But in this inchoate form we have no reason to regard it as just and the range of cases in which it will be helpful is disappointingly small. In the following sections I argue that the perfectly competitive market does provide a criterion of justice, I define its scope, and I show how it can be used to determine the justice of a transaction in all cases except those where one cannot imagine a competitive market.

**Ideal markets as just procedures**

In the following section I argue that the fair market price is a criterion of justice because it is the product of a just procedure. In interpersonal transactions justice is not a structural feature of outcomes, instead, it is a feature of the process according to which the personal transaction is conducted. The perfectly competitive market is a just process
for ordering transactions because in this process no rights are violated, so the results of the ideal market are just, and the fair market price represents the just terms for dividing the social surplus in personal transactions.

The justice of a transaction cannot be judged by its outcome because outcomes cannot be completely separated from starting positions and are therefore unreliable indicators of the justice of a particular transaction. For all transactions involving heterogeneously valued goods there is there no structural feature of the outcome that is entirely independent of the parties’ starting positions. Equality, perhaps, could assess outcomes independent of starting positions, but the preceding discussion has shown that equality is impossible to measure when goods are valued heterogeneously by the parties to the transaction. Equality of gain is a more feasible way to measure equality in outcomes, but how much a person gains from a particular good or service will depend on how badly he needed or wanted the goods, which depends, in part, on his starting position. For example, A has little, his pre-transaction baseline is low, and B offers him employment at an abnormally low wage. A will gain tremendously from these earnings, and let’s say that A’s gains, when measured against his pre-transaction baseline, equal those of B and there is equality of gain in the outcome of the transaction. If equality of gain is a just-making feature of outcomes, then this transaction is just. But consider that the same transaction, offered on the same terms, could result in gross inequality of gain if A’s pre-transaction baseline were higher. The same transaction would then be considered unjust. A similar phenomenon occurs when one tries to ameliorate need, maximize utility (either individual or collective), or look for any other structural feature of a distributive outcome. Inasmuch as the justice of a particular transaction should not
depend on the level of a person's pre-transaction holdings, the justice of a transaction cannot be judged according to its outcome.

The problem of focusing on a just-making feature of an outcome is not only that it is difficult to measure, but, more importantly, that we cannot tell whether the presence or absence of the feature is due to the transaction or the starting position. A judgment based on a feature of the outcome will not judge the justice of the transaction, but instead the justice of the transaction when combined with a particular starting point. Unless we want an enormously complex theory in which we need to keep track of details such as circumstances and the starting positions of particular parties, we need to move away from justice as a feature of an outcome and instead look for some other just-making feature of transactions. Theories of justice sometimes focus on features of outcomes, sometimes on procedure, and sometimes on a combination of both. If justice as a feature of the outcome is unworkable, then the only remaining candidate is justice as a feature of the procedure. John Rawls gives perhaps the best description of this type of justice, a type he refers to as "pure procedural justice":

Pure procedural justice obtains when there is no independent criterion for the right result: instead, there is a correct or fair procedure such that the outcome is likewise correct or fair, whatever it is, provided that the procedure has been properly followed.\(^{21}\)

A criterion of justice that applies to the procedure rather than the outcome will circumvent both the impracticality of monitoring starting positions and the difficulty of assessing outcomes. If we can identify a just-making feature of a procedure and show that perfectly competitive markets, as a procedure, exhibit this feature, then the fair market price will reflect transaction terms that are just.
I argue that the ideal market is a just procedure through which to conduct voluntary transactions because in perfectly competitive markets, and only in perfectly competitive markets, do people get what they are owed, namely, respect for their rights. Justice requires equitable and appropriate treatment in light of what is due or owed a person, and all will agree that, at the very least, people are owed respect for their rights. Individuals have certain moral rights, and regardless of whether they are owed something more than respect for their rights, they are certainly owed nothing less. A violation of a moral right is a failure to give a person what he or she is owed, and is thus an injustice. The following argument shows that transactions conducted in the ideal market are just because they violate no rights, and only transactions that are conducted in the ideal market are just because all other social arrangements violate either a person’s rights to liberty or property or both.

The most basic moral right is that every person owns his own body and can do with it as he chooses, provided he does not infringe upon the same right of others. Many philosophers argue that this right to self-ownership produces derivative rights to life, liberty, and property. Some philosophers challenge this move from self-ownership to ownership of property, but in a later section I argue that their objections are unsustainable because they are based on an incoherent notion of self-ownership. I argue that self-ownership produces derivative rights to life, liberty, and property, and these rights are negative in the sense that the duties they require from others are duties of forebearance or restraint rather than action. If a person can assert a right to life, all other people are required to not interfere with her pursuit of her life, and she cannot be killed unjustly. In similar ways, rights to liberty and property are rights of non-interference.
Wherever an individual’s right to private property is respected a market will naturally develop. Property rights entitle a person to do whatever he wants with his holdings, provided he does not harm or violate the rights of others. If he wants to exchange his property for something he desires more, it is within his right to do so. When he does so, when two parties voluntary engage in an exchange of property, or voluntarily invest property in a cooperative venture, the rights of both individuals are respected because they are doing as they wish with their property. Thus the market is a just procedure through which to organize personal transactions because the liberties or rights of individuals are respected.

A principle that proposes any other feature as a criterion of justice will necessarily conflict with our rights and thus the procedure it requires will be unjust. For example, if a principle of justice requires equality in, say, the distribution of bread, and I trade my bread coupon for a philosophy book, my voluntary exchange has frustrated the equal pattern of distribution. To meet the requirements of such a principle I am obligated to not trade my bread coupon, but this interferes with my right to do as I wish with my property. The ideal market is, therefore, a just procedure for conducting voluntary transaction. Moreover, it is the only just procedure for conducting voluntary transactions because any other form of social organization will fail to respect individual’s rights to private property and will be unjust.

The ideal market as a just procedure does not guarantee that the outcome of all transactions will be just, it only guarantees that the terms according to which the transaction is conducted will be just. The ideal market does not, in itself produce a distributional state that is just. Insofar as the outcome of a transaction is a function of
both the terms and the parties’ initial holdings, whether an outcome is just will depend on
the justice of both components. That is, though a transaction may be just, the outcome, or
the person’s final position, could be unjust if the initial position was also unjust.
However, the market as a just procedure is justice preserving and it will preserve the
justice of the starting points of transactions.\textsuperscript{25} If the initial positions of both parties are
just, transactions conducted according to the conditions of the ideal market, then the
outcome will also be just.

Some object to the ideal market as a just procedure on the grounds that
individuals have positive welfare rights in addition to their negative rights, and even
though markets violate no negative rights, they can violate these positive rights and hence
be unjust. Some people hold that persons have rights to certain welfare goods, such as
shelter, food, healthcare, and other forms of assistance, and that these are positive rights
in the sense that others have a duty to provide a person with these goods if that person
cannot provide them for his or her self. In a society where the primary method of social
organization is the market, welfare rights can go unfulfilled. Thus the ideal market can
lead to violations of these rights and is, they claim, unjust.

This argument fails to show that markets are inherently unjust for the following
reason. Welfare rights, if they do exist, are not rights that individuals can exercise
against other individuals, except in special circumstances. Welfare rights carry corollary
obligations, and if welfare rights were rights that individuals could exercise against other
individuals, then we would all be obligated to help anybody and everybody in need. To
conceive of welfare rights as generating “perfect” corollary duties is to impose a general
obligation of beneficence that is simply too demanding. Instead, our duty to be
beneficent is more “imperfect” in nature, meaning that we can discharge our obligations by helping some people some of the time. In addition to these imperfect general obligations of beneficence, we can assume specific obligations to particular people either through our voluntary actions or special circumstances. Absent these specific obligations, however, we do not fail to discharge an obligation if we fail to assist a particular individual. Therefore, even if welfare rights exist, we do not violate an individual’s welfare rights if we fail to satisfy all of their needs in the course of an interpersonal transaction.

Welfare rights can exist in a general form if they are rights that individuals exercise against the state. The formation of a state, community, tribe, or other collective can generate certain rights that the individual can exercise against the collective, and this, in turn, will generate obligations for all participants in the collective. If a group of individuals agree to form a welfare state, then all individuals in the group have welfare rights they can exercise against the state, and all individuals in the group have an obligation to contribute resources to the state so that the needs of all participants in the state can be satisfied. Once a person has fulfilled his state required duties to welfare, however, once he has paid his taxes and forfeited his property for redistribution, he has discharged his obligations and has no specific welfare duties to particular individuals. In a welfare state, individuals can make no claims against others individuals, they can make claims only against the state. Once again we see that we do not violate an individual’s welfare rights if we fail to satisfy all of their needs in the course of an interpersonal transaction. Therefore, even in a welfare state, the market as a mechanism for organizing interpersonal transactions does not violate anybody’s rights.
As a just procedure the ideal market will produce transaction terms that are just, and, according to our model of exploitation, exchanges conducted according to these terms will not be exploitative. In order to understand how the fair market price actually resolves the problem of exploitation it will be useful to understand the conditions under which exploitative transactions typically occur. Exploitation usually happens when an inequality in bargaining power forces one party to accept transaction terms that are unjust. Bargaining power is best understood as one’s “threat advantage,” which is one’s relative willingness not to contract if one’s proposal is not accepted. One’s threat advantage is determined by many things, the two most important being expected utility gain and necessity. One’s expected utility gain is a function of one’s initial resources, circumstances, and preference structure. If A is comfortable with his substantial holdings, and prefers relaxation to material gain, then A’s expected utility from a proposed business transaction will likely be small, and A has a threat advantage over B because A stands to lose less if an agreement is not reached. If B knows that A is content to not transact, then A has more bargaining power vis-à-vis B. A can drive a harder bargain, impose terms that are less favorable to B, and B will accept in order to secure A’s cooperation. Bargaining power is also a function of necessity in that one’s initial resources, need, and alternative options also factor into one’s relative threat advantage. For example, if B needs food, and A, a local grocer, is the only one who has food to sell, then A has more bargaining power than B. He can charge more for the food because he knows that B will likely accept his terms rather than not transact.

The effect of inequality in bargaining power is that one party can feel forced to agree to a transaction in which the terms are unjust. If both parties are equally positioned when
negotiating the terms of the transaction, then rational bargaining will produce transaction terms that are mutually advantageous and mutually agreeable. The exact structure of the terms is a matter of debate for rational choice theorists, but if the parties are to overcome problems of non-cooperation the terms must be mutually advantageous and mutually agreeable. Inequality in bargaining power disrupts this process because non-cooperation becomes an asymmetrical problem. Thus the product of the bargaining process will be less advantageous and less agreeable to the less powerful party, and it is often unjust. If, however, circumstances are such that it is unreasonable for the party not to cooperate, even on such unappealing terms, then the party may feel forced to agree to the terms. She may feel forced in the same way that seductive offers can force: she does not want to transact under those terms, but the alternatives are even less appealing, and so she accepts. In this way inequalities in bargaining power can lead to exploitative transactions.

Here we can see that a person’s initial holdings are relevant to exploitation insofar as a person’s dissatisfaction with their holdings makes him or her vulnerable to exploitation. The state of a person’s initial holdings, however, is irrelevant to the evaluation of an exploitation claim. Exploitative transactions can occur regardless of whether a person’s initial holdings are substantial or meager, likewise, non-exploitative transactions can occur regardless of whether a person’s initial holdings are substantial or meager. All that exploitation requires is that a person be dissatisfied with his holdings for whatever reason, and this dissatisfaction can make him vulnerable and lead him to engage in a transaction in which he receive an unjust share of the social surplus.
Furthermore, the normative state of a person's initial holdings is also irrelevant to the question of exploitation. Exploitative transactions can happen regardless of whether a person's initial holdings are just, and non-exploitative transactions can happen regardless of whether a person's initial holdings are just. Again, exploitation requires that a person be dissatisfied, and dissatisfaction requires only that a person has less than he wants. Dissatisfaction in holdings sometimes coincides with injustice in holdings, but sometimes dissatisfaction coincides with justice in holdings. Sometimes people want more, even if their holdings are just, and wanting more can create an inequality in bargaining power, and this inequality could lead a person to engage in a transaction in which he is treated unjustly. Exploitation does not happen only when a person's initial holdings are meager, and it does not happen only when a person's initial holdings are unjust. Exploitation happens when a person is dissatisfied with his holdings, and this dissatisfaction creates an inequality in bargaining power, and this inequality in bargaining power leads to exploitation.

Ideal markets are characterized by perfect competition, and perfect competition preserves equality in bargaining power. Even though people may differ with respect to their resources at any given time, as long as there is perfect competition for the goods and services they are seeking their bargaining power will not affect the transaction terms. Moreover, even if people differ with respect to their resources and needs, these two features will not necessarily lead to inequalities in bargaining power. Under conditions of perfect competition bargaining is not a function of only need and resources, rather one's bargaining power is also a function of the size of the group to which one's opponent belongs. Regardless of the circumstances under which a buyer seeks a service,
his bargaining position is strengthened by the competition faced by the vendor. If a vendor tries to charge a higher price for a product or service, another will undercut him, and so on, until the buyer is presented with terms that approximate the production cost of the good or service. Again, in conditions of perfect competition all parties are “price takers,” no seller or buyer can influence prices by his own actions. Inequalities in bargaining power do not exist in the ideal market.

Exploitation typically happens when an inequality in bargaining power forces one party to accept transaction terms that are unjust. The fair market price, however, makes it impossible for one party to take advantage of the other, even if there is a gross disparity in bargaining power. When transactions are conducted according to the fair market price, even if A has B “over a barrel” he cannot use B’s vulnerability to drive a hard bargain and force B to accept terms that are unjust. The fair market price imposes terms that reflect the equal bargaining positions of agents in a perfectly competitive market, so even if agents feel forced to accept an offer, the terms of the offer will not reflect their vulnerability and they will no be exploited. Imposing a fair market price effectively nullifies the advantage an inequality in bargaining power can create and makes exploitation impossible.

I conclude that ideal markets represent just procedures through which to conduct interpersonal transactions because they respect all claims that persons can legitimately make in the context of interpersonal transactions. Ideal markets ensure that people get all that is owed to them in the course of the transaction. This justice, however, is only a feature of the terms of the transaction, not the resulting distribution and holdings. The
terms set by the ideal market are just transaction terms, but the resulting distribution will be just only if the starting point is just.

Real markets will differ from ideal markets in many ways, most important perhaps is that they can suffer from imperfect competition. This does not mean that we should simply dismiss real markets as inherently unjust. The challenge will be to manage the tension between ideal and real markets in a way that transfers the just features of an ideal market to the real market.

**Tension between the hypothetical and real markets**

The conditions of the ideal market produce transactions with terms that are just, and if the conditions of real markets approximate the ideal market then transactions in the real market would also be just. In real markets, however, agents often do not behave in ways that are perfectly rational, they seldom enjoy perfect knowledge, and transactions often take place in conditions where competition is less than perfect. The challenge, then, is to identify the ways in which real markets can differ from ideal markets and resolve this tension in a way that allows the model of justice to be applicable in real markets.

In real markets not all agents behave rationally and not all agents are perfectly knowledgeable about the goods and services available for exchange. Individuals participating in real markets are not always rational because they do not always efficiently seek their own gain. Sometime their concern for the welfare of others affects the terms of their transaction, it can even prompt an agent to transact when it is not in his interest to do so. For example, parents often transact on overly generous terms with their children, or transact with their children even though they have little interest in, or need
for, the product or service. It is also not the case that every individual’s preferences are ordered and transitive, or even that they act in accordance with their preference structure. For example, in the real world people often suffer from weakness of the will. Furthermore, agents in real markets rarely enter into negotiations with full knowledge about the product or service available for exchange. In the ideal market information about the quality, performance, and cost of alternatives is free and available to all, but in the real market such information almost always has a cost. This cost may be mere inconvenience, for example, the time it takes to research a product in Consumer Reports, or the cost may be monetary if the information is held by others as a proprietary good. Alternatively, the information could simply be unavailable if it is owned by another party and not offered for sale.

Real markets can also differ from ideal markets when they lack perfect competition among sellers, or perfect competition among buyers, or both. Real markets for some products are reasonably competitive among sellers and among buyers, and these markets approximate the ideal market and produce transaction terms that are just. For example, the many suppliers of gasoline and the millions of people who buy the product create a market in which there is near perfect competition among both sellers and buyers. Enough companies offer similar products that if one vendor were to raise its price buyers would simply look elsewhere; and the market for gasoline is large and stable enough that suppliers need not be concerned with securing the cooperation of any particular buyer. These conditions are competitive enough that the price of gasoline will approximate its production cost and thus settle at the equilibrium point that is the fair market price. Other markets, however, fall short of these near perfect conditions. For example, there is often
imperfect competition among the sellers of cable television services, which allows vendors to charge a price higher than their production cost. Conversely, when there is imperfect competition among the buyers of a service, for example, when an article of clothing sits on a showroom floor for too long, a vendor may be forced to sell an item for less than it cost to produce.

In ideal markets the reservation prices of individuals may vary, and there may indeed be a zone of agreement and a social surplus, but the point within this zone of agreement where the transaction will take place is determined by competition. Neither party can affect, by their own actions, the way in which the social surplus will be divided. In imperfect competition, however, the transaction could occur on any of several different mutually agreeable terms and the actions and circumstances of the parties involved can affect the way in which the social surplus will be divided. The challenge is to determine which of all possible points within the zone of agreement, or which, of all possible distributions, will be just.

**Resolving the tension**

It would be wonderful if the problem of just distribution in an imperfect market could be resolved by simply applying the fair market price. In imperfect markets, where transaction terms may be negotiable and there may be several sets of mutually agreeable terms for any given transaction, the just terms would be those that would occur in a perfect market. Resolving the tension between ideal and real markets in this way, however, fails to take into account certain factors that may be relevant to justice, namely, the history of the social surplus and the legitimate claims to which this history may give
rise. For example, the inventor and manufacturer of the Segway motor scooter enjoys an imperfect market with respect to supply and will continue to do so until ocompetitors produce a similar good. It would seem inappropriate, however, to say that the conditions of a perfect market should be artificially imposed, and that a just price for the Segway is one that represents its cost of production. The inventor and manufacturer of the Segway enjoys an imperfect market because he created it through foresight, innovation, and hard work; and to say that a just price would be the price produced by a perfectly competitive market is to say that others, not him, should enjoy the reward for his hard work. This seems grossly unjust. The history of the market imperfection matters when determining the terms of a just transaction in an imperfect market and a distribution of the social surplus that does not reflect this history, such as selling the Segway for the fair market price, seems unjust. It is unjust because the inventor and manufacturer should be able to claim more of the social surplus because he created it.

Instead of a straightforward application of the fair market price, I propose a model of justice that incorporates considerations of both the fair market price and history. Justice in an imperfect market will depend on the history of the market imperfection, and the portion of the surplus each party should get will depend on how that surplus came into existence. If either party can state a legitimate claim to the surplus, then they should get the social surplus or the appropriate portion thereof. To do otherwise would result in an unjust distribution because a person would fail to get what is legitimately his. If, however, neither party can state a legitimate claim to the surplus, then parties can claim only that their basic rights be respected. They should be treated as they would be in the ideal market, and the social surplus should be divided according to the fair market price.
The market, desert, and entitlement

When imperfect markets arise by accident, misfortune, or other unfortunate circumstances, these market imperfections bear no feature that can serve as a legitimate basis for a claim, and thus neither party should get any more of the social surplus than they would receive in an ideal market. In these cases the just terms for the transaction will be determined by the fair market price. For example, if a town has three plumbers competing for clients, and two of these plumbers happen to die in accidents on the same weekend, then the remaining plumber will be selling his services in an imperfect market. This imperfect market arose through unfortunate circumstance, which involved no action on his part, and thus he has no basis upon which to lay claim to the social surplus it creates. If, however, an imperfect market bears a feature that can serve as a basis for a claim, for example, a person's foresight, innovation, and hard work, then transaction terms must respect this claim in order to be just.

When we focus on the history of the market imperfection, in particular, whether it was brought about by the actions of either party to the transaction, we appear to be concerned with some notion of desert. If the market imperfection bears a property for which the market rewards, then the responsible party can make a desert claim to more of the social surplus; if the imperfection bears no feature for which the market rewards, then neither party has a desert claim to the social surplus, and it should be distributed according to the fair market price. As we saw earlier, however, desert claims are difficult to formulate in the context of the market because their object and moral force are both problematic. Here I argue that the concept of entitlement is the appropriate complement to the fair market price as a criterion of justice for personal transactions in real markets.
Entitlement is more promising than desert as the concept through which to express legitimate claims to the social surplus because entitlement claims allow us to discriminate between unfortunate and unjust states of affairs. Recall from an earlier section that desert based reasoning can lead us to confuse unfortunate situations with unjust situations. If a party can state a desert claim, and if the party exhibits the specified behavior, then we say that he or she ought to have the reward, and a situation is unjust if he or she does not receive it. If luck or other external circumstances cause a cooperative venture to fail, then the parties to the transaction would not get their deserved reward, and the resulting situation would be unjust. All things being equal, however, most would regard this situation as merely unfortunate rather than unjust.

Entitlement claims, on the other hand, do not confuse unfortunate situations with unjust situation. Entitlement claims in the marketplace merely assert a right of non-interference in the holding of a particular good. An entitlement claim is a rights claim and rights, or, at least property rights, are claims to non-interference. So a person can assert an entitlement claim in the market place only when the particular good already exists. According to entitlement-based reasoning, a situation is unjust if a good exists, and a person has an entitlement claim to it, and others fail to respect her property rights to the particular good. If a cooperative venture is successful, but a person fails to receive the portion of the profits to which she is entitled, then the situation is unjust. If, however, a cooperative venture is unsuccessful, then there are no goods to which she can make entitlement claims, and the situation is merely unfortunate.

The most cogent presentation of an entitlement theory of justice can be found in Robert Nozick’s work. According to his theory, a person can be entitled to a holding
either by the principles of justice in acquisition and or by the principle of justice in transfer.

If the world were wholly just, the following inductive definition would exhaustively cover the subject of justice in holdings.

1. A person who acquires a holding in accordance with the principle of justice in acquisition is entitled to that holding.

2. A person who acquires a holding in accordance with the principle of justice in transfer, from someone else entitled to the holding, is entitled to the holding.

3. No one is entitled to a holding except by (repeated) applications of 1 and 2.\textsuperscript{30}

Nozick does not provide detailed statements of either the principle of justice in acquisitions or justice in transfer, but he does say a few things about each. Justice in acquisition requires at least two things in order for a holding to be just.\textsuperscript{31} First, one must somehow mix one's labor with the unowned natural resource, and second, one must ensure that the position of others is not worsened by the appropriation. His principle of justice in transfer is far less developed, and he tells us only that it is meant to render unjust holdings obtained through theft, fraud, and the like.\textsuperscript{32}

Nozick's entitlement theory of justice is premised on his firm conviction that individuals have rights, in particular, ownership rights to themselves. Self ownership entails ownership of one's labor, talents, and other natural abilities, and through one's labor a person can also generate ownership rights to other resources and goods. Justice in acquisition allows that a person can come to own a previously unowned good upon which he has labored, provided nobody else's situation is thereby worsened.\textsuperscript{33} In this way a person can have legitimate entitlement claims to natural resources. Additionally, a person can have ownership rights to a resource he receives from another, provided the resource he received was justly owned by the other party, and the transfer was voluntary and free from coercion, fraud, and deceit.\textsuperscript{34} In this way a person can have ownership
rights to the gifts he receives, and he can be entitled to the wages for which he traded his labor, or the material resources for which he exchanged goods he already owned. Repeated applications of these principles also generate rights to created goods, those previously non-existent goods that are created with labor and resources one already owns. To deny entitlement to a holding generated by any of these methods will violate the rights of the person who holds it and would therefore be unjust.

Entitlement can generate claims to the social surplus if the market imperfection was created by labor, talents, or resources that a person owns. If a person is entitled to the means by which it was produced, then he is entitled to the created good that is the social surplus. If he is entitled to only some of the factors that produced the market surplus, then he is entitled to the portion of the social surplus attributable to those factors. Foresight, innovation, and positioning are examples of talents, abilities, and labor, and a person is entitled to whatever portion of the surplus these means produce. If, however, the surplus is created through misfortune or other accidental circumstances, these are factors to which no person is entitled, and neither party to the transaction can make an entitlement claim to the surplus that these generate. Thus, if either party has created the market imperfection in a way that generates an entitlement claim, then that party is entitled to the social surplus it creates; if neither party created the imperfection in a way that can generate a legitimate claim, then neither party can make a claim to the social surplus, and it should be distributed according to the fair market price.

This hybrid model of justice in transactions is only as strong as its weakest link, and there are several critics who regard Nozick’s theory of entitlement as unsound. Nozick’s critics seem to be particularly concerned with his theory of justice in acquisition, some
taking aim at his notion of self-ownership, and others objecting to his interpretation of the Lockean proviso. John Rawls, Ronald Dworkin, and G. A. Cohen, for example, object to Nozick’s idea that self-ownership entails ownership of labor, abilities, and talents, and they also object to the idea that (somehow) mixing one’s labor with an unowned natural resource can generate a claim to that resource. Cohen also disagrees with Nozick’s claim that others will not be made worse off by such appropriations, and thus objects to the idea that these claims are enough to generate property rights.

Critics such as Rawls, Dworkin, and Cohen object to first part of Nozick’s principle of acquisition, namely, that self-ownership can generate claims to previously unowned natural resources. They argue that people do not deserve their ability to labor or their other talents because these are distributed arbitrarily or by accident, so labor and talents are not owned by the person in whom they are embodied. If one does not own one’s labor and talents, then one has no claim to the things those talents produce. Mixing something one does not own with another thing one does not own does not generate claims to the resulting good, thus one cannot come to have entitlement claims to parts of the material world in the way Nozick posits.

If the notion of self-ownership that Rawls and Dworkin’s propose is coherent, then Nozick’s theory of entitlement is, indeed, problematic. A notion of self-ownership in which one does not own one’s labor, talents, or other fortunate features is, however, difficult to sustain. One immediately runs into the sorts of difficulties that arise in G.A. Cohen’s “eyeball lottery.”

In my experience, leftists who disparage Nozick’s essentially unargued affirmation of each person’s right over himself lose confidence in their unqualified denial of the thesis of self-ownership when they are asked to consider who has the right to decide what should happen, for example, to their own eyes.
They do not immediately agree that, were eye transplants easy to achieve, it would then be acceptable for the state to conscribe potential eye donors into a lottery whose losers must yield an eye to beneficiaries who would otherwise be not one-eyed but blind. The fact that they do not deserve their good eyes, that they do not need two good eyes more than blind people need one, and so forth—the fact, in a word, that they are merely lucky to have good eyes—does not convince them that their claim on their own eyes is no stronger than that of some unlucky blind person.37

Surely we believe that, at the very least, each of us owns both of our eyes, kidneys, and other non-vital body parts, and any thesis that denies this fails to match some of our deepest beliefs about the self. Cohen, himself an opponent of Nozickean style self-ownership, tries to recover and argues that refuting the thesis of self-ownership does not mean that we have to give up our eyes, kidneys, and other body parts because we could claim a right to bodily integrity. In the end, however, he admits that the thesis of self-ownership cannot be refuted, and instead simply shows that we need not accept it, and that a world without self-ownership would not be as bad as we might think.

Cohen argues that there is a second reason why we should reject Nozick’s principle of justice in acquisition, one that does not depend on whether Nozick’s thesis of self-ownership is sound. He claims that Nozick’s interpretation of the Lockean proviso does not adequately protect the interests and well-being of those who were not fortunate enough to get there first. Initial acquisition of natural resources poses a problem of timing: those who were lucky enough to get there first enjoy the opportunity to acquire property, but eventually all unowned resources will be appropriated and those who come later, for example, those in later generations, will not enjoy the same opportunity to own property. When they complain that their lack of opportunity is unjust, a theory of property rights needs to show that they are better off in such a system of initial acquisition than they would be had the natural resources been left in common use, even
though they cannot now appropriate resources. Cohen argues that Nozick’s interpretation of the Lockean proviso fails to show that persons in later generations would be better off because Nozick uses the wrong baseline. Nozick compares the welfare of later generations to a baseline in which the natural resource remains in common use, whereas Cohen believes that there are other baselines according to which later generations would be better off, for example, a baseline in which all are given an equal share of the natural resource. When measured against Nozick’s baseline, the Lockean proviso does show that all people would be better off, but when measured against Cohen’s baseline, persons in later generations are worse off if natural resources are appropriated.

Regardless of whether the Lockean proviso is sufficient to justify initial appropriation, Nozick’s notion of entitlement remains sound for all other applications of distributive justice, including justice in transactions. Whether the proviso should be applied to a common use baseline or an equal share baseline affects only the justice of an initial acquisition, and this is not an issue that needs to be resolved for a theory of justice in transactions. To be sure, whether an initial acquisition is just will affect whether a pre-transaction baseline is just, and this, in turn, will affect whether the outcome is just. The justice of transaction terms, however, is independent of pre-transaction baselines. Justice in transactions is concerned with the social surplus, and though this is an “unclaimed good” it is not “unclaimed” in the same sense as unowned natural resources. The social surplus is created when two people, who value a good differently, come together for an exchange. In this way the social surplus is created by an act of the two parties and thus no party except the parties to the transaction should have a claim to the good. The Lockean proviso should not apply to how the social surplus is distributed among the
parties to the transaction. The only factors that should determine justice in the terms of transaction are the absence of coercion and fraud, which the ideal market guarantees, and the satisfaction of entitlement claims generated through the use of resources to which one is entitled, and a person is entitled to a resource if he created it with what he owns or if he received it through a transfer that was free from coercion and fraud.

**A hybrid model of justice: entitlement and fair market price**

The model of justice for interpersonal transactions in an imperfect market setting is as follows. The social surplus created by the market imperfection should be distributed according to the "fair market price" produced by the ideal market, unless either party to the transaction has an entitlement claim to some or all of the surplus. If either party can show that the social surplus was created through their efforts or talents, that party is entitled to the portion of the social surplus that is the direct result of his or her efforts or talents.

This distributional scheme is just because transactions in the ideal market respect the rights and claims that individuals may make. When we move from an ideal to a real market, however, individuals may have additional legitimate claims. A model of justice must be able to accommodate these new claims, otherwise it fails to provide individuals with what they are owed and thus creates transactions terms that are unjust.

Determining the just terms of a transaction in a real market will require two things. First, one must determine the "fair market price" for the good or service to be purchased. Then, one must determine whether either party can make an entitlement claim to the space between the fair market price and the other party's reservation price.
Recall the example in which Eric wants to sell his house and Paul wants to buy it. As is the case with many real estate transactions, this transaction occurs in an imperfect market and the space between Eric and Paul’s reservation prices creates a social surplus. Eric will not accept less than $150,000 for his house and Paul will pay as much as $175,000 for the house, so the social surplus is $25,000. To determine the just transaction terms we first determine the fair market price for the house, and in real estate a comparative market analysis (CMA) provides a close approximation. In this example the CMA shows that the fair market price for Eric’s house $160,000. The next step is to determine whether either party can make an entitlement claim to the social surplus. We first look to see whether Eric can make a claim to the space between the fair market price and Paul’s reservation price and we ask whether Eric is entitled to any of the factors that caused Paul’s reservation price to be $175,000 rather than $160,000. If Eric is responsible for the fact that Paul wants Eric’s house and wants it badly, if, for example, Eric invested in superior landscaping or interior decorating, then Eric will have a claim to portion of the social surplus that can be attributed to those factors. If, however, Paul’s reservation price reflects his substantial wealth, or the fact that he desires to live near his mother and Eric’s house is the only house in that neighborhood that is currently for sale, then Eric can make no entitlement claim to the portion of the social surplus created by these factors. In a similar way we also need to determine whether Paul can make a claim to the space between the fair market price and Eric’s reservation price. Only if Paul is entitled to the factors that pushed Eric’s reservation price below the fair market price can Paul make a claim to this portion of the social surplus. If either party can make such entitlement claims then the just transaction terms will reflect a distribution in which the entitled party
receives the relevant portion of the social surplus, otherwise the just transaction terms will reflect the fair market price.

The task of identifying a "fair market price" will be easy when a reasonably competitive markets and an imperfect markets co-exist or when we have enough information over time to reconstruct a reasonably competitive market. In some cases competitive markets and imperfect markets co-exist, for example, if I live in a city with a competitive market for plumbing services, but my pipes have burst and I can get only one plumber on the phone. Here I find myself in an imperfect market with respect to the particular plumber, but in a more perfect market with respect to other plumbers in the city. In this case the more perfect market can provide valuable information for determining the just terms for transactions in the imperfect market. In other cases there will be no competitive market for ready comparison, but it will be possible to construct a competitive market with data from past market activity. The comparative market analysis used in the previous example creates competition in an otherwise non-competitive market by compiling data on the features and selling prices of recently sold real estate. In cases where there is no competitive market to use for comparison, and one cannot be constructed, determining a "fair market price" will require comparing the good or service to similar goods and services for which there is reasonable competition. Establishing entitlement claims will require a similar type of comparative reasoning. Theoretically, the fair market price will represents the production cost of the good and will therefore be a particular price point rather than a range, but in some cases problems of knowledge may limit our ability to identify this point. These issues are difficult when dealing with production costs that must be quantified in terms of numbers and dollar
amounts, and in these cases perhaps the best we can do is identify a range. However, these issues are less problematic when dealing with production costs that need no quantification as we will see in later chapters.

The usefulness of this model of justice is evident when we apply it to a case that Alan Wertheimer finds particularly problematic. Wertheimer is concerned with, but at a loss to determine, a just price for the transaction he terms “the greedy snowstorm rescuer.” During a particularly bad snowstorm, A has positioned himself and his tow truck on a section of a mountain pass that often causes difficulty for people when driving in heavy snow. B comes along in his Mercedes, slides off the road and becomes stuck. Given the remoteness of the area and the unpleasant conditions, B would pay as much as $210 for A to pull him back onto the road, and given that there are no other vehicles in distress, A would rescue B for as little as $10. So their respective reservation prices are $10 and $210, and the bargaining range which spans $200 is the social surplus.

To establish a just price for this transaction we first need to determine what the “fair market price” for such a service would be, and we find that the going rate for towing a vehicle out of snow is, say, $65. Inasmuch as the “going rate” represents the price produced by a reasonably competitive market the going rate will serve as an indicator of the fair market price. Next, we need to determine whether B can lay claim to the space between the fair market price and A’s reservation price. B is entitled to this space only if this it was created by B’s labor, talents, or resources that B owns, which it was not. In fact, this space was created through A’s ability to reduce his costs for this particular transaction. The more interesting question is whether A has any claim to the space between the fair market price and B’s reservation price. A anticipated the need for a
service of a particular kind, and he endured cost and risk in situating himself so that he would be in a unique situation to provide the service. Therefore, some of the space between 65 and 210 dollars was created by A’s foresight and positioning and willingness to take risks. Additionally, A’s positioning provides B with a value added to the service: B doesn’t have to contact a tow truck and wait for one to arrive. B’s reservation price, however, reflects not only the urgency of his need, but also his ability to pay, and A has no claim to the amount this adds to his reservation price. The difficulty then lies in determining how much A should receive for the foresight, positioning, and added value to the service. The appropriate compensation for these entitlement bases will be difficult to determine, but we can approximate by using comparative reasoning to isolate their value in similar circumstances, and then proportionally applying that value to this service.

Conclusion

The model of justice produced by the ideal market is applicable to real markets and thus provides criteria for justice in interpersonal transactions. Transactions are just if, and only if, all entitlement claims by the parties to the social surplus are respected, and, in the absence of any claims, the social surplus is distributed according to the fair market price.

In the next two chapters I apply this model to human subjects research. In the Chapter 5 I begin by analyzing the types of goods that are exchanged in human subjects research and I discuss whether it is appropriate to place these goods in a market model. In the following chapter I present the “hypothetical clinic” as a version of the ideal market and I determine the “fair market price,” or the “fair study protocol” that this
"hypothetical clinic" will produce. In the final chapter I use this standard for justice in human subjects research to determine whether certain types of research are exploitative.
Five

Transactions in Human Subjects Research

The outcomes of medical research programs can be highly unpredictable for all parties involved and this unpredictability can make questions of exploitation difficult to answer. In some programs, researchers test on humans a drug previously tested only in animals, and nobody knows, with any degree of certainty, how it will affect the human subject. It might be beneficial, it might not show any therapeutic benefit, or it might be harmful. This uncertainty regarding outcomes is not limited to the subject, but holds for all parties involved in the research program. For example, a pharmaceutical company will never know in advance whether they will experience financial gain or loss when researching and developing a particular drug. Nor can we ever be certain of the effect a medical research program will have on society. Penicillin and other antibiotics brought with them a dramatic increase in life expectancy, but Thalidomide brought nothing but suffering to women who took the experimental intervention and their children who were born with phocomelia.¹

The unpredictability of the medical research enterprise makes discussions of justice in distribution difficult. How can we tell whether a subject is being treated justly when nobody knows what will happen to the subject? Furthermore, since a party must gain from a transaction before it can be said that it exploits other parties to the
transaction, it seems impossible to determine whether either party to a particular research program has been exploited until research and development has concluded, which could take as long as 8 to 10 years. While such delayed judgments may be of interest for some purposes, they will do little to prevent exploitation from occurring in the context of medical research. Not only would we fail to prevent exploitation in the particular case, but we would be unable to prevent exploitation in the future because we could never be sure that a similar study will produce the similar results.

We can avoid this difficulty if we concentrate on whether parties act exploitatively towards one another. That is, instead of focusing on whether one party did, in fact, gain in a manner that is unjust with respect to the other, we should focus on whether one party seeks to gain in a manner that is unjust with respect to the other. We should center our attention on the \textit{ex ante} value, or the value of the anticipated gain, rather than the \textit{ex post} value, or the value of the actual gain.\textsuperscript{2} This will allow us to make judgments based on the conditions under which research is conducted, without reference to the final results. This will also allow us to prevent exploitative behavior towards research subjects.

An \textit{ex ante} assessment of medical research programs will view a subject’s participation as a transaction between the subject and the researcher. When a person volunteers to participate in medical research he or she enters into a cooperative activity researcher. The goal of the cooperative venture between the investigator and subject is to produce a set of data, and this transaction will include costs and benefits. Some of these costs and benefits will be immediate and will affect only the subject and investigator, some will be more distant and may affect parties other than the subject and investigator.
Some of the costs and benefits will be certain and knowable, for example, the subject may know for sure that participation will involve the inconvenience of coming to the clinic 6 times in a 12 week period. Other costs and benefits of the transaction will be merely probable, for example, the health risks to the subject, the financial gain to the sponsor, and the public health benefit to society.

In order to determine whether parties act exploitatively towards the subject we will need to determine a just distribution of the costs and benefits of these transactions. This, in turn, will require an understanding of what they are and with whom they are associated. In the following sections I identify the parties to these transactions, the knowable costs and benefits, and the probable costs and benefits for research transactions. Then I group research activities into groups and make some general statements regarding the costs and benefits each group of activities presents to the parties involved. In the final section I show that it is appropriate to view these costs and benefits as goods that could be exchanged in the marketplace, and thus the ideal market is an appropriate standard of justice for research transactions. In the next chapter I posit what this ideal market would look like and the transaction terms it would produce, and I discuss whether there can be any entitlement claims to surpluses created by the imperfections of real markets.

**Parties to the transaction**

The current regulations and practices direct researchers and IRBs to consider only two parties when developing and reviewing protocols.
In order to approve research ... the IRB shall determine that ... risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.\(^3\)

Researchers and IRBs are required to weigh the risks to the subjects against the benefits anticipated by both the subject and society, and a research program is acceptable only if the total benefits to both parties outweigh the risks to the subject. While this requirement is effective in preventing certain types of inappropriate research, it does not prevent investigators, institutions, and society from acting exploitatively towards the subject. It is possible for a given protocol to satisfy this requirement yet present the subject with a cost/benefit ratio that is unjust in comparison to the cost/benefit ratio of the other parties to the transaction. For example, the current regulations and practices would allow recruitment of healthy volunteers for the early phases of testing a blood pressure medication. When preliminary animal testing indicates that the risk to the human subject will be low such studies are often approved because the knowledge gained and the products developed will be valuable for public health. In such a study, however, the subject can expect little health related benefit because he does not suffer from the condition the drug promises to correct. When the subject assumes some risk and anticipates no health-related benefit it is likely that his cost/benefit ratio will be unjustly large in comparison to other parties who stand to gain more, especially when they bear no health-related risk and thus fewer costs. The current regulations and practices allow society and other groups to act exploitatively towards the subject because they focus only on the costs and benefits of the research rather than the costs and benefits for each party to the transaction. When determining whether a subject’s participation in any given protocol is potentially exploitative, one must go beyond what is required by the current regulations and practices. We need to consider not only the risk to the subject, but also
the direct benefits to the subject and compare this to the costs and benefits experienced by the other parties to the transaction. This will require, among other things, identifying all parties to the research transaction who will pay costs, expect benefits, or both.

On one side of the transaction we have the research subject. The research subject will often be a single party, but can, in some circumstances, be two parties. When an individual consents for himself the subject is a single party consisting of a single individual. When the subject cannot consent for himself, the party will consist of multiple people. For example, an incompetent subject and a guardian, and incapacitated subject and a surrogate decision-maker, or a child and his or her parents. When there are multiple people on the subject’s side of the transaction and they stand to benefit in different ways, then the subject may consist of multiple parties. For example, if parents will receive monetary compensation for their child’s participation, then the parents will have a cost/benefit ratio that differs from the child’s and these two parties can be considered separately.

On the other side of the transaction are parties with whom the subject cooperates in an attempt to produce something of value. These are parties who cooperate in the sense that they also anticipate costs and benefits from the medical research transaction. The investigator will always be such a party, as he or she will incur costs and anticipate benefits when performing procedures outlined in a protocol and collecting data on the subject. When the investigator acts independently the parties to the transaction may be limited to the investigator and the subject. Oftentimes, however, the investigator is sponsored by another party who shares in the costs and also anticipates benefits. These sponsors can come in many forms, ranging from non-profit institutions, such as a
university or the National Institute of Health, to for-profit enterprises, such as a contract research organization and a pharmaceutical company. It is also not uncommon for a research program to enjoy multiple sponsors, for example, a investigators often work under the auspices of both their home institution and an outside sponsor such as the NIH.

In addition to the direct parties to the transaction, those who directly share in the costs and anticipate direct benefits, there are parties who stand to indirectly benefit from the results of medical research programs though they may only indirectly share in the costs, or sometimes not share in them at all. For example, basic science research and public health research often benefits all of society, but not all research of this type has direct public funding. Also, certain sub-populations, like those who suffer from a particular condition or disease, may stand to benefit from a research program even though they directly bear none of the costs of conducting the research.

It is an interesting question whether and under what conditions the subject of a research experiment can be simultaneously exploited by multiple parties, exploited by some but not by others, or even exploited by some on behalf of others. Subanalyses of this type, however, are beyond the scope of this dissertation. Instead, this dissertation will view the research experiment as a transaction between two parties: the subject and the researcher, where the subject represents the party whose participation will produce a set of data, and the researcher represents all parties who desire the set of data the subject’s participation will produce.
Costs and benefits of the transaction

The current regulations and practices also fail to prevent exploitative behavior towards the subject because they require researchers and reviewers to consider only the health-related risks a subject may experience rather than all of the costs a subject may incur. According to OHRP’s interpretation of the Common Rule, the current standards require researchers and reviewers to consider the health related risks a subject may experience, but discourage consideration of any non-health related risk or cost. In fact, they state that non-health-related benefits and costs, such as monetary payments or monetary costs like parking and lost time, cannot be factored in to decisions about approving studies.

Direct payments or other forms of remuneration offered to potential subjects as an incentive or reward for participation should not be considered a “benefit” to be gained from research. Although participation in research may be a personally rewarding activity or a humanitarian contribution, these subjective benefits should not enter into the IRB’s analysis of benefits and risks.4

When determining whether a research program is, on the whole, appropriate to pursue it seems reasonable to focus on the health related risks it poses to subjects in comparison to the health-related benefits and the importance of the knowledge to society and other groups of people. After all, if these are not balanced then the harm to the subject is unjustifiable and the program should not be pursued. Acceptable research, however, can still be exploitative even if the risk to the subject is balanced by the importance of the knowledge. If the subject bears health-related risks and expects no benefit, and society bears little or no risk but expects benefit, then the subject’s cost/benefit ratio may be unjust in comparison to society’s. Furthermore, the subject can still be the victim of exploitative behavior even if his health-related risks are balanced by expected health-related benefits to him. If the subject’s health-related cost/benefit ratio is just in
comparison to the cost/benefit ratios of other parties, but he incurs non-health related
costs that increase his cost/benefit ratio, then other parties still act exploitatively towards
him. For example, if involvement in the study requires frequent office visits, lost time,
and thus financial cost, the subject's overall cost/benefit ratio has risen and may no
longer be just in comparison to other parties to the transaction.

There are many different ways in which parties can act exploitatively towards one
another. One party may exploit another's body, good health, good will, profit making
potential, or any other feature that can create gain. It remains to be seen whether the
moral weight of exploitation can vary, and whether the exploitation of one feature is
worse than the exploitation of another. If we assume, however, that all types of
exploitation carry at least some moral weight, focusing on only health-related costs and
benefits runs the risk of answering the exploitation question with a false negative. If we
want to determine whether investigators and others act exploitatively towards the human
subject we must consider all costs and all benefits for all parties associated with the
transaction, and this will include both the health related and non-health related costs and
benefits of a research program.

*Health-related costs and benefits to the subject*

When assessing or measuring the costs and benefits associated with a transaction
one needs to consider not only their magnitude, but also the probability that they will
occur. In medical research the probability of health-related risks and benefits will depend
primarily on two factors: first, the probability of receiving a therapeutic dose of the
experimental intervention, and second, the probability of the experimental intervention
showing therapeutic benefit, causing harm, or both (therapeutic benefit with side-effects). The probability that a subject will receive a therapeutic dose of the experimental intervention is a function of the protocol design, and can be known with a high degree of certainty before the trial begins. We cannot, however, assign a value to the probability that the experimental intervention will be effective with any degree of certainty. The success of an experimental intervention depends on many things, and much to the chagrin of pharmaceutical and other for-profit companies, many of these factors are unknown. Predictions are in part based on scientific evidence, but more often influenced by optimism of sponsors and investigators. In the absence of a reliable indicator for the success of a particular intervention, the historical success rate for similar experimental interventions at a similar stage of development will suffice.

The magnitude of a health-related benefit will vary according to two factors: the subject’s preferences and the completeness of the response. Experimental interventions, as with all interventions, can produce a complete response, a partial response, or no response at all. A complete response typically entails the absence of all signs and symptoms of the condition for a specified period of time, and this response will be both measurably and clinically significant. For example, a remission is a complete response to a cancer treatment. On the other hand, a partial response entails only a measurable change in either the signs or the symptoms of the subject’s condition. This will include treatments that improve a subject’s quality of life but fall short of a cure, and this will also include treatments that do not improve a subject’s quality of life but produce a measurable effect in some other sign of the condition. For example, a decrease in tumor
size constitutes a partial response to a cancer treatment, even if this decrease in size does not change the cancer patient's life expectancy or quality of life.

Recall from Chapter 3 that the model of exploitation utilizes a preference satisfaction theory of gain, so a complete or partial response will constitute a gain for the subject only if it satisfies his or her preferences. The value a subject might assign to any given response, be it partial or complete, will depend on the severity of the condition or disorder from which the subject suffers and the strength of his or her desire for relief from the condition. For any given condition we can assume that a complete response will be a greater benefit than a partial response, but we cannot assume that the value a subject will assign to a partial response will be directly proportional to the value the subject will assign to a complete response. It is possible that a subject's preference schedule will include a desire for a complete response, but no desire for a partial response. For example, a person dying of cancer may not appreciate a therapeutic benefit that falls short of a cure, because though he may want to cure his disease, and he may not want to prolong his death. It is important to note that in these cases, when a subject assigns no value to a partial response, the probability of therapeutic benefit will not represent the probability that the subject will gain from his or her participation in the experiment.

Research on the motivations of patients who volunteer for clinical trials has shown that primary reason most patients enroll is to improve their health or to get better. Assuming that subjects understand the wide range of responses that qualify as therapeutic benefit, and would be satisfied with any of these responses, then the probability for therapeutic benefit is a direct indication for the probability of subject gain. The data from these studies, however, shows variation in how subjects might interpret therapeutic
benefit and indicates that not all subjects would be content with therapeutic gain as defined by the authors of the protocol. For example, Kass and Sugarman conducted a survey of 1,000 patients who had participated in cancer research and found that they “had joined the research in part to get better treatment.” Assuming that “newer” means “better,” data presented by Rothmeier shows similar results. In his survey of 44 parents who enrolled their child in pediatric research, he found that parents are often motivated by the desire for their child “to receive the newest drugs.” More difficult to discern are the underlying motivations when a subject reports that they enrolled in the trial because of “trust in their doctor.”

A theme of trust emerged from other aspects of the patients stories as well. Patients trusted their personal physicians, the hospitals where they received care, and the research enterprise generally. If a patient trusts that his physician is acting as a fiduciary, then the patient trusts that his physician has his health-related interests at heart. When a patient enrolls in a trial because he trusts his physician, he assumes that the physician thinks that participation in the trial is in his best interest. He assumes that the physician thinks the trial must be good for him, or at least better than what he can offer.

These statements of motivations make it clear that a patient who enrolls for therapeutic benefit seeks a therapeutic response that is better than the expected response from other therapies. When there are no effective therapies, a patient may be satisfied with either a partial or complete response. When there are standard therapies for a condition, however, the patient’s desires will be satisfied only with a response that is equal to or better than other available treatments. The value associated with either a complete or partial response will thus depend on the effectiveness of other treatments for the condition.
Like the probability of health-related benefit, the probability of a health-related harm depends on the likelihood that the subject will receive a therapeutic dose. If the subject receives a sub-therapeutic dose the likelihood for any effect, whether good or bad, is small. If the subject receives a therapeutic dose of the experimental intervention the likelihood of an effect is greater, and this effect could be good, bad, or both good and bad. In order to predict whether a subject will experience a gain we combine the probability of a therapeutic dose with the probability that the drug will be successful based on the historical success rate of similar investigation agents. In a similar manner, then, in order to predict whether a subject will experience a harm we should combine the probability of a therapeutic dose with the historical incidence of harm in clinical trials.

A third factor that will affect the likelihood of harm to the subject is the risk present in the protocol design. The protocol according to which a study will be conducted can introduce risks unrelated to the side-effects that may accompany the experimental intervention. Such risks include invasive monitoring procedures that are necessary to measure the effect of the experimental intervention but not necessary for the treatment of the subject's condition, non-treatment in a placebo controlled trial when effective therapy is otherwise available, and the risk of non-treatment or inappropriate treatment that occurs when the investigator is limited by protocol design and unable to tailor treatment to individual subject. Indeed, according to one study, almost one out of six cancer patients interviewed reported that they had declined an offer to participate in research because the risks presented by the protocol were unappealing. Specific reasons they had declined included the desire to know the treatment they were getting and the
desire to have treatment decisions made by their doctors and themselves, and not by researchers.

Just as the magnitude of a health-related benefit can be measured according to whether, how well, and for how long it satisfies a person’s preferences, the magnitude of a harm can be measured according to whether, how well, and for how long it frustrates a person’s preferences. The magnitude of a harm, like the magnitude of a benefit, is a subjective and thus relative measurement. Depending on the preferences a person holds, a particular harm might constitute a significant setback to one person, but only a minor set-back to another person. We cannot therefore assign objective values to anticipated harms, instead, we must evaluate the magnitude of a harm by considering not only its objective features but also the likely preference structure of the subject population for the particular experiment. It is possible that the health risk and discomfort associated with a sinus tap might be an significant harm to a healthy person, but a minor harm to a person who suffers from frequent and untreatable sinus infections and is desperate for an effective treatment.

*Non-health-related costs and benefits to the subject*

The limited research about what motivates people to participate in clinical research suggests that when there is a possibility of a health related benefit people are motivated to participate primarily by the desire for therapeutic benefit. When there is no possibility of health-related benefit, however, studies on subject motivation have shown that subjects participate in studies for a variety of non-health-related reasons. This same research also shows that even when therapeutic benefit is the primary motivation,
the non-health-related desires often function as secondary motivations for participation in research.\textsuperscript{11} The objects of these non-health-related desires can take many forms, and can be either tangible or intangible. The tangible benefits that subjects seek include material objects such as money, meal vouchers, and gifts.\textsuperscript{12} Other tangible but immaterial benefits include quid pro quo arrangements, for example, participation for favors, promotion, or academic rewards such as grades, extra-credit, or letters of reference.\textsuperscript{13}

In addition to desires for non-health-related tangible benefits, study subjects also reported desires for intangible benefits such as emotional or psychological gain. Some expressed a desire for hope, others a desire to help others or advance science. Almost all of the studies that examined why subjects participate in research found that altruistic desires played some part in the subject's motivational structure.\textsuperscript{14} Langley and Rothmeier et al both reported that most parents enroll their children in clinical trials for altruistic reasons such as the desire to contribute to medical knowledge and the desire to help others.\textsuperscript{15} Kass and Sugarman also found that a substantial number of patients enrolled in research because they desired to help others or to advance science.\textsuperscript{16} Some conveyed their hope that if they did not derive benefit personally, others would be helped by the research. Other patients felt that research allowed them to contribute to society when illness prevented them from contributing in other ways.

It is difficult to assess the benefit sought in altruistic behavior because, on some accounts, altruism cannot, by definition, bring any benefit to the agent at all. Altruism is generally defined as an unselfish motivation for helping someone else, and an act is altruistic only if the sole motive is to help others. If the agent expects to benefit then his act is jointly motivated by self-interest and the interest of others, and the motive is no
longer altruistic. The difficulty that arises when considering whether an motive is altruistic is determining what counts as a benefit to the agent. Some think that benefits should be defined in terms of material goods, such as money or other rewards, and an agent can expect to benefit if, and only if, he can expect a material gain. Others argue that psychological rewards, such as satisfaction or the good feeling that often accompanies helping others, should count as a benefit as well. If a desire for this type of pleasure is the motive of the act, then the motive would no longer be selfless but selfish.

It is thus questionable whether the motives of research subjects could rightly be classified as altruistic. When examining the ways in which a subject could gain from participation in research, however, the question of whether a motive qualifies as altruistic is beside the point. Most of the the studies reported that subjects were motivated by a desire to help others, or a desire to advance medical knowledge and science. Whether a subject can expect to gain from a transaction is determined by the probability that the subject’s desire will be satisfied, and unlike a desire for health-related benefits, there is no uncertainty as to whether a desire to help others will be satisfied when a subject participates in a research trial. Regardless of whether the trial shows that the experimental intervention is efficacious, the results of the trial will contribute to the advancement of medical science and in that way benefit every person. If a subject has a desire to help others, and if satisfying this desire will constitute a gain for the subject, then the subject can, with certainty, expect to benefit from participating in a trial, regardless of whether we choose to call this motivation altruistic. The only uncertainty regarding the expected gain for a subject who desires to help others is the magnitude of the gain, as determined by the quanitity and the quality of the help he gives to others. A trial that
proves an intervention to be effective will help others more than a trial that proves an intervention to be ineffective; a trial that studies an intervention for a condition that affects many people will help others more than a trial that studies a condition that affect few people; and a trial that studies an intervention for a grave condition will help others more than a trial that studies an intervention for a minor condition.

Subjects also report hope as a second type of psychological benefit that can come from participation in studies. In their interviews with cancer patients, Kass and Sugarman found that, in addition to a desire for therapeutic benefit, many patients listed hope as a motivational factor. Even though they realized that the probability of therapeutic benefit was low, that there was even a chance to get better would give them hope, and this hope was valuable in and of itself. Hope is a psychological state, and a desire for hope is realized if and when a person experiences hope. In this sense, a patient’s perception is a direct indication of their gain. If they experience it, if they feel hope, then they have satisfied their desire. When considering whether to join a study, patients will often know in advance whether the conditions are sufficient to produce hope. If hope is something they want, and they think the conditions of the study will produce it, then subjects who participate in a study can expect, with certainty, to experience this kind of benefit.

Though the available research focuses primarily on the subject’s motivations for participation, one can assume that there are reasons why a subject might be disinclined to participate, ways in which the protocol can present costs rather than the promise of benefit. In addition to the health-related burdens of short or long term physical harm, individuals might bear other physical burdens such as discomfort and pain. They may
also bear non-physical burdens such as inconvenience, loss of time, or expenditure of effort. Some may even fear that participation will lead to social stigmatization. HIV positive patients are sometimes hesitant to enroll in a trial unless they are certain that their participation will be kept confidential.

*Non-health-related benefits and costs to other parties*

Desires for tangible and intangible goods can also motivate investigators and sponsors to participate in the research. Investigators are often paid handsomely for their participation in a research program, and a desire for money can be a strong motivational force. Also, research is often thought to be a prestigious activity, especially when it leads to authorship on publications. A desire for professional recognition or advancement can also motivate investigators to participate. For-profit sponsors, such as pharmaceutical companies, often engage in research and development activities as a profit seeking venture. Society can also reap tangible benefits from research when the results produce a reduction of morbidity and mortality. All things being equal, a society is stronger when its citizens are healthy and productive rather than unhealthy and in need of assistance.

Though there is no evidence supporting this, one would like to think that investigators, sponsors, and society also have a desire to help others and are motivated to participate in research by altruism. Investigators might have a direct desire to help others, or a desire to advance the field of medicine so that more people can be helped in the future, and the satisfaction and good feelings that follow from satisfying these desires can be a benefit for the investigators. It is more difficult to determine whether sponsors or society can benefit in this way because it is not clear whether these parties can have a
desire to help others and feel pleasure in the satisfaction of this desire. Nevertheless, we should say that a non-profit sponsor or a government agency act altruistically when sponsoring research from which they expect no immediate and direct gain. For profit sponsors can also act altruistically, though this will often be a secondary motive, when they pursue a research program both for profit potential and a desire to help others.

The non-health related costs that other parties may experience are primarily related to resources. Investigators, sponsors, groups, and society cannot bear the costs of physical discomfort or pain because they cannot contribute their bodies. They can only contribute their resources such as time and money. Investigators often will incur the costs of time and effort, and sponsors will bear the burden of cost.

Categories of research

Medical research consists of a wide range of activities, and given the variety of experimental interventions, protocol designs, procedures, subject populations, locations and settings, it often seems as if each study presents a unique cost and benefit ratio. Some research programs may promise health related benefits to the subject whereas others will not, indeed, even within the same program some stages of testing will promise health related benefits whereas others will not. The non-health-related costs and benefits for the subject and other parties can also vary greatly. The actual distribution of costs and benefit in a given study will depend on the particulars of the protocol, so it will be difficult to form general statements about cost/benefit ratios of all human subjects research. It seems equally difficult to support sweeping judgments about exploitation in medical research. Retreating to a case-by-case approach to questions of exploitative
behavior, however, would be not only unfruitful but unnecessarily defeatist. Even though protocols can vary greatly, there are often remarkable similarities in the pay-off structures among certain types of research activities. While it is true that one cannot generalize across all of medical research, one can generalize across types and stages of research with similar pay-off structures. Answering the exploitation question would be more manageable if we change the scope of the question from particular studies to groups of studies. Therefore, to determine whether medical research threatens to exploit the subject, one must find a way to group together protocols with similar pay-off structures.

Medical research studies can vary along many dimensions, including the character of the experimental intervention, protocol design, procedures, subject populations, location and setting. Studies can be grouped together based on any one of these features. Answering questions of exploitation, however, requires knowledge of pay-off structures, and this, in turn, requires information regarding cost-benefit ratios for particular parties. We need to group studies together based on a feature that correlates with cost/benefit ratios to the subject so that all studies in a particular group will be similar in regard to their pay-off structure. A survey of the literature and current practices suggest three ways in which to group research activities. The Declaration of Helsinki encourages researchers and reviewers to distinguish between therapeutic and non-therapeutic research, while the Common Federal Rule requires reviewers to differentiate according to level of risk and prospect of benefit. Finally, the Food and Drug administration divides research activities into four categories depending on the stage or “phase” of the research program. In the following section I examine each of these three distinctions for both soundness and its ability to group together studies with similar pay-off structures. I
conclude that a modified version of the FDA classification system will provide the best method through which to group together research activities with similar pay-off structures.

The first distinction among research related activities was presented by the World Medical Association (WMA) in 1964.

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research. Research in which the aim is to benefit a particular patient should be distinguished from research in which there is no intent to directly benefit the subject. This distinction between therapeutic and nontherapeutic research is an important one for many reasons, primary among them is that it recognizes that different types of research could pose different risk benefit ratios to the subject. If a physician is experimenting on a sick patient, with the aim to benefit the patient, then his activity could at the same time be viewed as treatment and should be handled as such. If, however, a physician is experimenting on a healthy volunteer, with no aim to improve the patient’s health, then the activity could not be viewed as treatment and must be conducted differently. Among the important differences in how these two activities are conducted is a more stringent requirement for informed consent.

While this distinction is important, and the idea behind it survives even today, its soundness was relatively short-lived. Not even ten years after the publication of The Declaration of Helsinki the soundness of the distinction was challenged. The publication of The Belmont Report in 1973 brought with it a new definition of research that rendered
the distinction between therapeutic and nontherapeutic research not only unsustainable but downright misleading.

"Research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.22

This definition of research makes it apparent that in no case will research activities present the same risk/benefit ratio as therapy. Any systematic investigation, whether done in a sick person or a healthy volunteer, poses the risks of the protocol. The risks the protocol presents to the healthy volunteer are rather obvious and include all risks associated with the set procedures. The risks presented by the protocol are not so easily seen for the sick person who would have undergone therapy anyway. Sometimes these risks are limited to additional monitoring, which could be significant if the monitoring is invasive. Other times risks appear when the appropriate course of treatment strays from the procedures set in the protocol. The protocol can pose even more risks simply by its design, for example, if it includes randomization into a non-treatment control arm.

According to the definition presented in The Belmont Report, the goal of research is to test an hypothesis, and this goal is often incompatible with the goal of benefiting the subject. Activities which aim at benefiting the patient cannot be considered clinical research or even medical research at all. Moreover, even if they were considered research, it would be misleading to label as therapeutic activities that introduce more risks than standard therapy. It is still debatable whether this distinction is sound, but regardless of whether it is sound, it is clearly unfit for the present task of grouping research activities according to their pay-off structure. While it might distinguish between research that presents the prospect of a direct health related benefit and research
that does not, it provides no indication of the size or probability that the benefit will be realized. We need more information about the pay-off structures than this distinction can provide.

A second distinction among research activities can be found in the Common Federal Rule (CFR) in the section pertaining to research in pediatric populations. Here the regulations introduce a four-category classification system based on the level of anticipated risks and benefits and the stringency of the requirements for child assent, parental consent, and the limits on overall risk varies with each category.

DHHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that …

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that …

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that … the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition …

DHHS will conduct or fund research that the IRB does not believe meets the [above] requirements … only if …

In presenting the regulations for research on children the common rule unwittingly introduced a new four-category classification system for research activities. Category 1 research includes all activities that present minimal risk, regardless of the promised benefit. Category 2 research includes activities that present greater than minimal risk with the prospect of direct benefit. Category 3 research includes activities that present
greater than minimal risk with no prospect of direct benefit but are likely to yield
generalizable knowledge about the subject's disorder or condition. Category 4 research
includes activities that present greater than minimal risk with no prospect of benefit to
either the subject himself or the subpopulation to which he belongs. Though these
distinctions were meant only for research on children the system of classification has
been informally adopted by researchers and reviewers. In the review process a protocol
is often designated as category 1, 2, 3, or 4, and the category to which it is assigned often
determines the rigor of the review process. Category 1 research is typically pushed
through an expedited review process, while category 2 research is sometimes reviewed
by teams who present their findings to the full board, and research assigned to categories
3 and 4 often receives a full board review.27

This system of classification seems to present a generalized account of the health-
related cost/benefit ratio for the subject, and as such would be useful in examining
questions of exploitation. With some general assumptions about the non-health related
costs and benefits to the subject and other parties we could draw conclusions about
whether the subject is likely to be exploited when participating in certain types of
research. For example, it would be useful to know that category 4 research is likely to be
exploitative unless there are appreciable non-health related benefits for the subject. If
this were the case, then regulations could require that such benefits be present, or at least
force reviewers to look closely at the problem.

This system of classification, however, is unsuitable because it is both unsound
and impractical. It is unsound for the same reason the distinction between therapeutic
and non-therapeutic research is unsound: to regard research as an activity that presents a
prospect of benefit for the subject confuses activities designed to test an hypothesis with activities designed to benefit a patient. Even if the distinction were sound, even if we could classify research activities according to whether they do or do not present the prospect of direct benefit to the subject, this system of classification would be impractical for the purpose of evaluating exploitation claims because the categories are unreliable indicators of a patient’s health-related cost/benefit ratio for several reasons. First, the distinction does not present a ratio between costs and benefits, it merely acknowledges the prospect of a benefit in the face of risks. Protocols may be similar in that they both present a prospect of benefit, but if they have dramatically different probabilities that the benefit will be realized then their pay-off structures are different. For example, both placebo controlled and active controlled trials qualify as category 2 research because both present the subject with a prospect of benefit. However, the probability of realizing benefit in an active controlled trial is sometimes two or three times the probability of realizing benefit in the placebo controlled trial. The probability of realizing benefit is directly related to pay-off structure, and this feature is not reflected in this system of classification. Knowing that the subject has a prospect for some benefit in the face of risks without the information regarding the probability of benefit is useless for determining pay-off structures.

The Food and Drug administration proposes yet a third distinction among research related activities in their guidelines to sponsors of new drug applications. This distinction separates research activities into four categories depending on the stage, or phase, of the research program. Once the FDA has approved a sponsor’s application for an investigational new drug (IND) the sponsor can begin testing on human subjects. The
first phase of testing (Phase 1) attempts to determine the maximum tolerated dose of the drug, and the second phase (Phase 2) determines both the therapeutic benefit and the side effects of the experimental intervention when delivered to a small subject population at the dose determined in Phase 1. If Phase 2 testing is successful, the drug enters the third phase of testing (Phase 3) where investigators more carefully measure the therapeutic benefit and side-effects on a larger subject population. If the results of the Phase 3 study show that the drug's therapeutic benefit outweighs its side effects then the FDA will approve the drug for marketing. Once a drug is available on the market a final phase of testing (Phase 4) gathers post-marketing information.

Though studies may be investigating different experimental interventions or procedures, the goal of each phase of research is the same and this leads to similarity in protocol design among studies in the same phase. The research activities Phase 1 studies are the first administration of an experimental intervention in man, and their object is to determine the maximum tolerated dose, identify the type and extent of toxicities or side effects associated with the drug, and, if possible, gain early evidence on effectiveness. The standard method of a phase 1 study is to group subjects into cohorts and deliver successively increasing doses to each cohort provided the prior dose was tolerated, until the maximum tolerated dose is determined. Phase 1 studies may vary in terms of the sample size, but almost all Phase 1 studies are dose-escalation studies.

Once Phase 1 studies have been completed and investigators have determined a safe dosage level and schedule, Phase 2 studies can begin. These are the first studies designed to test the effectiveness of a drug in humans. The subjects are patients with the disease or disorder the experimental intervention is designed to treat, and the studies are
typically small, involving no more than several hundred people. The subjects are randomized into either an experimental group, in which subjects will take the drug at doses and on the schedule found to be safe in phase 1 trials, or control groups. When possible, both investigators and subjects are blinded to group assignments. Phase 3 studies are similar to phase 2 in terms of structure and goal, but differ in terms of size. Phase 3 studies include a larger subject population to gather a more comprehensive set of information regarding the good and bad effects of the experimental intervention. Like the phase 2 study, they are controlled, and randomized and double-blind when possible, but larger and longer. A phase 3 study can include anywhere from several hundred to several thousand participants, and often takes years to complete. Phase 4 studies aim to learn more about the drug after it has been approved and marketed. They are all similar in that they are performed post-marketing, but unlike the other phases of research, not all phase 4 studies share the same goal. Some are randomized, controlled studies designed to gather more information about the efficacy and toxicity of the drug, others are randomized, controlled studies designed to test the efficacy of the drug for a new indication.

The control used in any four phases of research can be any of the following four types: (1) placebo, (2) no treatment, (3) a different active treatment, or (4) a historical control group. Subjects randomized into a placebo control will receive an identical-appearing treatment that does not contain the test drug or any active substance, whereas subjects randomized into a no-treatment arm will receive no treatment at all. In an active control trial, subjects are assigned either to the test treatment or to an active, already approved, control treatment. A historically controlled trial will compare a group of
subjects receiving the test treatment with a group of patients external to the study and treated at an earlier time or in another setting.

Inasmuch as a subject’s probability for therapeutic benefit depends on the probability that he will receive a therapeutic dose and the probability that the drug will be effective, the phase of a study and its control arm are fairly reliable indicators of a subject’s chances for health-related benefit. The probability that a drug will be successful differs according to the stage of research, and drugs that make it to phase 3 stand a greater chance of success than drugs in phase 1 or 2 of their research program. Drugs in the fourth phase of testing are almost always effective, except when being tested for a new indication. The probability that a subject will receive a therapeutic dose of a drug will differ dramatically with the control used in a trial. A subject’s chances at a therapeutic dose in a study using a placebo or no-treatment control are dramatically less than a study using an active or historical control. In active and historically controlled trials, all subjects receive a therapeutic dose of a drug, whereas in placebo and no-treatment controlled trials, the subjects randomized into the control arm will receive no dose at all.

The phase of a study and the control used in the study are the most reliable indicators of a subject’s therapeutic benefit, thus the FDA system of classification, modified to include the type of control, provides a good way to generalize across research activities. The FDA guidelines, however, apply only to experimental drugs and devices that will be submitted for FDA approval, so the original scope of the four phase system of classification covers only of research programs that seek to market a drug or device. The FDA guidelines do not apply to any other type of human subjects research, including
research on new surgical techniques, non-invasive procedures, and basic science research. The limitations of the authority of the FDA, however, does not affect the applicability of the four phase system of classification as a taxonomical method. Though the scope of the authority of the FDA guidelines extends only to research that seeks to market a new drug or devise, the four phase system of classification could easily be applied to all types of research with human subjects. Basic science research, for example, would be grouped with other phase 1 studies because it is conducted on healthy volunteers who expect no therapeutic benefit for their participation. Research on new surgical techniques and other experimental interventions would be classified as phase 2, 3, or 4, depending on the stage of research, and would be assigned to subgroups according to the control arm of the study.

Study activities that fall within the same phase of research and use the same type of control will exhibit similarities in both the probability that the subject will receive a therapeutic dose and the probability that the experimental agent will be effective. These studies may or may not exhibit similarities in the magnitude of the results, which is the value of a therapeutic gain or harm to a subject, because this will depend on the subject’s preferences and the severity of the condition for which the subject is seeking treatment. The similarities that we will find across groups of research activities, however, will be enough to make generalizations on pay-off schedules for subjects, and these generalizations will enable us to address and resolve questions of exploitation.
Cost benefit analysis for each category of research

Phase 1 studies are sometimes conducted with a healthy subject population and sometimes conducted with a sick subject population, so the potential for health-related risks and benefits will depend on the subject population. These studies are usually conducted in healthy volunteers, though they are sometimes conducted in sick populations when information on effectiveness is not possible in healthy subjects, or when adverse drug effects are potentially serious. If the study recruits from a healthy population it will present health-related risks but no potential for health-related benefits. Only when the study recruits from sick patient populations will it present any potential for a health-related benefit, but here the probability of benefit is often very low. The majority of phase 1 trials are intended to minimize toxicity, which, ironically, ensures that the majority of participants are treated at doses that cannot produce responses. Meta-analyses of phase 1 studies have shown that 54-61% of participants in phase 1 oncology studies received biologically inactive doses. Consequently participants face little risk but also stand little chance of receiving a dose large enough to produce therapeutic benefit if the drug is effective. When combined with the probability that the experimental intervention will be effective, the overall probability of therapeutic benefit is low. Estey et al have shown the therapeutic response rates for “classic” phase 1 oncology trials with a single investigational chemotherapeutic agent to range from 3%-6%. A more recent study confirms this finding, but also shows that when phase 1 oncology trials test combinations of chemotherapeutic agents, and at least one of the anticancer agents is already approved, the average response rate improves to 17.8%, and an addition 34.1% showed a health-related benefit that was a less than partial response.
The rate of toxic death with both classic and new phase 1 oncology trials stayed constant at 0.5%. In general, phase 1 trials for non-cancerous conditions present risk with a low potential for benefit, and classic phase 1 oncology trials follow this trend, but new phase 1 combination oncology trials appear to present risk with a greater potential for health-related benefit.

Whether this probability for therapeutic benefit represents the probability for health-related gain for the subject will depend on the availability of other effective treatments for the disease or condition. If there is no effective treatment for their disease or condition, then the probability of benefit, even though it is low, presents a chance of satisfying their health-related desires. If, however, there is an approved course of treatment for their disease or condition then participation in a phase 1 trial may or may not satisfy their health-related preferences. Some patients will participate in medical research, even in phase 1 medical research, because they want to receive newer or better treatments. Statements of patient motivation indicate that desires of this type are not merely desires for the newest or latest treatment, but instead, a desire for the best possible treatment because what the subject really wants is to get better. So participation in the phase 1 trial will present a health-related benefit only if the marginal improvement promised by the newer or better intervention is still an improvement over the approved intervention when adjusted for the probability that the treatment will be effective and the probability of that the subject will receive a therapeutic dose of the experimental intervention. Only in the cases where there is a great difference in the benefits promised by the approved intervention and the benefits promised by the experimental intervention will the subject find a better prospect for a health-related benefit in the phase 1 trial.
Even though most phase 1 studies will offer, at best, minimal chances for health-related benefit, participation in the study may still be beneficial for subjects if it satisfies other non-health-related desires. Research by Kass et al has shown that the primary motivation for many of the healthy subjects who volunteer for phase 1 research is financial gain. Subjects reported that they saw study participation as a way to make money, and thought it was “easy work.” When subjects want money, and researchers offer money, then participation will result in a non-health related benefit for the subject. Participation in phase 1 research can also create other non-health-related benefits such as feelings of hope and feelings of satisfaction in helping others. The non-health related costs that are typically associated with phase 1 research include the pain and discomfort that accompany the frequent blood draws or other invasive monitoring techniques, and the inconvenience and the lost time associated with participation.

Phase 1 research can also produce costs and benefits for parties other than the subject. Investigators who conduct phase 1 trials sponsored by for-profit companies are often paid handsomely, and they often receive professional recognition in the form of prestigious publications. Investigators can also enjoy the good feelings and satisfaction associated with helping others and advancing the field of medicine. If the drug proves to be successful, for-profit sponsors will financially benefit, the group of people who suffer from the disease will receive health-related benefits, and society will benefit from the reduction in morbidity and mortality among its members.

Phase 2 and phase 3 studies offer the subject a better chance for therapeutic benefit when compared to phase 1 studies because in these studies more subjects will receive a therapeutic dose. Though studies in these phases often place more subjects in
the control arm of the trial, all subjects in the experimental arm will receive a therapeutic dose, as opposed to phase 1 studies where only subjects in the later cohorts received a therapeutic dose. In placebo and no-treatment controlled trials, only the subjects in the experimental arm will receive therapeutic doses, but in active and historically controlled trials all subjects will receive a therapeutic dose. In active controlled trials subjects will receive a therapeutic dose of either the experimental or the active intervention, and in historically controlled trials all subjects will be placed in the experimental arm and will thus receive a therapeutic dose of the experimental intervention. Since the probability of receiving a therapeutic dose of an agent is higher in phase 2 and 3 than phase 1, a subject’s potential for therapeutic benefit is higher in these studies, except when the experimental intervention in the phase 1 promises such a high probability for effectiveness that, even when multiplied by the lower probability that the subject will receive an therapeutic dose, the overall probability for health-related gain is higher in that phase 1 trial when compared to phase 2 and phase 3 trials for other experimental interventions. Unless the phase 1 experimental agent is exceptional, phase 2 and phase 3 trials offer a higher probability for health-related benefit. Furthermore, since the probability of receiving a therapeutic dose is higher in active and historically controlled trials than in placebo and no-treatment controlled trials, it follows that active and historically controlled phase 2 and 3 trials offer a greater potential for therapeutic benefit than placebo and no-treatment controlled trials. Insofar as potential benefit also depends on the probability that the agent will be successful, there will also be a difference in potential benefit between phase 2 and phase 3 trials, because experimental interventions
that progress to phase 3 have a higher success rate than experimental interventions in phase 1 or 2 of their testing program.

As was the case with phase 1 studies, the therapeutic benefit promised by phase 2 and 3 trials will a produce a health-related gain for the subject only if: (1) there are no standard treatments for the condition from which he or she suffers, or (2) the marginal benefit promised by the newer or better intervention is still an improvement over the approved intervention when adjusted for the probability that the treatment will be effective and the probability of that the subject will receive a therapeutic dose of the experimental intervention. For all types of phase 2 and 3 trials the probability that a subject will experience therapeutic benefit is affected not only by the risk of not receiving a therapeutic dose, but also by the uncertainty of the experimental intervention, and this will reduce the overall promise of benefit for the newer intervention. If the newer intervention promises a benefit so great that it surpasses the benefit associated with the approved intervention, even when reduced to compensate for the probability that the subject will not receive a therapeutic dose and the probability that the experimental intervention will not be successful, then the participation in the study will further the subject’s health-related interests. If, however, the approved therapy promises a benefit that is greater than the adjusted promise of benefit associated with the experimental intervention then participation in the study will not further the subject’s health-related interests.

The non-health-related costs and benefits available to subjects in phase 2 and 3 trials are similar to phase 1. The subject may satisfy desires for financial gain or other material goods, enjoy feelings of satisfaction in helping others, or acquire hope. The
costs are similar as well in that subjects will be inconvenienced by multiple clinic visits and they may experience lost time. The costs of discomfort and pain may or may not be as high as phase 1 trials depending on the ways in which the patient’s progress is monitored. The costs and benefits other parties will experience will be almost identical to phase 1 studies, expect there will be greater likelihood of success in phase 3 studies and thus a greater likelihood that the benefits will be realized.

Placebo or no-treatment controlled phase 4 trials will be present a potential for costs and benefits that is very similar to the phase 2 and 3 trials. So the pay-off structure for all parties will be similar to phase 2 and 3 trials, only the probability that the benefits will be realized will be higher. In phase 4 trials that use active or historical controls all study subjects will receive therapeutic doses of an already approved agent, thus their potential for therapeutic benefit will increase to the point where it approximates the standard of care. In such trials subjects will satisfy any desire they have to get better, as well as desires to help others, but they may experience more costs than are usually associated with non-study related treatment. Such costs include the health related risks posed by the protocol, such as invasive monitoring, and the non-health-related costs of the inconvenience created by multiple visits to the clinic.

Conclusion

Clinical research offers health-related benefits which can be enjoyed by both the subject during the course of the study, and the group of people who suffer from the condition or disease once the research program is completed. The health-related harms that are associated with clinical research, however, are primarily born by the subject. The
physical costs of discomfort and pain are, again, born primarily by the subject, but the
non-physical costs such as inconvenience, time, and money can be born by the subject,
the investigator, and the sponsor. Material items as benefit are available to the subject,
investigator, sponsor, and society. The subject, investigator, and sponsor can experience
financial gain as a result of their participation in a research program, and society can
experience material gain when there is a reduction in the incidence of morbidity and
mortality among its members. Investigators can also experience the additional material
benefit of professional recognition, advancement, and prestige. Additionally, subjects
and investigators can benefit by the good feelings that come with helping others, and the
subject can sometimes experience an added psychological benefit of hope.

These are the costs and benefits associated with research transactions, and in
order to determine whether exploitation is occurring we need to determine whether they
are distributed in a way that is just. Given that our model of justice is the fair market
price adjusted by entitlement claims, determining whether the distribution is just will
require inserting these costs and benefits into the model of an ideal market. The result of
this hypothetical construct and entitlement claims, the adjusted fair market price, will
indicate the just distribution of these costs and benefits. Once we have a criterion of
justice we can determine whether certain transactions result in unjust distributions, and
then we can say whether the parties who engage in these transactions act in a way that is
exploitative.

Some, however, may object to placing these particular costs and benefits into a
market model. They may say that it is inappropriate, for example, to put altruistic
behavior up for sale or that advancing medical science should never be rewarded with
money. To place these items in a market model, however, does not necessarily commodify them in the objectionable ways these criticisms might suggest. Inserting costs and benefits into a market model does not mean that they will be exchanged for money, it simply means that they will be exchanged for other goods or services. The market model merely captures the idea that people will rarely expend effort of contribute resources unless they get something in return. Inserting particular costs and benefits into a market model is an attempt to identify the nature of a person's contributions and identify the way in which the person should benefit, along with the ways in which others should benefit from that person's contributions. These benefits may come directly from the contributions of others, as in a straightforward exchange, or they may be created by the cooperative ventures of the parties. The good feelings that accompany helping others, for example, is a benefit that is created by the act of helping others, and one would be remiss to analyze the justice of a transaction without taking all costs and benefits into consideration.

To be sure, in some cases goods and services will be exchanged for money, as may happen when a healthy volunteer receives money for his time and discomfort. For a discussion of the actual commodification of such goods I refer the reader back to Chapter 2 where this issue was discussed in depth. The market model does not require that goods and services listed above be exchanged for money, it merely provides a method by which we can determine the just terms of exchanges involving heterogeneous goods. The market model will produce the just terms of a transaction even if there is no money exchanged. If, however, we assume that it is not inappropriate to exchange goods and
services of this nature for money, as we will in the present discussion, then the market model can tell us how much money would constitute a just trade for such goods.

In the next chapter I construct a model of the ideal market in the context of human subjects research, and term this “the hypothetical clinic.” Into this model I insert all of the above mentioned goods, and determine the fair market price, or the “fair research terms” for research transactions. I discuss ways in which real clinics can vary from the ideal clinic, and I examine whether any of the social surpluses that might result can be the object of an entitlement claim.
Six
The Ideal Clinic and the Just Research Terms

In medical research the transaction that occurs between the researcher and subject is a cooperative venture to produce a set of data, and in the process of generating this data both the researcher and the subject will experience costs and benefits. Different trials will offer different types costs and benefits, for example, some will offer the subject therapeutic benefit and others will offer material goods or feelings gratification for helping others. Even among those trials that offer the same types of costs and benefits, different trials will offer different distributions. In fact, any given trial can have a number of different distributions because researchers sometimes have choices regarding trial design, the costs of the protocol, and the amount and types of benefits they will offer for participation. The choice among trial designs will be limited by both the researcher’s and the subject’s reservation prices. Some trial designs will produce data so poor that it would have no value to the researcher and he will refuse to transact. Likewise, some trial designs will require so much and offer so little to the subject that he too would refuse to transact. Both the researcher and the subject will have a reservation price for transacting because for each party there will be a certain point beyond which he will refuse to transact. In most cases, however, there are a number of different transaction terms that will fall between the parties’ reservation prices and constitute a bargaining range. This
bargaining range creates a social surplus, and if this social surplus is divided in a way that is unjust to either party then the research transaction is exploitative. In this way the researcher, and any other party he represents, can act exploitatively toward the subject, and the subject can act exploitatively towards the researcher.

In order to determine whether a particular clinical trial exploits the subject we first need to establish criteria for the just distribution of the costs and benefits associated with the transaction. Using the method proposed in the earlier in this thesis, we start with an ideal market and use this ideal market to determine the fair market price. Then we identify the real world reservation prices for both parties to the transaction, and this will determine the bargaining range and the social surplus. If either party is entitled to the space between the other party's reservation price and the fair market price, then a just distribution will be one that reflects this entitlement. If neither party can make an entitlement claim, then the just distribution of the social surplus is the distribution required by the fair market price.

Applying the ideal market to medical research transactions will create what I term an "ideal clinic" and this hypothetical clinic will yield the "fair research protocol." I begin this chapter with a review of the conditions of the ideal market, then I describe how these conditions would characterize the ideal clinic. I speculate on the research terms that perfect competition would produce, and then discuss the ways in which real clinics differ from the ideal clinic and the social surplus these market imperfections will create. Finally, I show that neither party can make an entitlement claim to the social surplus, and I conclude with general statements on the just research terms. In the next chapter I
compare current research practices to the just research terms and discuss the moral
weight and force of the exploitation claims that follow.

The ideal market and the ideal clinic

The ideal market is a set of assumptions which, when taken together, constitute a
hypothetical market that functions with perfect competition. The terms under which
transactions would take place in this hypothetical market constitute the fair market price
for that good or service, and this fair market price can be used as a criterion for justice in
real markets unless entitlement claims justify different transaction terms. Absent an
entitlement claim, one can say that a transaction in the real world is just if, and only if,
one can show that the parties would have transacted on those terms in an ideal market.
Determining justice then requires hypothesizing an ideal market for the particular good or
service, and this, in turn, requires hypothesizing the way in which the various
assumptions regarding buyers, sellers, products, and the state of competition would be
actualized.

As explained in Chapter 4, the ideal market is a set of 5 assumptions that
characterize the market, buyers and sellers, products and services, the state of
competition, and the way in which these features will interact to produce standardized
transaction terms. The first assumption is that the market is privately owned, and
individuals enter the marketplace armed with their “initial factor endowments”. An
individual’s endowment includes ownership of his person, skills, labor, and whatever
additional resources and means of production he may have. The second assumption is
that both buyers and sellers are fully informed about the products and services available
to them. They are knowledgeable about the performance and quality of the products, and they are aware of the alternative ways in which the products can be produced and acquired. Third, buyers and sellers behave rationally in that they seek their own gain and are not moved by concern for the welfare of others. Their preferences are ordered and transitive and they select appropriate means toward their chosen ends. Fourth, they are motivated to transact in the sense that they want something and they are looking for the best terms on which to get it. Finally, the products and services offered for exchange in the ideal market are fungible and there are enough suppliers and enough buyers to create competition on both sides of the transaction. All of these assumptions, when taken together, create a market in which there is perfect competition. In such a market no party feels any pressure to transact with any particular buyer or seller, all participants price-takers rather than price-setters, and the fair market price is set at terms that approximate production costs.

An ideal market for human subjects research, or the “ideal clinic”, is a marketplace in which there is perfect competition among researchers for subjects and perfect competition among subjects for a place in a clinical trial. This perfect competition renders all parties price-takers rather than price-setters, and this, in turn, ensures that transactions will occur on terms that approximate production costs. These terms represent the fair market price, or the “fair research protocol”. The production price of a clinical trial, however, is a very difficult thing to determine. This difficulty is, in large part, due to the fact that there is considerable ambiguity regarding the goods and services being produced and traded in any given research transaction. Recall from Chapter 5 that some people enter the clinic looking for health care, others for money or
professional recognition, and still others enter the clinic seeking the opportunity to do something charitable. There are, in fact, a number of goods and services that parties seek in the context of clinical research, each with its own production costs. The result is multiple iterations of the ideal clinic, each addressing a different type of transaction between researcher and subject. The differences in these ideal clinics, and the resulting differences in the fair research protocols, will become evident as we actualize the assumptions of the ideal market with respect to the researchers, subjects, and clinical trial protocols.

The first assumption of the ideal market is that individuals come to the marketplace armed with their initial factor endowment. Individuals enjoy ownership of themselves, and this includes their labor and their skills which may be traded for other goods and services. Additionally, individuals enjoy ownership of whatever means of production and additional resources they bring to the market. The purpose of this assumption is to establish the ideal market as one in which the means of production are privately owned and goods are traded freely between individuals, but when constructing an ideal market for a particular good or service the initial factor endowment of the participants can reveal a great deal about how the market will function. A person's holdings and the state of those holdings indicate what he can trade for the goods and services he seeks. For example, a person who seeks health care and is endowed with a surplus of time, but little money and no health insurance, will not enter into a marketplace in which money is traded for health care. Instead, he will find a market in which he can trade the resources at his disposal for the good he wants. In this way differences in the landscape of subjects' initial factor endowments can lead us to different
research transactions, and different research transactions will require different ideal clinics.

All potential subjects come to the ideal clinic enjoying ownership of their body, but not all bodies are in the same state of health. Indeed, some individuals in the ideal clinic are healthy, and others are sick, and those who are sick can be sick in different ways and to different degrees. The state of a person’s body will often determine the type of study for which he is eligible, and this will determine the opportunities he will have to trade the things he owns for the things he wants. Healthy subjects are typically eligible for any and all phase 1 studies, and other non-research related opportunities, but ineligible for later phase studies. Unhealthy subjects are often eligible for only phase 2, 3, and 4 studies, and only for those studies testing interventions designed to treat the conditions from which they suffer. Healthy individuals and unhealthy individuals will offer different goods for trade, so their opportunities will be different, as will the types of transactions in which the two groups will engage. Therefore, the two groups will have different ideal clinics.

Individuals whose initial factor endowment includes an unhealthy body not only differ from those who are healthy, but they can also differ from each other in terms of whether there is a treatment available for their condition. Whether there is an effective treatment for the condition from which an individual suffers in the real clinic will determine the opportunities available to that individual in the ideal clinic. Though the ideal clinic can correct for market imperfections such as lack of competition or defects in knowledge, it cannot create goods, services, or opportunities that are not be available in the real world. Abstracting from conditions of imperfect competition on the supply side
merely posits more sellers of the same product or service, it does not introduce new products or services of a different type. So individuals who suffer from conditions that are treatable may have a choice between purchasing care or enrolling in a clinical trial with an active control, a historical control, or a placebo control. However, individuals who suffer from an untreatable condition will have only two options, a clinical trial with a historical control or a clinical trial with a placebo control. Again, the opportunities open to a person will affect both the competition their suppliers face and the types of transactions in which they will engage, so populations with different sets of opportunities will have different ideal clinics.

Individuals whose initial factor endowment includes an unhealthy body can differ from each other in a second way in their ability to access health care if that is the desired good. If an individual’s initial endowment includes access to health care through sufficient monetary resources or a third party payer, then there are at least two transactions through which he can seek his desired good. He (or third party) can pay for the desired care, or he can trade the use of his body for it. Alternatively, if an individual’s initial factor endowment does not include sufficient means to purchase care or a third party payer, then he will have much fewer options. His only means for acquiring the desired health care is to trade the use of his body. A person’s ability to purchase health care through commercial venues affect the opportunities open to him, and the opportunities open to a person affect the way in which the ideal clinic will function. So populations with the means to purchase care will have a different ideal clinic than populations without such means.
Critics might argue that a theory of justice that treats those who have insurance differently from those who do not is, in itself, unjust. Some argue that people have a right to health care, others refrain from talking about rights but support a general obligation to provide health care for all.\(^2\) Regardless of the way in which they support their claim, there are many people who agree that whether a person has access to health care is a matter of justice, and those who lack access are victims of an injustice. If we allow different ideal clinics for these two groups then it is possible that the fair market prices will be different, indeed, justice may require more favorable terms for those with insurance than for those without. If the criteria demand less for people without insurance, and their lack of insurance is an injustice, then they might argue that such a theory only compounds the problem injustice.

Regardless of whether we agree that access to health care is a matter of justice, we can separate these two groups without jeopardizing the justice of the ideal market. Recall from Chapter 4 that the ideal market is a just procedure that guarantees people will be treated justly in the process of the transaction. It does not guarantee that outcomes will be just because justice in an outcome relies, in large part, on justice in the starting point. The ideal market cannot remedy the injustice of background conditions. It merely ensures that the parties to the transaction treat each other justly during the course of the transaction. So not only is it not unjust to separate these groups into two ideal markets, it is necessary to do so for the ideal market to function properly and produce just terms.

Consider the following comment by Alan Wertheimer:

It is important to note that while a hypothetical market price abstracts from some features of an actual market, such as defects in information and noncompetitiveness, it does not abstract from other background characteristics of the buyers and sellers, such as risk. Just as the fair market value of a house
depends on location (location and location), the hypothetical market price of interest rates for low income borrowers will, ceteris paribus, be higher than the hypothetical market price of interest rates for high-income borrowers.  

The ideal market can abstract from noncompetitive circumstances by positing additional buyers and sellers of the same goods, but it cannot abstract from features that define the transaction. Just as it cannot compensate for noncompetitive circumstances by creating products or alternatives that would not be available to the party even under circumstances of perfect competition, it cannot abstract from background circumstances that affect the types of transactions open to a person who seeks health care. A person who can trade only the use of his body for health care should be placed in a market with perfect competition for such exchanges. Likewise, a person who can trade money or the use of his body for health care should be put in a market with perfect competition among both types of transaction.

Actualizing the first assumption regarding initial factor endowments, and recognizing differences in the landscapes of these endowments, therefore leads us to three ways in which ideal clinics can be different. They can differ with respect to the health of the candidate subject, they can differ with respect to the treatments available for unhealthy subjects, and they can differ with respect to an individual’s ability to acquire health care outside of research.

The second assumption of the ideal market is that buyers and sellers are fully informed about the products and services available to them. They are knowledgeable about the performance and quality of the products, and they are aware of the alternative ways in which the products can be acquired. This means that in the ideal clinic subjects will understand the non-health related costs and benefits of study participation, as well as the probability and magnitude of both the health-related risks and benefits. Subjects will
be knowledgeable about the stage and type of research, the trial design, and the way in which these features determine, among other things, the probability that they will experience health-related benefits from participation.

Subjects in the ideal clinic will also be aware of the alternative ways in which to acquire their desired good. If they desire a health-related benefit, they know that the probability of experiencing a benefit changes with differences in trial designs. For example, they will know that an active controlled Phase IV study presents a considerably higher probability of health-related benefit than a placebo controlled Phase III study of the same agent. On the other hand, if it is money that a subject seeks, the subject will be aware of the other ways to acquire it. For example, a subject will know about other job opportunities, what they require, and how much will they pay. If a subject desires to help others then he will know which activities are most effective in helping others. Similar to the way in which an informed donor will research and compare the operating costs of charities before he makes a donation, an informed person in the ideal clinic will know the size of the target group for any given study, the severity of the condition the experimental intervention promises to alleviate, and the comparative magnitude of the help he could expect to offer others through the alternative ways in which he could donate his body, efforts, or time.

The third assumption states that buyers and sellers behave rationally in that they seek their own gain, their preferences are ordered and transitive, and they select appropriate means toward their chosen ends. This means that researchers and subjects will be motivated only by their own goals, whatever these may be, and they are capable of determining whether any given protocol is the best means through which to pursue
their goals. If a person is motivated by money he will seek and enroll in those studies that will pay the most without regard to the effect the study will have on others. Likewise, if a person is motivated by a health-related goal he will seek and enroll in those studies that offer the highest probability for a health-related benefit, without concern for the quality of the data and how it might affect others like the researcher, sponsor, or target group.

The fourth assumption characterizing the ideal market states that buyers and sellers are motivated to transact. Though this assumption is meant to circumvent the problems associated with non-motivated buyers and sellers, when constructing an ideal market for a particular good or service information regarding the motivations of the participants can reveal a great deal about how they will behave in the marketplace. A subject’s motivation for participating in a clinical trial indicates what he hopes to gain, and this determines the goods that are exchanged in the transaction. Because different transaction types require different ideal clinics, information regarding the motivations of the participants will affect both the number and character of ideal clinics.

Recall from Chapter 5 that subjects and researchers can be motivated to participate in clinical trials by a variety of desires. Some subjects are motivated by desire for health related benefits, such as a cure for their condition, alleviation of symptoms, or any measurable improvement. Others are motivated by a desire for tangible non-health related benefits such as money, meal vouchers, gifts, job related rewards, and academic rewards. Studies also show that some subjects seek intangible benefits such as the gratification that comes from helping others, or, for those who suffer from a condition for which there is no cure, the opportunity to turn desperation into hope. Researchers can
also be motivated by a variety of desires, for example, they may seek money, professional recognition, or gratification in furthering science and helping others. Each of these desired goods, however, are secondary to a scientifically valid set of data in the sense that the data is the means to money, professional recognitions, and other types of gratification. In order to get other objects of desire, if a researcher desires such objects, the researcher must first have scientifically valid set of data. Therefore, what the researcher seeks through his transaction with the subject is a scientifically valid set of data. The magnitude of the benefit this data will bring him depends on what he intends to do with it, but this will involve transactions with parties other than the subject and these transactions will not be examined here. It will suffice to say that in his transactions with the subject the researcher desires a scientifically valid set of data. Given that the researchers’ desires remain static, each of the three motivational forces behind subject participation leads to a transaction that produces a different good for the subject, and each of these three transaction types requires a separate ideal clinic. So we have three more ideal clinics: one in which subjects seek health-related benefits, one in which they seek non-health-related but tangible benefits, and a third in which they seek non-health-related intangible benefits.

The final assumption states that the goods and services offered for exchange in the ideal market are fungible and there is amply supply to meet demand. Goods and services are fungible when they are interchangeable with other goods or services that promise the same usefulness. Recall from Chapter 2 that widgets are fungible because, “One widget is a good as any other.” Goods and services within each ideal clinic are fungible in the sense that they are interchangeable with one another without any loss of
quality or usefulness. Keeping in mind that healthy subjects and sick subjects have different ideal clinics, within each clinic the goods offered by subjects are interchangeable. Though it would be absurd to say that all people are the same, it is true that the use of one healthy body for research is as good as the use of another. In a similar way, the use of an unhealthy body that satisfies the inclusion criteria for a study is the same as the use of another. Subjects in the ideal clinics are fungible because, as far as the researcher is concerned, within each clinic one subject is as good as another. Clinical studies that produce the same goods are also are also fungible and can be compared to each in terms of the quantity of the costs and benefits they offer. For example, if a subject desires money, studies that produce this good are qualitatively the same, though they may differ in terms of the quantity of the net gain they promise. In this sense, one study is as good as any other, and a subject will simply “shop” for the study that promises the best deal. Likewise, the researcher will “shop” for the subject that promises the best deal. In each ideal clinic there will be such “shopping” because there will be enough researchers to create competition among trials, and enough candidate subjects to create competition for enrollment in a trial.

**Perfect competition and the fair research protocol**

All of these assumptions, when taken together, create a market in which there is perfect competition. In such a market all parties are “unpressured” in the sense that no party feels pressure to transact with any particular buyer or seller. Whereas in the real world there are times when a buyer might feel pressured to accept certain terms because there is only one seller, in the ideal market there is an ample supply of goods and
services, and enough buyers and sellers to create competition. This competition renders all participants "price-takers" rather than "price-setters" because no buyer or seller can influence prices by his own independent actions. No vendor can charge a higher price, and no buyer can offer less because competitors will offer better terms. The competition among vendors and competition among buyers will keep the price of goods and services at the point where they approximate production costs.

In each of the ideal clinics there will be perfect competition that eliminates pressure, renders parties price-takers rather than price-setters, and pushes the transaction terms towards the cost of production. Subjects who enter the ideal clinic will not feel pressured to enroll in any particular trial because they will have several clinical trials from which to choose, and some subjects will even have alternative activities which produce the desired good. Subjects can compare the cost and benefit of trials and the alternative activities and select the trial or activity that presents the most benefits with the fewest costs. Investigators will not feel pressured to enroll any particular subject because they will be able to choose among an ample supply of subjects who will meet the inclusion criteria for their study. Investigators can compare the costs and benefits of enrolling any particular subject and select the subject that presents the most benefits with the fewest costs. Subjects will be offered participation in a study only if their costs and benefits are competitive with the other subjects who seek enrollment, and investigators, will reach enrollment for their study only if the study presents costs and benefits that are competitive with other studies and alternative activities. If a researcher can find another subject with more favorable terms he will enroll that subject, or if a subject can find another study will more favorable terms he will enroll in that study. This competition
will push subjects to reduce the costs and increase the benefits associated with their participation, and this competition will push investigators to reduce the costs and increase the benefits associated with their study as much as is compatible with scientifically valid data.

The production cost of the data in the ideal clinic will depend on the goods needed to produce the data and the units of exchange for these goods. That is, the production cost will depend on what the researcher needs from the subject and what the subject wants from the researcher. Competition among researchers will ensure that the production cost represents the researcher’s reservation price, or the research terms below which the data will have no value and researchers will refuse to transact. Whether the production price will also represent the subject’s reservation price will be determined by the alternative activities open to the subject. If the subject has alternatives, then he will compare the costs and benefits of the researcher’s terms to the costs and benefits of the alternative activities and pursue the activity with the more favorable terms. If the costs and benefits associated with the alternative activities is more favorable than the costs and benefits associated with the trial, then the subject’s reservation price will be higher than the researcher’s and the subject will pursue the alternate activities rather than enroll in the trial. If there are no alternatives, or if the costs and benefits associated with the clinical trial are more favorable than the alternatives, competition among subjects will ensure that the subject’s reservation price is not lower than the production cost.

So each change in what the subject offers, what the subject wants, and alternative ways in which the subject can pursue his desired good will result in a different fair research protocol. Given the variations in the subject’s ability to fill the researcher’s
needs, the subject's desires, and the alternatives open to the subject, we end up with seven different ideal clinics. They are as follows: (1) insured subjects suffering from a condition for which there is effective treatment who desire health-related benefits; (2) uninsured subjects suffering from a condition for which there is effective treatment who desire health-related benefits; (3) unhealthy subjects suffering from a condition for which there is no effective treatment who desire health-related benefits; (4) healthy subjects who desire material goods; (5) unhealthy subjects who desire material goods; (6) healthy subjects who seek gratification from helping others; (7) unhealthy subjects who seek such gratification. This classification system is a deliberate attempt to simplify the complexities of the world, and, to be sure, not all candidate subjects will neatly fit into one of these seven ideal clinics. Nevertheless, the conclusions that follow will be useful when evaluating exploitation claims for subjects who occupy one of these seven ideal clinics, and the method by which we reach these conclusions will be helpful in determining the fair research protocol for subjects who occupy another ideal clinic, and this will be useful when evaluating exploitations claims for subjects who occupy any other ideal clinic.

The first ideal clinic is composed of insured individuals who seek care for a treatable condition. These patients are sick, motivated to transact because they want treatment, and looking for the best deal on that treatment. These individuals have at least two options through which they can pursue their desired good: first, they can have their insurance provider pay for their care; and second, they can enroll in a clinical trial. The first option achieves the desired goal of a therapeutic dose of effective treatment, with little to no cost to the individual. The second option may or may not achieve the desired
goal, depending on the experimental agent, the phase, and the design of the clinical trial. Phase 1, 2, and 3 trials testing the efficacy of an experimental agent, and trials at any phase that are conducted with a placebo or no treatment control cannot promise a therapeutic dose of an effective treatment. Phase 1, 2, and 3 trials cannot promise an effective treatment, and phase 1, 2, 3, and 4 trials with a placebo control cannot promise a therapeutic dose. Participation in these trials will present a health-related benefit only if the marginal improvement promised by the newer or better intervention is still an improvement over the approved intervention when adjusted for the probability that the treatment will be effective and the probability of that the subject will receive a therapeutic dose of the experimental intervention. Only in the cases where there is a great difference in the benefits promised by the approved intervention and the benefits promised by the experimental intervention will the subject find a better prospect for a health-related benefit in the phase 1, 2, or 3 clinical trial.

Phase 4 trials that use an active control do promise a therapeutic dose of an effective treatment, but they also present the costs associated with the protocol. For example, such trials might require visits to the clinic that are medically unnecessary, as well as unnecessary monitoring, procurement of biological samples, and so on. The costs associated with the protocol will, of course, vary from study to study, but all studies are likely to produce costs that are higher than those associated with standard treatment procedures.

When comparing his options, a subject will see that commercially available care will produce a higher benefit with fewer costs when compared to all phase 1, 2, and 3 trials except those in which the there is a significant difference between the benefits
promised by the approved intervention and the benefits promised by the experimental
intervention. The ideally situated subject will also see that commercially available care
will produce similar benefits with fewer costs when compared to all active control phase
4 trials. Informed, rational, unpressured, and insured individuals seeking the best deal on
care for a treatable condition will not enroll in a trial in the ideal clinic unless the
experimental intervention is exceptional, and they will not enroll in a phase 4 trial under
any circumstances. Using this type of reasoning they will form the following preference
schedule: phase 1, 2, or 3 trial for exceptional interventions, commercially available
interventions, phase 1, 2, or 3 trials for unexceptional interventions.

A motivated subject’s reservation price will be determined, in part, by the most
appealing opportunity open to the subject. The phase 1, 2, or 3 trial of an exceptional
intervention sits highest on the subject’s preference schedule, but this does not mean that
a subject will refuse to transact for anything lower. The subject merely uses this
preference schedule to choose among the trials available to him in the ideal clinic, and for
any given subject this selection may or may not include a trial for an exceptional
intervention. The clinical studies available to an individual in this ideal market will
mirror those available in the real world in terms of the interventions to be tested and their
phase of development. Though the ideal clinic can correct for market imperfections such
as lack of competition or defects in knowledge, it cannot create goods, services, or
opportunities that are not be available to a person in the real world. Correcting for
imperfect competition cannot change either the experimental interventions available for
testing or their phase of development. If there is an exceptional experimental
intervention which is designed to treat the condition from which the subject suffers then
his ideal clinic will include trials for this intervention in the corresponding phase of testing. If, however, there are no exceptional experimental interventions in any phase of testing in the real clinic, there will be no exceptional experimental interventions available in the subject's ideal clinic. Subjects in this clinic will survey the opportunities available to them, select those opportunity that sits highest on their preference schedule, and choose the opportunity with the least cost.

Abstracting from the conditions of imperfect competition cannot change the experimental intervention or phase of the studies available to the subject, but it can affect the way in which the trial is conducted. When the ideal market corrects for imperfect competition on the supply side it posits more sellers of the same product. For example, if a subject suffers from a particular condition for which there is an exceptional experimental intervention in the third phase of testing, his ideal clinic will consist of several researchers, competing with each other, each trying to recruit for his own phase 3 study. Any given researcher will offer better terms in an attempt to best the competition, his competitors will then try to best him, and so on, until the probability of benefit to the subject reaches the highest point that is compatible with the researcher's goals. If a researcher can offer the subject better terms, and still get scientifically valid data, then he will, and another will offer better terms, until they reach the point where the either the quality of the data will be compromised or the data will be too costly to produce. This point represents the researcher's reservation price.

Given that the subject's reservation price will be the opportunity that offers the highest amount of benefit with the least amount of costs, subjects and researchers will transact only when the researcher can offer a trial of an exceptional intervention with
minimized costs. If the researcher cannot offer a trial of an exceptional intervention then the ideally situated subjects in this clinic will pursue their treatment through commercial avenues. Therefore, in this first ideal clinic where insured subjects seek care for a treatable condition the fair research protocol will include an exceptional experimental intervention with minimized costs. If a transaction occurs on terms lower than this and the researcher can not make an entitlement claim to the difference then the researcher acts exploitatively towards the subject. If a transaction occurs on terms higher than this and the subject cannot make an entitlement claim to the difference then the subject acts exploitatively towards the researcher.

In the second ideal clinic uninsured individuals will seek care for their treatable condition. Again, these people are sick, motivated to transact because they want treatment, and they are looking for the best deal on that treatment. Unlike the first ideal clinic, however, uninsured subjects do not have many options for seeking treatment. Inasmuch as they lack the resources to purchase care, and have no agreement with a third party to purchase care for them, they cannot seek care through commercial venues. The only option through which individuals in this ideal clinic can pursue their desired good is to enroll in a clinical trial. So they will compare the costs and benefits of the trials available to them and choose the study that offers the highest probability of therapeutic benefit with the least cost.

Individuals in this ideal clinic will be knowledgeable about the ways in which the phase and trial design can affect the probability that they will experience therapeutic benefit and they will use this knowledge to guide their enrollment decisions. They will know that active control phase 4 trials promise the greatest chance of benefit, and will
prefer this type of trial to any other. They will also know that active control phase 3 trials promise the second highest probability for therapeutic benefit. Using this type of reasoning they will form the following preference schedule for trial phase and design:
active control phase 4, active control phase 3, historical control phase 3, placebo control phase 4, placebo control phase 3, phase 2, and, finally, a phase 1 trial.

Again we see that a motivated subject's reservation price will be determined, in part, by the most appealing opportunity open to the subject. The phase 4 active control trial sits highest on the subject's preference schedule, but this does not mean that a subject will refuse to transact for anything lower. The subject merely uses this preference schedule to choose among the trials available to him in the ideal clinic, and for any given subject this selection may or may not include a phase 4 active controlled trial. The clinical studies available to an individual in this ideal market will mirror those available in the real world in terms of the phase of development, but they may be different from real world studies both in terms of the way in which the trial is conducted and the trial design. When the ideal market corrects for imperfect competition on the supply side it posits more sellers of the same product, researcher will compete with each other. We already saw how this competition will reduce the costs associated with a trial, but this competition will also push researcher to offer a higher benefit whenever possible. If a researcher can offer the subject better terms, and still get scientifically valid data, then he will, and another will offer better terms, until they reach the point where the either the quality of the data will be compromised or the data will be too costly to produce. Given that the most attractive study to the subject will be one that includes an active control, the
determining factor for the fair research protocol will be whether the researcher can offer the subject an active control trial.

Though the placebo seems to be the gold standard for a controlled clinical trial, researchers often have a choice of controls.\textsuperscript{13} The popularity of the placebo control is, in large part, due to the fact that they are easier to manage and less costly to run. It would be a mistake, however, to interpret their popularity as an indication that only the placebo can generate reliable data because, in many cases, an active control can also generate reliable data. Active control trials compare an experimental agent to an approved intervention, and test the hypotheses that an experimental intervention is superior to the approved intervention, equivalent to the approved intervention, or inferior to the approved intervention. For cases in which the approved intervention is reliably effective, a demonstration of equivalence or superiority is also a demonstration of efficacy. However, for cases in which the approved intervention is unreliable, a demonstration of equivalence will not be a reliable indication of efficacy and an active control trial will not yield useful data.

\ldots any condition in which large spontaneous or placebo-responses occur, or in which there is great day-to-day variability, or in which effective drugs are not easily distinguished from placebo, should be considered a poor candidate for an active control study.\textsuperscript{14}

When we have good reason to believe that the approved intervention would have beaten a placebo then an active control trial can yield useful and scientifically sound data, and in these cases a researcher can offer an active control trial without compromising the quality of the data.

This does not, however, mean that in all such cases the researchers will offer an active control trial because the terms a researcher can offer depend not only on the
requirements for good data, but also on the cost of producing the data. Recall that the
ideal market includes perfect competition among both sellers and buyers, and the
competition among buyers ensures that the fair market price will not go below the cost of
production. So the researcher's reservation price will also reflect the point beyond which
the data will cost more to produce than it will be worth to the researcher or any of his
sponsors or other interested groups. An active control trial will promise the highest
probability of therapeutic benefit for the subject, and it will yield reliable data, but active
control trials also carry higher production costs. An active control trial can provide
quality data regarding the difference between the active and experimental agent, but
because this difference will be smaller than the difference between the experimental
agent and a placebo, a larger sample size is needed to generate the power to detect and
prove that the difference exists. These larger trials introduce additional production costs
because they are often much more difficult to manage and much more expensive to run.
So, in cases where the value of the data, either in monetary or other terms, is enough to
offset these additional production costs, researchers can offer active control trials in the
ideal clinic.

The competition among researchers will push the benefits offered to the subject to
the highest point compatible with scientifically valid data, and this competition will also
push the costs associated with the protocol down the to lowest point compatible with
scientifically valid research. Subjects in this clinic want therapeutic benefit, and they
want to find the best deal. These subjects will shop around until they find the studies that
will offer the highest probability of therapeutic benefit, and when choosing among these
studies they will select the one with the lowest cost. Researchers will thus compete with
each other to offer lower and lower costs, until they reach the point where going lower will compromise the validity of the data.

In this second ideal clinic, the ideal clinic in which uninsured individuals seek care for a treatable condition, the fair research protocol will consist of the highest possible benefit researchers can offer to subject with minimized costs. The actual terms of the fair research protocol will vary according to two factors: first, the effectiveness of the approved treatment and thus the suitability of an active control; and second, the value of the data to the researcher or other sponsoring groups. If the approved treatment is reliable, and if the value of the data will offset the costs of producing an active controlled trial, then the fair research protocol will be an active controlled trial with minimized protocol costs. If the approved treatment is unreliable, or the costs associated with an active control trial exceed the value of the data that is produced, then the fair research protocol will be a placebo control trial with minimal protocol costs. In either case, if a transaction occurs on terms that are worse for the subject when compared to the fair research protocol, and the researcher can not make an entitlement claim to the difference, then the researcher acts exploitatively towards the subject. Alternatively, if a transaction occurs on terms that are better for the subject, and the subject cannot make an entitlement claim to the difference, then the subject acts exploitatively towards the researcher.

In the third ideal clinic insured and uninsured individuals alike will seek care for their untreatable condition. Like the previous two subject populations, these individuals are sick, they want treatment, and they are looking for the best deal on that treatment. Unlike the previous populations, however, they have very few options. Regardless of whether the individual has the means, that is, regardless of whether the individual is
insured, he cannot seek care through commercial venues because he suffers from a condition for which there is no commercially available treatment. The only product that might offer therapeutic benefit is an experimental intervention, so his only option for pursuing treatment is to enroll in a clinical trial. As with the previous ideal clinics, the phase of the trials available will depend on the state of development in the real clinic, but unlike the previous ideal clinic, an active control trial design is not a possibility because there is no effective intervention that could serve as an active control. The only research opportunities for individuals in this clinic are placebo and historical control trials of the experimental interventions that exist in the real world.

Given their desire for therapeutic benefit and their knowledge of the way in which trial design affects the probability of therapeutic benefit, subjects in this ideal clinic will prefer historical control trials to placebo control trials, and they will prefer trials in which researchers have minimized the protocol costs. The determining factors for the fair research protocol in this clinic are first, whether researchers can offer historical control trials, and second, whether the expected value of the data will offset the production costs for the historical control trial.

Researchers will offer historical control trials only if they can produce scientifically valid data, and there is good reason to believe they can not. The International Conference on Harmonization and the FDA, as well as other scholars on the subject, all emphasize the need for concurrent control groups. Historical control trial lack a concurrent control, and this precludes randomization and allows other factors, besides the intervention, to be responsible for the differences between the control group and the intervention group.
Inability to control bias is the major and well-recognized limitation of externally controlled trials and is sufficient in many cases to make the design unsuitable. The externally controlled study cannot be blinded and is subject to patient, observer, and analyst bias; these are major disadvantages. It is possible to mitigate these problems to a degree, but even the steps suggested in a previous section cannot resolve such problems fully ... it is well documented that externally controlled trials tend to overestimate efficacy of test therapies. It should be recognized that tests of statistical significance carried out in such studies are less reliable than in randomized trials. ... Alternatively, and generally preferably, in dealing with serious illnesses for which there is no satisfactory treatment, but where the course of the disease cannot be reliably predicted, even the earliest studies should be randomized.16

In most cases the data produced by historical control studies is so unreliable that scientists would insist on a trial with a concurrent control in all cases where this is possible. Only when the natural history studies of the condition show a uniformly dismal outcome, and there is a very strong belief that the test therapy is superior to all available alternatives will an historical controlled trial provide valid data, and even then concurrent controls are preferable.17 Also, there are situations where ethical and social concerns require that researchers use a historical control, and these concerns are especially strong when the condition is life threatening, there is no effective therapy, the only concurrent control is a placebo, and the promise of the experimental intervention is well-known by all. Social concerns, ethical concerns, and scientific concerns are each distinct forces, and all should play a role in shaping the trial design, and we should recognize that these three forces can sometimes pull in different directions. Even though social and ethical concerns might require the use of a historical control, scientific concerns will never support the use of a historical control. Inasmuch as researchers in the ideal clinic are mutually disinterested, that is, they are concerned only with their own gain and are not moved by concern for the welfare of others, they will not let social or ethical concerns determine the trial design. Instead, the preferences of these researchers and the
competitive forces of the ideal clinic will determine the trial design. The researchers
desire scientifically valid data, and because historical control trials compromise the
validity of the data, researchers in this ideal clinic will never offer trials with this design.
In this third ideal clinic researchers will offer only placebo control trials, and only those
that will produce data valuable enough to offset production costs. Therefore, the fair
research protocol will be placebo control trials with minimal protocol costs. If a
transaction occurs on terms that are more favorable for the subject when compared to the
fair research protocol, and the subject can not make an entitlement claim to the
difference, then the subject will acts exploitatively towards the researcher. Alternatively,
if a transaction occurs on terms that less favorable for the subject, and the researcher
cannot make an entitlement claim to the difference, then the researcher acts exploitatively
towards the subject.

In the fourth ideal clinic healthy individuals will seek material goods. These
people have desires for certain material goods and they are looking for the best way in
which to satisfy these desires. Individuals in this clinic will have the opportunity to
participate in clinical trials, but because they are healthy their trial options will be limited.
They cannot participate in trials designed to test the efficacy of an intervention, so their
research opportunities will include only phase 1 trials. They may also enjoy non-research
related opportunities when there are other opportunities to trade the goods they have,
namely, use of their body, time, and unskilled labor, for the goods they want.

Given that subjects in this ideal clinic are motivated by money or other material
goods, their preference schedule will be a direct function of the amount of material goods
promised and the associated costs. They will prefer the opportunities that pay the most,
and among those options they will prefer the opportunity that presents the fewest costs. For example, if two opportunities pay the same, subjects will choose the one that is easier or more enjoyable, and if two clinical trials pay the same, subjects will choose the one with fewer office visits or the one with less severe side-effects. Again, a motivated subject’s reservation price will be determined, in part, by the most appealing opportunity open to the subject. The payoff associated with the opportunity that sits highest on the subject’s preference schedule, be it a research or non-research related opportunity, will determine the subject’s reservation price and thus the fair research protocol.

Researchers will then compete with each other to offer what the subject wants. They will offer better and better terms until they reach their own reservation price, or the point beyond which the researcher will fail to get what he wants. Since no amount of money will compromise the quality of the data, the researcher’s reservation price will be determined by the value of the data in comparison to the production cost of the trial. Given that researchers in this clinic are competing against vendors that produce the desired good in different ways, a researcher’s production costs may differ from those of other vendors, and he may or may not be able to match their offers. If, for example, money is the desired material good, and researchers cannot or do not pay a monetary wage that is similar to wages paid for comparable work, then this trial will fail to enroll in the ideal clinic. If the terms the researcher can offer present costs and benefits that are comparable to the subject’s other opportunities, then subjects will enroll in the trial. If, however, the costs and benefits of the trial are less favorable than the subject’s other opportunities, then subjects will pursue other options and the trial will fail to reach enrollment. In this ideal clinic the only fair researcher protocol is one in which the
subject's payoff is similar to the payoff associated with other opportunities. Absent legitimate entitlement claims, anything more favorable to the subject would exploit the researcher, and anything more favorable to the researcher would exploit the subject.

Subjects who desire material goods but are sick rather than healthy will face an ideal clinic that is very similar to that of their healthy counterparts and differs only in respect to the phase of the clinical trials available to them. Like the subjects of the previous ideal clinic, individuals in this fifth ideal clinic seek material goods and they are looking for the best way in which to satisfy this desire. They will have the opportunity to seek their desired good through participation in a clinical trial, and because they are sick they will be eligible for phase 2, 3, or 4 trials of any design testing experimental interventions intended to treat their condition. They also enjoy the non-research related opportunities that will allow them to trade the goods they have, namely, use of their body, time, and unskilled labor, for the material goods they want.

Their preference structure will be almost identical to the subjects in the fourth clinic because they also are motivated by money or other material goods, so their preference schedule will depend on the amount of material goods promised and the associated costs. Subjects in this clinic will prefer the opportunities that pay the most, whether these opportunities are research or non-research related. Among those options that pay the most, they will prefer the opportunity that presents the fewest costs. When considering a clinical trial, these subjects will not be concerned with the phase of the trial or trial design, except to the extent that these factors determine the costs associated with the trial. This is important in at least one regard, namely, subjects in this clinic will view staying sick as a cost associated with the trial, but a cost that can be offset by material
goods. If an active control trial and a placebo control offer the same amount of material goods, the subject will prefer the active control trial because it will minimize the discomfort of being sick. If, however, a placebo control trial offers more material goods as an incentive for participation, then these additional goods can offset the costs associated with being ill to the point where the cost/benefit ratio of the placebo control trial is more favorable than the active control trial.

Competition among researchers will push the amount of material goods offered to the subject to the point beyond which the researcher will fail to get what he wants. This attempt to best other researchers will force researchers to offer a placebo control trial design. Assuming that researchers have a choice of control, a researcher who chooses an active control design will spend more resources managing the trial and will have fewer material resources to offer the subject. A researcher who chooses a placebo control design can produce his data with fewer resources and will have more left over to offer the subject. Assuming the difference is enough to offset the cost of being sick, the subjects will prefer a placebo control design because it offers them more material goods. Thus, the researcher’s reservation price will be a placebo control trial with as much material incentive as he can afford.

Competition among researchers and their non-research competitors will also drive the amount of material goods offered to the subject up to the point beyond which no producer can cover his production costs. It is this reservation price that will determine the fair research protocol because it represents the best of all available options to the subject. If the researcher’s reservation price is comparable to the reservation price of other producers, then he will offer competitive terms and he will be able to recruit for his
study. If, however, his terms are not competitive, if other producers are able to offer more favorable costs and benefits, then subjects in this ideal clinic will not participate in research and trials will fail to make enrollment for his trial. Again, in this ideal clinic the only fair researcher protocol is one in which the subject’s payoff is similar to the payoff associated with other opportunities. Absent legitimate entitlement claims, anything more favorable to the subject would exploit the researcher, and anything more favorable to the researcher would exploit the subject.

In the sixth and seventh ideal clinics healthy and unhealthy individuals, respectively, will desire to help others. Like all other people in the ideal clinic, they are motivated to transact because they want to help others, and they are looking for the best way to produce the most of this good. Both populations will have the opportunity to pursue this good through participation in research trials, but the trials open to healthy subjects will differ from the trials open to unhealthy subjects. Healthy individuals will be eligible for almost any phase 1 trials, and unhealthy individuals will be eligible for any phase 2, 3, or 4 trial testing an intervention for their condition. Healthy and unhealthy individuals alike will also enjoy a variety of non-research related activities as alternative ways to produce their desired good. For example, they may donate their money or volunteer their time and efforts for other of charitable causes.

An ideal market place for desires to help others, unlike an ideal market place for desires for material goods or health related benefits, may be somewhat difficult to imagine. Many material goods are perceived as commodities, and health related benefits are, at least sometimes, perceived as commodities, so imagining ideal markets and clinics for these types of motivations is not that difficult. Altruism and altruistic behavior,
however, are not normally perceived as commodities. It is important to recognize, though, that placing altruistic behavior in the context of the ideal market does not attempt to commodify altruism, and these two ideal clinics do not seek to produce a “price” at which altruism can be bought and sold. Rather, placing altruistic behavior in the context of the ideal market is an attempt to understand altruistic behavior through a market model and an attempt to determine the terms on which ideally situated candidate subjects will engage in altruistic activities.

Like all other ideal candidate subjects, they will be knowledgeable about the trials, and the other ways in which they can help. They will know the size and identifying characteristics of target group and the severity of the target condition for any given study. They will also know the alternative ways in which they can help others. Given that subjects in this clinic desire to help others, they will prefer the opportunity through which they can expect to offer the most help, both in terms of quantity and quality. If a candidate subject is partial to a particular cause he or she will seek opportunities to help a specific population, and then compare these opportunities on the basis of their cost and benefit. If the candidate subject is not partial to a particular cause then he or she will seek all opportunities to help and then compare these opportunities on the basis of their cost and benefit. If two opportunities promise the same benefit, and one presents a higher cost, then the ideally situated person will select the opportunity with the lower cost. Alternatively, if two opportunities present the same cost, and one show a probability for greater benefit, then the ideally situated person will select the opportunity through which he can expect a greater benefit. The subject’s reservation price in this ideal clinic will be set by whatever charitable opportunity sits highest within the
individual’s preferences structure, regardless of whether this opportunity is a research or non-research related transaction.

As in other ideal clinics, researchers will compete with each other and each will modify his study to be more appealing to candidate subjects. They will minimize the costs associated with their protocol, and adjust their trial design within the range compatible with good science. Researchers, however, cannot alter the target group or target condition of their experimental intervention. This feature of the trial is set by the real world, and researchers bring this with them as a factor in their initial endowment. Therefore, the researcher’s reservation price is set at the most favorable cost and benefits he can offer given the limitations imposed by his particular experimental intervention and the production cost of the trial. If a researcher can offer a trial with costs and benefits that are competitive with, or more appealing than, other charitable opportunities open to individuals in these clinics, then these individuals will enroll in research. If, however, the intervention a researcher is testing cannot match the benefits to others promised by alternative charitable activities, then individuals in these clinics will not enroll in research.

Market and clinic imperfections

Just as real markets often fail to exhibit the perfect competition of the ideal market, real clinics, or the setting in which a real researcher offers a real subject participation in a trial, often fail to exhibit the perfect competition of the ideal clinic. The source of market imperfections can often be traced to a failure to satisfy one or more of the five ideal conditions, and the same holds true for real clinic imperfections. In fact,
real clinic imperfections are almost entirely due to the failure to meet two ideal conditions: first, that the participants be fully informed about the products and services available to them, and second, that there be enough products and services to create competition among both sellers and buyers.

Rarely are participants in the real clinic fully informed and knowledgeable about the products and services available to them, and this happens for two reasons. First, they often fail to understand the information given to them about a particular trial, and second, even if they understood it, this information is often insufficient to provide them with knowledge of the alternative ways in which the goods they desire can be produced. Knowledge requires not only possession of the relevant information, but also an understanding of that information. Though subjects in the real clinic are often presented with the information relevant to the particular study they are considering, evidence shows that many of the subjects do not fully understand this information. These candidate subjects often face any one of several obstacles to understanding, which can include too much information or information presented in an inaccessible manner because the reading level is too high or the text contains too much medical jargon. The way in which the researcher or his staff frame the information, or the subject’s state of mind when receiving the information, can also affect whether a subject will understand the material. For example, subjects seeking therapeutic benefit from a clinical trial, especially those subjects suffering from an otherwise incurable disease, often suffer from the “therapeutic misconception.” The “therapeutic misconception” is the failure of a research subject to appreciate that the goals of clinical research differ from the goals of clinical therapy. Subjects who suffer from this misconception fail to understand that the goal of a clinical
trial is to test an hypothesis, instead, they believe that the goal of a clinical trial is to produce therapeutic benefit. Recent studies show that as many as 70% of candidate subjects mistakenly believe that that enrolling in research trial will, with certainty, provide them with direct therapeutic benefit. 20

Subjects in the real clinic often fail to be knowledgeable for a second reason, not only do they have difficulty understanding the information they receive, but they never receive information about competing products or the alternative ways in which their desired good can be produced. Subjects in the real clinic rarely self-educate, and their only source of information is the researcher or his or her study staff. During the consent process the researcher and his or her staff will provide the subject with the information necessary to make an informed decision regarding whether to participate in this particular trial, but rarely do they educate the subject on matter of trial design and the way in which the phase of development and choice of control will affect the costs and benefits associated with the trial or other trials that may or may not be available. So subjects often do not know that there are different stages of research, that researchers often have a choice of trial design, that other trials could present different, and perhaps more appealing, costs and benefits, or that thy may be able to purchase effective therapy for their condition.

Subjects in the real clinic fail often to meet the ideal knowledge conditions because they do not understand the products offered to them and they are not aware of the alternative ways in which researchers or others could produce their desired good. This failure to understand and lack of awareness will affect the way in which the real clinic functions because both will push a subject’s reservation price to a point that is lower than
a subject’s reservation price in an ideal clinic. When the subject does not correctly appreciate the costs and benefits of a trial he cannot determine whether a trial will satisfy his desires. If the costs and benefits associated with a trial fall below the subject’s reservation price, but he agrees to transact because he thinks the trial meets his reservation price, his reservation price effectively drops to a lower level. Furthermore, subjects who lack awareness of alternatives cannot form an accurate preference schedule. For example, subjects who seek therapeutic benefit will not know that researchers often have a choice of control, and these subjects will not know that they would prefer an active control trial to a placebo control trial. So subjects who are presented with a placebo control trial will not shop for an active control trial. When subjects do not shop researchers have no competition, and when researchers have no competition they will offer the subjects less, and keep more for themselves, and the research terms will not run asymptotic to production costs. Subjects in the real clinic will face options that are less appealing than those in the ideal clinic. Given that a rational, knowledgeable, and motivated subject will refuse to transact on particular terms if a more appealing option is available, the options available to a subject, in part, determine his reservation price. Therefore, subjects in the real clinic will set their reservation price at a the best option available to them, and because the most favorable option in the real clinic will be lower than the most favorable option in the ideal clinic, the real subject’s reservation price will be lower than the ideal subject’s reservation price.

Though the subject’s failure to satisfy the ideal knowledge condition is sufficient for imperfect competition in the real clinic, the imperfection is further compounded by the fact that real clinics often fail to meet the fifth ideal condition that requires, among
other things, enough sellers, buyers, and fungible products to create competition. In real clinics, choice among research trials and choice among candidate subjects is rare. Real clinics almost never have multiple trials testing interventions for the same condition, and given that the state of a subject’s health determines his eligibility for a clinical trial, real clinics almost never have multiple trials to offer a particular subject. Subjects in the real clinic rarely have the luxury to choose among trials for different agents, and never have the opportunity to choose among trial designs for the same agent. Similarly, real clinics rarely have an over abundance of candidate subjects for any given trial. Some researchers have to work very hard to recruit subjects for their studies, and any given study can take years to reach full enrollment.

Like defects in knowledge, this lack of competition pushes the real clinic participant’s reservation price to a level that is lower the ideal clinic participant’s reservation price. In the real clinic some researchers, particularly those who have no competition and will have little difficulty filling their trials, will offer the subjects less and keep more for themselves. Subjects will set their reservation price at their most appealing opportunities, and if lack of competition makes their real clinic opportunities less appealing than those in the ideal clinic, the real subject’s reservation price will be lower than the ideal subject’s reservation price. Similarly, the some researchers, particularly those who will have difficulty filling their trials, will have to offer the real subject more as an incentive to participate. Real researchers will set their reservation price at their most appealing opportunity, and if their only opportunity in the real clinic will cost them more and bring them fewer benefits, then their real reservation price will be lower than their ideal reservation price.
Real clinics often fail to exhibit the perfect competition of the ideal clinic, and this failure is primarily due to the fact that subjects in the real clinic do not to satisfy the ideal knowledge conditions, and the number of researchers offering trials to particular subject groups does not satisfy the conditions for ideal competition, and the number of candidate subjects for any given trial does not satisfy the conditions for ideal competition. The imperfect competition causes both the real subject’s reservation price and the real researcher’s reservation price to fall below their respective ideal reservation prices. In the ideal clinic the ideal subject’s reservation price is the same as the ideal researcher’s reservation price, so when the real subject’s reservation price drops below the ideal subject’s reservation price space is created between the real subject’s reservation price and the real researcher’s reservation price. Even more space is created when the real researcher’s reservation price drops below the ideal researcher’s reservation price. This space creates a bargaining range and, in theory, the real subject and the real researcher will agree to transact on any number of terms. Subjects will agree to participate for benefits as low as their reservation price, and researcher will agree to pay benefits as high as their reservation price, so the unclaimed good created by the difference between their reservation prices constitutes a social surplus. This social surplus could be distributed in any number of ways, and both parties would agree to transact on any distribution. In order to determine whether researchers act exploitatively towards subjects or whether subjects act exploitatively toward researchers we need to identify which of all possible distributions is the just distribution of this social surplus.
Entitlement claims and justice in real clinics

Recall from Chapter 4 that justice in transactions requires that the social surplus be distributed according to the fair market price unless either party can make a legitimate entitlement claim to the surplus. Therefore, the just research terms in the real clinic will be the distribution required by the fair research protocol unless: (1) the real researcher can make an entitlement claim to the space between the subject’s real reservation price and the subject’s ideal reservation price; or (2) the real subject can make an entitlement claim to the space between the researcher’s real reservation and the researcher’s ideal reservation price. A person can make an entitlement claim to the social surplus only if he is entitled to the means by which it was produced. From the fact that he owns himself he is entitled to his labor, skills, and talents, such as foresight, innovation, positioning, and the like. Under certain circumstances, these resources can also entitle him to other previously unowned goods, such as natural resources.21 He can also lay claim to other goods when they are created with things that he owns. So a person can make a legitimate entitlement claim to a social surplus that is created by his labor, skill, talent, or material resources. Sometimes the market imperfections that produce a social surplus are caused by a single factor, and when the person owns that factor he is entitled to the entire social surplus. If, however, the market imperfection is multi-factorial, then he is entitled only to the portion of the surplus attributable to the factors that he owns.

The imperfections in the real clinic that create the social surplus are caused by three things, lack of understanding on the part of the subject, lack of information on the part of the subject, and lack of competition due to an insufficient number of trials in some cases and an insufficient number of subjects in other cases. In most cases, the researcher
cannot lay claim to the subject’s failure to understand the costs and benefits associated with research because this failure does not result from his labor, talents, or other resources. In fact, he often uses his labor, talents, and other resources to produce understanding on the part of the subject. If, despite his best efforts, the subject fails to understand the costs and benefits associated with the trial, then this failure must be attributable to forces over which the researcher has no control, such as the subject’s inherent capacities or state of mind. These things the researcher does not own, thus he can make no entitlement claim to the portion of the social surplus they create. Only if the researcher were to use his labor, talents, and resources to prevent understanding on the part of the subject could he lay claim to the subject’s lack of understanding and the portion of the social surplus it produces.\textsuperscript{22} In such cases, however, the researcher would not be allowed to enroll the subject in research because without this understanding the subject cannot give informed and voluntary consent, and without this consent a researcher cannot conduct research on a subject.\textsuperscript{23}

Market imperfections due to the subject’s lack of information will also fail to yield an entitlement claim on the part of the researcher. A person can have exclusive rights to information only when it is proprietary, that is, only when he created the information with his labor, skills, and other material resources. For example, a researcher can have proprietary rights to the chemical composition of an experimental agent if he created it. However, information that results from collaboration among people, and is presented in public forums such as journals and governmental publications is not proprietary. The information regarding trial design and probabilities of cost and benefit is public information, indeed, it is available in public forums such as governmental
publications and non-profit websites, so researchers cannot claim exclusive entitlement. Thus, they cannot claim the surplus that results when they withhold this information from the subject. Furthermore, even if the researcher were able to claim the information, intentionally withholding it from the subject would again compromise the process of informed consent, and the researcher would not be able to conduct research.

The third source of imperfect competition in the real clinic is an insufficient number of trials in some cases, and an insufficient number of candidate subjects in other cases. A researcher who offers a clinical trial often enjoys a sense of uniqueness because he is the only person in a given locale offering that particular trial. Sometimes there will be other trials testing similar interventions, and other trials recruiting from the same patient population, but such competition is rare. Foresight, innovation, and position can yield entitlement claims to uniqueness, and when a person brings a newly developed product to the market we often recognize his entitlement claim to the benefits of this imperfect competition. In this way, if the experimental intervention proves to be effective, and foresight, innovation, and position on the part of the researcher create uniqueness in the market place, then, when marketing the intervention, the researcher will be entitled to the social surplus created by this market imperfection.

In clinical research, however, researchers are not marketing interventions, but rather offering positions in a clinical trial designed to test the efficacy of an experimental agent. They are, in a sense, offering the candidate subject a job in the production of data, where the wages will be paid in a variety of ways. When inventors and entrepreneurs identify such a niche they are entitled to the social surplus in their transactions with those who purchase their product or service. In their transactions with their employees,
however, in their transactions with those who help them produce the product, they will be no such uniqueness. Justice requires that inventors and entrepreneurs pay their employees the going rate for comparable work, and justice requires that researchers offer their subjects the going rate for comparable work. Researchers, in their transactions with their subjects, cannot make an entitlement claim to the lack of competition, and cannot claim the portion of the social surplus attributable to this market imperfection. Therefore, the researcher cannot make an entitlement claim to the space between the subject’s reservation price in the real clinic and the fair research protocol because he cannot make an entitlement claim to any of the factors that produce this social surplus.

In a similar way we can see that the candidate subject cannot make an entitlement claim to the space between the researcher’s real reservation price and the fair research protocol. The subject can make a claim to this space only if he created the lack of competition that caused it. This lack of competition is caused by the fact that the subject’s body suffers from a particular condition which makes him eligible, perhaps uniquely eligible, for a particular study. Subjects, like all people, are entitled to their bodies, labor, and other products the two things can produce, but they are not entitled to the fortune or misfortune that alters the state of their body and makes them eligible for a particular study. In most cases we do not people blame for their illnesses, and when we absolve them from this kind of accountability we also negate any entitlement claims they might make in this regard. Candidate subjects cannot make entitlement claims to the fact that their body is unhealthy and uniquely eligible for a particular study, so candidate subjects can not make an entitlement claim to the space between the real researcher’s reservation price and the fair research protocol. Therefore, in the absence of any
entitlement claim in the real clinic, a just distribution of the costs and benefits of research will be the fair research protocol set by the ideal clinic.

Conclusion

This analysis shows that the just research terms will depend on many factors, the most important of which are the population from which researchers are recruiting, the requirements for scientific validity, and, in some cases, the value of the data to the researcher and other sponsors, and the quantity and quality of the therapeutic benefit promised by the experimental intervention. The first ideal clinic showed that when recruiting among unhealthy but insured patients who desire therapeutic benefit and suffer from a curable disease the just research protocol is an exceptional experimental intervention with minimized costs. When recruiting from unhealthy, uninsured patients who suffer from a treatable condition, the just research terms will include an active control design if the known intervention is reliably effective and the value of the data will offset the production costs of such a trial. Justice with respect to unhealthy subjects who suffer from an untreatable condition, however, is much less demanding and can be satisfied by a placebo control trial with minimized costs. When recruiting from healthy and unhealthy patients who desire material goods, justice does not require any particular trial design, but instead requires wages that are, at the very least, competitive with other opportunities open to the subject, and wages that are even higher when they will be offset by the value of the data. Finally, when recruiting from altruistic subjects, justice requires that the experimental agent promise benefits to others that are quantitatively and qualitatively equivalent to the benefits promised by other charitable opportunities.
The role of the subject population in determining the just research terms is an important finding because it shows that researchers need to be aware of the desires, goals, and opportunities of the subjects they enroll in their trials. When researchers fail in this regard, they run the risk of exploiting some, or even all, of the subjects in their trial. A researcher who recruits in an indiscriminate manner, or discriminates only according to his eligibility requirements, may exploit some, but not all, of the subjects who enroll in his trial. Even worse, a researcher who is not aware of the requirements for justice in a particular population may needlessly exploit all subjects in his trial simply because he recruited from the wrong population. If terms are exploitative when offered to one population, it does not follow that the protocol will always be exploitative. The same protocol could meet the requirements of justice when offered to a different population. For example, under some circumstances, a researcher who offers a placebo control trial to a group of people who seek treatment for a treatable condition will exploit his subjects. If, however, this same researcher were to run the same trial while recruiting from a population of subjects who are sick and want material goods rather than therapeutic benefit, then, as long as he pays them enough, his study will not exploit his subjects.

The just research terms will, to be sure, determine some trials to be unavoidably exploitative, regardless of the population from which they recruit. These are trial that fail to satisfy the requirements of justice for any subject population. In some cases, this failure will be due to an unwillingness to offer the subject more and in other cases this failure will be due to an inability to offer subjects more. For example, if a trial fails to satisfy the requirements for justice in unhealthy and altruistic subject populations, and the researcher cannot afford to pay subjects a competitive wage, then the exploitative nature
of the trial will be due to an inability to meet the requirements of justice. If however, the researcher could have paid a competitive wage, but refused to, then the exploitative nature of the trial will be due to his unwillingness to meet the requirements of justice.

I begin the next chapter by analyzing current research practices, identifying the ways in which these practices exploit the subject who volunteers for medical research, and then discussing the moral weight and moral force of these exploitation claims. I then determine whether these exploitative practices result from an unwillingness to be just or an inability to be just, and discuss whether this information should have an effect on the moral weight and moral force of the exploitation claims.
Seven

Exploitation in Human Subjects Research

In Chapter 3 we saw that exploitation can refer to a variety of acts, in a variety of settings, but instances of pejorative exploitation are similar insofar as all display two necessary and jointly sufficient features, namely, that the exploiter gains through his transaction with the exploitee, and the exploiter gain in a way that is unjust with respect to the exploitee. It is easy enough to determine whether the exploiter gains, and in Chapter 4 I argued that the exploiter’s gain is unjust with respect to the exploitee just in case the social surplus of the transaction is not distributed according to the fair market price and there are no entitlement claims that justify the distribution. In Chapter 5 I identified the goods and services exchanged in research transactions, and in Chapter 6 I determined the just distributions of these goods and services for different subject populations. In this chapter we will use these standards of justice to determine whether and under what conditions researchers and subjects act exploitatively towards each other.

In the following sections I will examine three common and controversial practices in human subjects research: (1) offering money for participation in trials, (2) recruiting subjects from the clinic, and (3) advertising a clinical trial as a treatment option. For each practice I identify the subject population, present the just research terms for this particular population, and determine whether and under what conditions researchers who engage in

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these practices act exploitatively towards their subjects, and in one case, whether the subjects act exploitatively towards researchers. I conclude that, under certain circumstances, each of the three practices is exploitative, and I use the cases presented in Chapter 1 to illustrate each type of exploitation.

There will, of course, be many more practices that are potentially exploitative, and it would be a mistake to assume that the following analysis creates a comprehensive list of exploitative practices in human subjects research. The purpose of the analysis is not to create a comprehensive list of such practices, instead, the purpose of the analysis is to achieve the following two goals: first, show that these three practices are indeed potentially exploitative, and, second, demonstrate the way in which the model of exploitation and just research terms can be applied to practices in human subjects research to determine whether any given exploitation claim is true. I then discuss the ways in which researchers can avoid acting exploitatively towards their subjects, and I show that, in the context of human subjects research, exploitation carries a moral weight and force such that researchers should avoid exploitative behavior, and, when they fail to do so, others should prevent them from engaging in exploitative behavior.

**Offering money for participation**

Every day in the United States people receive money for their participation in clinical research. For decades investigators have paid subjects for participating in research studies, and some speculate that such payments will become even more frequent as the capacity for discovery and the commercial funding for clinical research continues to grow.\(^1\) People who live near medical centers are often inundated with fliers promising
money for participation in a particular study, and in most major cities similar offers are
played on the radio and advertised in the classified section of the newspaper. Whether a
subject answers such an advertisement, or is recruited by his physician during an office
visit, his participation in the study will likely be rewarded with some amount of money.

Neil Dickert and Christine Grady have discovered that the amount offered to
patients for participation in a clinical study is typically determined by any one of three
models. The first model, the “reimbursement model,” provides payment in the amount
necessary to cover the subject’s expenses. There are at least two versions of this model:
the “expense reimbursement model,” which provides reimbursement for only actual
expenditures such as travel, meals, and parking; and the “wage reimbursement model,”
which provides reimbursement for actual expenses and lost wages or time away from
work. The second model for determining the amount of money offered to the subject is
the “wage payment model.”

The wage-payment model operates on the notion that participation in research
requires little skill but does require time, effort, and the endurance of undesirable
or uncomfortable procedures. ... Participating in research is similar to many
other forms of unskilled labor in that it requires little skill or training, may involve
some risk, and often involves relatively little “labor.” The wage-payment model
thus involves the payment of subjects on a scale commensurate with that of other
unskilled but essential jobs. ... [this] would lead to the payment of a fairly low,
standardized hourly wage, augmented by increases for particularly uncomfortable
or burdensome procedures.

According to the wage payment model all subjects, for all studies, are paid the same
hourly rate for the work they do while participating in studies, with added and variable
payments determined by the specifics of the protocol. The wage payment model differs
from the wage reimbursement model in two important ways: first, the reimbursement
model will pay individual subjects at the rate they command in their other, non-study
related work, which could lead to different hourly wages for subjects in the same studies;
and, second, payments determined by the wage-reimbursement model do not reflect the level of discomfort or burden associated with a particular protocol. The third model presented by Dickert and Grady, the “market model,” uses money as a recruitment incentive for filling the study and sets the payment amount at the level required to achieve this goal.\(^6\)

The principle of supply and demand determines whether and how much subjects should be paid for participating in a given study at a specific site. ... Use of the market model would probably result in high payment for participation in studies that offer subjects no prospect of direct benefit but involve risky or uncomfortable procedures. Payment may also be high when investigators want to recruit subjects very quickly, or when few people are eligible to participate.\(^7\)

Currently all three of these models are in use, and the model used for any particular study will depend on a number of factors, including the budget of the trial. Trials sponsored by non-profit institutions and agencies, and trials with low budgets might use the expense reimbursement model, whereas commercially funded studies with large budgets and an incentive to enroll quickly might use the market model.

Depending on the model used, the amount of money offered to a particular subject for participation in a given trial can vary. Take, for example, Adam’s phase 1 study for a pain reliever delivered through nasal spray. Recall from Chapter 1 that the study takes approximately 33 hours and involves a screening visit, an extended stay at a phase 1 testing facility, administration of the pain reliever via nasal spray, and 13 blood collections. Assuming meals are provided, and the parking is free, payment according to expense reimbursement would likely include only transportation expenses for his two round trips to the facility, which would be $6 if Adam lives 5 miles away, drives his own car, and is reimbursed at a rate of $0.30 per mile.\(^8\) According to the wage reimbursement model Adam might not be paid anything since he is currently unemployed, whereas
payments to other subjects could exceed $660 depending on how much they command in hourly wages. On the wage payment model, this type of work might lead to payment of $10 per hour, with an added $10 for the inconvenience of taking the drug, and an additional $110 for the eleven blood collections, for a total of $450. If the money were used only as an incentive to recruit, then the amount could vary dramatically depending on how and where the recruitment takes place. If advertisements were placed in the *New York Times* or *The Wall Street Journal* then investigators might need to offer an amount in the thousands, but if they advertise in bus stations and homeless shelters then perhaps the 5 free meals might be enough incentive and no money would be offered at all. Indeed, the $75 dollar incentive was enough to secure Adam’s participation.

Application of these three models shows that current practices can lead to dramatically different payment amounts for the same study, indeed, both the reimbursement and market models justify different payment amounts for individuals enrolled in the same study. Dickert and Grady recommend that we reject the wage reimbursement and market models for several reasons, primary among them is the fact that they allow such inequality within a study. Equality among subjects is important, they argue, and subjects who make the same contribution should be paid the same amount for their participation. Additionally, they think that the market model, in particular, is problematic because it encourages competition among researchers for subjects and this leads to escalating costs for conducting research. Dickert and Grady argue for the wage model on the basis that it guarantees equal treatment of research subjects, it controls competition among researchers, and it controls the cost of conducting research. I agree with Dickert and Grady that we should reject the wage reimbursement
and market models, but not because they escalating research costs. I argue that we should reject the wage reimbursement and market models because they are potentially exploitative to both subjects and researchers.

Both the wage reimbursement and the market models are potentially exploitative to subjects because they allow pay-off schedules that are unjustly low to the subject of research. When money is offered for participation then people who desire money will enroll, and these models do not always produce pay-off schedules that meet the criteria for justice in research transactions for this particular subject population. Recall from Chapter 6 that the just research terms for healthy and unhealthy subjects motivated by money includes wages that are competitive with other opportunities open to the subject. Research conducted on terms that do not provide the subject with this amount fails to meet this condition of justice. When this happens the researcher will gain in a way that is unjust to the subject and thus the researcher will act exploitatively towards the subject.

The pay-off amounts determined by the wage reimbursement and market models could coincide with the amount required by the just research terms, but if they do it would only be by accident. These models could also justify any number of other pay-off schedules, some above and some below the pay-off required by the just research terms. If the pay-off is below the amount required by the just research terms, then the researcher acts exploitively towards the subject. If the pay-off is above the amount required by the just research terms, then the researchers do not act exploitatively towards the subject, though such a pay-off might create other problems, for example, seduction, or exploitation of the researcher by the subject. When a researcher has difficulty filling his trial the market model will justify a pay-off that is larger than the incentive contained in
the just research terms. When a subject enrolls in the trial and accepts the incentive the subject gains in a way that is unjust with respect to the researcher and thus exploits the researcher. Neither the wage reimbursement model nor the market model is linked in a necessary way to the conditions for justice, so even though they might produce terms that are just, they also might produce terms that are not just. In this way both of these practices allow the researchers to act exploitatively towards the subject. Alternatively, the wage model will always produce an amount that meets the criteria for justice because both use the same method: they both require an amount of money consistent with wages paid for similar work. In this way the wage model is a sufficient condition for justice, and any research that pays according to the wage model will be just and non-exploitative.

This analysis helps us understand our initial uneasiness with the cases of both Adam and Bob. Though neither case had significant problems with coercion, seduction, or commodification, we now see that both cases have a problem with exploitation. In Adam’s case the amount of the payment was determined by the market model, and the market model produced a pay-off amount that was lower than the wage model, and the pay-off was therefore exploitative. As the previous analysis shows, the just wages for Adam’s participation in the phase 1 study would be $450, but the researcher paid Adam only $75. The amount Adam was actually paid was determined by the market model, and when advertising in the help wanted section the incentive of $75 was enough to reach enrollment. Whenever a researcher recruits among unemployed potential subjects the amount determined by the market model will likely fall short of the amount determined by the wage model and the just research terms. Indeed, the $75 researchers offered to Adam is significantly below the $450 required by the just research terms, so the
researcher gains from this transaction in a way that is unjust with respect to Adam and the researcher acts exploitatively towards Adam.

In a similar way we can see that the researcher also acts exploitatively towards Bob. Bob was motivated solely by monetary gain, so the just research terms will require wages commensurate with similar work. Bob's participation in the study required 4 office visits totaling approximately 6 hours, 4 blood draws, 2 sinus taps, and 10 days worth of medication, plus the risk of suffering the discomfort associated with untreated sinusitis. An analysis similar to above example will show that Bob should be paid $60 for his time, $40 for the blood draws, perhaps $50 for each of the sinus taps, $100 for the inconvenience of taking medication for 10 days, and, if we assume that suffering from sinusitis is worth $50 a day, and Bob has a 50% chance of being randomized into the placebo arm of the trial, an additional $250 for the risk of suffering the discomfort of untreated sinusitis. The wage model, and the just research terms, both require that researchers pay Bob $550 for his participation in the study, but instead they paid him only $60. This $60 payment may well be justified by the wage reimbursement model, especially if Bob's manual labor commands a wage of $10 per hour. Bob's participation in the study, however, requires enduring discomfort that far exceeds the value captured in 6 hours of manual labor, and we see that a payment of $60 is too low. Whenever a subject works a job with wages lower than what he contributes to the study the wage reimbursement model will result in a payment that is too low to satisfy the conditions for justice. In Bob's case the researcher used the wage reimbursement model and paid Bob only $60, when the just research terms require that he be paid $550, so the researcher
gains from this transaction in a way that is unjust with respect to Bob and the researcher acts exploitatively towards Bob.

Again, some might claim that there is no exploitation in either of these cases because both Adam and Bob volunteered, and both gained through their participation in the research. Recall from Chapter 3, though, that neither failure to gain nor failure to consent is a necessary condition for exploitation. Exploitation can occur even if the exploitee gains from the transaction, as long as the exploiter’s gain is unjust with respect to the exploitee. Likewise, exploitation can occur even if the exploitee consents to the transaction, because people sometimes suffer from vulnerabilities that lead them to consent to a transaction despite the fact that they will be treated unjustly. Indeed, both Adam and Bob suffer from such a vulnerability, and it is this vulnerability that makes exploitation possible. Both Adam and Bob labor in a market that functions under conditions of imperfect competition among employment opportunities. Though both seek full-time employment, Adam can not find any at all, and Bob can secure only part time work. Under conditions of perfect competition employers and researchers compete against each other, and this mechanism forces them to offer competitive wages otherwise they will fail to secure workers or recruit subjects. When there are not enough employment or study opportunities then researchers do not have to compete with other researchers or employers, and they can offer non-competitive wages and subjects will enroll. Subjects like Adam and Bob will enroll, and they will give voluntary consent, because they need money and they have no other options. They will fall victim to consensual mutually advantageous exploitation.
Since many employment and research markets suffer from imperfect competition, and it is not likely that these imperfections will be corrected, we cannot endorse a payment model that allows researchers to take advantage of the vulnerability this creates in potential subjects. The wage payment model ensures that researchers treat potential subjects justly regardless of whether they suffer from such vulnerabilities. Neither the wage reimbursement model nor the market model can assure just treatment when such vulnerabilities exist. Since the wage payment model, and only the wage payment model, prevents researchers from benefiting from these market imperfections and the vulnerabilities they create, only the wage model should be used to determine the amount of payment a subject receives for participation in a research study. Studies that use either the wage reimbursement model or the market model are potentially exploitative.

**Recruiting in the clinic**

Using money as an incentive to participate has become a common practice in subject recruitment, and at the same time a different but related trend has emerged: physicians who “wear a second hat” as investigator and recruit subjects from their own patient base. In recent years the research environment has become more commercialized and more competitive, with increases in both the number and the complexity of clinical trials. Monetary incentives have not kept pace with the demand for subjects to fill trials in a timely manner, so researchers and sponsors are using a variety of other recruitment methods, including the recruitment of physicians who can draw from their own patient base and professional networks.
Traditionally, sponsors and investigators have conducted clinical trials primarily in university hospitals or academic medical centers, but increasingly this type of research occurs in physician’s private practices. Contract Research Organizations or Site Management Organizations recruit privately practicing physicians to be the primary investigator for a particular site of a national study. These physicians draw from their own patient population, and get referrals from colleagues, and run the study according to the national protocol. For example, a physician running a bronchitis study will have an opportunity to meet with every patient who comes to his clinic complaining of bronchitis. These are patients who might not hear advertisements on the radio, or see the fliers, or read the classified section of the newspaper. This type of practice allows pharmaceutical companies and other sponsors to enroll subjects and fill their studies quicker than if they recruited only through university hospitals and advertisements.

... when asked what sponsors are looking for in placing a research study, both sponsor representatives and investigators told us that access to eligible patients is the key. Sponsors seek out investigators and sites with large patient populations when looking to place trials.15

This leads to an increasing number of privately practicing physicians “wearing a second hat” as clinical investigator and recruiting their own patients as subjects for a clinical trial. Bioethicists have long recognized that this practice of playing dual roles poses challenges to the consent process and creates a conflict of interest between the physician’s fiduciary duties to his patients and his duties as a researcher.16 I argue that, in addition to these problems, this practice is also potentially exploitative.

This practice is potentially exploitative because it allows pay-off schedules that are unjust with respect to the subject of research. When patients make an appointment to see their physician we can assume they do so because they are sick and they desire
therapeutic benefit. Recall from Chapter 6 that the just research terms for unhealthy patients motivated by a desire for health related benefits varies depending on certain features of the individual subject’s initial factor endowment. Specifically, the just research terms will depend on whether the individual suffers from a treatable condition and whether the individual has health insurance or can otherwise access medical care. Focusing only on the group of subjects who suffer from a treatable condition, it is easy to see how this practice could be potentially exploitative for both insured and uninsured subjects.

When insured patients seek health related benefits for a treatable condition the only research terms that are just are those in which the experimental intervention promises an exceptional benefit. No insured subject who wants to get better would choose to participate in a clinical trial of an unexceptional intervention because she could satisfy her preferences with fewer costs if she pursues treatment through the standard commercial venues. If her choices are, on the one hand, a single office visit and a single trip to the pharmacy, and, on the other hand, several office visits and medically unnecessary procedures, no rational person who desires only health related benefits would choose the latter. Therefore, researchers conducting a study on an unexceptional intervention act exploitatively when they recruit and enroll an insured subject who suffers from a treatable condition and desires only therapeutic benefit.

It is possible that the patient’s initial and only desire was for health related benefits, but when presented with the opportunity to participate in a trial the patient became more altruistic and also desired to help others, perhaps desired this even more than health related benefits. If the individual’s primary motivation is altruism then justice
is determined by a different set of criteria, and the trials offered to a person in this setting will likely meet those conditions. Likewise, if the individual’s primary motivation is a desire for tangible benefits, such as strengthening her relationship with her physician, then justice is determined by a different set of criteria and the trials offered to a person in this setting will likely meet those conditions. One cannot, however, simply assume that a person’s desires have changed without good evidence. A patient’s unsolicited presence in the clinic is prima facie evidence that she desires therapeutic benefit, so we need evidence to contrary to supplant this initial and supported conclusion. Absent a statement in which the person clearly states that she desires to help others more than she desires to get better, or that she simply desires to participate in the trial, for whatever reason, more than she desires to get better, we should regard research on insured subjects with a treatable condition who are recruited by their physician in the clinic as exploitative in all cases except those in which there is a significant difference between the benefits promised by the experimental and the benefits promised by the approved intervention.

This analysis helps us understand our initial uneasiness with Catherine’s case. Recall from Chapter 1 that Catherine suffers from a urinary tract infection and she desires treatment for her condition. Catherine is a busy woman, is fortunate to have insurance, desires nothing other than to get better, and could satisfy her desire with the least amount of cost if her physician simply diagnosed her condition and gave her a prescription. Instead, she enrolls in a trial that will require three additional visits, three additional urine collections, and four blood draws. Catherine does want to help others, but she already does this in ways that cause less interference in her life. She volunteers at her children’s school when she can, she coaches her daughter’s fifth grade volleyball team, she is active
in her church, and she and her husband donate to their favorite charities on a regular
basis. She enrolls in this trial not because she wants to contribute to the advancement of
medicine by participating in a clinical trial, but simply because her physician offered.
She trusts that her physician will do nothing but act in her best interest, so, she concludes,
this trial must be in her health related interests and she should enroll. We know that
participation in the trial is not in her interests, we know that her health related interest
could be served just as well by pursuing care through the commercial venues. Her
participation in the trial presents costs, but no gain when compared to her alternatives.
The researcher, however, gains through her enrollment. Indeed, given Catherine’s
desires, and the fact that the experimental intervention is unexceptional, there are no
terms under which her participation in clinical research would produce a pay-off that is
just with respect to her, so the researcher’s gain is unjust with respect to her, and he acts
exploitatively.

This exploitation is mutually beneficial because, even though Catherine
experiences a net gain that is lower than her best alternative, both Catherine and the
researcher gain through their interaction with each other. It is not clear, however,
whether this type of mutually beneficial exploitation is consensual or nonconsensual.
The vulnerability that leads Catherine to assent to a transaction in which she will be
treated unjustly is a vulnerability that also compromises the quality of her consent.
Catherine assents to participate in the trial because she suffers from the “therapeutic
misconception,” that is, she fails to appreciate that the goals of clinical research differ
from the goals of clinical therapy. She believes that her physician recommended
participation because it was the best way to treat her condition; and she believes that the
trial is a treatment option designed for people like her. Recall from Chapter 2 that consent requires, among other things, that the agent act with full understanding and clearly Catherine fails to meet this requirement. If, however we move away from strict requirements and use the sliding scale of risk-relative competence, given the minimal risk present in the trial, her consent, though compromised, might still be valid. Thus it is likely that the researcher exploits Catherine in a way that is consensual and mutually advantageous.

Bioethicists have long been troubled by the therapeutic misconception and its effect on the validity of consent. Indeed, the therapeutic misconception does pose problems for the consent process, but I argue that its problematic effect goes beyond the consent process and into the realm of justice. As we saw in the case of Catherine, and I am certain there are many others, the therapeutic misconception can lead to exploitative behavior on the part of researcher. When researchers recruit from their patient population during unsolicited visits to the clinic their behavior is likely exploitive unless they have good evidence that the subject’s primary motive is something other than a desire for health-related benefits. If the researcher does not clarify the motive then, in cases where the patient is insured and suffers from a treatable condition, the researcher likely acts exploitatively towards the subject.

**Advertising trials as an opportunity for treatment**

Recruiting strategies for clinical trials include monetary incentives, recruiting in the clinic, and marketing the study as a new treatment option to people who are sick.\(^{17}\) This type marketing includes advertisements in media outlets such as newspapers, the
radio, the internet, television, or posters in such places as public transportation or hospitals. Indeed, some marketing efforts also include press releases or news segments that present trial information as a news. Sometimes these marketing campaigns are national and include a toll-free number where a potential subject will be directed to a local site, and sometimes the campaigns are only local. Regardless of whether the campaign is national or local, the campaign will make a special effort to target the appropriate disease advocacy and awareness groups.

This practice of intentionally blurring the line between research and therapy is becoming increasingly more common because it is effective in recruiting subjects who might not be reached by other methods such as monetary incentives and recruiting in the clinic. This population includes sick and insured patients whose regular physicians do not participate in or refer to such trials, and sick patients who have no insurance and are looking for free access to health care. This type of misleading advertising has already received much attention from ethicists who are concerned with its effect on the validity of consent, but I argue that we should also be concerned with its potential for exploitation.

This type of advertising is used to market trials for new treatments for both conditions that have standard and effective treatments and conditions that do not. When the target condition has a standard and effective therapy sometimes these trials are active controlled and sometimes they are placebo controlled. I argue that advertising an active or placebo controlled trial as a treatment option for a condition with a standard effective treatment to insured patients is potentially exploitative, unless there is a significant difference between the benefits promised by the approved intervention and the benefits promised by the experimental intervention. Likewise, advertising a placebo controlled
trial as a treatment option for a condition with a standard and effective treatment to uninsured patients is also potentially exploitative.

When patients answer an advertisement for a new treatment option we can assume they do so because they are sick and they desire therapeutic benefit. Recall from Chapter 6 that unless the experimental intervention is exceptional there are no research terms that are just for insured unhealthy patients who suffer from a treatable condition when their primary motivation is therapeutic benefit. When these patients respond to the advertisement and are enrolled in a trial, regardless of whether the trial is active or placebo controlled, they are exploited in much the same way as Catherine. Patients can suffer from the therapeutic misconception even if they are not recruited by their physician. It is likely that patients who respond to these advertisements fail to understand the true nature of the research, and fail to understand that they could obtain similar treatment with less inconvenience if they simply went to their physician. As in Catherine’s case this is mutually advantageous exploitation because both parties gain, and though the therapeutic misconception compromises the quality of the consent, it is likely that the exploitation is consensual.

When uninsured individuals who seek therapeutic benefit answer these advertisements, the research is potentially exploitative if the trial uses a placebo control design when an effective therapy exists. Assuming that individuals who answer advertisements for treatment options desire therapeutic benefit, Chapter 6 showed that the just research terms for this population will consist of the highest possible health related benefit researchers can offer to subject with minimized costs. The actual terms of the just research protocol will vary according to two factors: first, the effectiveness of the
approved treatment and thus the suitability of an active control; and second, the value of
the data to the researcher or other sponsoring groups. If the approved treatment is
reliable, and if the value of the data will offset the costs of producing an active controlled
trial, then the just research terms will require an active controlled trial with minimized
protocol costs. When researchers advertise a study as a treatment option, and they use a
placebo control design despite the existence of a reliable treatment, and they recruit
uninsured individuals then the research is exploitative.

People often think that placebo controlled studies are permissible in this
population, despite the existence of a reliable therapy, because they present the prospect
of a health related gain to the subject. These subjects are uninsured, and could not
otherwise gain access to treatment for their condition, and the study offers them a chance
for therapeutic benefit because in the study the subject has a chance of receiving a
therapeutic dose of the experimental medication. It is true that in these studies the subject
does enjoy the prospect of gain. This prospect of gain, however, does not make the study
non-exploitative, it merely makes the exploitation mutually advantageous rather than
harmful. In this type of exploitation the subject gains, but not as much as she should.
The researcher gains in a way that is unjust with respect to subject and therefore the
research acts exploitatively towards to subject.

This type of mutually advantageous exploitation will likely be consensual, but the
vulnerability leading the subject to engage in an unjust transaction will depend on the
reason the subject enrolls in the trial. Uninsured patients, like insured patients, can suffer
from the therapeutic misconception and enroll in the trial because they believe it is their
best treatment option. When the subject’s decision to enroll is guided by this type of
false belief her consent is compromised but likely valid. The subject’s decision to enroll can also be guided by other reasons. For example, a subject might understand that the purpose of the trial is to test a hypothesis, and she might understand that she can get better care through commercial venues, yet still decide to enroll because she has no other choice. The subject might recognize that a placebo controlled is the best of the available options for seeking treatment. When the decision to enroll is guided by this reason the vulnerability from which the subject suffers is imperfect competition. Potential subjects who suffer from a treatable condition but cannot trade money for medical care often have very few options through which to seek care, and there are an insufficient number of sellers for this type of transaction to create competition. Under conditions of perfect competition researchers would compete against each other and this competition would force researchers to offer competitive benefits, otherwise they would fail to recruit. When there are not enough studies available to the subject the researchers do not have to compete and they can offer non-competitive benefit packages. Despite the fact that the benefit packages are non-competitive, indeed, unjustly low, subjects will still enroll, with voluntary consent, because they want therapeutic benefits and have no other options.

This analysis helps us understand our initial uneasiness with Deborah’s case. Recall from Chapter 1 that Deborah is self-employed, without a great deal of disposable income, she is uninsured, and she suffers from urinary incontinence. There are effective and reliable therapies for her condition, and she would like to treat her condition, but she cannot afford the medication. She is ecstatic when she sees a television advertisement recruiting subjects for a clinical trial testing a new delivery method for an established urinary incontinence treatment. Participation in the trial will be inconvenient, as it
requires 5 office visits, 5 blood draws, 5 urine collections, 1 EKG, and twice daily entries into a personal diary every day for 12 weeks. Deborah, however, wants free medication, and she is willing to endure the inconvenience of a clinical trial to get it. She is disappointed that she will have only a 50% chance of receiving a therapeutic dose, and she would prefer an active control trial, but because she does not have that option she enrolls in this placebo control trial.

When we realize that the manufacturer of the medication expects this new method of delivery to be successful and highly profitable, and could have run an active control study but decided not to, we realize that the manufacturer is exploiting Deborah’s lack of treatment options. The manufacturer gains through Deborah’s participation, and though their terms promise a chance of benefit, they promise less than they could, indeed, less than they should, so the manufacturers gains in a way that is unjust with respect to Deborah. In this study the researchers act exploitatively towards Deborah.

As long as we allow free access to health care to be a benefit of research we again open the possibility of exploitation. When there is an effective and reliable treatment for a particular condition, it is not enough for a study to merely offer a chance to receive therapy. Any study that is not active control will exploit those who participate because they desire free access to health care.

**Evaluating exploitation claims**

Offering money as an incentive to enroll, wage reimbursement, recruiting within the clinic, and advertising a study as a treatment option are all potentially exploitative practices, and when combined with a certain set of circumstances these practices will be exploitative. The sample cases in the above analyses are clearly exploitative, but not all
cases will be so clear and easy to evaluate. These sample cases were fictional, and when constructing a fictional case the author has the luxury of stating certain features as fact, when in reality it can be very difficult to determine whether these features are present. Exploitation claims therefore can be very difficult to evaluate in real world scenarios. In particular, two problems arise that make evaluation particularly difficult. First, subject populations are often heterogeneous and any given population will include subjects with different motives. If a practice is potentially exploitative only when combined with a particular subject motivation, it can be difficult to determine whether a research practice is, on the whole, exploitative. Second, subjects often function according to hybrid motives, and this also makes exploitation claims difficult to evaluate because the terms of justice in research are based on single motives.

Subjects participate in research for a variety of reasons and subject populations for any given trial are often heterogeneous with respect to their motives. Indeed, in any given population all three motives might be expressed. For example, even though money is offered for participation in Bob’s placebo controlled sinusitis study, participation is not limited to materially motivated subjects. Some uninsured subjects might enroll in the study because it offers a chance for free health related benefits, and some altruistic subjects might enroll just because it seems like a good way to help others. This heterogeneity among subject motivations can make exploitation claims difficult to evaluate because the exploitative nature of a clinical trial depends on a particular subject motivations, and we cannot know for sure that a particular subject, or even any subject in the trial, is motivated by this desire.
The preceding analysis showed only that the practices invite exploitation, and the problem presented by the heterogeneity of subject populations means that we cannot make sweeping and general claims of exploitation in human subjects research. Even though these practices invite exploitation, we cannot say with any degree of certainty that a researcher who engages in one such practice exploits all, or even any of his subjects. For example, if a researcher conducts a placebo controlled trial, but offers money as an incentive in an amount consistent with a just wage, then he might exploit some but not all, of his subjects. He acts exploitatively towards those who enroll for therapeutic benefit, but not those who enroll for the money. Even though the model cannot determine whether sweeping and general claims of exploitative behavior are true, the model is still useful because we can determine whether sweeping and general claims of non-exploitative behavior are true. Certain research protocols can be exploitative when paired with particular conditions, but research protocols can also be designed so that they are not exploitive when paired with any condition. That is, a researcher can avoid acting exploitatively towards any and all subjects by offering terms that will be just with respect to all subjects regardless of their motive. For example, a clinical trial would be non-exploitative, regardless of circumstances, if it pays the subject a just wage, is active controlled, and would satisfy the altruistically motivated subject in terms of helping a population that is sufficiently large, or alleviating a condition that is sufficiently severe, or both. It might be the case that we never know the motivation of a particular subject, but we can know that a researcher does not act exploitatively towards any of his subjects when he offers terms that are just with respect to all.
Even if a researcher cannot or does not want to offer terms that are just with respect to all, there are things that can be done to avoid certain types of exploitation, or at least make that type of exploitation less likely. If a protocol will exploit subjects with a particular motivational structure, then the protocol can be designed to exclude subjects motivated by these desires. For example, if a researcher cannot offer a just wage then he will exploit any subject motivated by material desires. If the researcher designs the protocol in a way that provides no money for participation, then subjects who are motivated by material desires will not enroll. Despite the fact that we do not know the motivations of the subjects who enroll in this trial, we can say, with a reasonable degree of certainty, that the researcher does not exploit material need.

Even if a researcher is limited in his trial design, and cannot completely exclude subjects with particular motivational structures, selective recruiting practices can minimize the potential for exploitative behavior. If a given protocol will exploit subjects with a particular motivational structure, then selective recruiting practices can discourage, or at least not encourage, subjects motivated by these desires. Though this does not lend truth to any claims, it will make exploitative behavior less likely. For example, if a researcher runs a placebo control trial when there are effective and reliable therapies available, then the researcher will act exploitatively towards any subjects motivated by health related desires. If the researcher refrains from advertising the study as a treatment option then these subjects are less likely to enroll, and he is less likely to act exploitatively towards any given subject.

Despite the fact that there is heterogeneity among subject motives presents us with a problem of knowledge in that we will have difficulty knowing any given subject's
motivation, we can make determine the truth of many exploitation claims. We determine whether a generalized claim that a research program does not engage in any exploitative behavior is true, we can determine whether a claim that a research program does not engage in a particular type of exploitative behavior is true, and we can determine whether a claim that certain types of exploitation are less likely is true. In some cases we can even overcome this problem of knowledge and determine whether claims that a researcher acts exploitatively towards a particular subject are true. The problem of knowledge that we encounter when evaluating individual exploitation claims can, in some cases, be overcome by more rigorous screening and enrollment processes.

Researchers can probe and clarify subject motivations in the process of interviewing and consenting subjects for enrollment in a particular trial. When researchers merely present information about the protocol and wait for a subject’s decision they might not know why the subject consents, but if researchers also engage in a dialogue about motivations they might discover why a subject wants to participate, and the researcher will then be able to determine whether he will act exploitatively towards the subject. For example, when recruiting an insured patient who suffers from a treatable condition for a placebo controlled trial, the researcher can ask the patient if she would be willing to forgo therapy for the advancement of medicine. If the patient answers in the negative then the researcher knows the patient’s motive is a desire for therapeutic benefit, and the researcher knows that he will act exploitatively if he enrolls her in the trial. More rigorous interviewing and consenting processes will enable the evaluation of individual exploitation claims, and such practices might also prevent the exploitation of individual subjects.
Another difficulty in evaluating exploitation claims is that subjects often function according to hybrid motives. It is possible that a subject might not have a single reason for participating in a trial, indeed, he might have several reasons for participating in a trial. For example, a subject might participate for material gain, but also for altruistic reasons. Indeed, he might choose this employment opportunity rather than another simply because it offers the chance to advance medicine and help others. In some cases hybrid motives will not present a problem in evaluating exploitation claims. For example, when a study is exploitative regardless of the subject's motive, then hybrid motives will not affect the truth of the exploitation claim that follows. There are, however some cases in which hybrid or multiple motives will present a problem in evaluating exploitation claims. When a research program will exploit the subject who acts according to a certain motive, but will not exploit subjects who act according to a different motive, it will be difficult to determine whether researchers act exploitatively towards a subject who acts according to both motives. For example, if a trial offers money as an incentive, but pays less than a just wage, it is difficult to determine whether the researcher acts exploitatively towards a subject who is motivated by a desire for money and a desire to help others.

When a subject is motivated by multiple motives the motives can interact with each other in different ways. Sometimes each motive will play an equal role in guiding action, other times one motive may be the primary reason behind an action, and the other motives may be secondary or reinforcing reasons for action. If the motives are ordered, then it might be the case that the secondary motives are reinforcing motives, but not strong enough to motivate on their own. For example, it may be that a subject's primary
motivation is a desire for money, and his secondary motivation is altruism, but he would not participate for altruism alone if there were no money involved. Indeed, research on subject motivations shows that in many of the cases where subjects expressed multiple motives, one motive was clearly primary. Kass et al found that when therapeutic benefit is possible, a desire for therapeutic benefit was almost always the primary motivation, and non-health-related desires often function as secondary motivations for participation in research. Kass and Sugarman reported that several subjects conveyed the hope that if they did not derive benefit personally, others would be helped by the research. In these cases, where one motive is primary and the others are merely reinforcing, the primary motive should be the motive according to which exploitation claims are evaluated. Unless a motive is strong enough to guide action on its own, it should not be the basis of an exploitation claim.

If the subjects motives are not ordered, all motivate equally, and each is strong enough to motivate action on its own, then a study is not exploitative unless it is exploitative when judged against every motive. If a research program is exploitative when judged against one of many motives, but the subject would perform the same act even if this motive were absent, then it is not clear that the research acts exploitatively towards the subject. Alternatively, if the study is non-exploitative when judged according to a motivation strong enough to guide the subject's action on its own, then the study should be non-exploitative. When motives function equally, and each is sufficient motivation on its own, then research is exploitative only when there is no motive according to which the researcher treats the subject justly.
In order to evaluate exploitation claims thoroughly and accurately, we need more information than we currently have on subject motivations for participating in research. Much research has been done on subject motivations in phase 1 studies, particularly phase 1 oncology trials and phase 1 studies that recruit healthy volunteers, but we do not thoroughly understand the interplay between motives when these subjects express multiple motives. We know even less about the motives of subjects who enroll in phase 2, 3, and 4 studies. We do not know whether they function according to a single motive, or multiple motives, and if they have multiple motives, we do not know whether they are ordered or equal. This type of information would be useful when evaluating exploitation claims, and useful when determining whether a research trial is potentially, or indeed, likely to be, exploitative. Despite the fact that we lack this important information, we can still evaluate several types of exploitation claims. We can determine whether a research is non-exploitative, whether a research program does not engage in a particular type of exploitative behavior, whether a certain type of exploitative behavior is more or less likely, and in some cases we can even determine whether a researcher acts exploitatively towards a particular subject.

**Preventing exploitation**

There are two ways researchers can avoid acting exploitatively towards the subjects of medical research. First, a researcher can offer a pay-off schedule that will be just with respect to all subjects, regardless of their motivations. Researchers can avoid acting exploitatively towards subjects by offering terms that are just with respect to any and every subject, regardless of their motive. A just pay-off to all subjects will require a
benefit package that includes a just wage for those seeking monetary gain, the highest possible health benefits for those seeking therapeutic benefit, and the highest possible benefit to the target population for those seeking gratification in helping others. A just pay-off will also include minimized protocol costs. If researchers offered pay-offs that were just to all then exploitative behavior would be avoided because all would be treated justly, regardless of any given subject's motive.

Some researchers simply cannot offer such generous terms. For example, some researchers simply do not have the funds to run an active control trial when effective and reliable treatment exists. Similarly, some researchers simply do not have the funds to pay all subjects a just wage for their time and effort. Other researchers, though they may be able, will not want to offer such generous terms. For example, a researcher might not want to fund an active control study, and he might not want to offer a just wage because such expenditures will compromise his profit margin. If a researcher can not or does not want to offer terms that are with respect to all, then he can avoid acting exploitatively by using selective recruiting practices. If terms are exploitative when offered to one population, it does not follow that the protocol will always be exploitative. The same protocol could meet the requirements of justice when offered to a different population. For example, a researcher who offers a placebo control trial to a group of people who seek treatment for a treatable condition will act exploitatively towards his subjects. If, however, this same researcher were to run the same trial while recruiting from a population of subjects who are sick and want material goods rather than therapeutic benefit, then, as long as he pays them a just wage, he will not act exploitatively towards his subjects.
The second way in which a researcher can avoid acting exploitatively towards the subjects of medical research is to selectively recruit and enroll only those subjects to whom he can offer just transaction terms. Selective recruiting includes at least three practices. First, a researcher can design a protocol to effectively exclude subjects with certain motivations. For example, if researchers can not, or does not want to pay the just amount of money for people who are materially motivated, then the researcher can still conduct his research in a non-exploitative fashion if he excludes subjects with this motivation by not offering any money at all. When there is no money exchanged between any of the parties to research, there can be no monetary exploitation. Second, a researcher can exclude subjects with certain motivations by requiring other motives as part of their eligibility criteria. For example, a researcher who runs a placebo controlled trial when effective and reliable therapy exists will not act exploitatively if he requires altruism as the primary motivation for a subject’s enrollment and excludes all subjects who profess as their primary motive health related benefits. Third, a researcher can alter his recruiting methods so that he does not solicit or encourage the participation of a subject with exploitable motives. For example, if a researcher runs a placebo control trial when effective and reliable therapy exists, but does not advertise as a treatment option, and instead advertises the trial as a way to make money, then he decreases the likelihood that he will act exploitatively towards his subject. In these three ways a researcher can avoid, or at least decrease the probability that he will act exploitatively towards his subjects. Insisting that researchers adhere to these practices is the way that others can prevent a researcher from acting exploitatively towards his subjects.
The role of the subject population in determining the just research terms is an important finding because it shows that researchers need to be aware of the desires, goals, and opportunities of the subjects they enroll in their trials. When researchers fail in this regard, they run the risk of exploiting some, or even all, of the subjects in their trial. A researcher who recruits in an indiscriminate manner, or discriminates only according to his eligibility requirements, may exploit some, but not all, of the subjects who enroll in his trial. Even worse, a researcher who is not aware of the requirements for justice in a particular population may needlessly exploit all subjects in his trial simply because he recruited from the wrong population. It is important that researchers be aware of subject motivations and the just terms for these motivations because it is important that behavior towards subjects be avoided or prevented.

The moral weight and force of exploitation claims

In the previous section I identified some of the ways in which researchers can avoid acting exploitatively towards their subjects, in this section I discuss whether researchers should avoid this type of behavior, or, and perhaps more importantly, whether we should require that researchers avoid this type of behavior and prohibit them from acting exploitatively towards their subjects. In this section we will examine the moral weight and the moral force of exploitation claims.

The moral weight refers to its degree of moral wrongness, and not all moral wrongs are wrong to the same degree. For example, theft and murder are both morally wrong, but, all things being equal, murder is wrong to a higher degree and thus carries more moral weight. Determining the degree or amount of moral weight is important for
many reasons, perhaps foremost among them is its usefulness in determining the moral force. The moral force of a wrong is "the various moral upshots or reasons for action that exploitation might or might not involve for parties to the transaction or for society."\textsuperscript{23} If, for example, exploitation has weak moral force, then society might not be justified in prohibiting actions that are exploitative.

Much of the work in determining whether exploitation carries moral weight, that is, whether it is wrong, is done when we separated pejorative from non-pejorative exploitation. Recall from Chapter 3 that we differentiated pejorative exploitation from non-pejorative exploitation by recognizing an element of moral wrongfulness, namely, treating another unjustly. A engages in an act of exploitation that is pejorative rather than non-pejorative when A gains in a way that is unjust with respect to B. Immanuel Kant provides the simplest and perhaps most compelling reason why treating another unjustly is morally wrong. In his second formulation of the categorical imperative Kant issues the following command:

So act as to treat humanity, whether in thine own person or in that of any other, in every case as an end withal, never as means only.\textsuperscript{24}

This principle is based on the idea that all rational agents have inherent moral worth, and failure to respect the moral worth of any other rational agent in one's actions represents a failure to recognize and respect moral worth of all rational agents, including oneself. Since we want to be respected and treated as a being with inherent moral worth, a being that is "an end in itself," we must respect every other rational agent. Exploitation violates this principle because the exploiter uses the exploitee as a means to his own gain, he effectively gains at her expense, and thus treats her as a "means" rather than an "end."

Exploitation is thus clearly wrong, but it is difficult to assess its degree of moral
wrongness, especially in relation to other moral concepts, and this makes it difficult to
determine its moral force.

To assign a moral force to all four types of exploitation strong enough to warrant
prohibition would require that exploitation carry more moral weight than autonomy and
liberty. Using coercive tactics to prevent exploitation would, in some cases, violate the
exploitee’s autonomy, and in all cases violate the exploiter’s liberty, so either these
violations must be otherwise justifiable, or the moral weight of exploitation must
outweigh the moral importance of autonomy and liberty in order for society to be
justified in prohibiting exploitative acts. Many people think that respecting autonomy
outweighs almost all other moral considerations, and many people think that the state or
others are justified in interfering with person’s liberty only when that person’s acts
threaten harm to others. Therefore it will be difficult to prohibit exploitation when doing
so interferes with either the exploitee’s autonomy or the exploiter’s liberty.

Assigning a strong moral force to nonconsensual harmful exploitation is relatively
unproblematic because prohibiting such cases would not violate the exploitee’s autonomy
because she did not consent to the interaction, and preventing harm to others is, all things
being equal, a justifiable violation of the exploiter’s liberty. Likewise, assigning a strong
moral force to nonconsensual mutually advantageous exploitation is relatively
unproblematic because such actions violate the autonomy of the exploitee, and, all things
being equal, one’s liberty rights end where another’s autonomy begins. Determining the
moral force of consensual harmful exploitation and consensual mutually advantageous
exploitation is slightly more difficult because it will involve both a violation of the
exploitee’s autonomy and a violation of the exploiter’s liberty. Exploitation is a moral
wrong, in general, but it is not clear that moral wrong of exploitation carries enough force for society and individuals to be justified in using coercion to prevent it.

The setting of human subjects research differs from the general settings in ways that have important implications for the moral force of exploitation. Recall from Chapter 1 that the Belmont Report played an important role in determining the ethical principles that should guide research. According to the Belmont Report, human subjects research should conform to the requirements of three principles: respect for persons, beneficence, and justice. No one principle is more important than another, and to be acceptable a research program needs to conform to the requirements of all three principles. The Belmont Report requires more of researchers, subjects, and society than we typically require of each other we will sometimes allow one principle to outweigh others. For example, we often refrain from paternalistic behavior, even when doing so will allow a harm to occur, so we often allow respect for persons to outweigh beneficence. Likewise, we sometimes allow consensual harms. To each his own we may think, and we all respect the importance of privacy and personal space.

The setting of human subjects research, however, is different from regular interpersonal relations in a way that supports more restrictive rules of conduct. Human subjects research is an integral part of the larger public project of advancing medical science. In this sense the transaction between the researcher and subject is not a private transaction, but instead a public transaction. We do not want the enterprise of medical science to be associated with these harms and wrongdoings, and we, as the public, do not want to be complicit in any of these harms and wrongdoing. The significance of the
Belmont report is that it articulates this higher moral standard to which humans subjects research should be accountable.

The Belmont Report states that human subjects research should conform to the requirements respect for persons, beneficence, and justice. The principle of justice requires, among other things, “that there be fair procedures and outcomes in the selection of subject.” Research that is exploitative in either a harmful or mutually advantageous way might respect the subject’s autonomy, but it fails to meet the requirements of justice and is therefore unacceptable. In the context of human subjects research exploitation carries enough moral weight to warrant prohibition, and IRBs and other regulatory bodies are justified in using coercion to prevent exploitative behavior towards subjects. IRBs should require modifications in protocols where there is potential for researchers to act exploitatively toward their subjects, and the potential for subjects to act exploitatively toward researchers. Moreover, researcher should be required to make such modifications or else be prohibited from conducting their research. For example, researcher should be prohibited from offering money unless they offer a just wage, and researchers should be prohibited from advertising a placebo control study as a treatment option when effective and reliable therapies exist. Moreover, in certain cases, we should require a statement of altruism in the consent process when researchers recruit from the clinic. Whatever practices will prevent the researcher from acting exploitatively towards the subject should be required.

Requiring that protocols have terms that are just with respect to their target subject population will be easy enough for most cases, but there are at least two situations that will present interesting problems. The first problem is that a researcher may no
longer be able to conduct his research. In some cases it will not be possible for researchers to avoid exploitative behavior and still enroll their trials. For example, if a trial fails to satisfy the requirements for justice in subject populations who seek health-related benefits, and if the researcher cannot afford to pay subjects a competitive wage, then the researcher is prohibited from recruiting from either of these subject populations. His only available subject population is those who are motivated by altruism, and if these subjects are unlikely to enroll because the cost to the subject is not balanced by a sufficiently large target population or a sufficiently severe condition, then his study will not fill. Here one might be tempted to allow exploitative behavior to either the subjects motivated by money or the subjects motivated by health related desires, and one might be even more tempted if the research were considered important. Perhaps one might think that the importance of the research could outweigh the wrong of exploitation. If, however, a study will not reach enrollment when recruiting from altruistically motivated people, it is not clear that the study is important enough to justify exploitation.

The second problem that can arise when protocols are modified to avoid exploitation is the introduction of another moral wrong. For example, if a particular trial requires a lot of time, or presents a lot of discomfort, or both, the just monetary pay-off to the subject might be quite high, indeed, high enough to create problems of seduction. When there is no space between the just wage and the seductive wage, correcting for exploitative terms will create seductive terms, and this can compromise a subject’s consent. If the trial offers no health related benefits, and will not appeal to altruistically motivated subjects, then the researcher must choose among exploitation, seduction, or no research at all. Again, in such cases there should be no balancing or outweighing, and
violations of the principle of justice and the principle of respect for persons should not be tolerated. It is worth noting, however, that seduction does not always violate a subject’s autonomy, and it does not always violate the principle of respect for persons. Recall from Chapter 2 that competence to consent is often measured against a risk-relative standard, so it would follow that when the risks to the subject are low a higher level of seduction can be tolerated. When the risks to the subject are high, however, neither seduction no exploitation should be tolerated, and if the researcher cannot recruit from another subject population he cannot run the trial.

Conclusion

In this dissertation I have constructed a model of exploitation, complete with a principle of justice in transactions, and identified the conditions under which exploitation occurs. Examination of the goods and services traded between the subject and researcher showed that at least some of the current practices are exploitative. I have also shown that if human subjects research remains committed to justice, and strives to treat all subjects justly, then exploitative behavior in research needs to be prevented. Therefore, we should prevent researchers from acting exploitatively towards their subjects and subjects from acting exploitatively towards researchers. This requires that we impose requirements on the amount of money offering for participation in a study, in particular, we require that the amount be determined by Dickert and Grady’s wage model. Preventing exploitation will also require restrictions on other recruiting practices, such as advertising a study as a treatment option and recruiting from the clinic. Imposing these requirements and restrictions will be a start, but in order to prevent all exploitative behavior in human
subjects research we need to continue challenging current practices and ensuring that the conditions for justice are met.

Evaluating our research practices according to the standards of justice presented in this dissertation will require a change in the way we think about certain problems in human subjects research. Moving to this model of exploitation and understanding justice in this way requires that we acknowledge that subjects participate in medical research for a variety of reasons. It also requires that we recognize and respond to the different motivations in order to treat subjects justly. For some people this will be a paradigm shift because it means we need to move away from what we think subjects want, or more appropriately, what we want subjects to want, and focus on what they actually do want. Many people think that research is, or should be, guided by altruism on both sides. They think researchers participate in research for the advancement of science and medicine, and they think that subjects volunteer for research because they desire to help others. It is important that we move away from this paradigm of “research as we would like it to be” and focus on “research as it really is.” This does not mean that we cannot transform the enterprise of medical research into an idyllic activity if we really want to, but in order to get there we have to recognize that some people are not motivated by altruism and we have to discourage or prevent them from volunteering. Replacing assumptions about subject motivations with facts and responding to these facts will be an important step forward in our effort to protect the human subject of medical research.

Such a paradigm shift will also clarify and perhaps shed new light on issues that have troubled us for a while. As Dickert and Grady point out, offering money for participation in research is a practice rife with controversy.
For decades, many investigators have paid subjects for participating in research studies, and this practice remains one of the most controversial methods of recruitment. Despite discussions over many years, ethical issues about payment remain unresolved. ... No consensus has emerged on when and in what manner it is ethical to pay subjects.26

This paradigm shows that the questions of when and in what manner are inextricably linked such that researchers can pay their subjects without risking exploitation when, and only when, they pay them a just wage. Alternatively, researchers can choose not to pay their subjects if they are conscious of what subjects desire and they choose to not recruit subjects who desire material benefit. Instead, they can recruit subjects who are motivated by a desire for therapeutic benefit by offering sufficient health related benefits, or they can encourage altruism and recruit subjects who are motivated by a desire to help others.

This paradigm shift also sheds new light on the controversy surrounding placebo controlled trials when there is an effective and reliable therapy. The question of whether placebo controlled trials are exploitative is typically framed in a way that renders it unnecessarily difficult to answer, and focusing on subject motivations frames the question in a new way. Whether placebo controlled trials exploit any and all subjects is indeed a difficult question to answer because the truth conditions of an exploitation claim depend on features that can vary from person to person. Instead, the question should be framed in a way that reflects the variations among subject populations. The question should ask which population of subjects will be exploited by such trials, and, more importantly, which population will not be exploited by such trials. Once we reframe the question in a manner that is both useful and answerable, then we can move to the more important work of preventing exploitation.
Chapter One


2. Ibid., 127-28.

3. Ibid., 132.

4. Ibid., 132.


6. Ibid., 154.


9. Ibid., 156

10. Ibid., 161


12. Ibid.


18. Ibid., 148.
19. Ibid., 151.
22. 45 Code of Federal Regulations 46. 201-409

Chapter 2

2. Ibid., 204.
4. Ibid., 448. (author’s emphasis)
5. Ibid., 450.
10. Feinberg, *Harm to Self*, 229
11. Ibid., 229.
12. Ibid., 231.
13. Ibid., 230.
15. Faden and Beauchamp, *A History and Theory*, (see chap. 1, n. 5).
17. Ibid., 209.


22. Term “materialistic reductionism” introduced by Baruch Brody. For more, see: Brody, Protecting Human Dignity, 111.


25. This argument is based on Immanuel Kant’s second formulation of the categorical imperative. For examples of Kantian critiques of commodification, see: Hanson, Biotechnology and Commodification; Cohen, Selling Bits and Pieces; Resnik, The Morality of Human Gene Patents; Arneson, Commodification and Commercial Surrogacy; and Brody, Protecting Human Dignity.

26. Radin, Contested Commodities, 103.

27. Ibid., 102-03.


Chapter 3


7. Reiman, Exploitation, 4.
11. Ibid., 764.
14. Roemer, Property Relations.
15. Ibid., 285.
16. Ibid., 286.
18. De Caro, What is Capitalist Exploitation?.
20. Ibid.
24. Ibid.
26. Ibid., 41.


29. Ibid., 178.

30. Ibid. 178.

31. Ibid., 181.

32. Ibid., 193.

33. Ibid., 200.


35. Ibid., 253.


40. Ibid., 20.


Chapter Four


2. A good can be created in the course of an exchange when the parties assign different values to the goods being exchanged. This “social surplus” will be explained in more detail in the next section.


4. Ibid., 21.

5. Why justice is not concerned with reservation prices in addition to the distribution of the social surplus: reservation prices reflect one’s circumstances and are therefore not normative, they are descriptive. It makes no sense to say that a person should have valued a good or service differently when the value a person assigns to a good is simply a function of his or her situation and utility schedule.


7. For more on desert claims, see: Sher, *Desert*.


12. "Initial factor endowment" comes from David Gauthier. For more, see: Gauthier, *Morals by Agreement*.


15. Ibid., 233.

16. Ibid., 232.

17. Ibid., 234.

18. Ibid., 234.


25. There are other ways to justify the ideal market as a fairness preserving procedure. For example, David Gauthier offers a contractarian argument that shows that the market falls completely outside the scope of morality because in the market individuals can pursue their own self-interest without interfering with others. As such, he believes the ideal market is a morally neutral and fairness preserving procedure though which to order personal transactions. For more see: Gauthier, *Morals by Agreement*.

26. One can incur specific duties to beneficence by virtue of the one’s relationships, and one can have a general duty to strangers if one is in a unique position to help.

27. Wertheimer introduces bargaining power as threat advantage, but Wertheimer and I disagree on the factors that determine one’s threat advantage. He thinks threat advantage is determined only by one’s utility gain, whereas I think necessity is also a component. For more on Wertheimer’s version of bargaining power, see: Wertheimer, *Exploitation*, p. 67.

28. As shown in Chapter 2, this type of force does not carry the exculpatory force of other types of force such as coercion, but it does compromise voluntariness and thus carries some moral weight.


32. Ibid., 152

33. Ibid., 178

34. Ibid., 151.

35. Though Nozick clearly intends entitlement rights to created goods, it is not clear that his two principles of justice in holdings allow this. Created goods are goods that were not previously in existence, and even though the creator may have been owner of the labor and other resources of which they are composed, if such goods are subject to the Lockean proviso it is possible the creator may fail to gain ownership.


**Chapter 5**


3. 45 *Code of Federal Regulations* 46.111.


19. Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA), *Handbook*

21. WMA, Declaration of Helsinki.


23. The Belmont Report (see chap 1, n. 20), 45 Code of Federal Regulations 46, 45.102

24. 45 Code of Federal Regulations 46.404

25. 45 Code of Federal Regulations 46.405

26. 45 Code of Federal Regulations 46.406

27. 45 Code of Federal Regulations 46.407

28. Based on personal experience with various IRB, reviewing practices are consistent with 45 Code of Federal Regulations 46.

29. CDER, Handbook.


32. Ibid.


34. Estey and others, Therapeutic response; and Horstmann and others, Risks and Benefits.

35. Ibid.


37. Ibid.
Chapter Six

1. There is an exception to this rule: when a phase 1 study is particularly dangerous researchers typically recruit only from an unhealthy subject population.


3. Wertheimer, Exploitation, 231 (see chap. 3, n. 2).

4. For example, if a researcher desires money then, before he commits to any given research program, he might enter into an ideal market where he offers his services as a researcher to pharmaceutical companies or others who might be interested in purchasing such service. Alternatively, he might conduct the trial on his own and enter into an ideal market in which he offers his data to those who might be interested in purchasing such data. Similar ideal markets will arise depending on whether the researcher desires professional recognition, desires to help others, or desires something else.

5. Ibid., 209.

6. Ibid.

7. Given that there are 2 possible researcher’s needs (healthy vs. unhealthy subjects), 3 possible subject desires (material benefits vs. health related benefits vs. altruism), and 2 dimensions, each containing 2 possibilities, that define the alternatives open to the subject, (insured vs. uninsured, and effective treatment vs. no effective treatment) there are actually 24 possible combinations. 4 of the combinations describe impossible states of affairs because they describe healthy candidate subjects who seek health-related benefits. These combinations will not be considered. They are as follows: (1) healthy subjects, who seek health-related benefits, who suffer from a condition for which there is an effective treatment, and who are insured; (2) healthy subjects, who seek health-related benefits, who suffer from a condition for which there is an effective treatment, and who are uninsured; (3) healthy subjects, who seek health-related benefits, who suffer from a condition for which there is no effective treatment, and who are insured; and (4) healthy subjects, who seek health-related benefits, who suffer from a condition for which there is no effective treatment, and who are uninsured. The remaining 20 combinations are contained in the 7 ideal clinics.

8. When a subject suffers from a condition for which there is no effective treatment, his insurance status does not affect his alternative options. This ideal clinic includes candidate subjects that satisfy either of the following combinations: (1) unhealthy subjects, who seek health-related benefits, who suffer from a condition for which there is no effective therapy, and who are insured; (2) unhealthy subjects, who seek health-related benefits, who suffer from a condition for which there is no effective therapy, and who are uninsured.
9. When a subject is healthy we can not discriminate according to conditions and treatment options, and whether the subject is insured or uninsured is irrelevant. This ideal clinic includes candidate subjects who satisfy any of the following combinations: (1) healthy subjects, who desire material goods, who are insured, and suffer from a condition for which there is an effective treatment; (2) healthy subjects, who desire material goods, who are insured, and suffer from a condition for which there is no effective treatment; (3) healthy subjects, who desire material goods, who are uninsured, and suffer from a condition for which there is an effective treatment; and (4) healthy subjects, who desire material goods, who are uninsured, and suffer from a condition for which there is no effective treatment.

10. When a subject is unhealthy, but does not desire health-related benefits, then his options to pursue his desired good do not depend on whether there is an effective therapy for the conditions from which he suffers; similarly, his options do not depend on whether he has health insurance. This ideal clinic includes candidate subjects who satisfy any of the following combinations: (1) unhealthy subjects, who desire material goods, who are insured, and suffer from a condition for which there is an effective treatment; (2) unhealthy subjects, who desire material goods, who are insured, and suffer from a condition for which there is no effective treatment; (3) unhealthy subjects, who desire material goods, who are uninsured, and suffer from a condition for which there is an effective treatment; and (4) unhealthy subjects, who desire material goods, who are uninsured, and suffer from a condition for which there is no effective treatment.

11. Again, when a subject is healthy we can not discriminate according to conditions and treatment options, and whether the subject is insured or uninsured is irrelevant. This ideal clinic includes candidate subjects who satisfy any of the following combinations: (1) healthy subjects, who desire to be altruistic, who are insured, and suffer from a condition for which there is an effective treatment; (2) healthy subjects, who desire to be altruistic, who are insured, and suffer from a condition for which there is no effective treatment; (3) healthy subjects, who desire to be altruistic, who are uninsured, and suffer from a condition for which there is an effective treatment; and (4) healthy subjects, who desire to be altruistic, who are uninsured, and suffer from a condition for which there is no effective treatment.

12. Again, when a subject is unhealthy, but does not desire health-related benefits, then his options to pursue his desired good do not depend on whether there is an effective therapy for the conditions from which he suffers; similarly, his options do not depend on whether he has health insurance. This ideal clinic includes candidate subjects who satisfy any of the following combinations: (1) unhealthy subjects, who desire to be altruistic, who are insured, and suffer from a condition for which there is an effective treatment; (2) unhealthy subjects, who desire to be altruistic, who are insured, and suffer from a condition for which there is no effective treatment; (3) unhealthy subjects, who desire to be altruistic, who are uninsured, and suffer from a condition for which there is an effective treatment; and (4) unhealthy subjects, who desire to be altruistic who are uninsured, and suffer from a condition for which there is no effective treatment.

14. FDA, *Placebo-Controlled and Active Controlled Drug Study Designs*.

15. ICH *Guideline E10*; the FDA has adopted ICH E10; Brody, *Ethical issues in drug testing*.

16. ICH *E10*.

17. Ibid.


22. Using labor, skills, talents, and resources to deliberately confuse a person, can, in some cases, justify an entitlement claim to the social surplus. There are some transactions that are, in a sense, a “battle of wits”, and if one of the parties can demonstrate superior wit, say, by cunningly confusing the other party, then he is entitled to a portion of the social surplus, or, perhaps, the entire social surplus. Consider, for example, the “shell game.” In this transaction the two parties each attempt to demonstrate superior wit. A tries to confuse B, and B tries to avoid getting confused. If A successfully confuses B, then A wins the social surplus, and if B successfully avoids getting confused, then B wins the social surplus.

23. There are exceptions to the informed consent requirement, but none of the exceptions would be applicable to these cases.

24. Both the Food and Drug Administration (FDA) and ICH post information regarding trial design on their publicly accessible websites. For more information see: [http://www.fda.gov](http://www.fda.gov) or [http://www.ich.org](http://www.ich.org).

Chapter 7

2. Ibid.
3. Dickert and Grady explain the difference between these two models, the names “expense reimbursement model” and “wage reimbursement model” are mine.
4. Dickert and Grady, *What’s the Price?*
5. Ibid.
6. Ibid.
7. Ibid.
8. Rate of mileage reimbursement is Dickert’s and Grady’s.
9. Hourly wage is based on Dickert’s and Grady’s speculations, additional amounts for blood draws and nasal spray are my own speculation.
10. Dickert and Grady, *What’s the Price?*
11. Ibid.
12. Ibid.
14. Ibid.
15. Ibid.
18. Ibid.
19. Ibid.
23. Ibid. 28.
26. Dickert and Grady, *What’s the Price?*