

DOING THE RIGHT THING: THE LOGIC & LEGITIMACY OF
AMERICAN BIOETHICS AT THE TURN OF THE MILLENNIUM

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To my parents, David Leinhos and Cecile Skeeles,
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ABSTRACT

This dissertation research project examines how contemporary academic bioethics in the U.S. balances the aspiration to guide biomedical research and practice with the need to become an institutionally legitimate influence in society. Since its inception three decades ago, to what extent has bioethics made biomedicine more socially accountable? At the same time, to what extent has bioethics been rendered a public-relations tool for academic and corporate biomedicine? This project investigates the co-production of the legitimacy and the logic of the academic field of bioethics by examining the activities of bioethicists in three professional arenas: the establishment of an academic bioethics unit, discourse on the legal liability of institutional review boards and health care ethics consultants, and the deliberations and recommendations of a federal bioethics commission.

Bioethicists' efforts to legitimate their field are viewed as competition and collaboration with other professional groups to stake out an emblematic expertise, which is then tendered to various societal clients. A case study of an academic bioethics unit was conducted to reveal how the unit's efforts to secure material resources and organizational legitimacy shape the center's intellectual output, drawing on the unit's archival documents and interviews with the unit's director, faculty, staff, and graduate students. Discourse analysis was used to explore what anticipated legal liability

reveals about the legitimacy of expertise claims and the shaping of those claims. The proceedings of the National Bioethics Advisory Commission related to the human stem cell research debate were used to examine the boundary-work conducted by the commission at the borders between science and ethics, and between ethics and public policy.

The research described here shifts attention in the budding sociology of bioethics from clinical to academic bioethics, and highlights the institutional and power relationships amongst bioethics, biomedicine, and public policy. This study also contributes to the fields of higher education studies and science and technology studies, where ethics, and the relationship between legitimacy and expertise, have not been fully explored. The findings presented here provide useful insight into the challenges and opportunities bioethicists face in cultivating socially responsible biomedical science and technology.

CHAPTER 1—
INTRODUCTION

Burgeoning developments in biomedical technology and molecular biology over the last forty years have inescapably provoked concerns about the social, legal, and ethical impacts of these new developments. For example, 1967 witnessed the performance of the world's first heart transplantation in South Africa, which spurred reconsideration of the criteria for determining death. In due course, an *ad hoc* Harvard Medical School committee established a new death criterion: irreversible coma. During the 1960s, several conferences, with titles such as "Great Issues of Conscience in Modern Medicine" and "Man and His Future" (Jonsen 1998, 13-19), were attended by leading figures from biology, medicine, law, theology, and the social sciences, reflecting the growing disenchantment of the public with the gods of science and medicine.

Out of such events emerged a coordinated movement and intellectual enterprise that came to be known as bioethics, which coalesced around three new organizations: the Hastings Center (incorporated in 1969, in Garrison, NY), the Kennedy Institute of Ethics at Georgetown University (established in 1971), and the Society for Health and Human Values (SHHV, a national professional association, founded in 1971). The SHHV's original statement of purpose suggested the goals of the new bioethics movement: "This Society

sees its task as identifying these [bioethical] problems, in forming groups that will develop methods to clarify and assist in solving them, and in developing change in both professional attitudes and public awareness in relation to them” (Fox 1985, 338). But what impact has bioethics made over the last three decades? A 1997 *Nature* article describes the growth and current prominence of bioethics, but asks “whether U.S. bioethicists have substantially shaped either the culture of science or the political decisions of recent years” (Wadman 1997, 658). Bioethicist Arthur Caplan admits, “Bioethics has a lot of authority but no real power” (Wadman 1997, 658).

This dissertation research examines the ways in which the legitimacy and intellectual content and organization of academic bioethics are co-produced (Jasanoff 1996) in the US. To succeed as an academic enterprise, bioethics needs to legitimate its moral authority within the institutional structures of biomedicine and the state, and develop the intellectual tools and content to grapple with the ethical aspects of biomedicine and biotechnology. The potency of bioethics is particularly critical today, in an era featuring a completed Human Genome Project, a thriving biotechnology industry, and daily reports of new biomedical discoveries—and new biomedical quandaries, as well as increasingly frequent litigation against clinical investigators and universities. It is hoped that this research will provide useful insight to the bioethics enterprise as it works to balance its

need for institutional legitimacy with its commitment to make the biomedical enterprise accountable to all of society.

Research Questions

The central research question of this project is: **How are the legitimacy and logic of bioethics jointly constructed?** By logic, I mean the epistemic content, approach, and social structure of the field of bioethics; that is, its knowledge content, and the organization of the field in terms of its interdisciplinary professional work, self-described identity, and its relationships to the constituencies it purports to advise. The logic of the field is the system of expertise it provides, and the basis for that expertise.

The research described here improves our understanding of the nature of bioethics' impact on scientific and medical practice, and the factors that influence that impact, providing clues about how to better pursue the goals of bioethics. The investigation proceeds at three loci of analysis:

First, **How are the legitimacy and logic of bioethics co-produced in relation to the environmental conditions under which academic bioethics units are created and sustained?** How do the conditions of institutionalization shape the approach and subject matter of emerging disciplines? This question is particularly important for fields such

as bioethics, ethnic studies, womens' studies, and environmental studies, which grew out of social movements in the 1960's and 1970's (Butler and Walter 1991; Rycroft 1991; Allen 1996; Slaughter 1997). Would-be disciplines must demonstrate their legitimacy amongst relevant constituencies, including the existing academy, to acquire the resources necessary for their establishment. Boundary-work is an important part of establishing such legitimacy, and involves both staking out a new intellectual homestead and forging diplomatic relations with supporting constituencies (Abbott 1988; Gieryn 1999).

Second, How are the legitimacy and accountable expertise of bioethics jointly constructed in juridical discourse? In spite of popular interest in bioethics and the growth of bioethics programs and publications, the job market for full-time bioethicists has been limited, reflecting an immature profession. The field lacks a clear set of skills or expertise with which to identify a bona fide bioethicist (Shalit 1997; Russo 1999). While powerful professions can achieve formal and legal authority over their jurisdictions through state licensure, the expertise of emerging professional groups can be legitimated through other means in the legal arena. In an increasingly litigious society, professional groups are often held accountable for useful expertise via tort claims. An exploration of the liability of institutional review boards (IRBs) and health care ethics

consultants provides an understanding of 1) the formal legal authority of IRB expertise, of 2) opportunities for bioethics to further legitimate its research ethics expertise in the courtroom and in university research regulatory compliance systems, and of 3) the ongoing construction of the accountable expertise of health care ethics consultants.

Thirdly, **How are the legitimacy and application of bioethics to U.S. public policy co-produced in the activities of the president's National Bioethics Advisory Commission?** Public bioethics advisory bodies have been a staple of U.S. public policy for addressing such societal disputes, in spite of the limited direct impact these bodies have had on science and technology policymaking. Kelly (2003) has argued that public bioethics advisory bodies serve an important tacit function as boundary organizations that stabilize the border between science and politics, thus preserving the autonomy of science from incursion by other societal stakeholders. These boundary organizations succeed in bounding and controlling the controversy by constraining the set of issues and viewpoints that are addressed, and by dictating the decision-making strategy in ways that privilege participation of some stakeholders over others and veil the intensity of the controversy. How do NBAC commissioners construct themselves and other stakeholders in the policy arena? How does boundary-work performed by the commissioners and their discourse affect

the legitimacy and substance of bioethics? In what ways does the NBAC itself constitute a boundary organization, establishing social order in the encompassing cultural milieu? To what extent do the democratic ideals of the original bioethics social movement remain focal?

Bioethics & the Challenge of Speaking Truth to Power

Bioethicists have distinguished their field from its progenitor, medical ethics. The tradition of medical ethics, focusing on the moral obligations of physicians and the appropriate doctor-patient relationship, can be traced back to Ancient Greece (Callahan 1998; Jonsen 1998). The term “bioethics” was first published in 1970 (Potter 1970), and broadened the scope of “medical” ethics to include biology generally, as well as aspects of environmental, population, and social sciences. Further, bioethics is more interdisciplinary in approach than is medical ethics, drawing from law, public policy, cultural studies, religion, and the social sciences; bioethics has likewise become a fixture in the popular media (Callahan 1998). What influence has bioethics wielded over the last three decades? To what extent has bioethics made biomedicine more socially accountable? At the same time, to what extent has bioethics been made into a public relations tool for academic and corporate biomedicine?

Several victories are claimed for bioethics in the protection of human research subjects and in expanding patient autonomy in medical care. Two former federal commissions with notable bioethicists amongst their membership are generally regarded as having been influential in these areas. The work in the mid-1970's of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission), in response to the Tuskegee Syphilis Study scandal¹, is credited with having transformed the climate of U.S. research, through regulations that it recommended in the *Belmont Report* (see Bulger, Bobby et al. 1995). Jonsen argues that the National Commission's work laid out the moral structure of research, making research a public enterprise (Jonsen 1998). During the early 1980's, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (President's Commission) issued several reports on a variety of

¹ From 1932 to 1972, the US Public Health Service conducted the Tuskegee Study of Untreated Syphilis in the Negro Male, performed on 600 African-American men without their informed consent. Most were illiterate sharecroppers, and about two-thirds of them had diagnosed cases of syphilis. The men were not given appropriate medical treatment for their condition, informed of the study, or given the option of leaving the study, even after penicillin became the recommended treatment in 1947. The study came to light in a front page *New York Times* story in 1972, resulting in public outcry, a federal investigation, termination of the study, and a class action lawsuit, which resulted in a settlement providing monetary reparations to the surviving study participants, their wives, and children. See Jones (1993) for a detailed account of the study and the social conditions that enabled it.

issues, most notably *Deciding to Forego Life-Sustaining Treatment*, which has been widely cited in court cases, bioethics literature, and medical ethics education (see McAllen and Delgado 1984; Bulger, Bobby et al. 1995).

Further, a study of state trial court judges finds that many judges with a variety of informational aids at their disposal regard ethicists' testimony as useful (Hafemeister and Robinson 1994).

But in spite of its past victories, steady growth,² press coverage and political attention, bioethics has been criticized or dismissed by many. Chambliss (1993, 649) charges that "Traditional bioethics, at least according to the latest sociological research in medical settings, is rapidly becoming irrelevant." Commentators fault bioethics for disregarding the social context of ethical issues, decision making, and ethical theory (e.g., Fox and Swazey 1984; Light and McGee 1998; Bosk 1999; Callahan 1999; Churchill 1999). Several observers of bioethics decry the predominant "principlism" ethical approach, which invokes four universal ethical principles (beneficence, nonmaleficence, respect for autonomy, and justice) to resolve ethical dilemmas (see Beauchamp and Childress 1994). Principlism is faulted for

² Pubmed citations to ethics grew from 253 in 1965, to 1867 in 1986, to 6487 in 2005. A 2001 survey of bioethics graduate training programs found that of the 65 programs indicating first year offered, 42 were established from 1990 on (ASBH, 2001). The American Society for Bioethics and Humanities, the sole national professional bioethics association has over 1400 members (ASBH Fall 2005 Newsletter; <http://asbh.org/resources/exchange/2005/ASB05Fal.pdf>, accessed 04/02/06).

being too idealistic (Chambliss 1993) as well as “acontextual, ethnocentric, reductionistic, and sterile” (Muller 1994, 451; see also Light and McGee 1998), especially in favoring the quintessentially American principle of respect for individuals’ autonomy (Wolpe 1998).

Even worse, critics charge that the biomedical establishment has assimilated bioethics, rendering bioethics not only impotent, but a hindrance to critical social reform. This state of affairs has been attributed to the couching of bioethical debates in medical and scientific terminology (Flynn 1991; Ettore 1999), and to the selective provision of funds to only “suitable” bioethics projects (Evans 1998; Bosk 1999; Stevens 2000). Some argue that as bioethicists accepted scientific ideology (Stevens 2000), forged a “jurisdictional alliance” with scientists over moral authority (Evans 1998), and became professionalized, bioethics came into service legitimating biomedical progress. The biomedical establishment was thus able to defuse and redirect potent challenges from consumer and patient activists, diminishing public controversy by removing debate to an expert arena (Kelly 1994; Bosk 1999; Stevens 2000; Wolpe and McGee 2001).

Furthermore, by focusing on ethical conundrums of the affluent (e.g., managed care, assistive reproductive technology), bioethicists may reinforce interests of wealth and power, delaying progress on the pervasive social problems of the disadvantaged (Bosk 1999; Churchill 1999).

The activities and transactions of bioethicists are in fact coming under increasing scrutiny. In September 2000, bioethicist Arthur Caplan was named a defendant in a lawsuit alleging fraud and negligence in the recruitment of a research subject, Jesse Gelsinger who died during a gene therapy experiment; the bioethicist had helped write the informed-consent form used in the study (Gose 2000).³ An August 2001 *New York Times* article raises concerns about the conflicts of interest bioethicists face when they accept donations and paid consultancies from corporations. Such predicaments are abetted by the lack of guidelines for bioethicists working with industry, and the fact that companies can pick and choose from a variety of expert bioethical viewpoints (Stolberg 2001).

One need not search very long to find criticisms of bioethics, but locating comprehensive empirical studies that explore and verify such

³ Caplan had advised the gene therapy researchers to conduct the trial on adult subjects with a mild form of the disease rather than terminally ill children, reasoning that parents of such children are unable to give truly informed consent. He was not the primary defendant in the complaint that was filed, which also named the University of Pennsylvania, the corporate sponsor of the trial; the principal investigator and founder of the corporate sponsor, two attending physicians, the CEO of the university medical system, and two children's hospitals as defendants. The case never went to trial and was settled out of court for an undisclosed sum. Caplan and the health system CEO were dropped from the suit in the settlement, after the plaintiff learned that these men were uninsured and decided not to pursue their personal assets (<http://www.yaledailynews.com/article.asp?AID=13509>, accessed 04/05/06). See the full civil complaint at <http://www.sskrplaw.com/links/healthcare2.html>, accessed 04/05/06).

claims is more challenging. Although sub-disciplines of sociology and anthropology are devoted to the study of medicine, social scientists have been slow to notice bioethics. Renee Fox is arguably the principal pioneer of the sociological study of bioethics (Fox 1974; Fox and Swazey 1974), spurring others to follow (Fox 1976). To date much of the sociology of bioethics has concentrated on the clinical setting, yielding ethnographic case studies of such diverse sites and issues as the “medical morality” in China (Fox and Swazey 1984), brain death and organ transplantation in the US and Japan (Lock, 2001), the surgical ward (Bosk 1979), and in the US, genetic counseling (Bosk 1992; Rapp 1998; Ettore 1999), intensive care units (Zussman 1992; Anspach 1993), alternative medicine (Frohock 1992), and bioethics committees (Flynn 1991; Flynn 1991; Moreno 1995). These studies have examined and affirmed the ways in which bioethical decision making at the bedside is shaped by its cultural, institutional, professional, and epistemic contexts.

Several scholars call for more cogent social-science analysis of bioethics, and for the extension of study to other settings. Cooter finds the history-of-medical-ethics literature to be a “rather bloodless substitute for the political and social history of medical power, practice, and epistemology” (Cooter 1995, 263). DeVries (1995) laments the dearth of attention to the institutionalization and professionalization of bioethics, and to extra-

medical factors encouraging the bioethics enterprise. Reminding readers that bioethics addresses not just medicine but the life sciences generally, Hanson observes that DeVries' and Subedi's edited volume *Bioethics and Society* (1998) "reflects the promise and the infancy" of the sociology of bioethics, and (Hanson 1999, 427).

Social science perspectives can help bioethicists reflect on the fit between the results they produce and their intentions. Anthropologists can refine bioethical analysis and foster critical reflection in bioethics by attending to the transformation of bioethical concepts by various constituencies, such as policy makers and journalists, and by studying the practitioners as well as the issues of bioethics (Muller 1994). Sociology can handily counter the twin assumptions that the domain of ethics lies outside of social structure, and that "the right thinking with the right values" is sufficient to resolve ethical problems (Bosk 1999, 65). Bosk provides a laundry list of questions for sociologists to ask of bioethics, including "What do bioethicists do? For whom? Under what conditions? ...How are bioethicists trained? How do those in the field define their domain of responsibility? How is orthodoxy established? ...How is moral authority constructed and legitimated in the case of bioethicists? How is the role and moral authority attached to it connected to an increased concern for ethics in other societal domains?" (Bosk 1999, 66).

A small group of social scientists have heeded these calls for research and engaged in penetrating sociological analyses of bioethics, in previously unexamined settings. These studies underpin the research project proposed here. In her historical study of the cultural context of the rise of bioethics, Stevens concludes that bioethics became successfully institutionalized because it diffused, rather than represented, the social challenges to biomedicine that arose in the 1960's. In its early years, bioethics exhibited a shift from critique to management of ethical quandaries; bioethics adopted "the limited role of establishing guidelines for the use of procedures and technologies that it largely accepts as inevitable" (Stevens 2000, p. 158). The early history of the Hastings Center, the first bioethics institute in the U.S., reveals the challenges of remaining an independent voice and stalwart critic to biomedicine, in the face of constraints stipulated by powerful biomedical resource providers. Stevens argues that the landmark Karen Quinlan case, which recognized the legal right to refuse life-sustaining medical treatment, served to bolster biomedical interests and strengthen bioethics' foothold in the cultural milieu. Although it is oft remembered as a challenge to physician's authority, the highly publicized *Quinlan* case may be better understood as a reduction of organized medicine's liability.⁴

⁴ In 1975, 22-year-old Karen Ann Quinlan suffered irreversible brain damage from respiratory failure following consumption of alcohol and tranquilizers in a fasting state. When hospital officials refused to remove Karen's ventilator

Altogether, Stevens' examination of bioethical issues and events of the 1970's provides a foundation for further exploration of the cultural and institutional context of bioethics in more recent years. Her work invites further investigation, closing with the question, "will it [bioethics] be able to free itself from the sources that help generate the dilemmas it seeks to resolve?" (Stevens 2000, p. 159).

A few studies have examined the roles of governmental bioethics commissions in public policy, and the institutionalization of bioethics. Essays commissioned for the Institute of Medicine's *Society's Choices: Social and Ethical Decision Making in Biomedicine* (Bulger, Bobby et al. 1995) provide comparative analyses of the National Commission and the President's Commission (Gray 1995), national and state level ethics bodies (Brody 1995), and national bioethics commissions in France and the U.S. (Charo 1995). Other, sociohistorical investigations have explored the political motivations behind the Atomic Energy Commission's precursory introduction of informed consent in the 1940's (Moreno and Hurt 1998), the President's Commission's review of human genetic engineering in the 1980's (Evans 1998), and the role played by expertise in the workings of the

at her parents' request, they filed a lawsuit. The New Jersey Supreme Court awarded Karen's father legal guardianship to make decisions about Karen's medical treatment on her behalf. *In re Quinlan*, 70 NJ 10, 355 A.2d 647 (1976), *cert. denied*, 429 US 922 (1976).

Human Fetal Tissue Transplantation Research (HFTTR) Panel in the 1990's (Kelly 1994).

Evans and Kelly examine more-recent federal ethics bodies as the scene of jurisdictional conflict between biomedicine and bioethics over the management of biomedical progress. Both scholars consider the relationship between the nature of panel deliberations and resource allocation. In Evans' view, the President's Commission deliberations on human genetic engineering exhibited a Weberian rationalization, in which the logic of the deliberations became more systematized and less substantive (Evans, 1998). This rationalization was accompanied by procurement of state resources by bioethicists for reproducing the rationalized ethical system, and the development of a jurisdictional alliance between scientists and bioethicists, that advanced the interests of institutionalized biomedicine. Kelly (1994) finds that the deliberations of federal ethics bodies have become less representative and more technocratic as biomedicine and bioethics engaged in an ongoing power struggle over resource allocation, with the consequences of discrediting opposing viewpoints, legitimizing the biomedical establishment, and deterring institutional change. Given "the problematic role of formal bioethical evaluation in affecting the technological imperative driving medical

innovation,” found by both these scholars, Kelly calls for “further examination of the boundaries of medical science and bioethics” (p. 315).

Bioethics has been roundly criticized for neglecting to grasp its own social context, raising questions about the field’s ability to foster more socially responsible biomedicine. Sociological scrutiny of bioethics will aid bioethicists in reflecting on their own work and its implications, and will also advance our understanding of science and technology by revealing in more detail the relationships among ethics, science, technology, and society. Kelly argues that bioethics has provided a moral imperative for the technological imperative of biomedicine, calling for further study of the ethical work that is done in the legitimation of science and technology more broadly (Kelly 1994).

The dissertation research described here seeks to 1) augment and update the findings and analysis provided by prior sociological studies of bioethics, 2) provide insight into the balancing of the need for institutional legitimacy with the commitment to make the biomedical enterprise ethically accountable. Accordingly, this research project investigates the co-production of legitimacy and knowledge content in recent academic bioethics, by examining the jurisdictional contests waged by bioethicists to sustain their academic departments, establishing their expertise in the judicial forum, and guiding the activities and recommendations of the most

recent national advisory body. This study highlights the complex institutional context and multiple constituencies to which bioethicists are accountable as they work to persuasively inform the uses of biomedicine.

Theoretical Approach

Science and technology studies (STS) has made considerable progress in explicating the ways in which science and technology are socially constructed, and can similarly improve our understanding of the social construction of bioethics. In the same way that science and technology are not value neutral, bioethics (and ethics generally) is subject to its own ideological framing, and has its own devices for obscuring its ideological underpinnings. In particular, STS offers useful conceptual tools for post-structural analysis of bioethics as socially constructed knowledge, as an emerging profession interacting with other professions, as an organizational enterprise, and as a participant in the public policy arena.

Knowledge serves a number of important social functions independent of truth-seeking and rational logic. Ideologies, as a knowledge form, most obviously function socially “to distort, justify, or mystify group positions and interests” (McCarthy 1996, 5). Knowledge functions “in generating what we know social reality to be in providing us with a sense of social unity, spurious or not; in creating and sustaining forms of

domination, legitimate or illegitimate; in rendering our personal lives and relations meaningful” (McCarthy 1996, 6). Clearly knowledge serves not only a descriptive but also a constructive function, complicating the presumed relationship between our knowledge and reality. It is beyond the scope of the present discussion to ponder the epistemological implications of the social foundations of knowledge (see for example analyses by Lynch and Woolgar 1990; Ashmore, Edwards et al. 1994; Bloor 1994; Sismondo 1996); the present investigation is concerned primarily with which knowledges dominate and why (as opposed to which ones have veracity), and secondarily with the very real consequences of the present state of the knowledge regime. In particular, whose knowledges are constitutive of the bioethics enterprise, and accordingly, whose interests are promulgated and legitimated when bioethics participates in the construction and shaping of public opinion and policy?

Boundary-Work and Professions

Thomas Gieryn adopts map-making metaphors to grasp theoretically the dynamics and strategies of scientific knowledge production. Perceiving science as a cultural space, “as part of enduring cartographic classifications of cultural territories that people use to make sense out of the world,” Gieryn expounds a theory of cultural map-making, or boundary-work,

referring to “the discursive attribution of selected qualities of scientists, scientific methods, and scientific claims for the purpose of drawing a rhetorical boundary between science and some less authoritative residual non-science” (Gieryn 1999, 4-5). As with political maps of countries, cultural maps of science reflect changing boundaries, contingent on historically situated struggles. For Gieryn, boundary struggles in science constitute credibility contests wherein cultural map-makers vie for epistemic authority, “the legitimate power to define, describe, and explain bounded domains of reality” (Gieryn 1999). The research reported in this dissertation examines boundary-work performed on the cultural spaces of bioethics and biomedicine, and the contested boundaries between these spaces.

At the start of the 21st century, professionals, including bioethicists, are amongst the primary cultural producers in the U.S., paid to apply their expertise in various settings (Evans 1998). Early critical examinations in the sociology of professions culminated in the **monopoly model** of professions (Freidson 1970; Larson 1977), which regards professionalization as the quest for dominant authority, wealth and autonomy, achieved through organizational and ideological monopolization of the market. Critical of other scholars’ focus on professional autonomy and single professions in isolation, Andrew Abbott argues that professions are best

understood comprehensively, as a **system of professions** competing for jurisdictional control over tasks (Abbott 1988). For Abbott, the hallmark of a profession is possession of an abstract knowledge system, which enables redefinition, protection, and appropriation of the problems and tasks of a profession.

Gieryn argues that Abbott's systems model of professions provides useful tools for the study of boundary-work. Abbott's **jurisdiction contests**, analogous to Gieryn's credibility contests, occur in three arenas: the actual work sites of professionals, the legal arena of legislatures and courts, and the public arena of mass media and public opinion. Abbott also identifies a set of contextual factors that shape jurisdictional contests and settlements, a set of rhetorical strategies for arguing jurisdictional claims, and a set of jurisdictional settlement patterns. The social worlds aspect of boundary-work theory also refines Abbott's model, by examining cooperative projects across boundaries as well as jurisdictional contests, and by highlighting the fluid and heterogeneous membership of groups engaged in boundary projects (Gieryn 1995). The research described here makes use of composite tools from boundary-work theory and the systems model of professions, examining and comparing boundary projects in bioethics in the three arenas of the academic workplace, the courtroom, and a national public policy body. Abbott's tools for dissecting jurisdictional contests will

be used to examine how professional bioethicists, jurists, physicians, scientists, and theologians conduct boundary projects, and explore the consequences for the legitimacy and content of academic bioethics.

Organizations

Organizations also play crucial roles in boundary-work, at once providing the necessary resources for professionals to pursue boundary projects, and placing contextual constraints on their efforts. Social scholars have explored how professionals' power and authority is based on the rallying of material and organizational resources (DiMaggio and Powell 1983; Collins 1989; Kay 1993; Fuchs 1994; Kevles 1995; Slaughter 1997). Moore (1996) observes that organizations, like rhetoric and material or conceptual boundary objects (Star and Griesemer 1989), constitute boundaries; organizations create durable sets of rules and routines that stabilize social relations. Moore describes how scientists' creation of public interest science organizations in the 1960's stabilized the boundary between science and politics by constructing an enduring representation of science serving the public interest and obscuring the political nature of knowledge production (Moore 1996). Guston elaborates theory on boundary organizations by incorporating the principal-agent perspective, underscoring the accountability of boundary organizations to their principals (Guston 2000).

Hackett (2001) probes the organizational perspectives of resource dependence, new institutional theory, and technocratic organization theory for their utility in studying new organizational forms in research universities, and suggests that they provide complementary explanations. The **resource dependence** approach explains the strategic action of organization members in terms of changes in the organization's environmental resource base; organizational actors seek stable resources from external agents, such as a government, to sustain the organization, resulting in a struggle for control of the organization between internal and external actors (Pfeffer and Salancik 1978; Slaughter and Leslie 1997). While it yields testable predictions, resource dependence tells only part of the story: given empirical cases of small resource exchanges, resource dependence affords an unsatisfactory account of organizational actors' considerable efforts to please external resource providers, an account devoid of reference to the semantic, cultural implications of the exchange (Hackett 2001).

New institutional theory remedies the semiotic deficits of the resource dependence perspective, explaining the tendency toward homogeneity in an organizational field in terms of organizations' quest for legitimacy and hence, resources (DiMaggio and Powell 1983). However, the theory is unclear as to the mechanisms by which coercive, isomorphic

pressures operate, and overlooks power, ideology, and the impact of the pursuit of legitimacy on the content of the organization's work and products (Hackett 2001).

A possible response to pressures for institutional conformity is to generate new organizational forms that alleviate such pressures (Croissant 2000). Heydebrand (1989) describes the recent phenomenon of the technocratic organization, a post-bureaucratic organizational form marked by informal, nonlinear authority and responsibility structures, permeable conceptual categories, and flexible structure and strategies, secured by a strong intramural cultural solidarity. Hackett (2001) argues that university-industry research relations embody technocratic organizations, but laments that Heydebrand's concept lacks causal and developmental explanation, and is silent on the impact of this organizational form.

In contrast to Heydebrand's primarily descriptive concept, the theory of **academic capitalism** (Slaughter & Rhoades, 2004) endeavors to account for both the process and implications of college and university integration into the new economy. The new economy treats knowledge as a raw material and commodity, and impacts higher education due particularly to its global scope and its reliance on non-Fordist manufacturing approaches, a highly educated and skilled workforce, and technology-savvy consumers. The neoliberal state fosters the new economy and academic capitalism by

mobilizing resources towards production functions, and by enabling individuals as economic actors instead of emphasizing social welfare functions.

Rather than viewing higher education institutions as discrete, bounded entities, academic capitalism highlights the networks of actors that link universities to other universities, corporations, and various government agencies. Academic capitalism does not see higher education institutions as being passively corporatized or subverted by external actors, but instead describes how various actors inside universities actively employ various state resources to link their academic institutions to the new economy by creating new knowledge circuits. These activities have had a significant impact on both academic research and undergraduate, graduate, and professional education, which Slaughter and Rhoades interpret as a shift away from a public good knowledge/learning regime (grounded in Mertonian norms and the separation of public and private sector activities) towards an academic capitalist knowledge/learning regime (promoting the privatization of knowledge and profit taking by institutions, faculty, and corporations). There has not been a wholesale regime change; the two knowledge/learning regimes coexist in uneasy tension in the postsecondary sector.

One manifestation of academic capitalism is the emergence of interstitial organizations, such as university technology transfer and

economic development offices, which manage new activities related to the generation of external revenues for higher education institutions, helping administrators and faculty tap into opportunity structures in the new economy. University centers and institutes, a longstanding organizational form, also further the aims of academic capitalism, with many center and institutes promoting partnerships with industry and state entities, encouraged by neoliberal policies. A substantial number of academic bioethics programs are housed in university centers and institutes, and the research presented here will examine the implications of academic capitalism for bioethics.

Organizational perspectives provide considerable insight into the structural aspects of the bioethics enterprise. These theories suggest questions and approaches for examination of the co-production of legitimacy and knowledge in university bioethics centers and federal bioethics commissions. How do bioethics organizations constitute Gieryn's cultural boundaries? What boundary-work do these organizations perform? What strategies do these organizations employ to secure legitimacy and resources, what institutional pressures do they face, and with what influence on the products of these organizations? Is bioethics employed by actors in higher education institutions to tap into new opportunity structures, and how? These questions are addressed in subsequent chapters.

Poststructuralist Policy Analysis

Kevles' (1995) historical study of physics in the U.S. attests that the successful discipline is one that provides useful service to governments. For thirty years, bioethics has played a regular role in public policy formation as it pertains to science and technology, most visibly in federal advisory commissions. The boundary-work perspective asks, what characterizes the cultural maps bioethicists produce for the policy arena, to whom in the policy arena are such maps useful, and for what? Gottweis (1998) rejects prevailing political science approaches to science and technology policy, which uncritically accept science and technology as apolitical truth-seeking activities, and neglect important relations among knowledge, language, meaning, and power. Likewise, while "conventional schools of political science privilege either actors or structures in their accounts, poststructuralist political analysis avoids such a dichotomization by offering a language or discourse-analytical perspective that acknowledges the importance of structural phenomena and contexts for the understanding of politics without reducing actors to 'outcomes of structures'" (Gottweis 1998, 12).

How can discourse analysis provide an explanation of policy formation? Such a tactic seemingly fails to account for the negotiation that created the discourse, and is not privy to closed-door negotiations that

produce the final policy outcome. Poststructuralist policy analysis “looks at the texts of government not only as declarations of interest or as statements of strategy but also as material practices and as strategies to create order—as representations and interventions that actually shape politics” (Gottweis 1998, p. 333). Likewise, Foucault asserts the profound importance of discourse itself, which is “not simply a **translation** of struggles and of systems of domination, but that for which and by which the struggle is waged, **the very power that is at stake**” (quoted in Larson 1990, 36, emphasis added). In essence, language constitutes politics. Thus, bioethicists’ discourse is seen as **enacting** policy, in part by legitimating a political agenda that serves the interests of bioethics and its resource providers and jurisdictional allies. Legitimation is accomplished by a process of inscribing events and artifacts, such as embryonic stem cells, with political and social meaning.

In summary, legitimacy and knowledge in bioethics are co-produced as the result of jurisdictional boundary projects pursued by bioethicists and other professions in various societal arenas and organizational contexts. Theoretical perspectives on boundary-work in science, professions, organizations, and poststructural policy analysis provide functional approaches to revealing the nature of bioethics boundary projects and the societal interests consequently served or slighted, thus affording a means to

begin assessing the role of bioethics in cultivating socially responsible biomedical science and technology. It is the aim of the research described here to provide such an account of legitimacy and knowledge production in academic bioethics practiced in the U.S..

Legitimacy and knowledge production, and ethics generally, are of direct but insufficiently explored interest to the fields of both higher education studies (HES) and science and technology studies (STS). There has been little HES analysis of higher education's role in shaping the larger culture through knowledge production, other than episodic philosophizing about institutional mission. In his career retrospective, Burton Clark calls for more organizational analysis of disciplines and academic departments, asserts the relevance of studying science as a social institution, and admonishes a fixation on an ecology of education framework that obscures the agency of higher education organizations (Clark 2000). STS has generated considerable critical scholarship on the politics and sociology of scientific knowledge, but has tended to neglect ethics (for an exception, see Chubin and Hackett 1990) and the institutional conditions of knowledge production in universities. This dissertation project seeks to begin remedying these overlapping knowledge gaps in the HES and STS fields by examining the co-production of legitimacy and intellectual development in bioethics, in light of the institutional contexts of bioethics. Accordingly, it is hoped that

this research will provide useful insight to the bioethics enterprise as it works to balance its need for institutional legitimacy with its commitment to develop effective tools for making the biomedical enterprise ethically accountable to all of society.

Methodology: Overall Approach & Justification

The central question of this research project is, how are the legitimacy and logic of bioethics co-produced? Analysis of this question proceeds on three levels: the establishment of bioethics academic units in higher education, the construction of accountable bioethical expertise in juridical discourse, and boundary-work performed in federal public policy discourse created by the National Bioethics Advisory Commission.

My research relies heavily on the techniques of discourse analysis and field study. Fieldwork has been used extensively in science and technology studies (STS), first in the single-site approach, as employed in laboratory studies of the manufacture of scientific knowledge (Knorr-Cetina 1981; Latour and Woolgar 1986); more recently multi-sited ethnography has been used to examine macro-level knowledge politics, such as AIDS activism and research (Epstein 1996) and the emergence of the trope of immunity in the U.S. (Martin 1994). Fieldwork has long been valued for “thick description” from extensive observation, suggesting that multi-sited

ethnography might sacrifice understanding of the tree for the forest. But Marcus notes, the “cultural logics so much sought after in anthropology are always multiply produced, and any ethnographic account of these logics finds that they are at least partly constituted within sites of the so-called system” (Marcus 1998, 81).

Accordingly, a multi-sited field work approach permits analysis of how the legitimacy and content of bioethics expertise are multiply co-produced in the American knowledge economy. This investigation “follow[s] the people,” as Marcus describes (1998, 90-91), or more specifically bioethicists, as they seek to legitimize and expand their expert knowledge at various sites of the system—in university bioethics departments, as expert witnesses waging jurisdictional contests in the courtroom, and in the federal public policy arena. This approach highlights the importance of social and organizational contexts in the negotiation of knowledge content and legitimacy, and reveals actors’ negotiation tactics.

Discourse analysis is closely associated with post-structuralism, which perceives language as constitutive of social reality. Actors shape reality through the use of socially constructed languages, constrained by the social milieu. Scholars have used poststructuralist discourse analysis to explain how legitimation is accomplished. For example, Slaughter used discourse analysis to demonstrate how the language of official ideology of

higher education, as expressed by AAU presidents, legitimates a conservative domestic public policy agenda in the service of private interests (Slaughter 1991). Gottweis (1998) and Wright (1994) conducted poststructuralist discourse analysis of biotechnology policy in the U.S. and Europe. Recently, scholars further used discourse analysis to show how legitimation strategies affect the intellectual approaches of bioethics (Evans 1998; Stevens 2000) and Afro-American studies (Small 1999). Jasanoff (1998) and Halfon (1998) used discourse analysis to study the politics of expertise contained in testimony during the O. J. Simpson trials. In the study of legitimation and knowledge production in bioethics, discourse analysis allows deconstruction of rhetorical and ideological strategies of legitimation, and reveals the language categories shaping the character and trends of bioethics as an intellectual construction.

This study uses a multi-sited fieldwork approach to examine the co-production of the legitimacy and content in bioethics knowledge, as they occur in postsecondary academic units, court documents and transcripts, and the federal public policy arena. Data used include the primary bioethics literature, departmental Web sites, archives, and documents, interviews, professional association materials, NSF institutional research rankings, juridical discourse, and National Bioethics Advisory Commission publications and meeting transcripts. Questions for analysis include: How

do bioethicists portray their own profession in relation to potential resource providers, other professions, and the institution of biomedicine? What rhetorical strategies are employed to legitimate the authority of bioethics? How do such rhetorical strategies shape the approach and content of bioethics knowledge, and its ability to influence biomedicine?

To paraphrase Andrew Abbott's characterization of the professionalization process, the boundary-work performed in the legitimation and knowledge production of bioethics is best seen as "the multilevel, contagious, complex social process that it actually is," not as "a simple collective action by a cohesive group" (Abbott 1991, p. 380).

Accordingly, the three levels of analysis explored in the proposed project will provide interrelated, complementary accounts of boundary-work in bioethics, yielding clues about how the legitimation and knowledge produced are mutually reinforced in the three arenas studied. Some bioethicists have entered all three arenas, and comparing their corresponding activities will illustrate the complex societal context of academic bioethics. The different organizational cultures of the three arenas suggest the probability of slightly different legitimation strategies. Are these strategies consistent with each other, and with the aims of the field? Given that the meso and macro levels of analysis are constructed at the micro level, and that the micro-level units in this study (academic

bioethics departments) are the main and most permanent affiliation of bioethicists, we are led to ask whether academic units play a special or greater role in boundary-work than the other two arenas, and hence whether academic bioethics departments warrant more attention from policy makers. This investigation's multilevel, qualitative analysis of bioethics aims to enhance our understanding of the challenges and opportunities bioethicists face in their efforts to shape the practice and application of biomedicine for the good of all.

PART I:
BIOETHICS IN THE UNIVERSITY COMMUNITY

How do the conditions of institutionalization, and the pursuit of institutional legitimacy, shape the approach and subject matter of emerging academic fields? This question is particularly important for fields such as bioethics, ethnic studies, womens' studies, and environmental studies, which trace their roots to social movements in the 1960's and 1970's (Butler and Walter 1991; Rycroft 1991; Allen 1996; Slaughter 1997). Would-be disciplines must establish their legitimacy amongst relevant constituencies, including the existing academy, in order to acquire the resources necessary for their formation and stability. Boundary-work is essential to establishing such legitimacy, and involves both staking out a new intellectual homestead and crafting diplomatic relations with supporting constituencies (Abbott 1988; Gieryn 1999). Accordingly, boundary-work shapes the logic of the emerging field.

How do institutional conditions shape the emerging academic field of bioethics? What jurisdictional claim are bioethicists making in the academy? What value do master's degree programs in bioethics provide to students, and to the academic bioethics centers that offer them? The next three chapters of this dissertation will address these questions.

Universities represent the primary workplace and institutional home of the bioethics jurisdiction in the system of professions. The academic wing of bioethics, like the academic wing of other professional fields, serves several functions, including knowledge production, education, and legitimation of the field at large (Abbott, 1988). Legitimation is accomplished by tying the professional work of the field to larger societal values, and communicating those links in professional and public discourse.

In order to examine the legitimacy and logic of bioethics in the academic sector, I conducted a case study of an academic bioethics center and its master's degree program in bioethics. I supplement the case study data with discourse from the bioethics literature to provide a richer account and to tie my case study findings to the broader universe of bioethics in the US. Resource-dependency, new institutional, and poststructuralist boundary-work theory are used to generate an account of the institutionalization of bioethics and the construction of its jurisdiction in the academy, in the case of the bioethics center studied.

Chapter Two provides an account of the establishment of a bioethics center, drawn from interviews with faculty members and documents from the bioethics center's archives. Chapter Three examines the professional jurisdiction of academic bioethics by examining the self-perceived identity of faculty members at the bioethics center, and the relationships between the

bioethics center and other key constituencies on and off campus. Chapter Four investigates the value of master's programs in bioethics, both to bioethics centers and to their students, drawing from faculty and student commentary presented in a bioethics journal, and from student interviews conducted during my case study.

Together, these three chapters explore how the institutionalization of the center, its relationship to other constituents, and the perceptions of its faculty and students reflect the ongoing construction of an academic and professional jurisdiction for bioethics in the existing organizational field, or arena, of professions and academic disciplines. In so doing, these chapters provide an assessment of how well one academic bioethics center has been able to pursue a rigorous ethical critique of biomedicine, and why.

CHAPTER 2—
ESTABLISHMENT OF AN ACADEMIC BIOETHICS CENTER:
ENTREPRENEURS OF ETHICS

In the 1990s and beyond, the number of graduate training programs in bioethics has increased by at least 42, a 182% increase (ASBH, 2001). A significant portion of these programs are housed in bioethics centers and institutes (C&Is), most of which have an institutional home in, or are affiliated with, academic medical centers. University C&Is of all kinds have proliferated in the post-WWII era, contributing to the expansion of academic research, and aimed at mediating between the applied knowledge demands of society and the basic research emphasis of university researchers (Geiger, 1990). C&I boundary-spanning between society and the university brings both benefits and challenges. While C&Is improve the relevance of university products, the particular societal needs to which C&Is respond are driven by the funding interests of sponsors (Stahler & Tash, 1994). Accordingly, one ongoing concern about C&Is is that their programmatic focus may be too driven by “chasing dollars” (Stahler & Tash 1994, p. 545).

C&I development represents a strategy pursued by university administrators on the one hand, and by academic researchers on the other hand. From the perspective of administrators, C&Is are start-ups incubated

by the university; successful ones will survive and contribute significantly to the funding base and research productivity of the institution (FCEPRI, 2003). C&Is, as well as interdisciplinary programs, have been cited as contributing to institutional competitiveness in national research university rankings (Geiger, 1990). From the perspective of entrepreneurial researchers, C&Is serve as an opportunity to pursue interdisciplinary collaborations (also of interest to university administrators, as a research productivity strategy), and as a means to establish an institutional foothold for emerging academic fields, such as bioethics. An academic C&I may be promoted to the more stable and prestigious organizational form of university department if the C&I can secure stable research and tuition funding streams, arguably signifying its societal relevance and academic credibility to the larger university community (Larson & Barnes-Moorhead, 2001). Critical to academic credibility is the fit of the C&I mission with the university's goals and mission and portfolio of academic programs; the C&I should "represent a logical initiative within the university's overall research program" (Stahler & Tash, p. 550).

Slaughter and Rhoades (2004) describe a growing tension in higher education between the traditional **public good** knowledge/learning regime and the newer, expanding **academic capitalism** knowledge/learning regime. The latter is associated with a policy trend at various levels promoting,

amongst other things, the growth of C&Is, which connect academe to outside constituencies, namely the state and industry. A related manifestation of academic capitalism is the emergence of interstitial organizations, such as university technology transfer and economic development offices, which manage new activities related to the generation of external revenues for higher education institutions, helping administrators and faculty tap into opportunity structures in the new economy.

The theory of academic capitalism (Slaughter & Rhoades, 2004) describes how universities have integrated with the global, knowledge-based new economy. The neoliberal state has worked closely with industry to build the new economy, focusing on developing individuals as economic actors, rather than emphasizing state social welfare functions. Higher education institutions operating in the academic capitalism regime have benefited from privatization and commercialization policies and regulatory changes pursued by the neoliberal state. Academic capitalism has been further promoted by reductions in state funding for higher education, slowed growth of federal research grants and contracts, and heightened consumer sensitivity to tuition increases, all of which have encouraged colleges and universities to pursue corporate revenue streams.

The new economy has posed additional challenges for academic medical centers. Rising competition from managed care (see Meyer et al.

1998; Page 1996) and cutbacks to Medicare and Medicaid due to the Balanced Budget Act of 1997 resulted in calamitous operating losses for many academic medical centers, which had relied on high fees for service and federal monies to offset the costs of medical education, research, and indigent care (Beller, 2000). Academic medical centers are now also faced with competition for pharmaceutical industry research dollars, from contract research organizations (CROs) and site management organizations that promise to deliver study results more quickly than their academic counterparts. Over thirty medical colleges have set up centralized clinical trial offices modeled on the private sector, in hopes of streamlining academic research competing successfully against CROs for industry grants (Washburn, 2005). Medical faculty members are simultaneously under pressure to see more patients and win more research grants and contracts, to increase revenues.

The aggressiveness of universities and their medical schools in pursuing research dollars is reflected in lobbying activity on behalf of higher education, and in collective efforts to curtail federal regulation in favor of institutional self-policing. The higher education sector now outspends defense contractors on lobbying efforts (Brainard, 2004). After the US Department of Health and Human Services issued relatively mild draft regulations in 2001 on conflicts of interest in human subjects research,

national higher education associations demanded their withdrawal, and succeeded in replacing them with voluntary self-policing measures (Washburn, 2005). A substantial portion of university professors who serve as institutional review board (IRB) members have consulting relationships with pharmaceutical companies (Campbell et al., 2003), and according to bioethicist George Annas, IRBs are under pressure to approve studies to bring in desperately needed research dollars (Washburn, 2005). In 1999, University of Toronto president Robert Prichard was exposed for lobbying top Canadian government officials to change drug patent regulations, in order to preserve a \$20 million donation that the university was negotiating with a major pharmaceutical company (Deverell, 1999).

Medical schools and their faculty members are thoroughly enmeshed with the biomedical industry. Medical schools take equity in professors' startups, run venture capital funds, set up C&I incubators, and extract royalties from their faculty entrepreneurs. Faculty work on grants from industry, are paid to be authors on scientific articles ghost written by industry, hold stock options in companies they consult for, and relinquish to the sponsoring companies protocol design and ownership of, and sometimes even full access to, clinical trial data (Washburn, 2005).

Clearly, the new bioethics C&Is of the 1990s faced quite a challenge, establishing themselves in affiliation with crisis-stricken academic medical

centers. How does bioethics represent a “logical initiative” within university and medical school research programs, caught in the tension between the public good and academic capitalism knowledge regimes? In what ways do bioethics C&Is reflect the interests of university administrators, and the interests of academic bioethicists? Does the growth of bioethics C&Is represent attempts to tap into biotechnology-related opportunity structures? Ultimately, how well have bioethics C&Is succeeded at securing a stable funding base, preserving a firm, self-defined mission, and providing rigorous ethical critique of biomedicine? This chapter presents a case study of the development of a bioethics C&I (from here on referred to as a bioethics center for simplicity) at an American university, examining how its relevance is established to stakeholders, how it secures stable funding, and how it demonstrates academic credibility.

National Profile of Bioethics Academic Programs

Before presenting the results of the case study, in this section I outline some broad features of the institutional landscape of academic bioethics in a profile of bioethics programs housed in US colleges and universities. What, if any, characteristics apply to all or most bioethics units? How heterogeneous are they as organizations? The starting point for this profile is a national graduate program survey conducted in 2001 by the American Society for

Bioethics and Humanities, which I supplement with university rank and funding data collected by the National Science Foundation. Note that graduate training programs in bioethics do not map exactly to the set of bioethics C&Is; some C&Is do not have graduate programs, and some bioethics graduate programs are supported by other academic units, such as philosophy departments.

The American Society for Bioethics and Humanities (ASBH), the sole professional bioethics society in the US, conducted a survey of graduate bioethics programs in North America, in cooperation with the Canadian Bioethics Society, and supported by a Greenwall Foundation grant. The ASBH Status of the Field Committee compiled a list of programs and directors, and contacted those directors asking them to complete a web-based survey designed by the committee. The Committee's report (ASBH, 2001) analyzes the responses of 47 institutions, which offer a total of 108 bioethics graduate training programs (each degree offered was counted as a separate program, e.g., one program might offer an MA, a PhD, and one or more joint professional degrees such as JD/MA and MD/PhD).

MA programs, whether offered alone or as joint degrees were most prevalent at 63 programs, followed by 19 PhD programs, 13 fellowship programs, 11 certificate programs, and 2 "other." Bioethics graduate programs reflect a diverse array of organizational bases (department 43%,

center 29%, division 9%, institute 4%, interdepartmental/interdisciplinary 4%), institutional homes (college of medicine 33%, college of arts & sciences 20%, medical center 11%, graduate school 9%), and disciplinary homes (philosophy 29%, medicine 26%, inter/multidisciplinary 15%, religious studies/theology 6%), and faculty disciplinary backgrounds (aggregate: philosophy 20%, medicine 15%, law 13%, religious studies/theology 12%, nursing 10%, history 6%, sociology 4%).

One of the report's appendices catalogs open-ended responses on the strengths and weaknesses of the bioethics programs, as reported by the program directors. Themes in the strengths reported include inter/multidisciplinarity, grounding in philosophical theory, and the provision of clinical experience/environment to students. Thematic concerns about program weaknesses include funding, provision of practical experience, student preparation, uncertain program future (e.g., related to recruitment, funds, marketing, or inadequate faculty size or institutional support), and contribution to students' career trajectory (e.g., lack of training in getting published, job placement abilities).

In its "Points for Discussion" section, the report highlights the expansive growth of bioethics graduate training programs since 1990 (42 programs established, a 182% increase), and conveys alarm about the lack of placement data kept by programs, particularly in light of the general

overproduction of PhDs in the US, especially those in the humanities. The presence of a “significant minority” of programs indicating that they consider their MA, certificate, or fellowship programs to be adequate preparation of full-time bioethics work, and a lack of data about what full-time bioethics jobs are available, raises concerns about programs’ obligations to and responsibilities for their current and prospective students. However, as clarified in a separate article by two of the Committee members, it may be the case that few bioethics students are “traditional,” but instead are professionals already holding positions (Aulisio & Rothenberg, 2002). The report raises the concern, “will the current disciplinary diversity of the field be lost to a growing disciplinary homogeneity” as more degrees and programs are identified specifically as bioethics or medical humanities?¹

In order to examine some further institutional characteristics of bioethics graduate programs, which are clearly diverse in many respects, I culled and augmented the pool of programs from the ASBH survey. First I omitted the certification and fellowship programs, in order to focus on actual graduate degrees in or related to bioethics that are likely to generate graduates who will contribute to the professionalization and

¹ See Mullins (1972) for an account of the stages and social structures involved in the development of new scholarly specialties, as illustrated by the case of molecular biology. Initially, according to Mullins, diverse scholars are drawn together merely out of interest in the same conceptual problem, but over time they organize and distinguish the stylistic and methodological approaches of the new specialty.

institutionalization of bioethics in the academy. Of the programs offering graduate degrees, some of the degrees are in traditional disciplines, such as philosophy or theology, and some are specified interdisciplinary degrees in bioethics, medical humanities, or a similar designation. I also omitted the five Canadian bioethics programs in the ASBH survey, in order to analyze the bioethics programs against data on US research universities, including their receipt of federal research dollars, an indicator of institutional quality and prestige.

Uncertain as to the completeness of the ASBH survey, I employed lists of bioethics graduate programs available from bioethics.net and the American Philosophical Society's 1997 Survey of Programs in Bioethics, developed by the society's Committee on Philosophy and Medicine, to find more programs.² I identified nine additional bioethics programs offering graduate degrees, and added them to the population.

The unit of analysis is somewhat complicated, because some programs are jointly offered by two or more institutions (e.g., Baylor College of Medicine and Rice University share the Center for Medical Ethics and Health Policy), and some institutions offer several discernible programs; for example, the University of Virginia offers an MA through the Center of Biomedical

² The results of the survey are available at <http://www.apa.udel.edu/apa/governance/committees/medicine/survey/> (accessed 10/29/05); this survey has not been repeated.

Ethics, an MA and PhD in religious studies with a bioethics concentration, and an MA and PhD in philosophy with a bioethics concentration. For the purposes of examining institutional characteristics, I use the institution as the unit of analysis, sometimes considering the institutions of jointly sponsored programs together as a hybrid, as noted. Altogether there are 48 institutions, and 44 bioethics graduate degree-granting programs. One, Western Michigan University, formerly but no longer offers an MA in philosophy (applied ethics with a medical ethics concentration); it is included in the population of institutions as the only known expired program.

Bioethics graduate programs are skewed geographically, concentrated most heavily in the eastern seaboard states, and in the Midwest. New York has the most bioethics programs with six, followed by California with four; Illinois and Ohio each have three, and Wisconsin, Texas, and Michigan each have two bioethics programs. States with largely rural populations and no top-ranked research universities have few or no bioethics programs.

Bioethics programs have a strong association with elite higher education institutions. Bioethics programs are strongly associated with top-ranking institutions in terms of research funding. The Center at the University of Florida has categorized National Science Foundation data on 616 research universities into four classes based on the amount of federal research dollars they received in FY2000—more than \$20 million, \$5-20

million, \$1-5 million, and less than \$1 million.³ These classes are referred to as Tiers One through Four, respectively. Universities with bioethics graduate programs are overrepresented among Tier One universities, with over 74% bioethics programs housed in Tier One institutions; only 26% of all federally funded research universities are categorized as Tier One. Five of the institutions with bioethics programs were not listed in the Center's data tables as receiving federal research dollars. Private universities are also somewhat overrepresented among institutions with bioethics programs. About 39% of universities receiving federal research funding are privately controlled, but that group of private institutions possesses about 54% of the population of bioethics programs.

Not surprisingly, bioethics programs are also strongly associated with the presence of a medical school. While approximately 20% of universities receiving federal research dollars have medical schools, 62.5% of bioethics graduate programs share a campus or an affiliation with medical schools (all four of the bioethics programs that are jointly sponsored by two institutions have a medical school at one of the institutions). Of the thirteen institutions with bioethics programs but no medical schools, six have strong research programs in the life sciences or environmental sciences (dedicating 40% or more of their research dollars in these areas) and four have highly ranked

³ http://thecenter.ufl.edu/research_data.html, accessed 10/29/05.

philosophy departments according to the National Research Council (there is some overlap between these two groups). Eight bioethics programs remain unassociated with medical schools, strong biological research bases, or high-ranking philosophy departments.

In summary, bioethics programs are diverse in their disciplinary and organizational foundations, suggesting somewhat individualized development driven by local needs and opportunities. However, bioethics graduate programs have been more likely to arise in prestigious institutions with biomedical education and research resources, and their numbers have grown dramatically since 1990. Is the presence of bioethics graduate programs a **result of** academic capitalism, a calculated **means to** acquiring more academic capital, or both? Does bioethics primarily play a supporting role to medical and other professionals, serving educational and advisory functions, or is it emerging as a distinct field with largely self-defined objectives?

Case Study of a Bioethics Academic Unit

Contextualized by the national profile of bioethics programs, my case study examines the co-production of legitimacy and intellectual development in an academic bioethics unit. Several criteria were used for selecting potential study sites. The bioethics C&I that I studied does not so much represent an “average” bioethics unit, but rather more of a model bioethics

unit, in terms of successful institutionalization. I chose a relatively secure bioethics C&I at a Tier One institution, in the top research-funding quartile of all institutions with bioethics programs, which would provide me with a good opportunity to examine winning strategies for establishing the legitimacy of bioethics, and the relationship between bioethics and academic capitalism. Accordingly, candidate academic units for my study ideally were entrepreneurial in nature (actively, even determinedly, seeking and successfully procuring external funding), featured one or more core faculty who are prominent in the field, and offered a graduate degree program.⁴ Graduate degree programs not only confer prestige and status on their sponsoring departments, they have implications for the professionalization of bioethics, and hence have been the subject of lively debate in the bioethics discourse, as we will examine in Chapter 4. A key question is whether and how managerial incentives influence a unit's developmental strategies: to what extent was the C&I that I studied being deployed as a tool by its parent institution to establish external legitimacy, to tap into new opportunity structures?

⁴ When I conducted my fieldwork in 2002, I was able to identify eighteen bioethics C&Is at post-secondary institutions offering bioethics graduate programs. There are other academic bioethics C&Is that do not as of this time offer affiliated graduate degree programs, such as Stanford University's Center for Biomedical Ethics.

Some of my respondents asked that their individual identities, and the identity of their organization, be kept confidential. Given the small number and size of bioethics C&Is and the predominance of males in the field, all of my twenty-eight case study respondents are anonymized as female, although both male and female faculty, staff, and students participated in the study. I refer to my study site as the Bioethics Center (or simply the Center, or BC), and its post-secondary parent institution as Letters University. One third of the faculty, and about half the graduate student body at the Bioethics Center were female at the time of my visit in 2002. In addition to the Center director, I interviewed about 54% of the faculty (38% of these were female), including several core faculty, education program directors, adjuncts, visiting, emeritus, and joint faculty who pre-dated the Center as tenured members of other departments on campus. The faculty members I interviewed were evenly split between junior and senior faculty (excepting the Center director). Notably, I was able to get an interview with only one of the clinicians on the faculty, the director of education in the medical school. I interviewed only about 15% of the enrolled students (nearly two-thirds of these were female), due to lack of more volunteers. I also interviewed 29% of Center staff (80% of these were female), including research and administrative personnel.

Honoring the request for confidentiality requires me to omit several important axes of variation in my analysis and presentation, including

gender, race, disciplinary affiliations, and faculty rank. Similarly I do not identify the particular topics faculty chose to study, and omit other variables that would reveal the Center's identity.

For the most part readers will be unable even to associate quoted statements made by the same individual. I expect that bioethics scholars personally familiar with my study site will likely be able to guess its identity, but they should be able to associate only a few interview responses with particular persons, and these revelations are not damaging.

In spite of these limitations, I was still able to answer most of my intended research questions to my satisfaction, although it would have been possible to present an even more compelling story if it were permissible to draw more fully from all the data I collected. I was able to address some variables indirectly by using responses from participants that compare different categories of nominal variables, such as institutional type and geographical characteristics.

I conducted a three-week field visit to the Center at Letters University to collect my data. Sources for the case study include archival materials, center documents and publications, the Center website, classroom observations, and semi-structured interviews with Center faculty, staff, and

graduate students,⁵ with a focus on the founding director. My analysis of these data first focuses on interests and resources central to the creation of the BC, and then I examine faculty concerns about securing resources, institutionalizing the Center, and legitimizing its work. What strategies are employed to secure legitimacy and resources for the Center, what institutional pressures does it face, and with what influence on its knowledge products? How does the Center's portrayal of itself reflect the concerns of resource providers?

Establishment Of The Bioethics Center

What conditions enable the establishment of bioethics centers at some colleges and universities, but not at others? What factors shape the formation of bioethics curricula, and the development of new academic bioethics centers? Slaughter (1997) observes that “most American scholars of the post-secondary curriculum continue to write about curricular formation and change as if it were **internal** to community colleges, colleges and universities” (p. 2; emphasis mine). Rather, she argues “continued connections with clients, sponsors, and advocacy groups external to the university are central to the maintenance of the status, prestige, funding,

⁵ Student interviews did not provide helpful data regarding the establishment, institutionalization, or political environment of the Bioethics Center, and so their responses are not incorporated in this chapter. However, student voices figure prominently in Chapter 4, and also appear in Chapter 3.

popularity, and sometimes existence of specific curricula” (1997, p.3). With respect to bioethics programs, which have grown steadily in number since 1990 (see ASBH, 2001), Kreeger (1994) contends that media, professional, and governmental attention to bioethical issues have stimulated student and faculty interest, which together with support from administrators and alumni have resulted in institutional and individual commitment of resources to bioethics programs. In what follows, I will more carefully scrutinize these and other factors, providing a more comprehensive account of the development of a bioethics center, contextualized by some general observations about the overall population of bioethics centers in the US and some comparative comments made by some of my study respondents.

Geography

Two of my respondents at the Bioethics Center, both career academics, emphasized the importance of “geography” in bioethics, meaning the physical layout of the campus and the consequent configuration and intellectual permeability among disciplinary departments within the institution. For example, one respondent noted that at Harvard (which does not have a bioethics center *per se*, but does have a non-degree-granting Center for Ethics and the Professions), enclaves of scholars are physically separated by the Charles River. The second respondent made the point more emphatically,

stating that the close proximity of a medical school to the rest of its university campus is “the [single] most important factor in making bioethics work.” Geography is also significant to bioethics at the regional level; bioethics spread from east to west in the US, because of the concentration of medical schools in the east, providing “incubators” where “you could learn a lot about what the [bioethical] issues were.”

Institutional Characteristics

Beyond geography, a university’s institutional character affects the development of bioethics programs. One respondent noted that early institutional leaders in bioethics tended to be associated with educationally innovative medical schools, such as Case Western Reserve University, whereas older, more traditional medical schools, such as Harvard, have been “late bloomers” in bioethics. She explained that this was “not due to conspiracy, but merely a lack of personnel with a bioethics vision and/or the entrepreneurial skills to make it happen.” Other institutional characteristics, particularly a university’s public or private status, and its related teaching or research emphasis, would reasonably be expected to have a relatively straightforward influence on its bioethics activities. For example, a private university training physician-researchers might be more likely to emphasize biomedical research ethics (e.g., informed consent, genetic

privacy), while a public university with a greater commitment to training medical practitioners might be more likely to foster a focus on clinical ethics (end-of-life care, allocation of scarce medical resources) in its bioethics activities. Similarly, private and public universities have different “power points,” as one respondent explained; being accountable to state legislators instead of trustees and private donors allows for comparatively less freedom in academic bioethics programs.

Students

What role do students play in curricular formation? Slaughter (1997) finds inadequate the standard **demographic** explanation in higher education studies, which sees curricular change as rational faculty and institutional responses to accommodate student demand; in several cases, such as for African-American studies and women’s studies, curricular change was instead the result of forces originating outside universities. Similarly, student demand, though present, appears to have played little role in bringing bioethics to Letters University.

The founding director of the Bioethics Center cited students as one of the key factors in establishing the Center, recalling that “students were agitating in medical school class to get medical ethics into their curriculum.” When probed further, she explained that by 1994, while most medical schools

had medical ethics programs, Letter students didn't, "and I think they just felt like they were getting left out."

However another Center faculty member, whose faculty tenure at the university stretches back before the director was brought in to head the new Bioethics Center, dismissed the causal role of medical students. She explained that in the 1980's, a group of senior medical students developed a bioethics component for the second-year medical curriculum (consisting of four one-hour seminars led by a medical student leader often accompanied by faculty leaders, according to a subsequent bioethics task force report). Students also put pressure on the medical school's academic dean to provide more ethics training, she said, but the dean "cooled them out" with a lecture series and some underwriting for their student journal. My cynical faculty respondent observed that the demands of a transient student population are easily ignored, and that the medical school was taking credit for doing wonderful things in ethics long before the Center was established, and even at the height of student complaints.

Indeed, student demand was cited neither in the bioethics task force report, which called for an expansion of ethics training, nor in the subsequent proposal for a regent/trustee professorship in bioethics. When asked about the origins of the Bioethics Center, the director of medical education spoke of the medical school's need to "catch up" with other universities, all but one or

two of which already had medical ethics programs, or at least a one-half full-time-equivalent biomedical ethicist on the faculty. She did not mention student demand. Most likely, the primary reason that Letters medical school needed to catch up with peer institutions was the recent introduction of new accreditation requirements for medical ethics education, invoked respectively by the Liaison Committee on Medical Education in 1989 and the Accreditation Council for Graduate Medical Education in 1990. Taken together, these accounts imply that student demand was insufficient to bring about a medical ethics education program, let alone the Bioethics Center, to Letters University. Accreditation requirements and institutional isomorphism were more powerful influences, capable of instigating curricular change.

It is not my contention that students have no impact on curriculum and educational practice, but rather their influence is likely to be more incremental. For example, a faculty member's article in the Center newsletter cites two instances where student concerns resulted in changes in practice. First, medical students in the gross anatomy course objected to the course's use of unclaimed bodies from the local Medical Examiner's Office; according to the newsletter, "Feedback of these concerns to those responsible for that decision was well-received and the decision to use such bodies was reversed. In the second instance, student concern about the adequacy of

informed consent language for a clinical trial at Letters, discussed in a pharmacology course, “refocused the attention of those responsible for the form, and helped redirect our efforts in informed consent processes.” Student demand, from a captive, transient audience, is unlikely to impel faculty and administrators to locate and dedicate the necessary resources for developing new courses, programs, and academic units, without accompanying consequential institutional pressure from other universities, accrediting bodies, or the state.

The Director of Medical Education

The **learned disciplines** account of curricular development in higher education studies suggests that faculty members, not students, are key instigators of curricular change, purveying the progressive, rational development of scholarly disciplines. “Great Man” narratives, in which individual persons are credited with a leadership role in curricular change, are consistent with this viewpoint. However, the learned disciplines perspective overlooks the politics of knowledge, which constructs the legitimacy of curricula in a complex organizational context (Slaughter, 1997). In the case of the Bioethics Center, several respondents cited the director of medical education, Dr. Campbell, as a valiant and even crucial figure in the development of bioethics at Letters University. The Center director not only

named Dr. Campbell as one of three contributory parties in establishing the Center, but also pointed to Dr. Campbell's counterpart at another university in the region, explaining, "clinicians that really grapple with ethical issues [due to their specialties] and earn lots of income for the [university] hospital can have lots of impact". Two other veteran faculty members were complimentary about Dr. Campbell's efforts in medical ethics education, but expressed that she lacked the power to bring about the Bioethics Center. While they described Dr. Campbell as "heroic," "valiant," and a "major shaper of the curriculum" who had "pushed hard for a bioethics presence" and "kept bioethics teaching alive," they viewed the dean of the medical school as the ultimate executor of the Bioethics Center.

While in the end it appears that the Bioethics Center owes its existence mainly to the medical school dean and the director of the medical school's Biotechnology Institute (whose parts I will turn to shortly), Dr. Campbell's role in laying the groundwork for the Center and focusing persistent attention on bioethics at the medical school was indispensable. At the least, Dr. Campbell helped make the Center happen sooner than it might have otherwise, by exercising leadership in proposals and justifications for the Center.

As a first step towards bringing the ethics portion of the medical curriculum up to speed with that of peer institutions, Dr. Campbell said she

had proposed that the medical school dean create a task force to develop a comprehensive bioethics education proposal. A bioethics task force was convened with Dr. Campbell as its chair, and given the charge “to evaluate the current education in bioethics in the [medical school] and develop a more comprehensive bioethics program for undergraduate, graduate, and continuing medical education” (Task Force Report).

The Medical School Bioethics Task Force

Finding that then-current bioethics offerings were “inadequate,” with a “lack of overall coordination and breadth of educational content,” the task force proposed that an academic bioethics program be developed in three phases. The program would begin with the undergraduate medical curriculum, progress to the graduate and continuing medical curricula, and culminate in the development of a multidisciplinary center in bioethics to facilitate cross-campus academic collaboration and provide an organizational structure. The report of the task force recommended that the new program be integrated into existing medical courses and include both knowledge and competencies in bioethics. Furthermore, the task force called for the creation of two full-time bioethicist positions with support staff, so that the bioethics program would be “directed and implemented by faculty with expertise and training in the subject.”

The task force's recommendations were supported by a Statement of Beliefs, which justified the legitimacy of a bioethics program (and in so doing, revealed expected challenges to the legitimacy of bioethics) and shed light on the task force's conception of bioethics. First the Statement of Beliefs asserted the centrality of ethics to medicine, stating that "competence in identifying ethical issues and in making ethically-informed decisions **is as necessary to a physician as competence in the medical sciences**" (Task Force Report; emphasis added). Second the Statement of Beliefs emphasized the authoritative **teachability** and **testability** of bioethical knowledge, affirming that ethics constitutes "**objective** topics with **educational content that can be taught and learned,**" and that the standards in bioethics education should be on par with the medical curriculum, "including examinations, minimum acceptable competencies, and grading" (Task Force Report; emphasis added). Finally, regarding the scope of bioethics, the Statement of Beliefs pronounced that the bioethics curriculum should be comprehensive, including both ethical theory and its application to medical practice, and encompassing "issues related to the interface of bioethics, law, and medical practice" (Task Force Report). Taken together, these stated beliefs establish the legitimacy of biomedical ethics as an academic subject, by establishing its status as objective knowledge and its relevance to and inseparability from the field of medicine. The

persuasiveness and impact of the task force report's justifications is not clear. However, the task force's recommendations for a bioethics curriculum were immediately approved by the medical school and its faculty, and Dr. Campbell assured me there was widespread support for and interest in the recommendations within the medical school.

Proposal for a Regent/Trustee Professorship in Bioethics

A subsequent proposal submitted to the medical school dean, again spearheaded by both Dr. Campbell, as well as the vice dean of medical education, sought the creation of a professorship in bioethics. The person hired to fill the professorship would play a leadership role in planning and implementing the medical school's bioethics curriculum, and in developing a new bioethics center, then under consideration. The professorship proposal expanded arguments for the legitimacy of academic bioethics beyond local curriculum and medical practice, shifting the focus towards the regulatory and funding environment of biomedicine. The proposal appealed to new accreditation requirements for undergraduate and graduate medical education in bioethics, which were invoked respectively by the Liaison Committee on Medical Education in 1989 and the Accreditation Council for

Graduate Medical Education in 1990.⁶ Furthermore, grant-making bodies, chiefly the National Institutes of Health, were beginning to make funding conditional upon the recipient's provision of formal ethics-training programs.⁷ The proposal deduced that the medical school had "the urgent need" to develop a strong bioethics program in order to compete with leading medical education institutions nationally. Citing the medical center's short-term plan, the proposal asserted the "necessity for joining new strength in bioethics" to the medical center's growing strength in molecular biology. This necessity, the proposal noted, had already been recognized by federal funding agencies, exemplified by the 90 to 150 million dollars (these figures were underlined in the proposal) allocated for the ethical, legal and social implications of the Human Genome Project. The medical school needed to pursue bioethics not merely out of scholarly and practical interest, but in response to environmental expectations and new opportunity structures. While Dr. Campbell and her colleagues on the task force were undoubtedly motivated by a scholarly commitment to do the right thing by bringing

⁶ The proposal for a Regent/trustee Professorship in Bioethics cited text excerpts from the Liaison Committee on Medical Education 1989 recommendations, and from the Accreditation Council for Graduate Medical Education revision of general requirements, approved June 1990. Fuller references may have been provided in appendices to the proposal, which I did not receive. For related discussion in the medical literature, see Dickstein, Erlen & Erlen, (1991), and Iserson & Stocking (1993a, 1993b).

⁷ On the 1989 NIH ethics training requirement, and institutional programmatic responses to it, see Eisner (1991).

bioethics into medical education, clearly they also recognized the utility (and likely, the necessity) of appealing to institutional competitiveness in the academic capitalism knowledge/learning regime in order to bring bioethics to Letters.

The Medical School Dean

Key faculty respondents provided somewhat divergent accounts of the medical school dean's motivations and enthusiasm for creating a bioethics professorship, which eventually became a reality. Delay in creating and filling the professorship was variously attributed to lack of enthusiasm for internal candidates (including Dr. Campbell), and difficulty identifying and recruiting distinguished external candidates, in part due to limited funding availability.

Based on respondent's reports, the emergent account of the dean's motivation suggests that he had little interest in bioethics, at least until funding and a compelling vision of bioethics' contribution to the medical school's interests materialized. Dr. Campbell recalled that the dean had been receptive to the professorship proposal. However, in a cost-reduction environment, the search committee was charged with getting "the best bioethicist we can afford." Another long-time faculty member stated that although the dean is widely viewed in retrospect as having been enthusiastic

about bioethics, during the two-year-plus candidate search the dean was in fact “lukewarm” about bioethics, and did not offer much money to “recruit a distinguished person.”

The search was revitalized when the director of the Biotechnology Institute offered a substantial amount of money to help establish a formal bioethics presence. According to faculty respondents, the institute director felt it was important to convey the medical center’s seriousness about ethical concerns, particularly related to in-house biomedical research. The medical school dean was responsive, agreeing to cover the remaining expense, and as Dr. Campbell put it, “betting big” on biomedical technology with the Institute director. The director of the Bioethics Center explained that the medical school dean “decided to make a big commitment in the area of genetics and thought that ethics would be helpful to the growth of the genetics initiative—both for deflecting criticism, [and] for raising issues ... it would be both a shield and a sword.” Another faculty respondent commented that the dean “got what she wanted” out of the deal, namely a highly visible new specialty center that brought public attention, and presumably business, to the university medical center.

Academic medical centers faced tremendous environmental resource challenges in the 1990s, including a highly competitive health care market and shrinking Medicare payouts. Like many of its peers, the Letters

university medical center first attempted to gain a competitive edge through expansion, acquiring hospitals and private practices to bring more patients and thus revenues to the system. The university medical center also cut hospital expenses by tens of millions. The medical school dean also adopted an expansionist approach within the medical school, creating eight new C&Is (including the Bioethics Center) and recruiting more than a dozen departmental chairpersons to head the C&Is and fill other positions, all during the first six year's of the dean's tenure (Letters campus newspaper article, 1995). The dean took an aggressive approach in expanding the medical school's activities, and extended it to include bioethics once she recognized its potential to enhance the medical academic portfolio.

Development of the Center: Financial & Intellectual Independence

With adequate funding provided, the bioethics professorship was soon filled, and the new bioethics center was under way. Dr. Campbell, credited with helping the new director "establish credibility" in the medical school community, also encouraged the director to seek departmental status early on. However, departmentalizing bioethics is a formidable challenge.

Canadian bioethicist Christine Harrison explains, "existing university departments, chairs, and promotion committees often struggle to understand how bioethics can 'fit' into existing models. This may hamper career

advancement and other academic rewards [for academic bioethicists].” (2002, p. 20). Harrison’s comments are applicable to academic bioethics in the United States as well as Canada. Letters University’s medical school requires its department-based faculty to generate overhead through grants, as do most academic research institutions. In the medical school paradigm, promotion awards are based on winning grants and publishing articles, but bioethics faculty are more likely to publish books than prestigious journal articles, and receive fewer and more modest grants than their biomedical colleagues. Accordingly Harrison explains, “in Canada hospitals and universities are currently unwilling or unable to make a long-term commitment to bioethics programs and services, due in part to the lack of stable funding.” Again, the case is much the same in the US. Would-be bioethics departments must make a compelling case for such status change and negotiate for different promotion and tenure criteria, or rely on hybrid faculty with joint clinical and bioethics appointments who can meet more traditional medical-scientific standards.

Outside the medical school at Letters University, the College of Arts and Sciences (CAS) was also unlikely to house a bioethics department. One faculty member commented that CAS probably would not take in a bioethics department because it was not a discipline; other interdisciplinary programs, which had been created under special conditions and were vulnerable, had a

history of being phased out. Another respondent noted that medical school departments, on the other hand, are not necessarily disciplinary but “practical” (e.g., emergency medicine). Thus, the questionable status of bioethics as a discipline per se would not hinder the establishment of a bioethics department in a medical school. Altogether, however, the financial logic of medical schools and the disciplinary orientation of colleges of arts and sciences, make it difficult for academic bioethics centers to departmentalize, as demonstrated by the small number and size of bioethics departments, relative to the population of bioethics C&Is in the US.

Rather than deal with departmentalization challenges, the new BC director pursued other strategies to foster the center’s financial stability and intellectual independence. When she was hired, the director had warned the medical school dean that she would not be granting “protection” to the medical school; on the contrary, she predicted that she would more likely be a “source of aggravation,” which has been true, according to the director. Dr. Campbell described the center as “organizationally under the [medical school] but functionally between schools” at Letters University, which established some “strategic distance” from the medical school and promotes intellectual collaboration with other campus organizations. The director explained that her strategy in setting up the center included acquiring “intellectual and financial capital,” and some “political scoping out,” to pursue the activities of

education, research, and outreach. As an outreach activity, hosting conferences not only serves to address pertinent bioethics issues, it also promotes the center's visibility outside the medical center.

Many bioethics programs receive funding from medical school overhead, and the Bioethics Center is no exception. But without department status, most bioethics programs and centers lack guaranteed support. The center director maintained that the "safest" way to fund a bioethics center was to seek diversified income from four categories of sources—the university, federal granting agencies, foundation grants, and private gifts from corporations, patient groups, and wealthy patrons. Furthermore, a center should not be "over-reliant on any one source," lest it be "vulnerable to pressures." She cited the need to "stay in touch with all constituencies," and the importance of openness, noting the great illusion among academics, presuming the "goodness" of government and foundation sources compared to corporate funding sources.

In spite of the Center director's diversified funding source strategy, the freedom of faculty to study bioethical problems and issues they found compelling was constrained by the interests of funding providers from all sectors, and faculty members at the Center were openly aware of the ways in which foundation and government funding opportunities shaped their work. Respondents noted that their interests in producing scholarship on, for

example, reproductive rights, and distributive justice in health care, were not attractive to foundation or government sponsors, which focus instead on genetics and other high-profile issues. One faculty member noted that extramural collaboration with scholars at other bioethics centers is attractive to funders, and also benefits bioethicists through the mutual enhancement of collaborator reputations. Another respondent predicted that research ethics will create an enormous demand for bioethicists, and accordingly research on research ethics will become a primary activity in the field.⁸

Although the fledgling center was unable to pursue much independent research on its own, a number of other programs at the medical center approached the Bioethics Center about serving as a co-investigator on various projects. While several collaborations resulted, providing the new center with several organizational ties, it failed to secure any funds for research at the Center. According to the Center's first annual report, funding agencies valued the center's involvement in projects, and were even "positively influenced toward making awards to [university] programs," but

⁸ While research on research integrity has not been a central topic in academic bioethics discourse, it represents a funding opportunity to those interested. The Office of Research Integrity (ORI) in the US Department of Health and Human Services initiated an extramural research program in 2001, offering just over \$1 million. In 2005 the allocation for extramural grant funding totaled nearly \$2.6 million, and the number of applications nearly doubled the 24 submitted in 2001. See <http://ori.dhhs.gov/research/extra/award.shtml> (accessed 04/01/06). For an account of the development of ORI and its performance as a boundary organization, see Guston (2000), Chapter 4.

“the Center has been dropped from funding in every case on the grounds that ethics is or should be included in grant overhead.” In response, the annual report promised the center would change its focus to independent grants sought by Center faculty, and fundraising with private and individual donors.⁹ However, a new problem accompanied the pursuit of independent grants. One of the Center’s later annual reports describes the hardship created by the facilities and administration (F&A) fees imposed on sponsored research, which the university charged at a rate that was “prohibitive for many foundations that traditionally fund bioethics research.” The report acknowledges Letters University for allowing proposals to go forward with less than the full F&A rate, urging that such concessions continue.

The Bioethics Center’s home in the medical school defines not only funding opportunities, but also the conditions of promotion and tenure of Center faculty. Faculty at the medical school were evaluated on the basis of regularly publishing articles in top-tier medical journals and securing RO1 grants from NIH. Publishing books counts for little in the promotion and tenure scheme of academic medicine; in the rapidly developing field of medicine, book contents are likely to be obsolete by the time the volume hit

⁹ While not described as part of its fundraising strategy, the report also noted discussion at the Center about creating a Master’s program in bioethics, observing the existence of “an enormous appetite for expanding teaching in the area of bioethics” throughout the university.

library shelves. Several of my faculty respondents expressed anxiety about promotion and tenure requirements for the Center's junior core faculty, as they anticipated the eventual departmentalization of the Center. These young professionals were trained in humanities or social sciences disciplines that expect book writing, and not necessarily a steady stream of research grants. From the base of a formal department, bioethics faculty would gain the opportunity to directly influence committees that determine promotion and tenure criteria, but would have to communicate a compelling justification for establishing rules more appropriate to their work products. These circumstances would appear to favor the promotion of academic physicians over humanities or social science scholars among faculty, if the Center were to departmentalize within the medical school.¹⁰

Several faculty respondents discussed the dilemma of accepting corporate funding for bioethics. One noted that unlike the Letters Cancer Center, the BC was always questioning whether to take corporate dollars, but while she was wary of corporate dollars, she felt it was necessary to do so. Respondents noted ways in which they actively limited any perceived or real undue influence from corporate sponsors, including limiting the amount

¹⁰ A faculty position announcement appearing in the Center's newsletter specifies, "ideal candidates must qualify for a faculty appointment in one of the departments of the University's graduate or professional schools." Non-medical faculty members at the Center may be better able to secure employment stability through joint appointments in departments outside the medical school.

accepted, and balancing it with grant monies from non-profit foundations and government agencies. They also cited various measures to discourage conflict of interest, including accepting funding only on the conditions that faculty members fully disclose their industry involvement and sponsored work, retain the academic freedom to publish their research findings, and clearly express that acceptance of funding support does not entail acceptance of the sponsor's policies, products, or services.

The Center's sixth annual report acknowledged as one of its major challenges the need to "make certain that the Center uses its expertise in cutting-edge bioethics to first, chart the course of research, and then to find dollars to support it, rather than first finding dollars and then creating a research agenda to fit the dollars. While the Center is exquisitely suited to explore emerging areas, it is difficult to fund such areas." The report outlines a three-year strategic plan to put the horse in front of the cart. Notably, the plan called for establishing standing research programs in "fields of strength at the Center," and for developing grant support for these long-term projects. The plan also called for the creation of "a standardized approach to respond to requests for sponsored research by for-profit organizations consistent with University protocols and academic freedom," and specified a target of five projects sponsored by corporations.

Eighteen months later, the Center had made considerable progress in diversifying its funding streams. At the beginning of the period, the Center, according to the sixth annual report, was operating with two federal agency grants and seven foundation grants, with half the total monies coming from the government grants. Eighteen months later, according to the subsequent annual report, the Center had secured thirteen additional grants, including three from corporate sponsors, representing nineteen percent of new grant revenues. The Center was awarded five grants each from government and foundation sources, with government providing 68% of new grant revenues. The thirteen new grants more than quadrupled the proceeds of the nine grants from the earlier period. The gift funds received by the Center at the end of the period were also diversified, with 22% donated by individuals, 33% by corporations, and 45% by non-profit organizations; gift revenues totaled less than seven percent of sponsored research revenues.¹¹

Even with a diversified funding portfolio, as mentioned earlier, bioethics scholars are subject to the research and program agendas of their patrons, irrespective of sector. But bioethics is especially vulnerable to the power of the biomedical corporate sector, which has penetrated the academy in ways foundations and government do not, at least in the United States.

¹¹ “Gift Funds” included monies contributed for a variety of transactions, such as media appearances, workshops, and symposia; the Center director habitually donates any consulting fees she earns to the gift fund.

Bioethicist Carl Elliott explains in *The American Prospect*, “Corporate money is so crucial to the way that university medical centers are funded today that no threats or offers need actually be made in order for a company to exert its influence. The mere presence of corporate money is enough “ (2001, p. 17).

Elliott, a firm opponent of bioethicists’ acceptance of corporate funds, argues that the public credibility of bioethicists “rests on the perception that they have no financial interest in the objects of their scrutiny” (2001, p. 20).

However, his observation about corporate funding of universities renders it all but impossible for bioethicists to claim no financial interest in corporate biomedicine, because the university medical centers that house most academic bioethics centers rely on corporate dollars, even if the bioethics center does not itself have direct involvement with corporations. There is no escape from corporate ties for these centers.

It is both essential, and a tremendous organizational challenge, for academic bioethics centers to establish a measure of organizational and financial independence, in order to maintain an independent voice and credibility. The Center director tested this independence at Letters University early in her residence at the Center. She had publicly criticized a local health care company that had made substantial financial contributions to the medical school. Consequently, the company CEO demanded the BC director’s termination from the medical school dean. But the dean refused,

citing academic freedom and the Center's autonomy, denying any responsibility for the Center's activities. Such deniability is important to the director, who strives to ensure that the Center's faculty feel they can speak out freely—she views it as her job to “cover them.” She contended that in general, the Center has “lots of autonomy and independence,” and that neither the medical school dean nor the university president keeps track of the Center's activities. “In some ways it's better that the university president doesn't exactly know what's coming out of here [the Center], it can be very provocative or upset people,” observed the director, “there is a certain kind of power in being distant administratively.” While this instance of preserved academic freedom is heartening, it does not assure *carte blanche* for the Bioethics Center or its director, or that bioethicists at other universities could be that openly critical without imperiling themselves professionally.¹²

The Organization & Institutionalization of the Bioethics Center at Letters University

When asked about challenges to the influence and expertise of the Bioethics Center, the graduate program director stated that the biggest influence on the Center was “larger institutional forces.” The Center director

¹² Indeed, prominent medical professors have been terminated for taking stances contrary to pharmaceutical sponsors of university research. See for example Washburn's (2005) discussion of the cases of Nancy Olivieri, David Healy, and James Kahn.

affirmed that the biggest challenge for bioethics is its traditional home in the academic medical center, an “institution in flux,” facing fiscal challenges and the managed care paradigm. Bioethics, often viewed as an overhead activity, is “vulnerable to elimination.” This weakness is made more acute, she said, by the fact that bioethics “hasn’t figured out professionalization.”

By way of summarizing my findings thus far, I now discuss the establishment of the BC using the complementary perspectives of resource dependency and new institutional theory. These rather structural interpretations will be balanced with a more agent-oriented account of the identity of bioethicists and the boundaries of their jurisdiction in the next chapter.

Resource Dependency

It is clear from the preceding account that resource dependency (Pfeffer & Salancik, 1978; Slaughter & Leslie, 1997) was a key challenge for the establishment of the Bioethics Center. The endowed chair necessary to spawn the Center was not created until the director of the Biotechnology Institute partially underwrote the position, which also likely guaranteed that she would have congenial relations with the new BC director, and possibly veto power in the selection of that director. Once established, the new Center’s efforts to bring in grant revenues were constrained by high indirect

costs charged by Letters, and by the funding conditions set forth by grantors. Center faculty's initial selection of scholarly projects was undoubtedly shaped by the collaborations they were invited to undertake with established medical school faculty traditional biomedical departments.

The Center director was acutely aware of the fiscal constraints imposed by funding sources, and took the strategic approach of pursuing a diversified funding portfolio for the Center, as possible. Other Center faculty members were also aware of the influence of funding sources on the work they selected, and all sought precautions against conflict of interest in the acceptance of funding from corporations. However, as mentioned earlier, corporate influence is unavoidable, due to the strong ties that the medical centers have with the biomedical industry.

Institutional Isomorphism

The concept of institutional isomorphism (DiMaggio & Powell, 1983) provides a compelling account of why and how bioethics has, by necessity, a close, and amicable, relationship with professional medicine that leaves it vulnerable to charges of being a lap dog, and of why establishing and maintaining professional autonomy is a significant challenge for bioethics. Essentially, because bioethics C&Is are most commonly created and housed in academic medical centers, they resemble medical departments or other

biomedical C&Is, and the work of academic bioethicists is structured in a way similar to that of their physician colleagues. While on its face this observation is not profound, recognizing the depth and nature of the similarities, and their implications for professional work, is. I now examine these implications of the three different types of institutional isomorphism for academic bioethics.

Coercive Isomorphism. The dependency of the Center on the university medical center is a tremendous source of coercive isomorphism. The medical school's promotion and tenure requirements and overhead charges to grants generate considerable pressure on the Center to conduct its academic work as medical departments do, even though the nature of bioethics scholarship is quite different from academic medical research. However, the similarity of bioethics to traditional medical school departments in terms of sharing a practical rather than disciplinary orientation, as well as the more favorable funding environment of medical schools, makes the university medical center a more likely home for the Bioethics Center than the College of Arts and Sciences. Coercive isomorphism also worked to cultivate a need for bioethics units at medical centers, as new training requirements from NIH and accrediting bodies, and new funding opportunities, created a role for bioethics in the medical center.

Mimetic Isomorphism. Competition with other medical schools was cited as a factor contributing to the establishment of the Bioethics Center. One BC faculty member indicated that in controversial or complex matters, such as developing rules for working with corporations, the Center looks at what other bioethics C&Is around the country are doing. It is also worth noting that the Center director was recruited from a position at a bioethics center of another university, and her prior experiences at that center undoubtedly shaped her development of the Center at Letters.

Normative Isomorphism. The medical school bioethics task force report, by way of justifying the inclusion of ethics in the medical curriculum, emphasized the ways in which ethics knowledge is similar to other components of the medical curriculum, in terms of objectivity, teachability, learnability, and testability; these expectations undoubtedly shaped the way in which bioethics was integrated into the medical curriculum. The 1998 consolidation of three bioethics societies into one, the American Society for Bioethics and Humanities was likely induced by, and further contributes to, normative isomorphism in bioethics. However, some factors in the bioethics organizational field may serve to counter normative isomorphism. First, the interdisciplinary nature of bioethics means that bioethics C&Is will be staffed by faculty with degrees in different disciplines, and will bring an array of somewhat divergent professional norms to the table. Similarly, because

bioethics is a young and therefore small field, many bioethicists are isolated, as one of my faculty respondents noted. Many bioethicists will be one of a kind at their universities, and will call a disciplinary department rather than a bioethics C&I home. As bioethics continues to professionalize, we can expect to see more normative isomorphism, particularly as bioethics Ph.D. programs emerge. I will examine the professional identity of bioethicists in Chapter Three, and revisit the role of training programs in normative isomorphism in Chapter Four.

It is important to consider the ways in which being housed in academic medical centers can serve the traditional goals of bioethics, and not just shape them. Perrow noted that elites, in spite of their resources, have limited power to shape organizations because “the complexity of modern organizations makes control difficult” (quoted in DiMaggio & Powell, p. 157). Universities rival governments in their bureaucratic complexity, and as such may have helped make it possible for the Center director to criticize a corporate patron of the medical school, without penalty. Affiliation with medical centers also confers bioethics C&Is with a measure of prestige, and with direct access to biomedical culture and practice, necessary for effective scholarship and teaching.

Slaughter (1997) critiques the three predominant narratives curricular change in the higher education literature, arguing that faculty members are

not the only, or even the prevailing, authors of curriculum. Rather, social movements, the politics of knowledge, and the political economy play major roles in constructing curricula. The preceding account of the establishment of the Bioethics Center is consistent with Slaughter's assertions. At Letters University, strong student interest was not sufficient to spur faculty initiation of formal curriculum in bioethics, and in fact was not even necessary. The later compulsion of medical school faculty to add bioethics to their curriculum appears to have been driven by the need to compete with their peer institutions, to meet granting-agency training requirements, and to address accreditation requirements, rather than by student demand. However, no bioethics professorships, program, or center became a reality until university administrators recognized the potential of institutionalized bioethics to tap into opportunity structures in the world of biomedicine.

The Bioethics Center at Letters University is clearly an example of interstitial organizational emergence, influenced by intermediating organizations including government agencies and accrediting bodies, and crafted by administrators and bioethics professionals in response to institutional competition and new opportunity structures in biomedical technology. By starting up a bioethics center, the university medical center would be able to legitimize the pursuit of potentially controversial biomedical research by the explicit or implicit imprimatur of the bioethics center, and

also could hope to avoid or at least foresee ethical quandaries associated with forthcoming research pursuits.

The entrepreneurial institutional environment into which many bioethics C&Is were born in the 1990s constrains the academic freedom of scholars in the emerging field, caught in the tension between the public good and academic capitalism knowledge/learning regimes coexisting in higher education. The Bioethics Center appears to have been able to establish at least a limited independent critical voice, allegedly by maintaining some distance from university and medical center administration. However, in spite of deliberate attempts to diversify its funding streams, faculty members at the Center still find themselves attentive to the issues that most interest funding providers. The qualitative implications of the academic capitalism knowledge/learning regime for the relationship of bioethics to established professional stakeholders in the academy will be explored in the next chapter.

CHAPTER 3—
THE ACADEMIC BIOETHICS JURISDICTION:
A STRAINED DIALOGUE AMONG DISCIPLINES

This chapter continues my case study analysis of the Bioethics Center, examining how it seeks to establish its identity and its academic credibility within the Letters University community and beyond. As mentioned before, the fit of an academic center's mission with the university's goals and mission and portfolio of academic programs is critical to academic credibility. Accordingly the center must "represent a logical initiative within the university's overall research program" (Stahler & Tash, p. 550). Here, I explore how faculty and student perceptions of bioethics, and the relationships between the Bioethics Center and other constituencies on and off campus reflect the ongoing construction of an academic and professional jurisdiction for bioethics in the existing organizational field, or arena, of professions and academic disciplines.

Academic professionals legitimate the work of their profession, in the context of larger societal values, by demonstrating "the rigor, the clarity, and the scientifically logical character" of that work (Abbott, 1988, p. 54). The academic part of a profession serves the three functions of legitimation, research, and instruction, and the extent to which academic professionals succeed at these functions affects the susceptibility of the jurisdiction to

outside intrusion. Abbott observes that “medicine’s recent narrowing of its legitimation to science and technology has proved dangerous, since late-twentieth-century cultural values increasingly conceptualize health as quality of life” (p. 54), which he argues contributed to the “humanistic” legitimacy supporting the rise of clinical pastoral education in the 1970s. From the short-term perspective of 1988, he speculates about whether this is a passing phenomenon. I argue that this humanistic legitimacy contributed to the formation of the field of bioethics. However, bioethics has also developed in a period when the professional class has increasingly moved away from an ideology of **social trustee professionalism**, grounded in the ideal of service to the public good, and towards an ideology of **expert professionalism**, legitimated simply by specialized authority over a defined area of formal knowledge (Brint, 1994). This shift, combined with a more competitive professional marketplace resulting from a growing professional class, has rendered professions more entrepreneurial in nature. The context of these shifting professional ideologies poses a particular challenge to the legitimation of bioethics. While the field originated in the ideal of service, it faces pressures to seek legitimacy through expert professionalism. Furthermore, the biomedical professions that bioethics seeks to influence have become heavily invested in the ideology of expert professionalism.

In Abbott's terms, bioethics can be viewed as having achieved a weak advisory jurisdiction settlement with the strong jurisdiction of medicine, where the powerful profession permits the weaker professional group to serve in a limited advisory capacity. Public claims are particularly important to sustaining an advisory jurisdiction. Abbott remarks, "It is inconceivable that such [advisory] claims could endure without strong public support. Thus the clergy's practical invasion of hospitals originated as much in a public feeling of the hospitals' inhumanity as in the clergy's own jurisdictional claims" (1988, p. 76). Accordingly, the public image of bioethics, and public concern about the ethical implications of biomedical technology are important to the legitimacy of the bioethics jurisdiction.

Evans (1998, 2002) describes how bioethics worked out a weak advisory jurisdiction with life scientists in the moral debate on human genetic engineering, with the result that the state and other bureaucratic institutions became the mediators between science and the public, limiting the scope of the debate. Biologists first succeeded in narrowing debate about interspecies DNA transfer to the issue of safety, effectively excluding the question of whether such DNA transfer should be pursued at all. By circumscribing the debate in this way, biologists kept decision making about genetic engineering within their jurisdiction, because of the technical expertise required to assess biosafety. Life scientists were also successful in

institutionalizing the government advisory committee, beginning with the Recombinant DNA Advisory Committee in 1976, as the standard treatment for addressing the social implications of the life sciences, a remedy far preferable to these experts than uncontrollable public outcry leading to restrictive regulation.

An interdisciplinary group of academics (i.e., bioethicists) began to appeal to the public to challenge the jurisdiction of life scientists, arguing that human genetic engineering had the potential to be dehumanizing, and should be limited. However, the audience for bioethics shifted from the public to the state, as state control of science started to become institutionalized. Bioethics commissions became the state's mediator between scientists and the public. The bureaucratic context and form of these commissions promoted rationalization of the expertise of bioethics, providing the state with a much-needed legitimate means for ethical decision making. Thus, a secular inference scheme was created in bioethics to appeal to the state and compete with the theology jurisdiction. For example, bioethics provided semantically narrow, neutral, universalistic ends (such as beneficence and justice) which were not grounded in any particular religious tradition, and that policymakers could use to make decisions on behalf of "we the people."

Meanwhile, life scientists continued to successfully restrict the scope of debate on the morality of tasks in their jurisdiction. For example, they

limited the scope of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to the subject of human experimentation only (instead of the broader area of “health science and society” advocated by Senators Mondale and Kennedy) and established the commission as advisory rather than regulatory. Evans concludes that bioethics is working out a jurisdictional settlement in an advisory capacity to the biologists’ jurisdiction, which retains decision-making power. Furthermore, the rationalized, narrow, secular approach that bioethics has largely chosen to adopt is a function of how well that approach maximizes resource acquisition for the profession, strengthening jurisdiction through cultural production of ethical approaches for the state to use that are acceptable to the biology jurisdiction.

What sort of jurisdictional claims are being made for bioethics in the academic workplace? In this chapter, I examine the boundaries of the bioethics jurisdiction as it manifests in the Bioethics Center at Letters University. I begin by developing an account of the self-described identity of bioethicists from interviews with thirteen Center faculty members and eleven students enrolled in the Masters in Bioethics program at Letters.¹ Then, I examine the relations the Center has with other key constituents on and off

¹ At the time of my site visit, the Center was only accepting enrolled MBE students in its classes. Some of these students were enrolled in dual degree programs, such as MD/MBE or Nursing PhD/MBE.

campus, including academic medicine, nursing, philosophy, social sciences, IRBs, non-profit foundations, and corporations. To study these relationships I not only draw upon my interviews and Center documents, I also supplement my analysis with accounts from the bioethics literature that relate my findings to the broader universe of bioethics in the US.

The Ambivalent Identity of Bioethicists

Science reporter Nell Boyce writes that the general public views bioethicists as “having a public service role akin to that of a journalist, a government official, or a judge.” (2002, p. 17). The opinions of bioethicists are regularly sought by journalists, Congress, and presidential advisory committees, as current events present new ethical challenges, or new instances of perennial challenges. But as Boyce explains,

Many scholars reject the title ‘bioethicist’ because of its ‘secular priest’ connotation, despite the fact that they work at bioethics centers, write for bioethics journals, and attend bioethics conferences. If the diverse community of philosophers, lawyers, scientists, physicians, and others who study bioethics can’t even agree on what to call themselves, how will they reach consensus on their proper public role and their corresponding obligations regarding conflicts of interest? (2002, p. 17).

The diversity of the field and its reluctance to don the mantle of moral authority suggest that this professional group has not yet figured out its desired role and place in the system of professions. A 2001 member survey conducted by the American Society for Bioethics and Humanities (ASBH)

found that society members were indeed concerned about the professional identity of the field. Preliminary analysis of the survey responses published in the society newsletter summarized members' diverse concerns related to the public image and state of the field:

Many [survey] respondents specifically stated that the ASBH should develop professional certification standards and accountability measures for clinical ethics consultation. Others wanted ASBH to determine whether there are too many doctoral and master's degree programs in bioethics or to take a leadership role in developing public policy. Some respondents stated an interest in developing the public image of ASBH and the field, expressing concern about the credibility of the field in the public eye (Gordon, 2002, p. 6).

My case study of the Bioethics Center at Letters University aimed in part to examine faculty members' perceptions of themselves, their field, and the identity of bioethicists. During my visit to the BC I asked faculty several questions about the direction and identity of the field and its practitioners: What are the goals, or what is the task, of bioethics? What is the biggest challenge for bioethics, and what progress has been made? What distinguishes a "real" bioethicist, and do you consider yourself to be one? Is bioethics a field, an emerging discipline, an emerging profession, or something else entirely?² The responses of BC faculty and students as a whole suggest that the identity of bioethics is ambivalent and still developing, and identify several likely obstacles to the cohering of a distinct professional identity in bioethics.

² See appendix for the semi-structured interview schedule I used.

To begin with, some of the faculty I spoke with explicitly or implicitly contested the very idea that bioethics is or can be a singular, easily defined enterprise. One respondent chided the pervasive “tendency to essentialize bioethics,” explaining that the term signifies a whole range of activities, directed towards a large set of audiences; there is religious bioethics, and there is secular bioethics—“the diversity amazes.” As one of her colleagues echoed, “there is no [one] thing called bioethics.”

When asked about the goals or task of bioethics, several faculty members described tasks revolving around (often public) dialogue facilitation, and they were emphatic that it is absolutely not the goal of bioethics to preach or provide authoritative answers. One respondent stated that the goal of the field is to “provide information and skills to let the right questions be asked”; another reported that the goal is to “provide guidance” on large, difficult, and long-lasting issues. Said one of their colleagues, the task is to “make **translations** between experts and technology and the people that need to use it” [emphasis mine]. Two faculty members expressed the goal of bioethics in terms of bringing **perspective** to stakeholders grappling with bioethical issues. One said that the goal is “to bring multiple perspectives to difficult issues, and the other explained that it is “to help policymakers and the public think through the moral implications of biomedical practice and research, to give them some ironic distance.” Another respondent noted that

in the U.S., bioethics provides a “common language” for dealing with biomedical advances and their social milieu, a language that is compatible with other viewpoints in society.

One respondent asserted that “bioethics is a conversation, not an answer,” that the purpose is not for bioethicists to give judgments about right and wrong, “because once you do that you’re just another opinion.” Rather, the task of bioethics is “to facilitate the public conversation, to say, ‘look, we’ve thought about this a little longer than you have and we know a little more about the background of it and perhaps even the science of it and so having thought about it a little longer and a little harder let us tell you what we think the issues are.’” Frequently, she explained, the general public does not grasp what the really critical issues are. She provided a striking illustration, worth quoting at length:

It’s taken me a long time to try to get people to see that they’re thinking about the wrong issue in genetic discrimination.... if you give them [the average person] the kind of insurance line, which is that “genetic mutations are a risk factor just like smoking or any other risk factor, or preexisting condition, and so what’s wrong if we give a genetic test to everybody equally and adjust insurance rates based on that, why is that discrimination, when that’s what insurance is supposed to do-- to take people who are more at risk and people who are less at risk and generalize that across the population so that everyone subsidizes risk, but in addition charge people who have identifiable greater risk, more?” And there are a number of answers to that, but one that people don’t normally recognize is, that the discrimination will come not because they’re not giving genetic tests fairly, but because the genetic tests we have were developed because of research on specific populations—Amish,

Mormons, Ashkenazi Jews, Icelandics, Finns, French Canadians...they're fairly genetically homogenous, so they make good genetic subjects.

What that ends up meaning is that we have genetic tests first for those diseases that these populations have. And therefore even if we give those tests to everybody, they will disproportionately impact those populations... the very populations that have given their time and effort to geneticists to allow them to further the field. Meanwhile other groups who have not been under the geneticist's microscope may have other diseases, but we don't have tests for them yet. And so those people's genetic weaknesses will not be identified, while French Canadians' will be. And therefore even if you give the genetic tests we have to everybody, they're still discriminatory. Well, you're [i.e., the average person] not going to think of that just thinking about, 'Are genetic tests discriminatory?' ...**That's one of the roles of the bioethicist is to deeply understand the issues and then be kind of an emcee for the public conversation that needs to come from that.** [emphasis mine]

A couple respondents ascribed more active goals to bioethics than the facilitation of conversation. One described the task of bioethics in terms of general academic functions: the task of bioethics is to create knowledge, educate the public, and perform outreach. She explained that outreach "can include trying to actually bring about practical things that can help people in clinical settings to improving corporations to trying to bring about public policy changes." One of her colleagues took a more radical stance, saying that the goal is

stopping the corporate biomedical machine, a little bit, making them pause before they just plow forward. ...I don't think that the medical system should be for-profit. ...I think in some ways bioethicists are pretty radical thinkers and while some of them think that it's okay to have a for-profit health care system, I do

think that they have a critical role. That's one of the broad goals. They're really charged with raising questions ...and they try to do it at the forefront of decisions. And that in itself is pretty admirable, even if they don't necessarily do it early enough.

Another faculty member, however, viewed bioethics as failing at reformism. She commented that in the 1970s, bioethics was attractive because it was "largely toothless." The consumer rights movement, which was calling for the institution of patient advocates, was far more confrontational than bioethics, which presented a more "gentle social solution" that was "in league with, not against, medical authority." However, she still saw considerable value in bioethics, asserting "the world is a much better place with bioethics than without it."

After asking faculty respondents about the goals of the field, I asked, "What is the biggest challenge for bioethics?" Their responses addressed the themes of legitimacy and identity, development and use of critical skills, and structural issues.

A few faculty expressed concerns related to the identity of the field. One respondent viewed the biggest challenge for bioethics as "defining its spheres of influence." She elaborated,

For example, is it clinical, is it research, is it theoretical? Is it philosophic or sociologic or anthropologic? And the answer to all of those can be yes, but I think we have to say up front 'here's what we do, and here's what we don't do.' ... As with any discipline, those who aren't as well entrenched in it may not

recognize all the spheres and may establish a hierarchy of the spheres and then say, 'here's what I do, and here's what you do.'

She indicated that there were few individuals she considers to be bioethicists, and noted that one of those individuals “crosses boundaries between the spheres very well.” One of her colleagues commented that the field is “sort of floundering around” trying to figure out what it is, and that “it’s a lot of different things.” She was not herself uncomfortable with this ambiguous identity, but thought it might be uncomfortable for others desiring bioethics to be a legitimate field.

Other respondents’ concerns reflect the sense that the field has a problematic identity, in terms of what are the key competencies that characterize bioethics. One faculty member felt that the biggest challenge for the field was to bridge the gap between philosophical discourse and practice, observing that it is really difficult to develop both skills. One of her colleagues asserted that bioethics is “philosophically thin”—that the field has no canon, making training difficult. Taking a different perspective, another faculty member argued the field needs to do a better job of using social psychology and economics in bioethics work. One faculty member said that what most needed attention was improvement of research skills, “if bioethics is to emerge in a holistic fashion”; another declared there is a lack of good cross-cultural bioethics research. According to one respondent, the field needs to establish a “solid intellectual and technical base,” such as

instruments, scales, and benchmarks for scoring how well legislation and policy addresses bioethical issues and goals. From these observations, it would appear that the field as a whole is not currently doing an effective job of bridging the various “spheres” putatively embraced by bioethics.

Several faculty members identified structural issues as the biggest challenges for the field. The Center director felt that the biggest challenge is the “traditional home” of bioethics in academic medical centers, which as a whole represent “an institution in flux,” likely leaving bioethics centers vulnerable. One faculty member stated that what most needs attention in bioethics is to establish independence from the press and “high-profile issues of the day.” Another respondent asserted that bioethics is not a vibrant, growing field, but just seems large and powerful because of its media presence. The Center director also cited diversity as an important structural challenge, noting “in bioethics it’s important because diversity helps give you more perspectives on ethics issues.” She said that while there are more women in the field now, there are few minorities, a situation she attributed largely to the fact that there are few minority academics in health care fields, or in universities generally.

Another challenge for the field of bioethics is what I call **biotechnofetishism**, an excessive fascination with or regard for sensational

biotechnology that overshadows the chronic, systemic unglamorous challenges of biomedicine. One of my faculty respondents reflected,

The tension between following the technology and trying to be useful to healthcare is another challenge for bioethics.... There's always a pull to the new interesting technology, and yet most people aren't affected by that. I mean they are, to talk about it socially, but if you're really in the healthcare system you still want to know why you have to wait four hours before they see you in the ER, and why there are so many uninsured people, and why are nursing homes a mess. That's a tension. It's not insoluble, **it's just a challenge to kind of cover the areas and not get seduced by the fancy cool technology all day long...** I write about a lot of fancy cool technology stuff—transplants, stem cells, human experimentation—but I do try to write periodically about nursing homes, rehab medicine, managed care, and health insurance... **I don't want to forget to hit the mundane problems of health care, for all the gee-whiz problems. The field needs to struggle with both.** [emphasis mine]

I found that the philosophers amongst the Center faculty were the most likely to “get seduced by the fancy cool technology,” whereas the clinicians on faculty were more likely to grapple with issues in clinical practice and research (e.g., end of life care, informed consent), as evidenced by their recent publications listed in the Center's annual report.

The Identity of Bioethicists: Multidisciplinary Quasi-Professionals?

Is bioethics a discipline? Is it a profession? Is it becoming one or both of these things? What is a bioethicist, exactly? During my site visit to the BC, I asked both faculty and students whether they considered bioethics to be a

profession, and what they felt distinguished someone as a bioethicist. I also asked faculty whether bioethics is a discipline, or becoming one.

Students were familiar with the debate on the identity of bioethicists, and a few were more comfortable than faculty in calling themselves bioethicists—in spite of the fact that faculty would be more readily identified as bioethicists, given their positions in university bioethics centers, programs, and departments. Furthermore, several faculty members expressed dismay that some Master's in Bioethics (MBE) students would call themselves bioethicists. One student remarked that perhaps philosophers and theologians were more likely to adopt the title of bioethicist than were scholars and practitioners from other disciplinary backgrounds. Another student, who was not comfortable calling herself a bioethicist, stated that she would rather be called a student of bioethics, in the same way that one would prefer being called a painter rather than an artist. One of her peers, who also was reluctant to call herself a bioethicist, quipped that students would come out of the program “with just enough knowledge to be dangerous.”

Several students pointed to the combination of a related formal knowledge base, (including having a foundation in a traditional discipline such as medicine, law, or philosophy, and being versed in the tools and rigorous analysis typical of the field), and appropriate firsthand experience (e.g., work a clinical setting, or conducting research) as the hallmarks of a

bioethicist. One student speculated that bona fide bioethicists probably have degrees in philosophy, but that it was on-the-job learning, and a keen interest in ethics that mattered; bioethicists “don’t need a sheepskin,” because there is no defined beaten path for work in bioethics. Another student asserted that **self-developed** expertise, through education, clinical experience, and research, was the signifying characteristic of bioethicists. One of her classmates made a slightly different distinction, pointing to expertise, **relative** to the lack of bioethical expertise of other professionals in a particular setting, as the defining feature; this student felt she would be comfortable calling herself a bioethicist in the clinical arena. Another student questioned whether one could be a bioethicist without being a nurse, doctor, or some other health professional. When it comes to clinical ethics, she argued, bioethicists need a thorough knowledge of the human body. Regarding lawyer-bioethicists, she felt that these individuals would really need to engage in close relationships with health care providers.

I asked faculty members at the Bioethics Center what signifies a “real” bioethicist, given the lack of a defining credential. I also asked how comfortable they were being designated a bioethicists themselves. Most respondents reported that they either were uncomfortable with the title, or did not consider themselves to be bioethicists, instead primarily identifying themselves by the disciplines in which they were credentialed (e.g.,

philosopher). A couple were only “sometimes” uncomfortable, and two were comfortable calling themselves bioethicists, although one qualified her response in terms of her definition of bioethicist, i.e., having the organizational title or appointment, professor of bioethics. Discomfort with the title of bioethicist, I was told, is rooted in a strong skepticism of the very idea of moral authority. As one faculty member put it, she is “troubled by the idea that somebody knows right from wrong, and has special skills in that area. The name [bioethicist] sounds like that.” Several of her colleagues reported discomfort with being called a bioethicist, particularly in situations “where people want to be told what to do.”

As mentioned earlier, several faculty members expressed dismay that students in the MBE program comfortably called themselves bioethicists, because these academicians believed a master’s degree could not provide sufficient training to prepare a student for that role. One faculty member reconciled the disconnect between faculty and student comfort with the bioethicist designation, explaining,

Bioethics started out as a field where everybody could come in regardless of discipline or background, and it’s starting to professionalize, and it hasn’t figured out what to do about that. There’s a lot of tension about “Am I a bioethicist, or am I just a sociologist that studies bioethics?” Younger people have no doubt what they are; if we give them a degree in bioethics, they’re bioethicists. They’re going to say, “Of course I’m a bioethicist, I have a degree in it.”... It’s going to change the issue of “Can it be interdisciplinary?” to, “Is it just one more subject area?”—it’s not

pulling people together [from different disciplines], it's just full of people who are bioethicists, that's what they do.

As the younger generation of bioethicists, now being trained in full-fledged bioethics graduate programs begins to populate faculty positions and participate in annual ASBH meetings, it seems reasonable to expect that programs will exhibit all three forms of isomorphism, generating a bioethics canon, a standard curriculum, and losing somewhat their individual niche orientations that resulted from their different agent-advocates, institutional cradles, parent departments, and development strategies. A few bioethics PhD programs have been established, and more are anticipated, suggesting continued recent growth in the field. If my prediction is accurate, we can expect the field to develop a more distinct, more homogeneous identity, provided that a stable jurisdiction is staked out in the professional arena, and bioethics continues to grow. If not, bioethics may recede back primarily to the function of clinical ethics education, with a marginal academic institutional presence.

Faculty respondents' various accounts of what signifies a "real" bioethicist and focus on social relations among experts, which bind together the interdisciplinary field that has been colonized by professionals with an array of credentials, experiences, and skill sets. Two faculty members did point to training in moral philosophy as a defining characteristic of bioethicists (neither of them held a philosophy degree, and neither considered

themselves a bioethicist). Some respondents gave seemingly tautological answers. One faculty member asserted that the **work** of bioethicists is their defining characteristic—that is, research and teaching in bioethics; similarly, another respondent stated that bioethicists “produce things other bioethicists recognize as bioethics.” She continued,

There are some things that give you clues as to who the bioethicists are—they work in [centers] like this, they belong to bioethical organizations, they publish in journals about ethical issues. And the borders are murky, but in that sort of critical mass, people are either accepted or not accepted based on their works, and so it’s a consensus kind of thing... Journal articles and public conversation about bioethical issues, those are the products that brand one as a bioethicist.

Acceptance into the fold of bioethics, suggested my respondents, was contingent upon such characteristics as publishing in the right places, and having appropriate clinical experience (e.g., as a health care provider, chaplain, hospital social worker, or ethics consultant). One faculty member stated that MBE recipients were “in the club, in some sense.” Having received this “trial membership,” MBE holders are then subject to “hazing rituals,” she joked, in the form of the requirement to publish, and otherwise keeping current with and engaging in ongoing activity in the field.

Most faculty members felt that bioethics is multidisciplinary or interdisciplinary, a field rather than a discipline. One respondent did remark that bioethics is “emerging towards a discipline,” as evidenced by a “common lingo” and “core [topical] interests.” One of her colleagues argued that

bioethics is “a subject area, not a discipline,” and felt that students should be trained in a discipline at the graduate level. Similarly, another respondent contended that bioethics has “no independent intellectual moorings,” and is a multi- or interdisciplinary activity in which scholars address “a domain of questions from disciplinary stances.” Yet another respondent felt that bioethics was multidisciplinary, not strongly interdisciplinary; it constitutes “an area of inquiry and action,” with a core set of questions and issues, and “latent themes.”

Faculty members at the BC were also rather hesitant to identify bioethics as a profession. As presented earlier, one respondent commented that bioethics is “starting to professionalize, and it hasn’t figured out what to do about that,” referring to the divergence between faculty and students designating themselves as bioethicists. One of her colleagues felt that bioethics is not a distinct profession, though it might become one; it currently lacks a location or arena of practice, she said. Another faculty respondent noted that bioethics does exhibit some hallmarks of a profession, such as the consolidation in 1998 of three bioethics societies into one, the American Society for Bioethics and Humanities (ASBH), and the proliferation of bioethics master’s degree programs.

Another *prima facie* hallmark of bioethics professionalization was the creation of the Task Force on Standards for Bioethics Consultation, which in

1998 published the report *Core Competencies for Health Care Ethics Consultation*.³ However, the report itself implies reluctance for bioethicists to professionalize, at least as clinical ethics consultants. The text recommends that the report be used as **voluntary** guidelines, rejects certification to perform ethics consultation, and similarly rejects granting accreditation via educational programs. The reasons given in the report for limiting the formalization of its recommendations underscore a prevailing aversion in bioethics to stake a claim of moral authority, as well as an ambivalence towards the embracing the ideology of expert professionalism.

The report notes that the Task Force “does not intend for its report [to be] used to establish a legal national standard for competence” (p. 31), for several reasons. First, certification is rejected because it “increases the risk of

³ The Task Force was convened by the Society for Health and Human Values and the Society for Bioethics Consultation, two of the three professional bioethics associations that merged into ASBH. The twenty-one Task Force members included several prominent bioethics scholars as well as representation from the Joint Commission on Accreditation of Healthcare Organizations, the American Medical Association, the Society for Healthcare Consumer Advocacy of the American Hospital Association, the Department of Veterans Affairs, the Association of Professional Chaplains, and the American Association of Critical-Care Nurses. The Task Force took two years to develop the report, which was supported by funding from the Greenwall Foundation and forty other organizations, including academic institutions and professional associations. Thirty-nine organizations submitted education and training materials for use by the Task Force. Over 1,400 copies of a discussion draft of the report were distributed to the bioethics community, and feedback was incorporated into a revised draft, which was reviewed and revised twice more by the Task Force before it approved the final draft that was adopted by ASBH.

displacing providers and patients as the primary moral decision makers at the bedside,” which “could encourage the type of authoritarian approach to ethics consultation the Task Force has rejected” (p. 31). Second, the report argues, “It is important that consultants have relevant competencies, not that they come from some particular professional or academic field,” and the Task Force does not want to “undermine disciplinary diversity” that “leads to a more balanced understanding of competencies” (p. 31). Third, certification “could lead to the institutionalization of a particular substantive view of morality,” of ethical approaches, or of conceptions of the relative importance of consultation skills (p. 31). Fourth, the report states, “it is unlikely at this time that a sufficiently reliable test could be developed to measure the required competencies” (p. 32). These justifications suggest an aversion not only to claiming moral authority, but also to defining the jurisdiction in terms of professional expertise. Rather, ethics consultants exist to advise other professionals and persons who actually make health care decisions, and may competently do so by drawing on overlapping but variable skill sets.

One of my faculty respondents at the BC asserted, “Bioethicists are not a professional group,” but a collection of people with a common substantive interest, and with different backgrounds. Rather, the “role” of bioethicist, she contended, is one that has been created by some of the leading personalities in the field, who identified themselves as bioethicists.

Rather ironically, it appears that acceptance of one's work by reluctantly self-identifying bioethicists, is the key to community membership. The field appears to be largely self-defining, wary of the treacherous moral-authority connotations of its designation, reluctant to define a standard expertise, and maintaining itself in recruitment mode, rather than drawing pointed distinctions between *bona fide* members and mere pretenders. Control of membership is exercised simply through the gate-keeping of publishing and hiring. At the same time, the established generation of bioethicists, who identify themselves primarily in terms of their discipline of origin, are also wary of institutionalizing bioethics credentials, because the field does not provide the distinctive methodology, rigor, theory, and canon that together characterize "pure" academic disciplines. There is also widespread aspiration in the bioethics community to preserve the multidisciplinary nature of the field, and concern that this aim will be difficult to achieve as the field becomes more institutionalized. Nonetheless, bioethics master's programs have multiplied, and graduates are far less reluctant than their professors to adopt the title of bioethicist.

The inherent multi-disciplinarity of the field is a characteristic embraced by its membership as an approach to addressing the complex relationship between biomedicine and society, but one that makes it difficult for the field to formulate, agree upon, and convey a strong professional unity

and outward identity, distinct from the various disciplines it draws upon. As former president of ASBH John Lantos observed in the society newsletter:

As a field we've carefully, although sometimes passively, avoided narrow specialization. Though there are now both undergraduate and graduate programs in bioethics, there are no standard curricula, no standard training, and no uniform certification in bioethics. Instead, we've let a thousand flowers bloom, trying to remain true to our interdisciplinary roots—to honor theology, philosophy, literature, film, disability studies, cultural studies, feminist studies, queer studies, clinical ethics, virtue ethics, principlism and casuistry, economics, law, history, the social sciences—while at the same time trying to bring some coherence to our inquiries, some relevance to the fact that the work we are doing is work in **bioethics** rather than one of those other fields (Lantos, 2002, p. 2; emphasis original).

It seems that bioethicists are consciously avoiding becoming either a discipline or a profession, although there are pressures pushing them towards and pulling them away from both of these categories. The need for legitimacy and financial resources push them towards claiming expertise, defining that expertise, packaging and marketing it in master's degree programs, and seeking research and training grants. To build that expertise. On the other hand, the reluctance to claim moral authority, and the entrenched power of the professions and institutions which bioethicists advise, restrict the influence and jurisdictional claim of bioethics.

The Relationships Between the Bioethics Center & Other Jurisdictions

Having presented my findings concerning the self-perceptions of current and fledgling bioethicists at the Center, I now turn to the boundaries between bioethics and other jurisdictions both on and off the Letters University campus. The jurisdictions discussed here are not exhaustive, but rather include several that emerged from the data as being of particular interest. My analysis draws on faculty interviews, student interviews, and Bioethics Center documents I collected during my site visit, and is fortified by accounts from the bioethics literature that relate my findings to the broader universe of bioethics in the U.S. One of the BC documents I used, referred to here as the Jenkins Report, was an evaluation of the Center, prepared by a consultant hired by the Center, in anticipation of a periodic review of the Center by the University. Here I consider the relationship of bioethics to academic medicine, academic nursing, philosophy, sociology, institutional review boards, hospital ethics committees, research integrity training, non-profit foundations, corporations, the public policy arena, and the community audience to which academic outreach is directed.

Bioethics and Academic Medicine

Given that the traditional home of bioethics is in academic medical centers, what dynamics characterize the relationship between the two? As

we have already seen, the medical school dean, the director of medical education, and medical students, as well as the director of the Biotechnology Institute, all saw value in bringing bioethics to Letters. The Center director reported that there was no resistance to the Center developing a role in medical ethics education at the medical school. She admitted being a little apprehensive at first, concerned about potential perceptions that the Center was imposing on the medical school, but observes that “people have been open.” At the time of my site visit, several medical school faculty were affiliated with the Center. One of my faculty respondents, who had extensive experience in clinical settings both as a consultant and in conducting ethics research, reported that the relationship between the BC and the university medical center was not contentious; she felt welcome at the university hospital. She observed, “Clinical staff are often frustrated because they feel their jobs are getting micro-focused by bureaucratic structures, and they worry about losing the big picture.” She provides an outlet for their frustrations, and they are “happy someone is taking a broader approach” to dealing with health care delivery issues. In fact, she described an occasion in which department heads had invited her to attend the planning meeting for a clinical trial. “They don’t want to lose the human side [of medical work],” she explained, reflecting that clinicians felt constrained by the system, and

wanted to feel they were justified, in a documentable way, for taking “heroic levels of action.”

While relations between the BC and the university medical center were reported to be cordial, I found no evidence that the BC was actively working to shape clinical policy and practice so close to home. When asked whether the Center makes efforts to shape University policy, one respondent, who works out of the medical center, said, “not at the [University] hospital... [the Center] doesn’t pressure the hospital.” She reported that there was not much “overlap” between the Center and the University hospital, noting that “a larger linkage is assumed, but they operate separately.”

Bioethics and Nursing

At the time of my visit, two nursing professionals were faculty affiliates of the Center. One of these faculty members, also a faculty member in the nursing school, told me that the local nursing ethics community was “thrilled” about the Center; one of them sat on the Center’s advisory board. She felt that bioethics is beneficial to nursing; it raises “big questions for nursing at appropriate times,” she said, and has, for example, improved the use of advance directives in clinical practice. There was a good relationship, she said, between nursing and the BC, commenting that “nurses are hungry for bioethics.” She pointed out that several graduate-level nursing students

were taking courses offered by the BC, and several nurses were enrolled in the MBE program. However, she contended, nursing ethics education needs to be very applicable to daily practice, and it would take a lot of time to integrate appropriate training into the BC curriculum. She described her role at the Center as bringing a clinical perspective when appropriate, and stated she did not feel the need to influence the Center. She also explained that nursing ethics takes a different approach than medical ethics; while medical ethics pragmatically addresses “what doctors should do,” nursing ethics is based on a theoretical framework, and employs several ethical models.

The MBE students I interviewed who came from nursing were a little more critical of the relationship between nursing and bioethics, both on the Letters campus and in general. One student acknowledged that while bioethics is broad, and nursing is just one subset of it, she viewed bioethics as a “medical” field, where the focus is on physicians and acute health issues, instead of on pervasive health care delivery issues. She remarked that she and one of her nursing peers in the MBE program often left the bioethics classroom “exasperated,” because of the difficulty getting their classmates “to think outside their area of comfort, which is all about high-tech medicine,” and engage with less exciting issues, such as how resources are being allocated to people who are marginalized.

Another MBE student from nursing said, “I get the sense sometimes that they [some of her professors at the Center] look at nurses as being less able to contribute.” When asked why she thought the contribution of nursing was underappreciated, she pointed to the fact that bioethicists are drawn primarily from the ranks of physicians, attorneys, and PhDs. She also reluctantly commented, “I think nurses are not always articulate, and they sometimes take a lesser role just because of the [subordinate nature of the] profession, but I think we have a lot to offer.” She predicted that as more nurses enter bioethics, they will have more influence on the discourse. She was also critical of the “alleged” connection between the Center and the Letters school of nursing. Although the nursing school offers, and advertises, a dual graduate nursing and bioethics degree, this student, and one of her classmates, she claimed, encountered articulation problems between the nursing and bioethics programs. Her advisor in the nursing school did not understand how the joint program worked. Similarly, the Jenkins Report, (an evaluation of the Center by an independent consultant), noted the lack of a close working relationships between the Center and the nursing school, recounting, “some [Center] faculty suggested [the Center should pursue] stronger ties with the school of nursing.”

Bioethics, Philosophy, and the Social Sciences

The Jenkins Report noted that “[Center] faculty expressed concerns about the perceived poor relationship between the Philosophy department and the Center, though were hesitant to place blame on anyone at the Center.” One of my faculty respondents was particularly aware of this issue, due to her experience with the Letters philosophy department. She described a disdain, or gulf, between bioethics and philosophy. In her view, philosophy championed analytic rigor, while bioethics championed real-world relevance. Philosophy, she asserted, “didn’t want to get its hands dirty.” But only if bioethics is “philosophically thin,” she argued, does philosophy have a serious critique of bioethics. As she noted, however, PhD programs that have bioethics components tend to be weak in philosophy. One of her colleagues affirmed that philosophy was intentionally remote and isolated from the world, in contrast to bioethics. Another faculty respondent contended that some philosophers harbor resentment and jealousy towards bioethics, for the attention and resources the field has garnered.

The social sciences have, in general, an ambivalent relationship with bioethics, due to the opposing intellectual orientations of philosophy and social science, and to the social-science aversion to claiming normative stances. One faculty member commented that philosophy and sociology are “diametrically opposed methodologically,” and she is not sure how the two

worlds can be bridged. However, she also cited the importance of balancing philosophy and social science in bioethics, to examine what is actually happening in the world, and also to pursue normative analysis. One of her colleagues echoed this sentiment, asserting that the field needs to “mix the normative [analysis] and social science more.” One of my respondents claimed that “social scientists hide at ASBH [annual meetings],” explaining that social scientists defend the claim of objectivity, and are uncomfortable supporting normative claims. Another possible reason for the tension between social science and bioethics is that social scientists have waged scathing critiques of bioethics, as I reviewed in Chapter One, and these critiques may not always be welcome.

Social scientists’ participation in bioethics is also reminiscent of natural scientists’ participation in public interest science organizations during the Cold War period, whereby “activist scientists sought new ways to maintain credibility simultaneously as objective scientists and as political actors serving the public good” (Moore, 1996, p. 1593). However, accusations of political and corporate taint in bioethics have made it difficult for social scientists to maintain objective credibility while simultaneously engaging with critique of biomedicine.

Bioethics and IRBs

As mentioned earlier in the chapter, one faculty member predicted that research ethics will create enormous demand for bioethicists, and become a primary activity in the field. However, considering the challenges faced by several bioethicists in engaging with IRBs, as evidenced at Letters University and elsewhere, the interface of bioethics and research oversight appears to be a problematic one, at least in competitive research institutions.

Some of my field sources expressed the need for bioethics to increase its engagement with research oversight. The Jenkins Report notes, in a section of the text addressing academic collaboration and community outreach, “Some clinical faculty expressed concern about the lack of a strong presence [by Center faculty] on the [Letters] IRB and strongly recommended [Center] involvement in that Committee.” One MBE student envisioned an active role for bioethics in relation to IRBs; observing that the IRB oversight mechanism “isn’t right yet,” she suggested that it may be up to bioethics to guide IRBs to not merely approve, but more actively monitor, research projects with human participants.

However, several faculty members I spoke with reported having clashes with the IRBs they had previously served on at Letters or elsewhere. One faculty member described her relationship with the IRB she served on at Letters as “contentious,” noting that “making too much noise” was

discouraged. The IRB is an “institutional creature, there to get research done,” she explained, a bureaucratic organization that promotes form over substance. She was frustrated with the process. She also noted that the Letters budget for IRBs had quadrupled, that a new chief IRB administrator had been recently appointed, and that a new triage system had been implemented to expedite exemptions. A BC staff member remarked that Center faculty “keep getting kicked off [Letters] IRBs,” due to differences of opinion about templates and review procedures, suggesting that the relationship between the Center as a whole and the Letters IRBs was contentious.

Other Center faculty reported serving on IRBs outside Letters, where their experiences varied. One respondent was an IRB member at a medical college elsewhere earlier in her career, but had not served on a Letters IRB. In her experience, there is a lot of tension when a bioethicist sits on an IRB; a bioethicist has different priorities than physicians and scientists. The IRB is a flawed institution, she said, but no reasonable solution has been offered that is not IRB-based. Another faculty member reported serving on an IRB outside Letters, and had a more positive experience. She reported it to be a “congenial IRB,” whose members were unaware of some issues, but otherwise “relatively well-informed.” It is notable that this particular IRB reviewed mainly social science surveys and protocols, and met only a few times per

year. I learned that the institution served by that IRB is not primarily driven by the motivation to earn revenues from large research grants or churn out research articles in top-tier journals, but rather had an explicit action-oriented mission, in contrast to the competitive biomedical research environment at Letters.

BC faculty members' experiences as IRB members are not unique to the research oversight culture at Letters. In *The American Prospect*, Carl Elliott of the University of Minnesota Center for Bioethics described his contentious experience as an IRB member for a psychiatric hospital. Although he invoked international, national, and university guidelines that prohibit placebo-controlled psychiatric clinical trials, and was supported by other IRB members, the board Elliott sat on still approved many such drug trials. He recalls, "Tables were pounded. Faces turned scarlet. Blood pressures soared.... The hospital administration eventually dissolved the IRB and reconstituted it with new membership" (2001, p. 18). The IRB counted amongst its members a number of hospital psychiatrists who worked with pharmaceutical companies to conduct placebo-controlled drug trials, and who correctly pointed out that the FDA requires evidence from placebo-controlled trials in order for new drugs to be approved, in spite of widely endorsed ethical guidelines. A recent study found that almost half of academic faculty members who serve on IRBs have had consulting relationships with

pharmaceutical companies within the three years prior to that service (Campbell et al., 2003). And according to bioethicist George Annas, IRBs are under pressure to approve studies to bring in desperately needed research dollars (Washburn, 2005). While IRBs constitute a forum in which the expertise of bioethicists is especially relevant, they are often difficult settings for bioethicists to engage effectively, given the close ties with industry and potential conflicts of interest that apply to many clinical researchers who sit on IRBs alongside the bioethicists.

At Letters, the Bioethics Center had better success engaging in other ways with the university's research oversight structure. The Center developed a research-ethics training program, to fulfill training requirements for all investigators at the University working with human subjects. Said one Center staff member, "We want to get more involved in the educational component [of research oversight]." She also conveyed that the Center had a close relationship with the director of Letters IRBs, who was reportedly supportive of greater BC involvement in human subjects protections activities at Letters, and expressed interest in University participation in the Center's research ethics improvement activities.

The relationship between bioethics and research oversight is a complex one. Many IRB administrators are probably receptive to working with bioethicists to guide and shape research ethics through empirical research on

research ethics, and through education. The problem arises when high-stakes biomedical researchers serve on IRBs with bioethicists. Particularly in competitive biomedical research institutions, the organization's achievement-oriented culture, aimed at procuring large grants and publishing in high-prestige journals, co-opts the research oversight mechanism. But IRBs are not always, or even usually, a rubber-stamping operation. I have seen IRBs get accused of being overly cautious in the protection of human subjects when faced with protocols involving genetic research that the board members were unfamiliar with, and heard investigators complain repeatedly about the tremendous challenges of getting a protocol approved by all the multiple IRBs overseeing a multi-site study. Bioethicists are undoubtedly welcome members on many IRBs, and may become more welcome as the threat of research malpractice litigation builds, an issue I will address in Chapter Five.

Bioethics, Hospital Ethics Committees, and Research Integrity

The relationship between the Bioethics Center and hospital ethics committees (HECs) and research integrity activities was less problematic than its relationship to IRBs, to the extent that Center faculty chose to spend their limited time engaging with these areas.

Hospital ethics committees (HECs) are a venue similar to IRBs, where bioethicists may serve as members alongside professionals from other jurisdictions. Like IRBs, HECs have been criticized both for going too far and for not going far enough in ensuring that physicians make ethical clinical care decisions. However, unlike IRBs, HECs are rarely a regulatory requirement,⁴ and there are no enforced standards for the composition or training of these committees.⁵ However, the courts have more often than not deferred to HEC decisions as expert decisions. HECs began to grow substantially in number during the 1980s, in response to the Reagan administration's efforts to require life-saving care for all disabled newborns (Rothman, 1991). Several major medical professional associations officially supported the establishment of HECs (Peirce, 2004), which were undoubtedly preferable to hospital administrators and health care providers than government regulation or adjudication of clinical ethics dilemmas in the courts. By 1998, more than 90% of US hospitals reported having an HEC (McGee et al, 2002).

⁴ Maryland and New Jersey have statutory requirements for HECs. See Hoffman (1991) and Scheirton & Kissell, (2001).

⁵ Notably, attempts to document the impact of ethics education for improved moral decision making have failed to establish any benefit. See Bardon (2004). For sociological critiques of HECs, see Bosk and Frader (1998), and Wolpe (2000). For a critique of the use of consensus in moral decision making, see Moreno (1995).

A Center newsletter published during its fourth year of operation reported that four faculty members at the Center served on HECs, but none of the faculty members I interviewed during my visit mentioned serving on HECs or commented on these bodies. I did not see in the literature or during my site visit any indication that the relationship between bioethicists and HECs is particularly contentious. Given the high-stakes funding behind studies reviewed by IRBs, which are populated considerably by investigators supported by state or corporate sponsors, and relative the lack of these dynamics in HECs, one would expect that bioethicist committee members have had better success at contributing to decision making of HECs than to that of IRBs.

I spoke with one Center faculty member about teaching research integrity training to graduate students in the life sciences at Letters. She and three other Center Faculty members had team-taught a course in research integrity a few years prior to my visit, though she was no longer involved with this activity. She said that they accomplished no real reform in this area, but they had inspired the students to be proactive in ensuring the integrity of their own research. Letters fulfilled the basic federal requirement for research integrity training, she said, but was not taking the innovative approach that some of its peer institutions were pursuing, such as employing simulations. The Center's involvement in such efforts was limited mainly by

available faculty time not by any desire by university administrators to exclude input from the Center. As of spring 2006, the Center was involved in providing NIH-mandated research integrity training to biomedical postdoctoral fellows at Letters. I did not identify any other explicit involvement of the Center in Letters research integrity activities.

Bioethics and Non-profit Foundations

As discussed in the previous chapter, the Center director and other faculty regard non-profit foundations as an important source of funding, as well as a stakeholder in what issues get addressed by academic bioethics. While faculty work is shaped by the priorities of foundations, one faculty member also pointed out that conversely, bioethicists also have some influence on foundation agendas. For example, she asserted that William Stubing, the president of the Greenwall Foundation, is receptive to input from bioethicists, and takes an interest in innovative work. The Greenwall Foundation only funds grants in the program areas of bioethics and arts and humanities, and disbursed over \$2.5 million in grant funding for bioethics in 2004. As its website states, “The Foundation is especially interested in supporting pilot projects and the work of junior investigators, and it is prepared to address issues regarded by some as sensitive or potentially

controversial.”⁶ Such controversial issues have included assisted suicide; one of the Foundation’s grantees is the organization formerly known as Choice in Dying (now called Partnership for Caring), which has been labeled a “right to die” group.⁷

Bioethics and Corporations

Bioethicist Carl Elliott is outspoken about his discomfort with accepting funding from corporations. To him, it “seems too much like bribery. If it’s not bribery, it becomes the perception of bribery” (quoted in Boyce & Kaplan 2001). Laurie Zoloth, past president of the American Society for Bioethics & Humanities (ASBH), has argued that rather than financial inducement, the real seduction for bioethicists is the prestige and attention conferred by corporate consultancies—and, as she notes, “For this sort of social capital, there are no restrictions, and no regulation,” in contrast to existing rules addressing financial conflict of interest (Zoloth 2001, p. 17). Arthur Caplan, first president of the former American Association of Bioethics, on the other hand, feels that conflicts of interest can be managed, and that there are real benefits stemming from bioethicists’ engagement with corporations, “where much of the controversial, cutting-edge science gets

⁶ <http://www.greenwall.org/exguide.html>, accessed 10/10/05.

⁷ Philanthropy Magazine, <http://www.philanthropyroundtable.org/magazines/2001/january/marker.html>, accessed 10/10/05.

done” (Boyce & Kaplan 2001). However, finding fault with corporate activities often comes at a price. For example, pharmaceutical manufacturer Eli Lilly halted its annual donation to the Hastings Center after the Center’s journal published articles critical of Lilly’s drug Prozac (Boyce & Kaplan 2001).

As discussed in the previous chapter, several faculty members at the BC emphasized the importance of limiting the amount of corporate funding accepted, and of taking steps to minimize conflict of interest and to protect academic freedom. However, a couple respondents also affirmed the value of engaging with corporations to achieve bioethical objectives. One respondent remarked that she found the success of some environmental consultants in the “greening” of corporations inspiring, and that bioethicists could make a similar impact by working with corporations. She also asserted that it is difficult for bioethics to directly shape public policy, and she thought that one might have greater influence by working with corporations. In fact, corporations sometimes seek out bioethicists; one faculty member was approached by a biotechnology company after one of its executives saw her quote in a weekly news periodical story. Another faculty respondent noted that in order to even pursue scholarship on some topics, such as embryonic stem cell (ESC) research, one almost **needs** to work with corporations; at the time of my field visit, there was very little government funding offered to conduct ESC research or investigate the ethics of it. Virtually the only way to

obtain access to ESC research, and funding to conduct ethical analysis of it, she said, was to “find a way to work with the people who do it [ESC research].” However, she also pointed out, as did one of her colleagues, that openly criticizing corporate biotechnology, such as pharmaceuticals, all but excludes any possibility of working with corporations in that sub-sector.

Bioethics and Public Policy

As just mentioned, one BC faculty member asserted that it is a significant challenge for bioethics to influence public policy. One of her colleagues made the distinction that while it is difficult to impact federal-level policy, “the future of bioethics,” she said, is in state-level policy. She cited the example human cloning. There have been several bills in Congress to ban cloning, but none were passed into law. Furthermore, a cloning ban could turn out to be unconstitutional, as a violation of First Amendment rights to freedom of speech (see for example Hsu 1999). In contrast, at the time of this writing, twelve states had enacted statutes banning reproductive and/or therapeutic human cloning, and two other states have legislated prohibitions against the use of government funds for human cloning.⁸ My respondent also noted, however, that there is less prestige and visibility associated with state-level policy work, suggesting that pursuing it will have

⁸ <http://www.ncsl.org/programs/health/genetics/rt-shcl.htm>, accessed 10/12/05.

less positive impact on the institutional legitimacy and public reputation of bioethics.

I will return to the issue of bioethics' interaction with federal-level policy in a later chapter, where I examine the interaction of bioethics with other professional jurisdictions in the National Bioethics Advisory Commission's deliberations on stem cell research. Although bioethics has become a fixture in federal policy, particularly in the executive branch, bioethics faces formidable challenges in carving out a strong jurisdiction there, just as Evans (2002) found in his examination of the negotiation of the bioethics jurisdiction in public policy debates on human genetic engineering, reviewed earlier in this chapter.

Bioethics Outreach to the Community

At the local community level rather than the federal level, bioethics has the potential to make an impact on issues by engaging with local organizations and social networks. Unfortunately, the Bioethics Center at Letters lost staff funding for outreach activities, the result of downsizing efforts by the university medical system. The Jenkins Report reflected the disappointment of BC personnel about the Center's loss of the outreach function. The report testifies,

In several meetings a variety of people expressed concerns about the outreach program and lack of community activities. Many

felt the loss of the outreach program was a major blow to the [Center], and that it would be very difficult, although not impossible, to rebuild the valuable connections that had been fostered. They see community outreach as an important part of the [Center's] mission, and feel strongly that it should be restored if the [Center] is to maintain a regional presence in clinical and community settings.

After the completion of the Jenkins Report, new funding was identified for outreach staff, and both new and restored activities were pursued.

Early in its history, the Center's annual reports emphasized the role of outreach in the mission and support of the Center. Three reports contained the statement, "The [Center's] high visibility and numerous outreach programs make fundraising through private and foundation sources the most likely strategy for obtaining financial resources to support [Center] work." However, the latter two reports went on to note, "There remain serious failures on the part of the medical center and university to capitalize properly on the fund-raising opportunities that the [Center] presents." One report described the repercussions of funding limitations for outreach activities thusly:

At current funding levels, [the Center] cannot maintain a high level of [outreach] support to the [Letters health system]... In addition, [the Center] must limit its conferences to only those underwritten entirely by corporate or foundation support... Finally, we need a way to create and market curricula for educating professionals and the public beyond conferencing. We want to reach out through standardized curricula in the areas of accreditation, ethics consultation, high school bioethics, and site-visit evaluations.

Restriction of outreach funding clearly limits the venues and audiences that can be targeted, and almost certainly the topics that are addressed at conferences fully underwritten by outside organizations.

The scope of outreach recognized by the Center, and that could be pursued by the Center with limited resources, is an important indicator of the Center's claimed jurisdiction. The preceding annual report statement indicates an aspiration to expand outreach activities in various ways, but is largely focused on a clinical audience. When outreach activities were renewed subsequent to the Jenkins Report, several outreach goals were enumerated, also largely focusing on a privileged, clinical audience. These goals included support for the health system's ethics committees; research on the function and efficacy of ethics committees; ethics application in venues like health care institutions, nursing homes, consumer groups; and bioethics conferences organized by the Center.

One of my respondents commented that faculty "go out of their way" to give talks at local high schools, churches, and other community fora; they "try to have a local focus." However, she also noted that there was a sizeable disenfranchised community in the area served by Letters, and that "there's not a great relationship" between that community and the university, even though the university medical center's patient population reflects that community. She noted that the way participants are recruited for studies

“raises some concern about whether your using the population here like tissues and throwing them away... lack of insurance brings up issues about patient injustice, consent forms, some of these people can't read, there are twelve-year-olds with children.” However, there is little sign of outreach to these populations by the Center. One of my student respondents remarked that “universities always want to demonstrate their commitment to the community,” but she was unsure how much university-wide outreach commitment there was at Letters. She was aware that a group of students ran a free clinic in the area, but said she was not familiar with the Center's community activities. She suggested it would be good if the Center operated an ethics hotline for the community.

To one degree or another, universities operate in networks of privilege, which is often reflected in the type of outreach activities faculty engage in. Opportunities to dovetail outreach and fundraising activities have special appeal for academic units as they work to stabilize their operation, especially for less stable, non-departmental entities, and especially in lean fiscal times. As bioethicists seek to make permanent homes for themselves in universities, both for their livelihoods and the social values they hope to pursue, structural pressures will direct them towards outreach activities that facilitate institutional legitimacy and build social networks that will contribute towards organizational and fiscal stability.

Conclusion

In this chapter, I have examined the identity of bioethics and bioethicists perceived by faculty and students at the Bioethics Center, and described the relationship of the jurisdiction of the Bioethics Center to other jurisdictions at Letters University, as studied during my site visit. Overall, the influence of academic medicine on bioethics, and a motivation to forge relationships with potential sponsors and other sources of prestige and funding, appear to be the factors driving the construction of the bioethics jurisdiction at Letters, which serves in a weak advisory capacity to the biomedical jurisdiction. While health care professionals seem grateful for bioethics input and guidance for specific cases and projects, the Center's lack of engagement with the university medical center at the level of institutional policy suggests that bioethics at Letters stops short of systemic, structural critique of biomedicine, and remains "largely toothless."

Although the goals of bioethics were reported to be facilitation of dialogue about ethical issues in health care and biomedical technology, work remains to be done by the Center to better facilitate dialogue on biomedical quandaries with stakeholders and disciplines with different perspectives and goals than bioethics, including nursing, IRBs in competitive research environments, academic philosophy, the social sciences, and marginalized groups in the surrounding off-campus community.

Bioethics at Letters University faces several obstacles in communicating with other academic subject areas and other stakeholders on and off campus. First, bioethicists are caught in the tension between the ideologies of social trustee professionalism and expert professionalism, the dominant ideology identified by Brint (1994). Pursuit of the ideology of public service requires bioethics to engage with other professions that are strongly influenced by the ideology of expertise. However, reluctance to clearly define the particular expertise of bioethics, and perceived weaknesses of bioethicists in key expertise areas including philosophy and the social sciences, make it difficult for bioethicists to be taken seriously and treated as intellectual equals by other professional experts.

Second, bioethics faces several structural challenges that place it in a myopic and reactive position, rather than a farsighted and proactive position, with respect to the topics it addresses. Operating from the home base of academic medical centers makes bioethics fiscally vulnerable and encourages bioethicists to be constantly vigilant for new funding opportunities, whereby they address the issues that public and private patrons are sufficiently concerned about to invest funds in. Close association with the mass media also presses bioethicists to analyze high-profile social issues in short-term, firehouse fashion, rather than reflecting on, defining, and working towards long-term priorities defined by the field itself. Susceptibility to

biotechnofetishism and a lack of demographic diversity amongst bioethicists also shape the set of topics on which the field focuses its attention.

Third, bioethicists' skepticism of moral authority further mystifies other stakeholders regarding exactly what bioethics has to contribute to resolving ethical conflicts in biomedicine. Reluctance to don the mantle of moral authority is understandable given the roots of bioethics in questioning the paternalism of the medical profession and championing patient autonomy. However, skepticism of moral stances does not immunize bioethics against bias in the direction of particular societal viewpoints.

Rayna Rapp (1999) provides an instructive account on professional moral authority in her study of genetic counseling. The need to distance genetic counseling from the eugenics movement of the early 20th century led the field to embrace value neutral, nondirective counseling. Rapp explains however that rejection of the ideology of eugenics simply resulted in the embedding of other values in genetic counseling. Counselors, primarily females from a white upper middle class background, focus on the individual or couple as the presumed decision making unit renders the role of social groups invisible in the counseling process, in spite of their importance in several ethnic populations and religious groups. Genetic counseling also fails to openly acknowledge that the technology it is based upon is not value neutral, but rather was developed to identify and thus eliminate diseased

fetuses. Furthermore, the ideal of nondirective counseling is not fully achieved; Rapp describes counselors challenging clients' rejection of prenatal testing for reasons such as fear of needles, and discusses allegations of counselors' activism against the use of prenatal testing for sex selection of fetuses. Similar to genetic counselors, bioethicists generally fail to recognize that the biotechnology which beguiles them is not inherently value neutral. And while ethics consultants may be averse to declaring moral stances at the bedside, bioethicists more than rarely express their personal positions on bioethical issues in the classroom and in statements to journalists.

Overall, bioethics appears to be quite similar to the fields of higher education studies and science and technology studies. These three academic fields were all created to manage a particular set of social problems associated with specific institutional settings and practices, and may never become fully institutionalized as common departments in universities. As a result of drawing on unlimited multidisciplinary tools to address practical problems, it is difficult for these fields to define an emblematic professional expertise with which to demarcate a freestanding academic jurisdiction. Bioethics may have some staying power by virtue of the outlook for the continued growth of biomedicine in coming decades, but the institutional and professional outlook of bioethics is unclear. Abbott's theory of the system of professions has limited ability to explain this Peter Pan occupational status,

wherein an emergent group of expert professionals persist in a holding pattern that stops short of fully institutionalized professionalization.

The ambiguous and problematic identity of bioethics as a field undoubtedly is not helpful in forging relationships with established disciplines outside the medical school, or with stakeholders not immersed in academic culture, in spite of the conversational nature of the espoused goals of bioethics. For aspiring emcees in the ivory tower of Babel, pointed dialogue within the field aimed at bridging gaps among the knowledge and skill bases of bioethics would likely also facilitate bridge-building to neighboring expertise jurisdictions on and off campus.

CHAPTER 4—
MASTER'S DEGREE PROGRAMS IN BIOETHICS:
A GROWING FRANCHISE

Master's degree programs have in recent years become both popular and controversial (Schneider 1999). Interdisciplinary, "boutique" master's programs are being offered in subject areas such as environmental-science journalism (Columbia University) literary biography (New York University), and general humanities (New York University, University of Chicago, Stanford University). However, the value of such degrees is in question. Proponents argue that the programs are career-driven, and can lead to higher-paying employment with faster advancement than a BA alone, or serve as a springboard to a PhD, offering "a kind of pre-professional initiation into academic discourse" (Schneider, p. A12). Critics argue that departments are simply exploiting students for tuition dollars, to offset financial losses from scaled-down PhD programs.

Slaughter and Rhoades (2004) similarly make the case that the development of new "professional" master's programs represents a concerted effort by academic departments in US universities to generate new revenue streams through such educational programs, but in a way that addresses the employment markets of the new economy. This effort is often tied to competition for internal resources, as some university administrators have

begun linking student credit-hour production to allocation of resources to academic departments. These master's programs, serving a continuing education function, are often relatively inexpensive for sponsoring departments because of the frequent elimination of the faculty-intensive thesis requirement. Further, students in these programs require little research support, and often pay higher tuition. "The development of new master's degrees is a dramatic break from the past and reflects a significant reorientation at the graduate level to the external employment market and to revenue generation. Part of the strategy is to forge closer ties to business," the authors explain, noting that business may then sometimes make curriculum recommendations and provide monetary support (2004, p. 191). These new master's programs are not geared towards training students for new employment, but targeted at students who are already employed, to upgrade or augment their skills.

Does the growing legion of master's degree programs in bioethics merely reflect the alleged trend towards "boutique" master's degrees, or does it address an actual workforce training need that students seek to fulfill? Recent commentaries from bioethics faculty members and students in a 2002 special issue of the *American Journal of Bioethics* (AJOB) provide insider perspectives on the functions and results of bioethics master's programs and the future of the field. Similar to other master's programs, graduate

bioethics programs, if they are primarily tuition driven, run the risk of enrolling too many students, spreading faculty too thin, and paying inadequate attention to graduates' career prospects, (Kukzewski & Parsi, 2002). David Magnus, previously the director of a master's program in bioethics at the University of Pennsylvania acknowledges the general benefits that master's students bring to bioethics centers, including a source of revenue and research assistants for faculty. Another benefit, particular to emerging academic specialties like bioethics, is the benefit of institutional legitimacy. Magnus quotes from an unnamed colleague, "nothing makes you real in a university like a graduate degree" (Magnus 2002, p. 10). In the field of bioethics, master's programs are arguably preparing the way, and perhaps creating demand for, a growing number of *de novo* bioethics PhD programs. Charles Bosk argues that the PhD "is nothing less than a legitimating chip, anted up in the bargaining for institutional resources and prestige," and accordingly "create[s] competitive pressures on peer programs to do likewise" (Bosk 2002, p. 22).

Who is enrolling in master's in bioethics programs, and why?

Unfortunately, detailed information on bioethics student demographics is lacking. Some students are recent BA recipients, viewing the master's in bioethics as a stepping-stone into a PhD program, or as a tool for deciding between graduate and professional schools. However, many other master's

students in bioethics are mid-career professionals or dual-degree seekers, looking to specialize or enhance their current or imminent vocations, not to switch careers (Kukzewski & Parsi 2002; Magnus 2002). Many bioethics centers explicitly state that their programs are not designed as a means to a career (Russo 1999; Magnus, 2002). Chaitin, one of the student commentators in AJOB, notes that even her PhD program in health care ethics at Duquesne University “cautions students that a degree earned through its program will not be a guarantee of a future in bioethics” (2002, p. w2). While some graduate programs publicize such caveats, the 2001 American Society for Bioethics and Humanities (ASBH) graduate program survey found that a “significant minority” of master’s program do claim to train individuals for full-time bioethics-related work (Ausilio & Rothenberg 2002, p.7).

Whether or not bioethics master’s programs are aimed at job training, AJOB commentators see implications of graduate education for the bioethics-related job market. Russo (1999) contends that clinical ethics consultation has not generated a vigorous job market, and hospitals may instead be meeting accreditation requirements via the use of unpaid ethics committees. Magnus speculates that it may not be necessary to employ separate clinical ethicists on staff at all. Instead, it may be more effective “to spread clinical staff with some bioethics education throughout the institution, ideally as part

of every team” (Magnus 2002, p. 12). Alternately, PhD’s and JD’s currently employed in clinical ethics positions may in the near future be displaced by less-expensive master’s recipients (Magnus 2002). Steady growth in the population of bioethics degree holders will create a buyer’s market in bioethics jobs, predicts Charles Bosk, a state of affairs that that he argues does not encourage independent, critical thought among practitioners. “Typically, the master’s degree is not associated with independent practice,” he explains, but rather with “administrative positions in professional bureaucracies,” as in the case of social work (Bosk 2002, p. 22). Although steadily growing in number, it is not clear the master’s in bioethics (MBE) programs will have a positive impact on the future of this embryonic professional field.

Kuczewski and Parsi argue from their observations as bioethics professors that the motivations of MBE students “generally sum up to the broader aim of being a member of the bioethics community” (2002, p. 14). In fact, the authors consider it to be the “only one [student motive] that can account for the rapid growth of terminal M.A. programs” in bioethics (p. 14). They acknowledge the desire for professional credibility, and intellectual curiosity, as other student motivators. However, students are not merely seeking access to bioethics knowledge, which is increasingly accessible.

Rather, they desire sympathetic interlocutors for ongoing support and mentoring. The authors explain,

Ethical issues are often complex and **implementation of new approaches tends to be difficult requiring long-term strategies and persistence**. For instance, seemingly simple issues of informed consent and quality end-of-life decision making **have proven recalcitrant and are continuously inviting renewed intellectual efforts**. **Maintaining morale and the will to address such matters** requires the support of a professionally trained community (p. 15, emphasis mine).

This account conveys not only the frustration regularly faced by professionals in the clinic, but also suggests that bioethicists serve as confidants as well as consultants, both sustaining morale and providing advice for recalcitrant problems.

However, this is not the only perspective on the functions of bioethics. Harrison lists particular skill areas she finds necessary for success in bioethics, including conflict resolution, critical evaluation of evidence, group processes and dynamics, research methodology, and policy analysis. She appears to question whether these skills are being taught effectively, noting that in her own graduate work, such skill acquisition was “coincidental” to the completion of degree requirements, and mentoring was “haphazard” (Harrison 20).

In contrast, Kuczewski and Parsi (2002), respective directors of the bioethics center and online master’s program at Loyola University Chicago, contend that MBE programs are shaped by student aims. Reflecting on the

history of bioethics master's programs, they recount "the main story many of us have been telling," in which the first programs were launched as tracks in traditional humanities departments (e.g., philosophy), in response to increased attention to medical ethics issues. The enrollees were largely clinicians, presumed by program designers to desire a foundation in traditional aspects of a discipline such as philosophy, although some students sought an applied ethics degree to supplement doctoral work in other fields. The programs consequently tended to consist largely of typical disciplinary graduate coursework augmented by a couple specialized courses developed for the track. However, this approach was somewhat misguided, because the clinician-students did not perform in coursework as well as the traditional graduate students did, and not surprisingly had a more practical than scholarly orientation. One can readily imagine pragmatic students with MDs getting quite exasperated from studying the decontextualized analytic intricacies of moral theories in a rigorous graduate course geared towards PhD students in philosophy. Kuczewski and Parsi argue that the trend in the 1990s, away from disciplinary tracks and towards the founding of new "genuinely interdisciplinary" bioethics programs, has come about because "no one discipline made a convincing case that bioethics is simply a subset of it, [thus] more diversified offerings are sought" (p. 14).¹ This trend suggests to

¹ Similarly, many existing programs from departmental tracks have migrated

the authors “that the concerns of persons enrolling are fairly practical in nature and likely to be ongoing” (13).

What are students seeking from MBE programs, and what are they actually receiving? What is the value of MBE programs, for students, and for the future of the field? To address these questions, I first examine the student commentaries in *AJOB*, and then I present findings from my case study of the Bioethics Center at Letters University, focusing on interviews with students. I was not able to collect data on tuition revenues generated by the MBE program at Letters; my investigation focuses instead on the perspective of students.

Student Commentaries in the *American Journal of Bioethics*

In addition to providing space for faculty commentary on the implications of the 2001 ASBH North American Graduate Bioethics and Medical Humanities Training Program Survey, *AJOB* also presented feedback from current and former graduate students in bioethics/medical humanities programs. To guide the responses, the *AJOB* editors asked each student commentator to consider three questions:

1. Why did you enroll in a graduate bioethics/medical humanities program?
2. How well did your graduate bioethics/medical humanities program meet your needs?

into new bioethics centers.

3. What do you think graduate programs like these mean for the future of the field?

I examined themes in the twenty-four student responses, related to motives for program enrollment, program features of salience to students, and satisfaction with their program experiences. Respondents were diverse in many respects, representing different student backgrounds, institutions, disciplinary orientations, and credentials. After reviewing themes in student responses, I will discuss the alignment between student and faculty perspectives and claims.

Student motives

Reasons given for pursuing graduate credentials in bioethics fall into the categories of existing job-related need, love of bioethics, and related career aspirations. Butkus and McCarthy (2002), students in the PhD track of the Healthcare Ethics program at Duquesne University, were both motivated by the need to learn and integrate both the abstract theoretical foundations and the tangible clinical experience they required for their work. Both students chose Duquesne because they felt it would provide them with the desired groundwork for ethics consultation and teaching.

Other commentators aspired to become well-rounded clinicians, and similarly influence their colleagues, with the help of bioethics education.

Bevins, a medical student, explains that getting a foundation in the medical humanities was essential to becoming the “kind of doctor,” and the “kind of person,” he wanted to be (2002, p. w1). Not surprisingly, he also notes that his program’s location at an academic medical center (University of Texas Medical Branch) provided a rich environment for pursuing diverse interests and goals. Nathanson, a psychiatric resident, begins by stating that “the current level of bioethics education at most medical schools is severely lacking (2002, p. w1). He felt that his graduate studies in bioethics (an MPH from Boston University, with a concentration in health law and medical ethics) gave him specialized knowledge and skills in the analysis and resolution of moral issues that will be invaluable to his future practice. Egan, an internal medicine resident, identifies bioethics as her medical “specialty” and plans to maintain a general clinical practice as well. Like Nathanson, she finds that medical humanities training for medical students is wanting, and decries most physicians’ deprecating attitude towards ethics training and habitual unethical behavior in clinical practice (2002, p. 27). Egan argues that “residents need to be taught that passive ethics education does not prepare them for the ethical challenges they will regularly face in practice” and that “clinicians not only need more ethics training exposure but also a reformulation of the role of ethics in daily practice” (2002, p. 27).

Other student commentators sought skills in research or clinical ethics. Veikher, an international student from Russia, cites an urgent need in Russia for experts in international research ethics. She was one of four students chosen by the Fogarty International Center to receive fellowships to study bioethics at Case Western Reserve University during the 2001-2002 academic year. According to Veikher, the Fogarty Center selected Case Western because its MA program provides a general theoretical and practical introduction to the field of bioethics of most use to international students. She particularly values the opportunities to learn consensus-building skills and to acquire practical experience through clinical rotations (Veikher, 2002).

Building clinical ethics skills was an important motive for other commentators. Chaitin (2002) is an intensive-care social worker, hospital ethics director, and medical school faculty. Although the combination of her MA and PhD education in bioethics enriched her practice by providing her with a “stronger holistic knowledge base,” she is not satisfied with the training in ethics consultation provided by her PhD program. Gurin (2002), an MD who increasingly found herself playing the role of ethicist, sought graduate bioethics education to acquire essential tools for addressing clinical ethics issues, which would benefit not only her own work but also her entire hospital community. McCrudden (2002) began his career as a hospital chaplain and later came to serve on ethics committees and as a health-system

administrator. He desired to increase his familiarity with clinical ethics issues and theoretical approaches to better perform his roles, and particularly to apprehend patient rights and organizational ethics “in order to remain a competent resource” in his workplace (2002, p25).

Beyond immediate job-related needs, many student commentators also cite love of bioethics and clear desire to work in that field as a motivation for pursuing graduate training in bioethics. Thaddeus Pope states simply that he enrolled in Georgetown University’s J.D.-Ph.D joint-degree program “to become a bioethicist” (2002, p. 37). Strauss, another graduate of Georgetown, reflects, “the field of bioethics satisfied my passion for the contemplative life, as well as my need to perform a public service” (2002, p. w1). Schonfeld became “totally enamored” with bioethics as an undergraduate “languishing somewhat aimlessly with a religious-studies major” (Schonfeld 2002, p. 32). He subsequently pursued a Ph.D., and became a professor of medical humanities. Solomon (2002) explains that while she had an interest in bioethics, she also needed a practical reason to study bioethics. As a secondary school science teacher, she began to find that more and more bioethics-related topics began to present themselves in her classroom, and realized that she wanted to teach bioethics.

Several other student commentators might be categorized as eclectic wandering scholars—reflective persons with diverse interests who eventually

found a home in bioethics. Sisti explains there was no single reason why he was drawn to bioethics, but “rather an amalgam of interests and goals somehow coalesced” and led him to what was for him “the perfect graduate program” (2002, p. 28). For Voss, who finds the way down life’s path often “tortuous and confusing,” health care ethics is “a field that invites those with diverse backgrounds to help those dealing with serious bioethical dilemmas” (2002, p. w1), and one where he could use both his veterinary and theological training. McGuire went from being an undergraduate psychology major to studying shamans in the Amazon rain forest before she pursued a joint J.D.-Ph.D. degree in hopes of achieving “a unique perspective on the legal and ethical issues involved in western medicine” (2002, p. w1). Suziedelis views her admittedly eclectic academic background in education, political science, and theology as “the perfect preparation” for doctoral work in healthcare ethics (2002, p. w1).

Other student commentators state that their career aspirations led them directly or indirectly to seek graduate-level bioethics training. Isinger developed an interest in bioethics as an undergraduate, and chose to pursue a Ph.D. because it “opens more opportunities for employment and advancement,” thinking that to succeed in a bioethics career she would need a “professional appointment, and academia was the logical choice” (2002, p. w1). Zilberberg enrolled in a philosophy Ph.D. program to become a

philosophy professor, and upon taking a bioethics course realized that she really wanted to pursue the field (2002). McCarthy knew as an undergraduate that what she “loved more than medicine was the art of teaching about medicine,” and soon found herself searching for a graduate program in healthcare ethics to pursue a teaching career in medicine (2002, p. w2).

Key Program Characteristics

Student commentators cite a variety of program characteristics as important to their educational experience. Salient features included interdisciplinary characteristics, program flexibility, balanced curriculum, opportunities for clinical practica, effective mentoring, and the possibility of gaining particular skills necessary for work in bioethics.

Some commentators highlight the role that a sense of community played in their graduate training. Butkus and McCarthy note that the students in their program “have a remarkable sense of community and a desire to assist one another,” contributing to a “positive, committed environment” in the program (2002, p. w2). Bevins describes the shared mindset of participants in his graduate program at the Institute for the Medical Humanities at the University of Texas Medical Branch, which includes amongst other things “a belief in the importance of language as a

means of individual expression and social change,” “a belief in an individual’s ability to develop himself or herself,” and “a commitment to affecting change through public discourse” (2002, p. w1).

Several student observers comment positively about the disciplinary diversity of the training and the student body in their programs. Butkus and McCarthy view student diversity positively, stating that their graduate program enabled them to build “an excellent knowledge base in law, philosophy, psychology, clinical medicine, and theology,” and “to develop a network of professional contacts in all areas of medicine and academia” (2002, p. w2) [this isn’t necessarily due to student diversity, but the array of professionals they worked with during program experiences]. McCarthy in particular values the opportunity to receive a “strong theoretical grounding in a variety of sources—religious, cultural, and philosophical” and partake of “a wide range of clinical experiences” (2002, w2). Zoubul finds student diversity was beneficial to her graduate experience, explaining that “by combining professional and traditional students from a variety of academic disciplines,” the diversity of her graduate class “allowed for insight from many perspectives” (2002, p. w1). Isinger found both the international and professional diversity of her Duquesne classmates to be valuable, because it generated enlightening commentary stemming from different theoretical frameworks (2002, p. w1). Suziedelis comments that the interdisciplinary

nature and flexibility of her program “makes it ideal not only for students with diverse academic backgrounds, but also for those such as I, who bring to it a wide range of life and educational experiences that we seek to pull together into new, integrated, midlife careers” (2002, p. w1).

Program flexibility was an attribute that figured significantly into several students’ assessments of their graduate training experiences in bioethics. McCrudden, a hospital administrator, finds that the online graduate bioethics program offered by Loyola University Chicago is an antidote to the time and travel constraints presented by typical continuing ethics education, meeting his needs for a highly accessible and flexible training program. He speculates that many professionals from various backgrounds are interested in expanding their knowledge of ethics, but the “lack of a program close to home that fits into a busy schedule” is a significant obstacle (2002, p. 26). In addition to convenience, McCrudden argues that with a good instructor, web-based education can also be very student-centered, observing that Loyola “has a reputation for having the most responsive and innovative faculty” (2002, p. 26). Chaitin also mentions that her doctoral program at Duquesne University “seems to be designed for the working adult,” offering night classes and online services (2002, w1). McGuire asserts that “if graduate programs in bioethics and the medical humanities are to survive... they must adapt to the changing needs of their

students” (2002, p. w2); she notes that she took advantage of her program’s flexibility to take classes in various departments, arrange an extended clinical practicum, and conduct her own research. Her fellow University of Texas Medical Branch (UTMB) student Bevins agrees that the medical humanities curriculum offered there is “flexible enough to accommodate people from all sorts of backgrounds with all sorts of interests and goals,” whether they want a broad or a more focused education (2002, w1).

Acknowledging that no one program can meet all needs perfectly, Isinger recommends that bioethics graduate programs offer a choice amongst a few of their required courses, to assist students in filling their particular knowledge gaps (2002, p. w2).

Student commentators also spoke of the importance of a balanced curriculum in graduate bioethics training, with some alluding to what Butkus calls “the disparity between clinical and classroom ethics” (2002, p. w1). Veikher (2002), an international student, notes that in Case Western’s program the core courses provided both theoretical knowledge and practical experience in the curriculum. Butkus and McCarthy (2002) testify that they received a thorough education in an array of relevant disciplines, as well as extensive applied clinical experience; their program not only trains students to competently examine the array of ethical, legal, and social challenges raised by modern medicine, but accommodates the wide array of clinical and

non-clinical backgrounds which students bring to the program. McGuire echoes that graduate bioethics programs must, amongst other things, take responsibility for “integrating theoretical studies with clinical experience and research” (2002, p. w2). Zoubul notes that at Case Western, curricular inclusion of “academic coursework and clinical observation allowed us to see bioethics as it is done in two very different settings, the classroom and the clinic” (2002, p. w1).

Some students judge their programs to be lacking in a balanced curriculum. As an experienced clinical consultant, Chaitin finds her master’s education in bioethics to have been lacking in adequate attention to the clinical environment and its legal context, and deems the clinical experience offered by her doctoral program to have been poorly designed and supervised (2002). Schonfeld comments that “in many programs there is often a dissonance between classroom education and practical application” (2002, p. 33) and suggests that adding more team or committee experience in the clinical ethics training of graduate bioethics programs would help students better understand the role of the ethicist in the collaborative clinical setting.

Several students specifically emphasize the importance of clinical practica in their training. Schonfeld, now a medical humanities professor at the University of Nebraska Medical Center, notes “part of the goal of the [graduate] practicum was to develop my sense of how a clinic worked, but

another part was also to understand the role of the ethicist in the clinic” (2002, p. 33). White, a former student of UTMB, finds that “total immersion in the culture of medicine was inescapable and a very important part of my education” (2002, p. 34). But when she began teaching medical students, she realized that “a primary weakness of my graduate training was that I had not spent enough time with the kinds of practical clinical information my students demanded” (2002, p. 34).

Mentoring and role modeling were also repeatedly mentioned as a crucial feature of good graduate bioethics training, particularly with respect to the clinical aspects of training. Sisti affirms the effective mentoring he felt he received at the University of Pennsylvania bioethics program, which he credits with helping him parlay a clinical ethics internship into a “more-or-less full time clinical bioethics role in a Philadelphia health system” (2002, p. 29). He also speculates that neophytes in bioethics are likely to get discouraged unless they receive the opportunity to develop “prudent reasoning through solid mentoring” (2002, p. 29). Schonfeld argues that role modeling and mentoring are an important part of professionalization, teaching students the roles and skills needed to become an ethicist, beyond what can be taught in the classroom. He comments that he would have liked the opportunity to shadow ethicists in the clinical setting, the same way he and his fellow students shadowed healthcare professionals, but also notes

that this would have required particular effort given that the faculty ethicists in his program are “primarily academic philosophy professors and do not spend much time in the clinic” (2002, p. 33). In agreement, Strauss states, “I do not think proper professional development is possible without good mentorship,” acknowledging her own mentors for modeling “ideal professionalism” and providing her with opportunities (2002, p. w2). Chaitin reflects that “the provision of a mentor [during clinical training] was invaluable to me for many reasons, not the least of which was a need to learn how to view what I was observing with different eyes”; her mentor taught her “to see a problem clearly through a prism rather than a magnifying glass” (2002, p. w1). Isinger (2002) similarly advises bioethics graduate programs at all institutions that mentoring for the first student practicum would be helpful. Zilberberg concludes, “the aspect of the program that has most helped me become a bioethicist and build a career is the mentoring and advice of helpful faculty members” (2002, p. w1).

Several student commentators emphasized the importance of particular skills or tools they felt they had gained in their graduate bioethics training. Interpersonal skills, including communication, consensus building, and tolerance were cited by some students. Schonfeld really valued learning to make presentations to clinical audiences and thus comfortable speaking to health care professionals. Veikher and Chaitin both acknowledged the value

of their program exposure to conflicting opinions, different religious perspectives, and various theoretical approaches, which taught them about themselves, about others, and about tolerance and achieving consensus. Other students prized the analytic skills they developed in their programs, including the ability to navigate complex ethical issues and the theoretical and topical complexities of bioethics, and to analyze and resolve ethical problems.

Program Satisfaction

Regarding the level of satisfaction with their graduate education experiences in bioethics, several student commentators give positive marks, while several others express concerns about their future career prospects, and about the role of graduate programs in the future of the field.

Satisfied program graduates feel that their experiences provided contributions not only to their individual professional growth, but also to a larger community. Pope feels that his program exceeded his expectations, stating “I went to Georgetown to become a bioethicist. Once there, I discovered that the role of the bioethicist is no more unitary than that of the lawyer or the doctor. I soon decided what **sort** of bioethicist I wanted to become, and Georgetown prepared me well for that role” (p. 37, original emphasis). Campbell comments that her program exceeded her hopes and

that “while I don’t pretend to be an expert in the field... I have the tools that will enable me to make a meaningful contribution to the field” (p. w1). Gurin states, “the entire community [at her hospital workplace] is benefiting from my education” (p. 34); she serves on her hospital’s institutional review board as the only ethicist, and also on its Ethics Facilitation Service, as the only physician. Veikher, who will take what she learned about research ethics back to Russia to fill an urgent need, feels that her program was “an outstanding success” as an experiment in placing an international student in a bioethics program at an American university. Butkus and McCarthy write, “We are beginning what we envision to be long careers in bioethics, and we believe that our program has provided us with an excellent knowledge base” and “has allowed us to develop a network of professional contacts in all areas of medicine and academia... We could not have asked for more” (p. w2). Bevins similarly concluded that he could not have made a better choice than the UTMB program, and that he “will be a better doctor for it” (p. w1). Isinger conceded that while no program can perfectly meet all needs, she would do it over again.

Commentators expressing career concerns speak of the need for more jobs in the field, the value of certification in research methods, the role of graduate work as a career stepping stone, and the role of graduate programs in the future of the field. Zilberberg feels there is a need to create or identify

more jobs in bioethics, and Voss deems that pursuing an additional certificate in empirical ethics research methods would “greatly enhance my chances of securing a desirable academic position” after graduation (p.w1).

Several comments concern the role of graduate work as a career stepping-stone. Shivas argues that interdisciplinary coursework and other interdisciplinary experiences are “a real asset to those hoping to pursue a career in bioethics,” (2002, p. 24) but she also cautions, “an interdisciplinary program on the Ph.D. level may leave one without the necessary theoretical grounding through which those interdisciplinary skills can be utilized and allowed to flourish” (p. 25). Sisti warns, “young scholars... should not enter a bioethics program with the dream of coming out a card-carrying ‘bioethicist’” (p. 29), but he concedes that “increasingly, jobs *are* out there,” (p. 29, original emphasis), and that “the doors have swung wide open for the professional domain expansion of bioethics and its practitioners” (p. 29). Zoubul feels that her graduate education and work experience would put her in a better position to meet her professional goals. Chaitin believes that her education enriched her practice as a clinical ethics consultant, and that she was mistaken in her previous thinking that what she learned from her clinical work as a social worker was sufficient preparation to be a successful ethics consultant. Zilberberg reflects, “the aspect of the program that has most helped me become a bioethicist and build a career is the mentoring and

advice of helpful faculty members” (p. w1). Nathanson thinks his program provided necessary skills in ethical analysis and problem solving that will be “invaluable” in his future practice, and that his research experience in health law was indispensable.

A couple students comment on the relationship between graduate programs and the future of bioethics. Isinger believes that “specialized’ degrees in this field will help establish and perpetuate the profession, but she also notes,

Most professions, when trying to establish themselves and gain recognition, usually undergo a process of monopolization and regulation of skills and knowledge. However, the multi- and interdisciplinary nature of bioethics/medical humanities is what makes the profession unique, interesting, and challenging. I hope that those of us trained specifically as bioethicists never come to believe that it is only ‘experts’ who qualify to ‘do’ bioethics (p. w1).

Zoubul affirms that graduate programs play an important role in bioethics.

“Although our professors spent a lot of time stressing the fact that we should not view the M.A. as a terminal degree,” she observes, “I think that graduate programs like this are integral to the future of the field” and “can be a stepping-stone in building a career in bioethics” (p. w1-2). For Zoubul, the value of the MBE is clear: “the combination of my graduate education and work-related experience in bioethics has put me in a much better position to accomplish my professional goals than if I had not completed the program” (p. w2).

Summary: AJOB Student Commentaries

What do students want from MBE programs, and why? Are they getting it? The student commentators in AJOB came to bioethics with a diversity of backgrounds and goals, and entered graduate bioethics programs with a variety of formats and orientations. Many have emerged or can be expected to soon emerge satisfied, on balance, with their educational experience, and most clearly articulate particular aspects of their training that they deem to be important. Several MBE students are mid-career professionals supplementing their skill sets, and others are embarking on careers as not only self-described, but credentialed bioethicists. Of course, one would not expect disgruntled students and dropouts to write and submit accounts of their experiences (or perhaps they would not be published), so one cannot conclude on the basis of these commentaries that most students are satisfied or glean career benefits from their graduate education. Several commentators offered constructive criticisms of their programs and the field in general, but none were scathing. It is noteworthy that several students refer to themselves as bioethicists, even explicitly entered programs to become bioethicists, and can clearly identify job prospects in bioethics, in spite of acknowledged warnings that graduate programs are not geared towards job placement as a bioethicist.

How do student responses align with faculty member commentaries in AJOB? The volume of student comments about the importance of mentoring in their graduate experiences is consistent with Kuczewski's and Parsi's allegation that students primarily desire to become a part of the bioethics community and receive support from it. However, students also spoke at length about the invaluable skills, knowledge, and first-hand experience that they desired from their graduate bioethics training, indicating that content as well as community is important. Students also relate specific career needs and goals to their training.

The discourse published in AJOB on graduate bioethics training conditionally suggests that MBE programs provide valuable preparation to students, as well as tuition revenues and legitimacy to academic bioethics programs. I next examine my case study findings to assess what value the MBE program at the Letters University Bioethics Center provides to its students and faculty members.

The Master's Program at Letters University

Planning documents for the Bioethics Center's MBE program differentiate it from both trendy and traditional master's degree programs. In a letter discussing the arrangements for the fledgling masters program, one administrator observed that the bioethics program "is distinguishable

from an MA or MS degree **that is a stepping stone towards a PhD,**”(emphasis mine), and consequently “the new Master’s would not shape or influence future decisions about creating a PhD in Bioethics.” An internal memo regarding the center’s marketing plan for the masters program expressed that the marketing goal was to double, if possible, the number of mid-career professionals applying to the program over the third and fourth years of the program. The marketing materials for the MBE program explicitly indicates that applicants should be mid-career health professionals, students already admitted in other graduate or professional degree programs at Letters. Prospective students with merely an intellectual interest in the field are also invited to apply, but with the provision that they understand the MBE by itself is inadequate for job placement. These observations indicate that the bioethics masters program was not conceptualized as a traditional academic program, but as a training program to augment the careers of established professionals.

In the marketing-plan memo, a staff member shared marketing ideas focused on the local health care community. The resultant list of marketing strategies provides a sense of the vast network of the Center’s potential constituents. On campus, this included schools, departments, centers, institutes, public-relations offices and ethics committees all over the university, clinical affiliates of the medical center, and continuing medical

education representatives. It also included extramural institutes, hospitals, managed-care companies, health care and ethics organizations in the region; professional health care conferences held in the vicinity; and local chapters of health-professional associations and patient/consumer advocacy groups. Other constituents mentioned were regional health-care publications and government offices such as the health departments. A related Bioethics Center meeting agenda also cited pharmaceutical companies as a promotion target. Clearly, the Center saw myriad opportunities to connect with an extensive network of interests and organizations in its environs, and intended to tap into it.

According to the graduate program director for the BC, the Master's in Bioethics was part of an initiative in the College of Arts & Sciences (CAS) to develop a set of professional master's programs in its Division of Continuing Studies (DCS). The dean of DCS, I was told, was an entrepreneur who wanted to expand offerings for a new market, mid-career professionals, as a way of bringing in revenues. At least one of these programs was highly successful and grew quite large (as of October 2005, there were six such DCS master's programs). Concerns emerged about the quality of these programs, due in part to the fact that many course offerings were combined with undergraduate course sections (such was not the case for the MBE program). Furthermore, although DCS had expertise in dealing with adult students, it

was not well run from an administrative standpoint, according to the MBE program director. The original vision for the MBE to be a CAS program was not feasible, because key faculty from CAS were not available to take major roles in the new program. Most of the coursework was consequently offered out of the BC, not through CAS. At the time I visited the BC, the MBE program, and its revenues, were about to be moved from CAS to the medical school, and the BC had considerable control over the program.

One would expect that operating the MBE program entirely out of the Bioethics Center might place a considerable work burden on Center faculty. The Jenkins Report, an independent evaluation of the Center, which I referred to in Chapter Three, suggests that Center faculty were indeed spread thin. The report cites student concerns that the classes were too big and that faculty members were already too busy for the program to expand further. Many students also expressed the desire for faculty to provide them with more structure and direction, particularly in student's clinical experiences. The report also states that some students got the impression that the program was "just added on" to the Center, and was not a priority. It would appear that perhaps the Center had an overly ambitious timetable for growing the MBE program, in terms of its faculty-student ratio and overall faculty workload.

Students at the Letters University BC

At the time I visited the BC, the graduate program director estimated that more than two-thirds of the students were mid-career professionals, the vast majority ranging in age from the late twenties to the mid fifties. The remainder of the student body consisted of dual-degree seekers (law or medicine in tandem with bioethics) and a few recent bachelor's graduates. She also explained that while the plurality of students were physicians, "we put a premium on diversity of experience," as evidenced by the nurses, veterinarians, psychologists, lawyers, pharmaceutical industry professionals, consultants, clinical researchers, and other professions represented in the Center's student body. The graduate program director estimated that eight percent of their students had been African American, and that smaller percentages were Asian or Hispanic, with an approximately equal gender representation. By comparison, one third of the Center faculty members are female.

I solicited volunteers from the Center's current and alumni student body for individual and group interviews with the help of a Center staff member, who sent out a couple of invitational e-mail messages via the Center's student listserv. Only eleven students completed interviews, all of which were one on one; seven of the students were female. All of the students interviewed were white, and two were from other countries. They ranged

from approximately twenty through sixty years of age. One program alumni had earned an MBE while in medical school, whereas all other interviewees were early or mid-career professionals. Two were program graduates, one of whom acquired a staff position at the BC after graduation; three were attending part-time over an extended term, one as a dual-degree seeker in (PhD, nursing); the remaining six students were in their second year of the program. From the group of currently enrolled students, I interviewed three physicians, two nurses (one turned health care consultant), two lawyers, one veterinarian, and one individual with a mixed entrepreneurial, government, and NGO professional background. For the sake of anonymity, I will refer to student respondents with feminine pronouns where required for readability.

I conducted taped semi-structured interviews with ten of the students (see appendix for student/staff interview schedule), most of which lasted less than an hour. One student declined to be taped. In general, student responses I received were less rich than the perspectives shared by student commentators in AJOB, which I examined earlier in the chapter. Students' responses were grouped under five themes drawn from the interview questions: their perceptions of the BC, their motives for entering the program, their expectations of the program, their perceptions of the value of a Masters degree in bioethics, and their perceptions about the goals of the field.

Perceptions of the Bioethics Center. Student interviewees conveyed some shared views of the BC. Five described the student body as diverse in their backgrounds and interests. Two described faculty as difficult to access, and three described faculty as biased in their views. Students were unclear as to the BC's role in the larger university or local community. While two of them cited the BC as playing an active role in the medical school, a third expressed surprise that the BC did not play a larger role on campus. A program alumnus and current BC staff member observed that while there were some collaborations with faculty in other parts of the university, the BC operated largely separately from the Letters University community. When probed, only three of the students commented on external factors or influences on the BC, and all cited current events as a significant influence. Two cited the need for funding as an important pressure, with one more specifically identifying competition with other bioethics centers for money and recognition as a salient influence.

Student Motives. Students cited a variety of career goals and other motives for pursuing an MBE and choosing the program at Letters University. Several mentioned teaching, consulting, and public-policy work as career goals related to bioethics. Motives for pursuing an MBE included personal enrichment and curiosity, acquiring job-related expertise, and seeking the

legitimacy or marketability associated with holding the degree. Seven of the students cited proximity as a major reason for choosing the Letters University program, although several also cited the BC's reputation as an important draw. One student relocated specifically to pursue a dual degree at Letters University, and another dual degree seeker commuted a long distance, feeling that Letters had more to offer than other universities in the region.

Student Expectations. Students commented on their expectations of and satisfaction with the program. While three students said they had no idea what to expect when they entered the program, others had explicit expectations. Three anticipated getting a good grasp of the foundations of the field, and one dual degree seeker had hoped that the MBE program would dovetail better with their other program of study. One student thought that bioethics would have a broader perspective and more openness, such as addressing environmental concerns, but found that bioethics as presented by the BC was “strictly medical ethics.” Students were mixed in their satisfaction with the program. One student, a dual degree seeker in nursing, was “really pleased” with the experience. Six students were mostly pleased with what they encountered in the program, but felt there was room for improvement, and four expressed significant disappointment. Students’

critiques related to the professional conduct of a few faculty members, and the curriculum. Two students felt the curriculum could be more balanced. One wanted more of a clinical focus, and felt that students received a biased presentation of the field. She also commented that “un-sexy topics” were not well addressed. Another felt there was too much philosophy, and wanted more theology in the program.

The Value of the MBE. I also asked students to reflect on the value of the program, and on the expected utility of an MBE. The students felt they were gaining both epistemic and social capital from their program participation. For these students, epistemic capital consists of learning the fundamentals of bioethics—the core topics and literature, a working knowledge of the key issues, the philosophical underpinnings and history of the field—and of developing skill in analyzing ethical issues, and dissecting and formulating ethical arguments. With respect to social capital, students cited the benefits of becoming integrated into the professional bioethics community. One student remarked that she could now “act like and talk to bioethicists,” and two mentioned that participating in the MBE program boosted their confidence. Two students mentioned participation in the American Society for Bioethics and Humanities conference as a benefit, and another mentioned the value of acquiring mentors to keep in touch with.

When further probed about the utility of the degree program to them personally, career-wise, and to their futures, students talked about the value of the credential, and how it would set them apart. One student felt the credential would make her “marketable,” particularly since few nurses and clinicians have an MBE, for getting a teaching position in a medical college. Two other students mentioned the utility of the degree for getting positions teaching ethics. Another commented that the MBE will give her a “niche,” and that it would “open doors” and “set her apart.” One student noted that her training “opened up a new way to discuss things” in the career she is pursuing. Other students mentioned that the degree would bring them “cachet” or recognition.

I asked students whether they had participated in faculty research or otherwise worked with faculty. Four students expressed regret at not working with faculty, due to reasons such as distance from campus, the constraints of dual degree programs, or otherwise not having enough time. Only two of the students I interviewed had worked with program faculty; another student had worked with a clinician not on the BC faculty, and two others indicated that they might pursue work with faculty in the future.

The Goals of Bioethics. Students were asked for their views on the goals, or task, of bioethics, and on what progress had been made towards those goals.

Overall, students' responses were consistent with the view that it is the job of bioethics to raise questions, "to enlighten," not to provide answers. Rather, as one student put it, the aim of bioethics is to "look at how we can make better decisions around issues affecting the human body and relationships with health care providers." One student said that it was the job of bioethics to ask, "whom does this [biomedical] technology serve?" and "what are our values?", as well as to question the technological imperative, and to emphasize the importance of considering patients' interests. Similarly, one student felt that bioethics is a means to addressing science's responsibility to society. Another commentator echoed that it was the task of bioethics "probably to serve as not a watchdog, but a buffer between what science and medicine can do versus should do," and to promote "time for self-examination."

A few students suggested slightly more active goals for the field of bioethics, such as improving policy and practice in areas like research ethics. One student stated, "bioethics is a diplomacy tool; we're not just referees," and went on to explain that bioethics brings an analytic framework to discussions that it is akin to brokering negotiation—a bioethicist needs to translate between views, to be a diplomat, to bring stakeholders to a common consensus. Two dissenters argued that bioethics is ideology, with one summing up the field as "WASP ethics," and another arguing that bioethics is

a “secular religion,” providing counterargument to religious arguments on bioethical issues.

Students differed regarding whether they perceived a change in their views about the goals of bioethics as a result of their MBE program participation. Three students felt that their views had not changed at all. Four students felt that they had gained a broader or more complex view of the aims of bioethics. For example, one now felt less confident that the field could convey a united front, and expressed concern about consequent loss of legitimacy, due to the explicit coexistence of multiple expert viewpoints.

Altogether, students observed that bioethics faced several challenges in achieving its goals. Responses fell roughly into two categories; first, that bioethics needed to do a better job of reaching its nonacademic audience, and second, that its impact was limited due to its newness and related lack of authority. With respect to reaching its audience, one student observed that bioethicists “primarily write for one another” rather than a broader audience. One commentator felt that the field needs to exercise stronger influence on lawmakers and the public, such as by bringing about more equitable access to resources for health care. Another deemed that bioethics needs to “get more practical.”

Several students noted the ways in which being a new field presents a challenge to achieving the aims of bioethics. Interviewees observed that the

literature of the field was not well defined, that no areas of inquiry are “saturated” yet, and that the field needed more exposure, legitimacy, and authority, to distinguish itself from “simple ethics.” One student stated that bioethics is “a profession that’s overwhelmed” by current events, “clueless people,” and the “overpowering force of money in biotechnology,” and compared bioethics to the little Dutch boy trying to plug the hole in the dike with his finger.

Conclusion

In this chapter, I have examined what students are seeking and receiving by enrolling in MBE programs. While the low participation rate of students in my study of the BC limits the power of my analysis, student interviews were informative, and together with analysis of AJOB student commentators’ responses, provides some basis for drawing tentative conclusions about students’ relationships to masters programs in bioethics. Overall, the responses from Letters students were consistent with the perspectives of AJOB student commentators. Both groups of students, many of whom were midcareer professionals, expressed interest in reaping both expertise and social benefits from MBE training, largely with particular career goals in mind. Some of the students at Letters also indicated that they expected an MBE to provide them with legitimacy, cachet, or an advantageous niche in their vocational pursuits.

As a whole, bioethics students at Letters University provided less glowing accounts of their program than those given by AJOB commentators, but still felt that obtaining the degree itself would be of value to them. The Jenkins report supports the contention that the mixed satisfaction of Letters students may be due to overextension of Center faculty. In spite of an undefined job market, MBE programs are perceived by students as desirable and beneficial, providing them with bioethics expertise, entrance into the bioethics community, and the legitimacy of a credential. Bioethics centers and their faculty also gain institutional legitimacy from MBE programs, in addition to tuition revenues. Although there is considerable consternation amongst tenure-track academic bioethicists about both the implications of MBE programs and students' apparent eagerness to adopt the title of bioethicist, MBE programs are unarguably contributing to the institutionalization, cohesion, and legitimacy of the field. It does not appear that the masters in bioethics is an isolated "boutique" phenomenon, but rather reflects the franchising of academic bioethics in colleges and universities across the US. These franchises are not producing PhD bioethicists that will go on to propagate academic bioethics programs at other universities, but are chiefly developing a cadre of professionals in healthcare-related fields who will continue to draw upon the bioethics community and expertise to address bioethical issues in their workplaces. In this respect,

bioethics is comparable to the field of higher education studies, which primarily trains administrative educational professionals who work in postsecondary institutions.

PART II:
BIOETHICS & THE STATE

The state has had an abiding interest in science throughout the twentieth century (Kevles, 1995), and after World War II, an increasingly formal and systematic relationship developed between the state and the institutions of science in the US (Leslie, 1993; Smith, 1990). In the immediate post-war era, a social contract approach characterized science policy, in which the state provided resources for scientific research and presumed that by priming the scientific knowledge production pump, the unfettered progress of science would generate useful knowledge and applications (Byerly Jr. & Pielke, 1995; Guston & Keniston, 1994). The social-contract model came under fire from the anti-authoritarian sentiments of the 1960s, and in the new science policy regime of collaborative assurance, the state has taken a more active role in assuring the integrity and productivity of science (Guston, 2000). After the Cold War, the state's interest in science shifted to focus on the goals of economic competitiveness (Slaughter & Rhoades, 1996).

As the state expanded regulation and funding of science, it also increasingly called upon expert advice to guide its decision-making. In the executive branch, advisory committees proliferated, including a lineage of

bioethics advisory bodies that originated in the 1970s (OTA, 1993). In the judiciary, expert testimony began to play a larger role in advising the court on technical issues (Solomon & Hackett, 1996).

Given the close relationship between the state and science, bioethics must effectively engage with both institutions in order to influence the conduct of biomedical research and practice. Part II of this dissertation examines how bioethics engages with the state, and the impact of that engagement on the legitimacy and logic of bioethics. In Chapter 5, I argue that professional liability is an overlooked indicator of the legitimacy of jurisdictional claims in the system of professions, and examine the implications of legal liability for the legitimacy and jurisdiction of bioethics. To do so, I first examine discourse on the liability of institutional review boards and its implications for the bioethics jurisdiction; I then analyze a report on the liability of health care ethics consultants, developed by the American Society for Bioethics and Humanities, examining the relationships between liability, expertise, and legitimacy.

In the federal executive branch, bioethics advisory bodies have become a staple of U.S. public policy for addressing such societal disputes, in spite of the limited direct impact these bodies have had on science and technology policymaking. Kelly (2003) has argued that public bioethics advisory bodies serve an important tacit function as boundary organizations that stabilize the

border between science and politics, thus preserving the autonomy of science from incursion by other societal stakeholders. These boundary organizations succeed in bounding and controlling the controversy by constraining the set of issues and viewpoints that are addressed, and by dictating the decision-making strategy in ways that privilege participation of some stakeholders over others and veil the intensity of the controversy.

The National Bioethics Advisory Commission (NBAC), a presidential advisory body during the Clinton Administration, constituted such a boundary organization. The creation of NBAC both directly legitimated bioethics, and provided opportunities for the further institutionalization of bioethics in the public policy arena. In addition to mediating the tensions between politics and science, NBAC was also faced with negotiating the boundaries between science and ethics on the one hand, and between ethics and public policy on the other. In Chapter 6, I examine the boundary work performed by NBAC in its deliberations on embryonic stem cell research, and its implications for the legitimacy and logic of bioethics.

CHAPTER 5—
LIABILITY & EXPERTISE: THE EMERGING PROFESSIONAL
JURISDICTION OF BIOETHICS IN THE LEGAL ARENA

This chapter provides an account of how institutional review boards (IRBs) and health care ethics consultants may be held legally accountable for their expertise and decision-making, and accordingly an explanation of how discourse on liability in the legal arena provides an opportunity to examine jurisdiction construction in the system of professions. Professional groups must meet different kinds of accountability requirements in the workplace, legal, and public arenas. In the academic workplace, bioethicists, like faculty in other disciplinary fields, have to meet accountability requirements tied to promotion and tenure, including publications, grants, public relations, and enhancing institutional function. As discussed in Chapter Two, bioethics C&Is are ultimately held accountable to establish both resource stability and academic credibility, to maintain their existence. For federal bioethics advisory bodies in the legal arena, the subject of the next chapter, accountability stems from the advisory body's status as a boundary organization, which confers distinct lines of responsibility and accountability to the political and scientific principals it serves. As clients and the state come to rely increasingly on a particular expertise, and accordingly confer it with greater authority or legitimacy, the providers of that expertise can

become more liable for negligence and malpractice, where the expert is held responsible for causing injury as a result of failing to provide a valued professional standard of skilled care.

What, then, does the issue of legal liability reveal about the jurisdiction of bioethics? Concerns about the liability of IRBs and ethics consultants are closely tied to issues of accreditation, certification, and licensure, all of which concern the appropriate and accountable ethical expertise of IRB members and ethics consultants.¹ Accordingly, discourse on liability provides an opportunity to examine the social, institutional, and legal legitimacy of bioethics expertise, as such legitimacy is constructed by relevant professional groups, institutions, and the legal system. I begin this chapter by reviewing Abbott's theoretical approach to professional jurisdictional claims in the legal arena, and making a case for further elaborating the role of the legal arena in shaping jurisdictional claims. I then analyze discourse concerning the expertise for which IRBs and ethics

¹ As Bosk (2003) notes, while a wide variety of occupations from massage therapists to vascular surgeons are subject to licensing and certification requirements, these requirements have different social meanings for different occupations. Bosk argues that licensure and certification are more consequential for occupations such as vascular surgery, where lay judgment of competent skill is difficult, and moreover, the consequences of incompetence are a serious matter. IRB judgments and ethics consultations can have a major impact on risks present to research participants, care of patients, and on sponsoring institutions, investigators, and care providers, should they be sued for clinical or research malpractice. Accordingly, the delineation of competent ethical expertise is important to all these stakeholders.

consultants may be held liable, and discuss the implications for the jurisdictional claims of bioethics.

Claims of Professional Jurisdiction in the Legal Arena

One hallmark of powerful professions is the achievement of legal monopoly control of work through successful lobbying for licensing regulation. Physicians, attorneys, and several other professions have secured this legal claim of jurisdiction. These claims can include monopoly of certain activities and types of third-party payments, and control of certain work settings and of certain kinds of language. Contests for legal jurisdiction are waged in all three branches of government, although legislative bodies have dominated the legal structuring of professions in the US. Abbott explains that the legal definition of professional jurisdictions is a locus of what Gieryn (1999) would describe as boundary work:

Boundary areas [at the margins of professional jurisdiction] are firmly delineated with formal definitions that are in fact uninterpretable in actual situations. Thus, a crucial boundary between law and psychiatry concerns the point where legal definitions of responsibility give way to psychiatric ones, the point at which the insanity defense becomes tenable” (Abbott 1988, p. 63-64).

Legal rules were established to mark this point between law and psychiatry, but as Abbott attests, these rules have been continually disparaged due to their inapplicability to real-life circumstances.

As a result of such arbitrary formality, the formal legal jurisdictions of professions do not reflect the complex nature of actual professional existence. For example, the definitions of the beginning and end of life, perennial issues in bioethics, sit uncomfortably at the border of law and medicine.² Abbott contends that despite the prominence of legal matters in the mass media, the legal jurisdictions of professions reflect, rather than determine, the impact of external forces on professional jurisdiction. However, one exception noted by Abbott is that dramatic changes in jurisdiction can be imposed by the state if control of professions is exercised primarily by the executive or administrative branch, as it is in France, rather than by the legislative branch. In England and the US, Abbott argues that legislatures have dominated determinations of the legal jurisdiction of professions.

I contend that in the US, the federal executive branch dominates legal control over the professional jurisdiction of biomedical research, but that control is exercised differently than in the French model Abbott describes. While in France the administrative branch of government exercises considerable direct control of jurisdiction, professional organization, pricing, and service delivery, the U.S. federal executive branch exercises indirect regulation of the professional jurisdiction of biomedical research through the

² See Lock (1996) for a comparative study on the definitions of death in North American and Japanese cultures, and Rado (1987) for an account of the network of multidisciplinary elites associated with the institutionalization of the brain-death concept.

provision of research funding targeted at state-determined research priorities, and accompanying regulatory requirements imposed on government-funded research. It must be noted that biomedical research professionals populate state agencies that oversee research funding and regulation, revealing a tightly coupled relationship between the state and research professionals. Nonetheless, oversight of the biomedical research jurisdiction by the US executive branch has tremendous and often unwelcome impact on professional work in universities, in spite of strong research-professional presence in the state. State regulation of publicly funded biomedical research on human subjects and live animals also influences the private sector, by generating considerable normative institutional pressure for privately funded researchers to voluntarily comply with state standards.³ IRBs, which I will discuss shortly, are a cornerstone of state regulation of biomedical research.

The legal arena provides other opportunities beyond state licensure and funding for the legitimation of professional expertise and the staking of knowledge claims, although these opportunities do not confer as much

³ The normative pressure for private-sector compliance with research oversight has two components: on the one hand, the value of public-sector IRB review is touted by policymakers and the public as a means to ensuring ethical research, and its widespread use in publicly funded research generates a certain amount of expectation that all research will comply. On the other hand, IRB review may be seen by sponsors and investigators as a means to both legitimate their research to the public, and to provide some protection against liability.

jurisdictional power. First, the judicial forum legitimates certain types of expertise by utilizing professionals as expert witnesses in court cases. Analysis of the expert testimony and its influence on court decisions can reveal strengths and weaknesses of jurisdictional claims.⁴ Second, the legal basis for negligence claims involves elements of expertise, and examining the nature of important expertise elements provides important clues to the strengths and weaknesses of a professional jurisdiction. Tort claims and court decisions indicate what elements of expertise are considered important by the audiences who consume those claims, and contribute to an explanation of the influence of those audiences on the professional jurisdiction, by revealing what expertise professions are liable for.

While these elements of professional jurisdiction claims in the legal arena are weaker than the direct legal controls of jurisdiction secured by powerful professions, they serve as indicators of professional jurisdictions in the making, such as that of bioethics, as they emerge in a litigious society. With increased power, comes increased responsibility. The legal formalization of professional jurisdiction confers, and defines, not only some degree of jurisdictional control, but also liability for malpractice in that jurisdiction. It is therefore prudent for professional groups to stake out their jurisdictions carefully, to the extent possible.

⁴ See Jasanoff (1998) and Halfon (1998) for analysis of the politics of expertise contained in expert testimony during the O. J. Simpson trials.

How does liability serve as an indicator of the bioethics jurisdiction? How does accountability in the legal arena relate to expert accountability in the other arenas, and to other sources of legitimacy? To answer these questions it is useful to consider the liability of universities, their IRBs, and biomedical faculty engaged in research, because bioethicists may serve these other liable parties in an advisory capacity. When court is adjourned, who (i.e., investigators, IRBs, or bioethicists) is held responsible for negligence and why, and with what implications for the jurisdiction of bioethics?

The Liability of IRBs

Institutional Review Boards, or IRBs, are committees designed to review research involving human participants, to ensure ethical conduct and protection of participants. IRB review is required for any research funded by the US Department of Health and Human Services and other federal agencies, and has also been widely adopted for privately-sponsored research. The US Food & Drug Administration (FDA) requires IRB review of any research involving the administration of investigational drugs or medical devices to human participants. IRBs have the authority to approve, require modifications of, or disapprove research projects. There are specific requirements for the constitution of IRBs, calling for the participation of both scientists and nonscientists, demographic and cultural diversity, and special

representation for the review of studies involving vulnerable populations such as prisoners. IRB member participation in protocol review is governed by conflict of interest rules.

Although well established, the IRB mechanism has a dubious reputation similar to that of the FDA: both institutions have been widely and simultaneously criticized both by those who find these institutions too lenient, and by others who find these institutions too restrictive. Decades of tweaking by policy makers have failed to diminish complaints about IRBs or suggestions for their improvement.⁵ IRBs have been around in one form or another since 1966, when the U.S. Public Health Service required that any research it sponsored be reviewed by a committee of associates, as part of providing assurance of compliance with human research regulations. Federal research regulations underwent several revisions over the next couple decades, and in 1991, major revisions resulted in what is known as the Common Rule (45 CFR 46), which was adopted by sixteen federal agencies and departments.

IRBs received renewed attention beginning with the 1998 release of the report *Institutional Review Boards: A Time for Reform* by the Department of Health & Human Services (DHHS) Office of the Inspector General (OIG).

⁵ See Emanuel et al. (2004) for an overview and categorization of problems with the current oversight system for human research, and recommendations for reform. For a substantive critique of the moral reasoning assumptions inherent in IRB reviews of research, see Eckenwiler (2001).

The OIG report sparked Congressional hearings, the revision of regulations by DHHS, and increased oversight by the Office of Human Research Protections, housed in DHHS. Scrutiny of IRBs was further heightened by the death of teenager Jesse Gelsinger in a Phase I gene therapy trial at the University of Pennsylvania in September 1999.⁶ The tragedy raised concerns about both conflict of interest and appropriate informed consent, led the FDA to temporarily suspend all of the university's gene therapy trials, and resulted in a lawsuit by the Gelsinger family. The year 2001 witnessed two more human research incidents, this time at Johns Hopkins University (JHU). First, JHU was sued by the family of Ellen Roche, a healthy subject who died in a Phase I clinical trial examining the use of the blood pressure medication hexamethonium as a treatment for asthma. The federal Office of Human Research Protections (OHRP) temporarily suspended all federally funded human subjects studies at Hopkins facilities. Subsequently JHU issued an angry response⁷ asserting, "OHRP's action seems to us to be an extreme example of regulatory excess." The Kennedy Krieger Institute, an affiliate of JHU, was also sued that year for negligent sponsorship of lead

⁶ See for example the 2002 Institute of Medicine Report, *Responsible Research: A Systems Approach to Protecting Research Participants*, commissioned by the US Department of Health and Human Services in response to the death of Gelsinger.

⁷ See JHU's response at <http://www.hopkinsmedicine.org/press/2001/JULY/010719.htm> (accessed 10/24/05).

abatement studies and inadequate informed consent from parents of children exposed to harmful levels of lead.

In response to these and related events, an IRB accreditation program was created in 2001 by the Association for the Accreditation of Human Research Protection Programs (AHRPP), which was newly founded by seven national professional and postsecondary organizations: the Association of American Medical Colleges, the Association of American Universities, the Consortium of Social Science Associations, the Federation of American Societies for Experimental Biology, the National Association of State Universities and Land-Grant Colleges, the National Health Council, and Public Responsibility in Medicine and Research (PRIM&R). Prior to that the Applied Research Ethics National Association, a division of PRIM&R, established the Council for Certification for IRB Professionals, which made certification testing, on knowledge of federal human subjects regulations, interpretations, and guidelines, available in seventeen states, the District of Columbia, and four Canadian cities as of October 2005. IRB accreditation and certification are voluntary, and do not at this time confer the same prestigious ethical distinction associated with the accreditation of animal research facilities by the Association for Assessment and Accreditation of Laboratory Animal Care (Resnik, 2004). However, as of October 2005, twenty-seven institutions in the US had received full or qualified AAHRPP

accreditation, including four private IRBs, one federal institution (Hunter Holmes McGuire Veterans Affairs Medical Center in Richmond, VA), and several hospitals and prominent research universities, including Baylor, Johns Hopkins, the University of Iowa, and the University of Minnesota, and Dana Farber/Harvard Cancer Center.⁸ The hope that accreditation can help prevent research litigation will undoubtedly serve as an incentive for participation by many research institutions.

It is worth noting that investigators, and not just study participants, may take legal action against IRBs, although it appears this will be less common. In *Halikas v. University of Minnesota*, a researcher sought a preliminary injunction against the university's IRB for publicly announcing why it had halted his research. The court denied the injunction, affirming that it would impair the public-protection function of the IRB, and that this harm was greater than the questionable harm claimed by the plaintiff. The court also found that the plaintiff had received due process in the IRB's investigation and actions, confirming that the IRB abided by federal human research regulations and the university's General Assurance Agreement, which provide for due process, but that the IRB was not bound by the university tenure code or hospital by-laws (Deem Corp., 2003). IRBs could be a target for future litigation by investigators, particularly where failures of

⁸ See the list of accredited institutions at AAHRPP's website, [http://www.aahrpp.org/www.aspx?PageID=11\\$1\\$100](http://www.aahrpp.org/www.aspx?PageID=11$1$100) (accessed 10/24/05).

due process can be documented. Research industry stakeholders have proffered both defensive and offensive reactions to IRB oversight, exemplified respectively by the Dimond and Alvarez 2004 preventive advice article “Investigator-Initiated Research: Proceed with Caution,” and the defiant “Researcher’s Bill of Rights” presented by Perlstadt in the Michigan State University Center for Ethics and Humanities in the Life Sciences Winter 2004 issue of the *Medical Humanities Report*. With research negligence lawsuits on the rise, however, one would expect the research enterprise, including universities, hospitals, biomedical technology firms, and individual investigators, to be more concerned with their own liability than with filing claims against IRBs.

The lead prosecuting attorney for the Gelsingers, Alan Milstein, has filed twenty lawsuits against universities, hospitals, investigators, and IRB members (Lockwood Tooher, 2005). Five of these cases, filed since 2001, named IRB defendants. Individual IRB members were named as defendants for the first time in 2002, in *Robertson v. McGee*, again by Milstein. The case was filed on behalf of twelve melanoma patients who participated in a Phase I cancer vaccine trial, alleging therapeutic misconception against the investigator, and failure to provide adequate continuing review against the University of Oklahoma IRB. This development was cause for alarm

amongst IRB members nationwide, most of who serve on a voluntary basis for their home or other institutions.⁹

Many clinical trial lawsuits have been settled out of court, and accordingly it remains to be seen what guidance will emerge after the courts have ruled on more of these cases. There have not yet been any successful negligence cases filed against IRBs or their members. However, Resnik argues that the number of lawsuits filed against IRBs is likely to increase, due to a general increase in research litigation, and the incentives that large settlements provide to plaintiffs' attorneys.

Mello et al. (2003) agree that "prospects for the growth of tort litigation in human subjects research are extremely favorable," due to developments including the diversification in number and type of claims filed by plaintiffs, the expanding array of defendants named in cases, and the growing use of class action suits. With respect to the diversity of claims filed, the introduction of fraud claims is particularly noteworthy, because of their powerful effect on jurors and potential for large damage awards, including punitive damages. The defendants named in suits now include not only

⁹ Universities are of course also taking note. For example, the University of Iowa Clinical Trials Office, established in July 1998 "to facilitate and increase industry-sponsored clinical trials at The University of Iowa," (<http://research.uiowa.edu/cto/>, accessed 10/22/05), has linked to its website a presentation entitled "Avoiding Liability in Clinical Trials" developed by attorney Kendra Dimond, who represents clients in the research and health care industries.

investigators, hospitals, universities, and pharmaceutical sponsors, but also top university officials and individual IRB members and ethics consultants, attracting more media attention. Clinical trials litigation is particularly amenable to class action suits, because of the large number and commonalities shared by clinical trial participants. Class actions pose advantages for plaintiffs' attorneys, who can achieve economies of scale by joining the forces of plaintiffs' firms, and earn higher contingency fees through a potentially large number of plaintiff awards.

Other factors arguably make research litigation cases more attractive to plaintiffs' attorneys than traditional medical malpractice cases (Mello et al., 2003). First, it is easier to question the intent of investigators than of physicians, who are generally viewed as intending to help the patient. Second, the legal standard of care relevant to negligence and malpractice cases has a different basis for research than for medical practice, where in the latter, professional standards of care are typically invoked and provide more straightforward guidance for the court to determine the required standard of care. The nature of the legal standard of care is key to the relationship between expertise and liability, as I will discuss shortly.

Other scholars have begun to reflect on the torts liability of IRBs and other parties in the research enterprise in light of the differences between claims of medical versus research malpractice, as a small number of research

lawsuits currently work their way through the courts. Resnik (2004) explains the legal duties of IRB members and their likely liability for negligence based on existing case law, and discusses the viability of some legal defenses for IRBs. Morreim (2004) observes that research-related tort claims have been unreflectively subsumed by the courts under medical malpractice law, and accordingly the body of case law does not yet adequately reflect the distinctive aspects of research-related injuries. She argues that tort doctrine needs some adjustment in order to treat both research participants and the various parties in the research enterprise fairly in clinical trial lawsuits. Shaul and colleagues (2005) note that it may not be obvious to health care professionals that the legal standards for informed consent is higher for research than for medical treatment; the informed consent process for research must reveal all known risks, including remote risks that could have severe consequences.¹⁰ The authors also raise the possibility that IRBs could be faced with lawsuits filed by the federal government. This risk is inferred from the Gelsinger case where the defendants settled not only with the Gelsinger family, but also with the federal government, which filed a separate civil action suit.

¹⁰ This should not be construed to mean that the risks of research are greater than the risks of treatment, which can also entail improbable but grave risks (Morreim, 2004); rather, informed consent in research has a different legal basis than the basis of treatment consent.

In the present climate, both investigators and IRBs short-change human subjects review and protections at their own peril. Although the responsible IRB was not named as a defendant, the *Grimes v. Kennedy-Krieger Institute* decision on the defendant's lead abatement study set a precedent in which the court effectively overruled the IRB's less-strict standards for human subjects protections. The court concurred with the plaintiff that the research was unjustifiable because the harm of exposing children to hazardous levels of lead outweighed any possible benefit, contrary to the prior conclusions reached by the Johns Hopkins IRB. "In essence," Mello et al. conclude, "the court replaced the expert judgment of the IRB with its own judgment of the risk-benefit ratio, suggesting that **neither the parents' consent nor the IRB's approval of the protocol would make the researchers immune from liability**" (2003, p. 42, emphasis mine). The ability of IRBs to protect research institutions and investigators from litigation has clearly been circumscribed, and the scope of judicial review and regulation of human subjects research has increased to include not only investigators' conduct, but also the deliberations of IRBs.

Plainly, IRBs are not immune to scrutiny by the courts, anymore than they have escaped criticism from the parties meeting one another across the informed consent form. On what basis, then, are IRBs legally liable for research-related injuries? In the next section I encapsulate Resnik's account

of legal liability, and indicate how determining the most difficult element of a negligence claim against IRBs presents an opportunity for bioethics to legitimate its jurisdiction in the legal arena.

IRBs & the Legal Concept of Negligence

Resnik (2004) describes six necessary elements to a legal claim of negligence, and their implications for IRB liability: duty, standard of care, breach of standard of care, cause-in-fact, legal cause, and damages (harm or injury). At least three legal theories could be used to establish the *duty* of IRBs to research participants. This legal duty may be based on the legal requirements of federal research regulations, on the theory of reasonable supervision of researchers, or on contractual duties to participants as third-party beneficiaries. Resnik cites two cases (*Kus v. Sherman Hospital* and *Gregg v. Kane*) that established the legal duties of IRBs under federal regulations. Although IRBs were not named as defendants in these cases, if they had been, Resnik finds that the plaintiffs would have had valid negligence claims.

There are various legal bases for establishing the **standard of care** implied by a legal duty. Several of these bases could be applied to the duty of IRBs, including the reasonable person standard, professional standards, and international standards, but one that seems particularly appropriate in the

case of IRBs is a statutory standard, where the law itself sets the standard of care. Several federal regulations, most notably the Common Rule, as well as some state laws, govern the structure and function of IRBs, and the conduct of IRB members. Two cases (*Grimes v. Kennedy Krieger Institute* and *Whitlock v. Duke University*) provide precedent for recognizing the federal regulations as the appropriate standard of care in research, and for applying that standard to IRBs. There are, however, some challenges associated with establishing a clear legal standard of care, an issue I will return to after outlining the remainder of the legal elements of negligence for IRBs.

Cause-in-fact can be legally established as either a “but for” cause or a substantial factor. In the first instance, the court must find that harm would not have occurred “but for” the defendant’s actions, which fall short of the standard of care. In the instance of a substantial factor, more than one defendant perpetrates a single negligent act, independently or jointly, each of who contributes a substantial factor. Resnik argues that cause-in-fact for IRB negligence could readily be established for failure to perform either the initial or continuing research review functions of IRBs. Individual members of the IRB may be implicated if the court finds that individual members of the IRB, such as the chair and the primary reviewer, assume different responsibilities for a harm; such individual responsibility could be tied to the professional roles of members, such as those of physician members and

ethicist members, or to functional roles, namely the IRB chair and the primary reviewer.

A viable negligence claim must also demonstrate **legal cause**, or proximate cause. Legal responsibility for injury often rests on the general proximate cause rule that the harm is a reasonably foreseeable, but not necessarily a probable, consequence of the defendant's conduct. Resnik envisages that in most cases, establishing legal cause of negligence by an IRB would be straightforward.

The **damage** resulting from negligence can include physical, psychological, and economic harm. The court may award damages to the plaintiff for these harms, as well as punitive damages for malicious or wanton behavior of the defendant. All of these damages can occur as a result of negligence in research on human subjects. A high-profile example of this is the settlement between the US government and the survivors and heirs of the Tuskegee Syphilis Study, which included damages for physical and psychological harm.

It is clear from Resnik's analysis that IRBs, and their individual members, could readily be found liable for negligence in the oversight of research with human subjects, especially when clear violations of federal

regulations have occurred.¹¹ However, he contends that establishing the legal standard of care for IRBs may prove to be a difficult task in many cases, for reasons explained in the next section. This difficult task is one that falls under the purview of bioethics, and may provide an opportunity for bioethics to reinforce its professional jurisdiction, as more suits charge IRBs with negligence and make it to trial.

Determining the Standard of Care for IRBs: A Role for Bioethics Expertise

Of all the six necessary elements to a legal claim of negligence, Resnik explains that the most difficult aspect of demonstrating IRB negligence will be establishing a breach in the standard of care. While federal regulations address the standard of care for research review and monitoring, there is a great deal of disagreement about the meaning of key terms in the regulations, and about how to interpret and apply the regulations. Attorneys, ethicists, researchers, government officials, and patient advocates dispute the meaning of regulatory terms such as risk, minimal risk, research, and therapy, and argue about how to apply the regulations for the purpose of

¹¹ Morreim (2004) argues that standard tort doctrine, including the usual conceptions of negligence, battery, and informed consent, does not appropriately address conduct in the research setting, which differs significantly from medical practice in its goals, sources of duty, the nature of injuries, and the inherently subjective nature of the decision to participate in research. The efforts of Milstein and other prosecuting attorneys to introduce new claims of dignitary harm from research negligence (Dembner, 2002, Lookwood Tooher, 2005) are consistent with Morreim's observations.

determining appropriate risk/benefit ratios, valid informed consent, the ethical use of placebo controls, and appropriate review, reporting, and monitoring of research protocols. Accordingly a defendant might appeal to ambiguity in the regulations, arguing that they therefore do not apply to the IRB conduct in question.

It is the responsibility of the court to interpret the legal standard of care entailed by human subjects regulations. The court should first attempt to discern legislative intent, Resnik argues, by examining the history of the statute and its language. Such investigation should include testimony relating to the history of human research abuses, and key documents that have shaped the regulations, such as the *Belmont Report*. If the courts are still unable to resolve the ambiguity, they may defer to reasonable and persuasive interpretation and expertise of agencies authorized by Congress to implement the regulations, including the National Institutes of Health, the Office of Human Research Protections, and FDA. Resnik envisages that even after these steps, in some cases a clear interpretation will still be lacking, because

Even if one can determine the meaning of key terms and phrases, questions will arise concerning their application to particular research studies. The regulations require IRBs to make many different decisions that involve a great deal of **judgment and discretion.... even experienced IRB members or federal officials may disagree about risk/benefit assessments and the reasonableness of risks in relation to benefits**" (p. 153-54, emphasis mine).

I argue that the problem of interpreting the regulations, and assessing whether appropriate judgment and discretion has been exercised by IRBs when experts disagree, reflects a jurisdictional opportunity for bioethicists, whose expert testimony may be sought by plaintiffs, defendants, or the court itself to clarify interpretation of the human subjects regulations.

Furthermore, bioethicists can and do provide education and consultation on research ethics for investigators and IRBs seeking to prevent unethical research, scandal, and litigation.

In cases of professional negligence, experts may testify based on their knowledge of a particular profession, such as medicine. Resnik contends that the courts would likely admit expert testimony, such as from bioethicists, to establish a **professional** standard of care for IRBs. However, whether the courts would **require** such testimony rides on whether the ordinary person can discern the standard of care in a particular case; only if they cannot does the conduct in question become a matter of professional negligence, requiring expert testimony. Since ordinary people (i.e., community members) are required by law to be represented among IRB members, Resnik expects a court could readily find an ordinary person able to understand the expertise of an IRB member.

Another approach to establishing the legal standard of care for IRBs is the application of international standards. Prior to the Gelsinger case, most

clinical trial lawsuits alleged medical malpractice, but Milstein, who represented the Gelsingers, has been credited with developing a new legal approach that cites the Nuremberg Code, an ethics guidance document adopted internationally in response to research atrocities committed in Nazi concentration camps, as well as the *Belmont Report* (Lockwood Tooher, 2005). In developing this approach, Milstein has attempted to make various arguments establishing a right to be treated with dignity, and furthermore that violations of that right fall within federal jurisdiction.¹² Resnik points out that three such cases citing the Nuremberg Code have been rejected by the courts due to lack of federal jurisdiction, but concedes that international standards could still be useful in establishing the standard of care for research participants in state court cases. It is possible, however, that US institutions engaged in international research, and their IRBs, may soon be found liable by US courts for violations of international standards of care under the Alien Torts Claim Act (Shaul et al, 2005).

Mello and colleagues (2003) contend that one of the reasons research litigation may be even more attractive to injury attorneys than medical malpractice suits is because of the different legal bases for standard of care.

¹² Milstein was not the first to pursue a claim of dignitary harm. Florida Attorney Stephen Hanlon filed a class action lawsuit on behalf of poor women with high-risk pregnancies who participated in a drug study. The suit contested the adequacy of the informed consent. The University of South Florida and Tampa General Hospital settled in 2000 for \$3.8 million and revised the consent forms, but admitted no wrongdoing (Dembner, 2002).

Whereas the professional standard of care in medical practice can be relatively straightforwardly evidenced by appropriate expert testimony, the standard of care in research is drawn from federal regulations, international guidelines, and the standard of what a “reasonable” IRB would require. The authors note, “**The use of a reasonableness standard gives judges and juries wider leeway** than a custom-based [i.e., customary professional medical practice] standard **in determining what should be required of IRBs** and investigators. In practice, this standard is tougher on defendants, who cannot invoke an ‘everybody does it’ defense” (p. 43, emphasis mine). As discussed earlier, the need for IRBs to exercise considerable judgment and discretion in determining the standard of care similarly makes the court’s task of discerning a “reasonable” standard of care a complex matter. Mello et al. contend that public concern about research safety will likely result in determinations of IRB reasonableness that favor plaintiffs.

The problem of establishing the legal standard of care for IRBs, which may be approached by interpreting statutes, professional standards, and international standards, is clearly within the jurisdiction of bioethical expertise, which provides multidisciplinary tools for illuminating various social and semiotic nuances that arise in the course of interpreting and applying the various standards. Bioethicists not only can provide expert testimony to assist with discerning the legal standard of care for research

participants, they also can provide more education and consultation to investigators and IRBs to better prevent negligent research and consequent lawsuits. Furthermore, if IRB accreditation becomes standard practice, and IRB members, including community and other nonscientist members, are regularly certified, research negligence could eventually come to be recognized as a matter requiring professional testimony. Given the elite organizations and institutions that have supported and sought IRB accreditation, I anticipate that it will soon be expected of all IRBs. These observations suggest a considerable opportunity for bioethics to acquire greater prominence and legitimacy in the legal arena, as the number of research-related tort claims increases. However, bioethics faces a couple challenges to reinforcing this jurisdictional claim, namely a reluctance to claiming moral authority, as well as the tension in the relationship between academic bioethicists and IRBs, both of which I discussed in the Chapter Three.

Seeking control of work by lobbying for licensing regulation is only one of several ways in which claims of professional jurisdiction may be staked in the legal arena. The forgoing summary of the liability of IRBs reveals that the federal regulations governing IRBs have created a new professional task, that of establishing the appropriate standard of care for IRBs. Interpreting and applying the Common Rule requires complex discretion and judgment on

the part of IRB members, and frequently results in disagreement amongst experts about the meaning and application of key terms. To the extent that bioethicists, or other professionals, are able to remedy these problems, they may stake a jurisdictional claim. In the current environment of research litigation, IRBs as well as courts will seek out and legitimate expertise that usefully illuminates the standard of care to which IRBs are held, for the purposes of both establishing and preventing judgments of negligence and malpractice (or alternately, avoiding expensive settlements). Universities and IRBs are highly motivated to avoid the negative publicity, research suspensions, and economic repercussions of research lawsuits.

Another implication of research torts for the professional jurisdiction of bioethics is the incentive created to pursue accreditation as a protection against lawsuits. Accreditation adds a new layer of social organization to research ethics, promotes institutional isomorphism, and clarifies the expertise and performance standards for IRB function and membership, both defensively for the research enterprise, and offensively for plaintiffs in research lawsuits. All of these effects of accreditation will arguably strengthen the legitimacy of bioethics by organizing and standardizing ethical expertise and affirming its utility for clients.

While bioethicists often face difficulties serving as IRB members, they can impact research ethics by contributing to the ethical discourse which

many IRB members and investigators drawn upon to design and review research protocols. The dialogue between IRBs and bioethicists is not entirely hostile. Recent annual PRIM&R conference programs have featured several prominent bioethicists as presenters in plenary and concurrent conference sessions, who speak to an audience primarily constituted by research and IRB administrators, IRB members, and government research oversight officials. It is also worth noting that the universities which have thus far sued for negligent research are all elite research institutions, where one might also expect to find the most cantankerous relationships between bioethicists and IRBs, given the tremendous pressure to procure grants and publish first-tier journal articles. Fear of litigation may well drive IRB members at these institutions into the arms of bioethics.

The legal liability of a professional jurisdiction is a clear indicator of socially-valued expertise, and establishes those elements of knowledge and skill that professionals need to master and use carefully. These elements can include not only specialized technical skills and knowledge, but also procedural knowledge and a commitment to professional virtue which in the case of biomedical science, is closely linked to sensitivity towards the expectations and interests of clients, and in particular, research participants.

The Liability of Ethics Consultants

The 1998 American Society for Bioethics and Humanities (ASBH) report, *Core Competencies for Health Care Ethics Consultation* (discussed in Chapter Three), defines health care ethics consultation as “a service provided by an individual or a group to help patients, families, surrogates, health care providers, or other involved parties address uncertainty or conflict regarding value-laden issues that emerge in health care,” and notes that ethics consultation includes the domains of both clinical ethics and organizational ethics (p. 3). Consistent with my earlier observations regarding the reluctance of bioethicists to adopt a moral stance, the ASBH *Core Competencies* report rejects both an **authoritarian** ethics consultation approach, in which consultants are the primary decision makers, and a **pure facilitation** approach, where the consultant seeks only to coordinate a consensus among involved parties, without clarifying the social, legal, and institutional dimensions of the moral choice. Instead, the report advocates an **ethics facilitation** approach, which incorporates both “identifying and analyzing the nature of the value uncertainty and facilitating the building of consensus” (p. 6). As will be discussed, the chosen approach of ethics consultants has implications for their liability.

Ethics consultation is nearly as old as bioethics itself, dating back to the late 1970s. The Society for Bioethics Consultation was established in

1985, and eventually merged with the Society for Health and Human Values in 1998 to form ASBH. In 1992, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO or the Joint Commission) presented new ethics criteria in its Accreditation *Manual for Hospitals*, which likely generated increased demand for ethics consultants (McCarrick, 1993). In a special issue of JCAHO's periodical Quality Review Bulletin, published the same year new ethics criteria appeared in the Joint Commission's accreditation manual, the potential for future litigation against ethics consultants is discussed (Brennan, 1992). Serious concern about the liability of ethics consultants can be traced to 1986, when a hospital ethics committee, as a whole and as individual members, was named as a defendant in *Bouvia v. Superior Court*, after supposedly directing physicians to insert a nasogastric tube in the plaintiff against her wishes. The suit was dropped after the plaintiff secured an injunction to have the tube removed, but ethics consultants were made permanently aware of their potential liability. Over ten years passed before a high-profile lawsuit named prominent bioethicist Arthur Caplan among the defendants sued by the family of Jessi Gelsinger, following his death in a gene therapy trial. Caplan had advised the investigators to conduct the study with healthy adults rather than sick infants; ultimately he was dropped from the suit. Over the last couple decades, consultation with ethics committees has been outpaced by

consultation with individual ethics consultants, which has undoubtedly increased the perception of vulnerability amongst consultants (Sontag, 2002).

In 2004, ASBH released a Task Force report on ethics consultation liability, to provide its membership with an overview of the issues and information on insurance options. In October 2003, Jonathan Moreno, then President of ASBH, commissioned an ASBH task force to produce a report on ethics consultation liability for members of the Society. The Task Force and report were spurred by an impetus from the ASBH Board of Directors to expand Society activities to better serve the needs of its member professionals, rather than simply organize annual conferences; accordingly, the liability of ethics consultants was identified as an area of increasing concern (Moreno, 2004). Moreno asked Gerard Magill to chair the Task Force, and Magill selected other members in consultation with Moreno and many scholars in the field, emphasizing a wide range of expertise and constituencies (see Appendix C of the Report). Ultimately ten other members were listed as authors of the report, and included five academic center/institute directors. Due to time constraints, the Task Force members served as an oversight committee for the report, which was primarily researched and written by the Task Force Chair. Members provided, at their own discretion, direction, critique, evaluation, and signed the report, in support, dissent, or with qualifications.

While the Report may thus be construed as considerably the work of one man, it was also arguably shaped and endorsed by other leading bioethicists on the Task Force, and its findings drew upon extensive review of the existing literature (over 180 works were cited) court cases, and “a large number” (p. 33 of the Report) of insurance companies. It is the only such comprehensive account of its kind on liability and ethics consultation, to the best of my knowledge.

In the following section of the chapter, I use the report to examine the relationship between expertise and liability in ethics consultation, and its implication for the jurisdictional claim of bioethics, particularly in the legal arena. I show that in the system of professions, the perceptions of other professional groups and the state as to the professional status of ethics consultants (and by extension, bioethicists in general) shape expectations about the liability of those ethics consultants, and consequently their jurisdictional claim. Accordingly I organize my account around these salient categories of interests. I begin by examining at length the perspective of the Task Force on the expertise and liability of ethics consultants, and subsequently I reflect on some key attitudes of health care professions, insurers, and the state about ethics consultants that emerge from the report. I conclude by considering questions about the construction of jurisdictional claims and the sources of legitimacy for those claims.

Ethics Consultants: An Uncertain Professional Group

As I discussed in Chapter Three, bioethicists are caught in a tension between an ideology of **social trustee professionalism**, grounded in the ideal of service to the public good, and towards an ideology of **expert professionalism**, legitimated simply by specialized authority over a defined area of formal knowledge (Brint, 1994). This ideological tension poses a particular challenge to the legitimation of bioethics, which in spite of its public service oriented roots, faces pressures to seek legitimacy through expert professionalism, pressures now exacerbated by concerns about liability, as will be evident shortly. The *Ethics Consultation and Liability* report argues that the professionalism, or the status of ethics consultation as a profession, influences both legal liability and insurability, but also observes considerable uncertainty within the field as to the professional status of ethics consultation. Much of the uncertainty about the professional status of bioethics stems from the diversity represented within the practice of ethics consultation. The first source of diversity is the array of professional backgrounds that ethics consultants represent. Accordingly, the report advises consultants to “speak frankly with patients and clients about their professional backgrounds, their limitations, and preferred methods of analysis” (p. 10), which can help to reduce liability. The practice settings of ethics consultants are another source of diversity; the report considers ethics

consultation in the settings of clinical ethics, research ethics, and corporate health care ethics. The report also describes the variety of social structures and roles that characterize the work of ethics consultants. For example, some consultants work as part of a health care team, while others work independently; consultants may fill various roles including advisor, educator, counselor, advocate, negotiator, or case manager, or some combination of these and other roles.

As mentioned earlier, a previous ASBH Task Force developed the report *Core Competencies for Health Care Ethics Consultation* (1998), which establishes a set of recommended skills and core knowledge, in spite of the wide scope of consultants' practice. In Chapter Three I discussed the fact that the Task Force promoted the **voluntary** adoption of these competencies, rejecting competency-based accreditation or certification. The core competency skills fall within the categories of ethical assessment skills, process skills, and interpersonal skills. Core competency knowledge comprises knowledge of ethical reasoning and theory, common ethical issues and concepts, health care systems and clinical context, local healthcare institutions and their policies, relevant ethical and professional codes of conduct, accreditation guidelines, and health law.

The heterogeneity of consultants' training, roles, and practice, as well as the voluntary nature of the core competencies, make it a challenge to

characterize the expertise of ethics consultants, let alone assess their liability for that expertise. The *ASBH Task Force Report on Ethics Consultation and Liability*, acknowledging debates about the objectivity of ethics expertise and its relationship to virtue, concludes that essential ethics expertise appears to encompass “appropriate knowledge of general principles and theories of ethics; analytical skills such as discernment and insight; and strength of will that prevents the ethicist from taking easy ways out of complex dilemmas” (p. 16). Consultants’ authority to provide this expertise, the report suggests, can derive from **social authorization**, in which consultants address difficult ethical problems found intractable by others; from **institutional authorization**, where the organizations confer authority by utilizing consultants; and from **legal authorization**, such as through laws addressing ethics consultants’ participation in decision making in patient care, or through court decisions that address ethics consultation or use ethics consultants as expert witnesses.

After establishing some fundamental characteristics of expertise in ethics consultation, the report turns to liability criteria relating to that expertise. The Task Force argues that although ethics consultation lacks several hallmarks of typical professions, such as standard training requirements, power of self-regulation, state licensure, and a code of ethics, it seems to be moving “toward greater professional recognition” (p. 19), which

will impact insurance companies' assessment of liability risks. The three categories of liability assessment criteria identified include competence, role types and activities, and authority, drawn from the report's forgoing analysis of the nature of ethics consultation expertise.

The report envisages, not surprisingly, that insurance underwriters will find consultants who have little or no formal training to be at higher risk for liability. Ethics consultants who serve as generalists rather than specialists for particular settings (e.g., intensive care) are also argued to be at greater liability risk, because there is far more literature for a generalist to keep current with. The report also contends that consultants who serve in facilitation or education roles will have a lower liability risk than those in an advice/intervention role, where the consultant takes more direct responsibility for decision making. Professional authority, as the final criterion, is found to be proportional to the risk of liability.

In spite of the broad scope of clinical ethics consultation practice, the ASBH Task Force identified characteristic expertise elements for which they felt ethics consultants could likely be held accountable in lawsuits. I now turn to the perspectives of other professional interests in the system of professions regarding the expertise and liability of ethics consultation.

Other Professions: Complex Relationships in a Complex Setting

The relationship of health care ethics consultants to other professional groups is complex, partly due to the fact that most ethics consultants have formal training in one or more of the health-care related professions, including medicine, nursing, social work, clinical pastoral care, and health law. Accordingly, ethics consultants may have some liability coverage as a result of membership in other professional associations related to their training, such as the American Medical Association. However, the report acknowledges that, “Because of the complexity in tracking all related professions,” the liability Task Force elected not to examine “whether these [other professional] associations might regard ethics consultation as part of their professional expertise” (p.3).

The relationship between ethics consultants and health care professionals is also made complex by the nature of the clinical setting. Several psychosocial, political, and moral factors come into play, such as the attitudes and institutional power of attending medical staff, problems of the origin of consultants’ moral authority, pervasive poor communications in hospitals, availability of consultation services, and the standing of the consultant’s recommendations, including whether they are included in the patient’s medical record (Frader, 1992). Several studies found that a majority of sampled physicians and nurses reported ethics consultation

services to be useful, for purposes such as clarification of ethical issues, education of the medical team, increased confidence in medical decision making, and improved patient management (McClung et al., 1996; Orr & Moon, 1993; LaPuma et al., 1988). Ethics consultations have also been associated with reduced health care costs and decreased use of inappropriately prolonged treatment (Schneiderman et al., 2003; Heilicser, Meltzer, & Siegler, 2000).

However, one study found that the ethics consultation services resulted in significant changes in patient management only 36% of the time (Orr & Moon, 1993). A 2001 study found several significant barriers to the use of ethics consultation by medical residents, including power inequities within the medical hierarchy, and negative perceptions about the use of ethics consultation, including concerns about relinquishing decision-making authority, fear of delays in provision of care, doubt as to the usefulness of ethics consultation, and fear of confronting attending physicians (Gacki-Smith & Gordon, 2005). Many health care providers may not understand the role of ethics consultation, and may be wary of seeking it. Sometimes consultation is viewed as helpful, but sometimes it is viewed as a potential hindrance to medical decision-making or as an intrusion into the physician-patient relationship.

As mentioned earlier, over the last couple decades, consultation with individual ethics consultants, rather than consultation with ethics committees, has become increasingly more common. One reason for this is convenience. Hospital ethics committees cannot be summoned immediately and only address one case at a time, whereas individual consultants can each be quickly called upon to address different cases (Sontag, 2002). Another likely reason for the popularity of using individual ethics consultants is that physicians are accustomed to consulting with medical specialists one-on-one, and are probably more comfortable seeking ethics consultation individually as well (Sontag, 2002). To the extent that health care professionals, patients, and their families rely on the input of ethics consultants, those consultants may be more liable for the expertise they dispense.

Insurers: Lukewarm about Ethics Consultation

The liability Task Force report observes that most academic ethicists will have some sort of liability insurance from their institution, and consequently focuses on the liability of individual consultants when they provide services beyond the purview of their institutions liability policy. However, the Task Force finds “there appears to be an ambivalence among insurance companies about recognizing ethics consultants as a profession” (p. 5). The final section of the report, providing results of the Task Force’s

investigation of insurance options states, “Preparing this section has been quite a challenge, not least from the widespread lack of interest among insurance companies about offering a professional liability policy for ethics consultants” (p. 29). This lack of interest was variously explained by insurers in terms of a requirement for a minimum \$5000 annual premium (the Task Force chair had suggested \$500 per annum in his inquiry to that insurer); ineligibility due to perceived high risk (no explanation was given for this assertion); ethics consultants’ lack of fit with any of the professional groups (e.g., medical professionals) covered by company programs. Some of these assessments are further considered below.

If the Task Force is correct in asserting a relationship between professionalism and liability, it appears that the insurance industry finds ethics consultation lacking in professional status. It also appears that the insurance industry is still figuring out where ethics consultation fits in the professional landscape; perhaps insurers are unfamiliar with the services ethics consultants provide, and in the absence of any case law concerning ethics consultation, find no basis for assessing liability. The Task Force report notes that one insurance company, Healthcare Providers Service Organization, “cannot [emphasis original] offer ASBH members a professional liability policy **because ethics consultants in health care do not fit into any professional group covered**” by their program (p. 38;

emphasis mine). Hartford Financial Products, on the other hand, which does not provide policies for medical professionals, “considered ethics consultation in health care to be within the category of medical services, even though ethics consultants typically do not have formal training in medicine” (p. 38). These two companies disagree whether ethics consultation constitutes a medical service, with the first putatively observing an important distinction in professional function, and the second affirming common institution or workplace setting as a key to eligibility. If and when a critical mass of lawsuits have been filed against ethics consultants, creating a sufficient demand for liability insurance, it will be of interest to see how insurers classify these consultants professionally.

The State: The Value and Accountability of Expertise

In the US, both the legislative and judicial branches of government are positioned to bestow ethics consultants with legal authority. Although there is no state licensure of ethics consultants, state legislatures have passed other statutes related to ethics consultation. Some states provide ethics committee members with statutory immunity from litigation, and there are several state laws that promote or require the participation of ethics consultants in controversial health care decision making, such as end of life

care.¹³ These statutory actions clearly indicate that ethics consultation provides value in the eyes of legislators, or at least that there is a need to be filled.

The judicial branch has also provided some affirmation of the professional jurisdiction of ethics consultants, by allowing and utilizing expert testimony from ethics consultants, providing some affirmation of their usefulness. At least five landmark bioethics cases (cases creating legal precedent, conferring distinctive authority, or representing the first court appearance of a particular bioethical issue) featured expert ethics testimony (Poland 1997; Spielman and Agich 1999). Cases include *Wetherill v. University of Chicago*, where the court was asked to assess the qualifications of an ethics expert to testify about standards of informed consent in research; one of Dr. Jack Kevorkian's trials, in which the qualifications of renowned ethicist Arthur Caplan to provide expert testimony were challenged (Caplan 1991); the landmark *Matter of Baby K*, regarding the futility of treatment of an anencephalic infant, which featured opposing ethics testimony from both the prosecution and the defense (see Fletcher 1997); and a case regarding the

¹³ Maryland provides statutory immunity from suits for ethics committee members, MD Code Ann., Health-Gen. I § 19-374(a) 2000. Maryland, *op. cit.*; Texas, Tex. Code Ann. § 405.53(4) 2001; Montana, Mont. Code Ann. § 37-2-201(1) 1999; and Arizona, Ariz. Rev. Stat § 36-3231(B) 2000, give ethics committees statutory authority to provide advice and recommendations to medical professionals. See discussion in Spielman (2001) at p. 169.

morality of withdrawing artificial nutrition, which upon appeal generated a reversal drawing heavily upon bioethical expertise (Paris 1984).

There have not yet been any successful lawsuits against ethics consultants, so their professional liability remains untested. The liability Task Force report notes that the 1998 *Core Competencies* Task Force report, even if voluntary, could impact the liability of consultants by establishing a set of professional expectations, which could be presented in court as evidence of peer standards. Accordingly, ethics consultants may be vulnerable not only to negligence suits, but to professional malpractice suits. Furthermore, the liability Task Force report soberly observes that “most consultants may not possess even a basic level” of these competencies. Even though the *Core Competencies* report was explicitly not intended to establish a legal national standard for competence (ASBH, 1998, p. 31), it could nonetheless in future cases be construed as such a legal standard, one which many ethics consultants may not currently be able to meet. It will be of interest to observe how the courts determine the legal standard of competence for ethics consultants in future cases, and the extent to which it relies on both expert ethics testimony and peer standards developed by ethics consultants.

Liability and the Jurisdiction of Ethics Consultation

The liability Task Force report concludes with an assessment of the advantages and disadvantages of professional liability insurance for ethics consultants. In its favor, insurance is cited as offering some protection from litigation, facilitating the clarification of the professional status of ethics consultants, and confirming appropriate assumption of liability in ethics consultation. Disadvantages of liability insurance are found to include possible stimulation of an increase in lawsuits, and the observation that it may be in the best long-term interest of ethics consultants to clarify their professional status amongst themselves, rather than having it clarified by insurance companies for coverage purposes.

The liability Task Force report and the forgoing account of expertise and liability in ethics consultation raise questions about the co-production of legitimacy and expertise in ethics consultation. Who decides that ethics consultants are liable for their expertise? And, who decides what that accountable expertise is? The answers to these questions depend in part on whether lawsuits are filed against ethics consultants in the near future. Until such a time, the onus is on ethics consultants to circumscribe debates about their liability and expertise, by developing some additional hallmarks of professionalism. Ethics consultants can frame these debates by clarifying their core competencies and the nature of their expertise, applying clarified

core competencies as standards to establish certification and accreditation programs, and establishing a professional code of ethics.

However, the multidisciplinary field of bioethics is ambivalent about the professionalization of ethics consultation and reluctant to demarcate jurisdictional expertise, due in part to external pressures to embrace the ideology of expert professionalism rather than the social trustee professionalism in which bioethics is rooted. This ambivalence will likely provide the courts, insurance companies, and other stakeholders with considerable opportunity to define the liability and accountable expertise of ethics consultants. In response to the question, “would you like the report to indicate that liability should accrue to ethics consultations?”, three of the Task Force members deferred to the courts, with one stating, “I do not think it is our role to advise the judiciary about whether liability will accrue to ethics consultants.” However, three Task Force members also affirmed the need for professional accountability, with one responding, “If what is meant is that ethics consultants should stop trying to avoid legal accountability, my answer is yes” (p. 43). Ethics consultants may actively address their own accountability, or wait for the courts and insurers to establish their liability.

One manifestation of acknowledging professional accountability is the creation of a professional code of ethics. This has been a perennial topic of debate in bioethics, the most recent round of which is published in the

September-October 2005 issue of the American Journal of Bioethics (see main article, Baker, 2005). The debate turns in part on the fact that such a code may marginalize parts of the field of bioethics, because a single professional code of ethics would be incapable of adequately addressing the various professional backgrounds and scope of work in the field. The *Core Competencies* Task Force report contains the rudiments of a code of ethics for consultants, although it is not presented as a code of ethics, but rather as a section entitled “Special Obligations of Ethics Consultants and Institutions” (ASBH 1998, p. 29). The *Core Competencies* report arguably makes a strong case for developing a professional code of ethics, by noting the potential for conflict of interest and abuses of power arising from the social authority of ethics consultants.

It is worth noting that the liability Task Force report does not address the adoption of a code of ethics as a possible prophylaxis of malpractice lawsuits. While a code of ethics would little address the content of the advice given by consultants, considering the many medical and research liability lawsuits that have claimed conflict of interest and other professional misconduct, such a code would seem to be a prudent safeguard, clarifying to the ethics consultant, as well as to the courts, what professional behavior is acceptable and unacceptable. The only liability remedy discussed by the liability Task Force report, besides insurance, is the use of an indemnification

clause in consultation contracts; the report even provides an example of one. However, the report also notes that one Task Force member opposed such indemnification, because such clauses are generally invalid in health care, and because it was deemed inappropriate for the report to help consultants evade liability.

The preceding analysis provides an account of sources of legitimacy for health care ethics consulting in the legal arena. These sources are external to the field itself, which may have different internal sources of legitimacy that matter primarily to ethics consultants themselves. Ethics consultants have legitimacy of technique in relation to health care professionals, who regularly seek their advice for patient care decision-making. The liability Task Force report, focusing on the competencies of ethics consultants, infers that technique will also be the basis of its legitimacy in relation to insurance companies and the courts. Indeed, the state has affirmed the value of ethics consultant expertise, through statutory provisions for its use and immunity, and the influence of expert testimony, in the judicial forum.

However, social structure also strongly shapes the legitimacy and liability of ethics consultation. The extent to which ethics consultants are informally perceived and formally designated as regular partners in a health care team, or as serving routine functions in health care institutions, they may share similar liability and legitimacy with other health care

professionals they work alongside. Widespread adoption of the **ethics facilitation** approach advocated by the *Core Competencies* report may limit the liability ethics consultants, by rendering their advice nondirective and nonbinding. If so, ethics consultants might play a larger role in defining their own legitimate expertise by asserting competencies determined by the profession. On the other hand, if consultants are named as defendants in future lawsuits, insurers and the state will take considerable interest in defining the accountable expertise of ethics consultation. In the system of professions, the perceptions of health care professionals, insurers, and the state regarding the professional status of ethics consultation (and by extension, bioethics in general) shape the legitimacy and liability of those ethics consultants, indicating their accountable expertise, or jurisdictional claim.

Conclusion

In this chapter I have discussed how institutional review boards (IRBs) and health care ethics consultants may be held legally accountable for their expertise and decision-making, and argued that liability in the legal arena signifies legitimacy in the system of professions. As clients and the state come to rely increasingly on a particular expertise, and accordingly confer it with greater authority or legitimacy, the providers of that expertise can

become more liable for negligence and malpractice, where the expert is held responsible for causing injury as a result of failing to provide a valued professional standard of care.

In the coming years, it will be of interest to observe who is ultimately held responsible for the ethicality of decision making in biomedical research. Principal investigators? Their sponsors or employers? IRBs? Ethics consultants? Research participants themselves? The matter of who is held accountable has important implications for the distribution of power amongst stakeholders, and for the extent to which IRBs or ethics consultants may reasonably be accused of merely protecting the autonomy of powerful biomedical interests. As mentioned early in the chapter, the court's ruling in *Grimes v. Kennedy-Krieger Institute* suggests that researchers can still be held liable for harm resulting from research, in spite of parental consent and IRB approval of research protocols. Arguably the *Grimes* court's decision to override the IRB's ruling is based on a relatively straightforward reading of Common Rule protections for child research participants. If the IRB had been named a defendant in the lawsuit, would it would likely have been found liable, but it is not clear what impact that would have on the liability of the investigators.

It is not currently possible to examine the pursuit of state licensure as a means of strengthening the jurisdictional claims of bioethics. It is possible

that licensure may never be sought for ethics consultants, if current sentiments amongst ethicists against certification, accreditation, and licensure are any indication.¹⁴ However, there are other ways by which jurisdictions are shaped in the legal arena. These indicators of jurisdictional construction include the liability of emerging professional groups, admission of testimony by expert witnesses in court case hearings and decisions, and the passage of statutes promoting the use of new expertise or based on the content of that expertise.

The liability of IRBs strengthens, and may continue to strengthen, the jurisdictional claim of bioethics for several reasons. First of all, the legal standard of care for IRBs is derived in considerable part from federal regulations, which promulgate bioethics concepts in the requirement for IRB review of publicly funded research. Second, the federal regulations are ambiguous and require careful interpretation in their application to each protocol, creating a need for expert knowledge and skill by investigators, IRBs, and the courts in order to determine the appropriate standard of care that the research enterprise must provide to study participants. This need is a jurisdictional opportunity for bioethicists, who can and do provide education and consultation to these parties, based on their knowledge of national and

¹⁴ In Chapter Three I discussed the arguments of the Task Force on Standards for Bioethics Consultation against mandatory certification and accreditation (ASBH, 1998). See also Bosk (2003) for another account eschewing certification and licensure.

international ethical standards, ethical theories, and ethical reasoning skills. One of my case study respondents from Chapter Two predicted that research ethics will create an enormous demand for bioethicists, and accordingly research on research ethics will become a primary activity in the field. This forecast is consistent with the jurisdictional opportunity created by the increasing liability of IRBs, universities, and investigators in research litigation.

Indeed, the times do seem to be changing. A 2002 article lamenting the dearth of research ethics education in the biosciences cited the autonomy-oriented ethos of the bioscience research community, the lack of and difficulty of producing a professional bioscience ethics code, the “absence of any traditional clients who might complain of research negligence,” and the lack of disciplinary mechanisms as factors hindering the development of research ethics education (Eisen & Berry 2002, p. 39). Three years later, a growing number of high-profile research lawsuits have presented biomedical investigators with participant complaints, a real threat of discipline, and an incentive to pursue research ethics training. Finally, IRB accreditation represents another way in which the liability of IRBs reinforces the bioethics jurisdictional claim. IRB accreditation, which came about through a broad-based consortium of elite research stakeholders, adds another layer of social structure to research ethics, promotes institutional isomorphism, and

clarifies the expertise and performance standards required for IRB function and membership. Accordingly, accreditation strengthens the bioethics jurisdictional claim by organizing and standardizing the expertise of research ethics, and affirming its utility to research institutions.

The liability of ethics consultants is even less well established than the liability of IRBs, but discourse on the liability of ethics consultants has implications for the jurisdictional claim of bioethics. First, other interests in the system of professions play important roles in defining the fundamental expertise and liability of ethics consultation, including the health care professionals who seek advice from ethics consultants, insurance companies who assess the risk and insurability of ethics consultation, and the state, which provides some legal authorization of consultants' expertise, and will judge the liability of that expertise in future tort claims. The impact of other interests on the jurisdictional claims of ethics consultants is rendered greater by the ambivalence of ethics consultation towards professionalism. Second, the discourse on consultation liability reveals several sources of legitimacy that may be invoked for ethics consultation, including legitimacy of technical expertise, legitimacy of location in social structure, and legitimacy of character, or professional virtue. Expertise and social relations appear to play important roles in the external legitimacy of ethics consultation, whereas legitimacy of character does not. However, it might be argued that

legitimacy of character, such as through the promulgation of a professional code of ethics, could be effectively pursued as a protection in case of malpractice lawsuits, in addition to circumscription of accountable expertise. The ASBH liability Task Force recognized the importance of staking the jurisdictional claims of ethics consultation carefully, as evidenced by their observations about the relative liability of different consultation approaches. However, the extent to which ethics consultants will be able to determine their accountable expertise depends on whether they seize the opportunity to do so, as well as on the perceived utility and liability of ethics consultation expressed by other professional interests and the state.

Taken together, analysis of the liability of IRBs and ethics consultants illustrates the complexity of the bioethics jurisdiction. In this chapter renowned bioethicist Arthur Caplan provides a striking example of the multiple roles that characterize the work of bioethics, and that may be performed by the same person: Caplan has given expert ethics testimony in court, served as an IRB member, testified as a research ethics expert in a Congressional hearing on the protection of human research participants,¹⁵ provided ethics consultation to gene therapy investigators, and was named as a defendant in the Gelsinger lawsuit. The jurisdiction of bioethics,

¹⁵ See May 15, 1997 Washington Fax story, Conflicts of interest, stresses on Institutional Review Boards, cited as threats to protection of human research subjects (<http://www.washingtonfax.com/samples/1997/19970515.html>, accessed 10/29/05)

constructed around the task of determining the right thing to do in the conduct of biomedical practice and research, encompasses experts with various disciplinary backgrounds, in multiple workplace settings, serving an array of clients, performing a range of tasks and services.

What is the relationship of liability to forms of accountability in the other arenas where jurisdictional claims are constructed? In the case of biomedical research, the pressure for investigators to be accountable in the university workplace by producing knowledge is undoubtedly contributing to their liability in the legal arena, as plaintiffs make conflict of interest and other misconduct claims against researchers in the judicial forum. For academic bioethicists, workplace and legal accountability are also closely linked. For universities, bioethics represents in part an opportunity to tap into opportunity structures and legitimate biomedical research; thus it behooves academic bioethicists to provide remedies for the liability of investigators and IRBs, to demonstrate their own accountability to academe. As we shall see in the next chapter, the public policy recommendations contributed by the National Bioethics Advisory Commission are accountable to both the functions of research productivity assurance and research integrity assurance, and include elaborate procedural recommendations that would assure the ethical conduct of embryonic stem cell research, consequently defining the liability of stem cell researchers.

An obvious feature of bioethics jurisdiction claims in the legal arena is the codification of bioethics concepts and tools into law. The case could be made that in the legal arena, it is not the goal of bioethics to establish legal protection of their jurisdiction, but perhaps instead to shape the practice of medicine and bioscience through the codification of various bioethics concepts into law. This codification has been occurring in the federal executive branch, most notably in the Common Rule, and also in Congress and in state legislatures, which have passed laws on bioethical issues such as the privacy and confidentiality of personal health information, informed consent, and genetic nondiscrimination in employment. As we will see in the next chapter, the impact of bioethics on federal regulations is heavily modulated by the expert jurisdictions of medicine, and especially science, which seek to protect their professional autonomy by setting limits on executive branch oversight of science by nonscientists (see Evans, 2002). This demonstrates yet another way in which professions stake jurisdictional claims in the legal arena—in addition to protecting control of their jurisdiction through state licensing requirements, professional groups also actively seek to limit the regulation of their jurisdictions by external interests. In the next chapter, I will examine boundary work conducted by the National Bioethics Advisory Commission at the border between ethics and science, and its implications for the regulation of biomedical research.

CHAPTER 6—

BIOETHICS IN PUBLIC POLICY: THE NATIONAL BIOETHICS
ADVISORY COMMISSION & THE STEM CELL RESEARCH DEBATE

Public debate about the morality of research using embryonic stem cells is one of many biotechnology-related controversies that have arisen over the last several decades. Public bioethics advisory bodies have been a staple of U.S. public policy for addressing such societal disputes, in spite of the limited direct impact these bodies have had on science and technology policymaking. Kelly (2003) has argued that public bioethics advisory bodies serve an important tacit function as boundary organizations that stabilize the border between science and politics, thus preserving the autonomy of science from incursion by other societal stakeholders. These boundary organizations succeed in bounding and controlling the controversy by constraining the set of issues and viewpoints that are addressed, and by dictating the decision-making strategy in ways that privilege participation of some stakeholders over others and veil the intensity of the controversy.

Science is interdependent with the state, which exchanges resources for the conduct of science in return for the economic and technological fruits of scrupulous scientific activity. This relation can be interpreted as a contractual one between government principals and researcher agents that is mediated by boundary organizations that facilitate the assurance of mutual

goals (Guston, 2000) and stabilize the science-politics boundary by negotiating the boundary's contingencies within the organization. Boundary organizations employ specialized mediators, who serve as dual agents to both the government principals and the scientist agents, catalyzing collaboration between the state and science.

The National Bioethics Advisory Commission (NBAC), a presidential advisory body during the Clinton Administration, constituted such a boundary organization. The creation of NBAC both directly legitimated bioethics, and provided opportunities for the further institutionalization of bioethics in the public policy arena. In addition to mediating the tensions between politics and science, NBAC was also faced with negotiating the boundaries between science and ethics on the one hand, and between ethics and public policy on the other.

In this chapter, I examine the boundary work conducted by the U.S. National Bioethics Advisory Commission (NBAC) at the borders between science and ethics, and between ethics and public policy, in the commission's deliberations and recommendations on embryonic stem cell research. Specifically, I examine the coupling of scientific and ethical uncertainty, and the coupling of research productivity and integrity assurance, in the commission's deliberations on embryonic stem cell research, and discuss how

NBAC's boundary work served ultimately to reinforce the authority of science and marginalize conflicting civic-sector concerns.

I begin by sketching the historical context of the relationship between philosophers and public policy in the US, which reveals pervasive tensions that underpin the engagement of bioethics with public policy embodied by NBAC. I then review different perspectives on the functions of executive advisory bodies generally, and related criteria for their success. Next, I provide some background on NBAC and the embryonic stem cell controversy, and describe features that characterize NBAC as a boundary organization. The heart of the chapter describes NBAC's boundary work between science and ethics, and between ethics and public policy. I examine how science and ethics are coupled in the construction of the embryo as a boundary object, how the boundary between ethics and public policy is negotiated in deliberations about the role of federal funding and oversight in ESC research, and how the commission's recommendations serve the mutual goals of science and the state, while at the same time legitimating bioethics.

Philosophers & Public Policy

American philosophers' involvement in public policy and debate has changed considerably over the course of the twentieth century. As Albert Jonsen explains,

The golden era of American philosophy spanned the last quarter of the nineteenth century and the first quarter of the twentieth. William James and Josiah Royce at Harvard, and John Dewey and George Herbert Mead at the University of Chicago, cultivated a style of philosophizing that combined an erudite appreciation of the classic philosophers with an appealing public voice about contemporary issues.... The tradition of the public philosopher culminated with these men, who incessantly addressed the public about the life of the nation and its affairs. Yet, even as these public philosophers were thriving, philosophy was becoming more technical, more academic, and more reticent about public affairs” (Jonsen 1998, p.68).

The tradition of the public philosophers faded as Continental logical positivism from the Vienna Circle came into vogue, bringing its devastating critique of normative ethics. Jonsen describes a major shift occurring in moral philosophy, namely that metaethics (a term coined in 1949), the study of the meaning of ethical terms and concepts, came to supersede normative ethics, which is concerned with discerning right and wrong, in philosophical discourse. In the middle of the twentieth century, it was political philosophers like Hannah Arendt and Sidney Hook, rather than moral philosophers, who tackled some of the moral challenges of the day, including the Holocaust, the Nuremberg trials, nuclear weapons, and McCarthyism. Finally, the political climate of the 1960s, culminating in Vietnam War unrest, compelled philosophers to again address society’s problems, at the urging of linguist Noam Chomsky (Jonsen 1998).

However, as philosophers were called anew to serve in the public policy arena, they soon experienced firsthand the fundamental tensions between

philosophy and public policy. In essence, philosophy is fundamentally aimed at determining **truth** through analytical reasoning, while public policy is concerned with optimizing the **consequences** of state action, through political deliberation (Brock, 1987). Furthermore philosophers, perceived as the quintessential ivory tower academics, must demonstrate their credibility in the pragmatic realm of policy. Weisbard (1987) is quite pessimistic about the capacity of philosophy to add value to public policy, contending that philosophical scrutiny often demands standards for justification that few realistic policy proposals can meet.

The relationship between ethics and politics is further complicated by fundamental, conflicting convictions within the American ethos.¹ On the one hand our classical liberal tradition champions a secular, minimal morality, consistent with the protection of individual freedom and equality, and tolerance of pluralistic differences. On the other hand, our American culture, tracing back to its Puritan roots, has had a continual penchant for moralism,

¹ Acknowledging scholarly debate about the nature and significance of the concept, Jonsen defines ethos as:

the characteristic way in which a people interpret their history, their social world, and their physical environment in order to formulate convictions and opinions about what is good and right. Ethos is not the actual behavior of a people.... It is the panorama of ideas and ideals by which a people judge themselves.... Nor is ethos the collection of rules and principles that are invoked. It is the matrix in which those rules principles and values are formed (1998, p. 389).

in that our ethos “is strongly tempted to endow various aspects of life with moral meaning in a capricious way” (Jonsen, 1998 p. 391). Jonsen notes that in the US, relatively mundane matters such as diet, exercise, and smoking have taken on “moral” dimensions, often inspiring moral crusades.

The competing liberal and moral impulses of the American ethos are evident in the abortion debate, and reveal the more general problem of how to resolve moral disagreements in a pluralistic society. Arguments supporting the legality of abortion invoke the right of women to make their own choices and control their own bodies, whereas arguments supporting the criminalization of abortion attribute to fetuses the status of personhood and accompanying rights, and cite the wrongness of killing. Few issues in the American political landscape are as polarizing. The prospect for reaching consensus on abortion, or on any similarly contested issues, is made all the more doubtful by the increasingly politicized climate that has taken hold in the US since the 1970s.

It now appears that the tension between philosophy and public policy has manifested in the disjuncture between philosophy and bioethics, as described by a few of my case study respondents in Chapter Three. Academic philosophy is once again averse to “getting its hands dirty” in the policy world, whereas bioethics is accused of being too driven by current events in

the media, in its quest to influence policy. As we shall see in this chapter, bioethics as proffered by the National Bioethics Advisory Commission adopts a public policy approach rather than a more philosophical approach, such that political consequences reigned in importance over moral truth arrived at by analytical reasoning.

Bioethics has indeed become a fixture in the federal policy landscape, facilitated by the current science policy paradigm of collaborative assurance, which succeeded the relatively laissez faire, social-contract science policy approach of the post-war era (Guston, 2000). The institution of science and its social-contract relations with the military came under fire in the social protests of the 1960s, which deemed science no longer trustworthy to manage its own integrity. In the subsequent collaborative assurance regime, government and science work together through a variety of jointly-operated mechanisms to mutually, collaboratively assure the productivity and integrity of science, through the leverage of state-supplied resources.

The Functions of Executive Advisory Bodies

Presidential commissions are perhaps the most recognizable of executive advisory bodies in the USA. The political science literature on presidential commissions has identified two broad categories of organizational purpose, problem solving and conflict management (Sulzner,

1974).² Problem solving includes defining and investigating a problem and providing recommendations for its solution. Presidential commissions assist presidents in making informed decisions, arguably in the face of factual and political uncertainty (Wolanin, 1975) or inadequacies in the existing executive advisory mechanisms (Flitner, 1986). Conflict management includes strategies such as building consensus, pacifying political opponents, and encouraging public support for a course of action that policymakers have already determined (Bell, 1969; Cleveland, 1964). Presidential commissions also manage conflict through symbolic functions, such as expressing the current Administration's concern about a particular problem, promoting societal awareness of a problem (Flitner, 1986), serving as a lightning rod for controversial issues, or delaying presidential action to a more propitious time. Delay can be viewed either negatively as constituting an evasion tactic (e.g., Cleveland, 1964), or positively as creating a constructive cooling-off period in policy-making (Sulzner, 1974).

Presidential commissions have frequently been disparaged as ineffective, as evidenced by articles with such titles as, "Why Commissions Don't Work" (Schmitt, 1989), "The Ambiguous Legacy of American Presidential Commissions" (Graham, 1985), and "Nuclear Committee Plays

² Here I rely heavily on Bledsoe's (1997) overview of the nature and operation of presidential commissions.

it Straight—And Draws Criticism from All Quarters” (Lanouette, 1981). Some of the criticism of commissions stems from disagreement over the criteria for their success, which of course vary with their variously ascribed functions. In reference to bioethics advisory bodies specifically, the Institute of Medicine’s Committee on the Social and Ethical Impacts of Developments in Biomedicine identified three categories of criteria for success, including intellectual integrity, sensitivity to democratic values, and effectiveness, presumably signified by implementation of a body’s recommendations (Bulger et al., 1995). Bradford Gray (1995) further notes that the definition of success depends on the time horizon of evaluation, i.e., short-term versus long-term impact, and the scope and intended audience of reports from advisory bodies.

There is some concurrence about the success and failure of federal bioethics bodies (for a review, see OTA, 1993); two former federal bioethics commissions in particular are generally recognized as having been influential in protecting human research subjects and in expanding the autonomy of patients receiving medical care. In response to the Tuskegee scandal, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) produced the landmark *Belmont Report* in 1979, which laid out the basic principles to guide the ethical conduct of research with human subjects and enumerated the

functions of institutional review boards to assure the application of those ethical principles. During the early 1980's, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (President's Commission) issued several reports on a variety of issues, most notably *Deciding to Forego Life-Sustaining Treatment*. These reports have been widely cited in court cases and medical ethics education (see McAllen and Delgado 1984; Bulger et al., 1995). In these two examples, **success** can be inferred to mean influence, or contribution to the reform of medical and scientific practice and regulation, particularly over the long term.

Science and technology studies (STS) perspectives, including the concept of the boundary organization, provide a more nuanced understanding of the "success" of advisory bodies, of the role of science policy advisors generally, and of the ways in which stakeholder interests shape advisory body results, function, and strategies for managing political conflict. The boundary-work approach exposes the ways in which particular cultural maps serve the interests of social actors who contend for authority, power, and resources. Gieryn defines boundary-work as "the attribution of selected characteristics to the institution of science (i.e., to its practitioners, methods, stock of knowledge, values, and work organization) for purposes of constructing a social boundary that distinguishes some intellectual activity

as ‘non-science’” (1983, p.782). Scientists, like other professionals, perform boundary-work to distinguish themselves from other enterprises, as they compete for crucial authority, power, and resources.

Boundary-work is not a one-time event, but an ongoing activity shaped by the “structural contexts of available resources, historical precedents, and routinized expectations that enable and constrain the contents of a map and its perceived utility or accuracy in the eyes of users” (Gieryn, 1999 p.10). Thus it is essential to apprehend the **context** of boundary-work in order to discern both the **goals** and the **strategies** of the boundary-work performed by a particular social group. Boundary-work analysis provides the beginnings of a cultural account of the changing allocations of power and resources among social actors over time, and invites us to reflect on alternate cultural maps that could be drawn.

STS scholars have described several ways in which boundary work is performed at the border of science and politics. Jasanoff’s (1990) study of science advisory committees finds that policymaking is facilitated by the intentional blurring of the boundary between science and policy, and conversely rendered more difficult when scientific advisors and policymakers attempted to strengthen distinctions between science and politics. Guston (2000) describes how boundary organizations facilitate collaboration across the science-politics border to achieve the mutually-desired goals of assuring

the productivity and integrity of science. To do so, boundary organizations employ specialized mediators who serve as dual agents to both government and scientific principals, catalyzing collaboration between the state and science, and stabilizing the science-politics boundary by negotiating the boundary's contingencies within the confines of the organization. Kelly (2003) argues that bioethics advisory bodies, as boundary organizations, contain and stabilize the tensions that exist between science and politics, thereby protecting science and policy practices from the scrutiny and interference of other stakeholders. Such protection is afforded in part by the use of an overlapping consensus approach to bioethics, in which academic reflection on shared societal values is used to determine the ends of public policy (see Rawls, 1987). A consensus approach can result in masking of underlying philosophical issues, underestimation of risks and opposition, neglect of unpopular views, and exclusion of some alternatives and information from consideration (Bulger et al., 1995), and in the case of public bioethics bodies, consensus simultaneously privileges bioethics experts as moral arbiters and limits and mediates the participation of other interests in the deliberations (Kelly, 2003).

Evans (2002) describes how the selection of a particular form of argumentation resulted in the substantive "thinning" of the public bioethical debate over human genetic engineering, in the proceedings of the President's

Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Different styles of argumentation, not surprisingly, produce different policy results: while substantive rationality is conducive to considering multiple means, long-term effects, and the banning of incongruous means, formal rationality focuses on one discrete means and its immediate effects, and favors exploratory development of means over bans (to better determine consequences and follow changing; societal means). In essence, the thinning of bioethical debate is part of the larger phenomenon of the Weberian rationalization of society. Evans finds that the thinning of the debate by the commission excluded the option of not engaging in any human genetic engineering. More generally, Evans observes that such thinned debate favors some interest over others and shifts the locus of debate away from the public and toward the bureaucratic, technocratic state.

The interests of different stakeholders, including the professionals who staff commissions, clearly shape the operation of advisory bodies and the trajectory of their inquiries. Rather than asking whether a particular commission or report has been a success by virtue of having its recommendations implemented, STS perspectives encourage us to ask whose criteria for success shape a commission's operation and products, how those criteria become legitimate, and with what consequences for all who hold a stake in the public good of science. In the next section I provide some context

for my analysis of the coupling of science and ethics resulting from the boundary work performed the National Bioethics Advisory Commission in its deliberations of stem cell research.

NBAC & the Embryonic Stem Cell Research Controversy

Several standing federal bioethics bodies preceded NBAC, beginning with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which operated from 1974-1978. However, more than a decade passed between the termination in 1983 of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and the creation of NBAC in 1995.³

The direct origins of NBAC can be traced to 1992, when the Senate debate on reauthorization for the National Institutes of Health re-stimulated Congressional interest in a formal role for bioethics in federal governance, nine years after the termination of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Senators Mark Hatfield, Edward Kennedy, and Dennis DeConcini asked the

³ The ill-fated Biomedical Ethics Advisory Committee (BEAC) was created by Congress in 1985. It took a year for Congress to select a board of congresspersons whose job it was to appoint the BEAC members; subsequently abortion politics dead-locked the board and quashed the advisory committee. BEAC operated from 1988 to 1989, meeting only twice and issuing no reports.

Office of Technology Assessment to review the history of bioethics in federal policy and evaluate prior bioethical policy approaches, in order to help Congress develop potential strategies for examining policy issues having biomedical and ethical import. Senators Hatfield and Kennedy introduced a bill in the first session of the 103rd Congress (1993) to establish a national bioethics commission.

That same year, the Department of Energy (DOE) and the National Institutes of Health (NIH) appealed to the White House Office of Science & Technology Policy (OSTP) for the establishment of a standing national bioethics commission. NBAC's charter was signed in July 1996 by Jack Gibbons, then Assistant to the President for Science and Technology Policy. NBAC's first priorities were to address "protection of the rights and welfare of human research subjects; and issues in the management and use of genetic information" (Executive Order 12975 of October 3, 1995, Sec. 5a). In response to the report issued by the Advisory Committee on Human Radiation Experiments in 1995, President Clinton also required relevant executive branch agencies to review their human subjects protection policies, and report their results to NBAC. NBAC was further granted the authority to deliberate on additional issues raised by the general public, other federal bodies and organizations, or NBAC itself.

Although the commission began with vocal support from both the executive and legislative branches, the congressional pledge to balance the federal budget in 1996 provided little funding commitment to the operation of NBAC. For the first two years of its existence, NBAC relied upon volunteered funding collected from various agencies by the efforts of Senator Mark Hatfield, a strong advocate for NBAC and then-chair of the Senate Appropriations Committee. Even with such a powerful champion, NBAC's initial funding was less than that of previous federal bioethics bodies.

NBAC's initial funding was less than that of previous federal bioethics bodies. On National Public Radio, bioethicist Art Caplan quipped that Spartan funding made NBAC more of a Yugo than a Cadillac (National Public Radio, 10/4/96). By fiscal year 1999, NBAC's budget of \$2 million, a 5% increase over the previous year, came entirely from the Department of Health and Human Services (DHHS), as per the Executive Order and the Charter establishing the commission. These founding documents also required DHHS to provide "management and support services" for NBAC, raising the estimated annual cost for NBAC operations to \$3 million in 1999 (NBAC, 2000).

Initial plans for the routine operation of NBAC changed considerably as the commission was asked to address an increasing number of topics. After the first meeting, two subcommittees were formed to address the two

priorities mandated in the charter, the protection of human research subjects, and the management and use of genetic information. Chairman Harold Shapiro had anticipated quarterly meetings at the outset, but in its first year of operation, the full commission met eight times, the human subjects subcommittee met six times, and the genetics subcommittee met five times. NBAC's workload increased unexpectedly in February 1997 with the announcement of Dolly the cloned sheep, when the President asked NBAC to address human cloning. Clinton's request for a report on stem cell research in November 1998 was another unanticipated request, and during the ten months that NBAC worked on the stem cell report, they were concurrently working on other projects, sometimes three at once.

In November 1998, three separate reports of the isolation and culture of human and hybrid embryonic stem cells (Shamblott et al., 1998; Thomson et al., 1998; Wade, 1998) prompted President Clinton to assign two tasks to NBAC. First, the commission was asked to promptly examine the implications of Advanced Cell Technology's announcement that they had created hybrid human-cow stem cells and report back to the President as quickly as possible. Second, Clinton requested that NBAC "undertake a thorough review of the issues associated with such human stem cell research, balancing all ethical and medical considerations."

Kelly (1994) notes that a recurrent theme in the history of federal bioethics advisory bodies has been the perpetual struggle between legislators and mission agencies to control jurisdiction over the approval of biomedical research funding, with the result that ethics investigations of bioethics bodies are directed towards political power and resource control. Both the Ethics Advisory Board's 1979 report on in vitro fertilization research and the HFTTR panel's 1998 report were instigated by grant applications requesting government funding for controversial research. The embryonic stem cell research controversy is no exception. The reports of stem cell research breakthroughs immediately provoked reaction at the National Institutes of Health (NIH), where concerns quickly arose that federal law might well prohibit public funding of research using the new stem cells. The statute in question was a rider attached to the DHHS appropriation in 1996 and subsequent years, which has barred the use of federal funds for any activities involving either the creation of human embryos for research purposes, or research in which human embryos are destroyed or subjected to risk of injury greater than that allowed for research on *in utero* fetuses by the Common Rule (45 CFR 46) and the Public Health Service Act (42 USC 289).

Harold Varmus, then NIH director, requested an opinion from DHHS about the legality of using DHHS funds to support stem cell research. Varmus chose the occasion of his testimony at NBAC's January 1999 meeting

to announce the DHHS decision: DHHS general counsel Harriet Rabb ruled that research on the use, although not the derivation, of stem cells from embryos could receive federal funding, explaining that “statutory prohibition on the use of funds appropriated to HHS for human embryo research will not apply to research utilizing human pluripotent stem cells because such cells are not a human embryo within statutory definition” (01/19/99 NBAC Meeting Transcript, pp.17-18). In February, seventy members of Congress responded to Rabb’s ruling by signing a letter urging DHHS to reverse Varmus’s decision to allow NIH funding of embryonic stem cell research. In turn, seventy-three prominent scientists endorsed a letter pressing the Administration to support Varmus’s decision (see Lanza et al., 1999), and thirty-three Nobel laureates, representing the American Society for Cell Biology, signed and sent another letter directly to President Clinton and Congress, supporting stem cell research.

Against this political backdrop, NBAC developed a report and recommendations for human stem cell research. The boundary-work performed by NBAC is only one of several instances of boundary-work performed by various interests in the stem cell controversy. Consider, for example, the proceedings of the Ethics Advisory Board convened by Geron Corporation, which funded the research behind two of the three stem cell research breakthroughs announced in November 1998 (see special

symposium in the Hastings Center Report, March-April 1999), and other stakeholders who advocated for a research focus on stem cells isolated from adult tissue (see Vogel, 2001). NBAC did not draw the definitive cultural maps of science, ethics, and politics in the debate. However, NBAC represents the Administration's efforts to incorporate bioethics into public policy at the federal level, and a substantial collection of stakeholder organizations were interested in the process and results of NBAC's analysis (Eiseman, 2003).

NBAC as a Boundary Organization

Boundary organizations internalize the contingent character of the science-politics boundary, and carefully negotiate those boundary contingencies by creating and using **boundary objects** and **standardized packages** to mediate collaboration between the interests of scientific and political stakeholders. Boundary objects are socially constructed entities that are "adaptable to different viewpoints and robust enough to maintain identity across them" (Star & Griesmer, 1989, p. 387), such that different stakeholders may refer to the same object in shared discourse, but attach different, viewpoint-specific meanings and ends to it. An embryonic stem cell is such a boundary object, as is NBAC's published report on ethical issues in research with stem cells. Standardized packages combine boundary objects

with consistent rules, procedures, and norms, which are sturdy enough to change local practices across settings in which they are adopted (or more likely, externally imposed) and applied. Contemporary ethical review of research with human participants employs several of these standardized packages, including institutional review boards, and the federal regulations and ethical principles these boards apply in evaluating proposed research.

In the proceeding section of the chapter, I examine how NBAC manages the coupling of scientific and ethical concepts, consequently managing the boundary between science and politics. I describe the ways in which NBAC manifests the three criteria of boundary organizations outlined by Guston (2000), paying particular attention to the ways in which NBAC employs the boundary objects of human cells and embryos, and the standardized packages—i.e., science policy tools—that have been developed over the last few decades to manage biomedical research in the name of public good. My analysis employs discourse analysis of the meeting transcripts and final report of NBAC dealing with the ethics of human stem cell research, as well as the commission's charter (see Appendix for additional methodological details). I argue that NBAC's boundary work, particularly the ways in which science and ethics, and ethics and public policy, are coupled, served ultimately to reinforce the authority of science and marginalize conflicting civic-sector concerns.

Criterion 1: A boundary organization exists on the frontier of relatively distinct social worlds, with distinct lines of responsibility and accountability to each. As a presidential advisory commission, NBAC had automatic responsibility and accountability to President Clinton. However, as discussed earlier, the creation of NBAC was proposed and supported by several members of Congress and executive branch agencies (by fiscal year 1999, NBAC's \$2 million budget came entirely from the purse of the Department of Health and Human Services). The commission's charter required it to provide an annual report to the President's National Science and technology Council and to appropriate Congressional committees, which was to include summaries of NBAC activities and recommendations, as well as responses to those recommendations received from government departments and agencies, and other entities. NBAC's formal ties to the executive and legislative branches were further reinforced by Congressional requests for testimony from NBAC staff and commissioners, and by NBAC's regular use of expert testimony from an array of executive-branch agency officials.

NBAC's accountability to the world of science was built into its charter, which required the commission's membership to be "approximately evenly balanced between scientists and nonscientists." The organizational charter specified that NBAC consist of eighteen presidentially appointed, non-government members, drawing at least one expert each from

philosophy/theology, social/behavioral science, law, medicine/allied health professions, and biological research. NBAC was additionally required to possess at least three members from the general public, bringing other expertise; to roughly balance the number of scientists and non-scientists; and to seek equitable geographic, ethnic, and gender representation. Of the seventeen NBAC commissioners who served at the time of the stem cell research deliberations, seven were women, and at least three represented ethnic minorities. Commissioners included two PhD biologists, five MDs, one RN, three jurists, three PhD philosophers/theologians, two PhD social/behavioral scientists, seven members of the Institute of Medicine, and three representatives of the general public, including the executive director of a mental health advocacy organization, and a representative from the biotechnology industry. However, only fifteen commissioners deliberated on stem cell research, because two commissioners eventually recused themselves from the stem cell deliberations.⁴ Of the remaining fifteen, five had prior

⁴ Commissioner Charo recused herself as of February 1999, to avoid the appearance of conflict of interest due to her role at the University of Wisconsin in making some recommendations about the work of stem cell researcher Jamie Thompson at the University of Wisconsin. Commissioner Greider recused herself in July 1999, when the stem cell report and recommendations were virtually complete; here again the intent was to avoid the appearance of conflict of interest due to her employment at Johns Hopkins University, which has a direct financial interest in the stem cell research of John Gearhardt.

experience serving on federal bioethics bodies or in other federal organizations.

Although NBAC members were somewhat diverse with respect to gender, ethnicity, and geographical distribution, critics found them to be ideologically biased: one Catholic commentator found NBAC to be “stacked with abortion, euthanasia and eugenics supporters” (Meehan, 1996),⁵ citing numerous links to pro-choice organizations.⁶ As per the recommendation of the Advisory Committee on Human Radiation Experiments, NBAC’s first priorities were the protection of human research subjects, as well as the management and use of genetic information. Accordingly, two advocacy groups for radiation experiment subjects sought the appointment of a research abuse victim to the commission. OSTP declined the request, allegedly due to concerns about the ability of victims to be objective (Meehan, 1996).

While Meehan (1996) justifiably notes that there were several current and former human-subject **researchers** appointed to the commission, it should also be pointed out that research subjects are rightfully represented on NBAC. Commissioner Flynn was the executive director of the National

⁵ These critics do not come from a world that NBAC is primarily responsible to; as we shall see, critics from religious and other pro-life organizations are marginalized in NBAC’s stem cell deliberations.

⁶ I was unable to identify any Republicans amongst the commissioners, but I did confirm three Democrats.

Alliance for the Mentally Ill, which both sponsors research and has many members who are research subjects; Flynn also has a daughter with a severe psychiatric disorder, who has participated in clinical research trials. Unlike the radiation victim advocacy groups, the American Psychological Association, the Biotechnology Industry Organization, and Senators Mark Hatfield (R-OR) and Daniel Moynihan (D-NY) were successful in getting nominees appointed to NBAC.

The commission's accountability to science was also arguably reinforced by the commissioners' strong identification with academic culture (eleven of the commissioners were university professors or administrators), as well as their reliance on scientific expertise to inform their deliberations.⁷

While NBAC's accountability to political and scientific principals was manifest formally in its contractual relationships to policymakers and scientific professionals, and its dependency on those principals for funding and critical information, the commission's accountability was also informally evident in its deliberations, particularly in the careful attention commissioners gave to the practical concerns of both bureaucrats and

⁷ Scientific issues and testimony occur first both in the deliberations and in the final report, whereas religious testimony and viewpoints were amongst the last heard, and are primarily relegated to a summary in an appendix of volume one, and are presented at length only in the third and final report volume.

scientists, and in designing workable oversight mechanisms, as I shall describe shortly.

Criterion 2: A boundary organization involves the participation of both principals and agents, and specialized mediators. The role of politicians and bureaucrats as principals of NBAC is fairly straightforward. President Clinton requested that NBAC “undertake a thorough review of the issues associated with such stem cell research, balancing all ethical and medical considerations” (the President’s letter of request, reprinted in an appendix to the final NBAC report). Congress was also very interested in NBAC’s analysis, as were NIH and FDA bureaucrats, given these parties’ competing interests in the federal control of both funding approval and research oversight. As principals of NBAC, the scientific community has primarily pragmatic concerns about ethics; most researchers steer clear of publicly debating the ethical implications and propriety of stem cell research, but are very interested in having policymakers spell out clear ethical guidance for the practice of research.

The pragmatic interest of stem cell investigators was reflected in the NBAC testimony of researchers James Thomson and John Gearhart, whose work on stem cell derivation had instigated NBAC’s investigation. At the University of Wisconsin, Thomson had isolated embryonic stem cells from

leftover embryos donated by couples who had undergone infertility treatment, and Gearhart had isolated embryonic germ cells from electively aborted fetuses at Johns Hopkins University.⁸ Although these investigators supported their research entirely with private funds from the Geron Corporation (see Marshall, 1998), both of them experienced similar difficulties navigating university requirements (based on federal regulations) for the ethical oversight of their research. In his testimony, Gearhart recounted:

Now we ran into our first series-I won't refer to them as obstacles, but certainly of review. It has taken us actually a several-year period to put into place many of the requirements that were necessary to pursue the work. I wish that we had had at our disposal a committee, like Dr. Varmus [does], who could give us a determination on this in a period of a few months, perhaps (01/19/99 Transcript, p. 36).

When asked to comment on the oversight function of NIH, Thomson answered, "from an investigator's point of view, we just want a set of rules for what's appropriate and not appropriate, what's ethical and what isn't ethical.... You can do basically what you want to do at a university but I don't think that's appropriate" (01/19/99 Transcript, p. 64). While they recognize the need for research oversight, and take seriously their responsibility to conduct research ethically, these investigators ultimately want to be provided

⁸ The properties of these cells will be discussed in the next section of this essay.

with clear rules and norms and efficient oversight, so that they can get on with what they see as the doing of science.

NBAC commissioners and staff served as specialized mediators for the political and scientific principals concerned with embryonic stem cell research. As a dual agent to both principals, NBAC sought to design flexible oversight for unpredictable science. In addition to uncertainty about exactly what therapeutic promise stem cell research could fulfill, and how soon, there was additional uncertainty about the promise of stem cells derived from adult tissue sources versus stem cells derived from controversial embryonic sources. After concluding that the therapeutic promise of embryonic stem cells was too compelling to pass up, NBAC deliberated on which embryonic stem cell sources could be appropriate for use in federally funded research. As agents for their political principals, NBAC conducted fact-finding and ethical and technical analysis, identified a moderate public policy position, and designed oversight mechanisms to assure integrity. As agents for scientific principals, NBAC sought to minimize hindrance to scientific practice and progress, provided ethical guidance and procedures, and produced indicators of scientific promise and integrity. NBAC also reinforced the authority of science by emphasizing the importance of scientific state-of-the-art and deferring to scientific expertise to set research agendas and priorities, via the merit assessments of peer review. It is worth noting that

NBAC could have chosen to provide advice on the stem-cell research agenda on the ethical grounds of the just distribution of resources; instead, NBAC chose only to recommend which sources of embryonic stem cells were appropriate for use in federally funded research, relying more on the testimony and analysis of professional ethicists than on theological views of ethical science.

Criterion 3: Provides a space legitimating the creation and use of boundary objects and standardized packages. NBAC, like the bioethics advisory bodies that preceded it, provided a space for identifying and fine-tuning the boundary objects and standardized packages that had been developed by the interdisciplinary field of bioethics. These boundary objects and standardized packages are the focus of discussion in the next section of this chapter. The central boundary object constructed by NBAC is the embryo, a potential source of stem cells. As we shall see, NBAC's boundary work exhibits a coupling of the moral status of the embryo to current scientific understanding of cellular development and differentiation. The standardized packages, or funding and oversight structures, recommended by NBAC served the mutual interests of the political and scientific principals, and reinforced the position of bioethics as a legitimate arbiter of ethical research practice, while

marginalizing theological perspectives and narrowing the range of ethical issues addressed in NBAC's report and recommendations.

In turn, I will examine boundary-work performed in the construction of the embryo as boundary object, the expanding role of federal funding and oversight, and the ESC research oversight approaches recommended by NBAC.

The Embryo as Boundary Object

Developments in somatic cell nuclear transfer (SCNT) or cloning, and in stem cell science at the end of the twentieth century increased the flexibility of human embryos as boundary objects at the science-politics boundary, and the science-ethics boundary. The birth of the cloned sheep Dolly in 1997 demonstrated that the nucleus of a terminally differentiated cell—that is, a cell whose genetic expression has been specialized for a particular adult function—can be deprogrammed to have the totipotency of a fertilized egg, or zygotes. **Totipotency** refers to the zygote's ability to divide repeatedly and differentiate permanently into any specialized cell type found in the adult organism. Similarly, advances in stem cell research reported in November 1998 by the laboratories of James Thomson and John Gearhart demonstrated that stem cells from human embryonic and fetal sources could

be isolated and cultured.⁹ These stem cells are **pluripotent**, meaning that they can proliferate and differentiate into several, but not all, of the specialized cell types that totipotent cells can give rise to.¹⁰ In adult organisms, some stem cells remain, which retain the ability to divide and differentiate into a limited variety of cell types to renew tissues throughout the life of the organism. Accordingly, isolated embryonic stem cells have considerable scientific and therapeutic promise in the generation of new tissue for the treatment of injury and disease.

With these breakthroughs in cloning and stem cell science, investigators were getting closer to being able to dedifferentiate cells backwards through their developmental programs, and to directing the

⁹ The cells cultured by Thomson's and Gearhart's research groups are designated respectively as embryonic stem cells and embryonic germ cells. For ease of reference, I refer to them here collectively as embryonic stem cells, or ESCs.

¹⁰ At the time of NBAC's deliberations, there was disagreement amongst developmental biologists (and in other circles) as to the precise meanings of the terms totipotent and pluripotent. Some defined totipotency as the ability to develop into a complete organism, and pluripotency as the ability to develop into any of the various cell types found in an adult, but without the ability to develop into an entire organism. Others defined totipotency as the ability to differentiate into any cell type (but not necessarily the entire organism), and pluripotency as the ability to generate more than two different cell types. More recently, the term multipotency has emerged in stem cell discourse. Development and debate of this terminology is beyond the scope of the present essay; for present purposes the reader may simply think of totipotent cells as having more developmental options than pluripotent cells.

forward differentiation of pluripotent cells into targeted cell types.¹¹

Accordingly, the perceived identities of cells are becoming more plastic, and different cell types—including fertilized eggs—are more easily viewed as constituting a fluid continuum, rather than as discrete categories, of cell types. The enhanced plasticity of cell identity, or alternately the increased uncertainty of cell identity, enters the ethical debate on the status of embryos with respect to personhood.

For those who believe that personhood begins not at the instant of fertilization, but at some point later in development, the enhanced plasticity of cells and their genetic programming reinforces treatment of zygotes and similar cells (such as SCNT products) as being little or no more deserving of special respect or treatment than other cells in biomedical research. That is, zygotes are viewed as no different in status from other cells; they just have developmentally different, but malleable, genetic programs. However, for those who believe that human personhood begins at fertilization, substantial caution is warranted to treat any potentially totipotent cell as a potential human life. Furthermore, in this view, the only way to determine whether a

¹¹ Applying the cloning technique (SCNT) to stem cell research is one approach being pursued, with the objective of creating Molly, the cloned stem cell, rather than Dolly, the cloned ewe, by inserting a differentiated cell nucleus into an enucleated stem cell. There has been an attempt to distinguish this use of cloning as **therapeutic** cloning, but this distinction has not yet succeeded in allaying fears that researchers might attempt to implant an SCNT product into a woman's uterus and produce a baby.

cell is totipotent is to implant the cell in a woman's uterus and let it develop, which would be unethical because the resulting being might be irreparably damaged by the manipulations that produced it. Therefore, any cell that might be totipotent ought to be treated with the utmost respect and care.

The embryo's flexible identity as a boundary object extends beyond the above concerns about its potential status as a human life. For disease advocacy organizations and patients, such as those concerned with Parkinson's disease, embryonic stem cells represent the promise of treatments or cures for numerous chronic and life-threatening diseases. Daniel Perry, executive director of the nonprofit Alliance for Aging Research, provided expert testimony to NBAC advocating for research on stem cell lines derived from embryos, arguing that "this research is too momentous, too large in its potential benefits, to impede, to stop, or to slow the thrust of current scientific inquiry" (1/19/99 Meeting Transcript, p. 68). For the higher education sector, the embryo represents a significant opportunity structure for research revenues, from both private and public sector sources. In March 2001, the presidents of the American Council on Education, the Association of American Universities, and the National Association of State Universities and Land-Grant Colleges, together with 112 university presidents and chancellors wrote to DHHS Secretary Tommy Thompson, supporting federal funding for embryonic stem cell research (Eiseman, 2003). Analyzing the

embryo as a boundary object enables us to illuminate the complex and multiple meanings of a contested object, and as Fujimura explains, the boundary object concept “promotes our understanding of translation efforts in the management of collective work across worlds,” (1992, p. 175) the unenviable task with which NBAC was faced.

NBAC was fully aware of the ways in which new developments in stem cell science were increasing the flexibility of the embryo as a boundary object in the debate over embryonic stem cell research. Overtly, the breakthroughs in the ability to isolate and culture embryonic stem cells brought science closer to making stem cell therapies a reality. This heightened therapeutic potential compelled President Clinton to request from NBAC “a thorough review of the issues associated with such human stem cell research, balancing all ethical and medical considerations” (President’s letter to Chairman Harold Shapiro of NBAC, 11/14/98; reproduced in Volume I of NBAC’s stem cell report). In the end, the promise of new stem cell therapies tipped NBAC’s scales in favor of limited federal sponsorship of human embryonic stem cell research: “we have found substantial agreement among individuals with diverse perspectives that although the human embryo and fetus deserve respects as forms of human life, the scientific and clinical benefits of stem cell research should not be foregone” (NBAC, Executive Summary, *Ethical Issues in Human Stem Cell Research*, 1999, p. 11).

Furthermore, over the course of their deliberations, several of the commissioners also acknowledged that scientific information often shapes our normative perceptions, despite scientists' allegations that science cannot answer questions of ethics. At NBAC's February 1999 meeting, Commissioner and geneticist David Cox asserted, "there is no scientific data that is going to answer that question [of when life starts].... It is not a scientific question now, despite the fact that people try to make it such" (2/2/99 Meeting Transcript, p. 102-103). But at the next day's meeting, Commissioner Brito, an academic pediatrician, observed:

It seems to me that the key here is going to be to **emphasize the scientific advances that have come about and how they may have changed our perceptions, our ethical viewpoint**. Even though David's not here to discuss this today, yesterday he said that science is irrelevant in terms of some of the ethical issues. I disagree with that. The more I've thought about that, I think the science has made it [sic] more relevant in terms of how we look at embryonic development because of the new findings. And I think the key here is going to be to highlight historically, in recent history, really, the last 30 to 40 years, of **how science has advanced to the point where we now understand embryonic development better, and how that may change some of the ethical viewpoints and public policy viewpoints on embryos** (2/3/99 Meeting Transcript, p. 64; emphasis added).

Commissioner Cassell, another physician, agreed, while Commissioners Shapiro and Capron noted that Brito's assertion was consistent with President Clinton's request, which was motivated at the outset by new scientific developments.

In essence, I am arguing that the President and the commissioners recognized (and uncritically accepted) that embryological science and moral understanding are constructed in tandem, or are coupled to one another. While researchers have come to recognize that invoking scientific explanations to justify moral claims serves to de-legitimate and politicize science, especially in the case of human embryos' moral status, some of the commissioners and the President acknowledged that science shapes our reality and beliefs, but failed to reflect critically on the normative influence of science.

Acknowledging that scientific understanding moulds our moral perceptions implies that moral standards will evolve in tandem with perpetual scientific progress. As Commissioner Holtzman explained,

An embryo is what it's always been—namely, something that given under normal circumstances, ordinary circumstances, goes on to become a kid. **What's changed is what is within the realm of the ordinary and normal in our experience now.** The profound lesson to me of Dolly was what's normal. What's very normally, ordinarily, within the next few years within the realm of what could be made into a child is changing profoundly (2/2/99 Meeting Transcript, p. 108; emphasis added).

Holtzman's observation does not mean that as novel technologies and artifacts become ordinary, they automatically become more ethically acceptable. It does mean that what constitutes "normal" evolves continually over time. However, in taking a balancing approach to its ethical deliberations (i.e., balancing ethical concerns against the ever-improving

medical benefits of scientific advance), and in concluding that the future benefits of embryonic stem cell (ESC) research warrant overriding some people's concerns about treating human embryos in an unethical manner, NBAC does presume that advances in stem cell science and technology will expand the number of morally acceptable ESC sources—and the number of appropriate for federal funding. In essence, scientific productivity in ESC research yields the extension of scientific integrity to the use of a wider variety of potentially more controversial ESC sources—the ethical acceptability of stem cell research is coupled to the productivity of that research.

Of Embryos & Oversight: The Implicit Morality of Bioethics in Public Policy

NBAC was faced with two volatile issues in tackling ESC research: the moral status of the embryo, and government funding of controversial research. Over the course of their deliberations, the commissioners chose to take a **public-policy approach** to their analysis, rather than a more incisive ethical analysis. The public policy approach of bioethics adopts the assumptions of liberalism and abstains from moralism. Thus, the public-policy framing of bioethics asserts that in a pluralistic liberal polity, there is unlikely to be a unified vision about what constitutes the good life for a

human being, and public policy should not and cannot take a position on what the unified vision should be (see Meilaender, 1995, ch. 1).

NBAC's charge with respect to the stem cell controversy was not well-defined at the outset, and the commissioners were left with some decisions about how to proceed. They were simply asked to "undertake a thorough review of the issues associated with such human stem cell research, balancing all ethical and medical considerations." However, President Clinton's letter of request also spelled out the need to revisit the thorny issue of human embryo research. Citing federal restrictions on embryo research instituted by his Administration, the President reflected that "although the ethical issues have not diminished, it now appears that this research may have real potential" for the treatment of "devastating illnesses" (NBAC, 1999, vol. 1, p. 89). Beyond this rationale for policy reassessment, the President's charge was rather vague, permitting NBAC to openly consider different approaches to its final report, approaches that by commissioners' own admission would have led to different recommendations, as we shall see. Let us examine how the commission chose to take implicit rather than explicit moral stances on ESC research, first on human embryos, and then on federal funding and oversight.

The Moral Status of the Embryo

In a January 1999 commission meeting, Chairman Shapiro led a reflection on their charge, clarifying the possible boundaries of their inquiry. On one hand, their “narrowest possible response” was to “look at the issues involved in using existing embryonic stem cells for research purposes,” although on another hand, noted Shapiro, it seemed likely that Clinton's letter encouraged them to go further-- to consider embryo research generally, and even the creation of human embryos for research purposes (01/19/99 Transcript, p. 170). However, over the course of the discussion, commissioners came to advocate a narrower, rather than a broader scope. Commissioner Capron, for example, cautioned them against trying to cover too much ground in their report, citing the unreasonable workload it would put upon NBAC staff, and agreeing with expert witness Patricia King that too much speculation about future issues was unwise, given the relatively undeveloped scientific knowledge of stem cells (01/19/99 Transcript, pp. 173-75). Accordingly, Capron recommended that they address some version of the question, “Should the Federal regulations relating to research on the embryo and fetus and on pregnant women be amended in light of the new science?” Capron's suggestion addressed the central policy concern in Clinton's letter, and accordingly the struggle between NIH and Congress. NBAC soon elected

to concentrate their inquiry on what categories of stem cell research ought to be eligible for federal funding, weighing ethical and medical considerations.

However, in eleventh-hour deliberations, commissioners expressed a curious confusion about the focus of their inquiry, suggesting that they might have felt conflicted about their approach. In particular, there was uncertainty as to whether they were focusing on the ethical issues raised by embryonic stem cell research *per se*, or federal funding of that research. In response to Commissioner Dumas' assertion that "our major focus is on the ethical issues and implications of the use of stem cells," from which "the issue of federal funding then follows," (06/28/99 Transcript, p. 29), Commissioner Greider countered, "I read this whole report as being very limited to the issue of federal funding.... Now if we were to address ... the ethical issues irrespective of funding, I would have a very different feeling for the recommendations. I would not come out in the same place that I do" (06/28/99 Transcript, p. 32).

After more debate on the matter, Shapiro asked them to retrace their footsteps. Citing their educational and policy recommendation roles, Shapiro explained that "One cannot deal with ... the ethics of federal funding without reminding ourselves what the general ethical issues involved here are" (06/28/99 Transcript, p. 37). He reminded the commission that they had decided early on to focus on the federal funding issue, and not on "what

would be morally acceptable for people in the private sector without federal funds to do” (p. 38). “What we are trying to do here,” Shapiro continued, “is recognize that there is moral disagreement out there and trying to design a federal policy that acknowledges the moral worth of other points of view besides our own and reach some kind of compromise...” (p. 40).¹²

NBAC’s decision to focus on federal funding of stem cell research clearly marked a shift away from a purely ethical analysis of embryonic stem cell research per se, an analysis arguably more pertinent to the concerns of the lay public, given the prominence of the abortion debate in late twentieth-century American society. Although several commissioners at various times expressed the desire to definitively address the core issue of the human embryo’s moral status, particularly during their March 1999 meeting, a public-policy framing precluded substantive treatment of the embryo’s moral status, further narrowing NBAC’s analysis.

Towards the end of NBAC’s April 1999 meeting, Chairman Harold Shapiro invited the other commissioners to consider the relative merits of discussing a range of views and deriving a position, rather than taking

¹² Following his lengthy clarification, Shapiro asked the commission whether they still agreed to the funding approach; several commissioners conveyed their agreement, and none dissented. My account in this essay should not be taken as an indication that Shapiro pressured the commission into taking a particular approach; Shapiro largely restricted himself to the role of facilitator, here paraphrasing and summarizing the commissioners’ discussion for the purpose of clarifying and forwarding their deliberations.

ethical stand. They may not agree individually on the morality of the various categories of embryonic stem cell research, he explained, but they could instead recognize “that there are differences of opinion on these issues in our country and we might feel that we have to recommend or should recommend something that is responsive to that fact.” The alternative, stated Shapiro, was “to put forward, for example, a particular moral perspective that we would then have to argue dominates all the others, which, I think, as we all know, would be a difficult task” (4/16/99 Transcript, p. 253-54).

In apparent concordance with the concerns Shapiro raised, the commission avoided making a strong moral argument about the moral status of embryos. But NBAC did adopt a moral stance on the issue. Critiquing NBAC for failing to advocate a fair compromise between liberal and conservative viewpoints, John Fletcher argues that

When the analogy between permissible abortion and research on hES [human embryonic stem] cells broke down, NBAC turned to urging a benefit:harm ratio. Ultimately it took the position that embryos are forms of human life but not human subjects of research. Whereas the couple who donate gametes are clearly subjects for purposes of research conducted on their embryos, the embryos themselves are not yet fully subjects. In short, NBAC took a stand on the moral status of the embryo, but simply asserted this stand and did not provide convincing argument for it (Fletcher, 2001, p. 32).

The commission drew attention away from the fact that it was indeed taking a moral stance, by reviewing the different viewpoints on the issue, and

justifying its own position as “an intermediate position, one with which many likely would agree” (NBAC, 1999, p. 50).

The Morality of Federal Funding & Oversight

Having sidestepped incisive moral analysis of the human embryo, NBAC turned its attention to the issue of federal sponsorship of ESC research. As with the moral status of embryos, the commission constructed implicit rather than explicit normative claims. The issue was first raised during a February 1999 discussion about NBAC’s agenda, when Commissioner Holtzman asked whether they were in fact going to advocate federal funding. Commissioners Capron and Shapiro replied that no, it was not their job to set research priorities or allocate the budget.

However, other commissioners felt that the issue of research priorities was pertinent to their inquiry. Commissioner Lo raised the issue again in the April and May 1999 NBAC meetings. In April he asserted that they needed better information on the promise of adult stem cell research, to assess whether it should get federal funding preference over the more controversial embryonic stem cell research, and determine the scientific cost of such a preference. Commissioner Miike disagreed, stating that it was not their task to determine such priorities. It was not a matter of placing all bets on one avenue, he argued, but rather, the promise of adult stem cell research was

pertinent to assessing where they stood on the federal funding of research on stem cells from embryos created expressly for research (4/16/99 Transcript, p. 226-27). Later in that meeting, Shapiro reflected on their focus, stating the need to address federal funding, which was different than the general issue for society as a whole. Specifically, he argued, they needed to articulate the arguments for the benefits of federal funding, which was distinct from arguing that the federal government **should** participate in the research via sponsorship.

In May, Commissioner Lo again raised the issue of research priorities. This time, he acknowledged social justice concerns that had been voiced in a special meeting devoted to religious perspectives, concerns that can be addressed by research funding priorities. Chairman Shapiro responded that their restricted focus on federal funding **eligibility**, rather than advocating particular research priorities, allowed them to put aside distributive justice issues with respect to federal health care research funding priorities.

Although NBAC concluded that assessing federal research funding priorities and addressing the attendant issues of distributive justice were outside their purview, the commission's argument that certain categories of embryonic stem cell research were **appropriate** for federal funding effectively asserted that those categories of stem cell research **should** be a federal funding priority, because federal funding would enhance the progress

of stem cell science, and provide for federal oversight of embryonic stem cell research. The commission made implicit arguments in favor of federal funding, rather than explicit ones.

In order to explain the commission's argument for federal funding, it is necessary to review the functions attributed to federal research funding and oversight over the history of federal bioethics bodies, which have evolved and expanded over the last three decades. In reviewing research involving IVF and embryo transfer in 1979, the DHEW Ethics Advisory Board (EAB) noted "that the procedures may soon be in use in the private sector and that Departmental involvement might help to resolve questions of risk and avoid abuse by encouraging well-designed research by qualified scientists. Such involvement might also help to shape the use of the procedures through regulation and by example" (EAB, 1979, ch. 6 Section D.). Thus, the EAB argued that federal oversight (and by extension, federal funding) promotes the integrity and ethical conduct of research, by setting standards and modelling good conduct.

Although the 1988 fetal tissue research panel's report did not express them as explicitly, the considerations of good scientific conduct also figured heavily in the decision of the panel chair, Judge Arlin Adams, to vote for its recommendations in spite of his opposition to abortion. In her January 1999 NBAC testimony, Patricia King recounted Adams's reasoning:

He says he was able to concur in the report of the HIFFRA [sic] panel because he wanted to prevent commercialization of fetal tissue use... He thought that with Federal funding we could employ more careful scientific approaches as well as utilize the highest professional standards, and finally, he thought that without government funding research would be unsupervised and not governed by guidelines (1/19/99 Transcript, p. 110).

In 1999, NBAC gave federal funding and oversight even more moral import in the arguments of its stem cell research report, expanding it to include scientific productivity as well as integrity. In addition to reducing risks and misconduct in research, the conditions attached to public funding “can stipulate that recipients... must share both research results and research materials (including cell lines)” with other researchers. Accordingly, federal funding “may lead to more widespread dissemination of findings and sharing of materials, which ultimately may enhance scientific discoveries.” The final report further noted that “a combination of federal and private sector funding is more likely to produce rapid progress in this field than would private sector funding alone,” and “Federal funding is probably required in order for the United States to sustain a leadership position in this increasingly important area of research” (NBAC, 1999, ch. 4).

Making a more emphatic case for the merit of federal funding, Commissioner Miike argued during an NBAC meeting that

some form of stem cell research has to be funded by the NIH and Federal Government. And it's not just for the promise of the research, but I think that, and the scientists can correct me if

I'm wrong, but I think that this area has such a big promise that if the NIH is not able to fund in this area, they are going to be a defective organization in terms of research as the years go by. They will be shut off from an area of research that is going to be so fundamental to the mission of the NIH, that **it's going to be a defect to their mission** (2/2/99 Transcript, p. 80. emphasis mine).

From the preceding account, we see that the function of federal oversight and research funding has evolved in the discourse of federal bioethics bodies from that of safeguard and exemplar against misconduct, to a deterrent to commercialization, to a means to scientific openness and sharing, to facilitation of rapid scientific progress, to preservation of the competitive edge of U.S. science, particularly at NIH. Public-policy based bioethics discourse has legitimated not only regulation but public funding as a means to ensure ethically sound and productive biomedicine. By so endorsing the values of federal funding, NBAC made implicit normative claims that ESC research should receive federal funding. And although stem cell research was and is still in its infancy, the commission assumed that we can count on a future stem-cell therapeutic reality.

Furthermore, NBAC's stem cell report in effect transforms the public-policy value of scientific productivity and progress into a moral value. When NBAC invited expert witness David Blumenthal to speculate on normative themes that come up in his research, he raised this important but overlooked distinction:

Well, I sometimes have trouble differentiating between ethical norms and norms that are meant to get the most out of what we're doing, that are more productivity-oriented... People tend to invest academic norms like openness with ethical content. And I don't know whether they are appropriately regarded as ethical norms as opposed to characteristics of universities that render them best suited to furthering public purposes. (2/2/99 Transcript, p. 145)

The commissioners appear to share Blumenthal's difficulty in differentiating between ethical norms and productivity-oriented norms—in fact they conflate them. The technological imperative of ESC research thus becomes not only inevitable, but also ethical.

In the forgoing account we have seen that NBAC chose not to pursue incisive philosophical moral analysis about the status of human embryos and government funding of controversial research. At the same time, the commission made implicit normative claims about those issues; it essentially argued that embryos are forms of human life but not human subjects of research, and that the federal government **should** fund ESC research. Through NBAC, bioethics has blurred the boundaries between ethics and public policy, elevated the productivity of science to a moral imperative, and narrowed the debate to minimize issues of general public concern, including the moral status of the embryo, and the just distribution of federally and privately funded biomedical goods in society. These developments raise concerns about the ability of bioethicists and bureaucrats to uphold the integrity of science when it comes into conflict with the productivity of

science, and to define integrity and productivity in terms of the public good as well as the interests of the scientific enterprise.

Standardized Packages: NBAC's Recommendations

Neither the science nor the consequent therapeutic technology is certain, and thus neither is the ethicality of unfettered ESC research. Further ethical uncertainty is generated by the particular circumstances of each ESC derivation, and the particulars of each research study. In such situations, respectful, ethical treatment of embryos, ESCs, and human research subjects requires regulatory assurance. To deal with this inherent uncertainty, NBAC customized several existing standardized packages from the public-bioethics toolbox for its recommendations, which were presented in its September 1999 report, *Ethical Issues in Human Stem Cell Research*.

NBAC began by articulating that certain types of ESC research should be **eligible** for federal funding, based on the sources of ESCs used in the research; cadaveric tissue, excess embryos from infertility treatment were deemed to be ethical sources of ESCs for research. Federal funding would enable the imposition of federal regulation to assure that the research met ethical standards. The rules and procedures required by the federal regulations, and the funding mechanisms that require their use, constitute standardized packages, which serve to stabilize tensions between science and

politics/ethics. Over the last three decades, federal bioethics bodies have variously promoted federal funding of controversial embryo research as a safeguard and exemplar against scientific misconduct, a deterrent to inappropriate commodification, and a means to scientific openness, rapid scientific progress, and US technological (and thus economic) competitiveness (see Leinhos, 2002). Indeed, NBAC cited nearly all of these as arguments in favor of selected federal funding of ESC research.

Secondly, NBAC recommended detailed informed consent and donation practices for the donation of so-called excess IVF embryos, modeled on organ and fetal tissue donation guidelines, to guard against coercive and other inappropriate incentives to donate.

Third, NBAC carefully outlined a three-tiered oversight system for federally funded ESC research, in the interest of dividing the labor while avoiding the moral hazards of self-policing. At the topmost level, a National Stem Cell Oversight and Review Panel (National Panel), housed at the Department of Health and Human Services (DHHS), would develop standard guidelines for protocol review at all levels and coordinate a variety of integrity assurance mechanisms (which will be discussed below). At the local level, institutional review boards would assure researchers' compliance with the National Panel's and other existing ethical guidelines for research conduct. To guarantee uniform ethical practice at government agencies, those

agencies sponsoring ESC research would ensure that agency-level review complied with the National Panel's requirements. Via the peer review process, agencies would give special attention to adequate justification for ESC use, as signified by each project's scientific merit.

Finally, NBAC called for voluntary compliance with and participation in the federal oversight mechanisms by privately funded researchers conducting research eligible for public funding, and for voluntary development of and compliance with private industry research safeguards and standards for research ineligible for public funding (e.g., research with ESCs derived through SCNT techniques).

NBAC's stem-cell research recommendations, not surprisingly, consistently serve the mutual interests of science and policymakers, even as those policymakers occupy different branches of government, and represent interests that at times compete. An examination of the proposed responsibilities of the National Panel illustrates this convergence well. First, the panel would review ESC derivation protocols, approving acceptable ones and certifying cell lines derived via them. Then, the panel would maintain a national public registry of approved protocols and certified cell lines, and it would link the registry to a panel sponsored public database of identifying information, data, and publications connected to approved protocols and cell lines. Finally, the panel would use the registry and database to track the

history and use of certified cell lines and report periodically to the DHHS secretary on the state of stem cell science and its attendant ethical concerns, re-evaluating the continued adequacy of NBAC's regulatory recommendations.

Clearly, the panel's suggested activities would not only provide means to and indicators of the assurance of scientific integrity in ESC research, but it also would coordinate and facilitate the entirety of the American stem cell research enterprise, by providing a centralized database of information on stem cell research. That is, the National Panel would function to assure both the integrity and productivity of stem cell science, mutually desired by the scientific community and the federal government. The panel's activities also serve to legitimate the field of bioethics as a mediator, by continuing the call for the services of bioethics experts, and by perpetuating the standardized packages developed in collaboration with those experts.

The measures that NBAC recommended were crafted to manage the scientific and ethical uncertainties that contribute to the tension of the stem cell research controversy. If the recommendations were fully implemented, the impact of uncertainty would be controlled and diminished through the use of standardized packages, by breaking the uncertainty into bite-sized procedures protocol by protocol.

However, NBAC lacked any effective standardized packages for dealing with the uncertainty of how their recommendations would be received, and whether they would in fact be implemented. Many government organizations, particularly those with relatively short track records, face similar uncertainties and are susceptible to whichever way the political winds are blowing. But advisory bodies appear to be particularly insecure in their ability to succeed as boundary organizations. Their ability to stabilize and contain the science-politics boundary at the site of controversy is often limited to the time frame during which the bodies' deliberations occur, unless their recommendations are implemented, or they are given some "action-enforcing power"-the authority to command either the acceptance of their recommendations by an executive official, or a public accounting of reasons for the official's rejection of the recommendations (Bulger et al, 1995).

Although the Clinton administration immediately distanced itself from NBAC's recommendations (Marshall, 1999), it appears that NBAC may have had some influence on the decision for NIH to implement a stem cell registry similar to that recommended by NBAC. Like the Human Embryo Research Panel before it, NBAC incited pro-life sensibilities by recommending a relaxing of federal embryo research restrictions, and contributed to congressional foment on the issue. But ironically, this may have had the effect of strengthening NIH's position in the political struggle, by making its

advocacy of limited embryonic stem cell research appear relatively moderate (Fallows, 1999). In the end, NBAC may have strengthened arguments in support of stem cell research, making it politically impossible for President Bush to prohibit stem cell research altogether, two years later. In a less conservative political climate (or perhaps at some future date, as implied by Commissioner Holtzman), NBAC's recommendations might have been implemented, and accordingly might have stabilized the science-politics boundary effectively through the execution of the various standardized packages advocated.

Conclusion

In this chapter, I have examined boundary work performed by NBAC in the controversy surrounding embryonic stem cell research, at the boundaries between science and ethics, and between ethics and public policy. I described the coupling of scientific and ethical uncertainty, and the coupling of research productivity and integrity assurance at these borders in the commission's deliberations on embryonic stem cell research, and argued that NBAC's boundary work served ultimately to reinforce the authority of science and marginalize the contrary moral concerns of some citizens.

The analysis in this chapter indicates that taking a public-policy approach in the bioethical argumentation of advisory bodies has significant

implications for the nature of the arguments and recommendations produced by those advisory bodies. If policy-makers frame the charges of advisory bodies for the purposes of political conflict management rather than purposes of genuine ethical inquiry, the output of advisory bodies may well limit debate in ways that privilege some societal interests over others. The public good would perhaps be better served by thoughtful construction of advisory body charges that specify inquiry of difficult questions, and attention to a variety of perspectives on those questions.

From an STS perspective, the chilly reception of NBAC's stem-cell research recommendations might be viewed as something of a default victory for participatory science policy rather than a boundary organization failure. Ideally, participatory science policy fosters access and inclusions of civic perspectives in the policy process, beyond the institutionalized elite viewpoints that dominate science policy, resulting in more balanced and informed public debate and decision-making (Kelly, 2003). Policy decisions subsequent to the release of NBAC's recommendations that take a more cautious and conservative approach to ESC research reflect the moral reservations of many citizens, although President Bush's decision to allow some federally funded research on a limited number of established cell lines managed to offend both moral conservatives and the scientific community (the available cell lines could not provide the basis for robust science).

Federal bioethics bodies might more effectively serve the public good and the multiple interests it represents by resisting political pressure and pursuing richer ethical inquiries. In a step towards such an approach, the charter of current President's Council on Bioethics stipulates that "the Council shall be guided by the need to articulate fully the complex and often competing moral positions on any given issue, rather than by an overriding concern to find consensus." However, the appointed roster of the Council includes only academics and no laypersons, placing the onus on the Council itself to seek and incorporate broad-based public input into its proceedings. Furthermore, accusations by a former Council member that the science presented in the Council's report on stem cell research was tainted by political bias suggest that the current iteration of public bioethics in the U.S. is not succeeding in meeting the ideal of participatory science policy (Blackburn, 2004; see also related Letters to the Editor in July 15 2004 issue of the New England Journal of Medicine).

Guston (2000, p.152) suggests that boundary work performed outside the confines of a boundary organization may be "worrisome," because, "there is nothing to prevent the boundary work, necessarily laden with interests, from being self-serving to the extreme. Outside of boundary organizations, outcomes are therefore more likely to be determined by the exercise of power." Because boundary organizations are beholden to two sets of

principals with overlapping but different aspirations, they can be expected to stabilize the science-politics relation without favoring one over the other. However, to the extent that science and politics exercise joint power to achieve mutual goals, the boundary work performed within science-politics boundary organizations may also be determined by the exercise of power, to the exclusion of interests outside the state and the scientific community. Furthermore, the boundary organization may serve to protect that exercise of power, assisted by the specialized mediators who have constructed a professional jurisdiction by serving the mutual interests of their political and scientific principals.

By arguing in effect that the biomedical benefit of stem cell science outweighed concerns about strong respect for embryos, NBAC coupled the concepts of scientific integrity and productivity as they apply to stem cell research, and combined the assurance functions for both. The risk of this combination is that productivity concerns may come to overshadow other values that associated with scientific integrity in American society. The continued reliance of public bioethics on expert committees, which privilege the scientific model of knowledge production and argumentation, is unlikely to yield science policy that captures the full richness of societal debate on bioethical controversies.

CHAPTER 7—
DISCUSSION & CONCLUSION

The analysis contained in the preceding chapters makes it clear that the question whether bioethics is a lap dog or a watchdog to the biomedical enterprise, in addition to being a false dilemma, fails to apprehend the myriad social intricacies that constrain the capacity of bioethics to develop and promulgate a rigorous critique of biomedical research and practice. In Part I, we observed that academic bioethics is viewed by university administrators as a means to tap into opportunity structures and protect or legitimate biomedical research, at least in the case of Letters University. However, medical education accreditation and granting agency requirements also compelled Letters University to beef up bioethics, and medical school faculty and students appeared to be genuinely appreciative of having access to bioethics. On a deeper level, we also saw that isomorphic pressures can have a pervasive influence on the way that academic bioethics “does business”—by virtue of being expected to perform to the same revenue-generating and promotion and tenure standards as other units and faculty in the medical school, the Bioethics Center at Letters and its faculty members are substantially shoe-horned into the knowledge-production model of the academic medical center they call home. Furthermore, close association with academic medical culture and structure likely makes it more difficult for

faculty members at the Bioethics Center to forge effective relations with constituents such as nursing and marginalized extramural communities.

The strained relations between the Center and the IRBs at Letters attest to the motivation of Center faculty to assure the ethical integrity of human subjects research and the protection of participants. As research litigation increases, so does the opportunity for academic bioethicists to contribute to research ethics, both in the IRB office and in the courtroom, but in order to do so, they must determine how to interact effectively with the actors and structure of the IRB oversight system, which are as firmly rooted in the research culture and infrastructure of the academy as they are in the federal regulations mandating their existence.

In the realm of law, the bioethical expertise which is considered relevant to biomedical research and practice is governed by federal and state regulations, tort theories and the case law of medical malpractice, the nature of the advice sought by medical practitioners and researchers, and the insurance companies that might indemnify them. Health care ethics consultants appear to have considerable opportunity for input into what constitutes their accountable expertise by means of defining and promulgating formal core competencies and a code of ethics, which would be legitimated by the courts as a documented peer standard of care in any tort cases heard against ethics consultants. However, the reluctance of

bioethicists to firmly demarcate their expertise, due to the highly prided interdisciplinarity of the field, a liberalism-based aversion to claiming moral authority, and goals more aligned with an ideology of social trustee professionalism than an ideology of expert professionalism, make it unlikely that bioethics experts will capitalize on this potential.

The strength of the professional jurisdiction of bioethics is arguably based more on external legitimacy, **constructed by other actors**, whether opportunistically or morally founded, than it is on conscious strategic attempts of bioethicists to control or build their jurisdictional claim. As a relatively weak advisory jurisdiction to medicine, science, and increasingly, law, the usefulness and therefore much of the legitimacy of bioethical expertise is constructed by the needs and motives of these elite professional groups.

Graduate education in bioethics is a major source of external legitimacy for bioethics, particularly for establishing academic credibility within the academy. MBE programs provide formal legitimacy by signifying that bioethics is a “real” academic field, and by generating tuition revenues for resource-strapped postsecondary institutions. They also reinforce a cohesive and organized identity for the field, through the institutional isomorphism that will shape and homogenize MBE programs, and by

providing degree recipients with concrete explicit evidence that they are, indeed, legitimate bioethicists.

In the public-state arena of executive branch bioethics advisory bodies, the public discourse of bioethics is constrained by the dual Weberian rationalization imposed by the institution of science, on the one hand, and by the liberalism-based public-policy approach of the state, on the other. The outlook for an autonomous and influential policy advising voice for bioethics is made all the more bleak by the close-knit interdependence of science and the state in modern US society, fueled by federal science policy and culminating largely in the knowledge-production engine of academia, also primary institutional headquarters of bioethics. The presence of bioethics in federal public policy has been legitimated by the institutions of executive advisory bodies and oversight procedures, but at the cost of incisive moral analysis of the truly divisive issues of the day.

Implications for Theory of Professions

Abbott (1988) argues that the primary limitation of the theoretical concept of professionalization is its focus on structure rather than professional work, and employs the system of professions as the central unit of analysis. In keeping with this, I have conceptualized the work of professions primarily as boundary work, and examined the boundary work

performed by bioethicists in the workplace, legal, and public arenas.

Additionally, I have relied upon organizational theory to develop an account of the distinctive institutional constraints governing the boundary work of bioethics, which must engage with the institutions of academe and the state, which produce and regulate the biomedical research and practice bioethics purports to advise.

Abbott (1988; 1991) has also chastised the tendency to reify professions and professionalization, which obfuscates some of the intricacies of expertise, power, and work in the social world. The work presented here provides more reason not to essentialize professions. Bioethicists, although seeking the power to influence biomedical research and practice, are explicitly ambivalent about professionalizing, as evidenced by their discourse, and by what is **not** in their discourse: namely, required competencies, accreditation, certification, and a professional code of ethics. Bioethics is intentionally and proudly interdisciplinary, non-exclusionary, and antiauthoritarian, though in an inverted sense: they are against their **own** (moral) authority, more than they are against the (expert) authority of others. And while bioethics does at some level seek to limit the authority of biomedical science when it violates ethical norms, its biotechnofetishism belies the underlying assumption that bioscience can, and perhaps should, leave no stone unturned on the road of progress. Perhaps more unfortunately, bioethicists' general penchant for

genetic gadgetry overshadows more mundane, and far more pervasive ethical challenges in medical care and research that would arguably benefit from more bioethical scrutiny, such as achieving a more just distribution of healthcare resources nationally and globally.

The preceding chapters also remind us that there is more to look for in the system of professions than jurisdictional contests. One searches in vain to find any other professional groups competing for the jurisdiction of bioethics, although the clergy would perhaps compete if they had more authority in the contemporary era. The lack of challengers to bioethics is partly because of the fact that all newcomers to the jurisdiction are welcomed into the bioethics community with open arms; the only qualifications are deep first-hand familiarity with biomedical practice, and one or more of several expertise sets that illuminates the social challenges that arise in biomedicine. With that established, prospective competitors are merely assimilated into the community. Philosophers and social scientists, to the extent they are able to overcome their own aversion to mucking about in real-world problems and making normative claims, may venture into the bioethics discourse from the comfort of their disciplinary homes, at the risk of derision from their department colleagues. But more important than the lack of serious contenders for the jurisdiction of bioethics is a distinctly symbiotic relationship between the bioethics and biomedical jurisdictions. The

institutions of bioscience and medicine, and the state, are well served by sustaining the advisory jurisdiction of bioethics, because it serves to buffer them from politics and controversy, and legitimate their activities. In this respect, the bioethics jurisdiction serves as a sort of boundary organization as described by Moore (1996), one that enables biomedicine to simultaneously maintain credibility as a scientific enterprise and as a professional community serving the public good in an ethical manner.

Abbott's account of professionalization does not adequately account for the state of professionalization or discipline formation that bioethics represents and shares with the field of higher education. Neither field has become a full-fledged profession, or developed a distinct disciplinary identity, but rather they have persisted in a quasi-professional state with no culminating metamorphosis in sight. Perhaps they instead represent a new class of emerging inter-disciplines that develop flexible expertise to train the flexible workforce of the new economy. These fields, developing during the ascendance of the academic capitalist knowledge/learning regime, draw from various knowledge sets to forge hybrid expertise to address problems stemming from the simplification of knowledge to raw material for economic productivity. However, bioethics is still rooted in the public good knowledge/learning regime, grappling the purposes of both.

In Abbotts' theoretical frame, professional legitimacy in the legal arena is quintessentially associated with successful lobbying for state licensure of a profession. However, there are a few other ways in which professional groups can achieve legitimacy in the legal arena, which are deserving of more study. In the contemporary litigious society, professional liability presents itself as an ironic form of legitimacy worthy of exploration. Claims of professional negligence or malpractice must be proven in court by demonstrating that a professional standard of care has been breached. The professional standard of care is a matter of expert knowledge, evidenced by formal professional discourse and the testimony of expert witnesses. In addition to liability, legal legitimacy of expertise may be conferred by several means, including statutes which encourage or require the use of expertise in certain circumstances, such as the required use of ethics consultants in controversial patient-care decisions; the codification of certain expert concepts into regulations, such as the requirements of informed consent in the Common Rule; and statutes conferring special immunity to certain expert decision makers in service to government institutions. Examining boundary work aimed at establishing expertise related to these claims in the legal arena can provide insights into the legitimacy and logic of the expertise in question.

Bioethics & the Fourth Estate: Bane & Boon

Noting the greater per capita quantity of radios and televisions in the US compared to Britain and France, Abbott construes that “pervasive media have thus kept the public arena central for professional claims in the United States” (1988, p. 165). The role of the media cannot be overlooked in an account of the logic and legitimacy of bioethics in the US.¹ In Part Two, we heard concerns expressed by established and future bioethicists that the field is too media-driven, and it is important to reflect on the way that media presence both legitimates and shapes bioethics.

The media represents a double-edged sword for bioethics. On the one hand, attending to current events does establish the relevance of bioethics to the public, and more importantly, provides a powerful megaphone for the voice of bioethics (Simonson, 2002; Hopkins, 1998). This megaphone can be wielded defensively as well as offensively, affording bioethicists limited protection from reprisal, on pain of bad press for the retaliator. On the other hand, a media orientation has a negative impact on academic credibility, as well as the reflexive capacity of the field, due to the reactionary, urgency-driven firehouse model of knowledge production it results in. Furthermore, ethicists who engage with the media are subject to the constraints of

¹ In the information age, the relationship of bioethics to the media arguably deserves attention in other nations as well. For an account of bioethics in the German media regarding preimplantation genetic diagnosis, see Graumann (2000).

journalism, the most significant one being the need avoid offending sponsors and corporate interlocks.²

Acknowledging that journalism constitutes “a special and crucial sub-region of the policy process,” Goodman (1999, p. 182) criticizes journalists’ common use of ethicists to pass moral judgment on news issues, and argues that journalists and ethicists have a responsibility to collaboratively cover issues and arguments without oversimplification, and to present intelligent disagreements without indulging in moralizing. But even poor media coverage has value to bioethics; Simonson contends, “bioethics can benefit from even the most sensationalized, sound-bitten and superficial portrayal. Every time such a story appears, the public significance of bioethical issues is reconfirmed” (2002, p. 35). The boundary between bioethics and journalism is clearly worthy of attention by sociologists of bioethics, and of reflection by bioethicists.

Implications for Higher Education Studies (HES) and Science & Technology Studies (STS)

The work described in the preceding pages contributes to HES and STS in several respects. First, I have focused attention on several aspects of knowledge production, a subject rarely addressed in HES. By conducting a

² For an account of the constraints faced by science journalists, see Nelkin (1995).

case study of the development of an academic bioethics C&I, I have given attention to discipline formation and examined the engagement of faculty with institutional pressures that shape their work, illustrating how the academic capitalism knowledge/learning regime impacts the knowledge faculty members produce. This study also sheds some light on the ways in which knowledge produced in the academy is linked to the larger culture in the legal and public arenas. By demonstrating how bioethics is affected by and engaging in academic capitalism, I extend Slaughter's and Rhoades' (2004) analysis of academic capitalism beyond hard science and technology fields linked more directly to the new economy. Bioethics may be viewed as an interstitially emergent function, cultivated not to manage activities directly related to the generation of external revenues, but rather to manage the political and social implications of revenue-generating biomedical science activities. Rather than technology transfer, bioethics manages cultural transfer of scientific results.

With respect to STS, the research described here places emphasis on the institutional conditions of knowledge production, and postsecondary educational institutions in particular, which have received little attention in STS. This dissertation also makes the case that bioethics is worthy of serious scholarly attention, and not "just politics" as some STS scholars have suggested (Leinhos, 2002). While it is true that bioethics is political, simply

saying so, without examining the ways in which bioethics is political and why, fails to appreciate the complex challenge of seeking institutional legitimacy and simultaneously working to speak truth to power. Bioethics faces significant institutional pressures as it seeks to advance social welfare goals in the new economy, and as its products, such as the informed consent process, are co-opted by other stakeholders for other purposes (for example, institutional use of consent forms as a protection against legal liability).

In fact, STS shares several instructive similarities with bioethics. Both have established interdisciplinary, weak advisory jurisdictions to science, and both were initially accepted in this role by the scientific community on the premise that these fields might serve as boosters to institution of science, and defuse some political criticisms of science (Winner, 2001). The science wars have soured the relations between STS and the science community, possibly permanently. Will bioethics eventually suffer from the same rift? At this time that seems unlikely, given that bioethics is more regularly accused of getting too intimate with biomedical corporations than of being too critical of biomedicine. This possibility is made further unlikely by the close relationship of bioethics to medical education and practice. Bioethicists must immerse themselves in the culture and assumptions of medicine in order to provide meaningful and valuable

expertise to medical professionals, and face disincentives to criticize that culture in a systematic way.

The Legitimacy and Logic of Bioethics

In order to influence even a small aspect of the social world, one has to participate in it. Achieving influence requires legitimacy, which can only be obtained by playing part in the existing institutions, cultures, and power structures, which in turn means being shaped by those institutions and power structures, throughout the social nexus.

The predicament of bioethics has some strong parallels to the challenge faced by AIDS activists in impacting AIDS research and drug development. In order to achieve credibility with the research establishment, activists needed to become scientific experts. But developing scientific expertise exposes activists to the lure of science, the seduction of knowledge and power, and inevitably moves them closer to the scientific worldview. “Ironically, Epstein observes, “insofar as activists start thinking like scientists and not like patients, the ground for their unique contributions to the science of clinical trials may be in jeopardy of erosion” (1996, p. 342). Some thoughtful activists are “reflexively engaged” in addressing such issues, and acknowledge the value of continual connection with the more visceral perspective of persons living with AIDS (Epstein, 1996).

Bioethicists face a considerably more difficult challenge establishing some reflexive distance from the seduction of biomedicine. Whereas many AIDS activists are themselves persons living with AIDS, and are thus dependent on AIDS research that both develops effective treatments and accounts for the human needs of AIDS patients, the dependency of bioethics on biomedicine takes a less explicit, less visceral form. The legitimacy bioethics depends on its ability to produce something of value to science, medicine, and the state, including both useful, substantive advice, and ethical authorization of scientific and medical progress. If bioethics is to earn legitimacy from the public as a watchdog, it must judiciously leverage the power of the media, resist the unreflective firehouse model of knowledge production, maintain some reflexive distance from biomedical professions, and build close ties with its original constituents: patients, research participants, and marginalized communities. From the headquarters of the elite ivory tower, that is a tall order indeed.

APPENDIX A:
INTERVIEW SCHEDULES FOR THE BIOETHICS CENTER CASE STUDY

Faculty Interview Schedule

A. General Questions

1. How long have you worked here?
2. How did you come to work here?
Why did you decide to work here?

B. About the Center

1. How does the Center compare to other bioethics centers around the country?
2. Describe the Center's role at Letters University.
3. What is the Center's role in the surrounding communities?
4. What external factors or influences have an effect on the Center?
5. How has the Center responded to these external factors or influences?
6. What predictions do you have for the future of the Center?
7. What has changed at Letters University since you have been here?
8. What has changed at the Center since you have been here?
9. Why was it decided to offer a Master's program at the Center?
10. What is the most important knowledge or skill students learn in the program?
11. What will a Master's degree do for program graduates?

12. How are students recruited and selected for the Master's program?
13. How does the Center's Masters program compare to Master's programs at other schools?
14. Has there been any change in emphasis with respect to the Center's teaching, research, and service/outreach activities?
15. Do Center faculty take a concerted, or directed, approach to bioethics methods and practice? Please describe it.
16. What factors go into promotion and tenure decisions?
17. Who is the audience or audiences of the Center's activities?
18. Please describe any relationships the Center has with other sectors and organizations, and how those developed.
19. What organizations and interests challenge the Center's influence and expertise?
20. How much political and intellectual clout does the Center have on campus, and why?
21. In local communities? Why?
22. At the national level?
23. Does the Center make efforts to shape Letters University policy, or public policy?
24. What policy goals does the Center support?

C. About faculty work

1. Please describe your service and outreach activities as a Center fellow.
2. What factors go into your selection, creation, and design of research, teaching, and service projects?

3. What particular types of funding, or particular sources, have you sought, and why?
4. Have you been approached by potential sponsors to conduct projects?
Explain how
5. Please describe consulting activities you have been involved in. How did they come about?

D. About the field

1. What is the nature of the relationship between bioethics and academic biology and medicine?
2. What relationship does bioethics have with university administrators?
3. What relationship does bioethics have with industry?
4. What relationship does bioethics have with government?
5. What are the goals, or what is the task, of bioethics?
6. The appropriate role of bioethicists?
Probe: Erik Parens has stated the role should be "gadfly"
7. What is the biggest challenge for bioethics?
8. What progress has been made?
9. What most needs attention?
10. Do you feel that other groups or organizations are trying to use bioethics or bioethicists for their own purposes?
Please explain
11. Those who are generally recognized as bioethicists have a variety of credentials and experiences, seemingly with no necessary commonalities. What distinguishes a true bioethicist?
12. Do these criteria match with public perceptions of bioethicists?

13. What is the biggest challenge for bioethics in becoming a distinct profession?
14. Should bioethics become a distinct profession?
15. Is bioethics an academic discipline in its own right, or becoming one?
16. What predictions do you have for the future of bioethics?

Is there anything you would like to add?

Staff Interview Schedule

A. General Questions

3. How long have you worked here?
4. How did you come to work here?
5. What is the nature of your work?
6. What are your career goals?

B. The Center

1. Describe some interesting or outstanding characteristics of the Center.
2. How would you describe the Center's students?
3. How would you describe the Center's staff?
4. How would you describe the Center's faculty?
5. Describe the Center's role in ethics on campus.
6. What is the Center's role in bioethics in the the surrounding communities?
7. What external factors or influences have affected the Center?
8. How has the Center responded to these external factors or influences?
9. What sort of relationship does the Center have with other organizations on campus, such as the medical school?
10. What sort of relationship does the Center have with the university's central administration?
11. What has changed at Letters University since you have been here?
12. What has changed at the Center since you have been here?

13. Why was it decided to offer a Master's program at the Center?
14. Who is the audience or audiences of the Center's activities?
15. What particular types of funding, or particular sources, has the Center sought out, and why?
16. Please describe for me any relationships the Center has with other sectors and organizations, and how those developed.
17. How much political and intellectual clout does the Center have on campus, and why? In local communities? Why?
18. What organizations or groups challenge the Center's influence and expertise?
19. Does the Center make efforts to shape university policy, or public policy?
20. What policy goals does the Center support?
21. What predictions do you have for the future of the Center?

C. About Bioethics

1. What, in your view, is the goal, or task, of bioethics?
2. What distinguishes a true bioethicist?
3. What is the nature of the relationship between bioethics and academic biology and medicine?
4. What kind of relationship do bioethicists have with university administrators?
5. What kind of relationship does bioethics have with industry?
6. What kind of relationship do bioethicists have with government?
7. Do you feel that other groups or organizations are trying to use bioethics or bioethicists for their own purposes?

Please explain

8. What predictions do you have for the future of bioethics?

Is there anything you would like to add?

Student Interview Schedule

A. General Questions

7. How long have you been a student here?
8. Describe some interesting or outstanding characteristics of the Center.
Academically
Socially
9. How would you describe the Center's students?
10. How would you describe the Center's staff?
11. How would you describe the Center's faculty?
12. Describe the Center's role in ethics on campus.
13. What is the Center's role in bioethics in the surrounding communities?
14. What external factors or influences have affected the Center?
Probes:
Community
Current events/Politics
Economic
15. How has the Center responded to these external factors or influences?

B. Questions about Graduate Work:

1. What are your career goals?
2. Why did you decide to pursue a Master's in bioethics?
3. Why did you choose the Center's program at Letters University?
4. What were your expectations of the program when you began?
Level
Academic character

Content

5. Have your expectations been met, so far?
6. Have your expectations changed?
7. What do you think you are getting out of the program?
Personally
Conceptually
Career-wise
8. What use do you think a Master's in bioethics will be to you?
Personally
Career-wise
9. Please describe any financial assistance the Center offers to students.
10. Are you participating in any faculty research projects, or doing other work for faculty? Please describe your involvement.

C. About Bioethics

11. What do you see as the goals, or task, of bioethics?
12. Have your views on the goals of bioethics changed since you entered the program?
13. What progress has been made towards the goals of bioethics?
14. What still needs to be done?
15. Do you think bioethics is a profession?
16. What distinguishes a true bioethicist?
17. What predictions do you have about the future of bioethics?

Anything you would like to add?

APPENDIX B:
METHODOLOGY—
NBAC'S DELIBERATIONS ON EMBRYONIC STEM CELL RESEARCH

Over the past three decades, the US federal government has called upon bioethics experts to assist in the navigation of policy dilemmas posed by new biomedical technologies and their societal context. Several bioethics commissions have provided bioethics with a formal role in US federal governance, the most recent being the National Bioethics Advisory Commission (NBAC) created by President Clinton in 1995. The NBAC's charter expired in October 2001; in August 2001 President Bush established a commission devoted entirely to human stem cell research, to be headed by bioethicist Leon Kass.

Federal advisory commissions provide a more prominent role for bioethicists in constructing boundaries of their own and others' expertise, compared the judicial forum. However, the roles of bioethicists are here constrained by their organizational structure: a presidential advisory commission. How do NBAC commissioners construct themselves and other constituencies in the policy arena? How does boundary-work performed by NBAC commissioners and their discourse affect the legitimacy and logic of bioethics? In what ways does the NBAC itself constitute a boundary

organization? To what extent do the ideals of the original bioethics social movement remain intact?

This study used the published reports, meeting transcripts, funding data, and charter of the NBAC (much of which is available online at www.bioethics.gov), as well as commissioners' outside publications, secondary literature about the NBAC and prior bioethics commissions, and the more general literature on presidential commissions. Biographical career data of commissioners was collected.

I conducted discourse analysis on the meeting transcripts and reports of NBAC relating to the stem cell controversy. To guide my analysis of the meeting transcripts, I generated summary forms, and read the transcripts carefully using categories and questions derived from my research questions. See blank summary form following this narrative. I also took detailed notes of the meeting proceedings and analyzed them for emergent themes and boundary-work.

Several features of the NBAC make it a suitable research site for studying federal policy discourse. Bioethics issues are the focus of various federal activities, particularly at the National Institutes of Health. However, NBAC is a high-profile setting, issuing reports and recommendations on several issues. The historical context of NBAC includes other centrally located federal bioethics commissions, including the influential President's

Commission, each with different effects on public policy, providing a comparative context for analysis of NBAC activities. NBAC commissioners come from various social spheres, and include several high-profile academic bioethicists, providing an analytic link between academic and government activities and concerns. While the advisory-only status of the NBAC is potentially detrimental to its policy impact, the non-binding nature of its recommendations provides an opportunity to examine the treatment of bioethics issues in the executive branch, visible as the extent to which recommendations translate into action or codified procedures. Non-binding recommendations also maximize opportunities for other stakeholders to co-opt or critique recommendations and justifications for their own purposes, appropriate to the study of legitimacy and knowledge production.

This investigation focused on the issue of human stem-cell research in NBAC discourse. Like the issue of human cloning, stem-cell research is rich in both scientific and ethical detail. However, stem-cell research has more extensive medical applications than does human cloning, and its realization as a useable biotechnology is closer to fruition than human cloning. Thus stem-cell research has promising commercial implications, and the policy discourse can be examined for the interactions of commercial pressure with bioethics legitimacy and concepts. Stem-cell research thus provides a model controversy for examining boundary-work performed by scientists and

ethicists, as they negotiate the tensions of academic and entrepreneurial interests.

**NBAC Meeting
Transcript Summary Form**

Meeting dates:
Summary date:
Transcript page count:

Prior events involved/discussed:

Commission Agenda & Testimony Presenters:

Main themes & issues addressed:

NBAC Personnel

- Who appears to be absent?
- Who fails to contribute substantively to the discussion?
- Who features prominently in the discussion, and how?

Relevance to my research questions:

- Institutional, resource, and role constraints
- How commissioners construct themselves, witnesses, and other constituencies
- How NBAC constitutes a boundary organization
- Boundary-work performed
- Impact of boundary-work on legitimacy and substance of bioethics
- Network linkages to other organizations

Other salient observations

New questions, hypotheses, speculations emerging from the transcript

What warrants closer scrutiny in further analysis of this transcript?

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