THE MAKING OF BIOETHICAL HISTORY

by

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This research is a diachronic case study of a series of sentinel ethical events at a medical research facility as represented in the media, in courtroom dialogue and in academic journals. Between 1981 and 1993, physicians at Fred Hutchinson Cancer Research Center (FHCRC) placed 85 criteria-eligible patients into sequential versions of a research protocol designed to improve their bone marrow transplant survival. 83 of these 85 patients are known to have died. The other two charts have not been located. In 2001, one of those research physicians worked with an investigative journalist to tell his experience with the protocol to the surviving families, to the public and eventually to the courts.

These events offer a rich ground for exploring the enduring moral problems of contemporary research medicine and the formulation of Bioethical history. My research provides a critical cultural analysis of the events surrounding the FHCRC’s retrospectively contested protocol and the narrative formulation of an ethical case.
I draw predominantly on court transcripts and the triangulated dialogue between FHCRC, the media and academic journals to explore how the particular ethical issues were framed, presented, contested and finally collapsed into an official account. My premise is that narrative is a key constructive – deconstructive process in Bioethics. It negotiates the ‘real story’ and determines what counts as history. My second point is that the shape of ethical debates and how they resolve are important artifacts of the cultural moment. Both things inflect the direction of academic and clinical Bioethics.

I interpret my findings from a cultural constructivist perspective to show how text, narrative and courtroom performance are active iterations of contemporary cultural themes, and how the resolution of key ethical events in medical research contribute to the evolution and to the historiography of Bioethics. Importantly, the analytic perspective brought to bear on this study moves past a Cartesian tethering to right or wrong. It challenges the reader to deconstruct the default master narratives in ethical debates. It offers a lens through which to imagine new approaches to the recurrent ethical problems arising within investigational medicine.
CHAPTER ONE: INTRODUCTION

This research study analyzes bioethics in investigational medicine as a culturally inflected, socially constituted, narrative process. This study is a diachronic, intrinsic case study of sentinel ethical events occurring at Fred Hutchinson Cancer Research Center (FHCRC, FH, the Center, the Hutch) between 1981 and 1993 that fell under intense public and legal scrutiny in the following decade. The project’s starting-point is a five-part article published in 2001 by the Seattle Times Newspaper about FH that drew public attention to a research trial active during the aforementioned years[1]. The article inferred that the Hutch persisted with this and another research trial1 in spite of poor patient outcomes because the founders had both a financial interest in the protocols and unchecked scientific optimism. It further claimed that the protocols were in early, thus riskier, trial phases and the patients were never fully informed either of that fact or of the available treatment alternatives. The article disturbed the body social. It drew waves of fiery social commentary, editorials, contradiction, and formal rebuttals2. Yet it also earned accolades as a 2002 Pulitzer Prize finalist for investigative reporting3. From the abundant data, two key polarized versions of the FHCRC story emerged: one painted medical research as nefarious and the other as heroic. This study looks at the cultural salience of the narratives, that is,

2 The Seattle Times series and some of the media responses can be viewed at http://seattletimes.nwsource.com/uninformed_consent/
3 http://www.pulitzer.org/finalists/2002
how they mirrored both contemporary cultural themes and common litigious pathways in North America. The research further analyzes how the narratives evolved, were embodied and performed in the courtroom, and how the ethical issues were framed, contested and finally collapsed into an official account represented in academic journals. In this case, the ambiguous meanings and quantifications of ‘risk’ were engaged as active agents in the final narrative shifts.

This research contributes specifically to the Cultural Studies of Science within medical anthropology. It fits within that body of work that deconstructs the putative neutrality and naturalism of scientific knowledge. The Cultural Studies of Science offer that ‘truth’ is partial and that ‘knowledge’ both expresses and constitutes aspects of the (scientific and) cultural moment[2-6]. The intrinsic case-study approach offers a conceptual model for further anthropological fieldwork in medical ethics[7]. It holds theoretical, methodological and practical implications for examining bioethics reflexively and, in part, as cultural performance[8-11]. A central task of this project is to investigate how the constitutive social processes and particular fruition of key ethical events in medical research contribute to the evolution and to the historiography of both clinical and academic bioethics in the United States[12]. Importantly, the analytic perspective brought to bear on this study moves past a Cartesian tethering to an ethical ‘right’ or ‘wrong’[13]. The issues that become ethical concerns, how they are framed and resolved may simply reflect different, and local, social knowledge[14]. My analysis offers a lens through which to imagine new approaches to the recurrent ethical problems arising within investigational
In this introductory chapter I will articulate the specific research objectives, provide an overview the study, and situate myself as researcher.

RESEARCH OBJECTIVES

The purpose of this study is to explore nodal moments of cultural construction in medical research ethics as exemplified through the social narrative about a specific case. Each story in the FHCRC case is at best a partial representation of ‘truth’, constructed along a common North American ethics theme of rights and responsibilities, and articulated to the end of moral persuasion. No doubt the raw material of experience for each participant in the protocol under investigation was intense, multi-layered and in large part inchoate. Yet twenty years later, a distillation of events was published which was seemingly accurate, but unavoidably partial and incomplete.

Essentially, the published investigative piece was the impassioned story of one inside observer who felt that FHCRC had placed scientific progress above patients’ safety. His story struck a collective nerve. For some it challenged the hope in and reliance on frontline medicine for saving life and buying time in cases of terminal cancer. Those voices defended the research standards of FHCRC and denounced the Seattle Times article. For others it affirmed a fear that medical research might be corrupt and self-serving. Those voices defended the Seattle Times article and denounced the research standards of FHCRC. What ensued was a culturally formulaic, energetic and polarized moral debate that
rippled through the media, cyberspace, social conversation and the courtroom
dialogue. Each core story was an inversion of the other: FHCRC either self-
vestingly experimented with human lives or it selflessly, tirelessly pursued a cure;
either the patients were victims of FHCRC or FHCRC founders were victims of
greedy lawyers and a slanderous press. Ultimately, these narratives were unified
during the trial through an exhaustive elaboration of ‘risk’ as it relates to cancer,
treatment and research and eventually found an integrated resolution in the
social need for research medicine.

These storylines, their movement through time and closing iteration
comprise a substantial body of the data for this project. Through this medium, it is
possible to see the situated arguments as cultural expression, the semantic shifts
as artifact of cultural process and the end story as a moment of cultural
construction. A further extrapolation of data suggests the role this process plays
in the construction of academic ethics, and in turn how it inflects the practice of
clinical ethics in research medicine.

Sentinel bioethical events similar to those at FHCRC are aggregated as
case studies to inform academic and clinic ethics. The accumulation of classic
Bioethical cases offers both a moral compass for clinical practice and a
seemingly forward trajectory in the field. Yet there remains a recognized,
persistent and at times disconcerting gap between its theory and practice. In
other words, ethical principles are at times insufficient to navigate the waters of
real-life complexity and ambiguity. Rather than attempt to align these two
manifestations (theory and practice), it might be useful to imagine that bioethics’
duality is analogous to physic’s rendering of physical matter as both particle and wave. Bioethics is at once an identifiable set of concrete situated values and a dialectical socio-cultural process. The multiplicity of stories told in the space between these two domains is a critical conceptual link – not to reconcile either with the other but to participate more consciously in the bioethical reality we create. To this end, the two specific objectives of this project are as follows:

1) To analyze the socio-cultural processes which inform the trajectory of academic and clinical bioethics in research medicine.

2) To evaluate how ethical issues in research medicine are given form, expressed and codified through narrative engagement.

The objectives will be accomplished through a narrative analysis of the dialogue between the media, the public and academic journals; through a linguistic examination of the opening and closing statements made by the prosecution and the defense during the court trial; through the identification and analysis of key master narratives; through a deconstruction of narrative performance in the courtroom; and through the evaluation of Bioethical residue in post-trial discourse. The data are taken from archival materials, media releases, legal proceedings, editorials, paid media advertisements, FHCRC website postings, newsletters and brochures, an external ethics review and report, court

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4 Articles, editorials, commentary and rebuttals were published serially, each referencing previous pieces.
5 A term borrowed from literary criticism meaning a grand, central or meta-narrative from which other narratives derive.
transcripts, conversations with key informants, observations during the court trial and post-trial journal articles.

This research will evaluate the role that narrative plays in forging the popular, the documented and ultimately the academically central version of bioethical history. It is perhaps this history that informs the direction of bioethical research, the practice of medical ethics, and ultimately the clinical experience. This study offers a point of cultural reflexivity for medical practitioners and ethicists and begins a rapprochement between contemporary ethical theory and lived reality of ethical problems.

OVERVIEW OF STUDY

Between 1981 and 1993 research physicians at FHCRC placed 85 eligible patients into sequential versions of a treatment protocol designed to minimize graft-versus-host disease (GVHD). GVHD is a serious complication of bone marrow transplant (BMT) accounting for significant morbidity and mortality. While the anticipated BMT treatment survival during the 1980’s was about 50%[16, 17], this particular protocol, protocol 126 (P126), had a significantly higher rate. 83 of the 85 research participants were known to have died, and the other two charts were not recovered. These were the numbers unreflectively reported by the 2001 Seattle Times article “Uninformed Consent”[1].

The physiology of Graft-versus-host disease as well as the process of bone marrow transplantation as treatment for blood cancer is more fully discussed in chapter 4 “Orientations”. GVHD results when the donor bone marrow graft – the new immune system – does not recognize, and thus ‘rejects’ the host.
numbers are startling, yet profoundly misleading and anachronistic. They drew the reader in. What followed was a provocative story about FHCRC, the Center’s founders, BMT, and P126 as told by an identified whistle-blower and investigated/reported by a local journalist.

In brief, the article made allusions to financial motive and blind optimism in the presence of an evidently futile protocol. It was seemingly an exhaustive indictment of Seattle’s esteemed research institution. On the heels of this article came a storm of editorials, letters to the editor, full-page public addresses and rebuttals. The surviving families of P126 participants were contacted and several agreed to pursue litigation against FHCRC. What had once been perhaps private stories of loved ones lost to cancer became a common theme of loved ones lost to research medicine.

Although no issue was taken with the overall mortality statistics for the patients enrolled in P126, it is important to note that with the exception of the five plaintiffs, the proximate causes and timeline of the participants’ deaths in relation to their treatment are not on public record\(^7\). The case eventuated in an eight-week trial beginning in February 2004 during which a competing and escalating assessment of various risks associated with disease, treatment and side-effects by both the defense and the prosecution led to what might be called an embodied ‘social amplification’ of risk [18, 19]. The dialogue at the closing of the trial was drawn away from the individual cases toward the public need for

\(^7\) Certainly a chronographic display of statistically expected outcomes plotted against the outcomes for all 83 subjects would be enlightening.
research medicine to enumerate and contain these risks. After five days of deliberation, the jury unanimously delivered a not-guilty verdict except for one case.

Medical research protocols designed for human application have a specific aim, are based in scientific evidence and are carefully drawn up to maximize the intended benefit while minimizing negative or unintended consequences. And with protocols designed for human application, there is an initial trial period when it is considered ‘phase-one’ research. Typically, a limited number of people are enrolled in phase-one research since not all the effects can be predicted. FHCRC’s P126 was no exception to this research standard.

The specific aim of protocol 126 was to reduce the incidence and severity of GVHD by depleting the donor marrow’s T-cells, a key component of the immune system. Most of the BMT centers around the world were hard at work developing a clinical application for this important idea. P126 was based on solid evidence that T-cells mediated the potentially fatal GVHD reaction. The actual method for reducing T-cells in human donor marrow had been scientifically conceived and tested but not yet refined. In part, the trials of P126 were carefully designed to evaluate any negative effects of the nascent process. After each limited trial period, P126 was critically evaluated, methodically revised and approved by the institutional review board (IRB) of FHCRC. P126 went through several iterations, remaining a phase-one protocol until it was stopped in 1993. The prosecution claimed that it was essentially the same protocol and was evidence that science had driven recklessly forward at the expense of human
lives. The defense claimed that this protocol was on the brink of a significant medical breakthrough for the evolution of bone marrow transplant and that each version was substantively modified in scientifically responsible ways.

As previously stated, the original events in each case of protocol 126 were undoubtedly unique and uniquely experienced by each participant. Undoubtedly treatment decisions were at times difficult to make and everyday values were on the line. Undoubtedly moments of moral uncertainty emerged and even perhaps residual ethical ambiguity lingered. This is the nature of extreme illness, extreme medicine, suffering and death[11, 20, 21]. There are many stories to be told and many ways to structure – or not to structure – each participant’s internal and social experience. When the case of FHCRC’s research conduct around P126 was filed, an obligatory binary legal conclusion - innocence or guilt - determined which problems could be articulated and how they could be framed. The prosecution in this trial pruned their data to fit three possible medical litigation pathways: fraud, conflict of interest and negligence.

Medical ethics litigation is perhaps a professionalized voice of contemporary North American values. Arbitration is frequently shaped and delimited by seemingly common sense rights and responsibilities with the goal of adjudicating culpability on the one hand and formalizing medical morality on the other. What this research intends to show, through an analysis of discursive materials, is that ethico-legal stories are in one way simply that: stories. Not fiction, but selectively crafted narratives that actively reflect, engage and construct their cultural temporality. The research analysis further offers some
thoughts on the evolution of storied bioethics that ultimately trickles down to clinic practice.

RESEARCHER LOCATION

Researcher location is inseparable from the study and from how it is conceived and finally represented [22-24]. The theoretical premises undergirding this research project are related to my personal, professional and academic values [25, 26]. The particular ethnographic methods I engage follow on from that theory formulation and evolve responsively to the accessible data. I offer a brief auto-ethnographic narrative to clarify my position(s) [27].

I have been involved since 1978 with the direct management and care of patients in burn, trauma, intensive care, oncology, and various organ transplant units in tertiary care settings, in research institutions, in hospice work and nearly always in multi-cultural settings. I have experienced extremes of illness and medicine in my professional, social, familial and personal life. I am unwavering in my belief that the construction of meaning in the face of illness and suffering is of paramount importance for those most intimately affected, and that narrative plays a central and dynamic role in this process.

I have both objective and subjective knowledge of medical uncertainty and of what I now regard as the phenomenology of medical ethics. By this I mean the very real moral dimensions of clinical medicine as experienced by patients, their families, clinicians, researchers and ethicists that constitute both an individually
and a collectively managed bioethical gestalt. I contend that the clinical and bioethical experiences, the challenge to personal values, and the disruption of everyday sensibility may be very different for each participant in a medical-moral drama. The inevitable ethical complexities that emerge in daily medical practice are intensified in the domain of investigational medicine.

Disciplinary, cultural and personal reflexivity are particularly important for anthropological work within the borders of one’s own culture and profession. In part this is because ‘life as usual’ doesn’t command attention. The growing body of work, drawn together as ‘Cultural Studies of Science’, deconstructs some of the assumptions in Western science, and is most compellingly accomplished by scientists themselves willing to think and speak ‘from the margin’[28]. Turnbull elaborated upon the importance of ‘conscious subjectivity’. He proposed that objectivity can only be approximated when the observer is first aware of his own experience as (at least) culturally positioned [29]. In this spirit, my observations are transparently incorporated into the conclusions chapter. I invite the reader to also bring a ‘conscious subjectivity’ to this work.
CHAPTER TWO:
FRAMEWORKS, PAST AND PRESENT

LITERATURE OVERVIEW

This study explores the social construction of Bioethical reality through the medium of narrative in the cultural context of investigational medicine. Specifically it examines the stories that evolved during a social and legal challenge to the ethical conduct of human subject research at a world-renowned cancer center, and how these stories shifted over time. A very fluid concept of risk was engaged during the trial as a semantic tool for creating, opposing, supporting and moving the narratives toward a compelling resolution.

The study draws on Renée Fox’s lifetime work in medical research, organ transplantation and ethics[20, 21, 30-34]; on Kleinman’s instrumental concept of clinical reality[35]; on Byron Good’s work with the use of narrative emplotment to respond to illness and suffering[36]; on M-J. D. Good’s work regarding the discourse of hope and competence among physicians[37, 38]; and on the narrative rearrangement of moral experience modeled in Young’s extensive and layered ethnography of Post Traumatic Stress Disorder (PTSD) treatment in a psychiatric facility and beyond [10, 39]. Additionally, it calls on authors who have directly or indirectly contributed to a cultural analysis of Bioethics as an offshoot
of Western philosophy and medicine [9, 13, 32, 40-57] and on various studies pointing to the phenomenology of ‘risk’[58-72].

The research is guided by a fusion of theories that might be regarded as “critical cultural constructivism”, and most closely aligned with the newly articulated reflexive studies known as the “Cultural Studies of Science” (CSS). This chapter presents a review of the CSS, and of the social science contributions to the field of Bioethics in general and to ‘risk’ in particular.

**CULTURAL STUDIES OF SCIENCE**

The ‘Cultural Studies of Science’ (CSS) is a conceptual category bandied about in the last 20 years. The body of work this term subsumes includes research and literature about the dominant sciences of European and North American origin that reveal these sciences as cultural expressions. Some of the studies are reflexive, generated from within a given scientific discipline. Some of the studies are observational, usually a cultural critique of scientific philosophy, knowledge or practice offered by the social sciences. It isn’t possible to circumscribe the precise boundaries of this literature since it includes writing accomplished prior to the terminology itself or by authors who do not subscribe to the retro-construction of this category. These works do not take issue with the facticity of science, but offer new ways to think about the imprecision, limitations and, at times, conflicting ideology of Western science and medicine. This study builds on what has been learned through the Cultural Studies of Science about
the instability of diagnostic categories, the interpretive work of scientific
representation, the performance art of medical practice and the cultural
formulation of ethical issues to deconstruct the narratives that evolved during the
Fred Hutchinson Cancer Research Center case.

Kleinman coined the term ‘category fallacy’ to explain the imprecision of
psychiatric diagnoses[73]. The core concept is that the affliction a person suffers
may not be the same as the organic disease. So while a clinician’s diagnosis is
based on the presenting constellation of symptoms, there are actually many
ways of grouping symptoms into meaningful patterns. The model that evolves
from this is ‘pathogenicity - pathoplasticity’, meaning that symptoms are rooted in
biology but how they are grouped and interpreted is culturally specific. Gaines
has developed this concept further by showing that psychiatric categories are
unstable over time and that biology might be as ‘local’ as culture[74, 75]. He
traced the evolution of the of the American Psychiatric Association’s Diagnostic
and Statistical Manuals (DSM) through its first 3 editions ending with DSM III-R,
to illustrate how the cultural value of self-control was articulated through concepts
of pathology. Gaines would concur that psychiatric symptoms exist but offers a
critique of the various labels of deviance. He traced the ‘progress’ of diagnostic
(im)precision from the neuroses in DSM-1 to the defensive reactions in DSM-2 to
the omnipresence of disorders in DSM-3. McCombie also offers evidence for a
cooperative cultural (mis)construction of illness[76]. For example, the flu means
influenza, a condition acquired from an airborne virus. In popular terms, the ‘flu’
includes symptoms related to gastrointestinal upset. It is such a deeply rooted
folk-concept that healthcare providers may invoke and thereby reify a diagnosis of ‘stomach flu’. These works point to the conceptual and temporal instability of subjective symptoms, clinical interpretation and diagnostic categories.

What can be observed is limited by the conditions of observation, including the position of the observer. This is a central tenet of physical sciences and is echoed by many critical thinkers within the social sciences, including Geertz and Kleinman[26, 28]. Some of the most compelling CSS works come from authors within their own scientific disciplines. Geneticist Keller cautions that sciences’ assumptions and language of neutrality obscure the core values that inform its objectives, selects theory, and guides research[77]. For example, the meaning of ‘experimental control’ semantically implies not only the statistical management of variables but a form of ‘control’ over what is seen, interpreted and recorded. She points out that metaphors often reflect the hidden values of the observer. They draw attention to and color certain clusters of observations while perhaps inadvertently obscuring others. This is made apparent in the writings of Spanier, Erwin, Martin, Sontag and others who highlight the spin on biology and medicine perpetuated by gendered, industrial or military metaphors [78-82]. Keller confesses that it is impossible to empirically ‘know’ nature, so, an important task for a given science is to learn how its language and assumptions construct what counts as knowledge.

Harding provides a critical-feminist critique that claims Western sciences are androcentric and self-serving[5]. Science itself is not the object of her analysis; rather, she examines tacit socio-politico-economic forces that authorize
one form of science over another. For example, she notes a simple physics’
equation makes nuclear power appear extremely energy-efficient but that these
energy equations do not account for the human and environmental costs
associated with inevitable accidents. Her philosophy aligns with Keller’s,
asserting that science speaks the values and interests of its sponsors. Her work
suggests scrutiny of the physical sciences for an inadvertent constriction of
knowledge.

Gordon’s work also alludes to the social implications of medicine’s
presumption of objectivity[83]. Her critique is directed toward the epistemology of
medicine rather than medicine itself. For example, Biomedicine might view
disease as external to a body rather than as a complex interactivity. She also
develops the idea that clinical uncertainty is managed through a seemingly
endless quantification of risk[84]. Martin and others cogently discuss the cultural
construction and meaning of illness, disease and symptomology; Etkin
illuminates how medicine determines what counts as a drug’s therapeutic versus
non-therapeutic effects; and Gifford’s work explores how population level risks
can become physically relocated to a breast lump [39, 76, 78-80, 82, 85-90].

A number of interpretive-empiricist studies of scientific representation have
demonstrated that scientific ‘reality’ conforms to itself by force of habit. That is to
say that selective methods produce similar data. What the data means is not
necessarily fixed, but is actively negotiated with peers based on previous
interpretations. The images, numbers, diagrams and models are not reality, but
reproducible, stable and portable 2-dimensional representations that can be
shared across the given discipline [91-95]. These studies are discussed in more depth in the methodology chapter. The central importance of these works is that the limitations of statistical analysis might parallel the limitations of scientific representation.

This research project is presently aligned with the CSS and contributes to the cultural constructivist view of Biomedicine. Within the orientations chapter and the data analysis are discussions of disease category, therapy, side effects, and medical complications as mutable ideas. It draws attention to the line constructed between therapeutic and iatrogenic, to the interpretive world of Bioethics and to a phenomenology of danger engendered by the particular presentation of risk statistics in this case.

**BIOETHICS**

The Seattle Times series “Uninformed Consent” and the legal case brought against FHCRC placed the ethical conduct of the center on trial. Each of five families made claims on four bioethical counts: lack of informed consent, fraudulent conduct, intentional infliction of emotional stress and negligence. Although each case was no doubt quite individual, involved different physicians, and took place at different times, the unified claims implied that the Center was directly responsible for recurrent ethical breaches. The way these issues were framed, supported and contested through both unselfconscious and deliberate narrative is the platform for this research. Medical decisions are often made
incrementally based on what can be known in a complex and rapidly changing clinical situation through what might be called ‘microethical’ moments[13]. The unified claims of this case were a common litigation pathway made possible by the available history of Bioethics. It is this history and its cultural specificity to which I now turn.

From its inception, Bioethics has sought to apprehend ever more precise theories that might guide moral decision-making in clinical and research medicine. It has necessarily fallen short of its goal to smoothly navigate moral quandary in complex, ambiguous and uncertain clinical situations. Nevertheless, the sustained attention to ethical issues in medicine has resulted in the opportunity for professional introspection, an enhanced social awareness of medicine’s ethical difficulties, the evolution of institutional ethics committees and recently a window of opportunity for collaboration between philosophy and the social sciences.

A reflexive dialogue has arisen within the discipline of bioethics, exploring methodological deficiencies and the persistent gap between theory and clinical application. Emerging internal critiques challenge the primacy of autonomy[96-100], suggest correctives that engage the social sciences and attend to context and ethnography in the clinical setting[12, 13, 56, 99, 101]), and offer cross-cultural comparisons[44, 102-110]. The ultimate goal remains the same: to develop a comprehensive theory of medical ethics that can guide action in morally problematic moments. The failure of bioethics to adequately accomplish this remains inevitable. It is, after all, impossible to contain uncertainty,
circumscribe morality, and bring a logical order to human variability. Bioethics has only started to appreciate the relevance of history, perspective, location, and cultural context for the constitution and framing of moral problems. In recent years, the dialogue in bioethics has been enhanced by a healthy plurality of voices, including the social sciences. In particular, the many anthropological approaches to bioethics enrich the field, by attending to the nuance of context[9, 50], demonstrating intra- and cross-cultural diversity[32, 43, 51, 111-114], exploring the historical and cultural specificity of medical ethics[32, 43, 115], demonstrating how the medical ethics’ debates express and animate culturally inscribed values and aspirations[30, 88, 116-118], and by phenomenological accounts of the construction and resolution of ethical dilemmas between individuals[9, 10, 39, 47]. Anthropology is uniquely situated to deconstruct the culturally informed assumptions of bioethics in the headlights of cross-cultural comparison and to illuminate the constitutive role that narrative plays in medicine’s daily moral process.

In this section I will first briefly outline normative bioethics and explore some of the methodological critiques internal to philosophy. Next I will offer some examples where philosophical ethics has opened the door for social science collaboration by venturing into the domains of context, ethnography and perspective. Finally, I will review the contributions made by the social sciences in general and anthropology in particular to the field of bioethics. Morality, as articulated in medical ethics, is a dynamic social process. It is a trope for complex social values and aspirations. It is full of ambiguities and tensions and remains
elusive. The anthropologically interesting moment happens when uncertainty impels a social response, as happened in the legal case against Fred Hutchinson Cancer Research Center,

Bioethics, a theoretical offshoot of philosophy and theology, emerged on the academic horizon in the late 1960's. It began as a response to extensive reports of the unacceptable treatment of human subjects in medical experimentation\textsuperscript{8}. But the literal origin of the term ‘bioethics’ comes from the work on cancer of biologist Van Renselear Potter who saw the carcinogenic results of the degradation of the biosphere\textsuperscript{8a}. Since that time, the field of bioethics has grown exponentially but not in the direction of an environmental ethics of the biosphere. Centers, conferences, national and institutional committees have been established, and a large body of literature has been generated. The media engages bioethical controversy in broadcasts dedicated to investigative reporting and even the vernacular of a right to know, autonomy, competence, informed consent, access to care, right to die, and brain death has become common place in public discourse. What began as a social movement to protect the rights of

\textsuperscript{8} The Nuremburg trials shortly after WW2 raised public awareness to the dark potential of research medicine, and the resultant international code was designed to protect prisoners from odious forms of experimentation. The American public seemed unprepared for the revelation that human rights violations were happening in peacetime, and on friendly turf. Beecher’s article entitled “Ethics and Clinical Research” exposed several abuses of human rights by known and publicly funded institutions. Included were such incidents as feeding live hepatitis vaccine to institutionalized retarded individuals; injecting cancerous cells into geriatric patients; withholding antibiotic treatment for streptococcal infections; and inserting catheters into neonates’ bladders, injecting fluid and performing serial X-rays. 119. Beecher, H., Ethics and Clinical Research. New England Journal of Medicine, 1966. 274(24): p. 1354-1360.

human research subjects has grown to include patient rights, issues surrounding life, death and personhood in the context of changing technology, resource allocation and cost containment[31, 53]. Bioethics is rooted in the cognitive traditions of western philosophy and law, and is premised on the sovereignty of the individual, self-determination, and individual rights.

Childress states that moral dilemmas arise when ethical principles are in conflict and it is the final task of biomedical ethics to glean direction from the interpretation and relative weight of various principles in clinical situations[120]. The direction deduced will necessarily appear very different depending on whether (and which) principles are applied to the (which) moral agent, act, goal, or actual consequences. In spite of this conceptual free-for-all, Childress asserts that the systematic, logical application of principles can guide ethical clinical action. To illustrate this approach, he offered a story about a father who declined to donate a kidney to his daughter but requested that the physician not disclose this fact to his family. The physician in this story experienced an ethical dilemma: the principle of truthfulness was in conflict with confidentiality. At stake were the girl’s medical needs, the father’s autonomy, and perhaps the family’s integrity. The physician achieved what Childress terms a ‘moral compromise’, by telling the family that the father could not donate for medical reasons[120]. From the perspective of principlism, the physician’s choice was morally justified by his equitable management of beneficence and confidentiality. From the perspective of virtue theory, the father might be deemed selfish and the physician benevolent. Deontological theory (judging the merit of the act itself), and
teleological theory (judging an action on the intended ends) might each
determine that the father acted unethically by refusing to donate his kidney and
the physician erred by simply failing to tell the truth. And consequentialist theory
(judging an action based on the actual outcome) might not weigh in until the
transplant was accomplished. This example, and those that follow, suggest that
the application of moral principles is an interpretive clinical art.

Principles common to the ethicist’s theoretical standpoints include:
autonomy, nonmaleficence, beneficence, justice, utility, fidelity, truthfulness,
information disclosure and confidentiality. The first four in this sequence are
considered by Beauchamp and Childress to be the primary principles, and the
remainder, derivative. In their approach, these four principles are considered to
be *prima facie* - that is the principles are binding if all else is equal, so any
deviation must be justified[121]. Principlism is pluralistic in Childress’ view,
because it doesn’t pre-assign importance to principles. Principles are deployed in
ethically problematic cases through a ‘deductive application’ and ‘intuitive
balancing’. The principles approach concedes that most issues do not require an
appeal to rules and principles, but that cases of conflicts actually require such
structure for ethical resolution.

In sum, these principles, maxims and rules play a central role in bioethics.
They are invoked by the theoretical alternatives to principlism mentioned above,
and by many of the critiques that follow. The argument for principlism is
ontological. The principles are validated by their *a priori* existence as moral
standards. Deductive reasoning and this principle driven approach gives ethical
problems the illusion of occurring between patient and doctor, between researcher and subject, or between health care providers. In fact, many variables affect what becomes an ethical problem, why it manifests in certain situations, and how the problem is framed and responded to once it emerges. Bioethics does not have an avenue for considering the ‘moral significance’ of groups, the nuance of experience, and the shifting semantics of the principles themselves. The question is not whether the principles are useful, but how to apply them. This also points to the interpretive dimension of bioethics.

To illustrate how bioethical theory and clinical judgment diverge, consider Komesaroff’s example of a rowdy prisoner brought in for medical care who refuses to be examined. The author states that while bioethics might try to make decisions about relative rights and responsibilities, or beneficence, the clinician is faced with an immediate problem for which the question becomes what to do next, and how to engage this person, considering the complex relationships and the context of the clinical situation[122]. Komesaroff suggests that an untidy clinical situation, the only kind that requires moral deliberation, calls for a microethical approach. By this he means that clinicians are faced with small but sequential medical decisions that will ultimately forge the encounter. Hoffmaster proposes that an ethnographic approach to bioethics might lead to a moral theory which is more responsive to clinical reality[13]. For example, in one study of neonatal intensive care units, the infant was said to ‘declare itself’ by either getting better or taking a turn for the worse. The staff allowed the neonate to ‘decide’ whether the medical response would be aggressive or palliative.
Contextually speaking, the response is reasonable, but it can neither be explained nor supported by the binary nature of contemporary ethics.

Ethnography gives a cultural and historical context to the movement of morality through time. Even when there is general agreement about moral principles, different perceptions of the situation may lead to different conclusions about (moral) action. For example, Anspach’s study in a neonatal intensive care showed that some health care providers based their prognoses on ‘objective’ data such as lab results and physical assessments, while others based their prognoses on the responsiveness of the infant[123].

The location and perspective of the observer changes how the moral problem is constituted and framed, even within the bounds of professional bioethics. The uncertainty is impossible to resolve, in part because morality, and the terms employed in ethical debates are ambiguously defined and differentially engaged. This should not be problematized. Rather, the presence of ambiguity and tension again suggests that ethics is an interpretive activity. Contributions from the social sciences and anthropology include cross-cultural examples of ethical relativity, intra-cultural examples of ethical pluralism, and research that historically and culturally situates bioethics, deconstructs its assumptions, and illuminates the issues that are refracted by the enduring debates. In the case of Fred Hutchinson, narrative played a key role in the constitution, constriction and resolution of the bioethical conflicts. Next I will review the contributions that the social sciences have made to our understanding of the cultural and narrative construction of ethical problems and moral solutions.
Jennings’ work highlighted the differences between descriptive and normative field analyses, and suggested that collaboration is likely to strengthen the work of bioethics[47]. His research examined how decisions are made in neonatal intensive care units (NICUs) from the perspectives of ethicists and from ethnographers. When to stop critical treatments or life support, and how to apply the “best interest” standard to voiceless newborns are issues which routinely crop up in the context of NICUs. In his study, ethnographers reported that the relative isolation of intensive care units from the rest of the hospital, the degree of expertise required to work there, and the volume of ethical problems that arose, contributed to the emergence of a consensus-seeking subculture for managing difficult decisions. They noted that a bioethical vocabulary was rarely employed, and that ethical dilemmas were medicalized. For example, especially with prognostic uncertainty, death was conflated with medical failure, and there arose an ethical imperative to err on the side of overtreatment, regardless of the various costs. They found that parents were not central to these treatment decisions - unless the team wished to either escalate or to cease medical intervention. The ethnographers in this study did not take issue with the ethical culture of the NICU, but generally advocated for an enhanced communication and negotiation between the health care professionals and the family in order to arrive at good decisions for each infant.

The bioethicists in Jennings’s study felt that the ‘best interest’ standard should be invoked for these surrogate decisions. They asserted that an infant centered standard would eliminate any decision bias arising from the anticipation
of future disability. The ethicists’ summarized the ethico-medical ideal for the NICU to include a balanced intensity of treatment, with an intuitive shift from aggressive to conservative treatment over time in light of prognostic uncertainty. Further, the benefits and burdens of treatment options should be explicitly discussed, values such as quality of life identified, and the parents should be actively involved in the decision making process. These parameters fit with the social values of individual rights and respect, but may not in fact have been easy to translate into this environment. Jennings did not question the bioethical prescription for change, but noted that the ethnographers brought the life-world of the unit to the table in a way that not only confounded simple answers, but also pointed to the effect that certain changes might have had on the stability and coherence of the NICU as a cultural unit.

In other domains, we see a pharmaceutical company’s petition to the Canadian government for unrestricted clinical use of Depo-Provera\(^9\) as a birth control option highlighting socio-economic factors that might frame ethical issues in medical practice\(^{[111]}\). In this case, the debate revolved around informed consent and autonomy. Informed consent was provided for the drug, more or less as a formality, since insufficient information about the long-term effects was available to either the clinician or to the client. The authors pointed out that the political impact of accepting Depo-Provera for widespread contraception use was

\(^9\) Depo-Provera, given by injection is a long-acting contraceptive. There are many studies that suggest it is not safe - diabetes, heart disease, stroke and birth anomalies have occurred.
concerning. The Coalition on Depo-Provera, a grassroots organization had questioned the ethics of having done the research on ‘third-world’ women, and the approval process did not include a woman’s voice. They noted that where Depo-Provera had been used, it was more often given to women whose reproduction was less valued and for whom ‘compliance’ was at issue (poor, disabled, ethnic minorities, sexually active teens). The translation of autonomy and informed consent in this case was therefore political and complex.

Miles and August’s analysis of written court records in various ‘right to die’ cases demonstrated how ‘gender patterned reasoning’ colored the interpretation of moral agency and autonomy[124]. For example, when trying to reconstruct the wishes of newly incompetent adults, the courts had described men’s statements as ‘mature and rational’, and the women’s statements as ‘unreflective and emotional’. In the court’s view, male patients were likely to be over-treated or ‘assaulted’ by technology, whereas females were vulnerable to medical neglect. For instance, women were described as ‘lying in a fetal position’ or being in an infantile state. It followed that the criteria for supporting termination of treatment was more rigorous for women perhaps as a move to protect them, in their allegedly vulnerable posture. Additionally, in the spirit of protection, executive health care decisions for women might be made that overruled her wishes. The court’s gender bias also meant that decisions made for men might have leaned toward an earlier cessation of medical treatment.
In the preceding examples, the researchers aim is not to challenge the basic precepts of bioethics, but to illustrate the relevance of context in how these may be translated or applied. Much of feminism to date has followed this course, engaging in the ethical debates as they are presented and in a dialogue about the rights and autonomy of women individually or collectively. These perspectives are important for elucidating gender bias, the social and political consequences of policy, and again, the relevance of context. Cross-cultural work by anthropologists has changed the understanding of cultural, hence ethical, relativity. It may be inferred that in a heterogeneous society there will be considerable moral diversity. Indeed, cross-cultural work serves to locate bioethics as simply one form of medical ethics.

Anthropology in particular is situated to offer some perspective on intra- and inter-cultural variance. Two contemporary ethical issues that have been explored across cultures are the definition of death and the distribution of scarce resources. Lock, Ohnuki-Tierney, and Lock and Honde explored how specific ways of knowing and responding to death and technology shaped the ethics of medical futility and transplant technology in Japan and North America[51, 112-115], and Kilner’s work demonstrated how different social knowledge leads to different decisions about health care allocation in Kenya[14].

The medical criteria for brain death - the loss of personhood and sentience - are not fixed or measurable categories. In Lock and Honde’s cogent analysis of the brain-death controversy in Japan as compared to North America, it becomes
clear that ethical issues are culturally and historically constituted. The topic of brain death in Japan, and its implications regarding organ transplant has drawn enormous and passionate controversy since it arrived on the technological horizon. Part of the difference is related to the locus of personhood. In the US, personhood is located in self-expression that requires the brain, whereas in Japan the real self is social and resides in the chest (kokoro)[114]. The definition of death impacts how organ transplantation technology is received. For example in Japan, heart-beating cadavers have not been acceptable for organ ‘harvesting’ until the late 1990’s, and it remains under watchful control. Some Japanese would contest organ removal from any corpse, because a lack of corporal integrity may impair the spirit’s journey into the next dimension. In Japan, the biological organism is comprised of an individual’s predisposition and talents given at birth. The person on the other hand is a social entity[112]. Lock notes that death rituals in Japan convert the biological death to a social one, and some individuals consider organ retrieval to interfere with this natural-social death process.

The specific medical criteria for death in North America perhaps reflect an attempt to wrest control of the emotional discomfort and legal uncertainty around end of life issues. Death in biomedicine is the equivalent to a body’s mechanical failure. This conceptual framework contributes to what has been termed the ‘technological imperative,’ and the ethical difficulty around cases of medical futility[33, 34, 88, 125, 126]. In Japan, Buddhist proscriptions against killing, and the sense of an eternal ancestral life may modulate decisions for terminal
care[105]. In North America, autonomy and an ethic of altruistic giving have led to an acceptance of the individuals’ organ donation[33].

In 1968, the Harvard ad hoc committee of the medical school revised their definition of death to include ‘irreversible coma’ and ‘brain death syndrome’. The committee’s decision was in part a response to the increased burden that patients, families, and hospitals faced with the ability to keep brain dead individuals biologically alive. Further, they reasoned, the obsolete criteria for death made organ retrieval problematic. Courts upheld this definition, allowing the termination of ‘life support’ in the case of brain death, and perhaps as importantly precluded the success of lawsuits initiated by survivors. The Uniform Determination of Death Act was proposed by a President’s commission in 1981, supported by the AMA, and became law in most states.

None of this, notes Lock, generated much public controversy. North America has accepted the definition of brain death, and the retrieval of organs for transplant without contest. The questions dominating ethical debates in North America arise in the context of specific cultural values and assumptions. For example, dialogue about the ‘use’ of anencephalic infants, ownership of the body, when to remove organs for transplantation, who gets the organs and where the supply comes from 10, all implicitly accept and promote the routinization of organ transplant as a normal, good and inevitable technology[11, 33, 113]. The debates correspond to the enduring bioethical issues of individual rights and the

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10 Organ allocation may be based on merit, medical need, ability to pay, or US citizenship. There have been ethical concerns about organs retrieved from prisoners or purchased from third world ‘donors’.
protection of disempowered others. Japan’s situated values resist the intrusion of Western individualism and what is perceived as super-rationalism in medicine. This pushes the debate into what Lock and Honde refer to as ‘rhetoric of difference’.

Several anthropological studies have elucidated the ethical relativity of decisions concerning resource allocation. Lieban contrasted the findings of Eidelman’s work in Israel and Subramanian’s work in India, Sri Lanka and Nepal to demonstrate the value and context specificity of treatment decisions for acutely ill infants in neonatal intensive care units (NICUs)[50]. In Israel, the supreme value of life was further reinforced by the Jewish history of selective extermination during the Holocaust, and fears of being outnumbered by neighboring Arabs. The government therefore funded acute care units, so that life support did not have to be preferentially allocated. In Subramanian’s study, physicians made executive treatment decisions based on their assessment of the infant’s future life quality. Their subjective evaluation included medical factors, cost of care, and the family’s ability to access medical care. Privileging the quality of life over quantity was consistent with the dominant Hindu belief in rebirth. Brown has noted that in China, India and Bangladesh, boys were preferentially valued over girls. This differential investment began quite early, affecting multiple aspects of health and survival. It fit the social logic, because in these countries, girls married into the boy’s family, so the productivity of sons, and their specific filial piety promised the parents’ security in old age, and family continuity[102].
Kilner described the moral reasoning among a group of Akamba in the Machakos district of Kenya in what he terms the ‘microallocation’ of scarce medical resources [14]. The Akamba, traditionally subsistence farmers and herders, were undergoing urban migration. The infrastructure was poor, and medical supplies only intermittently available. Healers were presented with hypothetical allocation decisions for this context. If only one person’s life could be saved, healers chose to save an old over a young man, and a childless man over one with family obligations - but it was preferable to save nobody rather than only one. This is in reverse of North American sensibility. Kilner explains that the difference was not in moral judgment, but in culturally different social knowledge. In the United States, youth are preferentially valued for their prospective productivity. The Akamba, by contrast, value the elders for their more complex social history and acquired wisdom. One Akamba healer stated that the childless man must be able to ‘raise up a name for himself’. Since the individual in this case is a crucial link in the ancestor chain, a childless man’s death would terminate his generational life as well as his own. Again this runs counter to the ‘generationally discreet’ view of North American personhood. Akamba healers also offered that it was better to treat two people partially than to decide whom to save. They reasoned that God healed if the healer did their best and acted in accordance with social values. In Kilner’s view, the difference in allocation decisions lay not in moral reasoning, but in what he terms ‘knowledge of a different social and spiritual order’.
Another example of ethical relativity comes from Lane and Rubinstein’s research on female genital surgery in Egypt. They found that the local social cost of not being circumcised outweighed the health risks imposed by the procedure. Egyptian women assessed the ‘moral problem’ differently than their North American counterparts, and the tradition persists[49]. Western feminists, according to the authors, have come to associate autonomy and self-determination with control over their sexuality. But Arab and African women adhering to the tradition of genital surgery said that circumcision completed their sense of being female and assured purity for marriage. The women who opposed circumcision still maintained that it was not the greatest ethical problem on their hands. Domestic violence, divorce and inheritance laws, access to education and legal rights were internally and immediately more relevant to the health and empowerment of Egyptian women.

Anthropology has contributed to understanding both bioethics and Biomedicine as cultural systems. For example, Fox and Swazey compared and contrasted Chinese ‘medical morality’ with American ‘bioethics’[32]. They challenged the ethnocentricity of bioethics, and offered a conceptual deconstruction of the discipline. The article situated Chinese medical morality and North American bioethics culturally and historically, illuminating how they each reflected and reproduced certain social values. It further examined the philosophies that shaped these ethics domains, the individuals and institutions that acted on them, and the issues that arose (and did not arise) within each.
Gaines deconstructed the biomedical assumption that race is biological. He qualified race as a ‘folk cultural concept’ with cultural, historical and local categorical specificity[127]. He cautioned that Biomedicine’s persistent attachment to race as a biological reality might have serious ethical consequences\textsuperscript{11}. Gaines traced the history of the concept of race, its arbitrariness as a construct over time and place, and the particular ways that the continued use of these categories might be problematic. While the media and research industries in the US have created a mutually reinforcing dialogue about racial difference, none of the identified races are ‘pure’, and the terms of inclusion/exclusion are inconsistent. For example, in the United States, geography defines Asians, language defines Hispanics, skin color defines African Americans, location defines Africans and Native Americans, and religion defines the Jews. In Germany, decent determines race while in France it is a person’s cultural group membership as determined by a shared language and civilization. The Japanese claim racial distinction between themselves, Koreans and Chinese - but in South Africa, Japanese are White while Chinese and Korean are Asian. Any ‘mixed race’ person in South Africa is ‘colored’, which would - disconcertingly for some - include most all individuals in the US.

As Bioethics and Biomedicine are so intimately related, a deconstruction of one naturally supports a deconstruction of the other. The cross-cultural comparison of menopause by Margaret Lock, for instance, brings the

\textsuperscript{11} In particular, there are real social, psychological and health consequences to research agendas, symptom interpretation, diagnosis, treatment, and differential resource allocation, which are based on racial categories.
medicalization of women’s lives under ethical scrutiny[128]. Work done by Gaines on cultural constructivism and ethnopsychiatry[4, 86, 129], by Kleinman demonstrating the category fallacy for cross-cultural comparison of psychiatric symptomology[73], and Jenkins, Kleinman and Good’s review of the cultural relativity of depression have all been paradigmatic[130]. Medicine is an inherently moral enterprise. How health and illness is framed, and the assumptions it holds and perpetuates have moral meaning and ethical import.

Another way that anthropologists have participated in the field of bioethics is by examining the values, history and cultural meaning behind contested issues. Lock’s analysis of the brain-death debate in Japan and North America, reviewed earlier, is an excellent example. And Ginsburg has shown how the meaning of women’s lives, and the restructuring of gender lie at the heart of the abortion controversy in North Dakota[116].

Rapp explored the power dynamics and changing cultural meanings associated with amniocentesis for multi-ethnic client base of New York City clinics[117]. She noted that social power locations were refracted through this technology. For instance one Haitian client disregarded the counselor’s concern that his future child might be cognitively impaired, saying that Haitian children were always called retarded. Gendered reasoning also appeared. For example, some Hispanic men demanded amniocentesis because they intended to reject a defective child, and some Hispanic women underwent the test clandestinely in order to retain control of their choice. Some women defended their right to mother even the most physically or mentally challenged baby and other women
asserted their right to abort. Some questioned the contested social definitions of women and motherhood, and still others perceived the test results as confirmation of dreams. Anglo women's reasoning called up ideas about self-actualization versus selfishness. Rapp noted that dialogue around reproductive technologies and rights revealed the cultural and social aspects of reproduction, as well as variations in power relations.

Finally, some of the recent work by anthropologists in the domain of bioethics has explored the phenomenology of the clinical encounter. Kaufert and O'Neil's research revealed the situated meaning and function of informed consent as a biomedical ritual[9]. In the process, they shed light on the interpretive aspect of meaning construction. Young's work explores the use of multiple narratives to negotiate moral meaning in a psychiatric diagnosis, and to manage ethical conflicts and dilemmas in the clinical setting[39, 131].

In theory, ‘informed consent’ is a clearly defined ethical imperative in medical practice that honors the autonomy of the client and offers a contractual basis for trust. In practice, the form and meaning of informed consents are contextually contingent. Kaufert and O’Neil work exemplifies this for the ‘ritual’ of informed consent in a clinic that served Native Canadians. They discovered that clinicians generally made executive decisions about the content and complexity of information to give the client. The Native Canadian explanatory models for illness were often quite different from the clinician’s, leading to the client’s
confusion over the relevance of a proposed treatment\textsuperscript{12}. In this clinic, linguistic interpreters also played the role of a cultural broker. They advocated for the patient and negotiated for the physician. The interpreter’s work was in effect a ‘black box’ of communication\textsuperscript{13} where the interpreter was free to rethink, re-imagine, elaborate, embellish, dismiss or otherwise reformulate the original messages. In this interpretive space the authors observed considerable free-style work by the interpreters based on their particular judgments about the medical urgency, the clinicians motives, the patient’s ability to handle or process the information, how to best convince the patient one way or the other, and what ad hoc information each participant needed about the other\textsuperscript{9}. The interpretive activity that happens in all communication and narrative is physicalized by the presence of an interpreter in this study. The interpreter may be said to represent the modulation of morality and meaning which otherwise occurs in the intersubjective space between individuals\textsuperscript{36}.

Young defined medical ethics as a ‘subset of moral beliefs’, comprised of both norm-ethics and feeling-ethics. He said that norm ethics are ‘rules and principles attached to social sanctions’, while feeling ethics are ‘rules and principles attached to dysphoric feelings’. He then differentiated ethical dilemmas from ethical disputes: dilemmas involve conflicting principles or outcomes, while disputes involve individuals with conflicting needs, goals or values. Young

\textsuperscript{12} Native patients generally assumed a passive posture in medical encounters because it was customary in traditional healing encounters, and because biomedical insurance coverage may have been contingent on patient cooperation.

\textsuperscript{13} Neither the client nor the physician had any way to know how their message was translated.
examined how patients suffering from Post Traumatic Stress Disorder (PTSD)\textsuperscript{14} and their psychiatrists used specific narratives to frame and then work through moral issues. He illuminated a complex phenomenology behind a set of clinical ethics that might more conventionally be reduced to autonomy versus beneficence. When dilemmas and disputes emerge in medicine, clinical narratives were employed by all players as a way to organize thoughts, direct action and construct meaning.

The physician's clinical goal for the patient to recover from PTSD may have conflicted with the patient’s need for the financial and emotional benefits of a disability diagnosis. The therapeutic process may also have been ethically problematic. The PTSD patient’s dilemma was that in order to restore order in his life, he had to first recall his combat behavior, accept responsibility for morally repugnant acts and revisit severe emotional distress. The physicians dilemma was that restoring the patient’s social order was not possible without leading him through emotional pain. These ethical problems were mediated in a number of concrete ways\textsuperscript{15}, but the most interesting process arose in the context of clinical narratives about the origin of PTSD.

\textsuperscript{14} PTSD is a diagnostic term that psychiatry has created to explain a loosely defined constellation of symptoms that, in this institute, are thought to result from the repression of a morally odious act. While many extremes of violence are witnessed during war, only those for which the client fears punishment will result in the level of repression necessary for PTSD to manifest. PTSD clients will continue to re-enact the behavior until they can call up from memory the moral crimes that they committed and submit to the painful process of healing.

\textsuperscript{15} For example, the clinician’s framework discounted the client’s claim that he knows what is good for himself; the patient experiences the chaos in his life as disabling, but the psychiatrist can insist that his disability is the source of his chaos; treatment teams
The clinicians had three etiological narratives that informed their clinical action. The narratives prescribed what Young calls a medical-moral cure, semantically morphing the patient’s feeling-ethics into feelings, and the feelings into symptoms. Thus, the recurrent moral anxiety about his war crimes was redefined as a primal feeling that now caused his living problems. The therapeutic focus was the patient’s subjective (timeless) experience rather than the objective (situated) event. The first therapeutic narrative was about self and time: as the client moved through time, he found himself in morally no-win situations, emotionally disassociated, and acted inhumanly. He was trapped by the gestalt of this unresolved past. Then, in therapy, he may gain the ability to convert those experiences into memory and restore his humanity again. The second narrative was about self and survival: in war conditions the client grew accustomed to violence and was instinctually bent on survival. Memory of the violence caused guilt, frustration and eventually eruptions of unacceptable behavior, followed by additional guilt. In this story, the client was offered a moral solution through re-identification as a war-victim on an ‘alternative moral landscape’. The third narrative was about self and betrayal: This is the story that physicians held for themselves about their clinical work with the problem of PTSD. Their patient’s anger was challenging and might generate fear for the clinician – either fear of the patient or fear that therapy could harm him.

collaborate to label ethical disputes as ‘acting out’ or ‘resistance’ in the client; and the treatment team responds ‘therapeutically’ to client rule violation through warnings, ward restriction, or simply discharge. All these means have a coercive element, because the psychiatrist has the final authority to proclaim or disclaim a client’s disability.
Alternatively, the clinician might identify with the client’s victimization and falter in delivery of the requisite ‘therapeutic pain’ of recovery. The narrative resolution for the clinician is a steadfast allegiance to the therapeutic philosophy and to the patient’s need for future symptom relief – a sort of delayed kindness.

Bioethics has provided a forum for the social negotiation of medical ethics that protects individuals from arbitrary and capricious decisions. On the other hand, the field’s history of a somewhat homogeneous demography contributes to the constricted perspective on what the issues are and how they should be approached. This perspective fails to consider the clinical reality and diversity of individuals, relationships, values, ideas and local particulars upon which clinical ethics are ultimately contingent. Internal Bioethical critiques primarily attend to the shortcomings of various methodologies. External critiques from feminism and the social sciences go further to expose the fault lines within bioethical thought. The social sciences have also contributed to moral theory through the exploration of narrative, ethnography and experience. The social science turn towards ethical relativity, context, and phenomenology has opened the way for new vision into the social, cultural and historical forces that shape the discipline and the questions it asks. The discipline of anthropology is poised to reveal bioethics as one form of medical ethnoethics, encouraging more critical thinking about how ‘issues’ are identified, framed and approached. Rather than problematizing the ambiguity of moral quandary, an interpretive anthropology may reconceptualize it
as the living canvas for a socially negotiated human response to suffering and uncertainty.

HISTORIOGRAPHY OF BIOETHICS

One of the more interesting things of late is the proliferation of literature scribing various histories of Bioethics[132]. Gaines postulates that these histories represent timely ‘origin myths’ that answer a need for disciplinary identity. The myths fall roughly into three categories: reactive, proactive and evolutionary. Each sets a slightly different projected path for future growth in the field of Bioethics. Histories that portray a reactive Bioethics point to technological advances, unregulated research trajectories and cultural pluralism as the impetus for the establishment of the field. A history of Bioethics as proactive is a call for individual rights and a less paternalistic medicine. Bioethics as evolutionary is represented in the growing collection of classic cases that offer a sense of progress in moral deliberations.

Literature on medical ethics is dominated by an ongoing analysis of selected ‘classic cases’ in clinical and research medicine from diverse philosophical standpoints. The impetus for work in this field has been to develop theories that can reliably guide medical-moral decisions. This goal is perpetually out of reach. While certain ethical tenets will fit ‘medicine as usual’, it isn’t possible to circumscribe one right thing to do in complex, ambiguous and
uncertain clinical situations. Yet studies of Bioethics’ classic cases continue to be the backbone of texts, academic courses and of physician education. Recently these selected cases have lent a sense of purposive evolution to sundry accounts of Bioethics’ history. These cases are central to Bioethics. They embody hidden assumptions, express core values, are the residue of quandaries past, and perpetuate existing theory. Importantly classic cases are both generated by and invoked as moral templates in clinical, legal, media and public deliberation. The resulting positive feedback cycle defines and possibly limits the trajectory of Bioethical dialogue.

THE ETHNOGRAPHY OF RESEARCH MEDICINE

In the post World War II years, liberal federal funding paved the way for an unprecedented growth in medical research, and a proliferation of medical specialties. This is the time that experimental medicine began to have dedicated clinical space, a sort of medical enclave with its own ethos. In those early years, only the most desperate medical cases, those with nothing to lose, would participate in experimental medicine. This is a time Fox called the ‘golden era’ of experimental medicine. She describes an environment of permissive patient-oriented clinical research: a necessary evil[20, 33].

As clinical research opportunities grew, a subculture of medicine formed that was infused with optimism and actively involved patients as collaborators in challenging medical ventures. Research participants often educated themselves
about the trials, were excited about their contribution to science, and held fast to hope on the edge of medicine. Fox observed that patients sometimes received local notoriety on the investigational medicine ward during the 1950’s, and research survivors formed relationships based on their shared experience. This same medical subculture thrives in research centers today.

“Out of their common predicament of chronic and terminal illness, high medical uncertainty and risk, severe therapeutic limitation, and constant closeness to death, and in response to their dual, often conflicting roles of physician-investigators and patient-subjects, the men of (experimental medicine unit) were collegially committed to medical research.” ([20]pp. 261)

Medical Oncology in the United States exemplifies this culture of optimism and risk-taking. It has become almost a moral imperative for cancer sufferers to power their recovery with hope and medical cooperation toward one of two transformations: a cancer survivorship or a heroic death. M-J Good examined a narrative process in oncology she calls the ‘discourse on hope’. In her research, physicians tailored their conversations about diagnoses, treatment plans and prognoses with the unarticulated goal of maintaining hope for themselves, for their practice, and for their patients[37]. For example, the physicians created an alliance with their patients and held space open for hope by staging the delivery of difficult news.

Hope, she found, was an essential element for recovery in the estimation of cancer patients and clinicians. Importantly, hope was variously experienced and meant different things at different times for the patients: hope for recovery, hope for pain control, hope for more time, hope for meaning, and hope for rest
were some of the shapes Good observed[37]. In the North American sense of hope for ‘the cure’, fueled by a selective statistical framework and research narratives patients may feel obliged to accept all treatment possibilities.

Ethnographic research in this area finds that treatment ‘choice’ and ‘consent’ are experientially altered in cases of life-threatening illness[11, 20, 21, 34, 38], Although some levels of medical intervention might be categorized as ‘expensive salvage therapy’, Good and Good found that physician’s narratives continued to construct a sense of hope. They report, for example, that the more optimistic statistics for routinized bone marrow transplant were invoked in an investigational setting where these statistical outcomes were far less probable. The Goods call this relational reciprocity between clinical research medicine and standard medicine a ‘biotechnical embrace’. It keeps the physicians and patients encouraged that investigational medicine is therapeutic. This is the premise of what has been termed ‘therapeutic misconception’ of research trials[133-137].

Another theme running through the culture of clinical research medicine is what Fox and Swazey term the ‘courage to fail’[34]. It has not been unusual for clinical investigators to optimistically pursue research that has inadvertently exposed patients to compounded risk and suffering. The confidence in scientific breakthroughs began in medical school, infused clinical research and contributed to taking risks in hope of one eventual success[21]. Belief in the next ‘magic bullet’ created what Fox calls the ‘therapeutic innovation cycle’. In this scenario, the research team’s excitement and faith in a new drug or technology can lead to an overestimation of its usefulness or an underestimation of its
potential harms. As evidence crops up for the toxicities or limitations of that innovation, the enthusiasm in the scientific community becomes quiescent until the next idea for ‘the cure’. The therapeutic innovation cycle sets up the possibility of hasty, thus, questionably ethical research. Fox observed this process, for example, during the 1980’s with cyclosporine and again with the Jarvik-7 artificial heart. Although these patients would have died of their disease, the research perhaps caused more suffering or an earlier death. In these types of research cases, a more tempered appraisal of the risks and benefits might protect patients from suffering, and toxicity or death. Additionally, it may factor in to patients’ decisions to participate.

Ethics in the context of research medicine has always been different from other settings. Today it is an ‘equal opportunity' medicine: patients qualify by diagnosis. Social access issues are not at the fore as they are with community medical care. With the proliferation of dedicated research centers and the participation of hospitals in research protocols, investigational medicine has become more commonplace. At times it may be perceived as a medical entitlement. The ‘informed’ component of patient consent for research is semantically ambiguous. The risks and benefits are not fully known. And risk is not so easy to calculate.

16 Cyclosporine was a newly discovered immunosuppressive agent that promised success with organ transplantation. This has come to fruition, but early research trials had high and possibly avoidable toxicities. In the other example, Barney Miller and 3 others received the Jarvik-7 heart prior to the product’s readiness for use with human subjects.
One of the interesting findings in this research was the extensive use and portrayal of various risks that the decedents had faced during the course of their illness and treatment at Fred Hutchinson Cancer Research Center. Risk was variously quantified, compounded, compared and disputed throughout the courtroom trial. Statistics were presented in part so the ‘reasonably prudent’ juror could determine retrospectively whether the decedents would have participated in the research protocol. The elaboration of statistical risk also contributed to a sense of danger and created a dependence on the expertise of medical scientists as risk brokers. Risk played a pivotal role in the narrative evolution of the FH case, in the resolution of this particular trial, and in the concluding moral assertions. These findings bring together the many facets of risk now discussed in social science circles from the standpoint of social functionalism, cognitive psychology, and cultural constructivism. Additionally, these research findings directly contribute to a specific phenomenology: risk was instrumental in the recreation of a research medicine gestalt and provided a vehicle for narrative movement throughout the trial.

Many of the contemporary philosophies of risk are derived from Mary Douglas’ cultural archeology of risk, the social constructionist views of Ulrich Beck and the constructionist- psychometric paradigms of Paul Slovic, Nick and Roger Kasperson, Baruch Fischhoff and others[18, 70, 138-140]. The largest body of qualitative research on risk relates to environmental hazards and public
health concerns. Anthropological expertise has been engaged instrumentally to explore cultural factors in risk perception and barriers to behavior change. Additionally focused ethnographies have illuminated the finer points of narrative in the construction and experience of risks. This section reviews these seminal works, and explores various contributions to understanding the risk world of Biomedicine.

The quantification of risk is historically rooted in the development of probability statistics during the mid-17th century, and the early elaboration of health risks in life insurance actuarial tables developed in the mid 18th to 19th centuries. Douglas notes that during this time, the meaning of risk shifted from chance or luck to danger. She states that the calculation of risk was originally a applied to gambling gains and losses. Today, risk is semantically more strongly linked to a potential for loss. Other authors have suggested that risk in North America additionally includes taking chances for positive reasons. Heroism, pioneering work, research medicine and adventure sports fit this genre.

Skolbekken noted an exponential increase of the assessment and explication of ‘risk’ in medical and epidemiological journals since 1969, attributable in part to a growing faith in the power of medicine and science to predict and control life’s uncertainty. Increasing technology, the growth of preventative medicine, attention to health promotion, a health consumer culture, the assumption of personal responsibility for risk exposure and importantly, the expanding use of computer technology have all contributed to a proliferation of statistical information and to what has been termed a risk epidemic[141]. The
social sciences’ behavioral and conceptual research on risk evolved contemporaneously.

Beck developed the notion of a ‘world risk society’ in which the unknown future consequences of technology and research are progressively suspect[140]. The risk society he identifies is the continual articulation of risks and correctives that unconsciously function as a natural social reflexivity. Elliott furthers Beck’s theory, identifying three social processes with import to individual risk experience[142]. The first process is privatization wherein individuals are held accountable for making the right choices to avoid risk; the second process is commodification through insurance and security products and the third process is what Elliott calls an ‘instrumentalization of identities’ through the construct of lifestyles. Privatization, commodification and instrumentalization of identities can at times be appreciated in the world of medicine. Individuals have been tacitly blamed for certain illnesses. For example, heart attacks at one time were linked to ‘type A’ personalities and individuals with lung cancer have been stigmatized because of the link to smoking. Patients and non-patients alike have been re-imagined as healthcare consumers. Tamoxifen has recently been marketed to healthy women in conjunction with an invitation to learn their breast cancer ‘risk number’. And finally, instrumentalization of identity is exemplified through the social proscription for an individual to take a hero’s journey through cancer. This pathway is not available for those suffering with degenerative conditions. These explanatory theories suggest that risk is socially instrumental, but do not address how risk is constructed and interpreted.
Logically, it is the choice of research question that determines which statistics will be generated. The way these numbers are then framed and communicated will influence the end risk perception, and possibly inspire social action or change individual behavior. Although uncertainty and chance exist in all aspects of life, it is only when it is identified and somehow qualified or quantified that it has individual import or social meaning. In this sense risk is always a cultural construction, with three conceptual building blocks: risk identification, risk communication and risk perception.

Douglas explores risk as a contemporary and secular extension of sin, impurity and blame. From her anthropological vantage point, the social articulation of sin or taboo protects the group from the dangers of individual misbehavior whereas the articulation of risk protects an individual from community dangers[143, 144]. This analogy might be extended to the way that risks in medicine are defined. Poor individual hygiene might put a community at risk for communicable diseases while unchecked marketing of pharmaceuticals might place individuals at risk. Blame and risk perhaps more often refract the position of the observer, in that they might be equally attributed either to a particular medical technology or to the lack of that technology.

Douglas notes that it isn't possible to unequivocally rate degrees of risk unless there is agreement about what matters and to whom it matters. She developed a box grid plotting certain - uncertain against contested - uncontested to predict the perceptual magnitude of a given risk. Because most risks are contested and uncertain, she posits that risk articulation reflects local changeable
politics and cultural values. She notes that even when several risks are known, certain ones will be highlighted and others diminished depending on a desired outcome. Asbestos for example was once widely used to prevent the risk of burning and is now primarily identified as an agent in asbestosis and lung cancer. Fischhoff states that risk only takes shape to the extent that it is observed and calculated[138]. In this way, even the identification of risk is subjective. He notes that, for example, the United States government has tighter surveillance on - therefore more ‘risk statistics’ on - carcinogens in food than in water or air.

Most social science research now considers the position of the risk audience and the social context of risk communication. Kasperson worked out a theory on the social amplification of risk, developing a flowchart for understanding risk perception[18]. He charted various interactive factors that facilitate, augment or minimize an individual’s evaluation of risk. The ‘social amplification of risk framework’ (SARF) illustrates that risk construction is a dynamic social process. SARF is aligned with Slovic’s work in risk ‘decision research’[70].

Decision research in part looks at how the acceptability/unacceptability of risk occurs. Slovic has developed a three-dimensional factor analysis graph that plots controllability, visibility and number exposed to estimate the relative magnitude of perceived risk. He has coined such terms as ‘signal value’, ‘stigma effect’, ‘intuitive toxicology’, and ‘affect heuristic’ to understand the interactive process of risk perception. A progression of related events, for example, oil spills and industrial waste dumping might be examples of signal value where an
individual occurrence represents a bigger environmental risk picture. An example of stigma effect might be the conflation of the risk for contracting E. Coli infection with a risk from eating spinach. Intuitive toxicology and affect heuristics are another way of saying that the end product of risk assessment is individual, qualitative and experiential. For Slovic, risk construction is participatory, though he, like Kasperson contend that whoever defines a given risk sets the trajectory for finding solutions.

In a broad sense, these risk philosophies have been applied to the field of Biomedicine. Statistics have been exponentially generated from active medical research fields and the concept of risk has been recast as controllable future disease. Risk has been naturalized as something that can be discovered with scientific tools and reason. One new task is to prevent pre-patients from becoming patients, and non-sufferers from becoming sufferers. Social policy and the campaigns in preventative medicine are strongly influenced by the selection and framing of risk statistics. In the clinical situation, population level statistics must somehow be translated to the individual circumstance. Kaufert and O’Neil’s research on hospitalized Inuit birthing and a deconstruction of breast cancer risk by Gifford are two contextualized examples of this phenomenon[90, 145]. In the first case political factors shaped the narrative and the interpretation of risk. The latter example suggests a clinician-client risk-phenomenology.

Kaufert and O’Neil report that a regional gap in the neonatal and perinatal Canadian mortality statistics during the 1970’s led to rural health stations’ policy to evacuate all pregnant Inuit women to hospitals hundreds of miles away. Local
health professionals supported the policy, but the Inuit women felt that, in the context of all life risks, birthing was relatively safe. They actively resisted by reporting to the health stations late enough that evacuation could not be timely – even when medically indicated. Kaufert and O’Neil’s ethnography elicited recollected stories consistent with Slovic’s risk ‘signal value’. The Inuit women’s reasoning revealed their learned and lingering distrust of the healthcare authorities. During the 1950’s, there was a forced evacuation of individuals with tuberculosis that led to permanent community displacement and high mortality. The Inuit live in remote regions of Canada where survival depends on collective community skills. Congruent with Kilner’s idea that differing judgments arise from different social knowledge [14], the Inuit knew that to lose (midwifery) expertise and control over birthing placed the community at greater risk than did the birth of a child. The authors concluded that the health providers’ use of risk statistics to gain federal funding, Inuit compliance for obstetric care, and evacuation was translated by the Inuit as a statement of dependency on government services. As the practitioners tried to communicate their position it became clear that the dialogue about ‘risk’ in this case was a meta-conversation reflecting power dynamics and political values[145].

Gifford’s and Love’s risk analyses of breast lumps demonstrate some ways that population statistics are applied to individual women and how those risks can become embodied as fear[90, 146]. For example, most women have some degree of lumpiness in their breast tissue, but if the woman has a
constellation of other risk factors, i.e. family history of breast cancer, is nulliparous, and is over the age of 40, her breast lumps may seem more dangerous. Fear can motivate a woman and her doctor to consider preemptive removal of the lumps or even the breasts to protect against the development of cancer[146]. The sense of danger in risk is presented in (often) conflicting ways. The potential danger is reified through an elaboration of statistical correlates as risk ‘factors’, amplifying some while eclipsing others. For example, Gifford states that while a woman is statistically more ‘at risk’ for breast cancer if she conceives her first child after the age of 30, this analysis obscures the personal and social benefits the woman might attain by postponing motherhood. Alternatively, a woman who has a child before the age of 18 is considered a high ‘social risk’, but statistically she gains protection from breast cancer. The selective identification and quantification of risk in these types of situations makes it difficult to interpret what the risk really means.

A woman who is diagnosed as ‘at risk’ for breast cancer might live in a state of liminal health and her life may become medicalized. The woman risks cancer and death if she doesn’t submit to medical surveillance and the doctor risks personal and legal liability if a diagnosis is missed. Gifford concludes that breast lumps in particular embody the risks for both the woman and clinician, providing a way to gain control of a nebulous situation. Cutting the lump out means cutting out the risk[90].

Gifford then considered the process through which the risk is (re)-constructed. She noted that from the clinician’s perspective, the fact that a
woman who comes into the clinic fits the risk profile described in the literature confirms that the risk exists. Transformation of theoretical knowledge into experience makes the risk real for the physician, giving it personal meaning and substance. As the clinician takes action on his/her perception of danger – by communicating concern, recommending mammography, biopsies or mastectomies – the sense of risk is created in the mind of the woman. In some cases, the woman will not have enough medical savvy to question her clinician’s view. She may defer to and embrace the newly articulated risk with its attendant sense of danger. Because the woman now experiences herself at risk, she may be amenable to medical surveillance and the suggested interventions. Medical decisions in this context evolve from culturally augmented perceptions of danger. In this case, the perception of danger to health (rather than the level of actual danger) and the actions that follow reflect and also recreate a culture of risk.

Svendson’s ethnography on the construction of risk in genetic counseling illustrates the power of the medical narrative to impute a heritable risk diagnosis and to create social relatedness from genetic family trees[71]. The risk calculations in genetic counseling are derived from compounded population statistics. For any one individual, they are theoretical and ambiguous. One statistic affirms that 80% of individuals who carry one of the identified breast cancer genes go on to develop cancer. Each of the next generation is at a 50% risk for getting the gene, so they are at a 40% risk of breast cancer. The next generation has a 25% chance of getting the gene, so only a 20% risk of breast
cancer. But risk doesn’t actually travel down generational trees. If the gene is not transmitted, the chance of breast cancer is on par with the rest of the population. If the gene is transmitted, the risk for breast cancer once again 80%. This sense of genetic risk movement and the moral responsibility to communicate the risk to cousins, nieces, etc., is in this author’s analysis, an example of culture creating biology.

Cross-cultural research in AIDS prevention again underscores the influence that social knowledge has in making health decisions. In Smith’s work in Nigeria, it was discovered that health care workers were ineffectual at communicating AIDS risk along with prevention strategies in part because individuals assumed that AIDS was a consequence of immoral behavior and was located in the ‘other’[147]. Personal morality therefore conferred a sort of HIV immunity. Additionally, it was suspected that prevention campaigns were designed to discourage sex or covertly control population growth. Smith notes that in 2003, only about 6% of the Nigerian population was infected with HIV and the relative incidence of AIDS was low. The lack of illness visibility further diminished participants’ experience of risk.

Hunt’s research explores a narrative process for Kasperson’s amplification or attenuation of risk perception[18, 148]. In the case of genetic counseling she observes something like a black box during the clinical moments when statistics and risk are communicated. At this time, although risk presentation might suggest the reasonable course of action, clients have room to reinterpret the information, and then map their own decisions. This idea is supported by Rapp’s ethnography
on the differential perception and response to communications of genetic risk in
the case of amniocentesis[117]. The risk of Down's syndrome, risk of the
amniocentesis procedure, risk of inaccurate testing, and risk of age were
weighted differently during each clinical encounter. Ultimately, Rapp found that
clients drew on their situated and gendered social knowledge to make decisions.
Hunt proposes that, in the case of genetic counseling, clients would be able to
make more informed choices if the conflation and ambiguities of the statistical
information was discussed[148]. That would perhaps undermine the rationale for
invoking statistics in the clinical setting. If it were possible to disentangle the
ambiguity and numerical conflations, then it would make more sense to deliver
that unclouded calculation to the client. This may be premised on an impossible
rationality. Even putatively rational choices can be skewed by the presentation of
statistics. McNeil et. al., discuss the framing of risk statistics in a population of
lung cancer patients who were to choose between surgery or radiation treatment.
They found that the group offered survival statistics for surgery (68%) were more
likely to opt for surgery while the percentage shifted toward radiation in the group
offered mortality statistics (32%).

Slovic designed a hypothetical legal case about a firms’ irresponsible
exposure of individuals to asbestos in which he evaluated the effects of risk
comparison. He found that contrasting the risk of a harmful outcome from
asbestos exposure to something more risky lessened an evaluator’s verdict of
culpability. He also found that when the researcher reviewed the strategic risk
comparison the evaluator was inclined to return to their original verdict in the
case. Johnson expanded on this study by offering the jurors a critique of these effects prior to the comparison being made. This had what he calls an inoculation effect. In other words, if the hypothetical jury was told that they would be offered a comparative risk that would affect their perception, they were less likely to change their position. Johnson notes that in the case of juried trials, this is quite an important point because if one side can anticipate a counterspin and offer it to the jury in advance as something that might alter their perception, it will be less effective.

Research medicine is a special case of risk construction, because statistics are endlessly generated to direct and evaluate research and its clinical application. As evidenced during the Fred Hutchinson trial, these statistics can be utterly confounding. Slovic and Fischhoff observe that when presented with a number of risks, individuals have to choose which risks to attend to but in the case of too many risks, they may feel impotent or overwhelmed and simply conclude that anything can go wrong[139]. This is particularly true in medicine where it is usual practice to offer an array of risk statistics assuming that a rational choice can then be made. How (and to whom) risks are identified and communicated can change the end-perception of what is the risk. Adelsward and Sachs state that statistical risk is confusing because there are several layers of translation necessary to move it from an epidemiological calculation to academic medicine to clinical practice and then to the layperson. In an effort to quantify data, to bring uncertainty under control, there is little attention to how those numbers are brought about or what they really mean. For example, if safety is
defined by 0% risk, then everything else holds degrees of danger[58]. Certainly in cases of extreme illness and in research medicine, there is no ‘safety’. The illness as well as any form of treatment has degrees of danger and uncertainty and nearly every phase of research generates statistics. But that statistical enumeration can be problematic. For example a certain risk calculation might apply to an individual, to the entire population, or to a defined group of people with similar factors. Even a fixed number might be interpreted different ways by the clinician, and communicated variously, depending on their evaluation of the patient and the medical context. In one instance, borderline laboratory tests might be deemed ‘problematic, normal, nearly normal, nothing to worry about, or something to watch’[58]. Each of these might mean very different things to the patient, in the setting of his/her own priorities and social knowledge.

Finkler’s study with risk narratives notes that statistics offer the illusion of control, and as Beck’s risk society imagines, individuals may live attempting to prevent tomorrows dangers[60]. With a mixture of purportedly controllable behavioral and predestined genetic risks, the individuals in her study didn’t know how to relate to the presence of disease and risk of future disease when they had ‘done everything right’. Kavanagh notes that embodied risks are difficult to apprehend because they are a part of the self[62]. While environmental risks can be avoided and behavioral risks modified, there is nothing much to do with embodied risk except medical surveillance and personal vigilance for evidence of disease. Scott’s findings agree with Gifford’s: individuals diagnosed ‘at risk’ are in a liminal state[69, 90]. Scott further observed that persons who were deemed to
be at moderate to high risk seemed to accept the risk and medical monitoring but
didn’t experience themselves as ill. Those who were at low risk seemed
centered that they were somehow left without sufficient risk and attempted to
inflated the meaning of whatever risk they did have. They were not offered medical
monitoring and Scott reports that some of these clients then jockeyed for a higher
risk position.

Research medicine is a special case of risk construction because patients
live in a state of continual embodied risk and every medical decision holds
uncertainty and elements of danger. The experiences are qualitatively different
for the healthy ‘at risk’ person and for a patient in the context of research
medicine making perhaps daily incremental decisions on which his life depends.
This research project further explores the construction and embodiment of risk.
CHAPTER 3: METHODOLOGY

Social science methodology, as Bernard has observed, encompasses at least three distinct aspects: 1) the selection of epistemological premises, 2) the data collection procedures and 3) the analytical approach[149].

This research, exploring a cultural phenomenology of medical ethics, is best suited to the epistemological premise that ‘truth’ and ‘knowledge’ are mutable, participatory, temporary, contingent, culturally specific and can be understood only partially [6]. Moving viewpoints offer a kaleidoscope of points to view. In other words, there is ‘more to the story’ from an interpretive standpoint. Phenomenology further eschews that the observer cannot be separated from the observed[150]. This premise invites reflexivity throughout the research and the analyses.

The study has adopted a ‘naturalist’ approach to gathering data. In short, the narratives for this project were collected exactly as they evolved without the elicitation, manipulation or experimental design of the researcher. The textual data was harvested directly from its source while performance data relied heavily on participant observation in the courtroom. The research design lies not in the data collection, but in the selection of a topic (the narrative construction of Bioethical reality) and of a representative research site (FHCRC) to yield an instrumental case study. Stake describes an instrumental case study as one in which the
specific case is important only secondarily to the issue or topic of the research[7]. This project seeks to identify how a particular ethical issue is constructed through the medium of narrative in the context of investigational medicine. FHCRC, the protocol under fire and the litigation are of secondary significance.

Finally, the analytic approach explores the data for both content and semantic movement through time. A qualitative narrative analysis is accomplished using a classic architecture of stories[151, 152] and the identification of semantic networks. Semantic networks is a term that is conceptually generalized from Good’s “semantic illness networks’ or SIN [36] in that it draws together words, feelings, reported experiences and performance that collectively give meaning to embedded themes. Additionally, the study employs a systematic analysis with detailed coding for themes and content[153], chronicles narrative shifts, and reflects on how these events are historicized. This chapter further delineates the tri-part methodology of epistemology, data collection and analytic method used for this project.

**EPISTEMOLOGY**

One aspect of the illness experience awaiting research is what might be termed ‘bioethical reality’. Bioethical reality as used in the research is an analogue to Kleinman’s ‘clinical reality’, a term he coined to
conceptualize the dynamic constitution of medical moments between patients and providers [35]. Bioethical reality encompasses the lived experience of moral uncertainty in medicine and the socio-cultural processes that give shape and meaning to the issues that arise.

Investigational treatment is a final resort for some patients in the face of an illness that cannot be effectively treated with conventional medicine. Often their prognoses are dire. It is this extreme illness situation combined with new and partly tested interventions that most often inhabit the world of research medicine. This world brings moral issues to the foreground of individual experience more poignantly than standard medical practice. The difficulties that arise are usually managed within the clinical context along a socially negotiated pathway, most often through direct communication and collaboration between the physician, the patient and their designated family\(^\text{17}\). Difficult cases may be taken further, including consultant physicians, ethicists, multi-disciplinary ethics committees and even judge and jury when mutuality cannot be reached. Occasionally, the social negotiation of ethical issues also goes public, as was the case for FHCRC’s protocol.

Bioethical reality might be viewed as a complex Möbius-like loop encompassing the articulation(s) of a problem, the social negotiation(s), and the medical-moral decision(s) that follow on from the initial feeling of

\(^{17}\) This has been the standard of practice in both routine and research medicine at least since the formalization of patient rights and growth of medical ethics as a field of clinical practice during the 1970’s.
ethical uncertainty or conflict in medical practice. This reality might further include the how the story is embodied and retold by individual laypersons and by the medical profession. The ethical event might see several iterations of this process over time as new experiences, perspectives and applications of the issue come to light. In the case of this research with FHCRC, a once completed bioethical loop was opened to public scrutiny and redefinition by the provocative article published in the Seattle Times newspaper. The embodied stories were retold and reworked in the context of a courtroom trial two decades after the clinic events, leading to revised bioethical realities for the original clinical players. That is to say, historical events lived out 20 years prior were then experienced differently by each participant as a direct result of new narrative.

This study is designed to explore the socio-cultural processes that inform and shape the ethical issues in these cases and the role that many forms of narrative play in the constitution of bioethical reality. To extrapolate a construction of cultural experience from the scribed and inscribed data is necessarily an interpretive process. The research conclusions, suggestions and emergent questions are inextricably linked to the interpreter. As such, this project is best approached from a position Kleinman refers to as “insider-outsider”[28]. The researcher for this study is ‘positioned’ as an anthropological observer (outsider) to a professionally experienced medical world (insider) intentionally to provide transparency for the reader.
The data collection and analytic method follow on naturally from this cultural constructivist epistemology. This chapter will discuss the research design and preparation followed by the process of data collection, narrative as the selected analytic modality, and importantly, the problems with narrative representation.

RESEARCH DESIGN AND PREPARATION

The research design selected for this project is a contextualized diachronic case study of the narrative phenomenon of cultural construction. Generally, it looks at how medical ethics are given form and meaning in the local culture of research medicine. Specifically it follows the (media, public, courtroom and academic) narrative reconstitution and metamorphosis of ethical reality over time in the particular case of one research protocol at a representative medical research site, FHCRC.

The initial preparation was an inquiry into the history and background of Fred Hutchinson Cancer Research Center, the nature of bone marrow transplantation (BMT), the types of conditions that BMT was used for, and how patients talked about their experiences. Specifically reviewed was how FHCRC evolved as a fruitful cooperation between mission-driven sponsors and visionary researchers. Further inquiry followed the early days of canine research, the successful clinical applications of BMT and the eventual growth of FH from a few beds in the Public Health hospital to the 1980’s configuration of the Hutch as a
self-contained clinic, clinical laboratory, animal research and patient care facility and finally to its present form as the exclusively laboratory-research arm of a multi-institutional collaboration designated the Seattle Cancer Care Alliance (SCCA)\(^ {18} \). Additional preparatory review included the history of gamma irradiation as medical treatment, the evolution of tissue typing, the history of identifying blood cancers and the intersection of these histories that led researchers to explore BMT as a logical medical therapy, and from there, the growth of this medical innovation into an entire medical subspecialty of hematology-oncology. A working knowledge was gained for this case on normal immunophysiology as well as the pathophysiology, disease course and symptomology of leukemia; the desired and undesired effects of radiation and chemotherapy; BMT as a therapeutic modality; Graft-Versus-Host-Disease (GVHD); and the medical application of monoclonal antibodies for T-cell depletion as GVHD prophylaxis. The sum of preparatory data was drawn from the researcher’s professional background, medical books, hematology-oncology journals past and present, the SCCA website, bulletins and reports published by FHCRC, as well as the autobiography and early articles published by Dr. E. Donnall Thomas, one of the co-founders of FHCRC. As needed, additional clarification was obtained through both former and current FHCRC research staff as ‘key informants’ specifically for this highly specialized field of medicine.

\(^ {18} \) A synopsis of this history is published by FHCRC and in condensed form is available on their website: http://www.fhcrc.org/about/history/index.html
DATA COLLECTION

The data for this research are what Gaines refers to as both 'embodied and disembodied discourses'[4]. These encompass all narrative manifestations of the FHCRC story: the written, spoken, performed and inscribed. Written narrative includes printed media, editorials, journal articles and internet dialogue; spoken narrative includes broadcasted news, advertisements and public relations pieces as well as anecdotal public conversation; performed narrative includes all aspects of the courtroom as theater; and inscribed narrative specifically speaks to the experiential world of embodiment.

A piece of investigative journalism was published in 2001 by the Seattle Times newspaper entitled “Uninformed Consent”[1]. It described in detail a former FHCRC researcher’s ethical concerns involving a 12-year run of two research protocols at the Center with unusually high mortality statistics. Although the events had taken place during the 1980’s, the article reported that litigation was pending, and in fact the case came to trial in 2004. The paper suggested that the researchers had personal and financial interests in the protocols, that they knew but failed to communicate the risks of this research to the patients, and that they disregarded the concerns of their own research review board. The crime-buster tone cast the patients and their families as victims of self-serving medical researchers. There was a flurry of editorials, rebuttals and commentaries published in the wake of this exposé.
It is typical for emotionally charged ethical topics to elicit a polarized debate. For example, in the case of abortion in North America, the dialogue might expound on a fetus’ ‘right to life’ versus a woman’s ‘right to choose’. End of life issues have pitted a patient’s ‘right to die’ against medicine’s ‘obligation to treat’. The public response to the Seattle Times’ article similarly split into two camps. Either the patients were victims of opportunistic medical research or the medical researchers were victims of an opportunistic press and litigation lawyers. That central way of framing opposing ethical storylines rippled through the media, the courtroom dialogue and academic journals.

While most research in Bioethics takes an ethical case as its object of study, my research takes its object of study to be the narratives about an ethical case. While temporally displaced, these narratives hold all the textual qualities needed for a Cultural Constructivist analysis of moral experience. In this instance the bioethical reality stemming from the investigative report includes the reactive public and professional sentiment, the courtroom performance, the changed life-worlds of litigants and the FHCRC team, the distillation of events found in academic journals, how they are recorded in bioethical history, and the impact of this case on future clinical experiences.

Armed with a base of information on the history and culture of FHCRC, leukemia, BMT and the research protocols pertaining to this case, the data collection began with a search of public legal records and the acquisition of (copies of) records, letters, and business documents related to the pending litigation. The participant observation involved daily attendance through the eight
weeks of court proceedings, a review of the complete record of trial transcripts, the flow of press releases, professional and academic journal articles, and keeping abreast of informal cyberspace discussions. In sum, this produced nearly 4000 pages of narrative data\textsuperscript{19}. Additionally, observational data was collected in the form of detailed field notes on context, performance, narrative style, and non-verbal communication that cannot be captured simply by transcription of words.

Legal discourse has been compared to literature and the courtroom to theater\textsuperscript{[154-159]}. Through this lens, the courtroom drama aligns with Turner’s analysis of ritual. It reproduces through symbols, ritual and instruction, a suspended moment of experience where participants engage in the construction of meaning\textsuperscript{[160, 161]}. Each phase of this research project fully appreciates that narrative is an important component of both inter-subjectivity and embodiment\textsuperscript{[162-164]}. In turn, narrative offers a window into nodal moments of cultural construction.

**NARRATIVE AS ANALYTIC MODALITY**

“Narrative can be thought not only as a set of contents but also as a form and a procedure. That is, its analysis can be formalized to a certain degree of abstraction, which allows its formal features, units, and combinatory principles to emerge, and thus permits morphologies and comparisons.” ([157]pp. 2)

\textsuperscript{19} The trial transcripts accounted for most of that data. Re-formatted to single spaced text, they ranged from 75 to 145 pages for each of 35 courtroom days.
The fields of Anthropology, Sociology, Ethics and Law have extensively mined narrative for its power to express, animate, construct, and deconstruct experience [8, 11, 12, 36, 37, 39, 60, 71, 80, 88, 99, 152, 155, 157, 158, 163, 165-171]. Words are one vehicle through which a moment can be captured, the past brought forward, or the future imagined. Good has drawn on the literary parallel of emplotment to illustrate how unfolding stories of illness are part of an experiential process with subjunctivizing qualities. In this sense, subjunctivizing means that multiple, indeterminate and shifting story lines create a living text with which participants actively engage. Good also contemporized a phenomenology of narrative by fusing Sapir’s theory on the constitution of social reality through local language habits with Bruner’s thoughts on the living moments of uncertainty that engage both the teller and the listener in meaning construction[36, 172, 173].

Narrative is a powerful analytic medium, in part reflecting the movement of experience and meaning over time[36, 51, 75, 80, 86, 99, 117, 174] – or, the movement of time through experience[10, 39]. This rich tradition of narrative analysis is drawn on to explore how the interplay of spoken and written word about the events at Fred Hutchinson Cancer Research Center was precisely that living text. The intentional and unintentional storylines expressed, animated, constructed and deconstructed the experience of participants, past and present. In particular the presentation of data will draw the reader’s attention to the narrative flow and to the importance of allegory, semantic imprecision and the structural alignment of opposing storylines to this particular case.
Narrative analysis is an intriguing interpretive modality that suffers and profits from its own indeterminancy. As an object of study, narrative is mutable. It may variously be viewed as a story, a performance, a process, a reflection, an expression, an inscription, a social tool, and an act of culturally specific reality constitution. Thus, the challenge for a narrative analyst is to determine what counts as narrative and what it represents. Commonly, narrative is regarded as a storied experience told for a reason[151]. In other words, a narrative is recognizable for its literary form and function. It follows linguistic rules of temporal and spatial organization, and (the narrator) intends to communicate something to the audience.

Not all verbal and textual data fall into a traditional literary narrative form. Like other types of public speech, much of courtroom discourse is rehearsed and carefully performed. It is replete with rhetorical stanzas, tactical characterizations, moral campaigns, and strategic sound bites. It is a linguistic community in its own right. Although law schools teach rhetoric, narrative and presentation, these things are not generally analyzed beyond their efficacy for legal cases. Brooks attributes the paucity of work on the narrative aspects of law to the profession’s culture of authority and relative exclusivity. In cases of litigation, Brooks describes legal narrative as persuasive performance for a judge and jury toward a binary determination of culpability[157]. By way of contrast, narratives offered in therapeutic encounters are co-constructed as an important means of framing an individual’s experiential world[36, 38, 39, 46, 175-179].
In this research, traditional storyline narratives are embedded in testimonies from defendants, plaintiffs and counsel on both sides and are the heart of storied media. They can be more or less extracted or distilled from their body of discourse. But these are not ad hoc narratives. These are not unself-conscious representations of lived experience. At one level, these narratives are meaningful as cultural monologues. A more process-oriented analysis would consider each narrative as part of the artful weaving of litigation-specific master narratives. At a more inclusive level, the narrative is set into a larger socio-cultural context, and conversationally considers dominant, reactive, counter-, anti- and meta-narratives.

Narrative analysis has its roots in sociolinguistics and structural functionalism. It might even be viewed as an artifact of Western social sciences, shadowing dominant cultural philosophies of empiricism (narrative represents reality) to relativism (narrative represents reality within specific linguistic communities) to post-positivism (narrative is the reality) to interpretivism (narrative is performance that both expresses and constitutes reality). Most narrative analysis reflects a syncretism of these theoretical standpoints, but continues to rely on the sensibility of a circumscribed narrative. Even if it were this simple, the social scientist still has the problem of representation, as discussed in the next section.
PROBLEMS WITH NARRATIVE REPRESENTATION

Riessman’s important guide to analysis of personal narratives offers a cautionary on the topic of narrative as representation. Assuming there is an actual ‘organic event’, she details (at least) five layers of the narrative process that contribute to distortion. She describes how the initial experience is colored by the observer’s selective attention, what is selected to be told, the transcription process, the choice of analysis, and finally how it is all understood by the audience. Any form of representation, it should be concluded, is both partial and partial. In other words a representation can only be part of the truth and holds an often-unacknowledged bias.

Even representations within physical science are partial …and partial. Woolgar’s ethnography of a solid-state physics lab illustrates what he terms the ‘artful practice’ of science[95]. He describes how phenomena are reduced to reproducible (and portable) artifacts, and then interpreted in a specific historical and social context. In his example, scientists measured electrical resistance, magnetic behavior and X-ray diffraction to represent the physical change of a formless metal alloy to a crystalline state. The raw data were nothing more than a two-dimensional graphic of what he refers to as “upward deflections, bumps and depressions”. What this graphic illustration looked like and meant to the scientists varied depending on what point in the structural transformation process it was. Initially, the scientists used texts, previous documents and data or anticipated results to interpret what they saw. If the data ‘disagreed’ with history, they first
tried to locate a procedural problem and would finally submit to the authority of senior scientists for an official explanation. Thus, the interpretation of this data reduction depended absolutely on an accepted historical trajectory of representations.

Kuhn’s theory about paradigm shifts in science[180] supports the notion that representation can be problematic. He claims that scientific data are generally pruned to fit existing theories until a critical mass of discrepancies present themselves. He contends that, at this point, a new theory might be developed to frame reproducible outlying data. This new paradigm might well deconstruct an earlier ‘fact’, but the new ‘fact’ is not necessarily more ‘true’. It is simply a better fit with the theoretical moment. What is ‘known’ depends on what is measured, and once again, how it is finally represented. The same is true for narrative.

The difficulties with narrative representation parallel the difficulties with other forms of representation. To begin with, only the dimensions of narrative that can be recorded in some form are available for analysis. In accordance with Latour’s discussion of scientific representations, narrative must be reduced to text so that it is portable in time and space[92]. Like Woolgar’s observations, a living process is reduced to a two-dimensional inscription. The interpretation of this ‘raw data’ must be actively negotiated until it conforms to what has gone before or to what is anticipated. Discrepancies might be explained as procedural error and interpretive authority lies in part with the elders of a given field.
Narrative is a reduction, a de-contextualization, and full of interesting anomalies. The most fundamental problem with narrative is that it is a narrow band of data. The transcription process eclipses all performative aspect of communication: social and cultural signifiers, linguistic habits, cadence, inflection, ‘rehearsed’ versus spontaneous, emotional tone and the interplay of the audience. Transcription is a radical reduction of narrative phenomena, but fits the criteria of portability in time and space. It is a suitable object for research. Reissman’s five points of distortion for narrative data (observing, reporting, writing, analyzing and listening) might be seen as moments when the ‘story’ helplessly transforms. These points of change might further be appreciated as nodal moments in narrative research. That is, they signal the time of engagement between the observer and the observed, revealing gaps where meaning is actively imagined, embodied and constructed.

NARRATIVE ANALYSIS METHODOLOGY

There is no unified approach to narrative data analysis. Most narrative in literary research is planned and authored text that suits a structured analysis. Most narrative in social science research is spoken and frequently elicited through interviews or questionnaires. Spoken narrative is suitable for coding and qualitative analysis. For this research project, some of the narrative is text, some is spoken, and a considerable amount is pre-prepared and performed. The study will explore three different dimensions of discourse: the narrative of text, speech
and performance and the conversations that happened within and across these levels.

Using a classical structured literary analysis, two narratives themes emerged from the news articles, trial notes and key courtroom transcripts. A reduction of each story into its essential elements - protagonist, antagonist, plot, motive, ending and moral conclusion – yielded two culturally common narratives that mirrored and opposed the other. These stories are mutable but recurrent throughout each level of data for this research. A word count was accomplished using a text management software ‘Hyperresearch’. All instances of recurrent terminology were tabulated, including ‘experiment’, ‘research’, ‘risk’, ‘cure’, ‘survival’, ‘GVHD’, ‘knowledge’, and nearly 50 others as a map for recognizing narrative patterns. Each instance of these recurrent terms was coded by highlighting its narrative context. This allowed an additional thematic coding and conceptual linkage of related words into semantic networks. For example, ‘risk’ ‘chance’ and ‘danger’; ‘experiment(al)(ation)’ and ‘investivat(e)(ational)(ative)’; ‘research’, ‘phase’ and ‘study’; ‘morbidity’ ‘death’ mortality’ and ‘survival’, were associated then the data was reviewed again to elicit themes. This was an iterative process that eventually revealed core themes that moved the story forward and allowed the selection of representative stanzas for the data chapter that illustrate a variety of narrative features and are able to capture the movement of storyline.

Next specific instances of each recurrent-word were explored for variations in semantic context. For example ‘standard’ was invoked as ‘standard
of care’, ‘standard care’, ‘standards of practice’ and ‘the standard BMT’. The term ‘survival’ and was used to refer to surviving BMT, surviving GVHD, surviving P126, one-year survival, and 5 year disease-free survival. Sometimes a nonspecific ‘survival’ was invoked (i.e. “none survived”). The differences in narrative context and meaning were at times nuanced but remained conceptually significant for this case. The text was further reviewed for semantic imprecision, semantic manipulation, embedded narrative and imagery. These were key moments in the storyline shift. And finally, the context, dress, manner, rhetorical style, cadence of speech, voice inflection and other aspects of narrative performance were noted. The data is presented chronologically offering a broad range of these narrative features, revealing the courtroom to be a rich interpretive anthropological field.
CHAPTER 4: CONTEXT AND ORIENTATIONS

The events surrounding protocol 126 at Fred Hutchinson Cancer Research Center during the 1980's, the tone of the 2001 investigative journalism piece published by the Seattle Times, the public response, the arguments invoked during litigation and the final resolution reflect specific cultural moments within biomedical research. This chapter will offer background information that is critical for the reader to fully appreciate the evolving cultural context, the nuanced narrative and the semantic shifts revealed by the research data.

Cancer research centers are unique medical environments. They are hubs of scientific discovery, excitement, courage and hope. These centers unite fine scientific minds and driven souls in a common crusade against cancer. They commit their careers. Research centers also attract very ill patients with little left to lose. They commit with all they have. Together they ignite hope, not only for each medical case, but cumulatively, for the larger cultural quest for cancer’s cure.

Fred Hutchinson Cancer Research Center is further distinguished by a selective specialization in bone marrow transplantation as a therapeutic modality. Bone marrow transplant medicine is an elite field with few true experts, and the transplant procedure is exceedingly complex. This said, here are two essential areas of orientation offered as a prelude to the presentation of research data: a
brief background of FHCRC and a basic overview of concepts and terminology relevant to bone marrow transplant and to this case.

**FRED HUTCHINSON CANCER RESEARCH CENTER**

Fred Hutchinson Cancer Research Center was founded in 1965 as the cancer division of the Pacific Northwest Research Foundation through the direct support of Dr. William Hutchinson. The Center was established in honor of William's brother, Fred Hutchinson, who died of lung cancer at the young age of 45. Dr. E. Donnall Thomas, a noted research physician, worked with Dr. W. Hutchinson to create the specialized center utilizing laboratory space and a few beds at Seattle's (then) Public Health Hospital. By 1972, the Center separated from Dr. Hutchinson's Foundation and in 1975 was able to move operations to its own building.

Dr. Thomas' clinical interest in leukemia and bone marrow began at Harvard medical school, continued into his residency at Peter Bent Brigham Hospital in Boston and his early opportunities for laboratory and medical research. It became his life work earning him the 1990 Nobel Prize in medicine. He had accomplished the first successful human bone marrow transplant between identical twins in 1950 but it wasn't until 1968 that a successful bone marrow transplant was accomplished in non-twin siblings. BMT techniques have been refined, largely through the progressive understanding and management of serious side effects, to permit transplants to take place between unrelated
donors. As survival rates continued to improve it became possible to offer the
treatment to a broader range of patients. Dr. Thomas was among the pioneers in
this young science and went on to become an internationally recognized leader
in BMT.

Richard Nixon’s declaration of the ‘War on cancer’ in 1971 followed later
that year by the National Cancer Act established specific government funding
that allowed for the rapid growth of cancer research and research centers. In the
Pacific Northwest, the national fight against cancer was embodied by Seattle’s
fallen baseball hero Fred ‘Hutch’ and Dr. Thomas’ team of medical researchers.
Scientific determination and research opportunity contributed to a sense of
medical hope, intellectual excitement and ‘in-the-trenches’ camaraderie at the
Hutch. Their ambition is captured in FHCRC’s mission statement: “To eliminate
cancer as a cause of human suffering and death”.

What began as a 20-bed unit in Seattle’s Public Health hospital, expanded
over the next several years to 60 beds, including a fully operational inpatient unit,
outpatient clinic, animal investigational medicine unit, and research laboratory
occupying a modest building on ‘Pill Hill’. The move reflected FHCRC’s fiscal
growth, symbolized BMT’s nascent emergence into mainstream clinical medicine
and quite dramatically raised local public awareness of cancer research. The
Seattle Cancer Care Alliance (SCCA) formed in the late 1990’s through a
visionary restructuring that partitioned laboratory and clinical medicine. The

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20 From key informants and trial testimony.
21 Pill Hill is the local vernacular for the sub-region of the Central District where several
major hospitals and clinics are clustered.
SCCA developed and built a prominent 11-acre campus on Seattle’s Lake Union where the administrative offices, outpatient clinics, and laboratory medicine are housed. FHCRC became the research arm of SCCA while extant liaisons were formalized for inpatient care with University of Washington Medical Center and Children’s Orthopedic Hospital.

The prestigious medical research group, still known as the Hutch, is locally iconic and internationally renowned for its singular focus and front-line work in BMT. At the time of this writing, they treat about 400 patients a year with either a bone marrow or a modified stem cell transplant, and receive nearly $150 million in annual federal funding. Over the last 20 years, BMT has become medically routinized. The procedure itself is no longer considered experimental, has secured third party payment authorization for a handful of diagnoses and is now available in many hospitals. FHCRC continues to treat the riskiest patient populations and particularly those who qualify for current investigational protocols.

The Center’s mission - “To eliminate cancer as a cause of human suffering and death” – is contagious for patients and staff alike. By the time patients are referred for investigational medicine, all other treatment avenues have been exhausted and in the case of leukemia, they often do not have long to live. Investigational medicine offers the possibility of success, in degrees, and from time to time significant breakthroughs. Through possibility, hope is restored. Asked to face some of the unknowns of investigational medicine, patients and their constellation of support often awaken to their own valiance, joining forces
with the Hutch in their fight to live. This ethos continues to be an essential component of what might be called a culture of hope that generates research ideas, attracts funding and reinterprets illness and suffering as meaningful[37].

Obviously, the therapeutic stakes at FHCRC are higher than in non-research contexts. The risks of lethal levels of radiation, bone marrow rescue, and sundry research protocols are balanced against an inevitable progression of a fatal disease. Everyday-values are challenged as patients, families and clinicians navigate the intense clinical uncertainty of both the disease and the treatment.

**CONCEPTS AND TERMINOLOGY**

The terminology for bone marrow transplant and the concepts drawn on in the case against FHCRC are more complex than in most medico-legal cases. The courtroom narrative is medically technical and at points would be difficult to follow without an explanatory overview. In anticipation of the need, a period of education was provided to the jury prior to the presentation of trial evidence. This section now offers the reader an introduction to the important and recurrent medical concepts and terminology used throughout the case including bone marrow transplant, graft versus host disease, protocol 126, T-cell depletion and phase-one protocols.

Bone marrow is a rich broth where progenitor blood cells are differentiated on physiological demand into red cells, platelets and white cells. Simplistically
described, red blood cells transport oxygen throughout the body, platelets are critical for clotting the blood at points of injury, and various types of white blood cells comprise the core of the body’s immune system. Abnormal production or function of any one of these cells arising from the marrow presents serious medical problems.

Three illness groups that portend life-threatening bone marrow aberrancy include aplastic anemia, the lymphomas and the leukemias. Aplastic anemia is an idiopathic, or sometimes iatrogenic, non-cancerous condition where the bone marrow fails to produce blood cells. Without a transplant, these patients have a life limited by temporary support of transfused blood products. Support can only be temporary because blood products are comprised of mature cells that function for just a few days and patients will develop resistance to repeated infusions of community-source blood products over time. In contradistinction, a viable bone marrow contains the young undifferentiated cells and will regenerate on demand.

Lymphomas are cancers originating in a subtype of white blood cells called lymphocytes (either B-type or T-type) that eventually manifest as solid tumors in the lymph nodes. Death from lymphoma can occur from a critical obstruction of lymphatic flow or from erosion through or metastasis to other vital tissues. Radiation is the treatment of choice for these solid tumors and a transplanted bone marrow will then generate a new and healthy line of lymphocytes. The leukemia subtypes include: acute myelogenous (AML), acute lymphocytic (ALL), chronic myelogenous (CML) and chronic lymphocytic (CLL). These cancers result in the disorganized overproduction of immature white cells
that suppress and displace the functional cells. The clinical picture and disease trajectory varies for each type of leukemia, but the net result is an ineffectual immune system and severely impaired bone marrow functionality.

Each of these illness groups and their subtypes manifest differently and are prevalent among different age groups, render different mortality/morbidity and call for different medical management. When blood product support, chemotherapy, and/or tumor-targeted radiation fail to achieve disease remission, a bone marrow transplant is the next therapeutic possibility. This was a new modality during the 1980’s, the time of FHCRC’s protocol 126. The first successful allogeneic (unrelated donor) BMT in a patient with leukemia had been accomplished by Dr. Thomas at FHCRC in 1979.

BMT differs in many ways from solid organ transplants. In solid organ transplant, a failing organ is surgically removed and replaced. The donated organ is the primary treatment followed by a lifetime of immuno-suppression titrated to ensure survival of the donor organ in an immunologically ‘hostile’ recipient. In the case of BMT, the patients’ bone marrow is sacrificed when the tumor or the errant blood cells are targeted for eradication with therapeutically sufficient radiation and chemotherapy. In that sense, BMT is not so much the primary treatment as it is a physiologically challenging rescue for otherwise lethal levels of treatment. The remainder of treatment includes, once again, titrated immuno-suppression. But in the case of BMT, it is designed to ensure survival of the recipient in the presence of an immunologically ‘hostile’ donor marrow.
The relative difficulty of the BMT is in part due to an array of histological incompatibilities between the donor and recipient. The exception to that is the case of autologous transplantation, where a portion of the patient’s un-diseased bone marrow is harvested, preserved and re-infused. But when the disease originates in the bone marrow, ablation of that marrow is necessary followed by an infusion of donor marrow. If a patient has a twin, an isogeneic (genetically identical) transplant can be performed, but more commonly, allogeneic transplants are accomplished using either sibling or unrelated donor marrow. Careful tissue typing is necessary to minimize the number of major antigen mismatches between donor and recipient. Each mismatched antigen creates tissue recognition problems between the donor marrow and the host leading to potentially fatal complications post-transplant.

BMT starts with what is referred to as a ‘conditioning’ regime with the end goal of eliminating the (host) bone marrow. It includes high dose chemotherapy followed by fractionated doses of gamma radiation. This is the therapeutic point-of-no-return for BMT that is reached in different ways with all types of organ transplants. A ‘therapeutic point-of-no-return’ implies that the medical treatment plan is fully committed and forward is the only direction. It is a medically critical window for all participants. The marrow infusion is followed by intensive medical support for acute radiation sickness. The patient is rendered vulnerable to overwhelming infections, hemorrhage, vital organ failure and complications stemming from immune system incompatibility. Recovery involves at least one intense month in the hospital and an additional two months of medically uncertain
outpatient time before the patient is potentially stable enough to return to their primary care physician. The first 30 days after a bone marrow transplant are fraught with medical difficulties. It generally takes up to fourteen days before the new marrow begins to ‘take’ (engraft). During this two-week window, the marrow makes no red blood cells, platelets or white cells. In addition to needing a steady supply of blood product transfusions, the patient has no immunity to common bacteria, viruses or fungi. Invasions are often rampant and they can be life threatening even with treatment. Colonization is sometimes systemic and sometimes expressed in sites not usually seen with an intact immune system. For example, painful herpetic lesions might manifest in the eyes, aspergillus can invade the brain, and cytomegalovirus might cause lethal pneumonia. Additionally, the mucosal tissue is badly broken down by radiation, leaving bleeding oral and gastrointestinal ulcerations, creating additional ports of entry for opportunistic organisms. Multiple antibiotics, anti-fungals, and anti-virals are given preemptively for fever spikes, unavoidably eventuating in resistant colonies. These are not the only complications. Cardiac and liver damage may occur as a result of the conditioning and finally, acute and/or chronic graft-versus-host-disease (GVHD) may present once the donor marrow engrafts and becomes robust.

GVHD is a conceptual inversion of solid organ transplant rejection. In solid organ transplant rejection, the ‘host’ rejects the ‘graft’. In the case of GVHD, the transplanted graft – the bone marrow – rejects the host. This ‘civil war’ may devastate the liver, skin and gut tissues. Some degree of GVHD is probably
inevitable, but the reaction between the competing immune systems is hard to either predict or control. Acute GVHD typically targets specific organs: liver, skin and gut. The clinical picture of liver GVHD ranges from mild to lethal hepatitis, skin GVHD ranges from a generalized rash to the ulceration and systemic sloughing of the skin. Gut GVHD might range from a sore mouth, dyspepsia and some diarrhea to full mucosal ulceration, and 5-6 liters of bloody diarrhea a day. Medical care includes symptom management and pharmacological suppression of an already meager immune system. Severe cases of acute GVHD cause unspeakable pain and suffering and are a leading cause of BMT mortality. Chronic GVHD can be a sequel to an acute flare or develop more insidiously. Its effects on the connective tissues can be profoundly disabling.

Graft-versus-host-disease is somewhat of a misnomer in that it isn’t exactly a disease but an expected and physiologically normal immunological response to a mismatched donor-host transplant. Naturally, the greater the histoincompatibility, or the more aggressively the new immune system grows in, the more severe this response/complication is likely to be. Even with standard post-transplant immuno-suppression, the incidence of mortality from acute GVHD in the 1980’s was about 10%\textsuperscript{22}. The T-cells are a subtype of white blood cells that play a key role in mediation of the GVHD reaction. Early murine studies with monoclonal

\textsuperscript{22} The incidence of GVHD mortality in 2000 has been quoted at 25% - 30%, but these newer statistics include both acute and chronic forms and both direct and indirect causes. Both ways of quantifying mortality are useful, but naturally the latter calculation is more sensitive to patients’ pre-existing co-morbidities. Statistical and diagnostic ambiguity will be further explored in the conclusions chapter.
antibodies (MAb) conducted during the 1970’s yielded encouraging results: T-cell depleted marrow effectively averted GVHD in mice. During the 1980’s, bone marrow transplant scientists had begun to develop techniques to reduce the population of T-cells in donor marrow with the goal of reducing both the mortality and morbidity of GVHD, and many research institutions were drawing up protocols to apply that research to human BMT. FHCRC’s was entitled “Protocol 126” (P126). P126 was a frequently revised phase-one protocol that was in place from 1981 to 1993. It accomplished an in vitro T-cell depletion using designer monoclonal antibodies and mechanical manipulation of the donor marrow.

Each MAb is a unique hybridoma created by a forced fusion of disparate cells. The ability to create cell lines was one of the most promising accomplishments of 1975 in the medical sciences[181]. FHCRC developed a technique that used a MAb cocktail in conjunction with a biological accelerant (‘complement’) for T-cell destruction. Cancer research institutions held out tremendous hope for the revolutionary technology of MAb in the treatment of GVHD. Such was the anticipation in the BMT community, that the usual order of medical research was suspended. For example, no studies were pursued in animals larger than mice before initiating research in human subjects. By Dr. Thomas’ own testimony, it would have taken years and been too long to wait. GVHD was an imminent and frequently lethal threat to BMT patients. Here is where ‘the story’ for this study begins.
CHAPTER 5: THE HEART OF THE CASE

INTRODUCTION

The heart of this case study is the triangulated conversation between the media, the courtroom, and academic journals about the contested perseverance with a failing research protocol at FHCRC. The Center piloted various permutations of “protocol 126” between 1981 and 1993. Ultimately 83 of the 85 study participants died. Certainly not all the patients died as a direct result of this research, but survival rates were poor compared to the 50% figure bandied about by BMT specialists at the time.

A former FH physician-scientist and Internal Review Board (IRB) member Dr. John Pesando states he was disturbed by the dismal outcomes of P126 clinical trials during his tenure at the Hutch and by what he perceived at times to be a caviler attitude toward gravely ill patients. He thought the protocol should be stopped rather than serially modified and reinstated. After numerous unsatisfactory responses to his objections at IRB meetings, chain-of command complaints, and correspondence on file with research authorities, he decided to talk to Seattle Times investigative reporter Duff Wilson. Pesando’s account of events, further elaborated by a collection of letters, documents, supplemental statistics and interviews at Wilson’s disposal, sparked a national public conversation. The families of the decedents were alerted, litigation began and the case was taken to trial. The only prominent case related to medical research
misconduct to reach a jury has barely left a trace in academic journals, but it has not, perhaps, escaped Bioethical history.

I present the narrative data chronologically and at three levels with concurrent commentary and analysis. The first level of data includes the Seattle Times series and the subsequent series of rebuttals and editorials. The second level of data is the courtroom discourse. The third level of data includes what is written in academic journals as the historical residue of these bioethical events. My analysis will be found in both the interstices and interludes. I provide the evidence for narrative movement that will offer the reader an opportunity to participate with the interpretation of my data.

As discussed in the methodology chapter, the largest problem with narrative analysis is representation. I am acutely aware of that problem at every turn. I have amassed over 4,000 pages of various forms of discourse, narrative, testimony and text for this research. Most of this data including the unabridged trial transcript is available in public records. Nevertheless, I treat the data reduction carefully, and try to preserve its essence. For the extensive media data, I provide meta-narratives that are faithful to the journalist’s tone and cadence. I support this secondary representation with excerpts from the original text. For the trial I present thematically related stanzas from the opening and closing statements of each legal team to show movement in the storyline over time, and the textual moments of change. It is a partial view of the courtroom events, but is a representative distillation. For the journal articles, I offer a
synopsis as evidence for the abbreviated narrative resolution. I open with a chronology of events.

**CHRONOLOGY OF EVENTS**

The Bayh-Dole act of 1980 paved the way for what is sometimes an uneasy alliance between academia, research institutions and commercial concerns. Genetic Systems (GS) was one of many startup biotechnology companies of that time. It was founded in 1981 through the business and science acumen of its founders, entrepreneur David Blech and FHCRC researcher Dr. Robert Nowinski. Their idea was to develop and commercialize innovative biological agents, including monoclonal antibodies which were anticipated to become medicine’s radical new ‘magic bullet’[182]. It was a perfect expression of the Bayh-Dole economy of science: both business and research could be advanced.

The ability to produce monoclonal antibodies... undoubtedly constitutes the greatest ‘breakthrough’ of the last decade....

These antibodies, each differing from the other, constitute true ‘magic bullets’ because of the remarkable specificity of their action.........
(excerpted from Dr. Thomas’ letter to FH IRB, October, 1983)

Of record, GS gave some FH researchers employment, advisory positions, and significant shares of founder’s stock. Additionally, GS offered the Center royalties in exchange for commercialization rights to several biologics,
including the monoclonal antibodies used in protocol 126. This was not an unusual synergism in the research world after 1980.

The first draft of Protocol 126 stimulated lively (per trial defense) or heated (per trial prosecution) Human Subjects Review committee (HSR) debates\textsuperscript{23}. The review board did their work to examine, question and require specific explanations for, or revisions to, P126. Per HSR records and memos, the concerns included many that were articulated in the trial proceedings - that no prototypical research had been done on the proposed marrow manipulation technique; that T-cell depletion itself had only been done in mice; that no statements could be made for either efficacy or toxicity; that no statistical parameters were established for stopping the trial; and that the inclusion criteria for this early trial was “good-risk” patients\textsuperscript{24}.

The archived HSR minutes of subsequent meetings for P126 are missing or incomplete, but there is evidence that these concerns were articulated at the start and that they set in motion the appropriate processes for the protection of human research subjects. This is not what Dr. Pesando believed. His testimony attests to HSR disempowerment through intimidation from the principle investigators. The HSR board did eventually approve each version of protocol 126 until it was stopped in 1993.

\textsuperscript{23} Human Subjects Review (HSR) was later called Internal Review Board (IRB). These monikers are used interchangeably in public discourse. I make the distinction in this writing as a reminder of temporality.

\textsuperscript{24} The proposed patient population (CML chronic phase and AML in first remission) had a better chance of achieving disease-free survival with a BMT than some other patient groups. These are ‘good risk’ diagnoses. Usually a new research protocol is piloted on ‘poor risk’ patients until toxicities are revealed or better understood.
By Dr. Pesando’s account, the HSR dialogue continued, the protocol continued, and P126 participants died. In May of 1991, he began correspondence with the New York Times, the Food and Drug Administration, the Federal Office for Protection from Research Risks, the National Institute of Health, and the Department of Health. His efforts to restrain protocol 126 had failed during his tenure at FHCRC. In fact, he asserts that his voice was an unwelcome challenge that drew criticism, anger and (he believes) eventual professional blacklisting by FH senior physicians. His letters to the national regulatory bodies reflect his progressive frustration:

“…(IRB’s expressed concerns about P126) met with stiff opposition from the senior medical staff…”
“…Dr. Thomas had a fearsome reputation – you crossed him at your peril”
“…(protocol causing) deaths and FHCRC senior staff insisted on its continuation”
“…very difficult for me to take the expedient course of doing nothing.”
(Excerpt: Pesando’s letter to Office for Protection from Research Risks, 5/1993)

“…murderous misconduct for financial gain at the Fred Hutchinson”
“…More than 20 patients were killed at the FHCRC…in pursuit of profit”
“…there could hardly be less concern if laboratory rats had died instead”
“If the wealth and power of those accused…prevent taking effective action on behalf of those who have died, then at least eliminate the travesty of the self-regulation for the sake of future patients”.
(Excerpt: Pesando’s letter to National Institute of Health official, 12/1995)

“The NIH has a long and distinguished record of bungling investigations…”
“The NIH’s handling of this…suggests that it was afraid of finding something”
“…profound apathy of those at the top…”
(Excerpt: Pesando’s letter to Medical Investigations Unit at the Dept. of Health, 10/1996)

After three years of letters and appeals for remedial action, Dr. Pesando sought out journalist Duff Wilson and became an informant for an investigative report. In March 2001, the Seattle Times published Duff’s findings in a 5-part
series entitled “Uniformed Consent: What patients at ‘The Hutch’ weren’t told about the experiments in which they died”[1]. The article offered a storyline of cancer-trial misrepresentation, financial entanglements, unchecked scientific enthusiasm, and universally devastating patient outcomes. FHCRC immediately responded with a series of full-page rebuttals placed in the Seattle Times as well as public information through radio, television and their internet website. The Times reporter contacted the families of deceased P126 participants with the story. Over the next year, several claims were filed against FHCRC and five of these eventually went to trial in February of 2004. The 8-weeks of legal proceedings was well attended and given daily press coverage. The defense team’s narrative gained dominance over the course of the trial, and Fred Hutchinson prevailed.

**THREE LEVELS OF DISCOURSE**

The data and analysis are organized around three levels of discourse. The first level is the media, including the Seattle Times investigative series, FHCRC rebuttals, and editorials. This level gives rise to culturally salient master narratives, provides a window into dominant cultural beliefs, and reveals a metamorphic storyline. The second level of discourse is the trial itself. The active ‘subjunctivizing’ elements of the narrative-in-progress are embedded within this level. It exemplifies the living text of social reality so brilliantly explored by Bryon Good[36]. The third and final form of discourse is drawn from academic journals.
before and after the trial verdict. Published articles represent the official version of events at FHCRC and indicate how this controversy will or will not be historicized.

The organizing force for all three levels of discourse is what might be termed ‘master moral narratives.’ Master narratives are mainstream cultural stories that are commonly invoked to frame events and issues[183]. Master moral narratives are the ethical equivalent, coined for this work. They are the commonsense storylines of least-resistance that emerge in the face of moral ambiguity. The data presentation is chronological, organized into pre-trial narratives, the courtroom dialogue and the final story as told in peer-reviewed journals. The presentation first opens with an explication of the two organizing master moral narratives of this study.

**MASTER MORAL NARRATIVES OF THE FHCRC CASE**

In this research, the discourse became polarized into two master moral narratives. They are first evident in communication between Dr. Pesando and national regulatory bodies, between the Seattle Times and FHCRC, and in the dueling editorials. The first narrative that emerged might be entitled ‘the whistleblower’, and the second, the ‘disgruntled employee’. They have similar themes and structural elements, but lead to two very different moral conclusions. The scaffolding for each narrative follows with the opposing elements aligned for comparison.
The first and initially dominant master narrative is about a whistleblower impelled by his conscience to expose deadly research misconduct. He eventually joins forces with the press to advocate for the voiceless dead. The researchers in this story covertly conducted reckless experiments on human subjects for their own fame and fortune. Tragically, the victims of terminal illness became victims of this experimentation. If left unchecked, medical research will endanger patients. Lives have already been lost. The whistleblower’s moral imperative is to protect patients’ right to know and to enforce researcher responsibility.

The reactive master moral narrative reframes the whistleblower as a disgruntled employee who is motivated by retribution. In this story, the litigation lawyer’s greed and the later version with the press’ pursuit of journalistic recognition are characterized as dangerously self-serving. The physicians are
recast as tireless heroes in the fight against cancer, and as recklessly victimized by irresponsible lawyers and press. If the reputation of research was tarnished, momentum will be lost. Lives will be lost. This story’s moral imperative is to support the social good of (social right to) medical research and enforce the social responsibility of the media.

PRE-TRIAL DATA

THE SEATTLE TIMES ARTICLE

The Seattle Times five-part series “Uninformed Consent” covers 15 very busy pages. The orchestrated layout simulates critical investigative television shows like PBS’s “Frontline” or CBS’s “60 minutes”. The series is replete with photographs of the entrepreneur-turned-felon, of the doctors who ‘wouldn’t stop’ a ‘lethal research protocol’, of a whistleblower engaged in self-reflection, and of the unwitting P126 participants. There are crisp graphic timelines, charts, partially photocopied documentary ‘evidence’, and a list for responsive readers labeled: “Who to contact”. The Seattle Times’ narrative is presented here in two formats. The first is a synopsis of the newspaper report. It is necessarily condensed and paraphrased, but it retains the original wording, narrative cadence and flavor. The second is simply the flow of headlines as published so that the reader may quickly compare or contrast the journalists’ topical framework and tone with this emulation.
NEWSPAPER REPORT SYNOPSIS

In March 2001, the Seattle Times newspaper broke an astonishing story of research misconduct at FHCRC. Bluntly put, senior Hutch physician-researchers’ personal greed and blind pursuit of scientific notoriety directly resulted in the deaths of many unsuspecting patients. It all began at two kitchen tables: one in New York where David Blech, a biotechnology entrepreneur sat imagining profits to come and the other in Alabama where Becky and her husband sat determined and hopeful that a BMT at FHCRC would cure her leukemia. The two stories came together in 1985 when Becky was enticed to participate in an experimental protocol (P126). The trial was known to be causing graft failures, new cancers, relapses and deaths at unacceptable rates. Becky didn’t know these things, nor did she know that FHCRC had extensive financial interests in the protocol’s biological compounds.

The IRB knew. From its inception, protocol 126 met with resistance from the review board. In return, the IRB met with even more resistance from senior staff and were pressured into approving the trial. The review board was concerned about the maverick protocol’s risk for graft failures and relapse. As patients began dying, the IRB was alerted to rumors that the lead investigators were financially vested in the success of protocol 126. They persistently voiced concerns to researchers about the poorly regulated use of the new monoclonal antibodies. They worried about the unprecedented leap from mouse research to human subjects and they didn’t think the consent forms were clear about the
degree of risk involved. When the IRB wanted an external scientific review, an open discussion about financial conflicts of interest, and a revised consent form that stated risks as clearly as the original research proposal did, the ire of Dr. Thomas was aroused. The IRB requests were refused. They were also “lied to, intimidated, ignored and punished” for questioning their superiors. The IRB reluctantly approved protocol 126, while calling for checks and balances on the research that never came. No external scientific review was authorized because of the expense, the research delay, and most importantly – the possible leak of scientific ‘secrets’ to competitors. The clamor of debate around protocol 126 rose. Voices were silenced. Patients died. More patients were enrolled.

“Martin was required to report the deaths to the IRB, but he did not. Inside the corridors of The Hutch and Swedish, however, word of the unusual deaths spread. And the drumbeat against Protocol 126 intensified.”

(Seattle times article reprint, pp. 4)

Meanwhile, Genetic Systems – the company started by “brash and ambitious” New-Yorkers, Blech and his Hutch recruit Dr. Nowinski, was sold to Bristol Myers for $294,000,000 five years later. Over this same five-year period, Dr. Thomas’ founders stock grew from $1,000 to $1,050,000; Hutch physician Dr. Hansen’s stock grew from $2,000 to $1,800,000. The foundation’s stock grew to $502,000 and Hutch physician Dr. Martin directly profited more than $100,000. Now (2001) in the hands of Bristol Meyers, the stock has grown an additional 500%. The Hutch founders refuse to entertain a discussion about financial conflicts of interest.
Dr. Thomas is both feared and revered. His word is manifest as policy.

Fred Hutchinson Cancer Research Center continues on a self-directed course.

Although many patients have benefitted from the research accomplished at the Center – the problematic secrecy and conflicts of interest remain unchecked.

THE SEATTLE TIMES SERIAL HEADLINES

>Uninformed Consent: what patients at ‘The Hutch’ weren’t told about the experiments in which they died

>Patients never knew the full danger of trials they staked their lives on

>In the trial’s 12 years, several doctors tried to curb it, disturbed by issues of science, physician profit and patient consent

>The blood cancer experiment: What patients were told *(and weren’t told)* to get their ‘informed consent’

>During Protocol 126, The Hutch adopted a rule barring scientists from work in which they have a financial stake

>Alarmed at the graft failures, review-board members sought outside review of the new drugs but the Hutch’s president refused

>Something’s really fishy here

>As the failures and deaths mounted, Protocol 126 was altered again and again, but new patients still weren’t told the risks

>Prospects for change: What’s happening around the country to reform clinical trials and how the culture of The Hutch resists change

>Pesando kept crying foul but found that opposing a revered institution and a winner of the Nobel Prize was ‘taking on the 800-pound gorilla’

25 Bold and italics are as published in the Seattle Times series. The headline review is offered in support and further elaboration of the immediately preceding newspaper synopsis.
President Day successfully defended The Hutch, but in the end a state official said, ‘There still remained doubt in our mind’

A year before Hamilton came to The Hutch, researchers knew the drug PTX was not working – and might even be making patients worse

‘It’s hard for me to imagine situations’ when raising already-fatal doses ‘would be morally acceptable,’ says an expert in medical ethics

The breast cancer experiment: What Kathryn Hamilton was told (and wasn’t told) to get her ‘informed consent’

‘I think that’s what bothers me so much,’ says Hamilton’s son. ‘She was relying on me… But I think I was given wrong information’

Many patients think that joining testing will help them, but often they’re mistaken

‘Two kids from Brooklyn’ recruited respected Hutch doctors to start biotech companies, spinning their academic cachet into cash

Selling vision and credentials

No wonder they call the place ‘Mother Hutch.’ Since the Fred Hutchinson Cancer Research Center was founded as a tax-supported nonprofit a quarter-century ago, it has spawned private companies worth more than $18 billion and an estimated $100 million in personal wealth for its doctors

Prospects for change: The Hutch operates in extraordinary secrecy justified in the name of commercial interests, grown from its maverick roots

‘The model should be one of transparency. There should be no secrets,’ says head of a national panel on human research

The Hutch won’t disclose financial connections of its research doctors or of the center itself. It won’t say what stock it owns. It won’t say what experiments it is performing for the companies whose stock it owns. It won’t say what inventions and patents it is licensing to those companies, or for what prices

System’s serious flaws have led many to call for regulatory reform

The investigative series was considered either inflammatory or provocative, depending which narrative the listener took up. The series
ostensibly set out to advocate for research participants’ rights to informed consent. The tone of indictment might dissuade patients from seeking needed treatment and clearly it threatened to tarnish the reputation of research medicine at the Hutch. The Seattle Cancer Care Alliance and FHCRC rebuttals and public education efforts were first out of the gate. Polarized editorials soon joined the chorus, revealing passionate convictions on both sides. As the Seattle Times had offered the ‘whistleblower narrative’, these ensuing narratives either expanded that theme, or recast the characters and told the story of a ‘disgruntled employee’.

REBUTTALS

The Fred Hutchinson submitted an immediate rebuttal to this article, and took direct issue with each allegation in “an open letter to the community, our patients, our staff and the countless number of Hutch supporters”. They began a comprehensive media-based public relations and information management campaign. Television ads, newspaper bulletins, radio advertisements and a dedicated website responding to the Seattle Times all quickly appeared. Full-page paid FHCRC public education pieces ran daily in the Seattle Times. The response did not vilify the press, but offered a clarification of the FH mission, their values and their community purpose. Their final submission was a collective declaration of service and of pledge of honor endorsed with the names and positions of all FHCRC’s faculty.
They made an understated appeal for community support: “The road to ‘conquering cancer’ is ‘long and hard’. “This week, it got a little harder.” They reframed what had been cast as ‘the problem’ the solution: “Fred Hutchinson believes that partnering with industry helps save lives.” They make a case for compassionate science: “Fred Hutchinson believes that science alone will not win the war against cancer.” And a case for the Center’s core offering of hope: “Behind every cancer patient there are a dozen more loved ones and friend who care. And every one of them is scared. What we offer these people goes far beyond just breakthrough science. We offer the most powerful treatment there is: hope.”

It might be implied that siding with the Seattle Times is a Hutch-patient team betrayal with far reaching consequences. They say: “If the net effect of the Times’ coverage of the Center is to scare people away from clinical trials, then we all lose.” This became the theme of Hutch-narrative supporters, and represents a rudimentary form of the moral imperative for the social good of medical research that ultimately concluded this case.

Soon, the Center began sponsoring health segments about cancer, cancer research and cancer treatment on the local televised news. They generated sound-bytes that were taken up and repeated in editorials, by the public, and even by both legal teams in the trial. For example: “Fred Hutchinson has helped save thousands of lives around the world.” It reinforced their raison d’être: “Our mission will continue” to “eliminate cancer as a cause of (human) suffering (and death).”
DUELING EDITORIALS

Good Medicine, Bad Journalism::Good Journalism, Bad Critique

Assistant managing editor of the Wall Street Journal, Laura Landro, spoke out against the Seattle Times article in an editorial entitled “Good Medicine, Bad Journalism” on March 19th, 2002. She identified herself as a cancer survivor and former 1992 FHCRC patient. She characterized Wilson’s investigative report as ‘sensationalist’ and ‘demonizing’. She felt he should not be receiving awards for journalism, but be investigated for media bias. Her editorial began: “Until the Center, known as the Hutch, helped pioneer bone marrow transplants in 1960’s, a diagnosis of leukemia used to be a death sentence. Transplanting marrow from a healthy donor offered a cure for thousands of people”. She went on to say that “leukemia patients who were in mortal danger with slim chances of survival participated in an experiment of a new treatment that gave them hope, but no guarantees, of a cure”. She stated that FHCRC stopped their T-cell depletion trials even when other centers did not.

Much of Landro’s vernacular contained assertions and phraseology from Cancer Center brochures. She solidly joined the first wave of opposing narrative, publicly referring to Dr. Pesando as a “disgruntled former Hutch employee” whose complaints were not corroborated. She asserted that there was no evidence to the effect of financial conflicts of interest at FHCRC and that irresponsible reporting would “have a chilling effect on scientific discovery, if patients were to sue every time a clinical trial didn’t work.” This manner of press
results in “frightening patients away from new treatments that may save their lives, confusing readers about the role of research in new drugs and therapies, and unfairly smearing the reputations of a responsible institution and its professionals.” She concluded that Wilson committed an all-to-common journalism offense in choosing drama over comprehensive reporting.

The Seattle Times republished Laura’s editorial and responded with one from their executive editor, Michael Fancher, entitled “Good Journalism, Bad Critique”. He stated that Laura campaigned for the Seattle Times to stop the press before the article was ever published. He found it ironic that on the one hand, Landro’s book “Survivor” advocates for cancer patients’ self-determination, and yet she seemed unconcerned with the self-determination of patients in protocol 126. He reiterated that the investigative process was rigorous and they had had little cooperation from Hutch officials. Hutch attorneys, he said, had tried to subpoena Wilson’s written communication with the families in case anything was said about problems with the experiment that would have started the one-year clock on the statute of limitations. He characterized that effort as the Hutch saying ‘we didn’t do anything wrong but if we did, you missed your chance to sue’. Fancher finished that Landro had admitted in an interview with the New York Times that her intent was to discredit the Seattle Times series and prevent recognition for its journalism.

The Wall Street Journal editor came back attacking Michael Fancher’s editorial ‘rambling’ and refusal to publish Laura’s piece in a timely way. He related that “Yes, the ambulance went by back in 1985, and was pretty much a
forgone until the Times dug up the tracks, along the way applying to the older trials today's medical knowledge and informed-consent standards.” The Journal claimed that it is easy to side with plaintiffs because their stories are often dramatic, whereas the longer-range benefactors of these same trials rarely get airtime. Laura is that voice. (Laura was treated at the Hutch, but did not receive protocol 126). He concluded with his take-home message: “We have long felt that medical research needs to be liberated, not inhibited.”

Laura Landro’s editorial appeared a full year after the series in the Seattle Times, within weeks of the April 2002 deadline for the Pulitzer Prize. The Seattle Times series had already been awarded several journalism prizes for the series including the 2001 George Polk award for medical reporting, the 2002 Scripps Howard Foundation National Journalism award for Public Service Reporting, 2002 Harvard’s Goldsmith prize for investigative reporting and others. The Pulitzer Prize is perhaps the most distinguished and coveted honor for journalism. Several media sources took up the Pulitzer Prize motive in their discussion, including the New York Times. Dialogue evolved questioning Landro’s personal stakes as well. For example, she didn’t identify herself as having a mutually beneficial relationship with the Hutch regarding the book she authored on surviving cancer. The conversation continued in ‘letters to the editor’.
Various Wall Street Journal editorials republished on www.fhcrc.org reiterate and support Laura’s point of view. In these, the Seattle Times report is denigrated as a crusade against FHCRC and sensationalism. The series is described as ‘tawdry’, shallow, filled with falsehoods and half-truths, ‘scurrilous trash’ ‘obviously absurd’, irresponsible, and unacceptable journalistic behavior. The Seattle Time editorials available at www.seattletimes.org lean the other way. They call the research misconduct ‘unacceptable’, ‘tragic’, ‘at cross-purposes to the Hippocratic Oath’, ‘appalling’, and ‘serious’. There were also supporters of the Hutch who wrote in to the Times that the series was ‘poor journalism’, a play at selling more papers, and a ‘sensationalized fallacy’.

The elements of this debate parallel the master moral narratives outlined earlier in this chapter. For example, Landro and Landro-supporting narratives assign the ambition and greed to the press in their relentless pursuit of the Pulitzer Prize. An attack on her credibility would continue to erode public trust in research. Fancher and Fancher-supporting narratives reassign ambition and greed to Landro in her attempts to discredit the Seattle Times and possibly gain readership for her book “Survivor”. Aligning with her would undermine patient self-determination in medical research.

26 The referenced editorials from the Wall Street Journal were submitted separately by: a heme-oncology doctor, a founding member of Genetic Systems, a former FHCRC employee, a former patient of FHCRC, a current FHCRC employee, and a cancer survivor.
THE TRIAL

Prior to the trial, the Seattle Times’ “Uninformed Consent” was the central narrative that stirred reaction. The published 5-part series was a selective and partial account of the facts with a particular spin, but it was also well researched and incisively presented. FHCRC responded with corrective narratives in published and broadcast news, in advertisements, in the form of rebuttals, and in the form of institutional transparency on their website. Lively editorials and public debate around the Seattle Times report persisted until the close of the trial in early 2004. Over the course of the trial, the positions of narrative dominance reversed. This section of trial analysis looks at the role that rhetoric and performance played in what might be termed ‘a narrative coup’. The stage set for rhetoric and narrative performance is perhaps as important as the elements themselves. This section will first discuss some important contextual features and provide an overview of the trial, then move on to the specific courtroom narrative.

CONTEXT

The trial attracted considerable public interest, was well attended and chronicled in the media. Those present self-segregated into FHCRC employees and supporters on the right and plaintiff supporters on the left. A few legal agents for the defense, including a medical claims expert and surrogate jurors, peppered in behind the plaintiffs.
The disparity between legal teams was frequently discussed in informal conversation about ‘how the case was going’. The defense team’s dress, grooming, manner, and especially their presentations were more polished and authoritative than were the prosecution’s. For example, counsel for the plaintiffs elicited fragments of physiology or medical science from witnesses in supplement to specific testimony whereas the FH team offered a comprehensive educational slide show on leukemia, BMT and GVHD at the start of their defense, halfway through the trial. The plaintiffs’ team used a series of hand drawn graphs on a paper flip chart to support their statistics. They were difficult to read and impossible to position for full court visibility. They distributed copies of three separate and overfilled loose-leaf exhibit notebooks to the judge, to the opposing counsel to each juror and to each witness. Their frequent reference (and mis-reference) to one exhibit after another - by notebook color, tab number, exhibit number or page number - was cumbersome, time-consuming and distracting. Jurors and witnesses were not always able to find the specified exhibit, and the Judge on occasion appeared to lose patience. In contradistinction, the defense team had scanned all their exhibits and computer-generated graphs into a power-point style presentation. These were easily referenced throughout the trial along with the earlier educational slides. This communicated an economy and coherence of facts and a respect for the court’s time.

The defense developed the FH founder’s individual biographies from their aspiring childhoods, through obstacles and opportunities through their professional lives, current work and international acclaim. They traced the history
of leukemia to the point where it intersected the founders’ biographies and extended the need for their particular cancer research into the future. By way of contrast, the plaintiffs’ counsel opened each testimony by briefly qualifying each witness with an account of their educational and professional credentials. The defense established narrative dominance early in their case by conceptually controlling the timeline for narrative emplotment. The plaintiffs as well as their expert witnesses were temporally nested within the FH founder biographies and their work with BMT. In turn these histories were nested in the timelessness of leukemia and the future.

There was an abundance of speech patterns, performative styles and theatrical staging from both trial teams that communicated at least as much as the narrative text itself. Isolated examples will surface in the conclusions chapter, but most are beyond the scope of this project. This subsection was limited to a few examples that began to set the tone for narrative authority early in the courtroom discourse and paved the way for a narrative coup. In the trial overview that follows, the commentary and analysis attends to rhetoric, linguistic turns and other semantic tools that contribute to and offer evidence for narrative movement over the course of the trial.

**TRIAL OVERVIEW**

The four original claims made against Fred Hutchinson Cancer Research Center parallel the Seattle Times “Uninformed Consent” series. They are articulated for the jurors in the prosecution’s opening statement:
> negligence on the part of the Hutchinson Center for falling below the standard of care of a reasonably prudent medical research center conducting such research on human subjects.
> lack of informed consent.
> fraudulent conduct by engaging in deceptive practices to induce plaintiffs and induce patients to enroll into this protocol.
> intentional infliction of emotional stress by not revealing to the patients the true nature and purpose of this experiment, hiding their financial conflicts of interest, engaging in deceptive practices that fall well below the standards that we expect in our society and the ethical principles that apply to human subject research.

The court ruled that the latter two, ‘fraudulent conduct’ and ‘intentional infliction of emotional distress’, were unsubstantiated by the evidence. Dismissal of these two claims at the close of the prosecution’s case was the defining moment of the trial. The purported motives were erased, and their narrative was rendered lifeless. The defense came forward for the second half of the trial, reordered the ‘facts’ of the cases and infused them with their own storyline. This was accomplished in two significant ways. First, using parody and rhetoric, they retold (and ridiculed) an exaggerated version of the prosecution’s narrative. Second, they re-framed that story with tempered and more credible elements. The lead attorney for the plaintiffs made several misstatements and unsupportable inflammatory insinuations about FHCRC and its founders. His narrative was wide open for reinterpretation. The defense accomplished it with ease.

On the surface, the trial was about the claims brought against Fred Hutchinson by the decedents’ family members. On another level, the question posed was whether GVHD was dangerous enough to justify some exceptions to
the usual order of research. FHCRC physicians are the undisputed experts in BMT. Their answer to this question – whether right or wrong - was more compelling.

COURTROOM DISCOURSE

In this section, a collection of thematically related stanzas are presented from the opening and closing statements to illustrate the rhetorical devices and inter-narrative dialogue that move the defense narrative to a position of dominance. Also evident is the devolution of the prosecution’s story between opening and closing statements. Where relevant, post-trial remarks made by the defendants, plaintiffs or jurors are included. These are both summation statements and narrative residue. The text between weaves narrative analyses, supplemental information and commentary into a research meta-narrative. Contrasting fonts are used for the prosecution, defense and the post-trial remarks to help the reader differentiate these voices from each other. Phrases within the statements are underlined in order to draw the reader to segments of interest. The text between excerpts is double spaced and formatted to be consistent with the body of this paper. Distinguishing font is used for all excerpts, they are single-spaced, and are coded (OP, OD, CP, CD) as follows:

- OP = excerpt from opening statement prosecution
- OD = excerpt from opening statement defense
- CP = excerpt from closing statement prosecution
- CD = excerpt from closing statement defense

*Italic print for post-trial remarks*
The flow of courtroom discourse is represented here more or less chronologically. It opens with the prosecution and defense telling the jurors what the cases are about. Each segment sets up a question, addressed by the next. The questions are not articulated in the discourse itself, but signify the audience’s anticipation of narrative trajectory. Each discourse segment is subtitled with the implied question.

What Happened?

(OP: Opening Prosecution)
This case that you will be deciding is about a research project, an experiment conducted by the Hutchinson Center during the period from 1981 to 1993 in which they enrolled 85 patients. 81 of the 85 died as a direct and proximate cause of the experimental treatment they were given. At the same time that the standard treatment which each of these plaintiffs and their spouses who died came to the Hutchinson for, they had cure rates of anywhere from 20 to 85 percent.

(OD: Opening Defense)
Let's go right to what this case is really about. Over 20 years ago now, five patients with terminal cancer....who had exhausted every available form of medical treatment, came to the FHCRC here in Seattle for a bone marrow transplant. Each and every one of these individuals agreed to participate in a research trial; a research trial that involved the receipt of a T-cell depleted bone marrow transplant to prevent graft-versus-host disease. That was the purpose. That's why they came here.

(CP: Closing Prosecution)
Now, a patient coming to the Hutchinson center expecting to get the best standard care and expecting a 50 percent cure rate from the best standard bone marrow transplant, is placed into this research, not because of any medical consideration, but because of the research objectives of the Hutchinson center.
(CD: Closing Defense)
These dedicated doctors that you've met, that have sat here for nine weeks, and they testified, and they answered every question. Dr. Martin was deposed six times. You saw that big stack. They attacked them. Even now they attack their credibility. These are dedicated doctors that tried to solve the problem of leukemia that tried to solve the problem of graft versus host disease that tried to solve every other problem that relates to these terrible victims of leukemia....

It's not funny to be accused of the things they have been accused of. Even what's left here of being accused of violating the standard of care, the oath that they took as physicians, that they take every day to the patient care that they have provided. That's what this case is about.

Post-trial remark by Dr. Thomas: “Finally. We can get back to work.”

In the opening statement, the prosecution made the charged statement that 81 of 85 patients died as a proximate result of protocol 126. It was wrong, a fact they seemed to learn during the course of the trial. The sensational statistic was the headliner for their case – a ‘fact' that immediately engaged the listener.

How could that have happened? Counsel for the plaintiffs intended to show that the defendants’ dogged pursuit of fame and fortune drove them to conduct an unusually risky experiment without fully informing the IRB or their subjects. In their opening, they contrasted the 3% survival for protocol 126 with 20-85% for a standard bone marrow transplant. These survival rates were offered as evidence of intentional protocol misrepresentation. In their closing, the prosecution standardized the chance of survival to 50% and offered it as evidence that patients were not informed of the greater risks of protocol 126.

In another report, 83 of 85 patients died, not all as a proximate cause of protocol 126.
Motive is a crucial element in narrative emplotment. It vivifies ‘facts’ with human agency, a marriage of form and function. In legal discourse, motive determines which way the scales of justice tip. When the court dismissed the claims for ‘fraudulent conduct’ and ‘intentional harm’, the prosecution’s ‘facts’ were stripped of explanation. Their story was gutted: this paucity of narrative is evident in the prosecution’s closing statements. ‘What the case was about’ had changed so radically that they never restate it in closing. The defense supplied the narrative glue by creating a much more hopeful story. The original elements of villain, victim and hero remained, acknowledging but redirecting the outrage of the listener. In the new narrative, the decedents remained victims, but the villain shifted to leukemia. The doctors were restored to heroes. They were tireless in saving lives and had been victimized by harmful allegations. Medical research, and its implied social good, had been needlessly and perhaps dangerously sidelined by this litigation. The jury held the redemption card.

How did it happen?

(OP) Unbeknownst to (the plaintiffs), unbeknownst to their referring doctor, however, at this very time, the Hutchinson Center had a priority system where these plaintiffs would be assigned automatically into what their own doctors described as the most highly experimental research protocol they had going on at the time. The first time they heard about this protocol, if at all, was when they were literally admitted into the hospital… They were in their hospital room and their hospital gown. Most of them had already a Hickman catheter placed in them to begin their chemotherapy treatment. At that point, a Hutchinson Center doctor, who just
happened to be the doctor assigned by the Hutchinson Center for the ward for that day, not necessarily a specialist in bone marrow transplant, not necessarily knowledgeable at all about the protocol; just the doctor who happened to be assigned to the ward that day....

...at this time they had no idea what would happen when they took the T-cells out. In fact, what you will see is that the first and primary objective of this study was to determine if you took the T-cells out, would it cause the death of the patient from graft failure or graft rejection. That was the purpose, the number one purpose of this study, was to determine if you took the T-cells out, would it cause them to die because they would get a graft failure or graft rejection......

And at the time, the Hutchinson Center knew from statistics going back as far as 1975 that a second transplant after the first one failed was uniformly fatal. It didn't work. They knew a second one wouldn't work. They never told a single one of these plaintiffs or their spouses that a second one wouldn't work. In point of fact, the only real shot they had to live and to be cured was the first bone marrow transplant. If that one failed, they were going to die.

(OD)

Now, you've heard it suggested by the plaintiffs that all of these patients came here with no idea they would be involved in any kind of proposed research. None whatsoever. And we sprung it on them at the -- after we stuck the tubes in them, that's when we finally mentioned it, if we mentioned it at all.

They are not sending ear, nose and throat specialists to go work the wards for these bone marrow transplant patients. They are all bone marrow transplant specialists.

Cancer specialists around the country who referred patients to the FHCRC, they knew they were referring patients for their last chance.

You were told that the principal, quote, objective of this study was to see whether or not t-cell depletion would cause graft failure. Well, the implication of that was that the doctors just wanted to satisfy their curiosity. Let's stick some antibodies into people, take out the t-cells and see if they die or not. That will be a fine experiment. Of course, they weren't doing that.

(CP)
The defendants say well, we claim that they secretly put into a research protocol. Well, you can pick whatever word you like. The truth of the matter is, and it's not disputed, they aren't told that they are not getting the 50 percent cure bone marrow transplant. They are put into this. And they are into this instead. And they are not told that. They have no preparation for that when they meet with the doctor at the family conference.

Well, okay. On one hand they say that, but on the other hand, Dr. Martin says the reason we don't tell people like JC that there's a phase three trial instead of just telling them that this is your assignment is they would be too confused; it would be too much of a decision for them to make. I don't think that they can have it both ways.

(CD)

Now, here is what they are saying. They're saying the clinical coordinator secretly assigned these patients to protocols without their knowledge.

Well, there wasn't any priority. There was no -- you see, there is an evil they are trying to suggest here. The evil is that these doctors at the Hutchinson Center wanted to experiment on these patients, so they put them into protocols, and they had them in a very weakened position and the Hickman lines in. Remember all that we heard? The Hickman line is in, and so they're trying to get these people in so they can experiment on them and see if they can kill them with graft failures. That's where it is. That's where it goes, the logic of what they said. But it wasn't true. ...That's the trust. That is the way it was.

Maybe assignment isn't a very good word on that sheet, I will grant you that, but they weren't assigning anybody to anything. And certainly not some secret assignment so they could experiment on these people and see if they could kill them with this T-cell depletion.

The goal wasn't just to do research on a bunch of people and publish papers. That's what they are suggesting. You heard that from the get-go in this case. All the doctors wanted to do was to bring a bunch of patients in, trick them into getting into this protocol, and then see what would happen. Maybe we'll kill them with graft failure, and then we can write a paper about it. That's what it is. I mean, make no mistake about it: that is what they are saying to you. And that is completely false. Because every one of these doctors around the world were trying to take care of these patients.
Do you think he was trying to fool his patients in New York? Let's lure them in, we can have some fun, too. This is like kids pulling wings off flies. That's not what these people do. That's not what motivates them. That's not what they think. They tell what they know, but what they know advances by inches.

Post-trial comment from juror: “I don’t think there was some evil plot to enroll patients in some evil protocol”

Some of the prosecution’s assertions had merit, but they implied a conspiratorial callousness that didn’t fit with FHCRC’s international acclaim in scientific and medical circles. For example, early placement of a central venous catheter (Hickman) would be beneficial to this patient group whether or not they continued treatment at FH. And while an evaluation of toxicity (and efficacy) is the primary goal of phase-one research, that is quite different from ‘seeing if it would kill patients’. It is on the other hand possible that patients were oversold on the anticipated benefit of P126, that they didn’t appreciate a real choice about participation, or that the attending physician (rotated monthly) was not fully apprised of every current research protocol. Over the course of the trial, evidence emerged in depositions and clinical chart notes that did leave these questions open. But it becomes a real stretch to imagine that patients were lied to or that just any doctor would be assigned to their case.

As the trial unfolded, the prosecution’s story became less inflammatory, progressively moderate, and at the close, quite constricted. In part this is because they had come out of the gate with some very extreme and unlikely statements about the FH team. Whatever facts they presented lost credibility by
association. The defense never allowed the prosecution’s concessionary narratives to stand. They continued to resurrect and add rhetorical texture and colorful imagery to the earlier motive-laden allegations. In this way, they began to control both narratives. For example, the description of a boyish nastiness ‘pulling wings of flies’ simply doesn’t fit with the idea of a renowned researcher. So, they either ‘tricked (patients) to see what would happen’, or they were serious scientists. The defense made the prosecution’s position sound preposterous, creating what might be called an anti-narrative: what did not happen. This is the beginning of the narrative coup.

Why did it happen?

(OP)
The second (objective) was if they didn’t die, whether this, in fact, would have some sort of benefit in terms of reducing what’s called graft-versus-host disease. It was theoretical. They had only done it in mice.

They had gotten a huge grant from the federal government in December of 1980. (Also) the doctors and the Hutch itself had gotten a financial deal from a biotech company called Genetic Systems, which was interested in the development, licensing and marketing of monoclonal antibodies that were used to deplete the T-cells. There was a tremendous amount of competition among centers at this time, and there will be testimony in this case from the Hutch’s own doctors that they believed they were losing out to this competition. They had gotten into this competition too late. They had to get into it quickly and get ahead of their competition. This was supposedly going to be the next phase of bone marrow transplants. They needed to keep their place as a preeminent transplant center in the world.

(OD)
What Dr. Day said was, applying a policy that said the appearance of conflict, is a conflict. Dr. D. agreed this
appeared, this gives the appearance of a conflict; and therefore, I want to appoint a special committee that's going to look at any use of MAb to make sure that the people who are selecting whatever antibodies ought to be used, can't be accused of anything. Can't be accused of having some agenda.

Now it's time to try it in humans. Because after all, why are we doing this research? We were not doing it to cure cancer in mice. We are doing it to cure cancer in people. And you can't find out eventually if it cures cancer in people or if it alleviates another illness in people until you finally try it in people.

(CP)
You know, these doctors may well have had the best intentions, and they may well have had the best goal in mind. (Dr. Thomas) tells them that undoubtedly MAbs constitute the greatest breakthrough of the last decade. No doubt he thought that. He goes on and says, you know, I think the committee members have not only an obligation to review the ethical aspects of this work but also an obligation to assist us and not impede our research, which is directed towards solving some of those problems that are killing the children and young adults who come to us with fatal disease. And undoubtedly they thought that. And what's the problem there? The problem is when you are impassioned, when the goal is so much in your mouth and in your eyes and you want it so bad, it affects your judgment. But history and our own experience tells us that no end justifies the means when the means are to run roughshod over the assurance agreements and the provisions that have been put in place to protect people.

(CD)
And think about how it must have felt to Dr. Martin who is leading this particular trial, to have gone so far and to got to that point, and then to see his patient..... I can't imagine how it must have felt to him. I'm sure it was terrible for the family. We are not taking anything away from these people. It was terrible, awful. But he thought he had an answer that could save not only these people, not only them, who could save thousands and thousands of people. That was the hope. That's why they were doing this all over the world. So think of how he must have felt. And then now to come back and be accused of all these terrible things, the malpractice and these terrible things. That's why we are here.
They accused them of fraud, of intentional infliction of emotional distress. Think of that, intentionally harming their patients. And that they had a conflict of interest that prevented them from treating their patients fairly. Fraudulent conduct by engaging in deceptive practices to induce plaintiffs and induce patients to enroll in the protocol. They are still talking about it. But you know it was dismissed by the court.

Post-trial remark by the jury foreman: Losing the claim for conflict-of-interest significantly weakened the case.

Initially, the prosecution stated that the doctors stood to gain substantially from pushing protocol 126 forward. They claimed that, motivated by financial ambitions and glory, FHCRC founders cut corners on the usual systematic order of research. The claim for conflict of interest was lost in part because the prosecution’s financial analyst witness did not understand the product, the research, or its potential for development. Although the witness substantiated financial ties between Genetic Systems and FH founders, and linked profits to specific MAbs, he was unable to connect those facts with P126 because he didn’t know what P126 was. He assumed FH’s financial “interest” lay with the potential of the MAbs on hand, as opposed to the potential for patenting the first successful T-cell depletion process.

The defense replied directly to the conflict of interest issue. They conceded that yes, it looked like potential conflict at the time, so a corrective policy was written. In the documented IRB communications and by testimony of some of the IRB members, the conflict persisted. Still, the charge lost materiality.

28 From testimony by the chartered financial analyst, witness for the prosecution, March 4th 2004.
in two ways. First, the defense offered no reifying resistance. Secondly, they bent a ‘fact’ into a ‘fact of appearance’.

The prosecution’s statement, that preventing GVHD with T-cell depletion was theoretical, challenged the scientific merit of protocol 126. In reply, the defense recreated a sense of urgency for movement in cancer research. It is communicated here with a rhetorical style that pairs opposing ideas with transitional temporality: “we were not doing it to cure cancer in mice. We are doing it to cure cancer in people”.

Evidence of the narrative coup, where the defense established dominance, was palpable as the prosecution delivered their closing statement. The first time they read from Dr. Thomas’ letter (below) to the IRB objecting to research limitations, it was early enough in the trial that narrative authority was in limbo. At that time it effectively characterized Dr. Thomas as a driven autocratic researcher who would not be held back by research-naïve IRB members:

“I think the committee members have not only an obligation to review the ethical aspects of this work but also an obligation to assist us and not impede our research, which is directed towards solving some of those problems that are killing the children and young adults who come to us with fatal disease”.

(excerpt from Dr. Thomas’ letter to IRB as read in prosecution’s closing statements)

In the context of a newly prevailing defense narrative, the same sentence would be heard differently. In the second reading of his letter, Dr. Thomas simply made an appeal for IRB cooperation on an exceedingly critical matter.

The prosecution tried to salvage their impoverished narrative by replacing ‘ambition and greed’ with ‘blind passion’: a narrative compromise that
inadvertently supported the defense. Their contention that ‘the ‘end’ goal (of curing cancer) cannot justify the means’ no longer resonated. In the case made by the defense, there might be exceptions to that rule.

What are the standards for stopping?

(CP)
(Dr. M. has said about Protocol 126.0), before the lawsuit, that it was awful, there was a lot of rejection and recurrent malignancy, meaning relapse. And so it didn't work, and it was a bad idea. ...you see that's precisely why you have stopping points. .................But because they did not have a stopping rule for efficacy at that time, the trial continued, JC had a graft failure and died.

(A week before JD) the researchers noted that there were two cases of grade two GVHD or greater. But because they had no stopping rule at that point in time, didn't think to stop.................Even though Dr. S., one of the co-founders of the Hutch, said there would be nothing more, in his opinion, to be gained from going on......Dr. Martin said, because you knew two graft failures was not a fluke, it was a serious problem...(and) two graft failures in protocol 126 out of the first nine patients..... occurred before RF came to the Hutchinson center. But the study was not stopped because there was no objective stopping rule.

(CD)
Dr. Gale talked yesterday about this stopping rule. And what did he do for you? He did a simple math calculation. Oh, well, we have got two (graft failures) by the time we get to eight (enrollees). Yeah, that (stopping) rule would have applied. Did they ask him the next question, should that have been the rule? No, they didn't ask him that question. Why? Because they knew what his answer would have been. It would have been, what, are you crazy? Put that in as a stopping rule? Why would you stop? You are advancing the ball tremendously if you get to that result. Why would you stop?

So who got on the stand and suggested that that two-out-of-eight rule used for its unique purpose in 126B should have been the stopping rule in 126.0, should have been the stopping rule in 126.1? Not one person. I don't care if he had a medical degree, had a Ph.D. or was a guy driving a truck down the street, not one person took the stand and
told you that, because nobody would tell you that. Now, what do we know about the stopping rules here? We know that 126.0 contained a stopping rule that said cumulative evidence of toxicity or lack of efficacy will constitute grounds for early termination of the protocol. What does that mean in context here? It means we don't know exactly what adverse outcomes we may see.

In closing the prosecution pointed out how the decedents were enrolled in protocol 126 after a stopping rule for either efficacy or toxicity would have halted the trial. Although the defense agreed that clear stopping rules were not in place, they affirmed that even if they had them, it would have been insane to enforce them. “What, are you crazy?” “Why would you stop?” The defense conceptually conflated the stopping rule for lack of efficacy with the stopping rule for toxicity. Clinically, these mean very different things for the patient. They likened researcher intuition with the common sense of a truck driver, rendering statistical data superfluous. The implication is that (decedents would have chosen and) jury members should easily see that nobody would have stopped this research unless they were either crazy or foolish. Part of the argument from the defense (earlier in the trial) was that while subjects were dying in record numbers from graft failures, some of them would be dying from GVHD if they lived longer, so the numbers were not as bad as they appeared.29

29 In fact, a marginally competent graft wouldn’t be strong enough to stimulate severe GVHD, and death certainly precludes it.
Should protocol 126 have been stopped?

(PO) They only concentrated on GVHD within the first 100 days. From their own statistics, that problem, GVHD in the first 100 days, was a direct cause of death of only about five percent of the cases. 95 percent of the time it's not a problem, according to their statistics.

And (IRB member) points out, here again, that at this very same time that they are trying to eliminate, prevent GVHD, they have a study going on to induce GVHD in patients precisely because of the data showing that it increases your chances of remission and overall will increase your chances of living.

Not one of these plaintiffs or their spouses was ever told that there were actually benefits to getting this GVHD, that maybe it shouldn't be prevented because there were actual benefits. Now, this problem with GVHD was only one of other complications. The principal complication was actually a form of pneumonia called interstitial pneumonia. That was the most important problem facing people with a transplant. It was the leading cause of death of people who did not survive past the first 100 days. Because, if you survived past the first 100 days, basically that is when you will have long-term survival. By long-term survival, they mean curing your leukemia.

(OD) That the Hutchinson center did studies to try to give people graft versus host disease, that wasn't the point of those studies. That wasn't the -- you saw what graft versus host disease looks like. And it's like a small fire on the prairie. If you light that match -- it would be great if everybody could get grade one graft versus host disease. And no more than that. But you can't stop it there. Sure, you'd get higher relapse rates if you cured GVHD because the people would still be alive and eligible to relapse. If you are dead, you can't relapse.

When somebody gets GVHD, the way you treat it is to immuno-suppress (the donor marrow). (So, the) patient (is) more susceptible to interstitial pneumonia or to any of the host of other complications. (That’s why) the patients who had GVHD who were surviving at only 20 percent versus patients who escaped it who were surviving at 75 percent. It's because GVHD either kills you by itself or it kills you in combination with something else. It's the "but for" cause of your death. If you hadn't had GVHD, you wouldn't have gotten this other infection that followed.
And in fact, GVHD was a direct or indirect cause of death in 25 to 30 percent of bone marrow patients over the age of 30. Not only that, if you survived it, it was a horrible disease even for those who did survive. Terrible quality of life. And ... the donor marrow (cells) eat away the surface... the surface red, eaten away basically by GVHD... it eats away at the bowel. It gets worse and worse and worse and eventually just eats away at those intestines. Skin GVHD, this is an example ...This patient didn't survive. It goes to the skin and eats away, creates open sores and ... It's a terrible, painful, difficult way to live.

(CP)
That if you remove the T-cells, you might increase the risk of relapse. Why is that a material risk for somebody? Because that means you are going to relapse. That means the bone marrow transplant you are getting with T-cell depletion isn't going to be as good as the standard in terms of keeping you in remission. It means you might have a relapse, which increases your chance of death and makes it a certainty that you will have to come back again.

Now, choice number one is the bone marrow transplant you have been told about and you are coming to the Hutch for. It has the 50 percent cure rate. It is something that they have done thousands of times so that they have this established cure rate. Does it have drawbacks? Of course. Have we ever said GVHD wasn't a problem? Of course not. I will say this, that when you look at the documents, you look at Dr. Martin's various statements about it, he said at one time it was ten percent, he says in the protocol it's 15 percent, including complications, he says in the article Exhibit 125 it's 15 percent, including complications, and on the stand he said it was 25 percent. Let's say it was the 25 percent. That's 75 percent, then, of the time methotrexate would work.

(CD)
The whole argument about relapse is not directed against T-cell depletion. And don't let them think -- don't let them make you think it is. Nobody ever suggested that there was something unique and different about T-cell depletion that would cause relapse to go up. All that they suggest is that if GVHD was cured, one by-product of that might be an increased rate of relapse. Well, that's logical for a couple of reasons. They had seen these studies that indicated that some moderate amount of GVHD actually did keep relapse rates down. The problem with that, of course, as Dr. Thomas explained, is it's like a little fire on the prairie. Once you light it and you back away, GVHD goes where it wants to go. So it's a terribly dangerous thing to do to try to induce GVHD. But the second point here is,
T-cell depletion would only, only lead to an increased rate of relapse only if it worked, if it prevented graft-versus-host disease. If it didn't work and you got the graft-versus-host disease, the whole theoretical basis for any possibility of relapse increasing evaporates, can't happen. ...Who says no to that deal? Who says no?

Here's what was said in the opening statement by plaintiff's counsel. GVHD in the first 100 days was a direct cause of death of only about five percent of the cases. 95 percent of the time it's not a problem, according to their statistics. The doctor told the review board the chance of dying from GVHD was about 10 percent maximum. 90 percent of the time it is not a problem. That's what counsel said in his opening statement. Why did they show that when they knew, they knew, that the 10 percent reflected only the direct cause? And there was another 15 to 20 percent of indirect cause such as the pneumonia and other infections. Why did they do that, when they've got to know it's true? They have to know it's 20 to 30 percent in this age group. Because they want you to believe that GVHD was not that big of a problem. And they want you to believe that if it wasn't that big of a problem, why in the world would T-cell depletion be done at all? ...Distort the truth so you will believe that T-cell depletion shouldn't have been done and these patients' spouses should not have been involved in T-cell depletion. That was their goal. But that didn't work.

It isn't possible to induce GVHD although it is possible to not prevent it.

The point of the prosecution's opening was that if some GVHD was beneficial, that might factor in to a patient's decision about whether to eliminate it via a very new research trial. P126 utilized a 'complement', an agent that accelerated T-cell depletion in the marrow, and as such was a more radical depletion than other methods being tried for T-cell depletion. The defense moved on the prosecution's misconception about this, and reinforced the prairie-fire imagery of GVHD. They conceptually separated the research method (T-cell depletion) from the goal (eliminate GVHD) by dropping the issue of graft failure in favor of the
prosecution’s tangent, a hypothetical relapse. It is clear that stopping a prairie fire is necessary, urgent and right. Preventing it is better. The narrative dominance shifted again toward the defense. P126’s toxicity (graft failure) was effaced by a theoretical chance of a leukemia relapse if T-cell depletion succeeded in preventing the prairie fire.

The prosecution’s discussion of risk was tied to the allegation that patients were not fully informed when they consented to P126. Again, between opening and closing the prosecution’s story moved right into the crosshairs of the defense. At first, they stated that the risk for GVHD mortality is only 5%. In closing, they adjusted the mortality figure to 25%, acquiescing to the defense’s more inclusive statistics. They weakened their own argument that the relapse-prevention benefits to contracting mild GVHD would be a material fact for informed consent. The defense further dematerialized that ‘fact’ by keeping the sense of GHVD danger imminent and leukemic relapse moot. In the closing they re-associated GVHD prevention with T-cell depletion. Now the protocol is a no-brainer: “who says no to that deal? Who says no?”

This section illustrates one important unspoken facet of the trial: an indirect challenge to the premise of protocol 126. For example, why was it that internal challenges to this research were unwelcome, that stopping rules were at the researcher’s discretion, that enrollment exceeded the approved numbers, and that they didn’t communicate the risk of a phase-one protocol to the decedents? Why was it that even truck drivers would vote to persevere? These questions were not explicit, yet always present. The answer was never explicit,
yet always present. Both prosecution and defense participated directly and indirectly with this particular debate to bolster their respective narratives. The defense argued that no rules were broken, but if they were, GVHD was dangerous enough to warrant breaking them. Counsel for the prosecution was left to make a case for the safety of prairie fires.

Each side attributed the statistical assessment of “5-10% GVHD mortality” to the opposition. The plaintiffs’ counsel originally retrieved the statistic from FHCRC documentation and used it to question what they then concluded was haste and carelessness in administration of P126. The defense implied the plaintiffs’ counsel had done their own (uninformed) figuring to arrive at the statistic, and were using it mislead the jury.

The defense had the academic edge. They frequently dropped into a statistical black box to dislocate attention, to reinforce their narrative plot of danger, and to complicate the assessment of risk. For example, in the 1980’s, GVHD was viewed as a discrete side effect of BMT. Infections, pneumonias and other potentially lethal complications were conceptually and statistically separate. During the trial, the defense conflated the mortality statistics (30%) for these complications and said GVHD was the direct or indirect cause of death. There is currency to that idea today, but at the time, statistics for GVHD mortality was reported to be 5 to 10%. The prairie fire analogy was used by the defense several times: digestible and memorable. Most of the semantic and temporal play imprinted a sense of relative danger in the audience. I will return to a discussion about GVHD, statistics and embodied danger in the conclusions chapter.
What was the role of the IRB?

There are two opposing storylines to explain the role of the IRB. Either the IRB ineffectually contested and opposed protocol 126, or they ironed out the questions and granted approval to proceed. The prosecution’s narrative conjures up a frustrated IRB eventually silenced by an autocratic and volatile Dr. Thomas. The defense paints the image of independent thinkers necessarily embroiled in academic discussion.

(OP)
What you will find in this case is the Hutchinson Center destroyed all of the tapes (of the IRB meetings), threw out all the tapes, or cannot find any of the tapes for any of the meetings. You will find that there are many notes from critical meetings that they have not been able to locate. You will find that their record keeping concerning this period and what happened and facts about how this approval process occurred just don’t exist.

And at the critical meeting where this was discussed, this IRB meeting where the IRB actually rejected the protocol, there were many concerns raised. The primary reason (the IRB gave) for the disapproval (of 126) at that time was a lack of toxicity and dosage data in higher animal species prior to (human) experimentation. There was also a concern stated by the doctor about second bone marrow transplants. And there was a specific concern that was raised about the consent form.

(OD)
And if any of you have been on a faculty or been to faculty meetings or knows somebody that's been to faculty meetings, you know these people are not wallflowers. Everybody has strong opinions. Everybody thinks his opinion is the best one. And these proposals, whether it was T-cell depletion or any other one at the Hutchinson Center, undergo vigorous debate. People speak their minds. And it's easy to come along 23 or 24 years later and say somebody in the crowd criticized this idea, you should have listened to him, it was negligent -- in fact, it was fraudulent not to listen
to him, because he turned out to be right. Well, life doesn't work that way.

(CP)
(Dr. Thomas said) he reacted violently against that IRB recommendation to a simple 60-day period in which they could simply wait and see what the effects were on the existing patients. Dr. Thomas violently opposed it. Dr. Thomas backed Dr. Kaplan down, and Dr. Pesando down. (Dr. Kaplan testified that) the researchers did not appreciate the IRB attempting to set restrictions on their research. (Dr. Pesando testified that) the IRB was intimidated by Dr. Thomas' response. Many of the witnesses, including Dr. Kaplan himself, put it bluntly: Dr. Thomas was, quote-unquote, the boss.

(CD)
This IRB was independent, it was conscientious, it was assertive. It pushed back as much as you have in this trial and more. It pushed back. That's the way it's supposed to work. God help us -- God help us if every time somebody proposes a clinical trial, you don't do it if anybody -- anybody -- voices a criticism of it. You name the scientific advance we have had -- I don't care what the field is, is it medicine, is it anything else, you name the advance we have had, somebody said before it was tried it's a bad idea, it won't work, you shouldn't do that. This will go wrong, that will go wrong.

This pulling and tugging in this faculty, in any academic setting, in any scientific endeavor, this pulling and tugging, there's an idea, there's intellectual tension. That's the fuel. That's what makes it work. Because when all that intellectual tension gets going, if enough people are voicing ideas so you can sift through the ones that make sense and the ones that don't, if the critics have a good point, people will see their point of view. The time won't be wasted, the effort won't be wasted, the money won't be wasted. You pursue the ideas that make sense in the end, in this context in order to try to save lives, in order over the long haul to take that person who has got a 30 percent chance of survival and get her to 34 percent by six months from now and to get the person who's just like her to 38 percent in a year and a half. You try the ideas that hold that promise. This one was a big one. This one was a big one, because as Mr. Leedom said, GVHD was the scourge of bone marrow transplant patients. This one could have been a quantum leap.
The legal questions were whether or not the IRB was free to function autonomously and whether or not their concerns were addressed. The defense countered the prosecution’s documentation with a hypothetical IRB scenario in which conflict is transmuted to intellectual tension. The prosecution’s facts were rewoven into the defense’s narrative. Finally, the danger of GVHD is revisited. The story was re-trued to the central theme of the defense: patients are dying now. The research was urgent. They were trying to save lives and had a shot at the quantum leap. They had to take it. Only fools and madmen would drop the ball.

The Case for Conflict of Interest

(OP) Dr. Kaplan had been trying since late 1983 to get the head of the Hutchinson Center, Dr. D., and the researchers to address the conflict of interest that existed. These doctors should not have been involved with this protocol. They had a conflict of interest. That was Dr. K’s view. He kept asking them to address it. And (Dr. K.) had heard rumors of financial conflicts of interest involving the researchers…. and wrote to Dr. Thomas. Now, Dr. Thomas responded angrily to this letter, denying that there were any such conflicts of interest, none whatsoever. This continuing problem with conflicts of interest continued on…….

(OD) The point is, this trial succeeded in stopping graft versus host disease, but at a price. An unexpected price, but at a price to be sure. Now, what I have discussed with you and shown you, evidences the fact that there's no scientific medical basis for these claims. So what the plaintiffs are doing is adding in what I will call a smoke screen. It's an
effort to try to attribute to these doctors some sinister motive for what they were doing. And what's that sinister motive in this case? It's the suggestion that they were trying to line their pockets. That that's why they did this research. That Paul Martin who drives a 1991 Honda was trying to line his pockets here. Most of you understand, can appreciate, that if you are going to try to commercialize something, particularly something in the biotech sector, you need to have a patent to, otherwise you come up with the idea and everybody else would do it. And these doctors did not apply for patents. Why? Because it was the farthest thing from their minds. They were not trying to commercialize t-cell depletion. Genetic systems wasn't doing it. These doctors weren't doing it. There was no way to make a profit from t-cell depletion. The market was tiny. And as you've learned, all the other cancer centers around the world were doing it. They had their own antibodies. Why in the world would they need to buy them from the Hutchinson Center? They had their own.

The fraud claim was dropped. The defense knew something few others in the courtroom knew. MAbs are unique products of forced cell fusion across species. These hybridomas are random, and cannot be recreated. Promising cell-lines can only be cloned. It wouldn't make sense to patent a cell-line unless it was linked to a successful technology or application[181]. Every research institution was at that time creating their own hybridomas, every institution was looking for the best combination 'cocktail' of MAbs, and each were working out the best technique for inducing degrees of T-cell depletion. If the protocol had been a success, there may have been something worth patenting. The T-cell depletion market might have been small, but the cancer market was and is not. It was expected that MAbs would eventually be developed to target any cell, especially specific cancer cells. MAbs, true to medicine’s lineage of militarisms[78], have more recently been called ‘smart bombs’. Here again, the
The Case for Informed Consent

(OD)
A lot of knowledge has been attributed to these doctors during the plaintiffs' opening statement. The doctors knew this, the doctors knew that, and they risked these patients' lives in spite of knowing that. You are going to find out that this knowledge was coming along in baby steps.... Imagine for just a second, ..you were asked to assess whether some NASA engineer should have known about the shuttle blowing up a year ago, should have detected it, and you are looking back 25 years. And all these events and all these documents get compressed together in a presentation, and it turns out that half of them happened after the explosion, not before the explosion, and another third of them weren't seen before the explosion. ...Wouldn't we all like it if our stockbroker could operate with hindsight every time he made a recommendation to us, or that we could say after buying a stock that he recommended, you were at fault because you sold me the one that went
down, and you should have sold me the one that went up. And see, look at the evidence from a year later, it went up. That's not the way life works in the stock market, and it's not the way life works for these medical researchers. They know what they know when they know it.

(CP)
The other risk that everybody agrees was a risk, and it's in the protocol itself, is the increased risk of graft failure. There were three camps at the Hutch. Camp one believed graft failure could occur from the damage to the stem cell. Camp two thought, well, maybe stem cells were necessary for engraftment. (And camp three) thought, well, maybe there's a reaction going on between the T-cells of the donor and the patient that would result in rejection. All three of these theories were being talked about in her testimony at this time, '82 through the '84 time period. At the same time that Dr. Gale said that reasonably prudent, careful researchers knew all three of these were a possibility in terms of increased risk of graft failure. It's in the protocol itself. It will be pointed out to the patient. There may, in fact, be an increased risk of graft failure.

(CD)
And you cannot say that somebody violated the standard of care when they don't tell people about graft failure, increasing graft failure, when it's not yet known. You have to look at the state of medical knowledge, what was known, what was not. That was not known then. It was known later. But we can only be held to what should be known or was known at the time.
Because if you believe that there was an increased risk, and we didn't tell you about that, well, then, no informed consent. But what if the truth is the reality? What if there wasn't an increased risk in graft failure in those mice or in people? And we know that's true. Then the informed consent is fine. Then the language in the consent is fine. And the language in the protocol is fine. Because it was the state of medical knowledge.

You decide if a risk is material, but an expert witness tells you if it's a risk in the first place. Assume for a second somebody comes in claiming I had T-cell depletion, and suddenly I am allergic to dairy products. You should have told me that T-cell depletion would make me allergic to dairy products. But you have got to hear from an expert first that T-cell depletion does, in fact, cause allergies or that doctors should have known at that point, because here's all the evidence that shows to any sensible
physician who is trained that it would cause these allergies. You can't just accept it because some lawyer tells you that it's going to cause allergies to dairy products, and then you are on your own to decide whether that's material.

Counsel for the plaintiffs claimed that the doctors knew there was a risk of graft failure associated with protocol 126 and did not communicate it to the decedents. In fact, graft failure was identified as a risk in the 1980 research proposal for P126. It was actively discussed and recorded by the IRB and at faculty meetings. The IRB documented their request that the risk be stated explicitly in the consent form. The defense used allegories that instructed the jury how to relate to the present issue. The message is that disaster happens when science ventures into unknown frontiers, that 25-year old evidence will be misleading, and that nobody can prove what was known and when, in the case against FHCRC. The stockbroker story conveyed the message that life is lived without the benefit of hindsight. Life is risky.

In closing, the prosecution knew which facts were solid, so they restated them with additional evidence. They no longer had the greed/ambition motive to answer why the doctors would fail to inform patients about a specific risk, but they had that orphaned fact and borrowed one the opposing team’s motives: passion. The simplest and most palatable reason for not telling patients about risks was filled in by the defense. The doctors didn’t know. In fact, the defense’s play on the meaning of known and unknown are examples of what they called the ‘semantical games’ they attributed to the prosecution. They testified that they
knew of the graft failure possibility but had been careful about drawing (statistical) conclusions.

The informed consent claim was derailed by pairing two scenarios: “If you believe that there was an increased risk and we didn’t tell you about that, well, then, no informed consent. But, what if the truth is the reality? What if there wasn’t an increased risk of graft failure in those mice or people? And we know that’s true. Then the consent is fine”. The defense is speaking to the jurors, contrasting (patient’s) belief with (physician’s) knowledge. The implication is that the prosecution had managed to dislodge truth from reality, leaving the jurors susceptible to belief rather than knowledge. Even though what they had just said was neither the truth nor the reality, there remained just one resolution: the consent is fine.

For the juror’s deliberation about what should have been disclosed to patients, the risk of graft failure (lethal) was displaced by the risk for milk allergy (innocuous). Food allergies are safe ‘toxicities’ to consider. By taking the sense of danger inherent in graft failure out of the equation, the decision is simply one of logic. Ultimately the jury needed to decide what a ‘reasonably prudent patient’ would expect to be told. The defense’s tactic offered an enhanced sense of embodied rationality – the decision could now be made with the impartiality of a scientist.

(OP)
The consent form made it sound like if the first graft fails, another one will be done without difficulty. He criticizes the consent form for making it appear that
it's easy to get a second bone marrow transplant. And of critical concern here is, he says, that if the consent forms actually stated these risks clearly to the patient, I think as a patient, I would be very hesitant to sign up if it was clearly stated. And the consent forms that you will see in this case are substantially, if not identical, to the ones that were used in 1981.

(OD) You've been told that the consent form that was used... was deliberately deceptive, designed to defraud patients that came there. Here's the form. It says........ That's what the doctors knew and believed as of 1983. Were they alone? Excerpt from Dana Farber, Harvard, University of Michigan forms) Slightly different words saying exactly the same thing, exactly the same concept as the Hutchinson center form. Were these people 3,000 miles away trying to defraud their patients as well? Same time period, same kind of experiment. ...Were they, too, just trying to defraud their patients, to pull the wool over their eyes?

(CP) Mr. Mernick said well, it's all a semantical game. It's not a semantical game. You and I know as being reasonable people and being patients in that situation that what a doctor tells you and the way they say it to you makes all the difference in the world, can have a tremendous impact. And Dr. Martin himself recognized that.

And what did we learn about those consent forms? That they are conflicting. They talk about three different procedures that cannot be carried out simultaneously. That was the testimony.

And when you look at this consent form, and when you read it over as a reasonably prudent patient might, what you will see is, this consent form presents this protocol in the best possible light. It spins forward to you the potential benefits. And it diminishes what those risks would be. And it tells you the risks are much more theoretical and unproven than the benefits that you would attempt to get or you could attempt to see.

(CD) Now, in this courtroom, as you have heard the plaintiffs' case, the English language has lost its meaning at times. You have heard that the word "may" means will, the word "might" means will, the word "possible" means won't. That's the only way you can accept the plaintiffs' logic here. Because we have heard again and again that the
protocol says it may increase and the consent form says it's possible, and somehow there is this mile of difference between those two concepts. Well, not with the English language that I learned as a boy. And, I suspect, not with the English language that any of you learned. And we heard Dr. Gale on the stand yesterday, and we flashed up the written opinion that he had given us, his own words, and what did it say? In it said in 1983, reasonably prudent oncologists would have recognized that T-cell depletion, quote, might increase the risk of graft failure. Not will. Might. What does that mean in plain, simple English? It's possible. What did the consent forms say? It's possible. ......We don't think it will, but it might. And that's what the consent form said.

I mean, why not tell people? Think about that for a minute. The motive and all that that they brought in, is out of the case. The deception and the motive and the fraud, that's gone. So why in the world would a physician not tell a patient, that they are going to enroll in the protocol, what they knew? Why would an IRB approve a document that sets forth the state of knowledge? Of course, they would. And of course, the doctors would say. And that is what happened in this case.

Post-trial remark from the jury foreman – that the consent form was ‘really shoddy’ but that all the information was there somewhere in the various consent forms and in the consent conferences. (Seattle Times 4/09/2004)

On the point of informed consent it isn't possible to answer the defenses' question “why wouldn't they tell?” because the ‘why’ was been removed from the prosecution’s case. There simply was no good reason why the researchers wouldn't have told the patients what they knew. So they must have.
The Case for Negligence

With respect to negligence, one of the remaining claims, counsel for the prosecution argued that negligence was constituted by FHCRC’s failure to follow standards of care in conducting protocol 126. Specifically, they argued that FHCRC did not provide timely information to the IRB and cooperation with IRB requests; they allowed financially invested researchers to present the protocols to patients, they failed to articulate clear stopping rules; and they enrolled more patients than the IRB had approved. A pretrial ruling determined that there was negligence in the processing of the first patient’s marrow. As there was no need to prove the negligence for this patient, counsel for the plaintiffs used that case as a platform to develop their theme of conspiratorial ambition. The defense simply attempted to limit FH’s financial liability by arguing that liver failure caused the patient’s death before his graft failure could.

(OP)
And then the IRB approved the protocol. And then they started enrolling people in the protocol. But the researchers, in their haste to get into this, didn’t even wait until the protocol was actually approved by the review board before they enrolled their very first person. ……
They had decided to take the rabbit serum out to get it past the review board, …….. it didn’t work. They couldn’t even get their t-cells out. So they went back to the review board, and they just put the complement back in, this rabbit blood complement, just put it back in. And ……they did it again. They enrolled the very first patient without ever having actually gotten approval. The actual approval came weeks after the first patient was enrolled.
What is significant here is again in their haste to get on to the program, to get going with monoclonal antibody research, they enrolled (him) before (126) was ever approved.
His honor has already ruled that they were negligent as a matter of law in handling that marrow. They lost 95 percent of it through sheer negligence. Now, did they go back to the donor and say we have lost 95 percent of the marrow, we need some more before we take the T-cells out and infuse it into this patient?
No, they didn’t. They just cut the marrow in half by removing the T-cells, so now they only had about 2.5 percent. And they infused it in (the patient), because they wanted to see what would happen. And he had a graft failure, and he died as a result.

(OD)
(The patient) had a totally independent problem that ultimately proved to be fatal. That problem was that (he) had severe liver failure. It was unrelated to whether he engrafted or not. That liver failure came about as a consequence of the damage that was done to (his) liver by the amount of radiation and chemotherapy that he had sustained both in Pittsburgh and then in Seattle. (His) bilirubin was above 45. Normal is one. Nobody survives a bilirubin level of 45.

(CP)
Now, you know, I appreciate Dr. Nathan is here to help his friends out that he’s known for a long time, and that’s all well and good. But the long and the short of it is that the Hutch itself put in its own records at the time that (the patient) died of sepsis due to failure of engraftment.

The defense accepted the Center’s responsibility for the singular tragedy. They suggested that negligence is negligence, regardless of how it is constituted. In the argument below, the ‘how’ of it – the ‘standard of care’ – was erased30. The defense also dismantled the materiality of negligence by positing that the patient’s death was inevitable.

(CD)
We were in charge of that lab, not the family. We had custody of that marrow, not the family. We screwed it up, not the family. So that is negligence on the part of the employee who did that and, therefore, the Hutchinson Center. He worked for us. The question is, did that negligence cause (the patient) harm?

30 The term ‘standard of care’ had inconsistent and contradictory meaning and use during the trial by both sides. It was never made conceptually clear enough to use as an objective measure of conduct.
Because of (the patient’s) low prospects for success with any bone marrow transplant, you have to ask yourself, did that problem with the marrow and the graft failure that resulted from it deprive him of that last small chance that he had? Or, in fact, was the cause of his death VOD, which has nothing to do with engraftment31?

...whether or not the IRB had approved the protocol at the time of his enrollment into Protocol 126. I have never said this to a jury before. It doesn't matter. In the end, it doesn't matter. The Hutchinson Center is negligent for the mishandling of (his) marrow, and if you choose to believe that the Hutchinson Center negligently enrolled him in that trial prematurely, they're still negligent, and they won't be any less negligent on the mishandling of the marrow if you find the other way on the enrollment into the protocol. No question.

There is no proof 20 years after the fact. There is no piece of paper that we can find. People's memories have faded.

Negligence is a foregone conclusion not broached in the defense opening.

In their closing statement, they used the uncontested claim as a focal point for all the negligence claims. In this way, the other plaintiffs’ claims receded.

Uncoupling the standard of care from negligence was a strategy that paid off for the defense in the discussion of the remaining plaintiffs cases. They laid the groundwork during the appeals time at the trial half-point. The defense distinguished research standards from standards of patient care for the judge and claimed that the case fell under the Health Care Provider Act. This act has an exclusivity clause written into it that disallows mixing health care conduct claims with research conduct claims. In this particular trial, the standard of care

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31 VOD is veno-occlusive disease, a complication of the bone marrow transplant process that causes micro-clots in the liver circulation. It causes transient or permanent liver failure in various degrees.
was a critical piece to the argument for negligence. For the plaintiff whose case had already been ruled, negligence was located in both research conduct and patient care. For the other plaintiffs, the negligence claim was located only in the research conduct. Moving the standard of care question to the bedside moved negligence in the case of all other claims out of reach.

"And I think now that you see their evidence that they presented, they didn't prove that there was anything going on at the Fred Hutchinson center other than what we said. Research, yes. But number one, first and foremost, therapy, treatment, medical care, designed to save the lives of these people. That's what they do today and that's what they did 20 years ago" (Defense to Judge successfully lobbying for the Health Care Provider Act).

(CD)
They claim that we were negligent when we enrolled and treated the spouses in the protocol. Enrolled and treated. That's their claim, enrolled and treated.

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**Closing Rhetoric, The Narrative Coup**

These trial excerpts are grouped thematically and presented as a conversation between the prosecution and defense statements. In order to demonstrate the diachronic process of narrative negotiation, the opening statements are contrasted with the respective closing statements. Given the volume of trial transcripts, this was the most efficient method. It is after all, the lawyers who told the stories. Once the prosecution lost their claim for fraudulent
conduct, their narrative faltered. The defense’s rhetorical tactics eroded it further. In closing, the prosecution had nothing more than a list of instances where harm could have been prevented. They couldn’t explain why world-renowned researchers would have violated the standards of care, except that they were passionate about protocol 126. The defense also characterized the researchers as passionate (about curing cancer). In closing, the prosecution had facts, but no narrative glue. The moral resolution they offered was a verdict that held individual physicians accountable for patient rights. The defense’s account established dominance during the trial. They conclude with a narrative overview and a prescription for moral resolution: a responsible verdict that allows the social good of medical research.

(CD)
In 1972, Dr. Thomas performed the first successful bone marrow transplant on an adult subject. Between then and 1981 is only a short nine years. And a lot happened in that nine-year period of time in terms of bone marrow transplant. Because, you remember, in Dr. Thomas' first study of 100 patients, only 13 people survived. And he got the Nobel Prize because that was such a tremendous increase over zero, which is what it was before. But as Dr. Martin said, God created leukemia. But man created graft versus host disease. That's why we are here. Graft versus host disease became the problem, the scourge, the thing that has not yet today been solved. That was the reason for protocol 126 and the various trials, graft versus host disease. They want you to say to doctors like that, don't be innovative. Don't think about new solutions to problems. When they come to mind, go really slowly with them. Because if it works, we are going to call you a hero. But if it doesn't work, we are going to come back after the fact, we are going to take every scrap of paper, we are going to take every sentence you wrote and parse it, and we
are going to see if we can get you to look like you mean
something different from what you actually meant when you
wrote it.
Meanwhile, 50 people a year in your hospital alone are
dying from graft-versus-host disease. But even if that had
happened, they'd say well, after the dogs, you should have
gone on to monkeys or baboons or chimpanzees or some such
thing. They want you to send the message that says when you
do that, we will look at your consent forms under a
microscope, and we will say the word "investigational" is
different from the word "experimental," and because of that
distinction, we are going to hold you as a guarantor of
what happened to that patient. If you accept that premise,
if that's the world you want to live in under those rules,
you know where medicine in this country is going and the
pace at which it will get there.
It is extremely unfortunate what happened to those five
people. It is extremely unfortunate what happened to these
five people having lost their husbands and wives, but the
culprit here is not these doctors. The culprit is leukemia.

Post-trial juror remark: “Even if they didn’t have informed consent, would a
prudent patient have decided differently?” (Seattle Times 4/9/2004)

The defense established control of the storyline through a more tempered
and historically situated narrative of selfless dedication. They used memorable
metaphors to fix key pieces of their story, they retold opposing counsel’s story in
absurd forms, and they collectively impressed the courtroom with intellectual
mastery of the medical data. The prosecution’s narrative was no match. In the
end, the facts were less important than narrative dominance.

BIOETHICAL RESIDUE: JOURNAL ARTICLES

There is a relative silence about this trial in academia. The ground is fertile
for exploration of how ethical problems are framed, and for an improved dialogue
between the moral experiences of patients, families and providers in the research context. Prior to the trial, there were a few journals that reported a synopsis of the allegations and pending litigation. The Lancet and the Journal of Law, Medicine and Ethics were among a very few reports of the pending litigation in 2001[184, 185]. The Lancet simply provides an account of the allegations, the Journal of Law, Medicine and Ethics suggest that “it raises policy questions about (1) the meaning of informed consent, (2) the extent to which investigators’ financial and career interests can compromise scientific research and patient safety, and (3) the government’s role in disbursing federal funds to institutions for cancer care and in ensuring the effectiveness and clarity of institutional safeguards designed to protect human research participants”. They recommend the expansion of federal agency to oversee it all.

At the close of the trial, two articles appeared. The American Bar Association Journal simply reported on the trial proceedings and verdict[186]. The American Medical Association published an article authored by a 3rd year law student and professor at California Western School of Law[187]. The law student is the first author. The case is discussed in favor of FHCRC and the conclusion is stated up front as a ‘learning objective’: “(To) understand the importance of public and patient trust in clinical trials”. This is all that remains.

Litigation requires a clear vote on culpability. The master moral narratives, revivified throughout the courtroom dialogue, offered resolution in two mutually exclusive moral domains: social good versus individual good. The narratives were therefore irreconcilable. It had to be one or the other. The defense
established narrative and moral authority in this trial. This no doubt played a significant role in the jury’s verdict. But certainly master narratives aren’t the only option for telling a story. The argument is perhaps something else altogether. In part it is a formalized social negotiation of ever shifting cultural values.

In the final analysis, jurors (thought they) placed themselves (but were placed) in the position of the decedents through an embodiment of the incalculable and ungraspable risk as they tried to decide if they would have gone through with protocol 126. Then, as jurors, they were indirectly asked to decide if they were willing to impede research, *while people are dying*, with an irresponsible vote for researcher culpability. The final chapter will further elaborate on this embodiment of risk and the trial-as-iteration of a culture of research medicine.
CHAPTER 6: CONCLUSIONS

This project is a diachronic case study of Bioethical history-in-progress. My contention is that narrative is a key constructive – deconstructive process in Bioethics that determines the official story and ultimately what counts as history. My second point is that the shape of ethical debates and conclusions are important artifacts of the cultural moment. Both things inflect the direction of academic and clinical bioethics. These concepts are woven into the research objectives:

1) To analyze socio-cultural processes that inform the trajectory of academic and clinical bioethics in research medicine.

2) To evaluate how ethical issues in research medicine are given form, expressed and codified through narrative engagement.

An additional dimension to this research emerged during the trial and now informs my conclusions. I believe that the culture of research medicine in general, and the ethos of the Hutch specifically, were experientially recreated as a stage for narrative performance. This has exciting implications for cultural constructivist research in judicial domains and challenges assumptions of legal rationality.

In this chapter, I will briefly review my research, discuss my findings and explore surprises. Next, I develop my conclusions through the lens of cultural constructivism. I will contrast this view with conclusions as they might be drawn
through the lens of critical medical anthropology. Finally, I discuss opportunities for future research in uncharted anthropological ‘fields’ to further develop the Bioethical Anthropology this work begins.

THE RESEARCH

The starting point for my research was the investigative report published by the Seattle Times alleging research misconduct at Fred Hutchinson Cancer Research Center. I brought a background in oncology, transplant, and research medicine to my understanding of the “Uninformed Consent” series. The Times intensively researched these cases, combed through hundreds of documents, conducted many interviews, and kept a constant fact-ratification system in place that included legal reviews and medical specialists. I began my own series of key-informant interviews, followed media conversations, attended the trial, took extensive notes, reviewed and coded thousands of pages of transcripts, and read pre- and post-trial articles on the FHCRC litigation in news and academic journals. All told, my research took place between 2001 and 2005.

There are three levels of discourse available to this study. The media represented a primary structural level that evoked compelling master narratives, gave voice to dominant cultural values, and demonstrated the evolution of narrative. The courtroom performance represented a dynamic constructivist level of discourse, providing an opportunity to capture instances of semantic shifts and
rhetorical maneuvers. Academic journal contributions represented the third level of discourse and might be considered a final cultural inscription.

THE FINDINGS

Despite the complexity of events surrounding the continuation of a failing protocol at FHCRC, the discussions that ensued had very little to do with the ethical issues at hand. Ethical dialogue, for example, might have included informed consent under conditions of a terminal diagnosis, narrowly defined conflicts of interest, or the extant separation of standards for research from those for healthcare. It might have turned to the use of medical resources along the lines of distributive justice, or it might have pointed out the disproportionate media coverage on the FH issue and the problems with that form of public trial. Instead, the media was deluged with impassioned editorials and letters of unwavering support for medical research and FHCRC, or with equivalent conviction supporting the courage behind the investigative report. The Wall Street Journal and the Seattle Times became embroiled in an editorial feud along the same vein. Academic journals joined the chorus, though with more reserve. Journal pieces that praised journalism contextualized the issues at FH with other classic cases. Journal pieces that supported medical research sounded warning bells about the effects of flagging public trust in medical research and rising litigation costs. Two master narratives emerged: “The Whistleblower” and “The Disgruntled Employee”.

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Both “The Whistleblower” and the “Disgruntled Employee” are frequently voiced master narratives from the corporate world. I presented these master narratives in their entirety, and pared them back to their respective literary elements. The oppositional plot development of these two versions as observed in the media, social discourse and the courtroom only seem to differ. They were comprised of identical elements, although the roles of the hero, villain and victim were cast differently for each story. Both tell a tightly knit story about personal ambition motivating a morally weak character to engage in unscrupulous behavior that ultimately cost human life. Both contained secondary subplots of hero victimization. The stories thematically resonated with each other yet they also led to disparate ethical conclusions.

There were subtle incompatibilities in temporality and moral resolution that made the narratives irreconcilable. In a nutshell, the whistleblower story sought to redeem lives already lost, advocated for the individuals’ right to have known, and called for physician responsibility; the disgruntled employee story seeks to save lives now through socially responsible journalism and the social right to the fruits of unhindered medical research. Parallel themes allow the superimposition of one storyline upon the other. That is precisely what happened. The narrative analysis of the courtroom discourse clearly illustrates the process in what I have termed a narrative coup.

The disembodied discourse through the media and academic journals are fixed evidence for the stories’ changed positions of dominance. A review of the court transcripts alone will reveal static points along that continuum of change.
This research is enriched with the live and informed observation of the legal narrative performance. During the trial, my attention was drawn to the moments when the story changed tenor and to the instances of incremental denouement. I was alert to presentation, posture, expression, mood, tone, locution and verbal styling of the speaker as well as audience response.

In my analysis, I discussed contextual aspects that weighed in on the issue of narrative authority. For example, everything about the defenses' team communicated confidence, preparation, and professional polish. The prosecution's presentation was simply less organized and less informed. I noted that certain structural features of the case held sway. The fact that BMT is a specialized, conceptually complex, and rapidly changing field gave FHCRC's team a definitive edge. And as all five cases were presented in one trial, though not in a class-action frame, there were moments of discontinuity in listening to and speaking the case. Both the teller and the listener tacked back and forth between general and decedent-specific modes – not always in time with each other. This compounded the difficulty of sorting out what happened.

The defenses' narrative was situated solidly in history and followed a laser straight path into the future. Their story began with a timeless leukemia that was first identified by medicine in 1850. It was uniformly fatal until Dr. Thomas began pulling patients back from “the gates of death”. Then, “man created GVHD” and

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32 The value of listener participation in the construction of narrative was not lost on the defense. They conferred on a daily basis with a small group of mock jurors in attendance. Counsel for the plaintiffs did not have this feedback.
the pioneers at FHCRC are still fighting that “scourge”\(^{33}\). The plaintiffs’ stories were limited to the period between 1981 and 1984, and the life of protocol 126 continued only through 1993. The plaintiffs’ illness stories were in effect contained, even temporally dwarfed, by the defense’s medical continuum. There were numerous examples beyond the scope of this project, but I want to point out to the reader that context and performance were at least as significant as the text. The central piece of my analysis, however, is the narrative itself.

I dissected the opening and closing statements made by both sides to demonstrate the storyline mutations while underscoring the rhetorical devices and narrative strands that capture the moments of change. I extracted interactive stanzas from opposing counsels’ statements where examples of this dynamic narrative function were most visible. Although I don’t include an exhaustive analysis of each trial transcript within the confines of this study, the data offered is a fair qualitative representation. I included a commentary to situate the discourse fragments within the larger trial context, and also to show that narrative dominance was at times more important than facts.

The claims made for ‘intentional infliction of emotional harm’ and ‘fraudulent conduct’ were both dismissed by the court at the trial’s midpoint. The judge concluded that there was insufficient proof. Once the narrative glue - the motives - had been removed from the prosecution’s story, all that remained were orphaned facts. The defense threaded these together on their own terms, substituting ambitious greed with researcher passion. The prosecution’s story

\(^{33}\) Quotations are excerpted from statements made by the defense during the trial.
made concessions at many points, particularly in their closing. Their statistical
data and motive agreed with the defense at the end of the case. The coup was
complete.

The defense had an impressive fluency with the common litigation tools of
semantic manipulation and tactical rhetoric. The prosecution’s litigation did not
demonstrate this level of sophistication. Perhaps this explains why the defense
team was able to act on both courtroom narratives. The prosecution was
compromised in a way that exchanged dominance for credibility. Some of the
narrative features that accomplished this shift in dominance included the
defense’s use of parody and rhetoric to unravel the prosecution’s narrative, the
use of vivid metaphors to fix the key story pieces in memory, and the use of
analogy to manage the emotional range of audience response. For example,
they inserted a risk for milk allergy into the conceptual space of a risk for graft-
failure and death. The defense both ridiculed the allegation of scientific
misconduct at FHCRC, kept the prosecution’s initial exaggerated statements
alive, then reduced them to a boyish prank of “pulling wings off flies”. The
defense spun the opposition’s story into an anti-narrative: the story that did not
happen.

The defense softened the charge for conflict of interest by changing the
prosecution’s ‘fact’ into an ‘appearance of fact’\(^\text{34}\). They followed this with a literal
disappearance of fact. In their argument for what didn’t happen, they conflated T-
cell depletion, protocol 126, and MAbs, and then dislocated the conflict and

\(^{34}\) Refer to data chapter and Dr. Day’s allusion to the ‘appearance of conflict’
actively denatured the substance of ‘interest’. This occurred in the moment when the court’s naïveté regarding the science of hybridomas allowed the reasoning to stand. The defense’s appeal to the logic of patent law disarmed the documentation that Genetic System held rights to commercialization and marketing in exchange for royalties to FHCRC. The latter fact does not necessarily indicate a conflict of interest because this was/is the nature of changed institutional relationships available under the Bayh-Dole Act. The disappearance of this fact from the courtroom was, however, a turning point in the case because it removed a significant source of motive from the prosecution’s story.

The defense moved the (absent) stopping rule for toxicity behind the far less critical (absent) stopping rule for efficacy. They then proactively engaged the listener, offering jurors a position by exception: only madmen and fools would have stopped protocol 126 if there had been a rule.

The unspoken trial was at times whether GVHD was enough of a menace to justify ambitious research. The defense kept the sense of heightened risk alive and primarily associated with GVHD using graphic photography of ulcerated tissue and metaphors of prairie fires. In contrast, no imagery was offered for graft failure or the various complications from total body irradiation. Additionally, they
inflated the (1980’s) accepted risk rate for GVHD\textsuperscript{35}, and a myriad of statistics were collectively used to create a sense of danger.

I highlighted one example of rhetorical pairing with a change from past to present progressive verbs in otherwise identically structured phrases. “\textbf{We were not doing it} to cure cancer in mice, \textbf{we are doing it} to cure cancer in people”. The grammatical tense change of transitional verbs creates a sense of movement, imminence and in turn a sense of urgency for cancer research today.

The ordering of relevance from past to present parallels the mutually exclusive quests identified in each master narrative: the prosecution’s \textit{sought} to redeem lives already lost while the defense’s \textit{is seeking} to save lives now.

Risk was both reified and dematerialized. The defense stated that the fact of research risk was known, but the specific risks of P126 were not. In this manner, they redefined one of the litigation hinge phrases in this case: ‘what was known’. So, while the researchers did know there was an increased risk of graft failure, they did not know the statistical risk for this problem. They asserted that it was therefore not a material fact for an informed consent.

In closing, the defense paired two fundamentally illogical logic (if-then) statements as a decision tree for the jury as proxy patients. “If you believe” there were undisclosed risks, then the consent is faulty. But, “if the truth was the reality” that there is not increased risk, then “the consent is fine”. The forced choice is between belief/uninformed consent and truth/informed consent. It was an

\textsuperscript{35} I mention that their statistics are drawn from the current conceptual conflation of direct and indirect causes of death from GVHD. This wasn’t the statistic used in the 1980’s, and is not a fixed category.
effective rhetorical tool at the end of the trial because the defense had already established narrative authority.

The claim for negligence was sidelined in all but one pre-ruled case. This was accomplished by disassociating the ‘standard of care’ from negligence. Then ‘standard of care’ was relocated from research conduct to bedside care so that the remaining plaintiffs’ claims were lost: “They claim we were negligent when we enrolled and treated the spouses in the protocol. Enrolled and treated.”

The narrative coup transformed greed into passion; IRB conflict into intellectual tension; and ambition for money into ambition for saving lives. The strongest evidence that narrative dominance had changed hands was when the counsel for the plaintiffs read an excerpt from Dr. Thomas’ letter to the IRB. The segment that the IRB had an “obligation to assist us and not impede our research.” was originally read convincingly as the voice of an impatient autocrat. In closing, that phrasing read by the same attorney in the same context, stood naked as an appeal to support life-saving research. The moral problem underwent a corresponding transfiguration when the defense suggested that lives would be lost if research slowed. They offered the jury an inverted invitation to join in saving lives. They propose that if litigation is an answer to unsuccessful research ideas, then “God help us”.

This is the only high profile case in medical research ethics that has gone to trial. It was a defining moment for Bioethics. Yet there are no ongoing academic or public discussions. The most detailed post-trial article I found was published by the American Medical Association. Their conclusion is captured by
the article’s ‘learning objective’ to, “Understand the importance of public and patient trust in clinical trials.”

It appears that this narrative coup has partially effaced an important and multi-faceted Bioethical event. It will not be recorded in the history of medical research ethics, nor will it achieve the status of a ‘classic case’ in academia. The highest cost is the lost voices of lived experience. This is wherefrom we have the most to learn. The historical remains of the P126 controversy are anecdotal references to the dangers of eroding public trust in research.

The observations and conclusions drawn in my research are by no means an opinion about right and wrong in the case of FHCRC’s research conduct and P126. Indeed there might never have been a ‘right’ or ‘wrong’. Each patient’s situation was unique, intense and complicated. Each iteration of P126 held renewed hope for the physicians, for their patients and for medical research. And finally, medicine on the edge of life is fraught with competing micro-ethical decisions. Hindsight, as the defense suggested, is not available in the immediacy of those encounters. Ultimately, the plaintiffs’ decision to litigate limited the form and resolution the issues could take, which data could be presented and to what end. The observations and conclusions drawn in my research are specifically trained on what narratives-in-process reveal about a cultural and historical moment of bioethics.
I sat through eight weeks of trial, taking detailed notes and keeping a log of my observations and experiences. I consciously kept an avenue for self-reflection open and I discussed my thoughts with other trial attendees. One of the most unanticipated findings was that, through narrative performance, many features of FHCRC’s 1980’s ethos were recreated in the courtroom. That ethos included the professional stature and authority of Hutch researchers, the disciplinarily cloistered BMT science community of the 1980’s, the lesser visibility of particular plaintiffs (or patients) to the big picture, and the community they formed. The most pointed and embodied experiences in the courtroom included the danger and incalculability of (variously located) risks, respect for Dr. Thomas’ lifetime of work, and a hope for research to come. I will expand on these features in this section, and offer a more involved conversation about the embodiment of risk through the lens of cultural constructivism in the following section.

I have mentioned the disparity between the legal teams. The defendants themselves were crisply dressed as well – except Dr. Thomas. He was singly dressed down in a tan sports coat. Under other circumstances, such attire would efface the presence of a person in the room. In this case, he stood out. It seemed contradictory for the most prestigious person in the room to be the least dressed of his team. Dr. Thomas delivered his testimony in a soft, amiable and measured manner. The content was predominantly his professionally inclined autobiography replete with recollections about his childhood and the early years
of BMT. He prefaced most cued questions with “Well…” followed by a thoughtful
pause. I counted 140 examples of this in his testimony. Although this was
rehearsed it carried as a considered response. It communicated humility and
character accessibility to the listener. I will add anecdotally that he was known as
“St. Father Thomas” around the halls of FHCRC in the 1980’s. His wife Dottie
and he have been called “Ma and Pa”, and FHCRC was known as “Ma and Pa’s
Shop” internally and “Mother Hutch” in the community. Dr. Thomas is deservedly
revered and admired.

The defense called up many of the BMT researchers from the 1980’s as
expert witnesses. BMT was an elite research-only medical field during those
years. The community was small and tightly knit. Most who stayed in the field
have now reached an impressive professional maturity and stature. It was an
extraordinary parade of education, wisdom and experience. Their testimonies
had some inconsistencies that are not discussed here, but the respect these
BMT elders commanded in the courtroom overrode those inconsistencies.

The prosecution’s expert witnesses paled in comparison. Although
impressively credentialed, none had the force of conviction that comes from
growing with one specialized field over many years. The defense seemed to run
circles around their testimonies, exploiting the gaps in historical knowledge. The
defense easily confused the testimony of several witnesses for the prosecution
engaging the conceptual instability of good and bad risk; splitting semantic hairs
between the ‘objective’ and the ‘purpose’ of a protocol; and invoking a staggering
array of ambiguous statistics. The effect was to create listener dependency on
the FHCRC team - the undisputed experts - to decipher the raw scientific data. This is not unlike the dependency of even the most educated and informed BMT patient.

I noticed that the plaintiffs formed the sort of relationships during the trial that are quite commonly forged on oncology and transplant wards. I believe this constitutes an ‘accidental community of memory’ based in this case on intense and traumatic shared experiences of immediacy, suffering, uncertainty and tenuous hope[188]. The plaintiffs’ individual testimonies were largely irrelevant to their cases. They were mainly inserted as a tool to humanize the collective claims against FHCRC and as witnesses to the suffering then and now. In some ways, the individuality of participants in research protocols is diminished too. That is not to say they don’t receive excellent and cutting edge medical care, but that in the big picture of medical research, they will finally be recorded as data points. This is perhaps reflected in Dr. Martin’s assessment of protocol 126’s success: “I don’t think survival is the best measure of outcome.”

I cautiously offer some additional observations. The reader is asked here to consider that there is a profound difference in degrees between the two experiences I am comparing. It is purely a qualitative similarity that might have

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36 The term ‘accidental community of memory’ was imagined by Malkki to describe relationships she observed in Tanzanian refugee camps. She makes a strong case for the anthropological study of unexpected and transitory events, particularly temporary unintended communities where the weight of the common event is greater than the differences that generally divide (Woodstock, war veterans, refugees). Her central proposition is that significant cultural events can create a common thread of shared ‘micro-biography’. She notes that while individuals generally return to their broader communities, the embodied memories alter their life experiences in similar ways. They share a conceptual community with interesting ethnographic implications.
led to the conditions of familiarity and the aforementioned accidental community. Of course, this may not be the story for any one individual, and none of the stories are finished. This qualitative comparison is simply made for the reader to apprehend the fact of a courtroom-FHCRC ethos in this case:

Dr. Pesando remains as passionate about the redemption of the plaintiffs as Dr. Thomas is about curing cancer. As a secondary effect of the doctors' commitments, the plaintiffs (decedents) had abruptly received word of their situation (condition), and were more or less summoned from their distant homes to Seattle to gamble on their only hope for redemption (cure). It is unlikely that plaintiffs (decedents) were informed that the trials (sic) themselves were not exclusively designed to help them as individuals, but to set an example (be a sample). Even though their chances were slim against FHCRC (cancer), they expressed a willingness to go through an arduous process in the hope that it would help others. As a result of the trial, the plaintiffs (decedents) may have suffered additional harm. Whatever stories (immune systems) evolved for each in response to past trauma (exposures) were negated (ablated) and they had come in need of a new and restorative narrative (marrow). As the trial progressed, the narrative (marrow) didn’t take (failed).

Throughout the trial experience, I appreciated how the defense’s early presentation of the Center's history, physician biographies, leukemia, the evolution of BMT, and the vivid slide show of GVHD reconstituted the reverence, hope and gratitude for Dr. Thomas and the courage behind his pioneering medicine that is part of the Hutch’s ethos. The horrors of GVHD left a lingering visceral angst. Patients assigned to protocol 126 were, according to testimony, shown similar photos during their admission process. GVHD is indelibly
impressed as an imminent threat for BMT. I have observed that FH case often returned to the question of whether GVHD was sufficiently dangerous to allow a bit of haste or rule deviation in the Center’s research conduct. The decedents, given the chance, might have wondered the same prior to their participation in P126. The trial was as much about embodied danger, fear and hope as it was about the logic of Bioethics. I turn my attention now to the embodiment of risk as ‘rationalized’ fear and the marketing of hope to a ‘rational’ public.

“Behind every cancer patient there are a dozen more loved ones and friends who care. And every one of them is scared. What we offer these people goes far beyond just breakthrough science. We offer the most powerful treatment there is: hope.” (Seattle Cancer Care Alliance ‘info-ad’ in Seattle Times 3/18/2001)

CULTURAL CONSTRUCTIVIST ANALYSIS

My first research objective was to explore socio-cultural processes that inform the academic and clinical trajectory of bioethics. I have illuminated strains of narrative restructuring in the courtroom discourse. I also observed that the courtroom experience was, on many levels, a recreation of the culture of research institutions in general and Fred Hutchinson in particular. One of the most fascinating phenomena was a recreation of the risk gestalt familiar to everyone involved with research medicine.

“Well, always when you evaluate a clinical research protocol, you have to weigh the potential risk to the patient against the potential adverse effects, both known and unknown. For patients who had a good prognosis, that is to say, whose leukemia was a type and at a stage where the probability of a cure by bone marrow transplantation, as it was normally performed, was high, those patients had a much different risk benefit profile than someone who had a much lower
chance of cure. So therefore, the latter group would have less to lose should something go wrong.” (Excerpt from testimony of prosecution witness Dr. Pesando)

I think they clearly could get different impressions, radically different, I would disagree with. What we tried to do, based on our experience, is factor in the age of the patient, history of previous viral disease, that influenced the rate of graft versus host disease. Other issues, even ethnicity could influence it. Japanese patients have a lower risk of graft versus host disease than Caucasians, for instance. So all of us have to work in our mind what is the risk for this one individual patient, and give our best estimate. That's our job. And that's what I was doing for several years before I did this family conference, is try to get a gestalt of what's my best estimate for this specific patient, risk of graft versus host disease and other complications. (Excerpt from testimony of defense witness Dr. Beatty)

The actual risk present for each decedent’s unique constellation of disease, co-morbidity, radiation, chemotherapy, treatment complications, protocols and toxicities was utterly confounding, yet very real. The logical extension was that the risk assessment and treatment decisions are better left to the professionals. In this section, I look at risk construction as a narrative and socio-cultural process that in this case, contributed to the trial outcome, and perhaps to the absence of these rich ethical events from Bioethics history.

Risk assessment was a central task for the jurors. The jury was required to objectively calculate the difference between death from protocol 126 and the percentage risk that the patient would have died from something else. This figure would be used to prorate the monetary value of the patient’s unlived life. The jurors were required to also consider risk subjectively. The jurors were instructed to place themselves in the position of a ‘reasonably prudent patient’ in order to determine if they would consent to protocol 126 - whether or not they had ‘all the
material facts’. This instruction required at least cognitive attention to risk assessment as it was understood in the 1980’s. But risk wasn’t possible to calculate.

The fact of risk was undeniable. It was constantly quantified and variously located. Both legal teams campaigned vigorously for the relative presence or absence of different risks. Risk was referenced between 90 and 300 times in each key testimony. We must recall that the trial went on for eight weeks. To make matters worse, each side had their own set of mutable numbers and relentlessly pitted one set against the other. Each set of statistics was calculated differently. For example, some statistics referred to the 1000 bone marrow transplants that FHCRC had accomplished up to the time of P126. This included patients suffering from aplastic anemia in addition to those with leukemia. Other statistics were diagnosis-specific, some represented a recent cohort and others pertained exclusively to a single patient. Some were longitudinal calculations and some referred to specific time frames. Some were nationally recognized figures and some were local. Some reflected historical data and some were more current. Usually, the statistical frame of reference was neither made explicit nor opened for question.

Risk was variously located and was of varying degrees of import. As well, it was either compounded, redundant or by definition mutually exclusive. For example, the risk for ‘age’ compounded the risk for GVHD. If a patient developed GVHD, they were at risk for pneumonia, infections and death – but they were already at risk for these things because of the BMT ‘conditioning’. Patients who
died early were not at risk for much else. If a juror was able to sift through this jungle, the next step was to more precisely calculate the overall risk for any one decedent. To illustrate the complexity, I offer a fairly complete list of all the forms that risk took throughout the trial:

**Forms of Risk in the Trial**

risk of developing GVHD
risk of developing serious GVHD (variously defined as grades 2-4 or grades 3-4)
risk of dying from GVHD
risk related to pre- and co-morbidities
risk related to time of diagnosis
risk related to disease and stage
risk related to age
risk of protocol 126
risk in phase of protocol (phase-1; phase-2; phase-3; pilot, pilot phase-2)
risk of T-cell depletion
risk of relapse
risk of relapse due to disease and stage
risk of relapse due to protocol 126
risk of relapse due to T-cell depletion
risk of graft failure
risk of graft failure due to protocol 126
risk of graft failure due to T-cell depletion
risk of 2nd graft
risk of 2nd graft failing
risk of BMT treatment

An added dimension of risk confusion is that patients were identified as good, bad, high or low risk depending on their disease, stage, and degree of transplant match. Based on the variable risks above, the same patient might be categorized more than one way. Defense said that patients enrolled in 126 were the "patients with the most to gain". That sounds gallant until you consider that they also had the most to lose. The gamble was greater for these patients and so
their relative risk would have been greater.

The conceptual fluidity of risk was played expertly by the defense. Sometimes it was to make or unmake a point, sometimes perhaps just to keep the data swimming. At the end of the trial, there was no choice but to defer to the experts at FHCRC. Even the prosecution modified their risk calculations to fall in more closely with the defense. The information overload induced a sort of risk-hypnosis where the calculation had to be intuitive.

Intuitive sensibility is one portal for what we call embodiment. In this case, the efforts to quantify a gut impression about risk, give rise to the curious sensation of ‘embodied knowledge’. Perhaps embodiment is more than one thing. For example, there are subtle similarities and differences between thinking you know what you feel, thinking what you feel is what you know, feeling what you know and knowing what you feel. All these permutations of embodied knowledge are experientially persuasive. The jurors lacked what the researchers possessed - an inscribed knowledge that comes from lived experience over time with many BMT patients. The jury would have had to rely on courtroom narratives to fill that gap. On this fertile ground, the defense continuously planted the seeds of imminent danger and deadly urgency to prevent GVHD. The imagery was unforgettable. Risk was real, overwhelming, and most clearly associated with GVHD. The enduring question in this trial, whether GVHD was serious enough to justify a few exceptions to research rules, was answered.
A CRITICAL MEDICAL ANTHROPOLOGICAL LENS

My second research objective is to evaluate how ethical issues in research medicine are given form, expressed and codified through narrative engagement. My analysis of triangulated conversations between the various levels of discourse shows narrative as structure, process and residue. In divergence from my cultural constructivist (CC) frame, I offer a brief commentary on this case from of a critical medical anthropology viewpoint.

Historically, critical medical anthropology (CMA) has offered regionally specific analyses of the political economy of health and medicine. There is no literature linking CMA to Bioethics. In fact, CMA research has expressed little interest in developed, economically stable countries. There is exceptional work done outside the field of anthropology that provides a model of thought for exploring this case through a CMA lens. Doyal, for example, provides an incisive, though now obsolete, analysis of Britain’s National Health System (NHS)[189], and Coney suggests that the makers of pharmaceutical estrogen expanded the market for their product by medicalizing menopause[190].

CMA analyses generally assume that the forces of capitalism differentially privilege individuals. In a capitalist equilibrium, the condition of privilege for the few requires deprivation of the many. That particular premise directs research into issues of health-care access, disease distribution and medicine-as-industry. One consistent finding in CMA research is that epidemiological questions – and answers - hide the ‘truth’ of politico-economic forces. If that is true, then a starting
point for the demystification of events might be to ask: ‘Whose interest does this serve?’ If I apply this question to my research, very different conclusions are reached than those elicited from the cultural constructivist frame.

In the case of the “Disgruntled Employee” narrative, the moral resolution lay in restoring the torn fabric of public faith in research medicine. Although putatively for the benefit of society, the resolution is also in the service of research interests. A CMA deconstruction might shed light on political events such as the establishment of the Atomic Energy Commission in the year following the Second World War. This commission was set up to promote peace-time applications of atomic energy, although one could argue that the military had a vested interest in the effects of radiation\(^{37}\). Radioactive substances were distributed to research universities, and funding was disproportionately allocated to medical physics in general and the use of ionizing radiation in particular. Dr. Thomas attended medical school at Harvard during those years. A combination of academic prowess and federal funding opportunity steered him in the direction of radiation research. Dr. Thomas’ professional dedication along with continued federal interest in the use and effects of radiation and then in cancer allowed FH and other cancer research centers to flourish.

A Critical Medical Anthropology perspective might reframe the Bayh-Dole act of 1980 as the wheels’ grease for political interests to harness economic forces. The biotechnology industry boomed. BMT remained an elite and

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\(^{37}\) ACHRE report under President Clinton, in particular, part 2 chapter 8: http://www.hss.energy.gov/HealthSafety/ohre/roadmap/achre/index.html
underdeveloped field until the late 1980’s when third-party insurance payments allowed the procedure to become lucrative for major hospitals. BMT was then ‘routinized’ and the path was paved for market expansion along a defined trajectory.

Medical physics continues to absorb large portions of the research funding for an ongoing ‘war on cancer’. No question has been raised about the resources channeled into cancer research. Neither has a focus of cancer research been challenged that privileges medical physics over immunology, toxicology, genetics, biology, ecology and a multitude of other disciplines.

From a CMA perspective, medical research now requires more human subjects than ever before, particularly with the growth of transplant medicine. Applied research is essentially a product, whether in the form of a pharmaceutical agent or the form of a procedure. For the purposes of a CMA analysis, BMT is a product in need of a market. It has been observed, for example, that the diagnostic categories for BMT trials have expanded over the years. Naturally, public faith is necessary for continued growth of what might be called the ‘business of cancer research’.

This can (and should) be said another way. BMT technology has progressed to the point where it can be offered to a wider patient population. No question that bone marrow transplant and its spin-off procedure of stem cell transplant has saved and continues to save lives, offering great hope to patients and their families.
CONCLUSIONS AND DIRECTIONS FOR FUTURE RESEARCH

The studies that discuss legal narrative concur that the stories are defined by their exclusive goals to achieve a binary verdict. A separate legal reality is so constituted that it often sidelines considerable textural detail, personal experience and knowledge. This is not restricted to litigation. Public discourse around visible ethical or legal issues also tends to fall into opposing camps. Ambiguity is pruned away like aberrant research results, and the debate is narrowly defined.

I suppose many people expect that resistance and antagonism weakens the perceived opposition. More often than not, I contend that the reverse occurs. Two-sided debates are mutually supportive because they must share assumptions in order to argue about something. This was made abundantly clear in the case of this research. At no time was there a discussion about the direction of research medicine, how conflicts of interest are defined and managed in the changing politico-economic environments, how legal language limits the construction of the problem, or what each plaintiff might have/wanted to contribute to the future of informed consent in research medicine. As is often the case, master narratives are adopted with conviction and are barely examined if at all.

Theories are not immune from this phenomenon - they express the master narratives of academia. If opposing theoretical frameworks actually reify each other, then Critical Medical Anthropology is Cultural Constructivism's greatest ally. Both theories assert that things are not what they seem (and) both theories
problematize its object of study. The constructivist lens sees research medicine as both an iteration of culture and a culture unto itself. The CMA lens sees research medicine as an iteration of local capitalism and an industry unto itself. Perhaps both things are true. The bus driver is neither ‘radio-controlled’ as the CMA would believe, nor is the bus driver asleep; the constructivist would argue that the bus driver is an agent and thinks and enacts her/his notions of driving and responsibility that are learned shared and transmitted by others in his/her world.

Perhaps the time is here to speak in terms of a Critical Cultural Constructivism. With some confidence, my research points to the cultural construction of risk, the embodiment of danger and the marketing of hope. It is curious that a mutagenic and potentially lethal medicine (chemotherapy and radiation) is the treatment of choice for a mutated and potentially lethal condition (cancer). I suspect our unexamined support of medical research along this trajectory is based on a deeply imprinted fear of cancer. Because there is a disproportionate amount of cancer research conducted in Biomedicine – compared to alternative medicines - a confounding array of statistics is available. More than ever, these risks have migrated from medical literature into health promotion campaigns and become common public ‘knowledge’. This contributes to the cultural construction of risk. When risk is embodied as danger, there is little room to ‘let go’ of wherever research has taken us so far. Thus there arises a personal and social complicity in what Fox calls the ‘therapeutic innovation cycle’ in the endless search for ‘the cure’[20].

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This research explored in some detail the unmaking of historically significant events in Bioethics. I used both text and narrative performance to show the relationship between the emergence of structuring discourse in the media, the narrative constitution of ethical reality in the courtroom and the minor historical residue found in academic journals. In my introduction, I discussed the conceptual difficulty linking ethics' theory with the immediate reality of the clinical (or judicial) situation. I compared this thinking to the particle-wave duality in physics. Particles express a moment in the undulation of a wave. Physical matter is represented by both. This research begins to define a methodology for researching Bioethics as both “particle and wave”. Future research in the narrative constitution of medical ethics might profit from this paradigm. I found the courtroom a surprisingly fertile anthropological field with regard to an iteration of culture and a stage for narrative performance. Extending this manner of inquiry into clinical settings might be of great value as well. In this way it may be possible to imagine recurrent problems in medical ethics through a different lens: one that embraces duality. As Kilner discovered, different ethical choices do not reflect a different morality. They reflect different bodies of social knowledge[14].


