Seattle Journal for Social Justice

Volume 3 | Issue 1 Article 37

11-1-2004

Ethics2: The Ethics of Bioethics in the Biotechnology Industry

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I. INTRODUCTION

Medical and scientific research today is being driven by private, for-profit biotechnology corporations, either acting alone or through collaboration with academic institutions in the form of large medical-industrial complexes. This alignment of the scientific academy with corporate capital is reaping enormous scientific dividends, with the potential for equally enormous financial gain. In fact, the linking of academic institutions and the scientific imperative[2] with the financial capital and profit motivations of the corporate sector has created something of a perfect storm.

The public has been assailed over the last several years with news of scientific breakthroughs regarding stem cell technology, therapeutic cloning, and reproductive cloning. The speed at which these developments have occurred has been awe inspiring, but also somewhat alarming if one believes, as I do, in the importance of reasoned, thoughtful discourse on this kind of research and its implications for society. If the research directions and decisions are being determined within the private boardrooms of corporate America (and the world), one might reasonably ask whether the wealth of bioethics literature, the public discussions, the presidential bioethics commissions, and the national advisory boards are having any impact at all on that decision making. In other words, is there room for bioethics discourse in the boardroom? If so, who will initiate it? How would a private, for-profit corporation create an ethical climate for decision making that welcomes and takes into account bioethics theories and principles?

Perhaps because I teach Bioethics and the Law, Professor Lynne Dallas's work on ethics and corporate climate[3] started me thinking about the application of her theoretical approach to this realm of bioethics. More specifically, I wondered how this kind of analysis might be applied to that of the biotechnology industry and the medical research enterprise, a setting that is a step removed from the direct delivery of health care services.

Given the enormous financial and scientific incentives at play, it seems a timely and potentially fruitful enterprise to apply the lens of corporate theory to bioethics decision making within this sector.

This article begins in Part II with a brief description of bioethics as a discipline, with particular emphasis on the role of bioethics discourse and discussion in the current societal debate over human stem cell research and therapeutic cloning. Part III examines the trend within the biotechnology industry of utilizing private ethics advisory boards as a mechanism for incorporating bioethics analysis into the corporate decision-making process, with a focus on corporate stem cell research. Part IV then explores the structural components of corporate bioethics consultation, the identity crisis that this form of consultation has created within the field of bioethics, and the extent to which these attempts to bring bioethics into the corporate boardroom have been effective in creating a "bioethical climate" for decision making. The article concludes with the assertion that the biotechnology industry, in the highly contested realms of human stem cell and embryo research, bears a corporate responsibility to integrate bioethical analysis and discourse into its decision-making processes.

II. WHY BIOETHICS?

A. Bioethics Defined

Bioethics is a field of academic study that originated in the 1970s,[4] and is defined as the "systematic study of the moral dimensions—including moral vision, decisions, conduct, and policies—of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting."[5] Although once focused on principle-based ethical analysis (autonomy, beneficence, distributive justice), the field of bioethics has greatly expanded its repertoire to include narrative bioethics, critical race and feminist perspectives, Aristotelian virtue bioethics, ethics of caring, and theories founded on religion, casuistry,[6] pragmatism, and even law and

economics. Those who practice the art of bioethics show a similar diversity, coming from the ranks of philosophers, theologians, physicians, nurses, and lawyers. Although on-the-job training with hospital ethics committees and research review boards once was the norm, many bioethicists now hold graduate degrees in the subject.[7]

Bioethics as a discipline has come of age in the past decade or so, and its practitioners have become prominent and influential players in the public policy arena. Clinical and academic bioethicists, who hold staff positions within hospitals and tenured faculty positions within university-affiliated bioethics centers, are increasingly a force to be reckoned with as they opine to the media on virtually a daily basis, advise the president and the administration through membership on influential governmental bioethics commissions, and provide expert testimony at congressional hearings on bioethics matters. In fact, critics accuse the bioethics profession of having anointed its members as society's "philosopher-kings."[8]

Why has society been so eager to turn to these self-appointed experts? Although the reasons are undoubtedly complex, and far beyond the scope of this article, one reason stands out: scientific advancements have forced us to confront novel issues, and we have turned to bioethics to help us make sense of this brave new world where everything (physical appearance, life span, genetic composition, even death itself) seems subject to alteration and manipulation. Thus, the field of bioethics has been at the forefront on such issues as the right to die, physician-assisted death, abortion, human experimentation, organ donation and transplantation, genetic manipulation, and most recently, human stem cell research, and cloning. These latter two topics, stem cell research and the cloning of human embryos, have embroiled scientists, government officials, the biotechnology industry, bioethicists, and the general public in an intense debate over the ethics of research on human embryos, with some seeking an outright ban and others seeking to accelerate the rate at which this type of research advances.

B. Human Stem Cell Research

Human stem cells are extraordinary cells in that they are pluripotent, meaning that they have the capacity, under the right circumstances, to develop into any type of cell (blood, heart, muscle, liver, kidney, etc.). Although stem cells can be isolated in adults,[9] the most promising source is the very early embryo, more accurately termed a blastocyst. In early embryological development, these stem cells begin to migrate and eventually differentiate and develop into all of the tissues and organs of the human body.[10]

The scientific potential for human stem cells is enormous—stem cells could theoretically be coaxed to differentiate into brain cells to cure Parkinson's disease or repair a quadriplegic's severed spinal cord, into insulin cells to cure diabetes or heart muscle to replace tissue damaged by a heart attack. However, because extracting the stem cells requires destruction of the human embryo, their medical and scientific promise has run afoul of the right to life debate. In 1996, Congress had passed an amendment (the Dickey Amendment) to an appropriations bill for the National Institutes of Health (NIH) that banned any federal funding for research in which human embryos were damaged or destroyed.[11] The goal was to slow down or stop this kind of research; however, the result was just the opposite because embryo research did not stop—it just moved to the private sector, where it was and is still completely unfettered by governmental control.

In 1998, scientists working in the private sector announced that they had successfully extracted stem cells from human embryos and cultured them into stem cell lines, which could then be used for experimentation.[12] This announcement caused quite a public stir, prompting President Clinton to ask his National Bioethics Advisory Commission (NBAC) to prepare a report on stem cell research.[13] In 1999, NBAC issued a report that supported federal funding for stem cell research using embryos already in existence (for example, spare embryos donated by individuals undergoing in vitro

fertilization), but not for research involving embryos that were created specifically for the purpose of stem cell extraction.[14]

In the meantime, the NIH, which had opposed the amendment banning federal funding for human embryo research, decided to try an end run around it. The NIH obtained a legal opinion from the Department of Health and Human Services that stated that although the amendment prohibited the NIH from funding research that directly created or destroyed human embryos, the NIH could fund research on embryonic stem cells extracted from embryos that had been destroyed by someone else.[15] Based on this somewhat strained interpretation, the NIH proceeded to publish guidelines in August of 2000 for federally funded embryonic stem cell research. However, before the guidelines could be implemented, the 2000 presidential election resulted in a change in administration and a shift in stem cell politics.

In April 2001, Health and Human Services Secretary Tommy G. Thompson ordered a halt to the NIH review of funding proposals so that the administration could review the issue, which effectively blocked the NIH from providing federal funds for stem cell research.[16] A few months later, President Bush announced that he would allow limited federal funding for stem cell research, but only if the researchers used stem cell lines[17] already in existence as of August 9, 2001.[18] He subsequently created his own bioethics commission, the President's Council on Bioethics, and asked for a report on the ethics and science of human cloning and stem cell research.[19] After six months of study and debate, a divided council produced a report in July 2002 that called for a four-year moratorium on the cloning of human embryos, but declined to recommend a permanent ban, disappointing the White House and conservative groups.[20] Since then, numerous attempts to pass a federal ban on all cloning activities have failed to make it through Congress.

Despite all of the twists and turns on this issue in the public sector, privately funded embryo and stem cell research has continued unabated.

One of the issues that has arisen is how to prevent a person's immune system from rejecting the "foreign" cells and tissues that might be derived from embryonic stem cells. Scientists funded by a company called Advanced Cell Therapeutics (ACT) hit upon human embryonic cloning as a way around this problem.[21] Simply put, they extracted the nucleus of a somatic cell from an adult (for example, scrapings of cheek cells from inside the mouth) and injected it into an egg from which they had removed the nucleus. By using chemical or electrical stimulation, scientists were able to stimulate this cell to start dividing, producing a blastocyst or early embryo that was the identical genetic clone of the adult who had donated the somatic cell. The theory was that stem cells extracted from this cloned embryo would not be rejected by the immune system of the adult who, for example, needed new heart tissue or new insulin-producing cells. This process was termed "therapeutic cloning," or more precisely, somatic cell nuclear transfer.

When word got out on what ACT had done, all hell broke loose. In addition to the ethical issues posed by the creation of embryos to destroy them and the manipulation of human genetic material through somatic cell nuclear transfer, people were concerned that this work might lead to "reproductive cloning," in which the resultant cloned embryos were actually transferred to a woman's uterus and brought to term. It is a brave new world, indeed.

These scientific developments, the corresponding ethical issues they have raised,[22] and the rather anomalous lack of regulatory control over privately funded embryo and stem cell research within the biotechnology sector, have led to an interesting phenomenon in which some members of the industry have voluntarily sought to bring bioethics into their boardrooms.

III. PRIVATE ETHICS ADVISORY BOARDS

The private ethics advisory board is one of the emerging mechanisms being used by corporations to import bioethics analysis into the

biotechnology industry. Geron Corporation and Advanced Cell Therapeutics are two of the many companies that have instituted private ethics advisory boards, and their experiences provide useful case studies through which to examine the benefits and problems associated with bringing bioethics into the corporate boardroom. These case studies raise important questions as to whether the use of private ethics consultation is a genuine corporate effort to bring societal values and concerns to bear on contested areas of scientific research, or whether bioethicists are being co-opted and used in the pursuit of corporate profits.

A. The Geron Experience

Geron Corporation, a publicly held biotechnology enterprise located in Menlo Park, California, has been at the forefront of research involving human stem cells. Its founder, Michael West, has variously been described as a "merchant of immortality,"[23] "a headstrong provocateur,"[24] and "a corporate, religious, scientific P.T. Barnum."[25] In his quest to develop replaceable cells and tissues to combat the aging process, West realized early on the tremendous potential of human stem cell research. In the kind of collaborative arrangement between private industry and the scientific academy that is so common today, Geron signed agreements with James Thomson, a scientist at the University of Wisconsin, and John Gearhart, a scientist at Johns Hopkins School of Medicine, to fund their work with embryonic and fetal stem cells.[26] As a result of Thomson's and Gearhart's efforts, Geron announced on November 5, 1998, that its teams of scientists had succeeded in establishing cell culture lines of human embryonic stem cells.[27] This breakthrough had tremendous scientific implications, but it also raised profound ethical questions.

Because the work involved extracting and manipulating stem cells derived from blastocysts (early embryos) and aborted fetuses,[28] the research raised important issues regarding the moral status of the embryos, aborted fetuses, and the cells derived from them, as well as "questions about the

interplay between private funding and public oversight of morally contested research."[29] In recognition of, and in preparation for, the media frenzy and public outcry that would almost certainly accompany public disclosure of this research, Geron had created an independent Ethics Advisory Board (EAB) in early 1998 to consult and give advice to the corporation on the bioethical aspects of the research it was funding.[30]

The Geron EAB was made up of five individuals with health care ethics experience and a range of philosophical and theological backgrounds.[31] It met over a period of months preceding the November 1998 announcement to consider the ethical issues surrounding research on human embryonic stem cells, and ultimately concluded that this type of research could be conducted ethically.[32] The EAB, however, did delineate a number of ethical conditions for research using human embryonic stem cells.[33] The EAB also acknowledged the need for continued public discourse on such difficult ethical issues as who should control the disposition of embryonic or fetal tissue, the proper relationship between proprietary biotechnology companies and ethics boards, and the role of consensus on contested moral issues in a deeply pluralistic society.[34]

As expected, within weeks of publishing the data, Geron and the two teams of scientists who had done the actual work were swept up into a frenzied political, scientific, and public debate.[35] One element of Geron's corporate response to questions raised about the ethics of human stem cell research was to make available the Ethics Advisory Board report,[36] presumably to illustrate the company's responsible approach to research and to help justify its decision to proceed with embryonic stem cell research. Once the work of the Geron EAB became public, other biotechnology corporations saw the potential utility of implementing this model, and shortly thereafter, ACT commissioned its own independent bioethics board.

B. The Advanced Cell Therapeutics Experience

ACT is a privately held biotechnology corporation located in Worcester, Massachusetts; interestingly, its president and CEO is Michael West, the founder of Geron.[37] After leaving Geron in 1997, West moved to Advanced Cell Therapeutics and proceeded to position it to compete directly with his old company. Because Geron held the exclusive rights to the processes for obtaining human stem cells from existing embryos and aborted fetuses, West began looking for an alternative source of stem cells.[38] He found that alternative source through experiments involving the creation of cloned human embryos from which scientists could derive human embryonic stem cells.[39]

If Geron had been treading on morally unstable ground with its stem cell research using existing embryos, ACT was diving headfirst into quicksand in its attempt to clone human embryos. West was undoubtedly aware of Geron's Ethics Advisory Board, through his prior connection with that company and because the Geron EAB's workings and report had been made public. Not surprisingly, ACT soon had its own private ethics advisory board, staffed by individuals with experience in health care and bioethics.[40]

On November 25, 2001, ACT announced that it had successfully created the world's first cloned human embryo, setting off another firestorm of media attention and raising additional ethical concerns.[41] These flames were fanned by public statements made by Glenn McGee, a philosopher and assistant professor at the University of Pennsylvania Center for Bioethics, that he had resigned from ACT's Ethics Advisory Board in October of 2000.[42] His resignation had been prompted by an incident in which a reporter had asked him to make a televised comment on an unnamed biotechnology company that had cloned a wild gaur, an endangered species. Professor McGee went on record to say that the company was inappropriately "playing God," only to discover later that ACT was the company that had conducted the cloning research.[43] ACT's secretive

nature, exemplified by its failure to disclose or discuss this work with the EAB, was the final straw that led to McGee's resignation.[44]

When Professor McGee went public with his concerns in the wake of ACT's announcement that it was beginning to experiment with cloning human embryos, commentators began to raise questions about the ethics of these private boards and the individuals who agreed to serve on them. This was an absolutely fascinating development: the ethics advisory board model for the private industry had created a crisis in ethics for the very profession that held itself out to be experts on the subject—the bioethics community.[45]

IV. BIOETHICS IN THE BOARDROOM

Although corporate ethics advisory boards have received the most attention, some companies have sought professional bioethics advice without going through the process of creating their own ethics boards. For example, the Jones Institute for Reproductive Medicine, a private fertility clinic in Norfolk, Virginia, consulted three separate panels of bioethics experts before mixing eggs and sperm to create human embryos solely to harvest their stem cells for experimentation.[46] Because the Jones Institute refused to name the panels that had approved its work, it was not clear who had participated in the deliberations, where these panels had come from, or whether this was a one-time consultation or a continuing relationship.[47] Another mechanism used by corporations has been to seek counsel from an individual bioethicist rather than a group of experts. That this is a common occurrence has become apparent as bioethicists are increasingly pushed, as a matter of professional ethics, to disclose their working and financial relationships with corporations.[48]

Whether by bioethics advisory committee, outside panel, or individual consultation, the biotechnology industry is now regularly bringing bioethics into the boardroom. Some of the questions relevant to corporate ethics in health care are whether this practice reflects a shift or maturation in corporate culture—a concerted effort to create a "bioethical climate"[49] that

both supports and encourages bioethics discourse and deliberation—and whether this practice has a beneficial effect on decision making within the research enterprise.[50] The answers to these questions requires a more in-depth analysis of corporate motivation and the structural components of the relationship between corporations and their bioethics consultants.

A. Corporate Motivation

The motivation question asks why corporations are choosing to bring bioethicists into the corporate fold. Is it for the laudable goal of adding bioethics-based analyses (which would include societal costs and benefits) into the mix so that private corporate research agendas are not determined solely on the bases of financial costs and benefits to the particular corporate enterprise? In other words, are these companies making a sincere effort to internalize bioethical theory and questioning, seeking guidance on novel issues, so that bioethics reasoning becomes part of the corporate ethical culture? Or, are bioethicists and ethics advisory boards merely intended as window dressing? Are they merely public relations tools designed to placate and pacify the public and the media, providing the appearance of morality and concern for the larger looming social questions and lending credibility to otherwise troubling research, while the corporations continue their pursuit of purely profit-driven agendas?

When ACT's cloning of human embryos caused a public stir, ACT did not hesitate to justify its work on the basis of the Ethics Advisory Board's conclusion that the cloned embryos did not have the same moral standing as conventional human embryos.[51] Is this an example of a corporate enterprise engaging in ethical research, or is the EAB just a public relations ploy?[52] As is so often the case, the truth probably lies somewhere in the middle. Motivation is always difficult to discern, and even more so when the actor in question is a corporate entity, which may have a public face but multiple layers of private interaction. Furthermore, corporations can operate with mixed motives, and private profit-based motives sometimes align and

coincide with larger societal interests. To some extent, we are left to infer motive from the way in which corporations structure their relationships with bioethics consultants.

B. Structural Aspects of the Bioethicist-Corporate Relationship

1. Objectivity and Independence

If the societal goals of bioethics consultation are to be met, it is critical that the individuals reviewing the research operate with as much objectivity and independence as possible. However, as a practical matter, how truly independent can a private EAB be from the corporation that created it? Are corporate EABs or individual bioethics consultants predisposed in favor of their corporation's research agendas? The answers to these questions depend in part on the criteria by which the bioethicists are chosen, the existence of uniform standards for bioethics consultation, and the financial arrangements between corporation and ethics advisor.

a. Membership Criteria

What are the qualities that a corporate sponsor should look for when choosing the members of an ethics advisory board or hiring a bioethics consultant? What constellation of knowledge, skills, experience, and beliefs provides the ideal background for doing this kind of work? If a corporation desires a robust debate, a critical review of research proposals from a number of different perspectives, and a process wherein the hard questions are asked and advisors are encouraged to be thoughtful and comprehensive in their analyses and recommendations, the structure of the advisory body should arguably mirror the size and complexity of the task. This level of research review would call for perhaps ten to fifteen individuals with wide-ranging experiences and a broad variety of backgrounds and perspectives (for example, community activists, philosophers, theologians, scientists, health care workers and consumers, and lawyers).

Because ethical consultation is an entirely voluntary process, there are no rules or regulations regarding EAB membership. However, a useful analogy exists between the EAB and another type of board, the Institutional Review Board (IRB). By federal law, all research performed or funded by the federal government that involves human subjects must be reviewed by an IRB; the IRB's purpose is to protect human subjects.[53] Pursuant to the federal regulations, all IRBs must have at least five members with varying backgrounds, with at least one member having scientific expertise and at least one with a nonscientific background. No IRB can consist entirely of members of only one profession.[54]

The numbers for Geron's and ACT's EABs, however, are somewhat lower and the heterogeneity appears to be considerably less. Geron's EAB had five members;[55] ACT's had nine.[56] It is not at all unusual for biotechnology corporations to hire only one ethicist to provide consultation and review of its research proposals.[57] Furthermore, it seems likely that corporations "shop" for bioethicists who have previously taken positions consonant with the research the corporation wishes to undertake. Advanced Cell Therapeutics went so far as to allow one of the principal investigators in its human embryo cloning research to sit on its EAB and participate in the ethics review of that very same research.[58] This is perhaps an extreme example, but as Dr. Daniel Callahan[59] remarked, "These companies are smart enough to know that there are a variety of views on these subjects, and with a little bit of asking or shopping around you can find a group that will be congenial to what you are doing."[60] Of course, if corporations are engaging in this kind of viewpoint cherry-picking, they are just following the lead of our political leaders, who have done precisely the same thing when setting up governmental bioethics advisory boards and commissions.[61]

b. Uniform Standards

Given that the choice of bioethics consultants may well be skewed in favor of corporate research objectives, the application of uniform bioethics standards, both procedural and substantive, in corporate bioethics consulting would assist in ensuring the desired level of objectivity. This is where a comparison to outside, independent auditors in the ordinary corporate setting may be particularly useful. One of the protections of the business auditing system is that outside auditors operate under a set of nationally standardized and accepted accounting principles and procedures. Unfortunately, within the discipline of bioethics, virtually everything is contested: overarching theories, underlying principles, modes of analysis, and the relevance of value systems, including religious beliefs. In fact, one of the primary goals of bioethics as a discipline is to encourage people to ask questions, to discuss, to educate themselves, and to look at these contested issues from multiple perspectives. This inherently non-standardized approach makes it difficult to imagine that the analytical framework could (or should) be agreed upon in order to provide protection against corporate coercion and influence and to ensure objectivity on the part of ethics consultants.

c. Financial Relationship

Another important determinant of objectivity and independence is the nature of the financial relationship between the bioethicist and the corporation. Some commentators have questioned whether it is ethical for bioethicists to receive *any* compensation for this kind of work,[62] and the financial compensation issue is causing a schism within the bioethics community. Positions run the gamut from essentially "we shouldn't take a penny for providing this advice"[63] to "of course we should be well compensated for our expertise."[64]

If compensation is appropriate, and there is certainly a reasonable argument that bioethicists should not be expected to work for free,[65] then

what level of compensation is large enough to adequately compensate ethics board members for their time and expertise, but not so great as to render them mere shills of the corporation? Members of Geron's EAB received a $1,000 honorarium for each scheduled meeting with staff and officers, but they were not compensated for time spent researching and writing, and members did not hold any stock in the corporation.[66] The ACT advisory board members set their own compensation at the outset; they chose $200 per day plus expenses for attending four quarterly meetings of the board, with no additional compensation for time spent on research, telephone, or e-mail conversations.[67] Although these amounts seem relatively *de minimis*, there are reports of ethics advisors to corporations making tens of thousands of dollars per year.[68]

A task force on bioethics consultation proposed the following limits on compensation: no contingency fees; the rate of compensation and the value of any equity interest should not depend on the conclusions reached; the compensation should not be so great that the consultant would be embarrassed if the amount became known; and finally, the compensation should not be large enough that the consultant comes to depend on the income.[69] Of course, the fact that the task force felt the need to propose compensation guidelines reinforces the concern that some bioethicists are making substantial amounts of money by providing consulting services to biotechnology corporations, and perhaps compromising their professional integrity in the process.[70]

2. Timing

With the remarkable rapidity with which this kind of science is advancing, and the premium that the market places on being the first to do something (with the concomitant race to the patent office), the timing issue looms large. Given this emphasis on speed, how can a private ethics advisory board or individual bioethics consultant take the time necessary to educate, deliberate, and produce advice to the corporation that is reflective,

thoughtful, and comprehensive? And yet, without an adequate time frame, the deliberative process and ultimate work product are unquestionably compromised.

The ethics review done by Geron's EAB is a good illustration of the timing problem. The ethics board, which was constituted in early 1998, apparently began its work *after* the company's research on human stem cells was already well under way.[71] Furthermore, the EAB statement of ethical guidelines for research with human embryonic stem cells was not drafted until September 1998 and was not finalized until late October, just a few days before the November 5 publication in *Science* of Geron's stem cell breakthrough.[72] At best, then, the EAB's guidelines operated as an after-the-fact ethics "stamp of approval" for the way Geron had already conducted its research, rather than providing guidance and advice beforehand. Furthermore, the incomplete nature of the bioethics analysis contained within the report that explicated the guidelines was, to some extent, a reflection of the relatively short time frame (several months) within which the board had to work. [73]

A cynical take on this timing would suggest that the Geron EAB was intended to operate as little more than a public relations arm of the corporation. However, this assessment is probably overly harsh. Geron and its EAB should be evaluated within the context of the difficulties inherent in trying to operate ahead of a scientific field that is advancing at light speed, and the fact that EABs were just coming into existence in 1998. Still, as one commentator remarked, it's hard to imagine that the members of Geron's advisory board felt free to disapprove of research that had already taken place and was on the verge of publication.[74]

In contrast, the ACT's EAB seems to have performed under a more reasonable time frame, which in theory would allow for more nuanced and comprehensive bioethics debate and deliberation. Over a year before ACT began its experiments to clone human embryos as a source for stem cells, the corporation had put its EAB in place and worked with it to try to

develop a responsible and ethical research plan.[75] Of course, the validity of ACT's claim to responsible research was called into question by one-time board member McGee's allegations that the company had not made a full disclosure of its research activities to the EAB.[76]

3. Corporate Accountability

The corporate accountability issue is the extent to which the corporation is required to give effect to the bioethics consultant's or board's recommendations. Interestingly, Michael West disclosed that when the idea of establishing an ethics board first arose at Geron, the company concluded that giving an ethics board the power to veto research projects would undermine the corporation's fiduciary obligations to its shareholders.[77] Hence the name "ethics *advisory* board." In keeping with this view, Karen Lebacqz, the chair of the Geron EAB, acknowledged that the company was "perfectly at liberty to ignore all our advice."[78] West took the same position once he became President and CEO at Advance Cell Therapeutics, asserting that veto power over research directions rested exclusively with the privately held corporation's board of directors.[79]

However, just because corporations do not bind themselves to follow recommendations or advice, it does not necessarily follow that there is no accountability. According to members of ACT's EAB, the company and its researchers took the ethics review process seriously, adopting every single one of the board's recommendations on its human cloning research, even when doing so slowed or impeded the research.[80] The Ethics Advisory Board postulated that ACT's responsiveness may have flowed from respect for the process it had set up, a genuine desire for guidance on novel scientific and ethical issues, and/or the realization that board members could embarrass ACT if its recommendations were ignored.[81] Publicly traded companies such as Geron may have an additional concern—that the public will hold them accountable for disregarding ethics recommendations by "voting with their feet." However, the general public can only hold these

companies accountable if it has access to the relevant information, which in turn rests on the degree of confidentiality that surrounds the bioethics consultation processes.

4. Transparency

Transparency in this context has two applications. The first is internal to the corporation and depends on an array of factors: whether the ethics consultants have access to all relevant information and to management and research-level employees; whether EAB members are invited to attend board of director meetings where research and development plans are discussed in detail; whether the consultants' questions are answered fully; and whether the ethics board members feel free to have candid discussions with corporate representatives. On this measure, the ACT board members described a system of transparency and free access to corporate officers, directors, and researchers.[82]

The other application for transparency is the extent to which the review process and any conclusions or recommendations are disseminated to the public, as opposed to being kept confidential within the corporation.[83] Are ethics board members free to talk openly and in public about the review process, the conclusions, and any disagreements over the corporate research direction? The chair of the Geron EAB revealed that ethics board members were prohibited from publicly discussing the nature of a project that Geron had wanted to fund but had then abandoned after the ethics board raised objections to it.[84] In contrast, although the ACT board members were required to sign a confidentiality agreement as to "nonpublic information," the agreement also included that "nothing . . . shall impair or restrict the right of any member of the Ethics Advisory Board to comment publicly, speak or write concerning ethical issues," provided that they didn't disclose non-public, technical information.[85] Michael West, the CEO of ACT, reassured the Ethics Advisory Board members that they would always have the "power of the pen" and the freedom to speak out whenever the company

ignored its advice.[86] It is interesting to note, however, that ACT's sitting EAB members have, thus far, used the power of the pen only to praise the company.[87] Might this reflect the subtle but real danger that bioethicists will refrain from criticizing their corporate partners out of a concern that "it is a rare corporation that will continue to fund bioethicists who are constantly and publicly criticizing corporate policy"?[88]

C. The Ethical Crisis Within the Bioethics Profession

What began as an issue of how to effectively bring bioethics into the boardroom of biotechnology corporations has now turned into an ethical crisis for the bioethics profession. The simple fact that the contact with corporate culture that has occurred through EABs and individual consultations has caused members of the profession to dispute whether bioethicists can, consistent with professional ethics, provide compensated or even uncompensated advice to corporations.

Within this debate there is certainly some common ground. For example, most members of the profession would agree that the bioethicist's first responsibility is to the public interest; the legitimacy of the profession comes directly from the fact that society has entrusted bioethics experts with the role of providing oversight to highly contested, complex, and potentially troubling scientific ventures.[89] Virtually everyone would also agree that serving clients whose primary interest is profit maximization poses serious risks to the profession's independence and integrity.[90] Bioethicists differ radically, however, on the appropriate response to these potential conflicts of interest, and their differences reflect a growing chasm within the field of bioethics. Will bioethicists become advocates for the corporate enterprise over time, working to facilitate and justify corporations and their actions? Will the entire profession become seduced and corrupted by corporate culture and the inducements it has to offer? In a very real sense, individuals on both sides of this issue are fighting over the "soul" of

the bioethics profession, and the arguments have been heartfelt and even acrimonious.

1. Working from Within

Advocates who favor ethics consultation with the for-profit, private sector assert that the profession has an obligation to promote the efforts of the business community to incorporate bioethics into their decision-making processes.[91] In essence, they make an argument against the "ivory tower" view of bioethics; they assert that ethical theories and principles can influence the corporate sector only if bioethicists are willing to come down out of their towers and engage within the business culture. For individuals on this side of the battle line, the key requirement is that any consultation, whether by group or individual, should be conducted in a responsible fashion that maximizes the bioethicists' objectivity, independence, and impartiality.[92]

Of course, there are a number of different ways that this end might be achieved. A task force composed of influential bioethicists approached the problem by developing a set of voluntary guidelines for ethical bioethics consultation.[93] The guidelines address several of the structural issues discussed earlier in this article such as the terms of the financial relationship between consultant and corporation, the need for both internal transparency, and at least some degree of public accountability.[94] Other commentators have focused on disclosure of corporate affiliations as the primary mechanism for addressing conflicts of interest, although it is not always clear precisely what bioethicists should disclose or to whom they should disclose this information.[95] Still others have suggested that although consultation activities are not per se unethical, compensation from corporations should either be limited (no stock options, no management board positions, *de minimis* payments)[96] or bioethicists should provide these services for free.[97] In response to this latter position, Professor Thomas Donaldson used a market analysis to argue that the idea of the bioethics

profession turning down compensation for consultation is downright "silly," and that the bioethics profession's "profit motive should be civilized, not destroyed."[98] He advocated the use of business ethics as a guide to the ethics of bioethics consultation, suggesting that guidelines developed to promote auditor independence in the accounting field can be applied equally well to bioethicists receiving compensation for their advice.[99] Other approaches advocated by various commentators include the development of uniform best practices for ethics advisory boards, communication across EABs, and the development of private review bodies that are completely external and advise several corporations rather than just one.[100]

2. Standing Above the Fray

Implicit throughout the various proposals described above is the proposition that corporate bioethics consultation is appropriate and within the bounds of professional ethics. Those who either vehemently disagree with this position or have serious concerns begin by noting that bioethicists, through their writing, teaching, consulting, and policymaking, have historically served as overseers of the medical and scientific enterprise.[101] The critical issue is whether the profession can maintain the integrity and independence needed to function in this role if its members are being paid or otherwise rewarded by the very entities whose activities they are entrusted to monitor. As Professor Carl Elliott so eloquently puts it, what happens when you "throw[] a bone to the watchdog?"[102]

Although bioethicists working within academia or the medical field are regularly paid for their services, the concern is that working for a for-profit corporation is fundamentally different. As Daniel Callahan explains, the cultures of business and bioethics are radically different in their motives and objectives, the interests they protect, and their moral subcultures.[103] Unlike hospitals, universities, and academic bioethics centers, corporations have a direct financial interest in the opinions formed and the views expressed by their hired bioethicists.[104] Biotechnology companies also have a great deal

of money to spend,[105] and most of these consulting contracts do not come with a guarantee of academic freedom.[106] As a result, Professor Elliott worries that "each corporate check cashed takes us one step closer to the notion of ethics as a commodity, a series of canned lectures, white papers, and consultation services to be purchased by the highest bidder."[107]

Monetary compensation is not the only inducement that corporations have to offer bioethics experts. Professor Laurie Zoloth suggests that the profession ought to be equally concerned about other types of inducements, those that can be termed "social capital."[108] Bioethicists who wish to advance their careers naturally value and pursue activities that enhance their professional reputations and increase the demand for their services, opinions, and expertise. They are only human and the lure of national fame—being quoted in the media, published in prestigious journals, named to national bioethics panels—is a potent elixir.[109] Corporate consultancies are an important piece of this social capital, and even non-paying consultancies can enhance a bioethicist's reputation and cachet. The potential conflict of interest is clear; it is simply not good business practice for a biotechnology company to hire an ethics consultant who publicly criticizes or calls for a halt to corporate research practices.[110] All of this taken together—the compromise to objectivity that can come from identification with and allegiance to a corporate client, the lack of external standards, the financial inducements, the seduction of status and fame—creates a rather precarious basis for the societal trust that is so essential to the field of bioethics and its practitioners.[111]

D. Corporate Responsibility in the Realm of Bioethics

The purpose of this article is not to solve the identity crisis within the bioethics profession, but rather to point out that the discussion thus far is surprisingly incomplete. What is fascinating about all of the soul-searching is that no one has thought to suggest that corporations might bear some primary responsibilities in this regard. Might biotechnology companies

have an obligation to utilize bioethics services in a manner that maximizes consultant objectivity and independence? Should corporations be responsible for creating an internal ethical climate in which these kinds of consultations are taken seriously rather than used as public relations window dressing? Should the issues raised regarding the structure of the bioethicist-corporation relationship be of concern to business as well as bioethics?

This is where interdisciplinary conversation is so helpful, and it returns us to the power of Lynne Dallas's conception of an ethical corporate climate. The corporate and business voices are irrelevant to this conversation only if one is willing to accept that the corporate form cannot evolve; that corporations cannot be encouraged, expected, or required to maintain and follow ethical standards; that corporations have no responsibilities beyond those owed directly to their investors and shareholders. Recent history, including the reaction to the Enron debacle, suggests that society and legal scholars are increasingly unwilling to accept these traditional premises.

This is not to say that the process of determining and directing corporate responsibility in the area of bioethics consultation would be an easy one. The federal government's position thus far to either deny or provide only very limited funding to embryo and stem cell research removes the spending power basis for federal regulation of the private biotechnology industry. In addition, much of the work in the wake of Enron's collapse has involved corporate responsibility in a context where it could be argued that implementing ethical practices would actually increase profits and shareholder value (or at least prevent bankruptcy). In the biotechnology realm, we are facing a situation where a corporate decision to follow bioethics advice and forego a particular line of research or pursue it in a more ethically acceptable, but also more expensive, manner would likely result in a reduction in profits and investor value.

The reality, though, is that we are not talking about widgets here. The corporate form is already an extremely complex moral and ethical playing field, but that complexity is magnified when the substrates with which the corporation works are the building blocks of life itself. There may come a day when human embryos, stem cells, and individual genes are so divorced from their traditional biological origins, so commodified, that they have lost even their symbolic value. Until that day, it is not unreasonable to expect corporate decision makers, despite the corporate profit-maximizing form, to answer to constituencies beyond the usual shareholders and investors. Bioethics is one mechanism by which societal values can be brought to bear on the corporate enterprise, but only if the climate is right.

What might a "bioethical corporate climate" look like? According to Dallas, the ethical climate of a corporation consists of the ethical meaning that employees attach to organizational practices and procedures that in turn reflect corporate norms and values.[112] Perhaps the most important factor in creating and maintaining an ethical environment is management's willingness to set the moral tone for the corporation.[113] Officers and directors can achieve this by adopting a values-based approach in decision making,[114] framing issues in ethical or moral terms when appropriate,[115] permitting ethical standards to actually influence business decisions,[116] and appropriately managing conflicts of interest.[117]

When one transfers these concepts from corporations generally to the biotechnology sector specifically, it becomes clear that many of the problems with bioethics consultations—suspect corporate motivation, conflicts of interest, lack of corporate accountability, insufficient public transparency—could be remedied if biotechnology corporations were to create a climate more hospitable to bioethical principles and process. In fact, what was framed earlier as an identity crisis within bioethics could just as easily be framed as a crisis of ethics within the biotechnology industry. While this may seem like mere semantics, looking at the structure and process of bioethics consultation as a matter of corporate responsibility as

well as an issue for the bioethics profession greatly increases the likelihood that meaningful structural reforms can be achieved. Solutions to many of the problems that surround the bioethicist-corporation relationship will require corporate initiative, or at least cooperation. Thus, it makes perfect sense to view these issues from the additional perspective of corporate responsibility, and to support the development of corporate climates that will truly value and utilize the rich resources that the discipline of bioethics has to offer.

V. CONCLUSION

In the words of one bioethicist, members of the bioethics profession, at their best, "introduce the social[] implications for the future, the history of past abuses, and the present considerations of justice," they "pull the narrative frame from the private view within the institution to the larger world that surrounds the institution, a world of obligation, of suffering, of injustice, and of potential," and they "see the problem of conflict as a radical opportunity, not an avoidable mistake."[118] Bioethicists "hold things in tension—the reasonableness of a marketplace, the realpolitik of private financing, the nature of social constraints of our health care funding, and the aspirations of justice," and they "unpack[] the narratives, the analysis of truth claims, the interpretations of reality that divide by culture, class, race, and religious tradition."[119]

Given the high stakes involved in biotechnology research, especially in the morally contested areas of embryo and stem cell research, and given the societal value that bioethics discourse and discernment can bring to the boardroom table, efforts to import bioethics into the business of biotechnology are surely worth the struggle. We ought not be surprised that the interface between bioethics and business cultures has the potential to produce change, positive and negative, in both cultures. The challenge is to continue to improve the model for that interaction; Professor Dallas's work on corporate ethics, which emphasizes corporate responsibility for creating

a favorable ethical climate, provides a powerful tool for furthering societal objectives within the for-profit biotechnology industry.

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[2] The scientific imperative can be thought of as a type of "manifest destiny," whereby individuals and institutions work to extend the boundaries of human knowledge, each scientist adding his or her own small piece of knowledge to the ever-advancing tide.

[3] *See* Lynne L. Dallas, *A Preliminary Inquiry into the Responsibility of Corporations and their Officers and Directors for Corporate Climate:The Psychology of Enron's Demise*, 35 RUTGERS L.J. 1 (2003).

[4] SOURCE BOOK IN BIOETHICS 1 (Albert R. Jonsen et al. eds., 1998).

[5] *Id.* (quoting 1 ENCYCLOPEDIA OF BIOETHICS xxi (Warren T. Reich ed., 1995)).

[6] Casuistry is a mode of pragmatic moral reasoning that, rather than relying on universal principles, applies "case ethics," with a particular focus on the factual similarities and differences between cases. *See* ALBERT R. JONSEN & STEPHEN TOULMIN, THE ABUSE OF CASUISTRY: A HISTORY OF MORAL REASONING 10–12 (1988).

[7] *See* Sheryl Gay Stolberg, *Bioethicists Find Themselves the Ones Being Scrutinized*, N.Y. TIMES, Aug. 1, 2001, at A1.

[8] *Id*.

[9] *See* Martin Körbling & Zeev Estrov, *Adult Stem Cells for Tissue Repair—A New Therapeutic Concept?*, 349 NEW ENG. J. MED. 570 (2003). Adult stem cells are most commonly isolated from bone marrow and peripheral blood. *Id*. Their usefulness in tissue repair is currently unknown but is the focus of intense research efforts. *See id*. at 579.

[10] *See generally* Irving L. Weissman, *Stem Cells—Scientific, Medical, and Political Issues*, 346 NEW ENG. J. MED. 1576 (2002) (describing stem cells, their nature, and their uses).

[11] Arthur Allen, *God and Science*, WASH. POST, Oct. 15, 2000, at W8.

[12] *Id*.

[13] Stephen S. Hall, *The Recycled Generation*, N.Y. TIMES, Jan. 30, 2000, at 30.

[14] *Id*.

[15] Allen, *supra* note 11.

[16] Rick Weiss, *Bush Administration Order Halts Stem Cell Meeting*, WASH. POST, Apr. 21, 2001, at A2.

[17] Stem cell lines are created by isolating embryonic stem cells from the inner cell mass of blastocysts and scientifically manipulating and culturing the stem cells so that they will grow and divide continuously, thus providing a ready source of cells for experimentation. John Gearhart, *New Embryonic Stem-Cell Lines—More Is Better*, 350 NEW ENG. J. MED. 1275, 1275 (2004). *See generally* Chad A. Cowan et al., *Derivation of Embryonic Stem-Cell Lines from Human Blastocysts*, 350 NEW ENG. J. MED. 1353 (2004) (describing this scientific process in more detail).

[18] Rick Weiss, *Promising More—and Less*, WASH. POST, Aug. 10, 2001, at A1. This limitation was an attempt by the administration to strike a middle ethical position, whereby federal funds could be used to support stem cell research for the benefit of humankind, but without federal complicity in causing further destruction of human embryos for that purpose. Although President Bush asserted that sixty stem cell lines would be available for federally funded research, *see id*., in reality only twenty-one cell lines are currently listed in the National Institutes of Health (NIH) registry and are available for research in the United States. George Q. Daley, *Missed Opportunities in Embryonic Stem-Cell Research*, 351 NEW ENG. J. MED. 627, 627 (2004).

[19] Rick Weiss, *Bush Unveils Bioethics Council*, WASH. POST, Jan. 17, 2002, at A21.

[20] Mary Leonard, *Panel Bush Named Rejects Full Ban on Cloning in Compromise, Divided Members Urge 4-Year Delay*, BOSTON GLOBE, July 12, 2002, at A2. For the full report produced by the Council, see HUMAN CLONING AND HUMAN DIGNITY: THE REPORT OF THE PRESIDENT'S COUNCIL ON BIOETHICS (2002).

[21] *See infra* Part III.B.

[22] *See generally* ANDREA L. BONNICKSEN, CRAFTING A CLONING POLICY: FROM DOLLY TO STEM CELLS (2002); CLONING AND THE FUTURE OF HUMAN EMBRYO RESEARCH (Paul Lauritzen ed., 2001); HUMAN CLONING, *supra* note 20 (discussing the ethics of human cloning and embryo research).

[23] Hall, *supra* note 13. West named his company Geron, which is Greek for "old person," and directed its resources to the exploration of the molecular causes of aging. *Id*.

[24] *Id*.

[25] Marilynn Marchione, *Ethical, Legal Questions Hardly Sway Scientist at Vanguard of Human Cloning*, MILWAUKEE J. SENTINEL, May 5, 2002, at A1 (quoting Dr. Arthur Caplan, director of the Center for Bioethics, University of Pennsylvania).

[26] *Id*. The University of Wisconsin and Johns Hopkins, where the actual work was done, retained the patents on the research, but Geron received exclusive rights to the commercial applications that flowed from the research. *Id*.

[27] Geron Ethics Advisory Board, *Research with Human Embryonic Stem Cells: Ethical Considerations*, HASTINGS CENTER REP., Mar.–Apr. 1999, at 31.

[28] The stem cell lines developed by John Gearhart's team at Johns Hopkins were derived from the gonads of aborted fetuses at two months of gestation. The stem cell lines grown by James Thomson's group came from fourteen embryos donated anonymously by patients who had undergone fertility treatments at the University of Wisconsin Hospital in Madison. Allen, *supra* note 11.

[29] Thomas B. Okarma, *Human Primordial Stem Cells*, HASTINGS CENTER REP., Mar.–Apr. 1999, at 30.

[30] Geron Ethics Advisory Board, *supra* note 27, at 31.

[31] *Id*.

[32] *Id*.

[33] *Id*. The Geron EAB's conditions for conducting human stem cell research were as follows:

- The blastocyst must be treated with the respect appropriate to early human embryonic tissue.

- Women/couples donating blastocysts produced in the process of in vitro fertilization must give full and informed consent for the use of the blastocysts in research and in the development of cell lines from that tissue.
- The hES [human embryonic stem] research will not involve any cloning for purposes of human reproduction, any transfer to a uterus, or any creation of chimeras.
- Acquisition and development of the feeder layer necessary for the growth of hES cell lines in vitro must not violate accepted norms for human or animal research.
- All such research must be done in a context of concern for global justice.
- All such research should be approved by an independent Ethics Advisory Board in addition to an Institutional Review Board.

Id. at 31–35.

[34] *Id*. at 35.

[35] *See* Allen, *supra* note 11.

[36] For the complete report, which was made available by Geron through a symposium in the Hastings Center Report, see *supra* note 27, at 30.

[37] Hall, *supra* note 13. Mr. West left Geron after becoming disenchanted with the company's leadership and direction. *Id*.

[38] *Id*.

[39] *See* Rick Weiss, *Firm Aims to Clone Embryos for Stem Cells*, WASH. POST, July 12, 2001, at A1.

[40] One stimulus to create the ACT ethics advisory board may have been the "public-relations fiasco" that occurred in October 1988 when West invited the *48 Hours* newsmagazine to film work that involved fusing human cells and cow eggs to create embryos for stem cell research. *See* Hall, *supra* note 13.

[41] *See, e.g*., Seth Borenstein, *U.S. Firm Clones Human Embryo; Religious, Political Leaders Appalled; Cells Die Quickly*, SAN DIEGO UNION-TRIB., Nov. 26, 2001, at A1. *See also* Cathy Lynn Grossman, *Furor Echoes the Questions on Stem Cells*, USA TODAY, Nov. 27, 2001, at D8; *Human Embryo Cloning Criticized*, S.F. CHRON., Nov. 26, 2001, at A1; *Researchers Claim to Have Cloned Human Embryos*, SEATTLE TIMES, Nov. 26, 2001, at A1; Rick Weiss, *First Human Embryos are Cloned in U.S.; Private Lab Seeks to Mine Stem Cells for Research*, WASH. POST, Nov. 26, 2001, at A1.

[42] Stolberg, *supra* note 7.

[43] *Id*.

[44] Rick Weiss, *Cloning Firm Is Accused of Ignoring Its Ethics Board*, WASH. POST, July 14, 2001, at A3.

[45] *See infra* Part IV.C. (exploring this phenomenon in more detail).

[46] Stolberg, *supra* note 7, at A1.

[47] *Id*.

[48] *See* Virginia A. Sharpe, *Science, Bioethics, and the Public Interest: On the Need for Transparency*, HASTINGS CENTER REP., May–June 2002, at 23, 25 (recommending full disclosure by bioethicists of all relevant outside affiliations, consultancies, and funding

sources on resumes, in biographical sketches, to university conflict of interest offices, to the media, and in published and oral presentations).

[49] By referring to a "bioethical climate," I am building on Professor Dallas's concept of an ethical climate within corporations by applying it to the biotechnology setting. *See* Dallas, *supra* note 3, at 22 (defining corporate ethical climate as "the ethical meaning attached by employees to organizational standards, practices, and procedures, including managerial behavior and reward systems that reflect corporate norms and values.").

[50] Professor Dallas makes the point that a corporation's ethical climate is an important determinant in employee decision making. *Id*. at 28.

[51] *See* Weiss, *supra* note 41.

[52] Not surprisingly, Professor Ronald Green, the chair of ACT's EAB and director of the Ethics Institute at Dartmouth College, argued in favor of the former view. He asserted that the advisory board had imposed numerous conditions on the human embryo research, including a requirement that women who wanted to be egg donors must have already had at least one child, as a precaution against the unlikely event that the egg donation process resulted in an inability to conceive in the future. Bryn Nelson, *Human Cloning Ban Urged*, NEWSDAY, Nov. 27, 2001, at A8. Professor Glenn McGee, formerly a member of the board, took the opposite view, stating, "It was very clear they were using their ethics advisory board as a rubber stamp." *See* Michael Hill, *From Cloning Sheep . . . To Cloning Humans*, BALTIMORE SUN, Dec. 2, 2001, at F1. *But see* Ronald M. Green et al., *Overseeing Research on Therapeutic Cloning: A Private Ethics Board Responds to Its Critics*, HASTINGS CENTER REP., May–June 2002, at 27, 28 (disputing McGee's credibility on the basis that he had neither attended the advisory board's meetings nor participated in the months of work required to get the embryo cloning research program up and running).

[53] *See* 45 C.F.R. § 46.101 (2003).

[54] 45 C.F.R. § 46.107(a)–(c) (2003).

[55] *See* Geron Ethics Advisory Board, *supra* note 27, at 31.

[56] *See* Green et al., *supra* note 52, at 27.

[57] The members of a task force on bioethics consulting reasoned that although a larger group provides the benefit of diversity of viewpoints, individual consultation has the advantage of a clearer result and greater speed. *See* Baruch Brody et al., *Bioethics Consultation in the Private Sector*, HASTINGS CENTER REP., May–June 2002, at 14, 17.

[58] *See* Weiss, *supra* note 44. Dr. Ann Kieffling, a Harvard professor and surgeon, both sat on the EAB and interviewed and recruited egg donors for the embryo cloning research. Dr. Kieffling denied that her dual roles constituted a conflict of interest. *Id*. But many would probably disagree with her conclusion, this author included. Contrast Dr. Kieffling's position with the federal regulations governing IRBs, the boards that review human subjects research. In these regulations, no IRB member may participate in the IRB's review of any project in which the member has a conflicting interest, except to provide information to the IRB. 45 C.F.R. § 46.107(e) (2003).

[59] Dr. Callahan is the founder of the Hastings Center, the first institute in the country devoted to ethics in medicine.

[60] Stolberg, *supra* note 7.

[61] For example, the President's Council on Bioethics, which President George W. Bush established by executive order in 2001 to study issues including embryo and stem cell research, cloning, and human genetics, was criticized on the ground that it was stacked with conservative thinkers who had taken public positions in opposition to research using human embryos. *See* Rick Weiss, *supra* note 19. Those charges were renewed when two of the council's most outspoken proponents of research on human embryos were summarily replaced by individuals whose views were reputedly more in line with those of President Bush and Leon Kass, the council's director. Weiss, *Bush Ejects Two from Bioethics Council; Charges Renew Criticism That the President Puts Politics Ahead of Science*, WASH. POST, Feb. 28, 2004, at A6. Dr. Elizabeth Blackburn, a scientist and moral philosopher, was one of the two individuals who were replaced. She asserted that the change in membership reflected a strong ideological shift in the council and was part of the current administration's pattern of manipulating scientific research for political ends. *See* Elizabeth Blackburn, *Bioethics and the Political Distortion of Biomedical Science*, 350 NEW ENG. J. MED. 1379, 1379–1380 (2004). *But see* Leon Kass, *We Don't Play Politics with Science*, WASH. POST., Mar. 3, 2004, at A27 (vehemently refuting charges that the change in the council's membership was ideologically or politically driven). *See generally* Robert Steinbrook, *Science, Politics, and Federal Advisory Committees*, 350 NEW ENG. J. MED. 1454 (2004) (further articulating the debate surrounding politics and bioethics). Lest anyone think this is purely a Republican phenomenon, opponents of embryo research asserted that the National Bioethics Advisory Commission (NBAC) under President Clinton's Democratic administration didn't contain a single member strongly opposed to research on embryos. *See* Allen, *supra* note 11 (quoting one critic of NBAC as stating, "The basic function of these panels seems to be to articulate reasons for what the people who appointed them already wanted to do.").

[62] *See, e.g.*, Carl Elliott, *Throwing a Bone to the Watchdog*, HASTINGS CENTER REP., Mar.–Apr. 2001, at 9–11. *See also* Daniel Callahan, *Doing Good and Doing Well*, HASTINGS CENTER REP., Mar.–Apr. 2001, at 19, 20–21 ("Bioethics was born financially naked and will be better if it stays that way.").

[63] *See* Callahan, *supra* note 62, at 20.

[64] *See* Brody et al., *supra* note 57, at 15.

[65] *See id*. (asserting that affluent, for-profit corporate clients are not the appropriate recipients of pro bono bioethics consultations).

[66] Stolberg, *supra* note 7; Geron Ethics Advisory Board, *supra* note 27, at 36 n.25.

[67] Green et al., *supra* note 52, at 28–29; *see also* Carl T. Hall, *Untangling Biotech Issues*, S.F. CHRON., Dec. 3, 2001, at A6.

[68] *See* Nell Boyce & David E. Kaplan, *And Now, Ethics for Sale?*, U.S. NEWS & WORLD REP., July 30, 2001, at 18. For example, Dr. Arthur Caplan has served on several ethics advisory boards, including that of Celera Genomics, which compensates him for his services annually in the form of company stock, which he then converts to cash and gives to his Center for Bioethics at the University of Pennsylvania. Stolberg, *supra* note 7. Dr. Caplan reported that one year, the converted stock was worth $100,000. *Id*.

[69] Brody et al., *supra* note 57, at 18–19. The task force was convened by the American Society for Bioethics and Humanities and the American Society of Law, Medicine and Ethics. *Id*. at 14.

[70] In an interesting twist, harsh critics of the task force's report expressed concern about the authors' motives and objectivity because, although they disclosed that eight of the ten authors engaged in for-profit bioethics consultation, none of the authors disclosed the amounts of compensation or the identities of their corporate affiliates. *See* Stuart J. Youngner & Robert Arnold, *Who Will Watch the Watchers?*, HASTINGS CENTER REP., May–June 2002, at 21, 21–22. To which, the task force authors claimed a right to privacy on the matter of compensation. *See* Brody et al., *The Task Force Responds*, HASTINGS CENTER REP., May–June 2002, at 22, 23.

[71] Carol A. Tauer, *Private Ethics Boards and Public Debate*, HASTINGS CENTER REP., Mar.–Apr. 1999, at 43. Working backward from the date of the publication in *Science*, Professor Tauer concluded that virtually all of Geron's scientific research had been completed *before* the EAB issued its ethical guidelines. *Id*.

[72] *Id*.

[73] *See, e.g.*, *id*. at 44 (taking the report to task for, among other things, failing to distinguish between the moral status of the embryo and that of the derived embryonic stem cells); *see also* Lori P. Knowles, *Property, Progeny, and Patents*, HASTINGS CENTER REP., Mar.–Apr. 1999, at 38, 40 (pointing out the inconsistencies in the report's position that commercializing embryos is wrong, yet condoning corporate profit-taking from stem cells derived by destroying those embryos); Glenn McGee & Arthur L. Caplan, *What's in the Dish?*, HASTINGS CENTER REP., Mar.–Apr. 1999, at 36, 37–38 (critiquing the report's use of embryonic and fetal development to attach moral status to the resultant stem cells); Lisa Sowle Cahill, *The New Biotech World Order*, HASTINGS CENTER REP., Mar.–Apr. 1999, at 45, 46–47 (praising Geron and its EAB for putting issues of genetic justice and access on the table, but suggesting that the report would have benefited from a fuller analysis of distributive justice, including notions of the common good and communitarian ethics).

[74] *See* Tauer, *supra* note 71, at 43.

[75] *See* Weiss, *supra* note 39. For example, the plan provided that women who were recruited as egg donors had to be fully informed that they would not benefit financially and that their eggs would be used for cloning embryos, and egg donors were sought only in areas not served by fertility clinics to avoid competing for eggs that might otherwise be donated to infertile couples for implantation. The company also hired bodyguards and installed video cameras to protect against theft of the cloned embryos by someone wanting to attempt to implant them into a woman's uterus. *Id*.

[76] *See supra* text accompanying notes 42–44.

[77] Hall, *supra* note 13.

[78] *Id*.

[79] *See* Green et al., *supra* note 52, at 29.

[80] *Id*.

[81] *Id.* at 31–32.

[82] *See id*. at 29.

[83] *See generally* Gladys B. White, *Foresight, Insight, Oversight*, HASTINGS CENTER REP., Mar.–Apr. 1999, at 41 (discussing transparency).
[84] Hall, *supra* note 13.
[85] *See* Green et al., *supra* note 52, at 29. The non-public information that was to be kept confidential was evidently defined narrowly, leaving board members to discuss publicly the scientific policies or practices that the board was evaluating. *See id*.
[86] *Id*.
[87] There are a number of possible bases on which the EAB members could have criticized the company. These include ACT's decision to publish the results of its cloning experiments in November 2001 even though the cloned embryos did not develop sufficiently to be able to extract stem cells (arguably a failed experiment) and the financially driven decision to publish in a new and relatively unknown online scientific journal, with special media exclusives to enhance the hype. *See Human Embryo Cloning Criticized, supra* note 41.
[88] Elliott, *supra* note 62, at 11.
[89] *See, e.g.*, Sharpe, *supra* note 48, at 24–25 (suggesting that bioethicists' first duty is to the public interest); *see also* Laurie Zoloth & Gregory Kaebnick, *Seeing the Duties to All*, HASTINGS CENTER REP., Mar.–Apr. 2001, at 15, 18 (stating that bioethicists' primary allegiance must be to "an informed, democratic civil polity"); Callahan, *supra* note 62, at 20 (stating that bioethicists' only motive should be "to help others, or society more broadly, make good moral judgments.").
[90] *See, e.g.,* Brody et al., *supra* note 57, at 15; Youngner & Arnold, *supra* note 70, at 21; Sharpe, *supra* note 48, at 25; Elliott, *supra* note 62, at 10–11.
[91] *See* Brody et al., *supra* note 57, at 15.
[92] *Id*.
[93] *See id*. at 15–19. The task force was convened by the American Society for Bioethics and Humanities and the American Society for Law, Medicine & Ethics. *Id*. at 14.
[94] *Id*.
[95] *See, e.g.*, Brody et al., *supra* note 57, at 18 (asserting that disclosure is a matter to be negotiated between the bioethics consultant and the corporation); *see also* Youngner & Arnold, *supra* note 70, at 21–22 (stating that at a minimum, consultants must disclose identity of corporation(s) and amount of compensation); Sharpe, *supra* note 48, at 25–26 (advocating full disclosure of consultative relationships to university administrators, on resumes, on personal and professional Web sites, to the media, and in published and oral presentations). The idea behind disclosure requirements is that they help others evaluate the motives, objectivity, and trustworthiness of an author or speaker. Youngner & Arnold, *supra* note 70, at 21–22. Some commentators worry, however, that disclosure requirements might actually make matters worse by implicitly encouraging bioethicists to accept conflicts of interest under the rationale that officially sanctioned disclosure somehow remedies all conflict problems. *See* Gregory E. Kaebnick, *Is Disclosure Helpful?*, HASTINGS CENTER REP., Mar.–Apr. 2001, at 3 (announcing new financial interest disclosure requirements for all authors publishing with the Hastings Center Report).
[96] Zoloth & Kaebnick, *supra* note 89, at 18.
[97] *See* Callahan, *supra* note 62, at 20.

[98] *See* Thomas Donaldson, *The Business Ethics of Bioethics Consulting*, HASTINGS CENTER REP., Mar.–Apr. 2001, at 12, 14. Professor Donaldson is with the Wharton School of the University of Pennsylvania.
[99] *Id*. Consistent with the guidelines for accounting auditors, he suggests that before entering into a consultation contract, bioethicists should seek to identify threats to their independence, the effectiveness of potential safeguards, and the acceptable level of risk to independence. *Id*. at 13. The threat to consultant or auditor independence is deemed to be high when the consultant is self-interested, audits his or her own work, acts as an advocate or has a close relationship with the client, and/or is subject to coercion by the client or another interested party. *Id*. at 13–14. The usefulness of Professor Donaldson's analogy is rather severely undercut by the fact that auditors are subject to uniform and independent accounting standards, a safeguard that is not present in bioethics consulting. *See supra* Part IV.B.1.b.
[100] *See* Green et al., *supra* note 52, at 32–33.
[101] *See* Elliott, *supra* note 62, at 9–10; Zoloth & Kaebnick, *supra* note 89, at 15–17.
[102] Elliott, *supra* note 62, at 9. Professor Elliott teaches philosophy at the Center for Bioethics at the University of Minnesota.
[103] Callahan, *supra* note 62, at 20.
[104] *Id*. at 10.
[105] Compensation can take the form of consulting fees, stock options, gifts, and honoraria. *Id*. at 9.
[106] *Id*. at 11.
[107] *Id*.
[108] *See* Zoloth & Kaebnick, *supra* note 89, at 17.
[109] *Id*. *See also* Youngner & Arnold, *supra* note 70, at 21 (arguing that bioethicists are influenced both by the desire to do good and the desire to do well, in the form of money, power, and prestige).
[110] Elliott, *supra* note 62, at 11.
[111] Sharpe, *supra* note 48, at 25.
[112] Dallas, *supra* note 3, at 22.
[113] *Id*. at 40.
[114] *Id*. at 18–19.
[115] *Id*. at 11.
[116] *Id*. at 55–56.
[117] *Id*. at 65.
[118] Zoloth & Kaebnick, *supra* note 89, at 15.
[119] Zoloth & Kaebnick, *supra* note 89, at 16.