Assessing Corporate Bioethics

A Qualitative Exploration of How Bioethics is Enacted in Biomedicine Companies

by

Jennifer Brian

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Graduate Supervisory Committee:

Jason Robert, Chair
Daniel Sarewitz
James Hurlbut
Jonathan Moreno
Mark Brown
Jane Maienschein

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ABSTRACT

Corporations in biomedicine hold significant power and influence, in both political and personal spheres. The decisions these companies make about ethics are critically important, as they help determine what products are developed, how they are developed, how they are promoted, and potentially even how they are regulated. In the last fifteen years, for-profit private companies have been assembling bioethics committees to help resolve dilemmas that require informed deliberation about ethical, legal, scientific, and economic considerations. Private sector bioethics committees represent an important innovation in the governance of emerging technologies, with corporations taking a lead role in deciding what is ethically appropriate or problematic. And yet, we know very little about these committees, including their structures, memberships, mandates, authority, and impact.

Drawing on an extensive literature review and qualitative analysis of semi-structured interviews with executives, scientists and board members, this dissertation provides an in-depth analysis of the Ethics and Public Policy Board at SmithKline Beecham, the Ethics Advisory Board at Advanced Cell Technology, and the Bioethics Committee at Eli Lilly and offers insights about how ideas of bioethics and governance are currently imagined and enacted within corporations. The SmithKline Beecham board was the first private sector bioethics committee; its mandate was to explore, in a comprehensive and balanced analysis, the ethics of macro trends in science and technology. The Advanced Cell Technology board was created to be like a watchdog for the company, to prevent them from making major errors. The Eli Lilly board is

different than the others in that it is made up mostly of internal employees and does research ethics consultations within the company.

These private sector bioethics committees evaluate and construct new boundaries between their private interests and the public values they claim to promote. Findings from this dissertation show that criticisms of private sector bioethics that focus narrowly on financial conflicts of interest and a lack of transparency obscure analysis of the ideas about governance (about expertise, credibility and authority) that emerge from these structures and hamper serious debate about the possible impacts of moving ethical deliberation from the public to the private sector.

DEDICATION

To Nan. Thank you for all the love and inspiration, and the best e-mail I've ever received:

> hi Jen -congrats!!!!!!!!!! I have been thinking of you for days. Must have been some vibes coming thru. The space bar is sticking and I cant type anyway soo please the sloppy mess. Peg and phil were in california all week and I just looked at email. will your job change, do you need any tuition money?or anything. I'm so proud of you I could burst. I love you so much, Nan,

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PREFACE

The practices and outputs of scientific and technological research and development influence our lives in profound and complex ways, and with new advances come new and complicated questions about risk, oversight and regulation, equity and access, costs and benefits, human nature, and human dignity. The research is carried out in a variety of contexts, including public and private institutions both locally and more globally, under varying regulatory frameworks and levels of oversight. Conversations about the ethical and social implications of science, medicine, and technology are equally fractured and fragmented. The field of bioethics emerged, in part, from "the need to bring the perceived chaos of biology and medicine into the order of moral principle" (OTA 1993, 2). And for the past three decades, federal, state and local governments, and pharmaceutical and biotechnology companies, amongst other institutions (such as hospitals and professional associations) have called upon bioethics to help resolve dilemmas that require informed deliberation about ethical, legal, scientific, and economic considerations.

But policymakers and bioethicists face significant challenges in deciding how to structure and deliver bioethical analysis and advice, regardless of the setting. There have been many interesting studies and analyses of the nine federal bioethics committees in the US, the first being The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974. However, while much has been written about presidential bioethics committees, we know very little about private sector bioethics committees, especially those in for-profit companies. This lack of attention to for-profit companies (and their ethics activities) is significant, given that most innovation and development takes

place within the private sector. In the private realm, instead of creating committees of bioethics "experts," pharmaceutical and biotechnology companies have often preferred to seek the advice of individual bioethics consultants, though a few companies, such as Advanced Cell Technology and SmithKline Beecham (now GlaxoSmithKline), established standing bioethics committees with a variety of structures and functions. Other companies, such as Eli Lilly, have employed external ethics consultants to help draft clinical research ethics guidelines. Even though there is little publicly available information about the prevalence of ethics consultants and the ways the companies use the consultants and the advice, both corporate bioethics committees and individual bioethicists employed in corporate settings have been subject to criticism from within the bioethics community. There is significant disagreement among bioethicists and those who study or observe the field of bioethics over the proper roles and functions that ethics consultants and committees can and ought to play (e.g., do the ethicists serve the public interest or the individual company?), over whether the ethicists ought to be compensated for their work, and over the necessary qualifications for an ethics consultant.

Many critics have raised concerns about the ability of bioethicists and bioethics committees to be impartial or objective (while assuming those characteristics are possible, necessary or desirable)—whether in the public or private realms; bioethics is frequently criticized as a field that has been "captured" by the very groups it purports to critique, a field that is merely 'byplay.'[1] Thus, when industry pays for bioethics advice, observers are even more

[1] 'Byplay' is defined as any action, carried out onstage during a performance, apart from the main action, or as incidental activity performed by an actor for dramatic effect. This project asks whether bioethics is just incidental activity

skeptical that the advice will be impartial and independent. I will investigate what has been and what can be asked of these kinds of committees, and look more closely at the challenges and opportunities for private sector bioethics committees. What, if any, authority—political or moral—are these committees granted, and by whom?

In chapter 1, I will explain the question the dissertation seeks to answer, which is, simply, "What is private sector bioethics?" The project attempts to understand what private sector bioethics is, what it is within the larger field of bioethics, and its role in shaping the social and moral order. I will sketch a brief history of bioethics committees from different sectors, and some of the issues these committees raise. Over the last fifteen years, for-profit companies have started to form bioethics bodies, and this dissertation explores three of them: the Ethics Advisory Board at Advanced Cell Technology, the Ethics and Public Policy Board at SmithKline Beecham, and the Bioethics Committee at Eli Lilly. In both the public and private sectors, there are questions about ethics expertise and who is qualified to sit on an ethics panel about scientific research and development, concerns about cooptation and bias and the motivation for seeking the ethics advice, and questions about the nature of the ethics advice.

There is a strong assumption against the legitimacy of ethics advice in the for-profit private sector. While there are increasingly more calls for open, accountable, and democratic governance of science and technology, attempts to include industry in conversations about the ethical and social implications of scientific research and emerging technologies are either rare or unproductive.

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performed for dramatic effect, or whether it contributes to the activities of science and technology in a more substantial way. What does bioethics need to do, structurally or substantively, to have a productive impact on the ends and means of science and technology?

This is despite the fact that industry provides more funding for biomedical research and development than the US government does. And yet, as Washington University School of Law professor (and former member of the President's Council on Bioethics) Rebecca Dresser points out, despite the growing dominance of the private sector, "scholarly and policy analysis of research ethics concentrates on government rules and conflicts of interest for academicians. Little attention is given to the internal ethical judgments influencing the choices industry scientists and other workers make about research" (2006, 115). The scholarship suffers from a lack of robust understanding of decision-making about ethics within private companies, and the impacts of those decisions both within the corporation and in society. It is interesting that both academic bioethics as well as the academic critique of bioethics have emerged with so little attention to where most research and development happens—in industry.

In chapter 2, I review the conceptual debates and the empirical research about bioethics and bioscience corporations. The literature review shows not only what has been said before, but more importantly to lays bare unexamined assumptions and neglected areas of analysis with respect to corporate bioethics. This dissertation draws attention to the nature of the roles, structures, relationships and consequences that have not been understood or interrogated.

Despite an overarching lack of attention to corporations within bioethics, and bioethics within corporations, many scholars have weighed in about what roles or functions an ethics consultant or a bioethics advisory board can and should serve for a pharmaceutical or biotechnology company. Many scholars have written eloquently and extensively about the problems of industry-sponsored bioethics research, and the dangers to the field of bioethics and the

public good more broadly that may result should ethics advice become something that can be bought and sold to the highest bidder. Others dismiss these concerns, and argue that disclosure of funding sources will be enough to avoid conflicts of interest. Others still have offered suggestions to mitigate concerns about the influence of industry funding (concerning, for example, the amount of funding or the kinds of advice), but the debate is often reduced to simplistic extremes, or rarely goes beyond this "fig leaf" critique.

There may be many compelling reasons for bioethicists to avoid working with the bioscience industry, and the bioscience industry has been financially successful without the help of bioethics. However, the concerns—about cooptation, corruption, and financial conflicts of interest—have been narrowly articulate and assume bioethics is easily manipulated. If it is the case that bioethicists are so easily co-opted or corrupted, that bodes poorly for bioethics as a scholarly domain. Chapter 2 thus also explores the reasons bioethicists choose to engage with or ignore industry, and the reasons industry may seek the help of bioethicists. Do companies only seek the help of bioethicists to increase their profit margin or insulate themselves from liability? To date, the results of research investigating the link between financial performance and corporate social performance (CSP) are mixed, and overall the effect of CSP activities are almost negligible (see, e.g., Waddock & Graves 1997; Hillman & Keim 2001). In light of this, what are the reasons for creating a bioethics committee, if increased financial gain is not an expected outcome? Do they seek legitimacy as an organization? Do they seek to create a more ethical environment within the company? To what stakeholders are they responding, if any?

In chapters 3-5, I examine the players, practices, products, performances

and impact of three private sector ethics committees. The first case study is the Ethics and Public Policy Board (EPPB) at SmithKline Beecham (SB). The second case study is Advanced Cell Technology's Ethics Advisory Board (EAB), which has, for the last ten years, reviewed Advanced Cell Technology (ACT)'s research protocols involving the use of human embryos and stem cells. The final case study looks at the Bioethics Network and the Bioethics Committee (BEC) at Eli Lilly. My research aims to understand why these boards were set up, why certain individuals were chosen to serve on the boards, what the boards and the board members do, and also how they are regarded by the company, the bioethics community, and outside observers. I draw comparisons to different ethics committees in hospitals, universities, and governments, to highlight similarities and differences and to trace the genealogies of these kinds of bodies. Genealogies and replications matter, because they highlight how and what ideas about governance are transformed and transported.

Following the analyses of the three case studies, the concluding chapters (chapters 6 and 7) explore ideas about governance that emerge from corporate bioethics, and suggest avenues for further research. Bioethics committees within the for-profit private sector are often dismissed because of an assumption that co-optation is unavoidable, and yet, the same criticisms do not always carry over to public sector bioethics committee, where prestige and partisan/ideological biases are also strong influences. I highlight significant findings and the similarities and differences between the case studies, and summarize my findings. My key findings concern expertise and representation, self-perception and legitimacy, evaluation, and secrecy and transparency. One of the main criticisms of private sector bioethics concerns its lack of transparency. However,

the findings from this dissertation encourage us to think less about *access* as the most important part of secrecy, and instead ask how the "inaccessible" shapes the world at large. As entities that straddle the public/private boundary, they reveal a lot about how ideas about governance are interpreted within different spaces. Private sector bioethics is a question mark in the larger ecology of bioethics. Many have dismissed it, yet it has replicated features of public bioethics. *To what effect?*

By analyzing and comparing the work of these different bioethics committees, this project aims to understand the various roles of and challenges for bioethics within the private sector. In the existing literature on ethics and industry, the focus tends to be on the bioethicist as an individual actor (as a container of expertise and tools)—not on the decision-making structures into which she is incorporated. But by focusing on individual actors, the literature is extremely limited in its ability to understand and clarify the relationships between ethics and private sector science. This project asks about those structures and their design and focuses on three particular ethics programs, the goals set by and for these programs, and the challenges they face. Private sector bioethics bodies are entities that occupy both private and public spaces. As such they face significant challenges in both spaces as they try to navigate these boundaries. In both spaces, people have very different views about what constitutes a good or effective committee, which means it is unlikely that arriving at a single definitive answer about what a private sector bioethics "should be" is possible. Among other things, private sector bioethics bodies are sites of (normative) controversy. This dissertation tries to understand that controversy better in order to provide empirical evidence to a larger normative debate.

Eventually, the goal is to develop frameworks to analyze private sector bioethics bodies with respect to their legitimacy, authority and credibility.

Decisions made by corporations in biomedicine help determine what products are developed, how they are developed, how they are promoted, and potentially even how they are regulated. In the last fifteen years, for-profit private companies have been assembling bioethics committees to help resolve dilemmas that require informed deliberation about ethical, legal, scientific, and economic considerations. Bioethics programs in the private sector struggle with many of the same problems as public sector bioethics programs, with respect to mandate, authority, membership, and legitimacy, but represent an important innovation in the governance of emerging technologies, with corporations taking a lead role in deciding what is ethically appropriate or problematic. This dissertation project seeks to discern the logics and rationale of private sector bioethics activities, with the aim of better understanding the constitution of valid and valuable ethics advice.

Chapter 1

INTRODUCTION

Hospitals, universities, governments and corporations now regularly form ethics committees to better understand divergent views on a range of controversial matters. Institutional review boards are mandated by federal regulations to evaluate proposed human subjects research protocols; hospital ethics committees and clinical ethics consultations services are the institutional mechanisms to resolve conflicts in health care delivery; and federal bioethics bodies often function like government advisory committees and clarify difficult emerging issues or controversies and offer recommendations to the President and Congress. According to long-timer chronicler of the history and politics of bioethics, Duke University's Robert Cook-Deegan, when an organization identifies a need for an ethics committee, they are responding to an erosion of shared values and moral pluralism (1998, 107). The mandates of various ethics committees seek to achieve different ends, but there are key similarities in their form and function. The structure and shape of these bodies offer clues about how ideas of governance—of how to address ethical issues and orient science and technology—are created, and sustained within different contexts.

Attention to the institutional structure of bioethics bodies in different institutions will reveal that some components are replicated across sectors and over time. There are notable similarities and differences in terms of the structure, mandate, membership and authority of ethics committees. Over the last fifteen years, private companies have started to form bioethics committees to deal with complex issues raised by their research and development. Bioethics committees in the private sector, specifically within pharmaceutical and biotechnology

companies, are harshly criticized by other bioethicists and by those who argue that bioethicists function as enablers of ethically ambiguous science. Corporate bioethics activities are often dismissed out of hand as public relations ploys, so critics have not looked carefully at the efforts of corporations to engage bioethical deliberations. Accordingly, it is unclear what exactly corporate sector bioethics is, who is involved, why they (both the corporations and the bioethicists) are undertaking such work, how the work is being done, and what the outcomes and implications are—for the corporations, for lawmakers and regulatory agencies, and for citizens.

This project attempts to understand what private sector bioethics *is* and what private sector bioethics *does*. These bodies are new and poorly understood systems of governance in institutions that powerfully influence economic and health outcomes in society, and therefore are worthy of investigation. Before we can pose normative questions about the value or effectiveness of these committees, we must first understand what work they do and what function(s) they (are meant to) serve. As the case studies—of SmithKline Beecham, Advanced Cell Technology, and Eli Lilly—demonstrate, corporations are creating deliberative bodies to address complex bioethical challenges. These corporate bioethics bodies, I argue, stand both in challenge to and in conversation with public or "official" bioethics bodies. The committees share some structural features with previous iterations of public sector bioethics committees, and face similar challenges with respect to mandates, membership and authority. There is significant crossover in terms of topics and membership; as the case studies reveal, the topics tend to be similar in subject and scope, and many of the members of private sector boards have experience on public bioethics bodies.

Despite the availability of much academic bioethics scholarship and the large library of transcripts and reports by public bioethics bodies on topics of interest to their companies, corporate managers deem it necessary in some cases to form their own bioethics bodies. This point may be non-controversial or uninteresting, but it raises questions about what *needs* public and private bioethics respond to and what *roles* public and private bioethics play. There is a significant body of knowledge in bioethics that corporate managers can use, and corporate managers are putting together bioethics bodies. Why do corporate managers see a need for more committees, more consultations? Does the bioethics literature fail to address the unique needs of corporations? (Incidentally, to what audiences *does* public bioethics speak?) Do corporations need consultants to help them understand, interpret and apply important bioethical knowledge? Some critics of industry argue that corporate managers are not interested in engaging bioethics work. Rather, according to critics, what might be most important to corporations is not the advice or work a bioethics committee does for the company, but the "show" or the symbolic value of having a bioethics committee. If having a bioethics committee matters to corporations and their stakeholders, how significant is the public relations aspect as compared to the actual deliberations and deliverables?

In her book *Designs on Nature*, Harvard scholar of Science and Technology Studies Sheila Jasanoff asks who represents bioethics in the US, the UK and Germany: "To whom does official bioethics give voice, and with respect to which set of issues?" (2005, 173). The present project is an attempt to ask similar kinds of questions of private sector bioethics. To whom are they speaking? To whom are they giving voice? What kinds of concerns and issues are they purporting to

address? From there, we can start to ask about the enterprise of private sector bioethics. Bioethics has existed in a structured way within the private sector for the last 15 years with little attention paid to its activities. What kind of thing is private sector bioethics within the field of bioethics? This chapter raises broad questions about the purpose and goals of bioethics, and the effect of the structure of a bioethics committee on its outputs. The private sector bioethics committees in the following case studies have structural features that resemble features of hospital ethics committees, institutional review boards, and federal bioethics advisory commissions. In this chapter, I briefly sketch the history of public sector bioethics committees, drawing attention to features of particular importance for this comparative analysis. I then introduce the case studies, and explain the methodology and the theoretical framework.

The Voices of Bioethics

For some bioethicists, bioethics works explicitly on behalf of the public. Most bioethics commissions aspire to – and receive legitimation by – reflecting the values of the public (see, e.g., Kuczewski 2001; 2007). The work of bioethics committees in the private sector is done behind closed doors, and is not accessible or accountable to the public. And yet, the outcomes of their deliberations have potentially significant influence, based on the power bioscience corporations hold. Academic bioethicists who have worked in prominent roles in public bioethics populate these corporate bioethics committees, and bring with them particular ideas about how bioethics is enacted in society. In many ways, bioethics committees in the corporate world represent perturbations of the boundary between public and private. Ideas about

governance are transported across the public/private sector boundary, and transformed in new settings. As an entity that transcends and occupies the public/private boundary, how does it occupy that space?

The structure, the genealogies and the replications of different governance structures matter because they offer insight into the different ways individuals or organizations understand governance. By investigating the structure of the committee, we can ask what ideas of expertise, representation, authority and legitimacy are replicated in these bodies. (And, relatedly, by creating committees in the likeness of previous bodies, do they give legitimacy to those earlier models?) In reflecting on the progressive nature of national bioethics committees, former Executive Director of the National Bioethics Advisory Commission Eric Meslin noted that so long as they are topic and time driven and are advisory in function, their impact will be limited and qualified (2010, 156). Corporate bioethics boards are advisory in function, but the ones in the following case studies had the freedom to be neither time nor topic driven. They have the freedom to perturb assumed structures, because as a type of bioethics committee they are relatively new, and also because there are no or few expectations as to their output. As discussed in the following chapter, many have been very critical of the relationship between bioethics and industry based on perceived unethical behavior on the part of pharmaceutical companies (see, e.g., Elliott 2012; Downie 2009), and thus are dismissive of attempts by corporations to engage in bioethical debate.

For a corporation, the decision to have a bioethics committee is often assumed by critics of industry to be a decision about, at worst, public relations and, at best, corporate social responsibility. In this project, I treat it, in part, as a

question of institutional design. According to Columbia professor Richard R. Nelson, "From one point of view, the job of institutional design is to get an appropriate balance of the public and private aspects of technology, enough private incentive to spur innovation and enough publicness to facilitate wide use" (1986, 186). On this account, bioethics may be acting as the "publicness" that facilitates widespread use of the technology. Bioethicists are helping corporations interpret public values, to move the technologies forward in an ethically appropriate way. According to sociologist and bioethicist Paul Root Wolpe (2009), bioethics provided moral justification for the products of biotechnology, and therefore legitimized the industry. Bioethics was strengthened by helping industry engage in and influence debates over key moral questions (Wolpe & McGee 2001).

Bioscience and biotechnology corporations can choose to form an internal advisory board, create codes of conduct, or form an external advisory board, and that particular organizational structure or program may be decoupled from or integrated within the key activities of the corporation. Because the committee is part of a for-profit company, such a committee will be designed to achieve results within the moral expectations properly assigned to such corporations. These moral expectations are most likely more than just making a profit for shareholders, and yet may vary significantly from the moral expectations of a government body. By interrogating their structural form, we can ask the following key questions: Where do the decisions to participate come from, and what are the subsequent impacts on decision-making processes? Who gets to participate? What kind(s) of structure(s) achieve the desired ends? And, importantly, how and on what criteria do we evaluate such committees?

By creating bioethics committees, businesses are adopting normative chores that have traditionally belonged to the government. This is an important innovation in governance, with potentially very significant consequences. As Shapiro and Meslin (2005) observe, national bioethics commissions are one of the sources of consultation for many countries' governments on emerging issues in science and technology. For example, President Clinton's National Bioethics Advisory Commission dealt with cloning and human embryonic stem cell research, while President Obama's President's Council for the Study of Bioethical Issues has dealt with synthetic biology. Their place in the conversation about health and science policy is firmly established. The following section will briefly trace the history of bioethics bodies, leading to these new iterations of bioethics governance.

History of Bioethics Committees

Hospital Ethics Committees

Starting in the mid twentieth century, there were small groups charged with making decisions on a range of controversial topics such as sterilization, abortion selection, organ allocation and dialysis selection. According to Post, Bluestein and Dubler (2006), hospital ethics committees have their roots in these smaller groups. The hospital ethics committee, though not mandated until the late 1970s, brought formal ethical evaluation into the clinical setting. According to Jonathan Moreno, hospital ethics committees were a "politically attractive way for moral controversies to be procedurally accommodated" (1995; 93-94). In 1975, a New Jersey woman named Karen Ann Quinlan suffered irreversible brain damage and her parents sought to have her ventilator removed. The 1976 legal decision that

settled the Quinlan case recommended all hospitals have ethics committees to "provide a regular forum for more input and dialogue" on end-of-life dilemmas and other controversies (New Jersey Supreme Court 1976; see also: Levine 2007, 1977; Post, Bluestein and Dubler 2006; Fletcher 1991; Fost and Cranford 1985). The 1982 "Baby Doe" case, wherein the parents of a baby born with birth defects opted against surgery, led to the creation of infant care review committees (American Academy of Pediatrics 1984). In 1992, the Joint Commission on Accreditation of Healthcare Organizations required, as part of the accreditation process, that all hospitals have a standing mechanism to address ethical dilemmas and resolve disputes. One might argue these committees are efforts to prevent litigation, which raises an interesting question: Why do accept such committees in hospitals but not in bioscience corporations?

In terms of structure, hospital ethics committees are responsible for hospital policy formation, education, and consultations. The "committees" usually follow one of three models: single consultant, small group and large committee, with the most common model being the small group (LaPuma *et al.* 1992; Rushton *et al.* 2003). Members have a diversity of professional backgrounds but tend to be medical professionals who have received some ethics training as part of their continuing medical education, and may include a representative from the community at large.

Over the last decade, there has been a significant shift in opinion with regards to clinical ethics consultation certification. In 1998, a position paper by the Society for Health and Human Values – Society for Bioethics Consultation

Task Force[2] detailed the core competencies required for members who participated in ethics consultations, but explicitly rejected certifying or accrediting consultants (Aulisio *et al.* 2004). The task force expressed concern that accreditation (or support for accreditation) would be interpreted as a sign that ethics consultations ought to be authoritarian in nature. They did not want an ethics consultation to undermine the relationship between physician and patient.

Without accreditation, however, it is difficult to argue against those who argue that the main qualification to serve on an ethics committee is or can only be "common sense" (Shokrollahi 2004). In the ensuing decade following the report by the task force, there has been growing concern among bioethicists about the lack of coherence among hospital ethics boards, and worries about the standards of ethics advice. The American Society for Bioethics and Humanities reversed course after a lengthy debate amongst members and in 2009 approved a committee to investigate and set guidelines for accreditation of clinical ethics consultants.

Hospital ethics committees, like institutional review boards, are embedded within the institutions they are meant to be overseeing. Confidentiality and other legal concerns prevent them from sharing the results of their deliberations, thus they are unavoidably opaque to outside scrutiny.

[2] The Society for Bioethics Consultation, which was formed in 1986 to study and support ethics consultation, merged with the Society for Health and Human Values in 1998 to form the American Society for Bioethics and Humanities.

Institutional Review Boards

Institutional review boards, as described in the next section, are ostensibly a body of rules in action—but they operate behind closed doors and no one knows who the members are. In response to revelations of medical abuse, institutional review boards were initiated in the 1960s, and were mandated following the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the National Commission) and the publication of the Belmont Report in 1979. The institutional review board (IRB) aims to "ensure that proposed experimentation falls safely within both professional and community norms for acceptable conduct" (Bosk 2008, 40; see also Belmont Report 1979).

Any institution engaged in federally funded human subjects research must establish an institutional review board to review and approve the research. One institution may set up multiple IRBs, or an institution may designate another institution's IRB to review their research protocols. Researchers are increasingly turning to private for-profit IRBs, which promise a faster review and approval process. While this provides some relief for overburdened IRBs, there are concerns about the transparency of the reviews and the potential conflicts of interest that arise when a researcher is paying for review (and expecting approval) of their proposal (see, e.g., Lemmens and Freedman 2000; Lemmens 2004).

There are federal guidelines that dictate the structure and membership of institutional review boards. An IRB must have at least five members, and these five members must have a sufficient range of expertise and experience to conduct complete and adequate reviews of common research activities at their institution.

The board membership must reflect diversity with respect to considerations of gender, of racial and cultural heritages, of community attitudes towards sensitive issues, as well as experience and educational background. It must include at least one member who has scientific training, and at least one member who has a nonscientific background, as well as one member who is not otherwise affiliated with the institution (Porter 1986; Greenwald *et al.* 1982). The board must also have a lawyer or someone who has the professional competence to evaluate the acceptability of proposed research according to applicable law, institutional regulations, and standards of professional conduct. If the IRB regularly reviews research proposals that involve vulnerable subjects (e.g., children, pregnant women, prisoners, mentally disabled persons), the board must consider including someone who has experience working with such subjects. Indeed, if the proposed research purposefully includes handicapped children or mentally disabled persons, the Department of Education requires the IRB to include at least one person who can act as an advocate for these subjects (34 CFR 350.3(d)2); 34 CFR 356.3(c)(2)).

Though IRBs are set up to protect human subjects from poorly designed, dangerous or otherwise unethical research protocols, there have been serious concerns about their effectiveness. Scholars have drawn attention to the problems inherent in an ethical analysis of risk (Weijer 2000), controversies about ethics and the design of research protocols (Freedman 1987; Weijer 1999), questions about whether incentives or penalties work best to protect patients (Brody *et al.* 2005), and the limits of the informed consent process (Applebaum, Lidz and Meisel 1987; Gostin 1995; King 2000). The IRB reviews the specific research protocol and ensures that it respects subjects' autonomy, does not cause

unnecessary harm, and that the subject selection is fair and appropriate. However, there is significant controversy over the value of IRBs. The role of the IRB is not to make judgments concerning the social value of the research protocol itself (Corrigan 2003), and it is not a mechanism for a more upstream engagement (Guston and Sarewitz 2002; Fisher, Mahajan and Mitcham 2006). Thus, critics argue that an IRB does little to serve the public interest.

For the purposes of this project, the membership and mandate of the IRB are most important. In their first meeting, the Ethics Advisory Board at Advanced Cell Technology compared their function to that of an IRB. Because ACT is a private company, they are generally not subject to the same rules as institutions that conduct federally funded research (unless they are conducting federally funded research). By creating an ethics board, ACT executives sought to fill similar oversight roles. The ACT EAB modeled their membership after that of an IRB, with research scientists, philosophers, clinicians, and one community member. They borrowed particular features of the IRB, and altered the structure to create a body that fulfilled the needs of the company, as identified by the CEO of ACT and the Chair of the EAB.

Federal Bioethics Committees

The National Commission, established in 1974, was the first of seven U.S. national bioethics committees. It was located within the Department of Health and Human Services. The members of this first commission had a very specific task: to articulate the principles of ethics needed to deal with human subjects research, and to use those principles to recommend actions by the federal government (Cook-Deegan 1998). Between 1974-1978, the commission published

ten reports, and many of their recommendations were translated into law. The National Commission was time-limited, topic-driven, and created specifically to recommend new regulations.

Following the National Commission, Congress recommended a successor body with broader authority. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was created in 1980 and was assigned specific tasks by Congress, but also had the authority to undertake studies on its own initiative or at the request of the President. This body was an autonomous entity under the President. Congress approved both the National Commission and the President's Commission. Following the President's Commission, then-Senator Al Gore decided that the broader mandate was useful, and led the Congressional initiative to establish the Biomedical Ethics Advisory Committee (BEAC) (Cook-Deegan 1998). However, the formation and work of the BEAC was derailed abortion politics—Congressional representatives could neither agree on the membership nor the topics of investigation (Jasanoff 2005; Hanna, Cook-Deegan & Nishimi 1993). Congress has not chartered a new bioethics body since the BEAC in 1988. (The National Bioethics Advisory Committee, the President's Council on Bioethics, and the President's Committee for the Study of Bioethical Issues were established through executive order from the President's Office.) Later bodies were meant to replicate the National Commission, but were not able to replicate the confluence of individuals, rules and conditions that made the National Commission function as it did.[3]

As noted by the Office of Technology Assessment (OTA) (1993), national

[3] One unique feature of the charter of the National Commission was a clause that forced all relevant agencies to respond within 90 days. Thus, their reports had a greater likelihood of turning into legislation quickly than the reports of any other federal bioethics commission.

bioethics commissions can serve as a forum for a variety of purposes: to crystallize consensus or delineate points of disagreement; to identify emerging issues; to defuse controversy or delay decision-making; to propose laws or regulations, develop guidelines, or formulate policy options; to review implementation of existing laws and policies; to aid judicial decision-making; to educate professionals and public; and/or to promote interdisciplinary research. One committee may do any or all of these things. There are also different mechanisms that might be more relevant to addressing certain topics. Depending on the number of issues at hand, the resources available, and the objectives of seeking advice, an *ad hoc* committee may be more appropriate than a national commission or a permanent agency, or vice versa (Cook-Deegan 1998).

Thus, there are no straightforward criteria by which to judge these bodies, and some bodies may have multiple functions. Presidential advisory commissions have been criticized for many different kinds of reasons. According to critics, they "are created by Presidents primarily to avoid taking effective action; are packed and manipulated by the White House; have members who are inactive, uninterested, and ineffective in the work of the commissions; and have their reports buried by the White House" (Wolanin 1975, 3). Though Wolanin did his empirical work on presidential advisory commissions over three decades ago, the same arguments are still made about their role and function.

Two of the primary roles of advisory commissions are agenda-setting and providing expertise, and there are deep disagreements about how to understand these conflicting and complementary functions. As a debate between Johnson (2006; 2007) and Dzur & Levin (2004; 2007) recently demonstrated, there are different interpretations of the possible and valuable roles of a public bioethics

commission. For Johnson, bioethics commissions can and should have a variety of roles and functions, and should be assessed accordingly. Johnson points to empirical work in political science that has identified multiple roles for federal commissions, including crisis commissions (Flitner 1986; Wolanin 1975), policy analysis (Zegart 2004; Smith *et al* 1998; Graham 1985), advisory or informational (Smith *et al* 1998; Zegart 2004), and national goal-oriented commissions (Graham 1985), among others, and argues that bioethics commissions can fill many different roles. Those roles include, but are not limited to, public engagement. Indeed, others have questioned the ability of bioethics commissions to represent the public (Hanna, Cook-Deegan and Nishimi 1993). According to Cook-Deegan (1998), "[a] national committee is better adapted to articulate others' positions, filter information, and facilitate communication among policymakers" (128). The mandates of various commissions demonstrate that education and public engagement are seen as important roles.

By contrast with Johnson, for Dzur and Levin, public bioethics commissions fail to prioritize their role as *public forums*. They argue that there is tension between the roles of agenda-setting and expertise for such commissions and argue that we ought to assess bioethics commissions on their agenda-setting role. In other words, we should evaluate bioethics commissions on their ability to spark, guide and learn from public debate. Because there are a plurality of philosophical approaches that guide social debate in America, and because bioethics got its start "as an anti-technocratic movement focused on patient rights, greater public scrutiny, and increased public accountability in medical institutions that had lost a good deal of social trust" (Dzur and Levin 2007, 134), they argue that bioethics commissions are best evaluated based on their

usefulness as public forums. The President's Council on Bioethics, for example, did not understand its primary role as one of expertise. Instead, the chair de-emphasized its expertise and emphasized their educational mission (Kass 2005; Brown 2009a, 2009b).

Presidential advisory committees are structures that are both flexible, because they are contingent, and inflexible, because they are persistent. These bodies are copied and then their infrastructures persist. The structural design aspect of bioethics is critical for this project. My dissertation explores the *spatial dislocation* of bioethics. Different models (or parts of models) are taken from hospitals, universities, and governments, and asked to act consonant with the model *and* the new space. As shown, there is no agreed upon criteria for evaluating federal bioethics bodies and yet criticisms of private sector bioethics committees import evaluative criteria without acknowledging any controversy. This dissertation explores the following questions: What ideas about expertise, representation, legitimacy and authority are evident in both the design of the committee and the criticisms? How are tacit ideas about governance and evaluative criteria built in to the structures themselves?

Case Studies

This dissertation is an investigation of three private sector bioethics bodies as case studies. The Ethics and Public Policy Board at SmithKline Beecham was the first bioethics committee within a private for-profit company. The Vice President of Research created the board in the mid 1990s, as SmithKline Beecham was rapidly expanding its genetics and genomics research division. The Ethics Advisory Board at Advanced Cell Technology took shape in 2000; the idea

initiated with the CEO who then recruited an academic philosopher to choose the members and organize the meetings. The final case study is the Bioethics Committee and Bioethics Network at Eli Lilly. The Bioethics Committee has been meeting irregularly for the last decade, but has recently developed new policies and procedures. Two full-time bioethicists at Eli Lilly, with the help of senior management and external bioethics consultants, run the bioethics activities.

These three committees are not the only private sector bioethics bodies. Hoffman La-Roche has a group of external science and ethics advisers who meet several times per year and offer advice about research ethics and corporate policy. Novo Nordisk has an internal Environment and Bioethics Committee, and a network of individuals throughout the company who are involved in bioethics initiatives and policies. The network at Novo Nordisk served as inspiration for the bioethicists at Eli Lilly, as they were developing their own new bioethics programs (Van Campen, interview, 2010). Dupont has actively integrated ethics into their company policies, Affymetrix has an ethics committee, and Synthetic Genomics and Monsanto both have ethics and public policy advisory groups.[4] In recent surveys of both bioethicists and corporations, Frankel (2007, 2008) found that ethics consultation was more common than public accounts suggest, with companies seeking advice fairly frequently on a wide range of issues.

The committees at SmithKline Beecham, Advanced Cell Technology and Eli Lilly are not more interesting, effective, controversial or well (or less) known than committees at other companies. I selected these case studies because they are different from one another in interesting ways. One of the committees was completely secret, the other quite public, and the third is just beginning to engage

[4] This is not by any means an exhaustive list, but a snapshot of the range of private sector bioethics activity that has emerged over the last fifteen years.

with other groups and publicize their work. Renowned academics in biological sciences, philosophy and law sit on all three of the committees, but only one committee has made an obvious attempt to seek a more pluralistic membership (in terms of expertise, training, religion and gender). Each committee is integrated within the company to different extents, though each committee reports to a senior executive. All the committees bring in outsiders and divulge confidential information about new research and development in exchange for advice on ethically appropriate courses of action.

The companies tended to deny or downplay any precipitating events that may have led to the creation of their bioethics committees. However, each company faced a controversial scientific or ethical dilemma (that was also a public relations dilemma) prior to forming its bioethics committee. In 1999, *The Washington Post* reported that Eli Lilly was using homeless persons in their clinical trials and was not properly screening or following up with the participants. Lilly hired small team of ethics consultants to investigate the issue and report on ethics of practice. They kept two of the ethicists on as regular consultants following that report. Those ethicists continue to serve on the Lilly Bioethics Committee. At Advanced Cell Technology, around the time the Ethics Advisory Board was being formed, the scientists were engaged in controversial cloning research, and wanted to pursue embryonic stem cell research. In late 1998, CEO Michael West testified before the National Bioethics Advisory Commission on the nature of the ACT research program. In his mind he was being upfront and honest; others found his announcement quite alarming. During the 1990s, SmithKline Beecham was developing their genetic research program, with a specific emphasis on genetic testing, and executives had to

decide what kinds of genetic tests to develop. The Vice President of Research put together a group of highly distinguished scholars to engage in philosophical conversations about the ethics and social and policy implications of their research. (It is unclear what influence the Ethics and Public Policy Board had, but at the time SmithKline Beecham decided to not develop any genetic tests for conditions that did not yet have decent treatment options.)

The bioethics committees differ in their mandates and intended impact. The SmithKline Beecham board was not reviewing research protocols and advising the company scientists on specific ethical dilemmas. Board meetings were about general ethical and policy issues raised by science, technology and medicine. The topics were relevant to SmithKline Beecham, but the conversations at the meeting were rarely *about* SmithKline Beecham and its specific research protocols. Scientists would share details about their research, and executives would share their views, but the conversations did not aim to produce recommendations or a consensus. Because the Ethics and Public Policy Board lacked any oversight or regulatory power, it is open to the charge that it was just window-dressing. And yet, it was never publicized, so that is an inadequate explanation for the EPPB.

The CEO of Advanced Cell Technology, in contrast, gave the members of the Ethics Advisory Board some oversight power. The EAB develops policies and procedures to make sure the research moves forward in a responsible and ethical way. They do not have veto power over the research projects, but they do have the "power of the pen." If the company ignores the board's advice and recommendations and the members of the EAB feel the company is acting unethically, they have the freedom to write about it, to speak out in the media.

Their meetings do not take place regularly; instead they take place when the company has a question or a problem with which they need help. This board is more public than most others, in that they have a strong presence on the company's website, the EAB members write openly about their work with ACT and their support for stem cell research, and because they have been called on by politicians to be *publicly accountable* for their work with ACT. The members of the ethics board do not get paid for their services. This is unusual, and challenges conventional ideas and rhetoric about bioethics and industry.

Whereas the members of the SB Ethics and Public Policy Board and the ACT Ethics Advisory Board are not employees of the respective companies, most of the members of the Eli Lilly Bioethics Committee are Lilly employees. Two external members, both of whom are well-known academic bioethicists, serve as consultants and attend meetings four times a year. Lilly has two full-time bioethicists on staff, and they are in charge of the Bioethics Program, which includes the Bioethics Committee as well as the Bioethics Network. The Bioethics Network is a series of educational events and seminars, to try to increase bioethics education throughout the research side of the company—Lilly Research Laboratories. This model differs from the other two case studies in that it is mostly an internal program. It is also more systematic and more bureaucratic than the other two. They have a tiered consultation service, to respond to queries by scientists and managers about ethical dilemmas, as well as a follow-up survey instrument to attempt to understand the impact and effectiveness of the ethics advice.

Taken together, these three committees offer a snapshot of the ways bioethics is arranged and interpreted in industry. In setting up each committee,

the companies had to delineate the boundaries within which bioethics work would happen. Executives at Lilly bounded bioethics within the research division of the corporation, whereas at Advanced Cell Technology, the boundaries are undefined, with the ethics board commenting on both research protocols and public relations material. The range of activities within these three companies offers a valuable starting point to analyze this innovation in governance.

Methodology

Through literature review, qualitative analysis of semi-structured interviews, and theory-building, I critically explored the nature and perceived effectiveness of the SB EPPB, the ACT EAB, and the Lilly BEC, as part of a governance-relevant knowledge system (system for the production, validation, and use of knowledge in political and corporate decision-making). This study was explicitly interdisciplinary, thus in order to address my research questions, I employed a combination of research methods from history, philosophy, and the qualitative social sciences. This methodological diversity allows for one given technique to correct for the weakness of another, and for the whole project to be richer and more complex than it would be had only a single methodological perspective informed it. A qualitative interview study helped me develop detailed descriptions of the committees and the way they functioned, and facilitated the integration of multiple perspectives. By using a critical perspective from philosophy I was able to analyze the normative dimensions of the qualitative data.

I used a snowball sampling method to decide whom to interview. For each case study, I started with a key informant, someone who was deeply involved with

the committee who helped me gain access to members of the committee, and executives and scientists at the company. With the help of the key informants, I compiled a list of individuals to contact. I contacted these individuals and attempted to schedule one-hour interviews. The interviews were semi-structured qualitative research interviews that inquired about an informant's role within the committee, their opinions about why the committee existed and the value of the committee to the company, the work of the committee, and, if relevant, how the private sector committee compared to experiences on different kinds of bioethics committees. I interviewed past and present members of the committees, as well as key opinion leaders within and beyond bioethics (including past and present staff of the councils, staff of the companies, commentators from major newspapers, policy centers, and non-governmental organizations), and individuals within industry (including research scientists and executives, where possible). Key opinion leaders helped me gain a better sense of how the committees were received, which in turn informs their legitimacy. Additionally, I interviewed a small sample of members of other private sector bioethics committees, from companies such as Geron, Hoffman-LaRoche and Monsanto, to compare the kinds of corporate bioethics work being done in different companies. I recorded the interviews and took very detailed notes, which I used to create a more complete portrait of what was going on within the committees and their respective companies.

The literature I gathered for my research included the published materials including scholarly, popular and journalistic writings, and House and Senate hearings. News articles, blog posts and journal articles were useful to develop a robust understanding of the companies and any controversies with regards to the

ethics committees or the companies.

The research methods were both deductive and inductive. A modified grounded theory approach (Glaser and Strauss 1967; Strauss and Corbin 1990) allowed me to build a theory inductively from the data I collected in interviews and to assess it in light of my initial hypotheses. This method allowed me to be both systematic and creative at the same time. Grounded theory is particularly useful for new areas of research—like this project—because the theories remain grounded in the observations. In coding, I identified key phrases and quotes with respect to relationships (between the committee members and the company, the committee members and other bioethicists, the committee members and the public, as well as ideas about representation and expertise), problem space (the responsibilities of the committee, the kinds of problems addressed, the deliberative method), and purposes and benefits (authority and impact and perceived effectiveness). When reading the transcripts, I searched for quotes that were analytically interesting and then quotes that were theoretically useful. I was trying to (a) get relevant, credible and timely information about what the committee was doing, and (b) figure out what the structure was doing *beyond* the vision of the actors. I was searching for patterns, links, and plausible explanations of where these committees came from and what they were doing (cf. Patton 1999).

Limitations

Comparative case studies lose the detailed richness of single case studies, and thus are limited in terms of the depth of the exploration, but benefit from a larger breadth of exploration. However, the project was to understand what

private sector bioethics is (and how it fits within the larger project of bioethics), and therefore it was necessary to study multiple cases to gain a better understanding of the range of activities within corporate bioethics.

I had no access to any committee materials because committee members and corporate executives were unwilling to share potentially sensitive information, beyond the minutes from the first ACT meeting (which were read to me by Ronald Green—I never received a copy), so I had to rely entirely on interviews for an account of what actually happens within the committee. There were sometimes significant gaps between their self-perception and (what appears to have been) the actual impact of their work. Also, Ethics and Public Policy Board at SmithKline Beecham has not met in over a decade, so there were sometimes conflicting accounts of what happened. Achieving comparability in my findings was difficult (cf. Hurley 1999). I got a different degree of information with respect to their deliberative process, problems the committee addressed and the impact. The data were sometimes difficult to validate after the interviews. For the SmithKline Beecham case study, I had to rely heavily on Dr. Poste for both information and access to members, and that posed a significant challenge.

One of the biggest challenges was thinking through the question of transparency and secrecy. I often had very little information beyond the accounts of the members (at SmithKline Beecham, the only executive I could speak with was Poste; at Advanced Cell Technology, no currently employed scientist or executive would speak with me; and at Eli Lilly I was permitted to speak with the Chief Medical Officer for only 15 minutes, though I did have an hour to speak with the VP of Global Patient Safety). Therefore, I expect I know very little that actually happened within the committees and then within the corporations. And

yet, I don't know that my analysis of the committees would be significantly different if I had access to that information, because their interpretations of and reflections on their work are most interesting and reveal a lot about the project they were undertaking, as well as the motivations for such a project. While I think the lack of transparency is problematic, I do not think it is the most interesting or important feature of private sector bioethics. The lack of access is itself data.

In this research project, I investigated an important domain for the first time, using the resources available to me. This project provides empirical evidence about the constitution of bioethics advice in the private sector, and is an important first step to evaluating private sector bioethics committees.

Theoretical Framework and Relevant Literature

This dissertation engages a wide range of scholarship on the roles of bioethics and corporations in shaping social norms and categories. It draws on key work in bioethics, science & technology studies, public policy, and management. The aim is to uncover dimensions of how ideas of governance (of how to address ethical issues and orient science and technology towards worthy ends) are currently imagined, how emerging models reinscribe or perturb these imaginations and what new questions they raise. By drawing on a rich interdisciplinary scholarship and qualitative interviews, the dissertation strives for a robust understanding of the bodies themselves and a robust understanding of how they have been received. How these bodies have been understood and received informs their legitimacy as ethics bodies and shapes their constitution.

This project asks where, why and how bioethics is done in the private sector. It is an examination of boundaries at an institutional level. Bioethics,

previously a very public exercise, has moved within the confines of the for-profit private company, and has had to adapt to new space. David Livingstone (2003) has focused on the implications of the place of science, asking questions such as "Does the space where scientific integrity is engaged have any bearing on whether a claim is accepted or rejected?" Livingstone argues that space enables and constrains discourse in important ways, and that place is essential to the generation of knowledge. Ideas are generated and then circulated, and as they move to different contexts and circumstances, the representations undergo a transformation.

The role of place in bioethics appears to be an important consideration. Bioethics occupies many different spaces, within hospitals, universities and local and national governments. Within academia, bioethics is still looking for its place, as it now occupies space in many different disciplines, including philosophy, law, biology, medicine, public policy, and sociology. The question of place also influences the kind of bioethics that is done and then legitimized. On the one hand, bioethics seeks to embrace a placelessness to secure objectivity or to occupy "a view from nowhere." Bioethics relies heavily on modern Western ethical theories, such as utilitarianism and deontological ethics. According to these theories, we come to know our moral duties or can identify which course of action is moral through the abstract process of reason. These theories demand a level of impartiality on the part of the actor: "The details of the emotional lives and the relationships of the particular persons affected are rendered irrelevant from the moral point of view, except insofar as these details contribute to overall measures of happiness or suffering" (Sherwin 1992, 40). For each moral theory, all persons are equal and essentially interchangeable, and moral agents must

distance themselves from their own experiences and concerns. Principlism, though it does not demand the same impartiality on the part of decision-makers, asserts the universal acceptance of four values: autonomy, beneficence, respect for persons, and justice. According to John Evans (2000), principlism gained widespread acceptance because of its predictability and calculability. The bureaucratic nature of the principles was appealing, because "[i]t is part of U.S. political culture to substitute supposedly impersonal calculation for personal, responsible decisions" (Evans 2000, 35). As a method, it promised transparency and objectivity, and became the legitimate standard to evaluate and convey information about bioethical issues. And on the other hand, place has also been used to exclude certain forms of bioethics. Corporate bioethics—because it lacks transparency and accountability and thus cannot be representative of the public's values—has been dismissed because of its location in the private sector.

I am not a geographer, so I do not extend David Livingstone's theoretical framework very far. However, I do use the concept of "problem space" to think about how bioethics changes in new environments. What kind of "problem space" do these private sector bioethics bodies occupy and how does the space influence the work that is done and the way that work is received, both within the corporation and within the larger community of bioethics and its observers? How are these spaces shaped, by whom, and to what ends? Notions of authority and legitimacy also change depending on the context and the norms of the space in which the bioethics work is being done.

Because I am looking at how bioethics changes and adapts in new spaces, "boundary work" has been an important interpretive concept. Gieryn (1983) argued that boundary work was "strategic political action" for the purposes of

establishing epistemic authority. Multiple moral visions compete against one other and bioethicists have become central figures in these debates, because they help interpret public values. This project queries the role of bioethics in helping industry establish epistemic authority in moral controversies. Corporations have established bioethics committees to navigate the boundary between their private interests and the public values they claim to promote. Critics of bioethics committees in the private sector contest this boundary, and claim the committees serve private interests. In her work on public interest science organizations, Kelly Moore describes the contentious boundaries between science and politics. She argues that public interest science organizations were "a new form of action that was neither purely scientific nor purely political" (Moore 1996, 1594). In this way, the organizations acted as a kind of "safety valve" for both professional science organizations and social movement organizations. Following work by Kleinman (1995), Lewenstein (1991), and Wolfe (1989), Moore investigated the way public interest science organizations acted as "boundary spanners", to understand how the gaps and bridges between science and other institutions are created. These organizations played a key role in aligning the interests of science and its patrons. In order to make demands for support and prestige, scientists must convince non-scientists that the interests and values of science are aligned with those of non-scientists (Moore 1996, 1597).

Bioethics committees in the private sector perform, to varying extents, this boundary-spanning role. The committees allow companies to engage with some of the claims made by stakeholders, without engaging the stakeholders themselves. The members of the Ethics Advisory Board at Advanced Cell Technology have been outspoken in their support for stem cell research. They

play an important role in helping scientists make the case to non-scientists that their interests align, that their scientific endeavors seek to achieve the results desired by everyone, namely the development of cures for serious medical conditions.

According to Moore (1996), one of the strategies first attempted by scientists who sought to reconcile competing scientific and political agendas was to use existing professional and academic organizations. Corporations, in seeking to engage bioethics, use existing structures, prominent individuals, and academic organizations. SmithKline Beecham hired some of the most respected scholars in science, philosophy and law; Advanced Cell Technology modeled their ethics committee on the IRB example; and by hiring the one of the architects of principlism, Eli Lilly enacted a particular form of bioethics within the research division of the company. Eli Lilly is also beginning to try to build connections with groups such as the American Society for Bioethics and Humanities, the Department of Bioethics at the National Institutes of Health, and the Stanford Center for Biomedical Ethics.

Two of the boards in the following case studies had explicit conversations about public policy and political strategy. In the case of Advanced Cell Technology, the chair of the Ethics Advisory Board was called before Congress to answer questions about ACT's work. At SmithKline Beecham, board members engaged in debates about the ethical as well as policy implications of the company's research and development projects. Following their deliberations as a committee, the VP of Research wrote white papers and lobbied the British government on behalf of the company. This dissertation does not explore the lobbying activities of these companies; however, creating a bioethics committee is

one of many possible activities that fall under the umbrella of corporate political activity (CPA) (Hillman, Keim and Schuler 2004). Corporate political activity is defined as corporate attempts to shape government policy in ways favorable to the firm (Baysinger 1984), and includes: contributions to political action committees, advocacy advertising, professional lobbying, lobbying by senior executives, and constituency building (organizing grassroots feedback from employees, dealers, suppliers) (Lord 2003; Keim and Zeithaml 1986). According to Hillman, Keim and Schuler (2004), the types and typologies of corporate political activities are extensive and underdeveloped. Private sector ethics and public policy committees may be considered a form of corporate political activity (though their effectiveness is significantly less empirically testable than that of political contributions or lobbying efforts).

Much of the work on CPA focuses on corporate influence on public policymaking, and comes from political science and management studies. These scholars have shown that corporate lobbying efforts and spending have increased dramatically since the late 1970s, and that such efforts can be incredibly influential in the policy arena (Vogel 1989; Petracca 1992; Keim and Zeithaml 1986; Su, Neustadl and Clawson 1995; Taylor 1983; Polsby 1981). Business firms spend considerable money and are among the most prominent political players, both in the United States and worldwide (Hillman *et al.* 2004; Heinz *et al* 1993; Wright 1990; McConnell 1966; Milbrath 1963).

Scholars have shown how policy changes in the United States led to changes in corporate culture and university-industry-government relationships. Some work has focused on patent holdings by bioscience companies (Parthasarathy 2007), the change of research cultures following academic-

industry collaborations (Krimsky *et al.* 1991; Varma 2000), and the commercialization of academic science and technology research (Slaughter and Rhoades 1996; Kleinman 2003). Corporations may be consulting with bioethicists more frequently in an attempt to avoid new policies and regulation (or at least to minimize scrutiny). Corporate social responsibility (CSR) is a business model focused on self-regulation, whereby a company demonstrates its compliance with ethical standards, the law, and international norms often in the hopes of avoiding government oversight (Carroll 1999). Over the last decade, "corporate social responsibility" efforts have increased considerably, reflecting both corporate recognition of their increasing importance in society and corporate strategy to appear positive in the face of growing public and political scrutiny. Novo Nordisk, a European pharmaceutical company, makes explicit reference to corporate social responsibility on their bioethics program website.

In *BioIndustry Ethics,* Finegold *et al.* (2005) argue that ethics is valuable because, among other reasons, it will increase the profitability of a company. The idea that corporations care about ethics only insofar as it improves their profit margins is one of the main reasons the relationship between industry and bioethics has been so heavily criticized. In the following chapter, I review the literature on bioethics and business in greater depth. The literature review explores the arguments and assumptions made about the relationship between bioethics and industry, as well as the questions that go unasked.

Chapter 2

BIOETHICS AND BUSINESS

During a plenary address to BIO (Biotechnology Industry Organization), then-president Carl Feldbaum argued that biotechnology companies have a deep responsibility to engage a broad diversity of stakeholders in conversations about the moral complexities raised by science and technology: "Just as religious leaders recognize their responsibility to learn about biotechnology, we have a responsibility to work with them, to educate them and to learn from them" (Feldbaum 2003; Eaton 2004). It is clear that the industrial sector is implicated in a range of ethical dilemmas; ethical, social, political, cultural, and economic challenges necessarily accompany both the scientific and commercial development of new technologies. And yet, we know very little about the ways in which the companies contend with these issues. In some cases, companies have retained ethics consultants and committees to help them navigate challenging territories; but these strategies have been widely criticized and dismissed by bioethicists as being little more than a public relations campaign, or worse, window dressing. Critics of industry argue that pharmaceutical companies have a long history of unethical activity and thus do not take seriously basic ethical standards. But these dismissals notwithstanding, scholars have not thoroughly analyzed the nature of these bioethics consultations. The nature of the advice, the institutional mechanisms through which it is given, the kinds of problems to which it is addressed, the locus of agenda setting authority both within ethics deliberation and of resulting recommendation, and the extent to which corporate executives and research scientists take seriously the advice given by bioethicists – none of these features of bioethics have been properly analyzed.

Because of the significant uncertainty that surrounds these efforts, critiques of private sector bioethics bodies are, at minimum, premature. We know very little about the nature of the roles, relationships, structures, and, importantly, the consequences and impacts of bioethics in corporate settings. The critiques about corporate bioethics are interesting because they reveal a set of assumptions about how corporate bioethics should work – or why it cannot work – that suggest tacit but unexamined assumptions about the right forms of bioethics governance,[5] the conditions under which robust ethical deliberation can or should take place, and the ways in which ethical advice can or should be used. This chapter reviews the literature on the relationship between bioethics and industry to carefully explore the debate, but also, and importantly, to probe unexamined assumptions and neglected areas of analysis with respect to bioethics in corporate settings. The analysis presented here attends especially to the institutional structures in which bioethics deliberation occurs, the specific roles bioethicists perform, the relationships between different actors, and the particular outcomes each group seeks to achieve. The aim is to uncover dimensions of how ideas of governance are currently imagined, how emerging models of bioethics bodies re-inscribe or perturb these imaginations, and what new questions they raise. In chapters 3, 4, and 5, I carefully describe the corporate bioethics bodies themselves, and also develop a robust understanding of how these bodies have been received (both within the corporation and within the field of bioethics writ large). Their reception informs their legitimacy, and shapes their constitution – whether because of common prior commitments or because of accommodation to larger set of ideas about how to properly undertake

[5] By "bioethics governance" I mean addressing ethical issues and orienting bioscience, medicine and technology towards worthy ends.

bioethics deliberation.

The question "what is corporate bioethics?" is important both on its own, and as part of a larger question about what I think of as the *ecology of bioethics*. Bioethics has undergone incredible transformations in identity since its inception in the 1960s. The field is very self-reflective, with numerous articles, special issues of journals, symposia, and books dedicated to making sense of the work of bioethics (see, e.g., Callahan 1996, 1999, 2003, 2006; Brock 2000; Powers 2005; Meslin 1996; Murphy and White 2005; Moreno 1995; Lindemann 2006; *Cambridge Quarterly of Health Care Ethics* 2005; *Daedalus* 1999). This literature carves out key tasks for bioethics, proposes new methodologies, topics and lenses, calls into question the "effectiveness" and goals of bioethics, and works to exclude certain kinds of tasks. In other words, there is important boundary work happening to clarify what should count as good bioethics and, simultaneously, to reject, to delegitimize certain kinds of bioethics, including corporate bioethics. Corporate bioethics is labeled as corrupted – outside the boundaries of bioethics proper, and thus an untrustworthy shade of the core enterprise. This boundary work demonstrates an indeterminate, changeable and fragile sense of legitimacy within bioethics.

Outside observers of bioethics also tend to dismiss corporate bioethics as an activity not worth serious reflection. In his most recent book, John Evans (2010) provides an interesting, careful and insightful history of the field and prognosis of the problems of bioethics. In it, he argues the bioethics board at Advanced Cell Technology cannot be considered a legitimate bioethics activity because the members cannot claim to be doing bioethics on behalf of the public. Bioethicists frequently argue that their work is to clarify public values and

promote the public good (see, e.g., Kuczewski 2007; Callahan 2003).[6] And even external analysts of bioethics, like Evans, use bioethicists' own definitions of the boundaries of their work. As such, activities like corporate bioethics fall outside of their field of vision. Querying the boundaries and adding corporate bioethics back in, however, will strengthen our analysis not only of the neglected private sector sites, but of the nature of the enterprise of bioethics *writ* large.

This project explores the nature of corporate bioethics by asking what work corporate bioethics committees do and to what effect. Corporate bioethics bodies are an innovation in ethics governance, with the corporation taking on *de facto* governance roles by determining the appropriate ethical values and implementing those values in decisions about research and development. Corporate bioethics bodies are a neglected area of investigation, but the debate about the relationship between bioethics (and bioethicists) and industry is substantial. The following section will review that literature from the field of bioethics, to highlight key ideas and assumptions about how, when, and where (corporate) bioethics work happens.

Can Corporate Bioethics Be Valued?

A number of bioethicists are convinced that it is important for the field to maintain a distance from the activities of pharmaceutical companies. These reasons include: financial conflicts of interest, complicity in what they may deem to be unethical business dealings, potential exploitation of bioethics and bioethicists to improve a company's public image, and worries about what might

[6] While the EAB at ACT does not claim to represent the public, they do argue that they work with ACT to promote beneficial stem cell therapies. Through its EAB, though, ACT is engaging bioethics governance, and—it could be argued—is doing bioethics on behalf of the public.

happen to the field of bioethics when moral counsel is bought and sold (Elliott 2001 and 2004a; see also Sontag 2007; Turner 2004). Bioethicists gain a certain amount of trust as ethics "experts", and that trust may be undermined when they are paid by particular interested parties. The university has interests, but they differ from those of the corporation. Universities have an interest in research more generally; academic freedom gives bioethics scholars the liberty to write what they please, both in terms of topic and opinion. When a bioethics scholar does consulting work for a bioscience company, they are limited in topic. Some argue that because the bioethicist will develop a sense of indebtedness and loyalty to the corporation – because the company is letting them in on company secrets – the bioethicist is then limited in opinion, as well: "Like the paid nurse and like doctors who accept gifts from drug companies, paid bioethicists are not inclined to bite the hand that feeds them. But in order to fulfill the mandate they are given, consultant bioethicists must at least look at that hand quite critically—and maybe, on occasion, take a bite" (deVries and Bosk 2004, 29). As deVries and Bosk argue, one of the problematic features of the relationship between industry and bioethics is that bioethicists do not answer the questions they are not asked. In other words, their analysis may be severely limited in scope and context to the particular part of the issue that executives and scientists have identified as problematic.

DeVries and Bosk (2004) draw a distinction between "bioethics in business" and "bioethics of business." They classify "bioethics in business" as a fee-for-advice arrangement, where corporations hire bioethicists to analyze the ethical problems and suggest solutions. "Bioethics of business" is a broader investigation (more often funded by governmental agencies) of an ethical issue in

its social, historical, medical, and scientific context. The task of "bioethics of business" is to examine the ethical and policy implications of new technologies. Because it sets out to answer questions that are much wider in scope than those industry has traditionally sought from bioethics consultants, deVries and Bosk suggest a hybrid model of funding. Governmental agencies, private foundations, and corporations all contribute to the funding pool, giving the researchers freedom to think critically about the breadth of issues possible solutions. In proposing this model, deVries and Bosk pinpoint the problem as the funding source. If funding came from multiple sources, the ethicist could not be "captured" by one particular group or interest.

Carl Elliott argues that bioethicists ought to be more worried about the direction of bioethics than the actions of a few heavy-handed corporate executives, because as bioethics and industry become more closely intertwined, ethics becomes just another commodity: "The danger of living in this vast corporate wilderness, is that someday there will be no rebellion, no protest, no dissent that has not been bought and sold" (2001, 11). Bioethicists who share Elliott's concerns worry about the integrity of the field of bioethics and the effect private sector consulting will have on bioethicists' independence, objectivity, and impartiality.

In 2002, the American Society for Bioethics and Humanities and the American Society for Law, Medicine and Ethics convened a task force to develop guidelines to maintain the independence of bioethicists doing private sector consulting work. The report briefly points to the work that argues this kind of consulting ought not to be done at all, but then the authors move on, asserting that one of their starting premises is that efforts by biotechnology and

pharmaceutical companies to seek bioethics consultation should be encouraged (Brody *et al.* 2002). The task force had ten members, seven of whom had previously served as consultants to pharmaceutical or biotechnology companies. The purpose of their report was to "identify risks and to develop strategies to manage them… to minimize threats to independence and objectivity and maximize trust in bioethics consultation" (*ibid*., 15). The report never labels an activity as unacceptable, but instead makes suggestions and raises issues for consideration. The report was heavily criticized upon its release. A commentary in the same issue dismissed the report as a "'how-to' manual for a new guild interested in promoting what it already does" (Younger & Stuart 2002, 21). An editorial in *Nature* highlighted the debate about the report (Boyce 2002).

In one of the few empirical studies that investigated the relationship between bioethics and the influence of industry funding, Sharp *et al.* (2008) reviewed articles published in major bioethics journals over the last 15 years, to evaluate the influence of for-profit sponsors on the results of bioethics research. Their report found that there was no evidence that bioethics was being co-opted by corporate interests, as only 5 of the 460 research reports they evaluated acknowledged funding from industry sponsors. Their research also found that bioethics research was supported by multiple sources, and therefore there is little evidence that bioethics is being co-opted by a few key organizations or stakeholders. However, as many of the commentators pointed out in their responses to this study published in *The American Journal of Bioethics*, the study design was problematic and the data sample was too small and unrepresentative, as it is limited to voluntary disclosures of conflicts of interest from empirical bioethics research, which, by Sharp *et al.*'s own admission,

accounts for only 5% of published bioethics research. Evans (2008), Tsai (2008), and DeVries and Keirns (2008) all point out that the study completely disregards the funding of *normative* bioethics research, which accounts for most of the work in bioethics. This is important because, as Evans asks, "If industry were truly trying to bias bioethical studies, why would they want to try to influence articles making empirical claims about the world?" (2008, 59). Thus, the Sharp *et al.* study missed the most controversial dealings between bioethics and industry, such as those noted by DeVries and Keirns, where "[b]ioethicists have been hired by industry to define the ethical use of homeless people in phase one trials (Beauchamp *et al.* 2002),[7] convene advisory boards on rationing to support the use of activated protein C in sepsis (at a cost of $6,000–10,000 per patient) (DeVries 2004 [and Tsai, 2008]), and to serve on commercial and proprietary IRBs (Lemmens and Freedman 2000)" (2008, 66). In addition to the problems pointed out by *AJOB* commentators, the design of the study and the logic of the paper were problematic. An acknowledgement of industry funding was taken as evidence of bias. In other words, if the individual researcher or their employer receives industry funding (and, presumably, discloses the source of the funding), Sharp *et al.* took that to indicate bias in favor of industry. As an empirical claim, this relationship is not straightforward. This flaw in the study design raises a serious question about what counts as evidence when we make claims about influence, conflict of interest, and bias.

The degree of influence of industry funding depends—at least—on both the amount of money paid to the consultant and the kind of role the bioethicist is asked to play within the company. There is significant disagreement and

[7] The company that hired Beauchamp *et al.* was Eli Lilly. Their ethics program and this particular paper will be explored in more detail in Chapter 5.

uncertainty about the roles and functions an ethics consultant or committee can or should play. Does the ethics consultant have a primary duty to serve the public interest or to give the company advice and leave the final decision to the client? While some believe that ethicists should never consult for bioscience companies, others believe that it is important for ethicists to consult for companies for public health interests. Mark Frankel conducted a two-part survey of ethics consulting in the biotechnology industry, as part of a larger project undertaken by the American Association for the Advancement of Science (AAAS). The study arose from AAAS's interest in "learning more about the mechanisms and resources on which companies, researchers, scientists, and others rely when assessing courses of action in response to the ethical and social issues raised by advances in medical, agricultural, and biotechnological research" (AAAS Survey of Biotechnology Companies and AAAS Company Responses, 2008). The Program for Scientific Freedom, Responsibility and the Law (now the Scientific Responsibility, Human Rights and Law Program) had a particular interest in professional ethics; as part of their commitment to "promoting high standards for the practice of science and engineering," they wanted to gain a better understanding of the ethical issues industry was struggling with and the kinds of help they sought. Biotechnology companies will play a significant role in bringing scientific technologies to market, and as such are heavily scrutinized by the public and government oversight bodies. Part one of Frankel's survey focused on the use of ethics consultants by biotechnology companies, and part two of the survey focused on ethicists who are hired by biotechnology companies to offer advice. In the first part of the study, Frankel found that companies are engaging ethics consultants on a wide range of issues, and more frequently than previous public

accounts suggest, with ten of eleven respondents stating that the advice had been "incorporated into company policy" and none reporting that the advice had not been used (2008a, 5-6).

In the second part of the study, Frankel found that the most frequently cited reason for consulting for bioscience companies was the "intellectual challenge" (though two of the 21 respondents did admit that money was a significant factor) and very few ethics consultants work on a *pro bono* basis, with hourly rates at an average of $150 and daily rates ranging from $200-$1,000. When asked how useful they considered themselves to the company, on a scale of one to ten with ten being "extremely useful", the average score was 8. And yet, the results also showed that one third of respondents did not know how their advice was used, if at all. As Frankel notes, "without that information, it is difficult for them to place a value on their work, as well as for the public to evaluate the consulting process" (2008b).[8]

One part of the survey asks consultants to list the top three opportunities and pitfalls associated with ethics consulting for biotech companies. The opportunities most highly ranked include: "promoting inclusion of ethical considerations in making business decisions, which is a service to society"; "practicing profession in real-world situations and exerting influence on research"; and "first hand knowledge of impending scientific developments" (Frankel 2008b). According to the survey, people undertook ethics consulting

[8] Mark Frankel is a paid member of the Hoffman-LaRoche Science and Ethics Advisory Group (SEAG). In an interview, Frankel told me that he did not know how Hoffman-LaRoche used the advice given to them by the SEAG, and yet also stressed the importance of their work as a committee. This might suggest that it is not in fact difficult for individuals to place a value on their work, but that engaging in evaluation of the larger purpose and impact of the work is seen as harder to do and/or less important.

work because they see it as a "*service to society*" (emphasis added). They are not accountable to the public when they do this work, but they see themselves as working in service of the public. Building relationships with others in the same field and gaining unique insight into the workings of industry were also listed as opportunities associated with ethics consulting for biotech companies. The two most frequently mentioned pitfalls were concerns about "being used as an 'ethical cover' for public relations purposes and to rubber stamp decisions" and "getting co-opted because of influence of compensation and/or the prestige of the work that could prejudice their judgment" (Frankel 2008b). There were also concerns about peer criticism, unwanted exposure to mass media, client-imposed restrictions on publication, and excessive time commitment. Unfortunately, only a small number of surveys were returned, so the pool of data was quite small.

Frankel provided an interesting overview of the landscape of ethics consultation within industry and shed light on the kinds of advice the bioethicists provided to corporations. Unfortunately, there have been very few papers that have explored the nature of the different roles for bioethics within industry. In a 2004 paper, Tim Lewens questioned the *nature* of the tasks the bioethicist can perform and the *value* a bioethicist adds to a corporation. He explored four different kinds of roles a bioethicist may play for a corporation: the marketer, the expert, the lobbyist, and a more dialectical role. As a marketer, the bioethicist would assess the product and suggest ways to maximize the acceptability. The metric for evaluation would be product sales and whether the bioethicist anticipated problems. A lobbyist role would require that the bioethicist *promote* a particular technology or practice. The bioethicist would help the company make an ethical case for a product to regulators. The expert would offer advice about

ethical facts – whether something was right or wrong independent of regulatory structures and commercial markets. While it is foreseeable that a company might want this advice, Lewens argues that bioethicists typically profess expertise only regarding arguments, rather than an expertise regarding ethical facts, and thus would be unable to assume this role. However, it seems Lewens conceives this particular role too narrowly. A company could seek an evaluation of whether this product or this decision was ethical, and a bioethicist could develop an argument in support of one conclusion (or show how different ethical arguments would derive different answers). The bioethicist offers an expertise in applying particular theories and values, and developing ethical arguments. But, Lewens argues that only a dialectical role is appropriate. In this role, a bioethicist would assist the company in formulating responses to different stakeholders and policies or stances on particular issues. As Lewens explains: "A corporation that seeks to formulate a stance towards, for example, research ethics, can benefit from the presence of an individual in the room who is able to show them how the concept of autonomy is being used in conflicting senses in two different parts of its research policy documents" (2004b, 151). The bioethicist in the dialectical role does not advocate for or even assess a particular technology or dilemma.

In the first half of the paper, Lewens argues that it is unlikely a bioethicist would change their opinion because of payment from a corporation. He argues that financial payment is neither necessary nor sufficient for a serious conflict of interest, and that concerns about compromised objectivity could be allayed if the majority of a bioethicist's work is academic, if there are strong values within the bioethics community that promote and support the importance of academic bioethics, and if the relations between a bioethicist's corporate involvement and

published work is open to tracking (Lewens 2004). As he notes, the latter condition is rarely met. Consulting work is rarely disclosed. However, despite arguing that financial conflicts of interest are not seriously problematic, and offering conditions to protect academic bioethics from being corrupted by corporate values, Lewens confines the bioethicist to a relatively easy and largely instrumental role. The dialectical role does not offer an opportunity to affect change within the corporation, or even prevent serious mistakes. By clarifying policy documents, the dialectical role comes close to more of a public relations role. And, as Lewens notes, the bioethicist in the dialectical role may inadvertently end up arguing on behalf of a product or practice they do not support. The ethics consultants surveyed by AAAS noted that the top reasons they worked with corporations were the intellectual challenge and to help the company "do the right thing" (Frankel 2008). The dialectical role offers neither of those opportunities.

While Lewens does not elaborate on the reasons this role is the most appropriate, his arguments reflect a deep discomfort about the relationship between bioethics and industry. The concern that companies can and will buy the kind of ethics advice they want, that they can shop for the particular answer they want and thus compromise the credibility and legitimacy of ethics more broadly, is serious and widespread. (This worry may, to some extent, say as much about bioethics as an intellectual domain as it does about corporations.) It is not just a worry about individual instances of a bioethicist doling out advice to a company, but a concern about the larger negative impacts on the field or activity of bioethics if bioethicists regularly act as paid consultants for industry.

What Value Might Corporate Bioethics Add?

As discussed, there are many morally persuasive arguments to convince us that we ought to be wary of the relationship between bioethics and industry (e.g., Elliott 2005a; Turner 1998; Dresser 2006; DeVries and Bosk 2004). There are important concerns about the aesthetic reaction of "an ethics in service of industry," the risk of bias, and the history of unethical actions by pharmaceutical companies (and worries about being complicit in that behavior). On the other hand, it is worth spending some time considering whether, as Arthur Caplan, the director of a bioethics center funded by numerous pharmaceutical companies, told a *New York Times* report, "A bioethics that is disconnected from industry is a bioethics that flies blind" (Caplan quoted in Stolberg 2001). In a letter to *Nature*, Rahul Dhanda argued that both bioethics and industry need to work together because bioethics can help bioscience companies understand the social, political, and economic context in which technologies are being developed, and bioscience companies can make bioethics relevant: "Failure to engage industry will eventually lead the discipline towards irrelevance, as it constructs artificial boundaries based on fashions that neglect the important and pervasive role of commerce" (Dhanda 2003, 573). While there are many potential benefits to a more open relationship between bioethics and industry, the argument that bioethics will be uninformed, ineffective and irrelevant without significant engagement with industry needs further attention. For some, the advantages of working with industry include gaining insider knowledge and bureaucratic power, but for some those advantages come at the potential and high cost of a loss of public credibility (Elliott 2003). On the one hand, to suggest that the field will be irrelevant if it cannot or refuses to help industry better understand the

social implications of their technologies reveals a narrow conception of what the field can achieve. On the other hand, ignoring the role of industry reveals a narrow conception of the fields of science, technology and medicine.

Whether a relationship between bioethics and industry can be mutually beneficial depends heavily on the kinds and quality of the connections. In his new book, Evans (2010) argues that bioethics cannot be watchdogs of science and medicine because they are now housed within the institutions of which they are supposed to be critical. However, some will argue that the design of the institutions matters significantly to the intended outcome. In a piece entitled "Toward a Better Bioethics", Jason Scott Robert argues in favor of extensive integration between (academic) scientists and ethicists. According to Robert, "embedded bioethicists have a much greater opportunity than outsiders to keep abreast of scientific advances, build trust with scientists, and effect change both locally and more broadly" (2009, 288). This idea, however, is highly problematic for some—either because of the reasons Evans articulates or because the role Robert argues for is significantly more demanding of both scientist and ethicist. Projects such as the Socio-Technical Integration Research Project (STIR) at the Center for Nanotechnology and Society at Arizona State University assert that they have value *because of* integration. STIR participants conduct "a coordinated set of 20 laboratory engagement studies to assess and compare the varying pressures on—and capacities for—laboratories to integrate broader societal considerations into their work" (STIR website). For ethics consultants in private industry, is there value to integration (to forming long standing relationships via bioethics committees) or does any level of integration pose a significant challenge to maintaining a critical will?

While many would argue that industry needs to consider different perspectives, and would benefit from ethics advice, what motivates a company to seek the advice? Dresser (2006) argues that pharmaceutical companies might put forward ethics statements (or create ethics panels) as a form of public relations or marketing, as an alternative or enhancement to regulation, or as a genuine commitment to the social good. It may also be some combination of those reasons. However, even though the pharmaceutical companies seek to assure their consumers that their commitments to ethics are genuine and influential in their decision-making, it is almost impossible for outside observers to evaluate the companies' actions due to a lack of transparency and accountability (Dresser 2006). Without further evidence, observers can take the ethical statements as little more than public relations tactics. There is a strong assumption against the legitimacy of ethics advice in the for-profit private sector.

While there are increasingly more calls for open, accountable, and democratic governance of science and technology, attempts to include industry in conversations about the ethical and social implications of scientific research and emerging technologies are either rare or unproductive. This is despite the fact that industry provides more funding for biomedical research and development than the US government does and despite the fact that the products and practice of biomedicine are mostly delivered by the private sector. And yet, as Dresser points out, despite the important contributions of the private sector, "scholarly and policy analysis of research ethics concentrates on government rules and conflicts of interest for academicians. Little attention is given to the internal ethical judgments influencing the choices industry scientists and other workers make about research" (2006, 115). But because of their growth, the ethical

judgments made within private corporations have a significant impact on the outputs of scientific, technological, and medical research and development.

Dresser's analysis comes as an outside observer. Because there is little information about the bioethics activities of corporations, outside observers have had to guess as to what a corporation was actually doing, what its motivations are, and what the impacts were or will be. Some scholars have argued that adopting a focus on ethics will increase the company's profits (Finegold *et al.* 2005), though the evidence for this claim is not clear (McDonald 2004; Hillman and Keim 2001). The case studies presented in this dissertation explore what bioethicists expect companies to gain, and what companies themselves expect to gain (and what the actual outcomes are). A study about lobbyists argued that "private interests have developed elaborate organizational structures in order to provide control over the processes through which they are represented, but the irony is that these efforts at control exacerbate problems of coordination and information exchange and may ultimately contribute greater levels of uncertainty in policy systems generally" (Heinz *et al.* 1993, 5). Hiring a bioethicist as a consultant or creating a bioethics committee might be a way for companies to gain more control of the process of research and development—through a deeper understanding of potential ethical, social or political dilemmas—but granting outsiders access to privileged information is risky. Companies have a heightened awareness for reputational risk (Bawden 2003); while the decision to employ an ethicist has public relations value, it also creates new expectations of social responsibility and may open the company up to increased levels of scrutiny. However, companies employ lawyers, economists, public relations and marketing consultants, experts in business systems, anthropologists and media experts to

help them navigate the complexity of corporate decision-making. Corporations have to navigate incredibly complex decision environments, and bioethicists may be able to play an important role in helping them. However, according to many bioethicists, to engage in a paid consulting relationship with pharmaceutical companies is to risk both serious conflicts of interest (being paid to provide an opinion) and being complicit in the harms committed against patients by drug developers and manufacturers.

What Forms of Value Does Corporate Bioethics Produce?

For decades, bioethicists have pointed out the dangers of conflicts of interest and the deeply problematic practices of the pharmaceutical industry. The history of injustices perpetuated by corporations is both a reason for bioethics to collaborate with industry as well as a reason to maintain a distance. Public health researchers have demonstrated how Philip Morris used philanthropy strategically to improve company image, influence policymakers and thus influence public health policies (Tesler and Malone 2008). But despite legitimate worries about the consequences of close ties between bioethicists and industry, it seems equally problematic to abandon connections to industry, or to assume that not accepting compensation will solve some of the problems. The role of the government in bioethical abuses has also been prominent (see, e.g., ACHRE 1995; PCSBI 2011) and no bioethicist has ever turned down a seat on a national commission to protest injustices in federally funded research.

Some bioethicists have argued that the relationship between bioethics and industry would be significantly less problematic if the bioethicist did not receive payment. However, unpaid work raises different challenges. Thomas Murray

argues that *pro bono* work is itself problematic, because in a society that so often assigns worth based on the price, ethics advice that is given away for free may be open to exploitative relationships, and may be dismissed as unimportant and/or as out of touch with reality, and. The aforementioned task force on private sector ethics consultation acknowledges the real risks that compensation poses but argues "ethics consultation is as deserving of compensation as other types of expertise. While pro bono compensation is laudatory, affluent for-profit clients do not seem to be the appropriate recipients of pro bono service" (Brody *et al.* 2002, 15).

Feminist scholars have argued for decades that the kinds of work that go unpaid are devalued. "Women's work"—raising children, being caretakers, and so on—is repeatedly dismissed, disrespected, devalued because we cannot and do not quantify it. In our society, professions that get paid more are often held in higher regard. If it remains a *pro bono* activity, does bioethics advice risk being dismissed and disrespected? If a corporation has invested nothing in getting the advice, will they be less likely to implement the advice within the company? What counts as the meaningful sphere of public economic production, and how does bioethics fit?

Bioethics in industry puts bioethics squarely in a messy, complex and necessarily pragmatic world. This new place conflicts with a deep narrative that tells us the producers of knowledge are not in society. Rousseau, Newton, Descartes, Emerson and Thoreau have argued convincingly that solitude produces philosophical knowledge, and thus, the social place of knowledge is nowhere (Shapin 2010). Science has used the "placelessness" of the laboratory as a way of securing authority, objectivity and credibility (Livingstone 2003).

Knowledge, space, and power are tightly interwoven – and science was supposed to generate knowledge "free from the imprint of the local" (*ibid*., 2). Bioethics seems to want to invoke the same placelessness (or wants to privilege one place over another), by arguing that certain spaces are inherently problematic, therefore dismissing the possibility that good or important bioethics work can happen within the industrial sector. The conflicts between the values of industry and academia have been clearly elucidated (see, e.g., Krimsky 2003; Lewis *et al.* 2001; Baylis 2000; Downie 2009; Kleinman 2003), however so too have the conflicts between academia and the policy process (Brock 1987). The problem space in which bioethics work is done shapes both the work and the reaction to the work. This in turn changes the legitimacy that work is granted, and the authority it is accorded.

This raises an important question: why does knowledge or science become something different in a different place or because of a different source of funding? There is significant concern that bioethics will become something different, something less desirable if it is a commodity. But what goods does bioethics make? What forms of value does it produce? (And how do forms of value get made, promoted, institutionalized so as to become powerful?) This project uses private sector bioethics to think about what kinds of goods bioethics makes, or what kinds of value added bioethics gives us.

If bioethics is a market activity, are there possible ways in which we may preserve the non-market dimensions of ethics advice? Margaret Radin (1996) presents a theory of partial commodification[9] in which she tries to preserve the

[9] According to Radin, "partial commodification" occurs when some but not all exchanges of a thing are commodified. "Incomplete commodification" is a state where something can be bought only under certain restricting regulations.

non-market dimensions of a market activity.[10] Radin's theory of market inalienability argues that some things are more usefully understood as incompletely commodified. In other words, it is a theory that tries to explain which things should be market-inalienable (non-commodified) only to a degree, or only in some aspects. Radin's theory is helpful here because it is a theory about structuring institutions, rather than about the distribution of goods. This dissertation seeks to understand how corporations have structured their organizations to incorporate bioethics advice. I also seek to gain a better understand the controversial relationship between bioethics and industry, and the arguments for and against payment for bioethics consulting services. Radin argues, "some contested things can be bought and sold, but only under carefully regulated circumstances. Such a regulatory regime both symbolizes the importance of nonmarket value to personhood and aspires to ameliorate the underlying conditions of inequality" (1996, 289). Radin offers this as a more pragmatic position between arguments for noncommodification (the domino theory) and arguments for universal commodification (a *laissez-faire* approach). Those who seek to prohibit the commodification of certain activities argue that those things that are non-commodified are morally better: "We cannot both know

[10] Radin develops her argument about need and commodification by drawing on activities such as surrogacy, prostitution, and organ donation. These activities are all deeply personal and embodied, but there are some interesting parallels that we may tease out. Bioethics consulting services are an example of the market value of a non-market activity being acknowledged. Previously, the service had been "free" (the bioethicist received no additional payment beyond their university salary) or not sought at all. Organ donation is an activity that has always been free (the organs are freely donated, the surgical services are not), but recently a black market for organs has emerged, and many people seek to sell their organs for money. However, the market value of the activity has not been acknowledged. There remains deep disagreement about whether organ donation should be market commensurable (complete commodification) or incommensurable (attempted non-commodification).

the price of something and know that it is priceless" (*ibid.,* 101). According to the domino theory, incomplete commodification is not possible because the fact of pricing necessarily brings with it the conceptual scheme of commodification. Those who support universal commodification argue that all things desired or valued are commodities. Anything that someone is willing to sell and another person is willing to buy can and should be the subject of free market exchange. Both perspectives are archetypes or caricatures, but roughly capture the two ends of the spectrum of views about commodification. The two different perspectives are frequently reflected in debate about bioethics and financial interests.

Bioethics advice is now something that is offered on the market, but many argue that there are overriding "non-market dimensions" that ought to be preserved and protected. One of the most persuasive arguments against the commercialization of bioethics (and of academic research more broadly) is the argument about a difference in fundamental values between the university and the corporation. Because it is not beholden to particular interests, it has the freedom (and protection) to speak out against the clinicians/hospitals/healthcare systems/insurance companies/pharmaceutical companies that are behaving in an ethically problematic way. Academic bioethics seeks to explore complexities and identify injustices, to develop ethical arguments and develop deep understandings of the problem from multiple perspectives. The motivation to cultivate that skill, to study the root of social and political problems and seek solutions, is a "non-market dimension of a market activity". Bioethicists are paid for their labor, usually through academic departments, but the payment alone does not motivate the work, nor does it exhaust the value of the work. This is an important non-market aspect. As Radin argues, "complete commodification of

work—pure labor—does violence to our notion of what it is to be a well-developed person" (1996, 107).

A bioethicist identifies a need for her services, a need for a particular kind of expertise, within a pharmaceutical or biotechnology company. If she believes that working with the company may influence the ways in which that company develops and distributes a technology for the better, then she may want to pursue that work, to correct or alleviate injustices. Radin develops the argument for partial commodification based on the idea that there is an underlying need to be addressed – one that does not go away if we limit or prevent commercial transactions. There is a worry that the financial incentive is inherently corruptible, but *if* the need for the activity remains, how might we arrange or oversee the activity to preserve integrity? Radin's argument about needs and commodification raises a few key questions: Is there an actual need for bioethicists to work within corporations? Have executives identified a serious need in their business organization, or have bioethicists identified a need for their services? There is also the possibility that third party groups have promoted the notion that private companies need external bioethics advice. Is there a real or an assumed need for bioethics advice? And how did this need come about?[11] This dissertation does not attempt to answer Radin's questions, but her analysis does push us to think about what corporate bioethics does and to whom (and for whom) it speaks.

Another important question concerns the role of bioethics more broadly. Universities have served industry for the past 150 years even as they have also

[11] One potentially interesting area of investigation might draw on Marx to ask how the need was *manufactured*. Does bioethics consulting satisfy existing and previously unmet needs, or is it manufacturing new needs?

been able to act as a critic in many domains. Bioethics, however, occupies only one role—and not well. As bioethicist and business ethics scholar Chris Macdonald has noted (2003, 2005), bioethicists do not want to associate with the "sinners" in industry; and yet, as some have noted, there are too few bioethics scholars willing to speak up against injustice (see, e.g., Baylis 2000, 2004).

Ethics committees are potentially valuable to the company's executives, research scientists, and lawyers. Shareholders and consumers may value the creation of an ethics committee, and the committee may promote the broader interests of the public by providing an outside critique of the research activities. Stakeholder theory tries to discern which stakeholders are most important for the firm to attend to by evaluating their legitimacy, urgency and relative power. The theory tries to explain to whom and to what managers actually pay attention, and those entities to which managers *should* pay attention (Mitchell, Agle & Wood 1997; Jones 1995). Jones (1995) stipulates that the core of stakeholder theory is that a subset of ethical principles, such as trust, trustworthiness, and cooperativeness, can result in significant competitive advantage. Thus, by responding appropriately to certain classes of stakeholders, a firm will be more likely to foster trust, trustworthiness, and cooperativeness. Mitchell, Agle & Wood (1997) offer a typology of stakeholders that allows predictions to be made about managerial behavior with respect to each class of stakeholder. Their theory of stakeholder salience holds that, "in order to achieve certain ends, or because of perceptual factors, managers do pay certain kinds of attention to certain kinds of stakeholders" (855). Did SmithKline Beecham, Eli Lilly, and Advanced Cell Technology create their bioethics committees in an attempt to respond to different kinds of stakeholders?

I do not assume that the executives at these three companies created bioethics committees to respond to stakeholder concerns. But stakeholder theory, social contract theory and the corporate social responsibility literature offer ways to understand and justify these bioethics committees. Importantly, these ideas and theories helped *enact* corporate bioethics.

This project is about different forms of governance, broadly conceived. Through the following case studies, this dissertation explores how institutions get made and sustained, and examines what kinds of notions of expertise, credibility, and authority emerge from private sector bioethics committees. In each case study, the corporations have relocated a resource of moral expertise and tried to make it mean something in a new setting. The new settings shaped the questions that were asked and the resulting deliberations. What new knowledge and new forms of social and moral order did these committees produce?

Chapter 3

THE CORPORATE CONSCIENCE: THE ETHICS AND PUBLIC POLICY BOARD AT SMITHKLINE BEECHAM

One of the most common criticisms of private sector bioethics is that it is "window-dressing", that the bioethicists are there to make the company look good, but have little power to influence change. However, one of the first private sector bioethics bodies was never publicized. No information about the SmithKline Beecham Ethics and Public Policy Board or its members appeared on the company's website. Considering that SmithKline Beecham had assembled an impressive cast of very distinguished scholars, it might have been to their advantage to advertise their bioethics board. This institutional arrangement thus challenges the dominant narrative that corporations seek bioethics consultants primarily for public relations purposes.

The Ethics and Public Policy Board was designed to act as a "corporate conscience" for SmithKline Beecham. It was a space within the company for deliberation of the role of science (and specifically, the role of corporate science) in society. The members did not give advice on specific research projects like an institutional review board does, but rather explored broad ethical implications and policy considerations. After a brief background on the company and how the Ethics and Public Policy Board came into existence, I analyze the board with respect to: (1) Relationships between actors: What are the relationships between different actors, and how do actors' conceive of their relationships and work? Do the actors' conceptions comport with the larger structure? (2) Problem spaces: The problems discussed by the committee are shaped as much by the context in which they are articulated as they are by how they are articulated. Relationships

significantly influence the kinds of problems addressed (and the proposed solutions). Does the committee function like stakeholder interest politics, or does it offer a "view from nowhere" objective moral expertise? (3) Purposes and benefits: How benefits are assessed depends on relationships and the problems and problem space. Ideas of appropriate relationships, worthwhile problems, and usefulness depend on larger ideas of what kind of expertise bioethics is, how it fits into a larger politics of delegation, and the kinds of spaces it can occupy.

Background

SmithKline Beecham (SB) was formed in 1989 from a merger between The Beecham Group and SmithKline Beckham. It was (and remains) one of the largest pharmaceutical companies in the world, with products ranging from Paxil, the antidepressant, to AquaFresh toothpaste to Tums antacid medication. After the merger, SmithKline Beecham sold many of its units, mainly in the consumer products area, and reorganized the consumer side as the consumer healthcare division. On the pharmaceutical side, SmithKline Beecham decided to concentrate its research and development efforts in five areas, including the central nervous system, the heart and lungs, anti-infectives, inflammation and tissue repair, and vaccines. At the time, the Human Genome Project was recently formally initiated, and SmithKline Beecham was particularly interested in developing its capacities in genetics and genomics research within each of these five areas.

In the early 1990s, SmithKline Beecham was eager to become a leader in the field of functional genomics, motivated by the prospects of diagnostic applications and more expeditious drug discovery, and sought key collaborations

to boost its capacities (Cook-Deegan 1994). J. Craig Venter announced the formation of the nonprofit genome research center, The Institute for Genomics Research (TIGR), in 1992. At the time it was the largest private investment in genomics research, and it was partnered with the newly formed for-profit Human Genome Sciences, Inc. (HGS), through agreements on intellectual property rights (Cook-Deegan 1994). SmithKline Beecham negotiated a multimillion dollar research collaboration agreement with HGS in 1993, to identify and describe the function of genes in the body. The deal, worth $125 million, gave SmithKline Beecham a 7% stake in HGS and the rights to develop drugs based on gene sequencing information developed by HGS. The deal with Human Genome Sciences did not yield any quick results in terms of new medicines, but it did uncover numerous leads for potential development. Thus, SmithKline Beecham entered into multiple research collaborations and licensing agreements with other pharmaceutical and biotechnology companies. One such collaboration, with Incyte Pharmaceuticals in 1997, led to the formation of a new company, diaDexus, tasked with discovering and marketing novel molecular diagnostics based on the use of genetics.

These collaborations arose because the challenge of mapping and sequencing the human genome was beyond the capabilities of any existing laboratory, and therefore required extensive cooperation and exchanges of data and materials (Hilgartner 2004). These new kinds of collaborations between different corporations, as well as new collaborations between academia and industry, were of great interest to SmithKline Beecham, and the evolution of genomics research consortia eventually became a main discussion topic for the company's Ethics and Public Policy Board.

As they moved forward to develop their functional genomics research division, SB was sensitive to how their moves were perceived. They argued that because the technology will generate lots of questions for both the company and society, they ought not engage these conversations in isolation. And so the Vice President of Research, George Poste, with permission from CEO, Jan Leschly, formed what he claims is the first private sector bioethics committee, the Ethics and Public Policy Board.

Relationships

To explore the company's social responsibilities, Poste and his staff assembled an interdisciplinary group of biologists, clinicians, theologians, lawyers, and philosophers to form a committee to deal with ethical and policy issues. He sought individuals who were knowledgeable about the potential medical applications of genomic science, as well as the potential legal issues, and the perceived social impacts, and who had eminent standing in their respective fields. This group met 3 times a year for 2-day meetings, alternating between the US and the UK.

Demographically, this group was all male, Caucasian, middle aged and highly distinguished. The members were:

- Ronald Dworkin, Professor of Philosophy and Frank Henry Sommer Professor of Law at New York University;
- John Harris, Lord Alliance Professor of Bioethics at Manchester University;
- Lawrence O. Gostin, Linda D. and Timothy J. O'Neill Professor of Global Health Law and Faculty Director, O'Neill Institute for National and

Global Health Law;

- Sir David Weatherall, Regis Professor of Medicine at Oxford University and founding director of the Weatherall Institute for Molecular Medicine (and 2010 recipient of the Lasker-Koshland Special Achievement Award in Medical Science);
- John A. Robertson, Vinson & Elkins Chair, University of Texas School of Law;
- Dr. Hamilton A. Moses III, Senior Advisor, Partner and Director of The Boston Consulting Group;
- Philip Reilly, J.D., M.D., former chairman of the board and CEO of Interleukin Genetics;
- Sir Ian Kennedy, Emeritus Professor of Health Law, Ethics and Policy at University College London;
- The Reverend Professor Gordon Dunston; and
- Sir Peter Lachmann, Emeritus Sheila Joan Smith Professor of Immunology at Cambridge University.

This group includes the leading scholars in science, law and philosophy. Weatherall is one of the world's experts on the clinical and molecular basis of the thalessemias, and Lachmann is a well-known immunologist who has served as President of the Royal College of Pathologists and Vice President of the Royal Society. Kennedy, Dworkin, Gostin, and Robertson are highly influential legal scholars. Kennedy was chair of the Nuffield Council on Bioethics from 1998-2002 (and is currently the chair of the Independent Parliamentary Standards Authority). Poste assembled an impressive cast; SB brought together some of the most revered thinkers in science and ethics to discuss—without public

fanfare—the responsibilities of a large pharmaceutical corporation to society.

The membership of the board was not pluralistic in terms of race, gender, or political affiliation; instead, Poste recruited some of the most distinguished scholars in relevant fields of expertise. When asked about the diversity of the membership, one member told me: "I don't think there was any extreme view on the committee. Nobody said there must not be any embryonic research, for example." Not supporting embryonic research is not an extreme opinion. Rather, this example speaks to the problem of representation. Excluding such views from a public body that was engaged to deliberate about research on human embryos, for example, would be problematic, but for different reasons. In that case, excluding such perspectives would appear to be a deliberate attempt to bring about a particular kind of outcome. At SB, there was no attempt to achieve a consensus or deliver a recommendation; rather, they were interested in pursuing a promising area of research and needed advice about the ethical and political challenges. It was reported they held "special ethics hearings" to find an acceptable way to frame and promote human embryonic stem cell research (McGee 2003,189).[12] The EPPB members were responsible for making a thoughtful analysis of the landscape of opinions. Instead of choosing a membership that represented that diversity of opinion, Poste chose a group of "wise elders" to understand and interpret a wide range of views.

One member defended the composition of the board by arguing: "I think the important level of diversity was not of opinion, but of profession. These

[12] In interviews, no member recalled the hearings or would offer more information, so I do not know who participated in these hearings, or if they were in fact any different than regular EPPB meetings; George Poste would not return my follow-up e-mails on the subject.

people came from very different kinds of work, with different attitudes from the concrete to the abstract way of looking at these problems." The executives at SB assembled an expert advisory body based on particular skill sets and experiences, rather than a more pluralistic model that seeks a broader diversity in order to speak for stakeholders, citizens at large or particular interests. The representation of the EPPB is the expertise as experience model, where the members are chosen not on their geography,[13] race or gender, but on the particular kinds of expertise they possess.

The members of the EPPB were quick to dismiss the idea that they were representing or speaking for the public in any way. Members drew a distinction between the EPPB and other kinds of committees. One member mentioned that he currently serves on a number of committees that are different, and where he is "concerned about why I'm there and what advice I ought to give". As members on public bioethics boards, members are representative of and responsible to the public. On a private sector board, members have a responsibility to the company. But because there was no clear mandate for the EPPB, the members felt no pressure to make any particular kind of decision or represent any particular position.

Critics of private sector ethics consultation argue that the integrity of bioethics advice will be compromised and consultants pressured to agree with the company if it becomes a commodity to be purchased. They worry that companies will buy whatever ethics advice they want, rather than seek a range of opinions. The members of SB's EPPB were paid—though none of them would disclose what that sum was. When asked about being paid for their services, members were

[13] The members were pretty evenly split between the US and the UK.

quick to argue that the money was not the reason they participated, nor did it affect what they said at the meetings. One member argued:

> None of us did it for the money. We were put up in nice hotels, the travel was arranged efficiently and we flew business class… all of that made for a very nice experience. But, none of us did it for the money.

This member was arguing that there were no conflicts of interest. However, he asserts a very narrow notion of conflict of interests, dismissing any conflict beside a financial one. This quotation gives an account of their self-conception and perceived legitimacy. They were treated well by the company, but they emphasize that they did not participate because of the perks. Instead, the EPPB members participated because of the intellectual experience, because they perceived their contributions to be worthwhile for the company (and because it was intellectually worthwhile for them). Participation was the main course; the perks were the garnish.

Another member admitted that he felt uncomfortable about accepting payment, because of a possible appearance of bias:

> But I think in this case—but I accepted the compensation—maybe it would have been better if I hadn't. Because it never happened and there was never any suggestion that it might happen, but I think if you're on a committee like this, and you're actually being paid by the company, there is always the possibility of people saying… if you write an article saying "I very much approve of genetic testing" (which I do), then people might say "well, he's getting paid. Otherwise he wouldn't say this." So I have a general view that people shouldn't get paid, but nobody's ever asked me for the money back, so… [laughter].

The risk of the appearance of bias did not seem to bother any other board member, each of whom argued that they deserved to be paid for their time, just as they are at the university or medical center. A couple of members argued that it did not matter whether others saw the EPPB as credible, because the board was not a public entity. While the potential financial conflicts of interest are extremely problematic for many observers, those within industry dismiss this is as a "silly" concern: "a refusal by bioethics consultants to accept remuneration would frustrate the market's attempt to allocate resources toward important interests" (Donaldson 2001, 12).

External observers also point to confidentiality agreements as an issue of concern, one that highlights the deep chasm between the values of the university and the values of industry (see, e.g., Lewis *et al.* 2001; Krimsky 2003). However, within industry, confidentiality agreements are necessary to keep secret commercial secrets. Initially, executives at SmithKline Beecham attempted to impede my research, arguing that I would have to obtain formal approval[14] (from the legal counsel of a company that no longer existed, about a board that had been dissolved over a decade ago) – otherwise the board members would be in violation of their confidentiality agreements.

The board members themselves seemed to have a different understanding of the agreements. When asked if he signed a confidentiality agreement, one member told me:

> No. I'm pretty sure not. But I can't be absolutely sure. I certainly don't remember signing one. I would have had reservations about it… I certainly made plain that I was going to write about some of these issues. And I don't

[14] I did, with George Poste's help, obtain formal permission from legal counsel at GlaxoSmithKline.

> think I used any secrets. I don't think we were given any secrets. [Laughter] But I certainly would not have accepted any requirement to show the company what I had written before I published it. There was nothing like that, nobody even hinted at that.

Another said: "I don't remember, but I must have. I'm probably breaching confidentiality now, but I was never in possession of company secrets". Those board members who remembered signing a confidentiality agreement and seemed to take it more seriously tended to be those who had previously worked with or within industry. Board members who worked within academia pointed to a casual camaraderie within the committee – many of the members remain friends, the meetings were counted among their most intellectually engaging activities. Because of this (and because no one knew the EPPB existed), most board members did not worry about whether outsiders considered the EPPB to be credible or legitimate. And yet, they also downplayed the significance of the committee by repeatedly pointing out that they did not influence corporate decision-making, that the company did not let them in on company secrets.

Shapin draws our attention to *embodied* practices of securing and maintaining credibility – "How did who you were figure in assessing the worth of what you said?" (2010, 9). These embodied practices of securing credibility are particularly evident in the SB EPPB. Poste chose highly distinguished scholars to represent different perspectives.[15] Few executives beyond Poste engaged with the EPPB, therefore it is unclear how much, if anything, other SB executives knew about the members and their work. However, for Poste, these individuals gave

[15] Similarly, executives at Lilly chose one of the principal architects of the dominant bioethics theoretical framework (as well as one of the leading experts on clinical research ethics) as one of their core consultants; see chapter 4 for discussion.

their committees a sense of legitimacy.

Problem Space

Deliberative Style

SmithKline Beecham was embroiled in a gene patent controversy in the late 1990s. SB attempted to capture the testing market for one of the most common genetic diseases in the United States – hemochromatosis, a disorder that interferes with the body's ability to break down iron. The firm Mercator patented the gene for hemochromatosis, and then merged with Progenitor, which then licensed the patents to SmithKline Beecham Clinical Labs. SmithKline Beecham aggressively enforced their patent rights against clinical molecular diagnostic laboratories, raising the costs of testing significantly, which led to an estimated 30% fewer labs offering the tests than would have been the case had the genes not been patented (Merz et al. 2002).

Gene patents raise challenging ethical questions about ownership and access,[16] and were a topic of conversation at the Ethics and Public Policy Board meetings. However, members have no recollection of discussing this particular case or controversy. The EPPB did discuss patent policy. As one member recalls:

> We did talk about patent policy. And I remember some of us, myself included, were anxious to limit the scope of patents. And my own view was that they should make as much as possible available for research, particularly in the field of cancer, which is so traumatic and emotional. But they stressed to us the importance of getting money for research.

[16] A proper discussion of gene patents is beyond the scope of this dissertation. For thoughtful analyses of the political, technical and ethical challenges raised by gene patents, see, e.g., Parthasarathy (2005), Sunder Rajan (2008), Dickenson (2007), Andrews (2002).

Reflected in this member's comments is a clear line between the company ("they"; the insiders) and the committee ("us"; the outsiders). The committee was kept at arm's length from internal corporate decision-making, and was not kept abreast of controversies. The meetings were not an opportunity to help the executives or the scientists with particular ethical dilemmas, but rather an opportunity to explore much broader questions about ethics and science. At meetings, George Poste would raise a question or issue for discussion, an invited guest or a member of the board would make a presentation, and each member would provide input. It was almost like a seminar or a focus group – each member would give his opinion, and then they engaged in a group discussion.

It is possible that the EPPB was structured to not have any power with respect to corporate policy making because Poste and the other executives did not see themselves as needing any help. To them the EPPB may have been an interesting endeavor, but one that ultimately did not matter. However, at meetings, members of the board would challenge the scientists and executives, and ask them to defend certain positions. Based on the interviews, it seems as though the meetings were very much a back and forth between SB employees and the external board members. According to one member, "It was very interesting, as an industry outsider, to hear their positions". It was not the case that the company scientists presented the external members with a dilemma and asked them to debate the issue amongst themselves. Instead, the external members engaged the company executives and scientists on their positions, and vice versa. If there was a goal or intended outcome, it was to engage in thoughtful deliberation about the relationships between science and society, with a particular focus on the roles (and responsibilities) of the corporation.

Though Leon Kass, in all likelihood, had no knowledge of the SB Ethics and Public Policy Board, the purposes and mandates of the Kass-chaired President's Council on Bioethics and the EPPB were similar. In interviews, both Poste and Kass lamented the polemic conversations about complex ethical dilemmas, and sought a more fundamental, philosophical exploration of the scientific developments. As one EPPB member put it: "We were interested in 'the problem' rather than the company's problem. We were talking about the issue and leaving to the company the question, very often, of how they ought to respond". According to Kass, the charge of the President's Council on Bioethics was "enormously broad, both in spirit and scope, not narrowly political or policy driven" (Kass 2005, 223-4). The Council was "to undertake "fundamental inquiry into the human and moral significance of developments in biomedical and behavioral science and technology" (Bush 2001). Both Kass and Poste promoted a different view from that of an instrumental bioethics. Both committees enacted a deliberative model, not aiming for consensus, but for opening up the debate and respecting differences.

Some have argued that such an approach is unnecessary and wastes an opportunity to exert an influence and make policy recommendations (e.g., Cohen 2005). Ronald Green, the chair of the Ethics Advisory Board at Advanced Cell Technology, argues that ethics panels work best when they "stay close to urgent issues requiring thoughtful guidance". He was critical of the President's Council on Bioethics for looking at broader, more fictional topics; he argued they should not be doing broad philosophizing about scientific issues in government because the government is "in the business of policy, not philosophy". Green both advances a view of instrumental bioethics and erects boundaries around the work

of bioethics within different domains.

Kass was trying to lead by example, by demonstrating that politics and bioethics could be different. They were *politicizing* bioethics, but not necessarily in a negative sense. As Brown (2009a) describes, the PCB represents a kind of republican politicization. Kass, like Poste, was frustrated by the lack of a certain kind of ethical debate – in Poste's opinion, there was nowhere to engage these larger, more fundamental questions about the role of science in society, about the roles of industry, government and the university. Kass wanted to shift the political discussion around bioethical issues, to foster a more nuanced conversation. Kass and the PCB located bioethics expertise "in institutional mechanisms that mobilize a wide range of epistemic resources" (Brown 2009b, 48), whereas Poste relied on the professional capacities and achievements of individuals. But in both cases, the members task was to "present various social and professional perspectives on a given topic" (Brown 2009a, 49; Brown 2008).

As described in Chapter 1, the roles and responsibilities of bioethics councils are widely debated. Kass and Poste, however, charged their committees with the responsibility of expanding ethical perspectives and policy options (Kass 2005; Dodds and Thomson 2006; Brown 2009a). Their committees were not trying to achieve consensus, but trying to create a space to discuss difficult and highly controversial topics.

The EPPB Problem Space

George Poste's role within the EPPB was similar to the role of the chair of an institutional review board (IRB) or a hospital ethics committee: he was responsible for convening meetings, setting the agenda and leading discussion.

The IRB chair is the liaison between the IRB and the university research community; similarly, Poste was the liaison between the EPPB and the company. In each meeting, someone—an invited external guest, a member of the EPPB or an SB employee—would make a presentation to initiate the discussion. SB scientists would often come to present their work, and to engage in debates about the ethical implications of their work. The board members had to rely entirely on the executives and scientists to transmit information about the inner workings of the company. An executive or scientist would have to identify a potential problem, and then bring it to the committee for discussion. When asked about perceptions of transparency between the committee and the company, one member told me:

> I had no way of knowing because I knew only 5 or 6 people. And I have no way of judging. I don't recall ever thinking, "They're not telling the truth. They're telling a falsehood." I'm sure that didn't happen. I don't think George Poste would have sanctioned that. But I also remember not thinking we were getting the whole story. Because when it touched on research developments which were important commercially, then I'm confident we weren't being told.

While committee members could ask questions to gain more information, they could only discuss the ethical, social and policy implications of the scope and depth of the problem SB chose to share. However, most of the conversations were about broader issues concerning the role of science and society rather than specific research ethics dilemmas. Like hospital ethics committees (and unlike institutional review boards), the nature of the EPPB was advisory. So rather than stipulating the ethics of the design and implementation of their research and

development projects, the EPPB was reflecting on broader ethics and public policy issues, such as intellectual property policies, that affected or were related to the company's research and development.

According to both executives and committee members, the committee rarely, if ever, put forward specific advice and recommendations that changed or influenced decisions about the research agenda. It was not that the company ignored their recommendations, but rather, the board members were just not given enough information about specific corporate activities to advise SB how to proceed. Their conversations were more philosophical and deliberative in nature. George Poste, the chair and architect of the board, said, "Decisions about the specific technologies were less likely to be influenced by the committee. The committee was kept up to speed, but the deliberations focused more broadly on external debates". This body was formed to do something different from advising the company on the ethics of their research projects. Rather, it was designed to be a place where the company and the board members could wrestle with compounding complexities, because senior executives at SB believed that they had a responsibility to stay engaged in external debates. In an interview, George Poste argued that there is a "fundamental responsibility of all three branches"—the government, industry, and academia—to explore, in a comprehensive and balanced analysis, the ethics of macro trends in science and technology. Robust philosophical discussions about research and development were lacking, and EPPB would fill that need.

Poste's argument is a fascinating insight; he not only identifies a role for corporations in the governance of science and technology, but argues that it is a *fundamental responsibility* of corporations (as it is for universities and the

government) to engage in ethical analysis significantly and thoroughly. Government, academia and industry are the three "branches" responsible for science and technology. Each assumes a share of the responsibility for oversight of emerging technologies, and together they form a system of checks and balances. The three branches Poste describes are not the three branches of government, the press, public interest groups or independent regulatory agencies (or their scientific advisory committees (Jasanoff 1991)); instead he identifies a central role for industry in the governance of science and technology. In articulating the reasons why such a board was deemed necessary, Poste said, "Corporations have many responsibilities: nominally, to shareholders; to society; and to the workforce within the company. There are harsh market realities that impose themselves, but there is a deep social responsibility that cannot be ignored". Through the EPPB, Poste could explore that responsibility with a group of trusted external advisors.

When asked about their own motivations for joining the EPPB, members largely pointed to two key reasons. One reason for participating was the intellectual challenge. Each member remembered the experience as being a rewarding use of his time. The other reason was that they saw it as part of a duty to the public at large. According to one member, he saw his work with SB as a chance to fulfill a duty, which he characterized as follows:

> a duty to disseminate as widely as possible the knowledge and information I gain. I do a lot of radio and television. Serving on a commercial entity is part of the general obligation to use what I know for the public good. And commercial organizations are entitled to good advice.

This member emphasizes the importance of public education and public deliberation, and frames his work with the EPPB in terms of the public good. According to him, his work with EPPB benefits both public citizens (who, in all likelihood, did not know this scholar was working with corporations) as well as private industry.

This kind of imagined role is similar to that of the "bridge agent", proposed by Albert Dzur. Bridge agents, according to Dzur, are "people who can mediate between complex institutions and members of the lay public who lack hands-on knowledge of these institutions and the political issues related to them" (2010, 3). Ethicists who engage in problem-solving within professional domains such as a business firm have a ground-level focus on key social problems. As an intermediary between the individual and the corporation (or the individual and the state), the bioethicist can facilitate public understanding in a way that mobilizes and informs citizen participation. Drawing on work by Habermas and Dewey, Dzur emphasizes the importance of opening up opportunities for participation. Bioethicists, with their expertise and access to powerful institutions, have an opportunity to expand democratic engagement by transmitting knowledge from "micro" domains to the larger public – and, it is often micro domains that have macro implications. By participating in conversations with industry, the scholarship, teaching, and public lectures of the EPPB members were improved by a greater understanding of the pharmaceutical industry. The bridge agent role [17] as they conceived of it was more diffuse, though

[17] "Bridging" or boundary work is crucially important. This dissertation calls attention to the boundaries in and across which bioethicists work, as well as the blackboxing of particular ideas or work. This boundary work highlights uncertainties about roles and responsibilities, and notions of authority, legitimacy and credibility. These committees—private sector committees that

a few members emphasized that—when not bound by confidentiality restrictions—they shared what they had learned with students and members of the public.

Purposes and Benefits

The EPPB was a place for meaningful debate about controversial issues in science and technology and public policy. The corporate executives and scientists had an opportunity to share their research and positions, and the board members engaged them in discussion. That they may disagree at the end of the day or fail to provide the company with any clear guidance did not matter to the executives in charge. In an environment that is focused on deliverables and quantitatively measurable impacts, this committee had been given the freedom to not worry about deliverables. Members told me that they generally did not know how their advice was used, but stressed the value of the exchange itself, because the company and the members learned from one another. As one member put it: "If they thought it was worthwhile, that was good enough for me". The potential impact of the committee seemed to be in the hands of George Poste:

> Insofar as it helped form George Poste's views, it would have whatever influence he had within the company. I didn't have the sense that the other executives were waiting with baited breath for our comments… You got the sense though that George Poste really did this for his own interest. He had quite a lot of leeway as a senior executive, and they let him do what he wanted.

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deliberate about public values—engender forms of social and moral order and thus are critically important political sites. The emergent politics, publics, and problem spaces that come out of these boundaries deserve significantly more attention that I can offer at this time.

The committee existed because Poste had a particular interest in expanding the debates about science and ethics to include the role of industry. From the interviews, I collected no evidence that the EPPB had any measurable impact within SB. That might be wrong; there might have been many ways in which the presence of the EPPB influenced individual scientists and managers and corporate decision-making.

In interviews with the members of the committee,[18] however, it is unclear whether they knew the purpose or intended impact of the committee (as envisioned by the senior executives). One member told me that the board had "no purpose" and that it was structured as a "high powered seminar on topics within the intellectual interest of SmithKline Beecham". When asked to reflect on the role of the committee within the company, another member said:

> I think, at least I believe, that the company got most benefit out of the committee not out of the advice that the committee gave, but by being people of some standing… who wrote, talked and who got some sense of what the company was thinking on these matters. There was an exchange of views and I think that it was probably as important for us to get a sense of the company's attitude on certain questions. Not just their attitude, but their interest in certain questions, so that we – in talking to other people, in writing, in teaching – could reflect a more sophisticated industry viewpoint. **I think that there was, at least through George Poste, a positive effect through our coming to understand that they were not just**

[18] Because some members and staff gave me permission to use their name and others did not, I have anonymized the quotes throughout the case study. The only individual I quote with attribution is George Poste. I do so because he was the chief architect of the board and the most senior executive involved with the EPPB. Because the EPPB was his idea and his creation, his reflections of the committee and the work they did are especially important for this analysis.

> **interested in money, that they really were reflecting on some of these issues.**
>
> Now I have to say, I don't know what happened in the company. There were several people from the company at the meetings. I don't know whether policies changed. **The impact, I think I should stress, was two-way. We learned about their ideas and they learned about our ideas.**

This exchange of ideas, to engage in a balanced conversation about developments in science and technology, seems to have been what Poste was seeking. He was frustrated by "polarized conversations"; he wanted to discuss important legal, medical, ethical, religious concerns, but he also wanted the conversations to be "grounded in pragmatism". By pragmatism, Poste specifically meant that the conversations had to reflect real corporate and political restraints and limitations. Poste was also seeking to influence the board members' thinking. By demonstrating to a group of influential thought leaders that a pharmaceutical company was reflecting on ethically complex issues in a thoughtful way, he was trying to shift the discourse surrounding private corporations. However, one member speculated:

> It sometimes felt like they were trying to present themselves as a company that is very ethically responsible. SmithKlineBeecham and GlaxoSmithKline both have mixed records on ethics, but they clearly saw themselves as being ethical, having an ethical self-image.

This member articulates a worry about enablement, but it is a worry about enablement only with respect to the internal company conscience (and not corporate policies or research and development).

When SmithKline Beecham became GlaxoSmithKline, George Poste left the company, and the EPPB was disbanded.[19] The ethics committees at SB and Advanced Cell Technology were created because there was an individual at the executive level who thought it important that their organization engage and respond to ethical responsibilities to society more broadly.

One of the most interesting aspects of the EPPB at SB was that no one outside of the company knew about the committee. The SB executives had assembled a group of incredibly well-respected scholars in what was likely the first private sector bioethics committee – and never made public this initiative. For some members, this was an important condition to maintaining a kind of credibility or legitimacy; once it becomes a link on a website, the board is open to criticism of being only window-dressing. For one member, it was important that the board remained private as an indication that the company valued them as individuals and valued their advice:

> Window dressing also connects to propaganda, if they say look we have this ethics committee. A committee has to be sensitive to its being used in that way. And they shouldn't allow it. They shouldn't allow public statements that there is this committee.

Another board member gave the company credit for not publicizing the EPPB, but admitted that he "always thought they were missing a trick". His own position was that "you might as well make public such a high powered board because they had maybe the most high-powered ethics board that ever was". SB declined to make public the existence or activities of the EPPB. This member argued, "I think

[19] GlaxoSmithKline did start its own Ethics Advisory Board a few years later, with different individuals. The Chief Medical Officer was the chair of the board. He retired recently, and the ethics committee meetings have stopped.

it was actually to SmithKline Beecham's credit that they didn't make anything of it. It was very impressive that they didn't capitalize on it, even though they were in a position to be able to do so". Even when the members of the ethics committee suggested publicizing the EPPB, corporate executives declined to do so.

Scholars have shown that corporations influence policymaking by "capturing" the regulatory process (Stigler 1971; Dal Bó 2006) by lobbying bureaucrats and politicians; through this, they are then able to achieve regulatory decisions that work to their benefit (Olson 1965; Laffont and Tirole 1991). The EPPB's relationship with SB is the kind of relationship that raises concerns about "capture". The relationships are not transparent or visible; they are not open to external scrutiny. It is unclear why the SB did not make the EPPB visible, but if they had, it may have significantly shifted the politics of the relationships. There were no other private sector bioethics committees at the time, and no ethics committees that looked like the EPPB (i.e., focused on macro issues, not regulatory or advisory, etc). By not publicizing EPPB, SB did not have to defend the model or the work of the EPPB.

But it is an interesting question: Why did SB have an ethics committee that no one knew about and that was not designed to give recommendations? It seems that the Vice President of Research had an interest in gathering a group of incredibly smart people together to discuss complex ethical, social, and policy problems; and he had the relevant connections and resources to be able to do so. George Poste is himself deeply engaged in these debates; he gives many talks on the problems of "dual-use" technologies, and sits on the Monsanto Ethics Advisory Board. He argued, "There is a need, anytime you are driving forward, a 'fiduciary responsibility' to shareholders and a responsibility to see that

technology is used productively and avoid making crass errors". According to Poste, this board was a means of "fulfilling obligations to shareholders and to citizens at large," by trying to prevent "gross errors" in the research and development (and dissemination) of their technologies. One of the central questions for the EPPB concerned the relationship of the company with the wider world, and the ways in which that relationship changed. Through these meetings, the company and the board would be able to promote the "productive" use of technology. In other words, the EPPB gave them a forum to share how they foresaw the development, use and value of particular technologies.

In her study of interest groups, Jane Mansbridge (1992) argues that interest groups play a central role in deliberative processes because they provide lawmakers with information otherwise not available. They provide an institution through which members can deliberate and come to the best decisions for the polity as a whole. A pharmaceutical company does not have regular access to philosophical and theological insights about the ethical and social implications of their research programs. The EPPB gave SB access to new kinds of information, to help build their knowledge base (and, presumably, to help improve the decisions the company makes), and gives SB a place to ask questions, hear new positions and ideas, and engage different kinds of conversations. Do the EPPB deliberations contribute to SB decision-making structures or influence internal processes? According to Jasanoff, "civic epistemology" is the process by which knowledge is made in political communities, by which claims are deemed credible. It refers to the way "a nation's citizens come to know things in common" (2005, 9) and apply that knowledge toward political ends. Civic epistemology, according to Jasanoff, is "the institutionalized practices by which members of a

given society test knowledge claims used as a basis for collective choices" (*ibid.,* 255). Within the private sector, SmithKline Beecham, Advanced Cell Technology and Eli Lilly are using their ethics committees to order particular knowledge claims. These companies have created bioethics committees to help them evaluate the "credibility" of different normative claims, to guide their decision-making.

According to SB executives, the motivation for starting the Ethics and Public Policy Board was three-fold. One, it was to better inform the internal strategy and approach of the company. Second, executives wanted to try to critically assess the momentum and content of the debate in society. According to the VP Research, George Poste, "we didn't want to be insular… but wanted to be open and critical in our analysis—to have a sanity check. The main question was—are we interpreting the frameworks of debate correctly?" Finally, it would provide the executives with an opportunity to ask what approaches the company should pursue with regards to public policy. In other words, according to Poste, "the purpose of the board was to better informed as a company. So, (1) the board functioned as an intellectual driver, to raise new questions and explore ideas, and (2) to prevent errors and minimize blind spots. The idea was to try to make a sophisticated analysis of the landscape of views, with the fundamental question being "Is our way of seeing the world an accurate one?"

But what views were interesting or relevant to the company? In conversations with Poste, the object to which he seemed to refer was views in society – he wanted to better understand many different perspectives on topics such as genetically modified organisms, intellectual property, and genetic testing. However, the EPPB members contributed their own perspectives (as external

experts), rather than seek to represent a diversity of perspectives. According to Brown, a "genuinely inclusive deliberation depends on a capacity to imagine other people's perspectives" (2006, 219; Goodin 2003). Rather, the members offered their own expert opinion, and occasionally engaged other ideas. Recall the member who dismissed "extreme" views against human embryonic stem cell research. The members offered the company a "view from nowhere" expertise, rather than an assessment of stakeholder interests.

The EPPB was convened to determine whether SB executives were "interpreting the frameworks of debate correctly". The members clarified different positions, and helped draw attention to particular points of interest. The EPPB also played a role in prioritizing certain issues as legitimate topics for debate while dismissing others and privileging certain experts and types of evidence over others.

When asked how they judged the effectiveness of the EPPB, executives admitted that they had no metrics, no way to assess the impacts, though it is unclear whether "impacts" is the right metric. An analysis of deliberative democracy, for example, that focused on impacts would be too narrow. As noted in Chapter 1, assessment is also a difficult issue for public sector bodies. Why is there so little focus on the desired outcomes of any bioethics committee? Instead, it matters that the deliberation was done at all, more so than the result of that deliberation. Thus, the way in which the deliberations happen matters. Their aim was to balance multiple perspectives, and have, according to Poste, "pragmatic" conversations about the use of new technologies, it was not to shape the direction of research and development at SB. For Poste, the focus on pragmatism was meant to draw particular attention to the role of the private sector. What was

possible within and by a pharmaceutical company? In Poste's view, there could be no effective or worthwhile ethical decisions if the role of the private sector was ignored or poorly understood. In this particular space, a "pragmatic" approach was not about coming up with recommendations to solve problems, but instead was about achieving a better understanding of the problem, the actors, and the conflicting values and responsibilities.

The executives raised a few key questions that they used to evaluate EPPB:

- Were any obvious mistakes made?
- Did we, as a company, remain better informed with respect to the ethical, political and social implications? Did the company become more sophisticated in its understanding of social implications?
- Did SmithKline Beecham contribute productively to the evolution of public policy?

For SB, the EPPB was successful with respect to those criteria. In their opinion, no big mistakes made their way into the public domain during the EPPB tenure. They also argued the EPPB was beneficial for many executives and scientists, in that they could engage in meaningful conversations about the ethics of their research with world-renowned scholars. However, one might argue the EPPB followed what Evans has labeled "the new subordinate jurisdiction of bioethics to science/medicine" (which he uses to describe the Stanford Research Ethics Consultation Model developed by the Stanford Center for Bioethics). The program is explicitly "advisory and collaborative rather than having decision-making authority" (Cho *et al.* 2008, 8). Evans argues this model undermines the original role bioethics fought to achieve, which conceived of bioethicists as much-

needed outsiders who forced scientists to adhere to the public's values (Evans 2010). The Stanford program offers ethics advice on all issues in science and medicine not currently covered by clinical ethics committees or institutional review boards. This, according to Evans, "is essentially setting up an ethical mechanism for the residual field of all issues outside of the clinical ethical jurisdiction where there is no structural mechanism for public ethical input like an IRB" (2010, 130). However, in this model, scientists—not bioethicists or the public—get to make their own decisions about what is ethically appropriate.

The EPPB is a mechanism to address issues outside of the jurisdiction of clinical ethics, and it does not seek public input. Does the same critique apply? The EPPB was not giving advice to scientists in an advisory or regulatory role; but it did create a space for a debate that, according to Poste, had no obvious home (some of the issues normally fall under the jurisdiction of regulatory ethics, others were significantly broader). However, the members of the EPPB were not so much ceding decision-making authority to scientists (though, by agreeing to serve on a board with no clear mission or responsibilities, they were doing this); rather, the EPPB members used to opportunity to engage in dialogue with scientists *and* industry executives. The question of authority was never something that concerned EPPB, because the project was either unclear or just very unlike that of an IRB.

George Poste argued that the board did contribute to public policy, by drafting a white paper on biobanking that was then quoted in the House of Lords (Poste 2000; House of Lords 2000; DeVries & Turner 2009, 188). Poste released the paper in 1999; he is listed as the author of the paper, however his arguments may have been influenced by EPPB discussions, since he would have been

developing the ideas and drafting the paper while EPPB was still meeting. And finally, it's impossible to know whether the company developed intellectual rigor with respect to their own views on the ethical and social implications of emerging technologies. The hope was that the opportunity to engage in serious and pragmatic debate would be beneficial for anyone who wanted to attend (though probably not in a measurable way).

Conclusion

The SmithKline Beecham Ethics and Public Policy aimed to create a new space for conversations about the role of business in the ethical development and implementation of new technologies. The board members did not strive for consensus in their advice to the company, but engaged larger debates about controversial issues. The focus was explicitly on the roles and responsibilities of corporations to a diverse range of stakeholders. As will become evident in chapter 4, bioethics initiatives at Eli Lilly had a very different character.

Chapter 4

THE WATCHDOG: THE ETHICS ADVISORY BOARD AT ADVANCED CELL TECHNOLOGY

In stark contrast to the very private nature of the SmithKline Beecham Ethics and Public Policy Board, the Advanced Cell Technology's Ethics Advisory Board is the most visible, publicly known private sector bioethics entity. Advanced Cell Technology is a small biotechnology start-up. In order to attract investors, they have to work hard to get in the public eye, and the Ethics Advisory Board is a part of that strategy.

Because the EAB members have the "power of the pen" to write about the company if they deem the work unethical, they are essentially outsiders who can blow the whistle. This is a messy case where no one involved in setting it up knew how it was supposed to act, and there are conflicting evaluations of its value.

Background

Advanced Cell Technology is a small biotechnology company that specializes in the development of stem cell research for application in regenerative medicine. Their current research programs are producing retinal pigment epithelial cells for treating macular degeneration, myoblasts for treating heart failure, and hemangioblasts for treating blood disorders and cardiovascular disease. After many years of financial instability, they have secured FDA approvals for clinical trials to use human embryonic stem cells to treat age-related macular degeneration, and are partnering with UCLA and the Oregon Health and Science University. With the impending start of the new clinical trials and the appointment of a new interim CEO, ACT seems to be attempting to revise

their public image, through a more active use of social media and new videos that explain what ACT is doing and who the employees and collaborators are.[20]

Since their founding in 1994, the company has drawn repeated attention from the media and Congress. Their first significant controversy came in 1998, when they announced that they had created human cow hybrid cells. Very soon after the papers by Thomson and colleagues in *Nature* and Gearhart and colleagues in the *Proceedings of the National Academy of Sciences* described how they had isolated and cultured human stem cells and primordial germ cells (respectively), Advanced Cell Technology issued a press release announcing that they had developed a human-cow hybrid cell. A front-page article in *The New York Times* by Nicholas Wade appeared the same day, November 12th. Also on that day, the Biotechnology Industry Organization (BIO) released a statement asking President Clinton to direct the National Bioethics Advisory Commission (NBAC) to review all relevant ethical issues and to make recommendations on how best to address the implications (Meslin and Shapiro 2002).

On November 14th, 1998, President Clinton sent a letter to NBAC asking them to review the ACT experiment and the potential ethical implications at their next meeting and to report back as soon as possible. The scientific experiment that ACT had announced had not been published in any academic journal, and some questioned whether it was real. NBAC had a meeting scheduled in Miami the next week, and the agenda was changed to accommodate the President's request. Michael West, the CEO of Advanced Cell Technology at the time, paid his own way to the meeting, where he answered questions about the experiments. He argued that he publicized the research because it was unethical to keep it behind

[20] http://advancedcell.com/company/leadership-team/senior-executive-officers/

closed doors.

Relationships

Shortly after the NBAC hearings, West put together an Ethics Advisory Board. He denies that the reaction to the human-cow hybrid cell announcement motivated the formation of the EAB. During his tenure at Geron, West had created a bioethics committee, and was interested in replicating the model. He had already begun the process of identifying possible members, and solicited new members at one of the NBAC meetings. Michael West met Kenneth Goodman at the NBAC meetings, and invited him to join the EAB. The roster of the EAB has changed over the last decade, but the current and former members include:

Current members:

- Ronald M. Green, Ph.D., Professor of religion, Director of Dartmouth University's Ethics Institute
- Kenneth W. Goodman, Ph.D., founder of the University of Miami Forum for Bioethics and Philosophy, director of the Bioethics Program
- Carol A. Tauer, Ph.D., Professor of Philosophy Emerita at the College of St. Catherine, and Visiting Professor at the Center for Bioethics at the University of Minnesota
- Jeremy B.A. Green, Ph.D., Senior Lecturer at King's College London
- Judith Bernstein, RNC, MSN, Ph.D., Associate Professor of Maternal and Child Health, Boston University School of Public Health, and Associate Professor of Emergency Medicine, Boston University School of Medicine
- Robert Kaufmann, M.D., Dallas Fort Worth Fertility Associates

Former members:

- Ann Kiessling, Ph.D., director of the Bedford Stem Cell Research Foundation, associate professor of surgery at Harvard Medical School
- Susan R. Levin, MSW, counselor in private practice
- Susan L. Moss, JD, PhD, former administrator at University of Minnesota and San Diego State University
- Kier Olsen de Vries, M.A., Senior Editor at The Communication Initiative
- Glenn McGee, Ph.D., John B. Francis Chair in Bioethics, Center for Practical Bioethics, University of Kansas
- David Albertini, Ph.D., Professor of Molecular and Integrative Physiology, University of Kansas Medical Center

Despite the negative attention that the human-cow hybrid cell announcement drew, ACT continued to seek the spotlight. In 2000, they claimed to be the first to clone an endangered species – an Asian bovine known as a gaur (it died two days later due to an infection). They also claimed to have an agreement with the Spanish government to clone an extinct mountain goat, the burcado. Controversy surrounding their animal cloning research program put the newly formed Ethics Advisory Board into the public spotlight.

On July 13, 2001, McGee posted his resignation letter (dated October 30, 2000) on the Medical College of Wisconsin Bioethics Discussion forum. McGee argued the company had not notified him of its animal cloning program, ignored the board's work, and used the board to justify ACT's controversial research. When he resigned, he had never attended a meeting. However, that was not a fact that was made clear by either McGee or West in a Senate hearing in 2001. McGee

reported to the Senate subcommittee that he was invited to join the ethics advisory board of Advanced Cell Technology in August 1999 and resigned in October 2000. According to McGee, he resigned "reluctantly", for two reasons:

> First, I have concern over corporate decisions in stem cell research in particular not to share all of the information about ethically relevant activities in stem cell research with the ethics advisory board that is convened to help the company, or in due course to share the full amount of information available with the public so that public debate can be developed, and second, because I was concerned about what I viewed as the excessive pursuit of intellectual property in stem cell research.

McGee also argued that the members of the EAB were paid to approve ACT's research programs. McGee used most of his testimony to describe the problems with corporate ethics advisory boards, and identify a list of things the companies and the boards must do to be credible governance bodies, including holding open meetings, being fully funded, advancing bioethics discussion about emerging technologies early in the research and development stages, and being kept informed about the company's research activities. He was highly critical of corporate attempts at self-regulation through ethics advisory boards.

His public comments angered the other members of the board, who felt he purposefully damaged their credibility for his own personal gain. When West was called to testify at Senate hearings on stem cell research in July and August 2001, he argued that the chair of the EAB, Ronald Green, was aware of the animal cloning program. He apologized to McGee, but argued that he "felt that the cloning of an endangered animal was a humane and good use of technology, and it did not occur to me that that was a matter of urgent concern for our EAB, and

so we did not discuss it with every member of our EAB, and that was wrong." The animal cloning paper was also published before the EAB had its first meeting.

A year later, the remaining members of the EAB wrote a piece in the *Hastings Center Report* to correct misunderstandings and defend their work, and answer criticisms (1) that impartiality of board members is compromised by consultant fees, (2) about secrecy with respect to how much the company discloses about their research activities and with respect to confidentiality agreements, and (3) that the board's advice goes unheeded. In that piece, they report high levels of satisfaction with respect to their relationship with the scientists and executives at ACT, and cite an example of a scientist changing his research project (with "one of his most vigorous cell lines") after seeking their advice (Green *et al.* 2002, 31). They argued that during his nine-month tenure, McGee had not attended any meetings or participated in their deliberations about ACT's therapeutic cloning program.

The members of the board were clearly aware of their own public image and reputation. However, one member argued that being seen as credible was not important:

> My own view is I don't particularly care if the EAB at ACT is credible to the public because we are not acting on behalf of the public and we are not responsible to the public. It's quite different if I'm on a government committee. [At ACT,] I don't really care if I'm credible to the public. I think we need to be credible to the people at ACT, so they take our advice seriously and follow our recommendations – to the extent that they can and they accept them.

This member argued that their responsibilities are to the company, and insofar as the company deems their work credible, it matters little what external observers think. This member draws stark boundaries between the public and the private sector, and understands there to be significantly different responsibilities in each realm. This stands in contrast to the views of some EAB members, who believe fervently that the public needs access to therapies developed from stem cell research and their work with the EAB will help achieve that goal because, at the very least, the EAB can try to prevent or resolve ethical controversies that may unnecessarily delay the research.

Almost none of the bioethics committee members interviewed (from SmithKline Beecham, Hoffman LaRoche, Geron, Eli Lilly, and Advanced Cell Technology) saw themselves as representing or representative of the public. However, according to one of the members of Geron's Ethics Advisory Board, Laurie Zoloth, a private sector bioethics committee can be worthwhile and effective *only* if each member sees his or herself as representative of and responsible to the public. She argues that the validity of the private sector body depends significantly on whether the members see themselves as having a fiduciary responsibility to the shareholders (personal communication, 2009). A private sector ethics body can be "done right" if the members are prepared to leave at any point and if they are prepared to make public their disagreements.

The members of the EAB are not paid. In the very beginning, the EAB members made a decision to accept the National Institutes of Health *per diem* rate, of $200 a day, plus travel expenses. Some members do accept the *per diem*, while others request to be reimbursed only for travel. However, according to some members, the company was slow to even reimburse travel sometimes.

Members were forgiving of this, pointing to ACT's financial difficulties:

> The company theoretically pays the *per diem*, but they don't pay it to me. Several of us have declined to be paid, so we could say honestly that we're not paid. And even when they paid the others, they often didn't pay them. It took months… The company has been like this: they get an infusion of $10 million from a private investor, and then we can meet.

With the significant controversies about payment and ethics consultation, EAB members seemed to want to place almost no importance on money. They were emphatic that money was not the reason they do this work – and indeed, it could not be the reason they do this work. The members of the board made this decision not to accept payment before the board began working. One member offers the following justification:

> I can't see any reason why people who have ethics advice or expertise ought not to be paid for it. I just happened to, in the current environment, had made a decision that I am trying to stick to. I have given talks for companies, I have flown here and there and I had accepted the honorarium but the consulting thing has been so abused by some of our colleagues that since I have said critical things about it, I want to be able to say, even though it's not a prescription or analogous, it allows me to say with a reasonably with clear conscience that I am unfettered in that way.

A member who does request the *per diem* rate argued that $200 is very unlikely to affect one's judgment: "With the kind of minimal amounts they're going to give us, I can't believe that would affect anyone's judgment. If you can be bought for that, you're pretty cheap!" This member pointed to groups like the American College of Obstetricians and Gynecologists, who had to raise their compensation

rates to $1,000 to attract the kind of people they wanted as consultants – and still had difficulty finding scholars and clinicians who were interested in participating.

Freedom from financial conflict of interest was important for the members of the EAB. They spent a significant amount of time debating the issue of payment. However, that does not mean they are free of any bias or conflict of interest. Some members were reflective of their biases. As one member explained:

> I would say that I came to this *a priori* with a bias, and the bias was in favor of the mission of the company to make this technology go forward. Certainly at the time and even now, it's very hard, it's extremely hard, for the technology to go forward in the public sector in the way that I certainly think it should. I think it's very important technology and can be done properly and can be ethical. So I came to it with all of those prejudices. So I feel in that sense, I'm not being biased by any kind of remuneration or reward, in that sense, material.

Each member is deeply invested in the prospect of stem cell based treatments for disease. Thus, they are quite motivated to help the research move forward, with as few problems as possible.

At SmithKline Beecham, the members of the EPPB were there because they found the group interesting, and they enjoyed the conversations. At Advanced Cell Technology, the motivations of the EAB members are different. They all expressed an interest in the intellectual challenge of participating, but some of the EAB members also feel strongly that participating in the ACT EAB is *the right thing to do*. They believe strongly that stem cell research will yield treatments that will cure millions of debilitating diseases, and to make sure the

research progresses, it must be done ethically. Thus, their role is to design appropriate safety and ethical guidelines to ensure the research is not open to attacks on any grounds other than scientific validity. They thus function as "lobbyists" in Lewens' taxonomy.

This bias in favor of stem cell research means that the members are already more accepting of this particular kind of potentially controversial research. Some critics argue that this is evidence that companies can buy whatever ethics advice they are looking for (DeVries 2004). Indeed, they use a quotation from Michael West to argue in favor of their position. In Stephen Hall's book *Merchants of Immortality* West is quoted as arguing that there are no ground rules when it comes to putting together the right ethics panel, rather "it all depends on who you pick" (West quoted in Hall 2003). However, members of the EAB argued that there was no "litmus test" for joining the committee. One member argued that "very well selected people who are supportive of ethically appropriate industry" are necessary for a functional and effective advisory board. Another member drew an analogy to Animal Care and Use Committees:

> There are people who completely and utterly oppose the use of animals in research, any kind of research. So you wouldn't want one of that on your Animal Care and Use Committee, which are required by federal regulations to review the research… [I]f someone believes animal research is inherently unethical you wouldn't want them to be on your committee because there is no way they can contribute to it in a positive way. It's a fundamental fulcrum, for that is a go/no-go position and you can't. If someone opposed human subjects research, if someone opposed organ transplantation, you can't put them on a transplant advisory board. There

must some agreement up to some point. **We don't oppose stem cell research in principle, we don't oppose animal research in principle, you don't oppose something or other in principle, *thereafter* we can disagree a great deal**.

The board exists to help a company that is specifically focused on conducting human embryonic stem cell research move that research forward in an ethical and responsible way. They must all agree from the beginning that, in principle, stem cell research is acceptable. According to one member, the board was put together based on the following reasoning: "We just didn't want to get into arguments about whether you could use embryos. But whether it was appropriate to use this many embryos, we wanted viewpoints that would be cautionary". From that one starting point, there can be many disagreements that follow.

However, robust debates require a diversity of viewpoints. The EAB has a diversity of expertise: its members have been nursing professionals, doctors, and social workers who work in the assisted reproduction field, scientific researchers in virology, developmental biology and reproductive endocrinology, philosophers, bioethicists, lawyers, and science writers. As one member put it: "We had a good series of expertises on all the dimensions of research ethics. We really needed all those expertises". While they have some diversity in terms of gender, there is little to no racial or ethnic diversity. And some members seek to have a greater diversity of viewpoints represented. They were trying to recruit more members, including someone who could speak from a religious perspective, but they have had difficulty attracting new members. The SB EPPB had many individual experts from a variety of fields and backgrounds, and ACT's EAB focused on getting representation from all the relevant expert institutions.

West brought this group of people together to create a group that closely monitored the company's activities. The board was advisory, but had a regulatory function. According to Michael West, the board could not have legal authority or veto power, but they could have the "power of the pen." West claims he wanted an EAB with veto authority, to keep the company from making gross ethical errors:

> I told my attorneys and my board I wanted to form an EAB and they advised me it would be illegal, or a breach of fiduciary duty or something. Not to have an EAB, but to give them veto power over a research program. I wanted to give them that. Why not? If there's something wrong with what we're doing, we shouldn't be doing it! I'm sorry, I know different people have different views about ethics, but **if a majority on an EAB thinks we shouldn't be doing this, there are other things to do.** I believe it was our attorney who said, "you're a private company, which might be public at sometime, but as a private company you have shareholders and your fiduciary duty is to your shareholders and you can't say superseding that is an EAB." So what I settled on is, what we can do is give an EAB advisory capacity, of course, and power of the pen. So what we can agree to, is that they can sit in on meetings, they can see everything going on in the company, nothing is withheld if they want to see it… But short of any proprietary data – and most ethicists don't care about what concentration of calcium you're using – so I don't even think that was a problem. **But short of that scientific confidential information, what the company was doing, the nature of the programs, they were free to talk about in any way they want** and

> if they disagreed with any of it, they could write an article in the *New York Times* and denounce the company**. And I thought that's good enough,** especially if you're a public company, **that's incredible power.**

The confidentiality agreements each member signed prevents them from sharing any proprietary information, which everyone seemed to understand as simply small technical details, but the members have the freedom to write about the company and their experience with the company. If any member has a grievance against the company, they may write and speak about it in a public forum. The "power of the pen" gives the members of the EAB a *regulatory* role by way of an advisory role.

Problem Space

Michael West did not have a particular model in mind when he formed the EAB at Advanced Cell Technology. (When asked if he created the EAB to be like any other bioethics committee, he said, "No, I don't have any knowledge of any other. We didn't follow any pattern, and we haven't compared them. Are there any others?") Geron had created an ethics board around the time Michael West left to move to Advanced Cell Technology.[21] At ACT, West turned control of

[21] According to West, he started setting up Geron's ethics advisory board after attending meetings with the Graduate Theological Union at UC Berkeley, in 1994. According to other accounts, Thomas Okarma, the head of Geron's stem cell research program, approached members of Stanford's Center for Biomedical Ethics and Berkeley's Graduate Theological Union to participate in 1997 (see, e.g., Eaton 2004). West left Geron in 1998 and never attended an ethics meeting. But he takes credit for Geron's EAB:

> "I actually got a call from Ron Eastman who was then running Geron and he thanked me, which I thought was a classy thing to do. He called me up and said "Mike, I want to thank you for setting up the ES cell program because it created a lot of value for Geron, and for doing that EAB. We

the EAB over to the chair, Ron Green, who organized the board meetings, decided on the structure, and chose a couple of the members. Green said the committee members drew on their experience as IRB members at their home institutions, but also went beyond that model:

> Michael West decided he needed an ethics committee, he never used the word IRB. We never thought of it as principally research oriented. We thought of it as novel research, like putting human material into cow eggs, which never came up initially, because that was not the direction they went in. They went in the direction of human eggs. The cow egg thing raised issues that would have been truly EAB/ESCRO type issues. IRB is human subjects, consents from donors. An EAB would look closely at the question of "should we really be fostering the use of bovine to create hybrid cells?"

Green draws a link between the EAB and ESCRO committees (Embryonic Stem Cell Research Oversight Committees). In a 2005 report, the National Academies recommended all research institutions conducting human embryonic stem cell research have an ESCRO committee to manage the myriad ethical and legal concerns. The guidelines are "intended to enhance the integrity of privately funded hES cell research" (NRC 2005, 1). The Ethics Advisory Board was set up to do the work of an ESCRO committee before the latter existed.

According to official minutes, the stated purpose and aim of the Ethics Advisory Board was to function like an institutional review board, to review the

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> shined that day". Because the day the papers were published, they put online all the proceedings of their [ethics committee] meetings and all the guidelines they had proposed for embryonic stem cell research – the same day. So it looked like they really had their act together".

proposed research programs and to identify ethical problems and challenges. The minutes of the first meeting of the EAB begin as follows:

> Advanced Cell Technology Ethics Advisory Board Minutes. August 28, 2000. Meeting at Hyatt Harborside Hotel at Boston Logan Airport. Present: Ron Green, David Albertini, Judith Bernstein, Ken Goodman, Rob Kaufmann, Susan Levin. Non-members: Kier Olsen de Vries, Michael West. Absent: Glenn McGee.
>
> *The aims and powers of the Ethics Advisory Board*[22]:
>
> At issue this meeting is how to ethically optimize a research study proposed by ACT that involves the activation of human eggs by means of nuclear transfer, with the resulting production of autologous, immunologically compatible stem cell lines for individuals. It is hoped that such cell lines could be utilized to treat persons with diseases such as type I diabetes. Because ACT is a private corporation with no relevant ties to a university, Michael West has appointed this EAB to conduct the kinds of inquiry and to set forth the kinds of guidelines typically under the purview of an IRB. At this juncture, the EAB's oversight is broad, the membership fluid. The purpose of this first meeting is to identify issues associated with the research where further review is necessary as well as to clarify those issues that are in need of immediate attention.

The IRB regulations provided a very basic framework that members could as a starting point; from that point, they could then expand their ethical analysis in scope and depth, as appropriate.

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[22] No one could remember exactly who wrote this, but they speculated it was most likely written by Ronald Green, in consultation with Michael West.

Some members were quite adamant that the EAB was not an institutional review board (IRB). One member emphasized that an IRB is required by federal regulations and has to follow specific guidelines. Another member argued that the two are not comparable because the scope of topics the ACT EAB deals with are much broader: "Our scope is whatever it is they want to ask or whatever it is we want to opine about". However, despite clear differences, the two bodies are similar in form and function. In terms of membership, an IRB must have at least five members who are independent from the research process, with varying expertise, attitudes and backgrounds. The EAB has a fluid membership of academic philosophers and ethicists, developmental biologists, and clinicians. Members who were there from the beginning told me they used the IRB as a model when building the EAB. But, they made changes, and saw it as an evolving entity. Over the years it has more closely resembled something like the IRB, and at other times it has been significantly different, because the range of topics they addressed was much more broad. The EAB discussed not just research protocols involving human subjects, but also research protocols involving animals, public policy questions, and intellectual property concerns. One member who joined the committee later argued that the board was more focused on the "strategic than the tactical" and therefore could not be compared to an IRB in any meaningful way.

An IRB is situated at the local level to be more familiar with the conditions surrounding human subjects research at particular institutions (Bulger *et al.* 1995). The EAB is part of Advanced Cell Technology, and is familiar with the scientists, the executives, and the mission of the company. Of course, the EAB does not have to follow any particular guidelines, and it does not have to

keep detailed records of its actions. ACT's funding is by no means dependent on the existence or work of the EAB, in the same way a university researcher requires IRB approval to use federal research funds for human subjects research. However, the EAB at ACT does review the research protocols, and seems to look at generally the same basic areas the IRB does: risks, informed consent, equity, privacy, vulnerable subjects, and incentives (National Commission 1976). In an article in the *Hastings Center Report*, the members of the EAB describe developing the informed consent process for egg donors, in which they considered what payment counts as an undue incentive, the risks of the procedures, the vulnerability of potential donors, and the equitable selection of participants. ACT's legal counsel objected to the consent process proposed by the EAB because "research by a private company like ACT does not come under federal human subjects guidelines" (Green *et al.* 2002, 30). The members of the EAB fought for their consent forms and process—and thus fought to have an IRB-like function—because, as they argue, "this feature of federal research regulations expresses an important ethical insight and has to be applied even in the private context" (*ibid.*).[23] The EAB imported important parts of federal research regulations into the private sphere based on a belief that these regulations expressed universal values and norms.

The EAB originally had a "community member", Kier Olsen de Vries, but decided not to fill the position after she left. Their reasoning about the community member position offers some insight about the way they were structuring the committee. Michael West gave Ronald Green complete control

[23] This specific dispute was about a request from legal counsel to add an explicit waiver of rights to any commercial benefits of the research. Language regarding waivers of rights in informed consent documents is explicitly prohibited by federal human subjects regulations.

over the committee, and Green and the other original members had to decide what this committee should look like. Reflecting on the changing structure of the board, one member told me:

> We were making it up as we went along, I mean some of the stuff that we have decided to do and recommend was based on what precedents there were in the IRB and the idea of the community member or for that matter the clinical ethics committee – the Joint Commission thinks that ethics committees should have a community member as well. We figured, okay that sounds reasonable. It pries it open a little bit. You know you have to be careful because of the terminology – it might give you credit for something you don't deserve. Community member is one person and by the way how do you represent a community without election. So I don't want to overstate it but it was just a good faith attempt to pry open the process a little bit.

The members drew on their experiences on federal advisory bodies, clinical ethics committees, stem cell research oversight committees, animal care committees, and institutional review boards when deciding how the EAB should function.

An IRB has significant authority – it has the force of law. When the IRB asks for changes to the design of a research study, researchers must comply with the recommendations in order to proceed. Michael West wanted to build an EAB to have a similar function:

> The function would be to have checks and balances… [B]ecause I predicted we would be entering a controversial area of biotech, I thought 'look, this ethics board would help make sure we don't thoughtlessly misstep. **You know, it's easy when you're trying to develop a therapeutic to just**

make a mistake, but not intentionally. I don't mean by what you say, but by what you do. It's hard for me to think of any examples, but I didn't actually have any examples in mind I guess. I was just thinking, **let's just have someone look over our shoulder and catch us before we made a mistake**. But I didn't even know what that mistake would be and I still don't know. **It just seemed like a wise thing to do.**

In this model, the ethics consultant or advisory board would have to have full information about the company's research and development activities.

Public/ity Problems

Later in 2001, shortly after the Senate hearings on stem cell research, Advanced Cell Technology was at the center of controversy again, for a paper published in *e-biomed* that claims they had produced the first cloned human embryo. This research attracted significant media attention – there were prominent pieces in *U.S. News and World Report* and *Scientific American* and Michael West appeared on 'Meet the Press' on November 25, 2001. However, the research itself was highly preliminary and critics said the experiment was a failure, as the most advanced embryo had divided to just 6 cells in 5 days (normal cells generally divide 50 to 100 times in 6 days). Three prominent editors resigned from the editorial board in protest of the publication of the paper. On December 4, 2001, both Michael West and Ronald Green testified at a Senate Appropriations hearing on cloning. They both argued that there is a significant difference between reproductive and therapeutic cloning,[24] and that therapeutic

[24] In this context, the terms "reproductive cloning" and "therapeutic cloning" refer to the same process – of somatic cell nuclear transfer – but different ends. In somatic cell nuclear transfer, the nucleus of a donor cell is transferred to an

cloning (or nuclear transfer) was justified based on its potential for producing life-saving treatments. Speaking on behalf of the EAB, Green argued that having an open and public discussion about ACT's research may reduce the chances that someone will pursue reproductive cloning, because the research shows that cloned human organisms are physiologically fragile. However, banning therapeutic cloning, in their opinion, is not an effective way to prohibit reproductive cloning. Green reiterated that the EAB endorsed the research, "with careful consideration" (Prepared statement, 2001).

When asked about reputation of ACT as a controversial organization that seeks media attention, one member initially denied that ACT had such a reputation (or that it was deserved), before admitting that it may be accurate:

> I mean, recently the main press they've gotten is for the clinical trials of the retinal cells. But, perhaps previously, yes. But I think the reason for courting the press was not just because they wanted a lot of publicity, I think it was because they needed money. They were trying to get people interested in investing in them, so they had to show them they were doing something different that would lead to some really good outcomes. I don't think it's because people wanted to become famous, I think it's that it was a very small company – it still is a very small company – and I think they were trying to make people aware of it and what they were doing in hopes of interesting people in investing.

ACT is a small biotech start-up that must attract investors. It is to their advantage to seek media attention so they remain visible. They seek publicity because it

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egg (whose nucleus has been removed); that egg is then treated with chemicals or an electric current to stimulate cell division. For reproductive cloning, the cloned embryo would then be implanted into a uterus. In therapeutic cloning, the cloned embryo would be harvested for stem cells for use in research.

helps increase their profitability.

Purposes and Benefits

Starting from a mutual agreement that human embryonic stem cell research was in theory important was critical because it helped develop a trust between the scientists and the ethicists. One member argued that the EAB could have an impact only because the ethicists were also interested in seeing the research produce treatments:

> Over time, the mutual trust led to a stance of guidance and conversation rather than cover or protection. I think it led much more to: 'We're with you, we think this important, but there are things you just can't do.' When we said 'you cannot do this', they did not do it.

Because the scientists did not feel threatened, they were open to engaging with the external ethics advisors. A few of the members described instances in which the EAB made a recommendation and the company complied, by changing their research design or delaying the research in order to make sure all the appropriate ethical safeguards were in place. West claims the company delayed their research for 18 months as the EAB designed the consent process for egg donation. When asked why the company and scientists tolerated such delays, West replied:

> Well, [the EAB members] all agreed that it was very valuable research. They weren't dragging their feet because they thought we shouldn't be doing this. They wanted it done perfectly. I think Ron and everyone recognized this was the type of thing that would be scrutinized in the future. I think we all assumed it would be scrutinized more than it was. We were assuming there would be Congressional hearings, and they would want to open up the

> minutes and depose the members. We assumed that everything we did would be scrutinized. So they were quite keen to make this their life's best ethics work. So it took time, as you might expect. But, right. The Glenn McGee nonsense, the delays… a lot of my colleagues said I was just being silly. There's no law that says you have to have an ethics committee.

The company's willingness to take their advice seriously justified the EAB members' participation on the board. As one member explained, "we justified it based on this: they are doing it anyway. We can actually be useful here. If there needs to be a break, we found that they will actually slow stuff up. We had a great sense of satisfaction that they listened to us on issues of consent and issues of IRB approval". The EAB members had a strong sense that they had a positive and significant impact within the company.

But the examples of the company stopping a line of research or delaying the start of a new study all come from earlier in the board's tenure. According one member, there is not a deep trust between the company executives and scientists and the ethics board members. When the EAB is consulted, it actually is brought in very late:

> Well, I would say one of the flaws is the way… and a slightly more dubious aspect of the committee as a whole… that we received information at a point where it was usually a *fait accompli*, in terms of the kinds of science. **By and large, I would say in all cases to date, there wasn't an ethical issue involved. But had there been an ethical issue involved, we wouldn't have been in on the ground floor. I mean, it was definitely clear, that information was kept to the point where we maybe got a head start on the public, but a very tiny,**

> **tiny head start. In that sense, we were not quite as privileged or trusted as the rubric kind of implied, that we knew everything that was going on well in advance. We did not and do not.** We know broadly where they're going. But we're not given the details of what projects are ongoing, and typically what happens is that in the agenda materials, we get sent a manuscript that's either in press or about to be submitted. Which is pretty late in the game when it comes to doing science.

Whereas scientists previously discussed scientific study ideas with the EAB before the study began, the scientists now only share the study with the EAB after it is finished. This signals a significant change in the EAB, and in the relationship between ACT and its EAB. It is also highly problematic considering the following reflection from one of the members about why ACT needed an ethics advisory board:

> I think they could not have identified the ethical issues on their own. I think that scientists being scientists, holding strong ethical views on certain things, are often opaque to the issues, and don't see the issues. I love working with scientists and I have the greatest respect for them, but they are technicians, who have a technical problem to solve and often want to get that problem solved and don't want to look back.

As mentioned, the members feel strongly that they are valued, that they have a beneficial impact. They can call a meeting whenever they want to have a meeting, but often wait until ACT initiates the meeting. They need ACT to share information about their new research projects. And so, there is a fundamental tension – they see themselves as necessary to the company because they don't

think the scientists could identify the ethical issues on their own, but they usually don't meet unless ACT thinks a meeting is necessary. And they meet significantly less frequently when the company is in financial difficulty.

But the members do not feel ignored or used: "[The scientists and executives] respected the EAB in the sense of seeing that we were not a group to ignore. We were a resource, but we were also a warning. Which I think is exactly the right role." They repeatedly emphasized that they were there to help the research move forward *cautiously*. Part of what makes the experience satisfying and worthwhile for the ethicists is the mutual trust they have developed with the scientists. Michael West recalled a couple instances when he delayed the research to wait for the EAB to come up with new guidelines. The executives and scientists in the past have slowed or halted the research because the EAB has asked them to, and the EAB trusts them to do so again, as necessary. However, it is unclear whether the new leadership has been or will be similarly disposed.

Evolving Roles and Responsibilities

At both SmithKline Beecham and Advanced Cell Technology, the ethics committees were conceived and enacted by one key executive. (This was not the case at Eli Lilly, as discussed in the next chapter.) At SB, the VP of research, George Poste, chose the individuals, organized the meetings, and acted as the bridge between the EPPB and SmithKline Beecham. At Advanced Cell Technology, the former CEO, Michael West, identified the need for an ethics committee, chose certain individuals to sit on the EAB, and gave them significant power within the company. Both SB and ACT had strong individuals at the executive level who thought it important that their organizations engage and

respond to ethical responsibilities to society more broadly. But the degree to which the ethics committee was integrated into the company's activities differed—at SmithKline Beecham, the EPPB was designed to be decoupled from the main activities and individuals at the corporation, whereas at Advanced Cell Technology, the EAB was much more integrated into the research program. When the key actors left their respective organizations, the ethics committees were either decoupled from the company's decision-making processes, as was the case at ACT, or disbanded completely, as was the case after SmithKline Beecham became GlaxoSmithKline.

Ethics programs that are *integrated* affect everyday decisions and actions, and the individuals occupying these integrated structures have the confidence of and regular interaction with other departments and managers, whereas ethics programs that are *decoupled* are marginalized from decision-making processes (Weaver, Trevino and Cochran 1999). According to management scholars Weaver, Trevino and Cochran, "an easily decoupled structure or policy provides the appearance of conformity to external expectations while making it easy to insulate much of the organization from those expectations. Although the structure or policy exists, there is no guarantee that it will regularly interact with other organizational policies and functions or that employees will be accountable to it" (1999, 541). Decoupled structures could, with attention and proper support, have an impact within the organization, but are often de-emphasized because they conflict with other institutional goals. "Theory suggests that external pressures for social performance encourage easily decoupled processes, but that top management commitments encourage both easily decoupled and integrated processes" (*ibid*., 539). Thus, the kind of ethics program that emerges is a

reflection of both external influences and the senior management's commitment to ethics.

The EPPB at SmithKline Beecham was a decoupled structure. They had no influence on decision-making with respect to the scientific research programs, though they may have had some influence with respect to policy goals. The EPPB was designed to be a place where informed and intelligent conversations took place, both for the benefit of the board members and for the benefit of the executives and scientists who chose to participate. The VP of Research wanted to influence the board members – not to agree with him or approve the research of SB, but to influence them to consider the role of industry in bioethics governance. The EAB, on the other hand, was an integrated structure in the beginning. The board had significant authority within the company, and was able to convince the executives and the scientists to delay, halt, or alter their research protocols when the EAB perceived a problem. However, when the management changed and as the company struggled financially, the EAB seemed to become more of a decoupled structure.[25] The role of an EAB member, according to one member, is nominally to give ethical advice to guide the company's actions, but "in practice, there are actually very few real ethical decisions that we actually have to make". Members report meeting more infrequently, being left out of key public communication about the research, and being informed about the research only after the projects were completed.

The Public Nature of Private Talks

Interestingly, some of the members expressed dismay that they were not more deeply connected with media relations. They argue that many of the

[25] William Caldwell, former CEO, and Robert Lanza, Chief Scientific Officer, both refused to participate in this research project.

controversies raised by ACT's research announcements could have been avoided if they had been in charge of the press releases. As one member argued:

> The worst problem we had with this company was that they would go off and do things without telling us, in the press frequently. **We didn't really play a role of vetting press communications. That was I think our single greatest error as a body.** In our role as providing guidance, we should have been in the loop for all the papers and all the press reports coming out… This is not an ethical question—it's not should they do this research, we approved the research. But then they went ahead and publicized some feature of that without first coming back to us and repeatedly got in trouble. The leading example being the Specter hearings, when Nature went ahead in that August publication and produced a press release about the article. The article made clear that those embryos were destroyed in the experiment, but the press release said they have been able to produce stem cells without destroying embryos. And Doerflinger jumped on the press release, which came out of Nature's press department. **We should have seen every one of these documents on sensitive work, they should have come before the EAB. I would give that advice to anyone doing similar work—the EAB should be the final stop in all major ethically charged communications. And we were not.** And every time they got into trouble it was because of that.

There is a deep tension that emerges here between the roles of watchdogs and communicators. The EAB is an entity that occupies the boundary between public and private sectors – they serve a private company that has an interest in

attracting media attention, but the members serve because they are interested in promoting the ethical development of stem cell therapies (which they think would be beneficial for the public). By arguing that they ought to be involved in communication to the press, the EAB members are claiming *new roles* for bioethics.

It is not the case, however, that bioethicists are necessarily the best people to communicate with the public. In Senate hearings in September 2006, Senator Specter made this point, by focusing on a statement to the media by Ronald Green, which he deemed deliberately misleading and dishonest. In his opening remarks, Senator Arlen Specter said:

> Dr. Green is quoted in the Washington Post as saying, "You can honestly say this stem cell line is from an embryo that was in no way harmed or destroyed." We are going to be asking you, Dr. Green, how you can honestly say that or if that was an honest statement.

After Robert Lanza, the vice president of Advanced Cell Technology, gave his presentation and answered questions, Ronald Green gave his statement. Before he could read his prepared statement, however, Senator Specter drilled Green about his statement to the journalist.[26] Green argued that it was a remark taken

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[26] Green's testimony began with the following exchange:
Dr. Green: Let me address that initially immediately. That was an elliptical remark taken out of context. The journalist I believe is actually here today, and the question –
Senator Specter: What's an elliptical remark, doctor?
Green: Well, it was part of my quotation, sir. It was part of my quotation. The full quotation was something to the effect – and I don't have the recording of it – something to the effect, if a stem cell line were produced using this method, then you could honestly say that. That was the full quote.

Sir, I read the paper. I knew that 16 embryos were eviscerated and that's the reality. Five or six cells were taken from each embryo, which is incompatible with that embryo going on to full survival. I would never personally as an ethicist have misrepresented that.

out of context in an interview over the phone, but Senator Specter seemed dissatisfied with this explanation. The entire hearing was very tense. It was the second time Ronald Green had been called to testify before the Senate about the work of Advanced Cell Technology.

But the members of the EAB wanted their work to be public. They wrote articles and opinion pieces in major publications and included the EAB as one of their affiliations, their pictures are on the ACT website, and they sometimes speak openly with the media. Members of the EAB argue that they had the "power of the pen" to write about problems, if they were in serious disagreement with the way the company decided to move forward with a research program, and that this was important to hold the company accountable and to prove that they were more than a public relations strategy. In contrast, the EPPB was never publicized. EPPB members worried that making their names and work public would diminish the board to window-dressing or a public relations ploy. This points to an interesting challenge in terms of transparency and accountability. Members of the EPPB valued the secrecy to maintain their own credibility, but the secrecy means that their work is unavailable to evaluation. In an interview, Michael West reflected on how a private sector ethics committee might come to be seen as credible from external observers:

> I don't have the answers, but my recommendation was always that there be a website and the minutes be public. Not every e-mail, but the activities

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Specter: Do you have the full quotation of which you say this is an elliptical extract?
Green: I'm willing under oath, sir, to say that I believe that the full quotation was something to the – was to the effect –
Specter: Answer my question. Do you have the full quotation that you say this is an elliptical extract?
Green: Sir, I was interviewed on the telephone. I was speaking to a journalist. He asked me a question.

should be public – run past the management to make sure that there isn't any scientific data that isn't unnecessarily included. I always thought it should be public. I don't know… did ACT do that? There was talk about it.

Interestingly, the minutes from the EAB meetings are not publicly available, and other than an occasional op-ed piece, the members have not written or spoken publicly about their work with ACT for over 5 years.

Evaluating Effectiveness

In an interview, Michael West expressed frustration about the criticisms of the EAB, but defended both the idea and the incarnation:

> I like EABs. The problems are time. As an executive, you don't have time to get the work done you need to get done. I'm taking the time to talk to you, I've got all these urgent things I should be doing right now. But why do I do it? For the same reason I set up an EAB. We have to take time, carve out time, to reflect on what we're doing and why and how we ought to be doing things… I would recommend that people do it because it's just part of being human, and there's an ethical dimension to life – or there should be. **In business, we need to take time to force ourselves to reflect on what we do. The downside is the time, and the upside is purely the human dimension of being in business.** Anyone who would set up an EAB as a publicity stunt or as a publicity move or to look good in that regard or to look better on paper, I think that's foolish. I would argue it generally goes the other way. If you set up an EAB, people will assume there's something ethically problematic in what you do. If you're doing it for PR or to cover up some unethical activity, I think the

> last thing you want to do is set up an EAB. When I got criticized by my colleagues, they didn't care about ethics, and they had the instinct to know if you're guilty of something the last thing you want to do is draw attention to it. So I think it's counterintuitive. I think that the only reason, the benefit, is the human dimension. You know what I mean by that, right? We want to feel good about what we do and we want to do the right things in our lives. The downside is that it takes time and can draw unnecessary controversy. As I said, there was actually a Senate hearing to address my EAB at ACT and how I was a scoundrel and how I didn't listen to them. It doesn't pay. There's no benefit other than knowing you did the right thing and sleeping well at night.

For West, the benefit of having an ethics committee is creating a space to discuss the ethical, political, social dimensions of the scientific work. It is the "right" thing to do. Having an ethics advisory board is a significant time commitment, which makes it an unappealing venture to many small biotechnology companies that have limited resources.

Is that the reason that ACT has an EAB? What is the motivation for ACT to have an ethics board? They were forced to answer allegations, before a Senate committee, that their ethics board was merely a group of paid consultants who serve more of a public relations function than anything remotely substantive. One of the members argued:

> I don't think that for ACT that we're window dressing at all. I think sincerely, from the very beginning, Michael West certainly had a deep interest in ethics and spiritual things in general, and he has written on that – in a New Age type way. He certainly was deeply interested in ethical

> issues I don't see it as window dressing at all – they wouldn't have to have us at all, they could just go ahead. They would need their IRB when they're doing human subjects research, but they don't need us.

This is an important point—no company needs to have a bioethics committee, so why have one? As West notes, having a bioethics committee draws *more* attention and skepticism, not less. The role is not cover, as one member notes, but is to help the company avoid serious ethical mistakes: "I don't really see it as cover, because that didn't function too well. If anything, just the opposite". This member saw the committee as playing both protection and guidance roles for the company, but the protection dimension came from the mutual interest in seeing the technology develop. The roles evolve with the needs of the company. The board members trust the scientists to pay attention to their ethics advice as the company changes and as the scientific projects progress.

As the roles and responsibilities shift, it may become difficult for board members to judge their effectiveness within the organization. When asked how we may judge the impact of these kinds of boards, one of the members said:

> I have no idea how to assess or evaluate these ethical processes or committees. One reason: ACT EAB helps ethically optimize the research; two, you are seen as having an interest in these things. Are you doing it to be seen as having an interest? I don't know their motivations, but I think that they actually wanted the advice.

Another member relayed that the board was a "very self-conscious" board, one that frequently questioned their place in the company and their own effectiveness. This may indicate that they received little feedback from the

company about their work and did indeed worry about their perceived credibility and legitimacy.

Conclusion

As discussed in Chapter 2, one of the few ways private sector bioethics is evaluated and criticized is through money and financial conflicts of interest. With the EAB, financial conflicts of interest are such a minor (even non-existent) dimension of the problems around Advanced Cell Technology. The members of the Ethics Advisory Board at Advanced Cell Technology argue that they have no incentive to stay other than an interest in seeing the research produce therapies. And yet, the EAB are not disinterested observers – they are deeply invested in the company and its work because of a belief in the potential of stem cell therapies. As the evidence demonstrates, the idea of what a conflict of interest is or can be is getting remade as bioethics is dislocated to new spaces.

EAB members have the "power of the pen" to make public their disagreements with the company. However, if they do not have access to information about the company's research activities, they will have little to write about. The EAB represents an interesting challenge to the usual criticisms of private sector bioethics consultation, and challenges us to think more broadly about the nature of conflicts of interest and what it means to have transparency in relationships between industry and bioethics.

Chapter 5

BUREAUCRATIC BIOETHICS: THE BIOETHICS COMMITTEE AND BIOETHICS NETWORK AT ELI LILLY

Unlike the bioethics committees at SmithKline Beecham and Advanced Cell Technology, most of the members of the Eli Lilly committee are internal employees. The Lilly Bioethics Committee is the most bureaucratic, the least political, and the most controversial. The expansion of the bioethics jurisdictional space is reproduced within Eli Lilly, led by the principal architects of principlism.

The new field of bioethics was embraced, at least partly, because it promised to provide a space for morally neutral, apolitical discourse (Englehardt 2002). But many have criticized bioethics for trying to remain morally neutral and apolitical, rather than engaging in serious normative critiques of science and medicine. Principlism, a morally neutral and apolitical theoretical framework, has been widely criticized over the years for assuming that "there is a single, correct solution for each ethical problem, which is largely independent of person, place or time" (Bosk 2008, 16; Bosk 1999). It remains, however, one of the most popular methods of bioethics. John Evans notes that its popularity stems in part from its ease of use – it offers the "lure of calculability and predictability" of a "formally rational" system of accounting (Evans 2000, 32).

The Bioethics Program at Eli Lilly is the most bureaucratic of the three cases. As described by Weber's principles of bureaucracy, there are regular activities, distributed in fixed ways as official duties (e.g., the full-time internal bioethicists charged with overseeing the Bioethics Program); authority is determined in a stable way, determined by rules (the Tiered Consultation Service); there are methodological provisions for fulfillment (only those who have

"ethics competency" are chosen to serve on the Bioethics Committee); and management is "based upon written documents" (the Principles of Medical Research and official Ethics Position Papers). Finally, the Bioethics Program "follows general rules, which are more or less stable, more or less exhaustive, and which can be learned" (Weber quoted in Birkland 2010, 111; Hyde and Shafritz 2008). The Lilly Bioethics Program is the most carefully implemented of the three cases and management at Lilly is making a significant effort to evaluate what the program is actually doing within the corporation.

Background

In 1996, the *Wall Street Journal* published a front-page article about homeless persons recruited by Eli Lilly to participate in Phase I clinical trials (Cohen 1996). The reporters had interviewed twelve men who had participated in clinical trials at Eli Lilly; all 12 were homeless and admitted to drinking heavily immediately before and after the trials. The article garnered significant attention and provoked a response that was deeply critical of Eli Lilly and their clinical trial practices. The criticism was compounded by the fact that the FDA had previously rebuked Eli Lilly in 1994 for recruiting alcoholics in their clinical trials.

In the wake of the scandal, Bruce Jennings, an Associate at the Hastings Center, sent a project proposal to Eli Lilly that said the Hastings Center researchers would be interested in studying the ethical issues of vulnerable and homeless research subjects. Eli Lilly was, at the time, a contributor to the Hastings Center, a non-profit think tank that relies on donations and grant funding for subsistence. If the Hastings Center were responsible for the project, it could have covered a great breadth, as part of a more general study of the ethics

of human subjects research. Jennings speculates that Lilly preferred to focus solely on their operations (and, perhaps, to avoid inviting comparison with other companies), and thus, rather than award a grant to the Hastings Center, they hired four individual consultants—Bruce Jennings, Tom Beauchamp, Eleanor Kenny, and Robert Levine—to conduct an investigation of Eli Lilly's clinical trial procedures and practices, and make any appropriate recommendations. According to Tom Beauchamp, this external consultation was necessary because "Eli Lilly had never thought about legal and moral protection in terms of research subjects. They didn't know the people were homeless, and they didn't know about bioethics." The four academic bioethicists compiled empirical data on a couple of trips to Indianapolis, interviewing the trial site staff, doctors and researchers, Phase I trial volunteers, nurses, Indiana University IRB members and staff, and organizations that represent and offer aid to the homeless population of Indianapolis (such as the Salvation Army, clergy, food banks, and shelters), and wrote an 80 page report to submit to Eli Lilly.

They published a shorter version of the report in the *Journal of Medicine and Philosophy* (Beauchamp *et al.* 2002), in which they argued that there is no ethical justification for a categorical exclusion of homeless persons from clinical trials. The publication of this article was negotiated before the authors began their consulting work with Eli Lilly:[27]

> The deal we made with them was that we would be free to publish our opinions on this topic once we had studied it in the context of their own operation and also based upon our own research. And we would not be

[27] There were more negotiations while the authors were drafting the paper for publication to satisfy Lilly's concerns about confidentiality and proprietary information.

> prevented from speaking publicly on the topic. In return for that, we promised that in the public article that we wrote, we would not make direct reference or get into details about Lilly's particular operation.

In exchange, they owed Lilly a proprietary report that included an analysis of what the clinical trial sites were doing wrong, how those errors should be corrected, and general recommendations about Lilly's clinical trial operations.[28] The authors argue that Lilly was accommodating and provided the information that would help them assess the problem:

> You have to be an adult about this and you would have to not be naïve. I think it is in the nature of corporations to resist transparency. But that said, I was very favorably impressed with their forthcomingness. I mean after all, they invited us in. We were coming in from the outside investigating them. They gave us full cooperation. They arranged all these interviews. Now you might say well they handpicked the people that we spoke with, and to a certain extent that is true. They did make the arrangement. We did not. A number of the people we spoke with were quite critical of some aspects of what was being done. They were not exactly hand-picked cheerleaders.

Even so, the report concluded that recruiting homeless persons as participants in clinical trials was not in and of itself unethical (Beauchamp *et al.* 2002).

Their paper is often cited as an example of pharmaceutical companies buying the kind of ethics advice they want (see, e.g., De Vries 2004; Elliott 2005). Tom Beauchamp defends the paper, and notes that the authors received very little feedback about or engagement with their argument from the bioethics

[28] There was no follow-up from Eli Lilly about the report or whether they implemented any of the recommendations.

community. The authors argued that their interviews with groups such as the Salvation Army convinced them that the freedom to participate in clinical trials was important for self-determination and autonomy because it gave the homeless a chance to earn a wage. Bruce Jennings, however, defended the argument, but pointed out how he might write it differently now, in light of new information about the clinical trial system: "If there is a limitation to the article that I now see, I think the article was really assuming a very good background system of human subjects research". (The authors did empirical research at the clinical trial sites, so it was either the case that the authors did not think about systemic problems in human subjects research because they were focused solely on trials run by Lilly in Indianapolis, or they could not draw on their empirical data for the paper due to confidentiality concerns.) In the report submitted to Eli Lilly, they did suggest new initiatives that Lilly could undertake to improve the quality of life for clinical trial participants (such as mental health and addiction counseling, job search training, and educational programs), but Lilly did not follow those suggestions.[29]

Shortly after that report was submitted to the company, Eli Lilly contacted Tom Beauchamp and Robert Levine to invite them to be regular consultants, and to serve on their newly formed bioethics committee, the Lilly Bioethics Committee (BEC). According to one of the external consultants:

> They wanted the integrity of their research to be intact and they wanted to feel they were taking the moral high ground rather than just criticizing the *Wall Street Journal* for taking the moral low ground, and they felt the best way to do that was to establish a bioethics committee that had external consultants.

[29] Though perhaps disappointing, this is understandable as such initiatives are not the responsibility of a pharmaceutical company.

And so, in 1999, Eli Lilly, the 10th largest pharmaceutical company in the world, became one of only a few pharmaceutical companies to have a bioethics committee. The membership of the committee has been fluid, but the members have always been senior leaders from various functional areas within and outside the Research & Development division (including medical, regulatory, patient safety, discovery research, legal, corporate affairs, international government affairs, and global brand development teams), as well as the two academic bioethicists. The role of the bioethics committee is to provide consultation and advice to R&D teams on specific bioethical issues and questions. An individual or an R&D team can request a bioethics consultation.

Relationships

Over the last several years, there has been an effort within the Research & Development division to expand the reach of the Bioethics Committee, and to create a more systematic bioethics initiative. According to the Lilly website, their goal is to create a "dedicated and systematic program in bioethics to identify, evaluate, and communicate bioethics issues related to pharmaceutical research and development activities".[30] The bioethics program is part of the Lilly Research Laboratories, and is overseen by the Chief Medical Officer; in addition to the BEC there is now also a Bioethics Network (BEN). The focus of the BEC is all aspects of R&D activities, with a primary emphasis on clinical research. The company has designed the committee with the aim that it "identifies and tracks developing bioethics issues, serves as an educational resource, consults on specific issues, develops company positions on specific bioethical issues, and informs global

[30] Website for the Eli Lilly bioethics program: http://lilly.com/responsibility/business/bioethics/default.html

policies". The Bioethics Network is an educational and communication initiative to increase interest and involvement in bioethics activities throughout the company.

Lilly Bioethics Committee

According to senior executives, prior to 2008 the BEC met irregularly – sometimes monthly, sometimes quarterly – and the initial enthusiasm had waned significantly. When Tim Garnett became the Chief Medical Officer in 2008, he inherited the position as chair of the BEC:

> [The BEC] had started off, I think, quite effectively, but over a course of time, it ceased to be quite as impactful. It was not meeting quite as readily and I think that I realized that if you are going to have an ethics committee that is affecting an organization of this size, it cannot be something that is on top of the rest of your role. If you are going to be the chair of that committee, you need to be able to dedicate a significant amount of time to it. And I realized as I was moving into my role that that was going to be a challenge for me – although I think on first principles, you probably would say it is the Chief Medical Officer is the person we would like to be the chair. Just taking on that new role, I knew that I was not going to be able to reinvigorate it the way that it needed to be so I asked Don Therasse [the VP of Global Patient Safety, to be chair].

According to Garnett, acting as chair of the BEC was not just an extra job on top of Don Therasse's responsibilities as VP of Global Safety, but "a clearly defined role within his responsibilities". It was Therasse's job to reinvigorate the bioethics committee. He wanted to put more resources behind the committee, to build

expertise and to follow-up on ethics consultations. Therasse hired Luann Van Campen as a full-time bioethicist. Van Campen had worked with Eli Lilly for ten years, in Scientific Communications, and had a PhD in Hearing Science and a MA in Bioethics. She is the Executive Secretary for the BEC, and she is Head of the Bioethics Program at Eli Lilly. One year later, she hired another scientific writer at Eli Lilly, Mitch Klopfenstein, as a Senior Bioethics Associate.

Bioethics Network

In addition to the Bioethics Committee, Lilly is also building a Bioethics Network (BEN) within the company. When Luann Van Campen became the head of the Bioethics Program, she searched the websites of other pharmaceutical and biotechnology companies to see whether and how others in the industry were integrating bioethics into the corporation. During the benchmarking process, she discovered the bioethics network at Novartis:

> The thing that really stood out for me, at least from what I could tell, is they have one full-time person. And then they say they have a network of hundreds of people. It did not explain what the network is or what they do. It just said the one sentence. And got me thinking, "If we could develop a network, what would that look like? And, what do we want that to be for us?"

Currently, the BEN at Lilly is an informal "grassroots" network of individuals who attend monthly seminars and lectures that are advertised mostly by word of mouth. According to Van Campen and Klopfenstein, there are about 55-60 people who are part of the network. Those involved with the Bioethics Program seek to have bioethics "fully integrated into decision-making at every level of

research". Van Campen sees the BEN as a crucial way of achieving that integration:

> We were thinking if we could develop a network of people that are (1) interested in bioethics, and (2) committed to their own education, then they can be little representatives around the company like little Johnny Appleseeds. The idea is if they become agile in bioethics and can influence their work area, then bioethics is going out. On the flip side, I cannot know what all is going on. So they can be bringing back what they see as issues to us so we know what is going on in the company and we can hopefully deal with it. That is the vision – to get a cohort of people that are agile in bioethics.

In order to monitor whether this is happening, Klopfenstein is soliciting feedback from those who attend the lectures. Lecture attendees are self-selected individuals from many different teams within Lilly. According to the surveys returned, not only do those who participate find it interesting, but "a number of people have given concrete examples how they have been able to use what they have learned or heard about in our sessions and apply it directly to their job".

The resources devoted to the Bioethics Program are relatively small at the moment. There are only two bioethics associates, and everyone else involved is volunteering their time – either to participate in the Bioethics Network activities or to sit on the Bioethics Committee. Repeatedly, the two bioethics associates stressed that the program was new, that they were only two people (in a very large company), and that every activity was still in a pilot phase. The Bioethics Committee has operated for over ten years, and that was a point of pride within the company. However, they were deeply reluctant to discuss the impact of the

BEC in its first 8-10 years, and were hesitant to discuss its current impact. Their focus is on getting to a point where they can be very proactive in identifying and responding to ethical concerns.

Collegiality and Criticism

Critics of private sector bioethics argue that the employees of a company are always biased to think favorably of their employer, and this bias (and the priority of the profit-seeking motive within the corporation) will prevent any ethics initiative from being effective. Van Campen recognizes the bias, but thinks the structure of Lilly's Bioethics Program is important to reducing the impact of that bias:

> To be perfectly honest, I think anytime you're in an organization and you feel committed to it, you're going to have a bias, you just put that on the table – there it is. But I think the way we're structured makes it conducive to being independent. Because we don't serve on any teams. You saw where we sit – we're an island.[31] You know, I know what's going on, what research we're doing, what's in the pipeline, but I'm not married to the success of that drug.

Van Campen argued that an important measurement of how others value the BEC is the kinds of questions that the BEC receives. When the BEC is asked the "more fundamental 'whether' questions" instead of questions about 'how' a team should conduct their research that is an indication that the BEC is taken seriously

[31] The two bioethicists sit in a bay of cubicles in the oldest part of the Eli Lilly building, close to the offices of both the VP of Global Patient Safety and the Chief Medical Officer. The cubicles are small and beige, the conference room next door is small and brown and contains nothing but a large table, chairs and a white board. The space for bioethics and global patient safety stands in striking contrast to the marble and steel lobby with vaulted ceilings and enormous windows.

by its peers, and it gives the BEC an opportunity to have a significant influence within the company.

Those involved with the Bioethics Program have drawn particular boundaries to make sense of their position within the company. The Bioethics Program is independent in the sense that they are not a part of any particular research team at Lilly, but they are not independent of Lilly Research Laboratories as a whole. Neither are they independent of the company. While Van Campen may not be "married" to the success of a particular drug, she is, in a sense, invested in the success of the company (and thus, many different drugs). It may, however, be the lack of independence that gives the Bioethics Program some influence. As members of the company, they are privy to confidential information that may help them better understand a particular ethical dilemma and evaluate what changes are possible. Their insider status may allow them to be more influential in convincing researchers and managers to make changes, because they are all part of Lilly.

The external consultants admit that they are biased to think favorably of Lilly, by virtue of the personal relationships they have established over the last decade. For Tom Beauchamp, the argument that there is an inherent conflict of interest when you work for a company is "predicated on the idea that money changes everything, but the real problem is bias." According to Beauchamp, "I think I'm a **purely objective ethics consultant** within Eli Lilly, but I'm biased to think favorably of the company." This is an intriguing remark, in which Beauchamp assumes a "view from nowhere". But then he argues that critics such as Carl Elliott damage their arguments because they cannot admit their own bias

against particular pharmaceutical companies.[32] This argument is a shift away from the "view from nowhere" to a more pluralistic perspective in which both he and Elliott are stakeholders and their views are different but equal. Beauchamp argues both that he is purely objective and also that being open about the bias is important to engaging in constructive debate.

According to Robert Levine, it is in Lilly's best interest that he is as critical as he can be, because that will help them improve and thrive. Bruce Jennings argued that he judges his effectiveness as a consultant "first and foremost by the rigor and the substantive quality of the advice given. As a consultant or as a bioethicist, I am not sure how much it is our responsibility to try to influence their practices apart from making the most persuasive, clearest arguments that we can make".

Neither of the external ethics consultants is concerned about appearances of credibility of the BEC, in part because they don't see how they can do anything to change appearances: "If we have critics, what do we do? No matter what we do, we won't be taken seriously. It might do more harm, therefore generally [the drug companies] don't do anything". Therasse believes that some external engagement is necessary to building the ethics program internally. It would be a valuable contribution to publish case studies (constructed from consultation requests) for educational purposes, and pursuing such scholarly endeavors is critical to the growth of the Bioethics Program. As Luann Van Campen notes, "we, the industry, or at least Lilly, have a certain expertise at this that we have not shared. So we are not sharing what we have learned, then neither are we learning from what other people have done". The Benchside Consultations at Stanford, the

BEC consultations at Lilly, and the NIH research ethics consultations can all potentially be improved if the groups shared their experiences, Van Campen argues: "How does that differ from what we are doing? Could that help us be more efficient? Or, could something that we are doing help them be more efficient? Right now, if you are not collaborating, you cannot learn from each other".

As mentioned earlier, one of the main reasons Lilly has not pursued these kinds of partnerships, collaborations or scholarly initiatives is a concern about confidential information. It is unclear what the future will hold in this regard, but it is at least imaginable that eventually historical case studies and analyses will be produced, once the risk of surrendering trade secrets has passed.

Problem Space

At the American Society for Bioethics and Humanities Annual General Meeting in October 2010, Luann Van Campen and Mitch Klopfenstein presented a poster describing the Bioethics Program and the Bioethics Committee. An individual or a team within research and development may submit a request for an ethics consultation. (They are encouraged to first address ethical issues by consulting Lilly's "(a) bioethics framework and/or position papers, (b) standards, policies, procedures, and (c) leaders and colleagues" (Van Campen *et al.* 2010).) The individual or team sends an inquiry to the Lilly bioethics consultant (Luann Van Campen), and the consultant then "triages" the request to the appropriate tier for consultation. The tiers are described as follows (Van Campen *et al.* 2010):

Tier 1 – Abridged consultation with internal bioethics consultant and chair of BEC. This kind of consultation occurs as needed, and is designed for less complex inquiries.

Tier 2 – Full consultation with Internal BEC.

This kind of consultation occurs monthly, and is designed to respond to inquiries that are broad in scope and/or require the input of cross-functional leadership.

Tier 3 – Comprehensive consultation with Internal BEC and external consultants.

This kind of consultation occurs quarterly, and responds to inquiries that are particularly complex, require external perspective, and/or have global or broad business impact. The external consultants ensure that advice is based on high level of expertise and relevant to issues that arise in research ethics.

The advice from the BEC is not binding; the committee is advisory in function. This is a benefit, acccording to Therasse, because it makes it easier for individuals to submit a request: "It is done in a way that is, and I think people recognize as, non-threatening because it is not governance, it is advisory. But also, on the other hand, you do not generally not take the advice of the Ethics Committee and feel good about that, you know".[33] By virtue of it being an "ethics" committee, the BEC has an authority within the company. A senior research scientist who serves on the BEC echoed this observation:

> I think that the buy-in is also helped by the fact that this is it is an advisory committee but it provides a way for if somebody on a team was

[33] The contrast he seems to be seeking is advisory versus regulatory. I would argue the Lilly Bioethics Committee *is* governance. It has a governing role in that it sets policies for the company, and they are replicating structures and conversations that are familiar within bioethics governance.

> uncomfortable with something or concerns approach they can say "well we ought to take it to bioethics committee and let's get their input on it." The bioethics committee then essentially becomes more of an impartial arbiter on this, which can be helpful in certain situations.

He argued that the BEC tries to articulate the "gray area" when they give advice, and strive to balance theoretical knowledge with a pragmatic approach. The problems are incredibly complicated, and the BEC must provide advice the teams can implement.

According to their analysis, the new Tiered Consultation Process resulted in an increased number of consultations, and decreased the number of days it took to respond to consultations. In the year since Luann Van Campen designed the Tiered Consultation Process, thirteen consults were solved in Tier 1, which allowed internal and external members of the BEC to focus on the more complex cases. Van Campen came up with idea after searching different pharmaceutical companies' websites to see whether and how they were integrating bioethics into their corporate activities. She found that Roche had a tiered consultation service: "It is different, but it is similar. I liked the idea that there could be levels of expertise that would be available to people".

Therasse sought to gain more feedback about the ethics consultations and how (if at all) the advice was used. Since the Tiered Consultation Process was implemented, Lilly has been keeping a record of the kinds of requests, the advice given, and the response from those who requested the consultation. They found that the most frequent areas for consultation were questions about stem cells, risk/safety, and informed consent. Post-consultation, they send a survey to people who requested bioethics advice. However, they have only a very small data

set – of the 18 people who received a survey, only 5 responded (all five indicated that their experience with the BEC was positive, their needs were met and the advice was implemented). For those who are involved in responding to consultation requests or who have used the service, the tiered consultation process seems to be a positive development. According to the ASBH presentation, "the tiered consultation approach provides an appropriate level of advice and maximally utilizes Lilly's internal and external resources" (Van Campen *et al.* 2010). The authors of the poster were quick to note, however, that a full evaluation is premature.

Constructed Boundaries

The jurisdictional space of the Bioethics Program is complicated, and necessarily and deliberately limits the impact of the BEC. The Bioethics Program at Eli Lilly addresses issues related to pharmaceutical research and development activities. In other words, and according to the Lilly Bioethics Committee members, it is located only within the research division of the company, and is unrelated to the business division. However, bioethics is a corporate strategy – through their position papers, they aim to set company policy, to shape business strategies. The BEC and the BEN are resources for the Lilly Research Laboratories. While the Bioethics Program may interface with the Ethics and Compliance group (which is located in the business division), they argue the two groups work on separate issues. The different work of these two groups is the result of the different ways the firm itself must interface with legal and regulatory requirements. While the Bioethics Program is free to experiment and figure out how it fits within Lilly, the Ethics and Compliance group is responsible for

ensuring that Lilly complies with all relevant laws and statutes. Don Therasse argues that they "do not have the expertise or the time" to collaborate with the business division on larger issues. The BEC was originally set up to address the problem highlighted by the article in the *Wall Street Journal*, and thus is focused on human subjects research ethics issues.

Lilly recently received (what was at the time) the largest criminal fine in U.S. history for off-label promotion of their anti-psychotic drug, Zyprexa. At the time of the fine, the BEC had existed for almost a decade. In light of the recent serious ethical violations, the credibility of the Lilly Bioethics Program is seriously compromised. And Lilly is unwilling to say whether corporate policies have changed significantly following revisions of position papers such as the one on Compassionate Use. Garnett admits that Lilly has a serious credibility challenge right now, and must address the crossover between the science and commercial arenas. For those in charge of the Bioethics Program, there are too many issues to look at within Lilly Research Laboratories, and the program activities must focus attention there. A senior research scientist argued that, in the face of such criticism, Lilly ought to pursue research that they believe will be of maximum benefit: "Hopefully by pursuing something that has a maximum opportunity that helps most people and may be beneficial is for us to ethically have a corporate conscience on these things, which is what I think a bioethics committee ends up being".

In an initial interview, Tom Beauchamp was adamant that an external ethics consultant should work only with the research science groups, and not with the marketing or public relations groups. When pressed to explain in a second interview, Beauchamp argued:

> In principle, there is an absolute firewall between the research and marketing departments. From my perspective, that's unfortunate because most of the ethical conflicts are about marketing. But we can't bring them into the conversation.

A significant number of controversies about the pharmaceutical industry are the result of business decisions – prohibitive pricing and deliberately overcharging state health care programs, direct-to-consumer marketing, drug representatives and their relationships with physicians, and off-label promotion. But the research division is also responsible for many ethically controversial practices, too, such as clinical trial recruitment, bias in experimental design, and incomplete data reporting. There are some practices, such as ghostwriting, which challenge this clear demarcation, in that they are both marketing strategies (e.g., getting an influential medical doctor to sign his name to a research paper that reports favorable research results for a particular drug) and serious research ethics infractions (e.g., dishonesty in authorship and a lack of integrity in reporting research data). External observers often do not distinguish between the research and business divisions of a pharmaceutical company. Therasse, Van Campen, and Garnett clearly delineated a boundary within which the BEC can and should work, though they are aware that external observers do not recognize that boundary. For the corporation's own normative assessment of efficacy, drawing clear boundaries is incredibly useful. But if observers do not see or acknowledge the importance of a difference, what are the implications for the credibility and the potential impact of the Bioethics Committee?

Purposes and Benefits

Expanding the Reach

According to Luann Van Campen, the Bioethics Program has five different kinds of activities they are currently developing: (1) write and revise position papers (e.g., Stem Cell Research, Pediatric Drug Development, Human Biological Samples) and the Principles of Medical Research (which, according to the website, is "an overarching statement about how and why Lilly conducts research, its relationship to researchers, and how it shares research and development results"); (2) increase communication both internally and externally; (3) ethics consultations; (4) educational initiatives; and (5) scholarly endeavors. The BEC is involved with most of the activities, and offers advice on the program as a whole. However, the committee has little to do with communication about the program, and the Bioethics Network is responsible for the educational initiatives. For the VP of Global Patient Safety, Don Therasse, the goals of the Bioethics Program are to develop the position papers and build up the internal consultation service, and then engage with external observers and different kinds of groups:

> What we would like to do, since I think we are approaching this a little bit differently than others have been, is to participate externally both in scholarly endeavors, but also to inform the external environment that we are actually doing things like this. And pharmaceutical companies can and should be doing things like this. So there is a bit of a presence that we want to be able to establish externally in terms of participation as well as making people aware of what it is that we do. **We have been doing it quite a while so I think we also may have some things that people could learn from us that we have been doing that frankly some of the**

> **academic centers have not been doing yet.** So those are our main kind of goals but the real mandate for Lilly Research Laboratories is for us to be proactively identifying these issues that are important. Identifying sort of a perspective that is unique to the sponsor and then creating these positions and communicating them as they relate to our role in the research enterprise as a sponsor.

Participating in scholarly endeavors is one of the key components of the Bioethics Program at Eli Lilly, with the particular goal of sharing the unique knowledge from the pharmaceutical industry. The poster presentation at the 2010 American Society for Bioethics and Humanities (ASBH) meeting was an initial step toward that goal. When pressed on the kinds of scholarly initiatives they are interested in pursuing, Van Campen pointed to the empirical data on their 2010 ASBH poster as an example of something they would like to expand upon. "I do not think that we are in a position yet to be normative, we have too much to learn. I would love that eventually the industry would be more cohesive on this". While Lilly employees express an eagerness to expand their bioethics activities, there is a hesitancy to share what they have done or to expand (too) quickly. Like George Poste at SmithKline Beecham, the Lilly group is also interested in drawing attention to the unique role of the corporation.

According to Therasse, a valuable goal for the Bioethics Program is to clearly articulate how Eli Lilly, a large pharmaceutical company, views and approaches key bioethics issues. The position papers are a resource for employees and articulate the company's position on controversial issues:

> The way we envision the position papers having impact is number one they can flow into policy and procedure. And, they should to the extent that

> there needs to be governance. Because what we put out is advice and guidance. So if you really wanted it to be fully institutionalized, then it needs to go into policy and procedure.

Currently, only a short excerpt of the stem cell research position paper is available on their website; the position papers are not publicly available. The ethics consultation requests and reports are also confidential. Everyone involved in the Bioethics Program said they would like to make some of the position papers and the ethics consultation reports available to the public, but that it may take some time:

> I do not think that anybody has really thought that much about it previously to be honest. And then what you always have to keep in check in the industry is that you do not want to give away **competitive advantage**. It is just a reality. Nor do you want to violate anyone's **privacy** and **confidentiality**. Those are really big things that we have to consider.

Those involved with the Bioethics Program recognize that the ethics consultation requests and reports and the position papers would be valuable case studies and resources for bioethics and business ethics students. However, Eli Lilly is worried about giving up a perceived competitive advantage and releasing privileged information. Both the Chief Medical Officer and the VP of Global Patient Safety indicated that they were quite open to having more individuals critique their consultation reports and position papers; the external bioethics committee members and the bioethics associates indicated that the reports and papers are not likely to be available any time in the near future.

According to Van Campen, in the near-term they are looking to increase ethics competency within Eli Lilly. They are considering offering ethics training

modules modeled after the Collaborative Institutional Training Initiative (CITI) Program, and they would also like to make it a requirement that all members of the BEC have some ethics training:

> One thing that we've discussed, that we're starting to feel pretty strongly, is that there needs to be a core competency in bioethics—not just that you're interested in it or that you're the loudest person in the room. But, truly that you have a core competency—whether that means you've got a certificate in bioethics, or a degree in bioethics, or you've served on an IRB for 10 years, or you've completed x numbers of continuing medical education.

This raises the question of what "core competency" is, how best to achieve "competency" and how such education might be incorporated into the structure of the company. This is a contested terrain in bioethics generally (Churchill 1999; Aulisio *et al.* 1999; Hoffman, Tarzian and O'Neil 2000; Bardon 2004), a detailed analysis of which falls beyond the scope of this dissertation project.

In addition to having members with some ethics training, it is also important that senior leaders in the company are involved with the BEC, because they "understand the science, the company, the industry, the business. They just have very broad and deep experience and it's extremely valuable when you're wrestling with these big heavy issues and problems". (Senior leaders can also be highly influential when trying to effect change within an organization, but that was not mentioned as a reason for their involvement.) The BEC has a significant number of members who are senior research scientists and executives. Despite this buy-in from senior management, neither the Bioethics Committee nor the Bioethics Network is well known within (or outside) the company. No global affiliates have submitted an ethics consultation request or raised any concerns.

Despite this, the Lilly Bioethics Committee has had a global reach both within the company and beyond. The following section offers a brief explanation as to how Lilly is enacting a *certain form* of bioethics through its consultants and the BEC, and the subsequent global impact of their bioethical decision-making.

Global Reach

One of the areas in which the Lilly consultants have been influential within Lilly is in developing the ethical standards for Lilly's international clinical trials. According to their website, Lilly employs approximately 40,000 people worldwide, and markets their medicines in 143 countries. Eli Lilly currently has major research and development facilities in eight countries and conducts clinical trials in more than 50 countries, though that number has fluctuated significantly over the last 10 years. According to Tom Beauchamp, Eli Lilly ended clinical trials in certain countries because of external criticism (such as the criticism after the HIV trials in Thailand):

> Their reaction to the criticism is if you don't want us to do research in that country because you have done something wrong, then we'll leave. And what that does is leaves an infrastructure that is built in that country without any reason for being and all the people who might been in research subjects as well as the dollars for the country gone. And you might say, if this is wrong you should fight it. But one of the things corporations have learned is once the criticism mounts to a certain level, you don't fight it, you just leave and go somewhere else.

Beauchamp used "their" to distance himself from Lilly's corporate decisions, but in his role as BEC member and external ethics consultant, he helped the former

Chief Medical Officer, Allen Bryer, develop the Principles of Medical Research, which articulate the ethical standard Lilly follows in setting up and conducting clinical trials. The document draws heavily on principlist objectivity to lay out ethical principles and protocols to guide the design and implementation of clinical trials worldwide.

Adriana Petryna argues "[c]linical trials are social institutions, and the question of whether to carry them out, where and how is a *political* one" (2007, 22, emphasis added). Eli Lilly is not interested in engaging in a debate about the politics of global clinical research trials. By hiring Beauchamp and Levine, they can control the conversation to focus on the *principles*—rather than the social context and the politics—of biomedical research. Beauchamp and Levine are strongly opposed to moral relativism, and defend one approach for all cultures and countries:

> It seems to be the perception out there that you're in a certain kind of country, whether it's India or it's China or it's Thailand or whatever, and it seems it makes a difference to accusations of your exploiting people that it's a certain kind of developing country. We've had a lot of discussions about that, to most of us national boundaries don't make a lot of sense. It's purely the ethics of the operation and how you recruit subjects for your trials and so on. But again, there is really no winning that battle, you are not going to win it at the level of academic argument.

The people chosen to be external consultants shape the Bioethics Program significantly. The Bioethics Program is a node is a larger regulatory apparatus, but it has international reach. Thus, more importantly, the consultants at Eli Lilly

influence the way Lilly sets up and conducts clinical trials around the world on hundreds of thousands of people.

Conflicted Evaluations

Individuals involved with the Bioethics Program gave different, sometimes conflicting evaluations of the influence and effectiveness of the program (though most were quite positive). Those in charge of the program are still trying to figure out how to evaluate their activities. One senior executive argued that one way to judge it was by how often other groups in the company come to the BEC to ask for advice. Do people know about and want to engage with the BEC? A second measure is whether the advice from the BEC is changing what Lilly does: "In other words, once we have an ethical position on an issue, are people following it, are they using it, are they applying it?" In order to evaluate the impact, the BEC relies on the survey data. That data captures (if and when the surveys are returned) small changes within the groups that requested an ethics consultation.

It is unclear how much influence the BEC has or could have in the future once the program is well established within Lilly Research Laboratories. One of the external members of the committee argued that the BEC had significant authority within Lilly:

> It's a little stronger than committees; for example, we actually have the power to set corporate policy in certain ways. That could be rejected by the CEO, so the power is limited, but still the CEO is probably not going to reject a policy proposal we put forward, but the CEO might ask us to reconsider or something like that.

The position papers are designed to feed into corporate policy and procedures. Though they have written a few position papers, the one that was most frequently mentioned was the paper on stem cell research.

The Bioethics Program took on the task of updating the position paper on Stem Cell Research when one of the research scientists in the Regenerative Biology Group in the Discovery Research division came to the BEC with a number of questions about the kinds of derivation and use of adult and embryonic stem cells permitted under the existing guidelines. The scientist worked closely with the Head of the Bioethics Program to revise the position paper. The BEC contributed to the draft, and eventually it was approved as company policy. This particular scientist has since stayed closely involved with the BEN. Because the paper produced corporate policy and expanded the BEN, the stem cell research position paper was held up by a number of people as a key example of the BEC and the BEN working with scientists throughout the company to produce something of value. Luann Van Campen argued that the stem cell research position paper is a model for the company:

> What I think is probably the best thing we did there, is the business needed to develop a business strategy on stem cell research, and they were working on that. In parallel, we were working on the bioethics position on it. So here is cutting edge technology that Lilly cannot move forward unless there is a business strategy and unless there is a bioethics position. Now that we have both and we worked in unison, then the discovery scientists are free to say, "Oh, I can pursue that collaboration, because now I know where we stand." Previously it might have been an interesting collaboration, but they did not know if they could do that. We had not

> really established either our business strategy or a bioethics position. So I see that as a model that I would love to do again with another biotech thing.

Van Campen regarded it as an opportunity to be more "proactive" (or, to be engaged with the science further upstream in development), where *both* the ethics and business strategies had an opportunity to precede the scientific research.

However, the Chief Medical Officer questioned the value of this particular contribution:

> There is so little work in that area going on in Lilly at the moment, that it is difficult to say. And most of the people who are involved in that work were involved in creating the paper. So they kind of knew what the answer was, it was pretty in alignment with their thinking. So it is difficult to say. Has it changed behaviors, has it changed thinking? And I think what we produced was actually very thoughtful and very appropriate. But has it actually changed their way of doing work? I would say that I just do not know that it has at this point.

While the Head of the Bioethics program had no stake in the Regenerative Biology group, the others involved in redrafting the stem cell research paper did. Thus, they had an interest in proposing particular kinds of guidelines or regulations. Stem cell research is not a significant part of Lilly's research portfolio, and therefore this particular position paper was not a high priority. This raises an interesting question: Why does something so peripheral to the company's research and development program get priority in the Bioethics Program? While those involved with the Bioethics Program argue that they need

to start small while they are building their capacity, others may point to this prioritization as evidence that such groups are designed to have a relatively insignificant impact on corporate decision-making.

When Lilly bioethicists wrote the stem cell position paper, bioethics acted as a corporate strategy, dictating corporate policies and guiding the direction of the research. And while each interviewee stressed that the Bioethics Program is unrelated to the business division of Lilly, the split seems to be more theoretical than practical. In practice, the research and business divisions are deeply intertwined. In a smaller company like Advanced Cell Technology, the research and business divisions are inextricably intertwined. The bioethics consultants at Eli Lilly work only within one section of the company, and are fairly removed from the business division. They interact with scientists, not marketing executives. The members of the EAB at Advanced Cell Technology, on the other hand, work with almost all ACT employees, so the boundaries are undefined.

Conclusion

At the beginning of the chapter, I wrote that the Lilly committee is the least political and the most controversial. Their goals for the immediate future are fairly banal: according to the bioethics associates, the immediate next steps are to better communicate the service within the company; to develop tools and templates to better assist individuals and teams identify issues and implement advice; refine the survey instrument to better measure impact; and to explore new external collaborations and partnerships. They do not seek to expand their reach to the business division of the company, and that is what is most controversial. By limiting bioethics to simple bureaucractic structures and

processes, Lilly is enacting a certain form of bioethics, one that prioritizes principles over particularities and one that views value pluralism as "a problem to be overcome" (Kelly 2003, 348). It is a bioethics that follows general rules (principlism) – rules that are stable, comprehensive, and can be learned. And yet, the general rules have been in place for over three decades, and the pharmaceutical industry behaves in a way some consider morally reprehensible – leading many to argue the general principles do not go far enough to protect subjects or articulate the complexity of public values.

Chapter 6

DISCUSSION

With this dissertation project, I sought to contribute empirically grounded guidance on the constitution of a valid, valuable bioethics advice. Following an extensive literature review and over 40 semi-structured qualitative interviews, the results of this project provide new information about previously unexamined structures – the private sector bioethics committee. I was able to discern the logics of bioethics advice-seeking in various corporate settings, and to reveal the varied rationales of both advice seekers and those whose advice they sought. Moving forward, with better empirical data in hand, the field of bioethics can begin to develop frameworks to analyze the legitimacy, credibility and authority of bioethics advice in both the public and private sectors.

In Chapter 1, I raised some questions about the roles and structures of private sector bioethics committees. In this concluding chapter, I return to that list of questions to summarize the case studies (see also Table 1), before I explain my key findings.

1. Where do the decisions to participate come from, and what are the subsequent impacts on decision-making processes?

The roles the committees play within corporations depend on their structure and their mission (or, if undefined, the members' understanding of the mission), and the social, institutional and historical contexts. Each corporate leader created their bioethics committee for a different reason, and that shaped the structure and the outputs of the committee. George Poste sought a place for broad debate about complexity and social responsibility, whereas Michael West wanted a committee to look over his shoulder and catch potential problems.

These different missions produced drastically different committees.

My findings support theoretical claims within the management literature that one of the biggest drivers of proactive, socially responsible performance by a corporation is senior management's commitment to ethics (see, e.g., Jones 1995). The board at SB dissolved when the chair left, the Lilly bioethics program expanded significantly when a new executive was put in charge, and the ACT board was decoupled from decision-making processes and met less frequently after Michael West left.

While the committee may need a strong leader to initiate proceedings and to help secure cooperation within the company, there is a confluence of factors that enable or constrain bioethics work within the private sector. As previously discussed, all three private sector bioethics committees were established in anticipation of or following a more public controversy. SmithKline Beecham predicted that genetic testing would be a topic of significant public debate (and then became embroiled in a controversy about patents and genetic testing); Advanced Cell Technology conducts inherently controversial research and had recently made itself the center of national attention with their announcement regarding human-animal chimera research; and Eli Lilly was publicly embarrassed when the *Wall Street Journal* published an article exposing their questionable clinical trial enrollment practices.

The social context beyond these particular public relations controversies also impacts the committees. All three committees were formed in the late 1990s and early 2000s. In the early 1990s, there were many topic-driven bioethics committees in the federal government (e.g., Advisory Committee on Human Radiation Experiments, the Human Embryo Research Panel), but a significant

period of time had passed since the last presidential or congressional bioethics advisory board. There was no high-profile centralized location where debates about values and norms and biomedical research were taking place. The field of life sciences was making significant advances, and industry is always eager to avoid burdensome new oversight and regulation. By creating its own bioethics committee, a company is trying to convince observers that they are proactively addressing ethical dilemmas.

2. Who gets to participate?

As previously discussed, Michael West is quoted as saying that the effectiveness of an ethics committees depends on the members: "There is, I think, a misunderstanding that if you set up an ethics panel there are some sorts of ground rules, like principles of accounting, and everyone knows what those rules are. In the field of ethics, there are no ground rules… It all depends on who you pick" (West quoted in Hall 2003). Critics often use this remark as proof that corporations will only hire those who will agree with them. However, the point West makes seems obvious. If a corporation has invested substantial time and resources into one particular research project, it is unlikely they will hire someone who fundamentally disagrees with that project. If the company is indeed interested in getting ethics advice and incorporating that advice to improve their research, then it would be most beneficial to hire individuals who take a supportive but critical stance toward the projects and company.

It is often the case that committee members are chosen selectively, to increase the likelihood of a "successful" outcome. According to staff members involved with creating the National Bioethics Advisory Commission, there was a deliberate decision to put together a membership that was predominantly liberal

(personal communication, 2010). The previous federal bioethics body—the Biomedical Ethics Advisory Committee—had "died in the political crossfire of abortion politics" (Cook-Deegan 1998, 118). Thus, in order to avoid a similar fate for the next bioethics commission, members were chosen for their liberal or centrist perspectives.

The membership was diverse in other respects, such as gender, race, religion, geographical location, and field of expertise. Despite (or because of) their lack of diversity with respect to political views, the work of NBAC was widely praised as fair, thoughtful, and substantive.

But the larger question of representation remains: Who belongs at the table in this thing that is private sector bioethics? Who needs to be there? Each committee had different ideas about who could best help them. SB sought distinguished scholars in science and philosophy and law, Advanced Cell Technology brought in the kind of people who might be on an institutional review board (philosophers, clinicians, scientists, social workers, and a community member), while Eli Lilly sought interested candidates from within the company and hired two external bioethics consultants to help them. There are advantages and disadvantages to each approach. Both Lilly and SB hired individuals who were well known and well respected in their fields, which may serve to increase the legitimacy of the committee both within and outside of the company. These members, however, tended to participate because it was interesting and intellectually engaging, not because they considered it something important—for their careers or for the public good. In contrast, ACT found a diverse group of people who were interested in the company's research; the members of the EAB believe their work is important and are more committed to giving meaningful and

practical advice.

3. What kind(s) of structure(s) achieve the desired ends?

As mentioned above, in setting up the EPPB, George Poste wanted to create a place for a broad debate about complexity and social responsibility. His committee was a group of highly distinguished scholars with a range of expertise that met two or three times a year to engage in philosophical debates. They did not meet to review SB's research protocols. In contrast, Michael West wanted a committee that could keep ACT from making serious errors. The mission of the committee and their granted access within the company most significantly influenced the outputs. None of the corporate executives or committee chairs had very much to say about the structural form of the committee. But the structure revealed key insights about the perceived role of the committee and the desired scope and reach of its deliberations. The deliberate boundaries that keep the Eli Lilly Bioethics Committee within the research division of the company speak loudly to the vision of bioethics that Lilly managers hold – a bioethics that is more narrowly focused on the 'point of delivery' (the research laboratory) rather than a bioethics that is concerned with upstream engagement about the value of particular research programs or more broadly concerned with questions of justice.

4. How and on what criteria do we evaluate such committees?

The question of "What was it?" (where "it" is a private sector bioethics committee) can only be answered in relation to a larger ecology of ideas about expertise, deliberation, representation, the good, interest, politics and governance. The criteria by which we may evaluate such bodies remains unclear

(as are the criteria by which we evaluate public sector bioethics bodies). It was important, in interviews, to ask how the people on the committees evaluated their own work, and to ask how observers evaluated private sector bioethics committees. Their answers were revealing with respect to their own self-image, as well as their own perceived legitimacy and authority. Rather than make a normative assessment of the work of each committee, I wanted to analyze the actors' conceptions because their own interpretations of their work matter. The various actors and the relationships between them also influence the problems they address and the perceived benefits of their committee deliberations.

Key Findings

There are four main findings that emerge from these case studies, and they concern expertise and representation, self-perception and legitimacy, evaluation, and secrecy and transparency.

Expertise and Representation

Eli Lilly's model of representation seems to aim for objectivity, which requires a "suppression of all particular social perspectives and political interests" (Brown 2009a, 49). This is in line with the morally neutral and apolitical commitments of principlism and universalism. Advanced Cell Technology's model of representation also resembled a legislative model; their goal was to provide advice and practical recommendations to the company. SmithKline Beecham's Ethics and Public Policy Board adopted a deliberative model, where the goal is to "present various social and professional perspectives" (*ibid*.) and aim to balance a wide range of perspectives and interests. According to Poste, the purpose of the EPPB "was to try to make a sophisticated analysis of

the landscape of views". Such an analysis requires impartiality, rather than objectivity. The SB EPPB is like a group of "wise elders", whereas the ACT EAB has a membership more that of an IRB.

Generally, the private sector bioethics committees demonstrated a less pluralistic interpretation of membership than federal advisory bodies (whose membership, according to the 1972 legislation, Federal Advisory Committee Act, must be "fairly balanced"). Diversity with respect to gender, race, culture, political affiliation was seemingly not important. Rather, members were chosen based on their field of expertise. Each committee sought a representation of the relevant *expert institutions*. Eli Lilly sought out particular *individual experts*, and SmithKline Beecham chose only highly distinguished scholars.

Self-Perception and Legitimacy

The SmithKline Beecham and Advanced Cell Technology committees are populated with external consultants; the members had to figure out the institutional context and their roles within that context. (At Eli Lilly, most of the members are internal, with two external consultants.) For academics, the advantages of being a biomedical insider are confidential insider knowledge and bureaucratic power, but these come at the risk of losing public credibility and impartiality. Very few interviewees took seriously the idea of "loss of public credibility". Their own perceived legitimacy and credibility came from their interpretations of how the company valued their work. The EPPB members mentioned they stayed in nice hotels and flew first class, but these statements were not necessarily revealing with respect to conflicts of interest, but about their own perceived legitimacy. The perks were symbolic of the value of their work to the company, they were not the reasons the members participated. Similarly,

ACT EAB members accepting no money reveals more about how they see their work as performing a service for the public.

However, to assess the legitimacy of the committee—beyond the committee members' own self-perception, we would have to evaluate the companies' public justifications for the committees (and the decisions the committees made) and whether the committees are accepted as legitimate entities by observers (Brown 2008). At the moment, very few people know that such committees exist; even fewer know what functions they perform within the companies. Evaluating the effectiveness and legitimacy of private sector bioethics requires access to information about their work. Furthermore, for critics of industry, a bioethics committee within a pharmaceutical company will not be legitimate because the institution within which the committee is housed (the pharmaceutical industry) has done nothing to facilitate public deliberation, and instead has deliberately denied access to information and has a long history of unethical behavior (see, e.g., Angell 2004; Elliott 2010).

Evaluative Criteria

The ways in which each of the three bioethics committees performed are very different. The Eli Lilly Bioethics Committee has the task of providing ethics consultation within Lilly Laboratories, the Ethics Advisory Board at Advanced Cell Technology has a mandate to loosely fill the role of an IRB (with significantly expanded jurisdictional reach), and the Ethics and Public Policy Board at SmithKline Beecham was expected to deliberate about broader, more complex ethical and policy challenges.

The evaluative criteria for private sector bioethics committees are as conflicted as are the evaluative criteria for public sector bioethics committees. SB

executives acknowledged they had no evaluative criteria for the EPPB. The EPPB was created to be a kind of *reflective* governance, in that it was a place for deep and thoughtful reflection, in a limited frame. EL executives are trying to evaluate their success quantitatively, by keeping track of how many ethics consultations they do and the survey data they collect following each consultation. The evaluative criteria for the ACT EAB is like that of an IRB on the one hand (if research proposal modified to pass ethical evaluation, the committee has been successful), but the members also see themselves as contributing to improving the public image of company, which is still known for its controversial research and business practices. These evaluative criteria are different than those asserted for public bioethics commissions, which tend to be evaluated based on their expertise or agenda-setting roles, or on their roles as public forums to engage citizens in debate.

Secrecy and Transparency

Many of the criticisms of the relationship between bioethics and industry argue that the problem is a fundamental difference in values. Academic scholarship is committed to transparency, academic freedom, openness and peer review, while corporations are concerned with increasing profits, and pursue business practices that are hostile to the norms of academia. Secrecy (the tightly restricted flow of information) is essential to industry, while the open sharing of information (the unrestricted dissemination of ideas and data) is essential within academia.

Questions of access and transparency emerged differently within each company. Advanced Cell Technology guards their technical information, but gives the EAB freedom to write about the company in any way and forum they'd like.

Because of this, the members of the EAB have the perception that scientists and executives at ACT are quite transparent with them. It is the case, however, that the EAB meets infrequently and only when called by the CEO, so the extent of their actual transparency is unclear. (None of the current executives or scientists at ACT would agree to speak with me.) Eli Lilly claimed that they would like to make their internal ethics consultations available as case studies for educational purposes, but acknowledged that that was unlikely to happen soon. They do not publish their position papers because they do not want to give away any competitive advantage, but they have started to engage with academic centers and governmental agencies to share their ethics consultation model. (Executives and managers at Eli Lilly were generous with their time, but I had no choice of whom I could interview.) SmithKline Beecham did not share any specific details of their research and development projects with the Ethics and Public Policy Board members—their meetings were about general bioethics topics of interest to both industry and policymakers—and yet executives initially tried to prevent me from talking to members ten years after their last meeting. In all three companies, I had minimal access to their deliberations, because I was never able to attend a meeting, read the minutes or an ethics consultation report, or speak with a scientist whose work had been directly affected by the ethics committee. And yet, I learned a lot about what kind of project the company, the staff, the ethics committee members saw themselves as engaged in.

In an interesting piece on science and secrecy, Michael Dennis (1999) argues that even though science and secrecy are portrayed as antithetical, the history of science reveals numerous examples of deliberate secrecy. He draws on texts by Edward Shils and Norbert Weiner to work towards the development of a

radically different view of secrecy, a view in which access is but one aspect and more attention is paid to the effect of secretive practices on the production of knowledge. According to Weiner, secrecy affects the content of the knowledge produced, and that "one gets a certain type of knowledge from a particular social organization" (Dennis 1999, 13). The knowledge produced is different than that which comes from a more open space, but it is not necessary "bad" or incompetent. Dennis argues that while we can not acquire all the relevant information, we do have to think about how to discuss the ways the classified world relates to the world we can access: "The question is not how to access this world, but how to assess that world's impact on what is visible" (Dennis 1999, 15).

Like Dennis, I do not want to argue that secrecy and a lack of transparency are unproblematic, but it seems unproductive to always treat it as such. Secrecy is problematic when it hides or covers up wrongdoing or prevents us from making informed decisions. It is not the case that classified information is problematic solely because of the lack of transparency (sometimes the lack of transparency protects individuals from possible discrimination or protects us from theft of intellectual property; see, for example, confidentiality and doctors, IRBs, HECs); nor is it the case that pharmaceutical companies will radically alter their practices and grant access to anyone who seeks information.[34] But the ethical judgments made within corporations about research processes and programs are important and carry powerful potential consequences. Rather than excluding the corporate world, we need to think about what kind of impact corporations have (on society, on policymaking, on bioethics scholarship), and how we might evaluate that impact.

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[34] Companies will not behave in such ways unless regulators require such action, of course.

Summary

These findings demonstrate that there is significant variation in the structures and functions of and rationales for private sector bioethics committees. Criticisms of private sector bioethics that focus narrowly on financial conflicts of interest and a lack of transparency obscure analysis of the ideas about governance—about expertise, legitimacy, representation, credibility and authority—that emerge from these structures. Each committee has different ideas about how bioethics ought to be structured and what it can achieve.

As a scholarly domain, bioethics has neglected engaging the role of industry in science and technology. Looking closely at private sector bioethics activities provides an opportunity to reflect on the roles and responsibilities of private companies in public debates about normative values and the possible impacts of moving ethical deliberation from the public to the private sector.

Table 1: Comparison of Committees

COMMITTEE	MANDATE	MEMBERSHIP	STRUCTURE	AUTHORITY/IMPACT	OF INTEREST
Advanced Cell Technology's Ethics Advisory Board	Functions of an IRB (loosely speaking); advice on public policy as well as public relations	Modeled on IRB, with different expertise represented and community member (more pluralistic than other two – some diversity in terms of gender and other kinds of experience) – all external members, plus VP Research	Infrequent meetings, by phone or in person; write ethical guidelines; reach a consensus	Their impression seems to be that they have a significant impact, though they generally only meet when the company calls them together	1. **Members not paid** – yet display greater allegiance to the company (or, at least, to stem cell technology) 2. Modeled after IRB 3. **Most public and well known private sector bioethics committee**
SmithKline Beecham's Ethics and Public Policy Board	Debated more philosophical or foundational questions about scientific research; did not provide specific advice and recommendations	Significant expertise and scholarship, with a diversity of training represented—all external members, plus CEO	Three two-day long meetings a year, alternating between US and UK. Agenda set by VP. Board engaged in debates about philosophical questions re: technology, as well as policy matters	Did not change the course of the research (according to Poste); committee members did not know how their advice was used	1. **Senior executive controlled committee**, had significant influence within the board and within the corporation 2. First private sector bioethics committee—**but not publicized** 3. **Paid, but not to give advice** about specific SB research and development
Eli Lilly's Bioethics Committee and Bioethics Network	Provide specific advice to ethics inquiries from employees; position papers; expand network (to educate employees, engage them in conversations about bioethics)	Senior representatives in the research division of the company, plus two academic bioethicists (external consultants) – almost all internal	Tiered consultation – 3rd level goes to full committee. Two day long meetings, every 3-4 months.	Must come to conclusion about what to do, because they are responding to requests from employees. But the extent to which their advice (and the subsequent actions) changes the direction of research at Lilly is unclear. (E.g., different opinions within Lilly about importance and impact of stem cell position paper)	1. **Question of scope** – bioethics committee and network only responsible for research division (not business division). 2. Very structured program; attempts to measure impact quantitatively – **bureaucratized** bioethics

Chapter 7

CONCLUSION

The decisions about ethics made within corporations are critical. And yet, corporations have, at various times, avoided engaging with other organizations and institutions, been excluded from the conversation, and worked to move questions of ethics and values from the public sector regulatory discourse and "into the sphere of private morality and "consumer choice"" (Jasanoff 2005, 190). Executives at biomedical companies are assembling private sector bioethics committees to evaluate whether their company is "interpreting the frameworks of debate correctly", to help prioritize certain issues as legitimate topics for debate while dismissing others (and privileging certain experts and types of evidence over others), to shape the company's scientific and political activities, and to provide the company with legitimacy by demonstrating its responsiveness to ethical concerns. Through their bioethics committees, private sector corporations are trying to influence normative debates about biomedical research.

Corporations both exclude others from their activities, and are excluded by others (see, e.g., Macdonald 2003, 2005). Private sector bioethics committees tend to be excluded from normative debate, especially by those who tend to define bioethics as a public enterprise. At SmithKline Beecham, George Poste created a private sector ethics committee to draw attention to the role of the private sector. It was not just anyone's attention he was interested in attracting, but the attention of some of the most influential scholars in science, law and ethics. He argued there could be no effective ethical decisions if the roles and responsibilities of the private sector were ignored or misunderstood. However, by keeping the SB bioethics committee secret, he did not bring industry into

conversation with ethics—he brought a small number of ethicists into industry. Rather than engage with a much broader audience and open the company up to criticism, Poste engaged a small number of highly respected scholars—to seek advice for SB, but also to introduce those scholars to industry's unique dilemmas, with the hope that those scholars would discuss and highlight the roles, interests and responsibilities of industry in their work. The chair of the EAB Advanced Cell Technology writes enthusiastically about stem cell research and highlights his work on the committee. This works to the advantage of Advanced Cell Technology, which—as a small biotech start up in need of venture funding—benefits from the added publicity. Executives at Lilly sought the advice of some of the most influential bioethicists when the company received a lot of criticism and negative press for their clinical research practices; Tom Beauchamp and Robert Levine have continued to work with the Lilly Bioethics Committee for almost a decade. By engaging bioethicists outside of the company, SB, Lilly and ACT have been able to participate in normative debates about clinical research. By participating in corporate bioethics activities, the members of the committees have gained some new knowledge about technologies in development and corporate decision-making in the biosciences.

Most of the debate within bioethics about relationships with pharmaceutical companies has focused on a difference in values and potential conflicts of interest. While this debate is important and it is crucial for us to understand the multiple sources of conflicts of interest, this kind of debate assumes that the boundaries of and between universities and firms and governments are clearly delineated, the values vastly different and firmly set, the roles static. The results of this dissertation demonstrate the need to revisit these

assumptions, which, upon examination, do not hold true. As demonstrated by the case studies, bioethics programs in the private sector have varied rationales and logics and struggle with the many of the same problems as public sector bioethics programs, with respect to mandate, authority, membership, and legitimacy. But these private sector bioethics committees evaluate and construct new boundaries between their private interests and the public values they claim to promote. They are entities that occupy both the public and private sector, and must figure out how they "fit" into each space.

Future Directions

This project is an initial attempt to understand how and why bioscience corporations incorporate bioethics into their decision-making structures. Recently, scholars have drawn our attention to the roles governments play in imagining (and creating) sociotechnical futures (Jasanoff and Kim 2009). As they take on new governance roles, corporations play a more direct role in shaping the world. Corporations are places where new socio-technical futures are imagined and created, and they are taking lead roles in shaping both the epistemological dimension of new technologies, as well as the normative dimensions. Moving forward, I will explore the ways in which such concepts as future imaginaries or norm entrepreneurship (Ingebritsen 2002; Finnemore and Sikkink 1998; Pozen 2008) and STS literature on institutions, trust, expertise and the politics of delegation can be used to analyze and situate the findings of this dissertation project.

Bioscience corporations invest heavily in research, and thus corporate standards and policies could have at least as much of an impact as those set out

by governments. Corporations are starting to take on roles and duties that have traditionally belonged to the government. Corporate boards that address ethical and public policy challenges may increase the role of the private sector in determining the political priorities of the government. This work raises an interesting theoretical question (that is out of the scope of this dissertation): *Do these corporate bioethics committees represent the neoliberalization of institutions of governance?* Neoliberalization stresses the efficiency of the private sector, and seeks to maximize the role of industry actors in determining the political and economic priorities of the country. Rather than wait for the public debate to play out in federal bioethics committees, corporations are taking an active role in determining for themselves the key values and norms. In a corporation, bioethics is displaced from its traditional settings in hospitals, universities and governments. Private sector bioethics committees are new and different kinds of advisory bodies, and they are taking on de facto governance roles that have previously belonged to the government. The question of whether and to what extent these bodies represent a neoliberalization of governance institutions requires a significant amount of theoretical work. In order to think about that broader question, we will want to answer questions such as: *How and why are these bodies authorized? What is their role within the larger ecology of bioethics governance?*

The role of bioethics committees, in shaping both the internal decision-making processes of a corporation and in shaping the world more broadly, can be studied from multiple different perspectives. From a management perspective, we might ask: what kind of corporate political activity (CPA) is establishing a private sector bioethics committee? Meznar and Nigh (1995) and Blumentritt

(2003) have drawn a distinction between two fundamental behaviors in CPA: buffering and bridging. Hillman, Keim and Schuler (2004) summarize these two behaviors as follows:

> Political "buffering" behaviors include proactive political actions on the part of firms, such as informing government decision makers about the impact of possible legislation, trying to actively reduce government regulation of the firm, and working alone or in trade associations to make campaign contributions, lobby, or otherwise influence legislative/regulatory processes… "Bridging," on the other hand, is a more reactive form of behavior. It includes such activities as tracking the development of legislation/regulation so to have compliance in place when passed and exceeding compliance levels for regulation.

Is a private sector ethics and public policy committee a "buffer" or a "bridge" or something else? Future research might explore what kinds of political activity bioethics committees are engaged in, and to what effect. The SmithKline Beecham board debated many policy issues and discussed the company's policy initiatives. The Advanced Cell Technology board members participated in Congressional hearings and discussed political strategy and policy initiatives. The Lilly board limited its debates to internal operations. However, there are other corporate ethics boards (e.g., at Synthetic Genomics and the J. Craig Venter Institute) that work explicitly on policy issues. What impact, if any, do corporate ethics boards have on policy debates?

Another way this research might be extended is by using social contract theory to develop means of evaluation of private sector bioethics committees. Businesses are different from many other key social institutions in that they are

almost entirely the product of human design.[35] Their artifactual character means that the rules, organization, and structures can vary dramatically (Donaldson and Dunfee 1999). Bioethics committees are also highly artifactual: many different kinds of structures and configurations can reasonably and legitimately operate as bioethics committees. Morally speaking, then, perhaps we ought to abandon the search for a single monolithic blueprint of a "best" bioethics committee structure. Instead, we ought to ask what moral expectations can properly be assigned to corporations, and how a private sector bioethics committee might be designed to achieve results that fit those expectations. It might be the case that private sector bioethics committees can be critiqued morally along many different dimensions, but we need a better understanding of industry and of the intended and perceived impacts of bioethics committees within corporations.

This project has attempted to make sense of the private sector bioethics body itself, along with the expectations for the sorts of effects that are appropriate to it. This dissertation draws attention to activities that had not previously been investigated. By providing empirical evidence of the work of corporate bioethics committees, this dissertation permits the development of future frameworks to help us better understand their impact and significance and evaluate them in terms of their legitimacy, authority and effectiveness. Thus, we will be able to better understand the project of private sector bioethics in the larger ecology of bioethics governance.

[35] For Donaldson, "artifactual" means an organizational design that is the product of human discretionary choice. The distinction is one of degree.

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