

2005

Bioethics Consultants: Corporate Reliance on a New Field of Consultation

Kevin Schadick

Follow this and additional works at: <https://scholarlycommons.law.case.edu/healthmatrix>

 Part of the [Health Law and Policy Commons](#)

Recommended Citation

Kevin Schadick, *Bioethics Consultants: Corporate Reliance on a New Field of Consultation*, 15 Health Matrix 433 (2005)

Available at: <https://scholarlycommons.law.case.edu/healthmatrix/vol15/iss2/9>

This Note is brought to you for free and open access by the Student Journals at Case Western Reserve University School of Law Scholarly Commons. It has been accepted for inclusion in Health Matrix: The Journal of Law-Medicine by an authorized administrator of Case Western Reserve University School of Law Scholarly Commons.

NOTE

BIOETHICS CONSULTANTS: CORPORATE RELIANCE ON A NEW FIELD OF CONSULTATION

Kevin Schadick[†]

I. INTRODUCTION

The technological advances made within the last several decades have given rise to myriad pharmaceutical and biotechnology companies competing for a stake in the market. The quest for knowledge and market forces driving the advancement of scientific research to develop cures, tests, and therapies for disease creates an inherent problem. Government regulation cannot keep up with the advancement of science.¹ The result is the potential for a decrease in both the safety of subjects participating in clinical trials and in the availability of federal oversight of ethical research endeavors.

Many of the institutional guidelines and regulations governing oversight of scientific research exist under the auspices of the National Institutes of Health (NIH),² the Department of Health and Human Services (DHHS), and the Food and Drug Administration

[†] Kevin Schadick, J.D., Case Western Reserve University School of Law (2005).

¹ See Michael J. Malinowski & Robin J.R. Blatt, *Commercialization of Genetic Testing Services: The FDA, Market Forces, and Biological Tarot Cards*, 71 TUL. L. REV. 1211, 1222 (1997) (stating that the regulations are being developed to respond to technology rather than in anticipation of its development). See also Chris MacDonald, *Stem Cell Ethics and the Forgotten Corporate Context*, AM. J. BIOETHICS, Feb. 2002, at 55 (stating that when "scientific advancement is rapid, legislation will always lag").

² E.g., Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 ENVTL. L. 183, 205-11 (1987) (discussing the internal guidelines of the NIH on biotechnology); See also Sharona Hoffman, *Regulating Clinical Research: Informed Consent, Privacy, and IRBs*, 31 CAP. U. L. REV. 71, 75 (2003) (noting the historic role of the NIH in regulating biomedical research).

(FDA).³ These agencies are designed to regulate federally funded research, and in the case of the FDA, research of drugs, devices, and biological products that will ultimately be available in the consumer market.⁴ However, many biotechnology companies and clinical trials receive their funding privately and therefore do not fall under the regulatory umbrella of the DHHS. In an increasing number of cases, biotechnology companies are creating genetic tests for diseases that circumvent FDA regulations by administering such tests in the developer's facilities.⁵ The developer thus administers the test directly or through a primary care physician and never sells the individual components and reagents (chemicals) comprising the test as a kit.⁶ Although the developer can now commercially market the genetic test, circumvention of federal regulations is possible using the label, "for investigational purposes only," because a lack in regulation exists pertaining to genetic tests.⁷

Genetic testing is not the only research that is capable of remaining unregulated. Although hotly debated among scholars, politicians, and the public as a whole, methods of therapeutic cloning are largely unregulated. In recent years, the FDA proposed to enforce regulations in the same manner in which it approaches unapproved drugs; by requiring a research proposal subject to authorization by an Institutional Review Board (IRB) and to require informed consent from all human research subjects.⁸ However, many members of Congress, as well as legal scholars throughout the country, question whether the FDA can extend its power this far to regulate.⁹ The result is the ability of privately funded biotechnology companies and scientists to perform therapeutic cloning experiments and similar research absent regulations requiring protection for human subjects.

The concern regarding a lack of regulation within the biotechnology community does not remain unnoticed within Congress. In 2002, Congress proposed the Human Research Subjects Protections Act of 2002, which sought to extend prior review requirements to all human

³ See generally, 45 C.F.R. § 46.101 (2004) (providing DHHS protection of human research subjects); 21 C.F.R. § 56.101 (2004) (defining the scope of institutional review boards under the FDA).

⁴ 45 C.F.R. § 46.101; 21 C.F.R. § 56.101.

⁵ See Malinowski & Blatt, *supra* note 1, at 1228-30.

⁶ *Id.*

⁷ *Id.* at 1230-31 & n.64.

⁸ See generally Rebecca Dresser, *Human Cloning and the FDA*, HASTINGS CENTER REP., May-June 2003, at 7 (presenting the debate over whether the FDA possesses the authority to regulate human cloning).

⁹ *Id.* at 7.

subjects research regardless of the source of funding.¹⁰ If enacted, the regulation would effectively require all research to undergo the same review process required of federally funded research. The bill has yet to pass, but the call for government action remains. One such call came from Ronald Cole-Turner of the Pittsburgh Theological Society, who proposed that the President's Bioethics Council be "given federal oversight responsibilities over privately funded research as well as publicly funded research."¹¹

Biotechnology and pharmaceutical companies appreciate the need for ethical responsibility and, with ever-increasing frequency, are creating private bioethics committees or utilizing bioethics consultants to establish protocols and review ongoing research.¹² In so doing, industry representatives hope that government intervention will remain dormant, allowing private researchers to self-regulate and establish their own policies.¹³ Industry would prefer to follow in the footsteps of government by allowing the guidelines and regulations that govern federally funded human subjects research to serve as an ethical standard for industry to incorporate as internal policies.¹⁴ Yet, corporate science relies heavily on secrecy to secure a competitive advantage, making industry-wide scrutiny of ethical research protocols and policies a difficult endeavor.¹⁵ The question remains whether it is possible for corporate biotechnology and pharmaceutical companies to create their own self-policing system of ethics oversight without government intervention in the form of regulation.

This Note examines the emerging phenomenon of corporate bioethics consultants and committees created to ensure ethical review of research proposals. Increasing numbers of research abuses are surfacing, ranging from the death of Jesse Gelsinger,¹⁶ a gene-therapy research subject, to the recent disregard of federal regulations at Johns

¹⁰ H.R. 4697, 107th Cong. (2002).

¹¹ Margot Patterson, *Small Step, Big Fuss: Cloning Experiment Highlights Need for Public Oversight*, NAT'L CATH. REP., Dec. 7, 2001, at 3 (discussing the debate for public oversight for all human cloning research).

¹² See, e.g., Sheryl Gay Stolberg, *Bioethicists Find Themselves The Ones Being Scrutinized*, N.Y. TIMES, Aug. 2, 2001, at A1 (describing the recent growth in bioethics consultation in science).

¹³ See John Miller, Note, *Beyond Biotechnology: FDA Regulation of Nanomedicine*, 4 COLUM. SCI. & TECH. L. REV. 5 (April 23, 2002), at <http://www.stlr.org/cite.cgi?volume=4&article=5> (discussing the problems expected with regulating nanotechnology based on attempts to regulate biotechnology).

¹⁴ See Bernard J. Ficara, *BIOETHICS' RISE, DECLINE, AND FALL* 149 (2002).

¹⁵ See *id.*

¹⁶ E.g., Sheryl Gay Stolberg, *Biomedicine is Receiving New Scrutiny as Scientists Become Entrepreneurs*, N.Y. TIMES, Feb. 20, 2000, at A26.

Hopkins in the death of Ellen Roche.¹⁷ Tragedies such as these represent failure at some level in the system and raise the question of whether bioethics consultants are competent to provide advice, whether this advice is taken, and what additional roles or functions a corporate bioethicist has within a corporation. Part II of this Note examines the position and qualifications of a corporate bioethics consultant or member of a corporate bioethics committee. This section will examine whether bioethicists should obtain a standardized license before providing consultation on human subjects research or other biotechnological endeavors. Part III discusses the problems of compensation and conflicts of interest that are prevalent when ethicists provide consultations for corporate biotechnology. Part IV analyzes corporate reliance on the advice of paid consultants, bioethicists' ability to speak out against a biotechnology corporation, and disclosure problems that result. Finally, Part V offers recommendations that might ensure adequate ethical oversight of corporate science.

II. RESPONSIBILITIES AND EXPERIENCE OF BIOETHICS CONSULTANTS

A. Bioethics Consultants

The rapid emergence of bioethics over the last several decades and the realization of its importance within both the academic and industrial communities¹⁸ created a boom in the number of individuals providing advice as a corporate bioethics consultant or a member of a corporate bioethics committee. Corporate bioethics consultants or committees possess no decision-making authority; and their employment does not include approving research or conducting ongoing review of clinical trials. Instead, their role is primarily preliminary and advisory. The four-fold function of a bioethics consultant is to (1) provide independent and informed advice for ethically questionable research proposals;¹⁹ (2) review and develop research protocols and informed consent documents that will withstand review of an academic Institutional Review Board; (3) provide commentary and ex-

¹⁷ E.g., Sarah Ramsay, *Johns Hopkins Takes Responsibility for Volunteer's Death*, 358 LANCET 213 (2001); Lori A. Alvino, Note, *Who's Watching the Watchdogs? Responding to the Erosion of Research Ethics by Enforcing Promises*, 103 COLUM. L. REV. 893, 893-94 (2003).

¹⁸ M. L. Tina Stevens, *BIOETHICS IN AMERICA: ORIGINS AND CULTURAL POLITICS* 12-13 (2000).

¹⁹ See, e.g., ADVANCED CELL TECHNOLOGY, ETHICS ADVISORY BOARD, at <http://www.advancedcell.com/eab.htm> (last visited Apr. 20, 2005).

planations to the public of research performed; and in some cases (4) to provide education to employees of the corporation.²⁰

Currently no definitive guidelines exist as to what qualifies individuals to claim that they are bioethicists. So then, what defines a bioethicist and what are the backgrounds of the members of the bioethics advisory committees at companies such as Advanced Cell Technology and Geron Corporation? Corporate bioethics advisory committees utilize an approach similar to IRBs and ethics committees by creating a board of individuals with various backgrounds, not all within bioethics.²¹ For example, the members of the ethics advisory board at Advanced Cell Technology have backgrounds in bioethics, theology, genetics, philosophy, law, and reproductive biology.²² Relying on this IRB framework for selecting members of a corporate bioethics committee may not be adequate. A Maryland study has actually shown that most members (approximately sixty-two percent) of ethics committees do not possess a bioethics background or appropriate ethics coursework.²³ Continuing education for members of IRBs and ethics committees is one way currently used to combat this lack of bioethics knowledge in the academic and hospital setting.²⁴ Presumably, corporations would not face this problem because they would select independent bioethics consultants or members of corporate bioethics committees who would already possess the requisite knowledge and experience before being selected to consult. Yet, a system does not exist to ensure that individuals claiming to be bioethicists possess the adequate training.

The popularity of bioethics has given rise to numerous bioethics departments and programs at universities throughout the country,²⁵ but

²⁰ E.g. Baruch Brody et al., *Bioethics Consultation in the Private Sector*, HASTINGS CENTER REP., May-June 2002, at 14, 15; 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, 29 (describing the role of the Advanced Cell Technology Ethics Advisory Board).

²¹ 21 C.F.R. § 56.107(a) (2004) (requiring the membership of an IRB to consist of at least five individuals possessing diverse backgrounds, expertise, race, and gender.).

²² Ronald M. Green et al., *Advanced Cell Technology, Statement by the Ethics Advisory Board of Advanced Cell Technology*, June 2, 2002, available at <http://www.advancedcell.com/2002-06-02-2.htm> (last visited Feb. 29, 2004).

²³ Diane Hoffmann et al., *Are Ethics Committee Members Competent to Consult?*, 28 J.L. MED. & ETHICS 30, 34 (2000) (stating that only 73 (38%) of the 192 responding ethics committee members had received some formal bioethics education and only 8.8% of the committees required an education in bioethics).

²⁴ *Id.*

²⁵ Currently there are over sixty graduate bioethics departments in the coun-

what does this training consist of and are there standards that should be followed? Many of the graduate programs around the country offer a Master's degree in Bioethics,²⁶ but this alone does not seem sufficient to be providing advice to corporations in matters that involve the safety of human research subjects. In fact, David Magnus, the director of the University of Pennsylvania's Bioethics program, states that the degree "is not designed to be sufficient training for job placement."²⁷ Further, students should be careful to "not enter a bioethics program with the dream of coming out a card-carrying 'bioethicist'."²⁸ Instead, stringent requirements such as clinical training programs and administration of standardized exams should exist to ensure rigorous standards of academic bioethics programs.

Clinical training programs are beginning to emerge within academic bioethics programs.²⁹ The Department of Clinical Bioethics at the Warren G. Magnuson Clinical Center of the NIH reevaluated its programs, instituted changes and developed new ones.³⁰ In revamping its educational program, the NIH created two major educational components: (1) training bioethics fellows and (2) training non-bioethicists in bioethics issues.³¹ The fellowship is a two-year program that combines a year-long bioethics seminar on fundamental issues in bioethics, an intensive course in clinical research, attendance and participation in one of the thirteen NIH IRBs, and clinical ethics consultations.³² In addition, fellows are expected to research a specific bioethics issue with the goal of producing two to four publications prior to the end of the fellowship.³³ The rise in the intensity and scope of the program to not only include theoretical scholarship but also practical experience will hopefully give rise to a more well-

try and several more worldwide. For a listing of some of the programs and links to their websites, see <http://www.bioethics.net/beginners/gradprogram.php> (last visited Apr. 4, 2005).

²⁶ Information about individual degree programs can be obtained by reading the descriptions under the university Internet links that are available at <http://www.bioethics.net/beginners/gradprogram.php> (last visited Apr. 4, 2005).

²⁷ See Dominic A. Sisti, *There He Is... Master of Bioethics*, AM. J. BIOETHICS, Nov. 1, 2002, at 28, 29 (citation omitted).

²⁸ *Id.*

²⁹ For information on programs requiring a clinical training component, see *supra* note 26.

³⁰ See, e.g., Ezekiel J. Emanuel, *The Blossoming of Bioethics at NIH*, 8 KENNEDY INST. ETHICS J. 455 (1998).

³¹ *Id.* at 460.

³² *Id.* at 460-61.

³³ *Id.* at 461.

rounded education and ability to garner the skills needed to competently provide advice.

B. Professional Standards

The biggest problem within bioethics, according to R. Alta Charo, a University of Wisconsin law and medical ethics professor, is that “anybody can stand up and claim to be an ethicist – there is no licensing, there is no accreditation.”³⁴ Licensing and registration standards exist in many occupations such as medicine, law, psychiatry, investment banking, and education.³⁵ These standards often consist of fulfilling a required curriculum and subsequently passing a standardized exam.³⁶ States possess the power to set their own regulations,³⁷ but significant similarities are present between such regulations, to ensure that licensing requirements are closely aligned across the nation.

The question remains whether it is possible to propose the creation of regulations or licensing requirements to ensure that bioethicists are competent to be providing advice that ultimately could affect the well-being of a human research participant. This is a difficult proposition because ethicists and the public as a whole could reject this proposal on the basis that any individual with a modicum of common sense possesses the capability to administer advice. Yet, when human lives are at stake, should there not be some standard? The following three examples illustrate the argument that a requirement for registration and/or licensing of bioethics consultants is feasible.

1. Teachers

Individuals seeking teaching positions at public and private schools must obtain a license to ensure that children receive a quality education.³⁸ Each individual state has its own Department of Education that requires a teaching certificate or endorsement that states that an individual has successfully fulfilled the necessary requirements to

³⁴ See Stolberg, *supra* note 12, at A16.

³⁵ See *Goldfarb v. Va. State Bar*, 421 U.S. 773, 792 (1975) (stating that states have an interest in establishing regulations or licensure requirements for a variety of professions).

³⁶ See *Miller v. Dep’t of Prof’l Regulation*, 658 N.E.2d 523, 531 (Ill. App. Ct. 1995) (holding that requirement of licensing examination for profession engineers is not a violation of equal protection).

³⁷ *Goldfarb*, 421 U.S. at 792 (rationalizing this power as a means to “protect the public health, safety, and other valid interests”).

³⁸ See, e.g., Ohio Dep’t of Educ., *Mission Statement*, at http://www.ode.state.oh.us/teaching-profession/teacher/certification_licensure (last visited Apr. 4, 2005) (outlining the goals of licensure).

become a public school teacher. In Ohio, individuals seeking to teach in elementary school must first receive a provisional license, valid for two years, by successfully completing a minimum of twelve semester hours in education.³⁹ The provisional license then leads to a second license requiring a performance-based standardized test administered by the Ohio Department of Education.⁴⁰ In contrast, Massachusetts has similar but more stringent criteria. Massachusetts requires an applicant to possess a bachelor's degree and pass both a Communication and Literacy Skills test and a subject matter test appropriate for the particular license sought.⁴¹

2. Stockbrokers

Stockbrokers are an example of an occupation for which the federal government requires licensing and registration. Under the Securities Exchange Act of 1934,⁴² the federal government made it unlawful for any broker to participate in an interstate commercial transaction of any securities unless that broker is registered.⁴³ Registration requires filing an application with the United States Securities and Exchange Commission and fulfilling the informational and documentary requirements.⁴⁴

Although the federal government mandates the general action of registration, states may also choose to exercise authority by legislating additional requirements.⁴⁵ The federal government maintains in the Securities Exchange Act that brokers or salespersons must meet requisite standards to protect investors,⁴⁶ as well as pass exams⁴⁷ designed in congruence with national associations and securities exchanges.⁴⁸

³⁹ OHIO ADMIN. CODE § 3301-24-05 (2004) (provisional license guidelines). *See also*, OHIO REV. CODE ANN. § 3319.24 (Anderson 2004) (minimum education requirements).

⁴⁰ OHIO ADMIN. CODE § 3301-24-04 (2004).

⁴¹ MASS. REGS. CODE tit. 603 § 7.04 (2003) (requirements and types of teacher licenses).

⁴² 15 U.S.C. § 78 (2000).

⁴³ § 78o(a)(1).

⁴⁴ § 78o(b)(1).

⁴⁵ *See generally* OHIO REV. CODE ANN. §§ 1707.14–1707.19 (2003) (making it unlawful to deal securities without a license and proscribing all of the requirements for obtaining and maintaining a license). *See also*, OHIO ADMIN. CODE § 1301:6-3-15 (2003) (describing Ohio's requirements for registration of securities dealers).

⁴⁶ 15 U.S.C. § 78o(b)(7) (requiring "standards of training, experience, competence, and such other qualifications as the Commission finds necessary or appropriate in the public interest or for the protection of investors.").

⁴⁷ 78o(b)(7)(B) (requiring dealers "to pass tests prescribed in accordance with [federal] rules and regulations").

⁴⁸ 78o(b)(7)(C) (stating that "[t]he Commission may cooperate with regis-

While the federal government requires brokers to pass an exam in general, the states possess the power to regulate specifically which exams to take.⁴⁹ Most states require brokers to pass the General Securities Registered Representative Examination (commonly referred to as Series 7).⁵⁰ In addition, many states require a second examination, the Uniform Securities Agents State Law Examination (Series 63).⁵¹

3. Investment Advisers

The final example most closely related to providing advice similar to that given by bioethics consultants is the occupation of investment advisers. An investment adviser is a "person who, for compensation, engages in the business of advising others . . . as to the value of securities or as to the advisability of investing in, purchasing, or selling securities."⁵² Certain individuals may be excepted from this definition of an investment adviser, such as if a banker, attorney, accountant, or other individual incidentally provides advice in addition to the duties of their chosen profession.⁵³ The federal government found that investment advisers were of "national concern" since their advice relates to securities traded over the national securities exchange and often takes place through interstate commerce.⁵⁴ Congress thus enacted the "Investment Advisers Act of 1940."⁵⁵

Under the Investment Advisers Act of 1940, it is unlawful to "make use of the mails or any means or instrumentality of interstate commerce . . . as an investment adviser" unless registered with the Securities and Exchange Commission.⁵⁶ If an investment adviser's

tered securities associations and national securities exchanges in devising and administering tests"). The major association responsible for designing and administering these exams is the National Association of Securities Dealers, Inc. (NASD). The NASD is a private, not-for-profit organization given self-regulatory powers by the federal government with the purpose of governing securities firms and ensuring investor confidence in the financial markets. NAT'L ASS'N OF SECS. DEALERS, NASD CORPORATE DESCRIPTION, at http://www.nasd.com/corp_info/corp_description.asp (last visited Apr. 20, 2005).

⁴⁹ See, e.g., OHIO ADMIN. CODE § 1301:6-3-15 (2003) (providing information on specific exams).

⁵⁰ U.S. DEP'T OF LABOR, OCCUPATIONAL OUTLOOK HANDBOOK (2004-05 ed.), available at <http://www.bls.gov/oco/ocos122.htm> (last modified May 18, 2004).

⁵¹ *Id.*

⁵² 15 U.S.C. § 80b-2(a)(11) (2000).

⁵³ See *id.*

⁵⁴ 15 U.S.C. § 80b-1 (Congressional findings with regard to investment advisers).

⁵⁵ Pub. L. No. 106-554, 114 Stat. 2763-A (1940) (codified as amended at 15 U.S.C. § 80b (2000)).

⁵⁶ 15 U.S.C. § 80b-3(a) (discussing registration of investment advisers).

clients all reside within a single state, there is no requirement for federal registration,⁵⁷ yet a licensing or registration requirement might still exist in the individual state.⁵⁸ Hence, the federal government gives deference to the states to determine their own registration and licensing requirements unless the investment adviser fulfills the criteria for federal registration.⁵⁹

Under the federal provisions, investment advisers may register with the Commission by submitting a completed application.⁶⁰ The application must consist of formal administrative information such as name, the State of business, and number of employees.⁶¹ More importantly though, the adviser must disclose his/her education, present business affiliations, business affiliations over the past ten years, and the means in which the investment adviser is compensated.⁶²

III. COMPENSATION AND CONFLICTS OF INTEREST

The major element distinguishing IRBs and Hospital Ethics Committees from an Ethics Advisory Board for a biotechnology company or an independent bioethics consultant is compensation. Bioethicists in the corporate world receive compensation for their time, effort, and advice, whereas members of IRBs and ethics committees traditionally volunteer their time.⁶³ The disparity between academic and corporate advisory boards has created a rift in the bioethics community. This section investigates the varying rationales behind compensation for ethical advice, the problems that ensue, and the potential remedies being considered.

A. Bioethics Consultant Compensation

The increased realization that biotechnology and pharmaceutical companies need bioethicists on staff has created a demand that facili-

⁵⁷ § 80b-3(b)(1) (no registration is required as long as all clients are residents of the state in which the adviser maintains his principal place of business and the advisor "does not furnish advice or issue analyses or reports with respect to securities listed or admitted to unlisted trading privileges on any national securities exchange.").

⁵⁸ § 80b-3a(b)(1) (requiring advisers to be subject to Commission authority).

⁵⁹ § 80b-3a(a).

⁶⁰ § 80b-3(c)(1).

⁶¹ § 80b(c)(1)(A).

⁶² 15 U.S.C. § 80b(c)(1)(B) (education and business affiliations); 15 U.S.C. § 80b(c)(1)(F) (basis of compensation).

⁶³ Academic IRBs are more frequently accepting money from corporate sponsors to review research protocols. See e.g. Nell Boyce, *And Now, Ethics for Sale? Bioethicists and Big Bucks. Problem City?*, U.S. NEWS & WORLD REP., July 30, 2001, at 18, 19 (discussing Stanford's acceptance of one million dollars from SmithKline Beecham).

tates varying levels of compensation. Biotechnology companies recognize the importance of staff bioethicists that stock options, gifts, and significant consultation fees are not excluded from the realm of compensation a bioethicist receives.⁶⁴ The range of compensation is vast, but monetary compensation may not be the sole problem. Money alone might not be what is driving a bioethicist to become a corporate consultant, as “[b]ioethicists tend to be seduced by more subtle lures than money.”⁶⁵ Academics and ethicists flourish as a result of their reputation and thus, the status and honor of being a corporate consultant might be of greater appeal than monetary compensation. Status among the bioethics community could create an individual who is “in demand – sought after as the expert in the field, invited to reflect in prestigious journals, to speak on panels, to be a member of national boards, [and] to be invited into discourse with the media.”⁶⁶ In addition, experience as a corporate bioethicist could provide additional support for tenure and publication of academic articles for those on faculty at universities.⁶⁷ Compensation in the form of recognition and praise is neither capable of regulation nor restriction since these intangible benefits afforded to them are non-monetary.⁶⁸ The result is such that intangible benefits create a fundamental problem in areas of conflict of interest and impartiality because even if no monetary compensation is present, the intangible benefits add to the profitability and net worth of the bioethicist. There seems to be no direct solution to this intangible benefit problem, therefore this section will focus on the heart of the public debate regarding the problems of monetary compensation provided for bioethics consultations.

There are two views about the legitimacy of accepting money for bioethics advice as it relates to the problem of conflicts of interest. A conflict of interest occurs when an individual’s ideals, opinions, or actions could potentially lose their objectivity because of personal interests for financial gain.⁶⁹ In bioethics, compensation for services could cause a bioethicist to find more favorably for the corporation providing the funds. One argument suggests that “[b]ioethicists must

⁶⁴ Carl Elliott, *Throwing a Bone to the Watchdog*, HASTINGS CENTER REP., Mar.-Apr. 2001, at 9 (“Pharmaceutical and biotechnology corporations need bioethicists . . . [s]o deep are their moral and spiritual needs that they are willing to give ethicists gifts, contracts, honoraria, consultation fees, and stock options.”).

⁶⁵ Laurie Zoloth, *Seeing the Duties to All*, HASTINGS CENTER REP., Mar.-Apr. 2001, at 15, 17.

⁶⁶ *Id.* at 17.

⁶⁷ See Lisa Eckelbecker, *A Question of Ethics*, WORCESTER TELEGRAM & GAZETTE, Aug. 11, 2002, at E1.

⁶⁸ Zoloth, *supra* note 65, at 17-18.

⁶⁹ *Id.* at 17.

avoid conflicts of interest *and* remain true to their profession's duty to serve the 'broader good'" and therefore reject any offer for compensation.⁷⁰ The belief appears to be that accepting money in exchange for providing ethical advice is contrary to the nature of ethics.⁷¹ In other words, the role of a bioethicist is to make informed decisions independent of corporate influence. If a monetary bond forms between a bioethicist and a corporation, then their decisions might not be on par with representing the public good.⁷² Arguably, bioethics consultants should volunteer their time similar to members of IRBs and hospital ethics committees. To date, only one biotechnology company, Geron, says it uses unpaid consultants.⁷³

The urgent need for bioethicists in the biotechnology and pharmaceutical industries warrants reasonable compensation for services. Arguments that bioethicists should not receive compensation for their efforts are counterintuitive, since industries seek to achieve advice from bioethicists by expending funds to search for solutions to their ethical problems.⁷⁴ To attract and work with the best and brightest bioethicists, some level of compensation must exist. In an ideal world, bioethicists might volunteer their time, but at what cost? If individuals do not receive compensation for their efforts, there is little incentive to routinely consult.⁷⁵ Therefore, a minimal level of compensation is necessary for bioethicists providing their expertise to corporate biotechnology to prevent bioethicists from concluding that consultation is not worth their time and effort.

While the IRB system works without compensation and individuals still participate, the analogy is poor, and at best, only tangential because the industries represented are completely different. Biotechnology and pharmaceuticals are driven to make large amounts of money, whereas the goals of academic institutions and hospitals are to

⁷⁰ Thomas Donaldson, *The Business Ethics of Bioethics Consulting*, HASTINGS CENTER REP., Mar.-Apr. 2001, at 12, 13 (analyzing means of rationalizing ways in which bioethical consultants can accept money without creating conflicts of interest).

⁷¹ See Zoloth, *supra* note 65, at 15.

⁷² See Leigh Turner, *The Greening of Bioethics: Corporate Funding of Bioethics Research*, 7 CAMBRIDGE Q. HEALTHCARE ETHICS 326, 327 (1998) (stating that "alliances between bioethicists and corporations could . . . serve to undermine reflective social criticism.").

⁷³ Vicki Brower, *Biotechs Embrace Bioethics*, BIOSPACE.COM ONLINE FEATURE, June 14, 1999, at http://www.biospace.com/articles/061499_print.cfm (last visited Feb. 20, 2005). Yet, newspaper reports state that one member of Geron's ethical advisory board, Laurie Zoloth, receives \$1000 per meeting. Stolberg, *supra* note 12, at A16.

⁷⁴ See Donaldson, *supra* note 70, at 12.

⁷⁵ *Id.*

increase the advancement of science and protect public welfare and safety. Hence, the individuals that participate in the IRB system might be representing themselves or their community to ensure the safety of human subjects in their area, and maintain a standard, representative of their own ideals.

A second and largely supported argument is that it is acceptable for bioethicists to receive money because ethicists are professionals using their skills to provide professional advice.⁷⁶ If one defines a "professional" as an individual with skills and knowledge dedicated to providing a "broader good that defines both expertise and service," then it is feasible that a professional bioethicist may be able to separate the benefits of receiving compensation from generating a conflict of interest with the responsibilities of providing sound and ethical advice.⁷⁷ If one is able to achieve this separation, then there is no reason to hold that they could not remain "true to the values of [their] profession."⁷⁸ The fear as stated previously is that without compensation, no incentive would exist to consult, and bioethicists would eventually stop providing bioethics advice.⁷⁹ If there is acceptance that corporations and society can consider bioethicists as business professionals, then separation of personal and financial interests from their role as ethical advisors is imperative to assure that they meet the needs of the client's interests.⁸⁰ Failure to separate such interests undermines the social good and protection of the public welfare that corporations and bioethicists purport this relationship is meant to achieve.

Bioethics consultants receive varying amounts of compensation for their work. Some bioethicists such as Ron Green, a theology professor and member of the Ethics Advisory Board at Advanced Cell Technology, choose to receive a compensation package that he believes to be de minimus and consists of a \$200 stipend per meeting similar to the compensation that grant reviewers for the NIH receive.⁸¹ In addition to this stipend, the members of this board receive travel expenses, but do not receive any compensation for time spent beyond the quarterly meetings.⁸² This stipend tends to be at the low end of the spectrum of payments to ethics advisors according to Green.⁸³ Laurie Zoloth, chairwoman of the Geron ethics board believes she also re-

⁷⁶ *Id.* at 13.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.* at 12.

⁸⁰ *Id.* at 13.

⁸¹ Green et al., *supra* note 20, at 29.

⁸² *Id.* at 28-29.

⁸³ *Id.* at 29

ceives a de minimus fee, albeit \$1000 per meeting.⁸⁴ Considering that many bioethicists are willing to donate their time to advisory boards under the belief that their occupation is meant to serve the greater good, \$1000 per meeting seems far from de minimus.

Other bioethicists such as Arthur Caplan, a bioethicist from the University of Pennsylvania, believe corporate money should be abundantly circulating and have no qualms about receiving huge salaries or even stock options.⁸⁵ This view that money needs to be more abundant in the bioethics community is because the amount of advice and the importance that biotechnology is placing on ethics should force them to realize that this is an investment in a worthwhile endeavor.⁸⁶ In addition to any consultation fees that Caplan receives from corporations, he also receives compensation in the form of stock options from Celera Genomics that he reportedly sells, passing the proceeds over to the University of Pennsylvania Bioethics Research Center.⁸⁷ It has been reported that one year, the stock was worth \$100,000.⁸⁸ Conflicting reports however, suggest that Caplan does not receive payment from corporations and in fact, Caplan states that, "I can be more outspoken if I'm not on the payroll."⁸⁹

Several examples describe bioethicists who are capitalizing on the availability of corporate compensation and the industry need for ethical advice. Janssen Pharmaceuticals pays its bioethics consultant, Evan DeRenzo, on an hourly basis to sit in on meetings, develop corporate policies, review research protocols and provide educational sessions.⁹⁰ DeRenzo is a staff member at the Center for Ethics at the Washington Hospital Center and feels that the argument that accepting compensation reduces impartiality and objectivity is nothing more than a "myth."⁹¹ A second example is "The Ethics Guy," Bruce Weinstein. Once a faculty member in the bioethics department at West Virginia University, Weinstein now provides ethical advice in

⁸⁴ Stolberg, *supra* note 12, at A16.

⁸⁵ See Boyce, *supra* note 63, at 18-19.

⁸⁶ Email from Arthur Caplan, Ph.D., Director, Center for Bioethics, University of Pennsylvania, to Kevin Schadick, Case Western Reserve University School of Law (Feb. 28, 2004, 17:29:04 EST) (on file with author).

⁸⁷ Stolberg, *supra* note 12, at A16.

⁸⁸ *Id.*

⁸⁹ Brower, *supra* note 73 (stating further that Caplan does not receive payment from Celera Genomics and donates the honoraria he receives to an independent foundation).

⁹⁰ Carl Elliott, *Pharma Buys a Conscience*, AM. PROSPECT, Sept. 24, 2001, at 16, 19.

⁹¹ *Id.* at 19-20.

the form of lectures and seminars to a wide range of businesses, for which he is generously paid.⁹²

Finally, the newest incarnation of advice providers has emerged through the Internet at Foreview.com.⁹³ Foreview hires ethicists and advisors to provide businesses with expert opinions and advice.⁹⁴ According to Carl Elliott, participating ethicists receive \$175 per question answered initially and, with more experience, the ethicists are assigned more extensive consulting projects for which they set their own rates.⁹⁵ Foreview takes a ten percent finder's fee, capped at a maximum of \$5,000.⁹⁶

B. Institutional Compensation

The compensation problem is not isolated solely to individual bioethicists. Academic bioethics centers are now receiving generous grants from biotechnology and pharmaceutical corporations for their role in researching controversial ethics questions.⁹⁷ In 2000, the Midwest Bioethics Center announced that Aventis Pharmaceuticals funded a new \$587,000 initiative.⁹⁸ Likewise, the Merck Company Foundation funded several international ethics centers around the world.⁹⁹ Universities such as the University of Pennsylvania and Stanford are well-known for their lucrative affiliations with biotechnology and pharmaceutical corporations.¹⁰⁰

Non-profit and university corporate sponsorships do not come without a price, however. In 2000, the first reported case of a corporation cutting a bioethics center's funding occurred when Eli Lilly rescinded its \$25,000 annual grant to the Hastings Center.¹⁰¹ The Hastings Center publishes the well-known journal, the Hastings Center Report. One issue of the journal dedicated itself to a discussion of antidepressants such as Prozac.¹⁰² One of the articles contained within

⁹² *Id.* at 19. Information on the services provided by Bruce Weinstein is available at his website, <http://www.theethicsguy.com> (last visited Feb. 28, 2005).

⁹³ Elliott, *supra* note 90, at 19. For a full description of the services available, see <http://www.foreview.com>. (last visited Feb. 28, 2005).

⁹⁴ Elliott, *supra* note 90, at 19.

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *E.g. id.* at 16.

⁹⁸ *Id.* at 17.

⁹⁹ *Id.*

¹⁰⁰ *See id.*; Boyce, *supra* note 63, at 19; Press Release, Center for Science in the Public Interest, CSPI Calls for Prevention and Disclosure of Conflicts of Interest in Bioethics (June 11, 2002), available at http://www.cspinet.org/new/bioethics_061102.html (last visited Feb. 22, 2005).

¹⁰¹ Elliott, *supra* note 90, at 17.

¹⁰² Symposium, *Prozac, Alienation, and the Self*, HASTINGS CENTER REP.,

the issue strongly criticized Prozac, Eli Lilly's flagship product.¹⁰³ As a result of the editor's decision to publish the article, Eli Lilly pulled the Hastings Center's funding.¹⁰⁴ Yet, the function of the Hastings Center and its journal is to produce unbiased work that embraces both sides of ethical debates and to inform the public that such issues exist.¹⁰⁵

The dilemma illustrated by the Hastings Center's loss of funding is the fundamental problem associated with conflicts of interest. How does one maintain harmony between the funding source and what is ethically correct? Additionally, how do interested parties know which bioethicists and what corporations have partnerships? Currently, neither regulations nor standards require disclosure of compensation received by bioethicists or their institutions. The highly debated question among bioethicists is how much disclosure is sufficient and where should this disclosure occur? As this is an important issue, many articles attempt to provide answers and solutions to this debate. The next section will include an analysis of disclosure proposals developed by various bioethicists when corporate consultants publish articles about controversial science or speak out against their clients.

IV. CORPORATE RELIANCE, THE RIGHT TO SPEAK OUT, AND DISCLOSURE

The role of a bioethics consultant is to advise biotechnology and pharmaceutical companies how to handle ethical issues with their scientific research, and how to proceed to ensure the protection of human research subjects. As with all business consultations, corporations may choose whether or not to heed that advice.¹⁰⁶ This choice follows from the facts that companies who utilize bioethics consultants and advisory bodies are not ensured that they are receiving good advice.¹⁰⁷ The inherent problems discussed in previous sections regarding conflicts of interest and inadequate experience might lead to bioethicists who provide misguided advice. Therefore, corporate entities retain the right to choose which advice to follow or discard.

Mar.-Apr. 2000.

¹⁰³ Elliott, *supra* note 90, at 17. The controversial article which resulted in the loss of one of The Hastings Center's corporate sponsors is David Healy, Good Science or Good Business?, *HASTINGS CENTER REP.*, Mar.-Apr. 2000, at 19.

¹⁰⁴ Elliott, *supra* note 90, at 17.

¹⁰⁵ See The Hastings Center, *About the Center*, available at <http://www.thehastingscenter.org/about.asp> (last updated Apr. 29, 2004).

¹⁰⁶ See, e.g., Brody et al., *supra* note 20, at 19.

¹⁰⁷ Brower, *supra* note 73.

Corporations that choose not to heed the advice of their consultants have received heavy criticism from bioethicists who disagree with this choice. There are two major criticisms that bioethicists put forward. First, the freedom for a biotechnology company to select which advice it would like to follow makes bioethicists nothing more than “corporate window dressing” or a “rubber stamp” approval system.¹⁰⁸ Second, bioethicists are heard only when controversial research subjects need smoothing over, thus making them no more than a public relations tool for the corporate entity to use.¹⁰⁹ This section examines individually the two criticisms presenting known examples of each. The section continues by discussing one remedy that is currently employed by bioethics consultants to ensure that they have opportunities to be heard if management decides not to heed their advice. Finally, the section concludes with a discussion of the problem of disclosure when bioethicists publish and speak out about controversial scientific research.

A. Corporate Window Dressing

In 1999, Jesse Gelsinger died from an experimental gene therapy trial.¹¹⁰ The trial conducted through the University of Pennsylvania was in conjunction with one of its professors, who funded the trial in part through proceeds from his personal start-up biotechnology company, Genovo Corporation.¹¹¹ The University of Pennsylvania consulted with Dr. Arthur Caplan as its bioethics advisor to set up the gene therapy trial to help infants with ornithine transcarbamylase deficiency (OTC).¹¹² The advice that Caplan provided was accurate advice, that infants cannot be used in clinical trials, and that this gene therapy treatment needed to first be studied on adults.¹¹³ Jesse Gelsinger, diagnosed with OTC but healthy at the time, volunteered and was selected for the gene therapy trial. Shortly after he began participating in the trial, his health rapidly decreased, ultimately leading to his death.¹¹⁴

Jesse Gelsinger’s family sued the University of Pennsylvania, Genovo Corp., and Dr. Caplan.¹¹⁵ During this period, the University

¹⁰⁸ *E.g., id.*; Green et al., *supra* note 20, at 28.

¹⁰⁹ *See* Elliott, *supra* note 90, at 20.

¹¹⁰ *See generally* Sheryl Gay Stolberg, *The Biotech Death of Jesse Gelsinger*, N.Y. TIMES, Nov. 29, 1999, §6 (Magazine), at 137 [hereinafter *Biotech Death*] (detailing the gene therapy trial and circumstances leading to Gelsinger’s death).

¹¹¹ Stolberg, *supra* note 16, at A26.

¹¹² *Biotech Death*, *supra* note 110, at 137.

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ Complaint, *Gelsinger v. Univ. of Penn.* (2000), available at

of Pennsylvania made several statements that it was not at fault, complied with all of the FDA's recommendations, and had in fact received advice from Caplan about the appropriate way to set up this trial.¹¹⁶ Caplan was dropped as a defendant from the suit, which later settled with the University of Pennsylvania essentially admitting that it was liable for its choices.¹¹⁷

Although the issue of this case pertained more to the use of Jesse Gelsinger as an inappropriate research subject rather than to incorrect advice or failure to rely on Caplan's advice, it illustrates the point that corporations and even universities are using bioethicists to attempt to avoid corporate liability and accountability. Corporations are more frequently listing on their Internet websites that they recognize their ethical responsibility and have assembled a board of bioethicists to analyze and advise them on issues of bioethics as they arise.¹¹⁸ The bioethicists on the board presumably are present to examine issues objectively and with impartiality.¹¹⁹ The information on corporate websites might mislead the public, who could believe that the board has some decision-making or veto power within management. Rather, since they are only providing advice, the role of bioethic consultants is really to ask the critical ethical questions and to examine where potential issues might lie should the companies proceed.¹²⁰ Critics further contend that the role of bioethicists is to give credibility to biotechnology companies conducting controversial research.¹²¹ As a result, those companies who deal well in the public's eye with controversial issues will see an increase in the market of their profits and general support from the public.¹²²

<http://www.sskrplaw.com/links/healthcare2.html> (last visited Feb. 22, 2005).

¹¹⁶ *Biotech Death*, *supra* note 110, at 137.

¹¹⁷ See Sharona Hoffman, *Continued Concern: Human Subject Protection, the Institutional Review Board, and Continuing Review*, 68 TENN. L. REV 725, 725 n.3 (2001).

¹¹⁸ *E.g.*, ADVANCED CELL TECHNOLOGY, *supra* note 19.

¹¹⁹ See Boyce, *supra* note 63, at 18; Virginia A. Sharpe, *Science, Bioethics, and the Public Interest: On the Need for Transparency*, HASTINGS CENTER.REP., May-June 2002, at 23 (discussing the need for bioethicists and corporations to disclose their financial interests).

¹²⁰ See, *e.g.*, Sharpe, *supra* note 119.

¹²¹ *Id.* at 25 ("Having an ethicist on board can enhance a company's public image, deflect criticism, or lend credibility to its actions.")

¹²² See Brower, *supra* note 73 (stating that the bioethics committee for the Biotechnology Industry Organization advises close to 100 companies and has been successful in showing companies how to handle controversial research endeavors).

B. Public Relations

Public exposure to controversial research leads into the second issue of a corporation's deference when accepting consultant advice; the criticism that bioethics consultants are only tools for public relations.¹²³ The ethics boards from both Geron and Advanced Cell Technology can be perceived as exemplifying this issue. In the case of Geron, the corporation sought the advice of both its ethics board and the bioethics committee from the Biotechnology Industry Organization (BIO) to determine a strategy to handle public relations issues pertaining to the upcoming publication of two of its stem cell studies.¹²⁴ According to Carl Feldbaum, head of BIO, the announcement of Geron's research "was very well-received" and a "textbook case of how it should be done."¹²⁵ But what exactly did the ethics board do to help Geron with their ethical responsibilities? In this case, no information is available to help elucidate this question.

In another example, the Ethics Advisory Board (EAB) of Advanced Cell Technology played a similar role in defending reports that the company was performing controversial human therapeutic cloning research.¹²⁶ Unlike the Geron ethics board, the EAB released a statement in June 2002 that it supported the ongoing research at Advanced Cell Technology and its role had been to recommend strict guidelines to management on appropriate strategies for conducting human embryo research.¹²⁷ In addition, although it supported the research, it stated that the research "should never be done in humans."¹²⁸ Critics argue that the EAB is playing an "activist role in arguing for what [Advanced Cell Technology] is doing," yet the members of the board contend that their advice has made a significant impact on the way Advanced Cell Technology performs its research.¹²⁹

C. The Right to Speak Out

Bioethicists seeking to disprove the criticism that they are nothing more than public relations tools and corporate window dressing are

¹²³ See, e.g., Elliott, *supra* note 90, at 20 (stating that "[n]o matter how outrageous a corporate policy, no matter how troubling a headline in the morning paper, it will be softened by the knowledge that the corporation in question has consulted with a team of ethics experts.").

¹²⁴ Brower, *supra* note 73.

¹²⁵ *Id.*

¹²⁶ GREEN ET AL., *supra* note 22.

¹²⁷ *Id.*

¹²⁸ Eckelbecker, *supra* note 67, at E1.

¹²⁹ Green et al., *supra* note 20, at 27.

instituting policies to ensure that their opinions will not go unheard.¹³⁰ Although biotechnology companies require bioethics consultants to sign confidentiality agreements, bioethicists are now contracting to possess a right to speak out, or the “power of the pen.”¹³¹ The “power of the pen” provision allows bioethicists to write articles or make public statements about the ethical issues involved with specific biotechnology so long as they do not disclose any confidential and proprietary corporate information.¹³² This allows bioethicists to maintain some form of independence without subjecting themselves to a situation where they represent a biotechnology company that decides not to heed their advice.¹³³ The members of the EAB at Advanced Cell Technology stated that the willingness of management to allow this provision gave them sufficient confidence that they would not be used as corporate window dressing.¹³⁴

D. Disclosure

With the infusion of bioethicists into the biotechnology industry, an increase in commentary and published journal articles is emerging within the field. Bioethicists are criticizing the works and contacts of their colleagues without disclosing their own conflicts of interests. Additionally, bioethicists with the “power of the pen,” or those commenting in favor of a biotechnology company, are also not revealing financial interests. The lack of disclosure of conflicts of interest presents a serious issue that could potentially “undermine the credibility of [bioethics] scholarship.”¹³⁵

The authority that a bioethicist possesses is dependent upon the public perception of the individual “providing social commentary and normative analysis not allied to corporate concerns.”¹³⁶ One concern of bioethicists should be to maintain credibility of and within their field.¹³⁷ With the increase in corporate funding and a lack of adequate disclosure, the perception of the public that bioethicists are working to further a “greater good” will begin to falter and could eventually be eliminated in the eyes of a distrusting public. Regardless of disclo-

¹³⁰ See, e.g., *id.*

¹³¹ *Id.*

¹³² *Id.*

¹³³ E.g., *id.*; ADVANCED CELL TECHNOLOGY, *supra* note 19 (noting that the company’s Ethics Advisory Board is autonomous and have no financial interest in the company).

¹³⁴ Green et al., *supra* note 20, at 29

¹³⁵ Turner, *supra* note 72, at 327.

¹³⁶ *Id.*

¹³⁷ *Id.* at 328.

sure, however, those that encounter bioethics consultants will be left to decide on their own whether or not they feel that “bioethicists [are] motivated to reach their conclusions by careful deliberation rather than the promise of financial gain.”¹³⁸

The first step to address the conflicts of interest problem ought to occur through bioethics journals requiring disclosure of conflicts of interests from their authors.¹³⁹ Journals are a starting point because evidence from scientific research demonstrates that financial ties influence scientists to either exaggerate or downplay the potential harm of a manufactured product.¹⁴⁰ The potential for bioethicists to exhibit similar influence as the result of highly paid consultation fees is likely.

The call for disclosure within journal articles varies. Some bioethicists feel it sufficient to mention that they simply perform consultations for various corporations without listing specifics,¹⁴¹ whereas others feel that full disclosure of all specific financial ties is necessary to adequately inform the public.¹⁴² There is also an additional debate over whether bioethicists need to repeatedly disclose their financial conflicts of interest in all situations or merely whenever they are commenting on the “research or products of a particular client.”¹⁴³ The editor of the Hastings Center Report, which published these conflicting viewpoints, responded by stating that individual journals may choose how much disclosure is necessary for a particular article.¹⁴⁴ Furthermore, journals must look to the subject of the article to determine whether a fully detailed disclosure is necessary or whether it is sufficient to merely mention that the author performs corporate consultations.¹⁴⁵

In a similar situation applicable as a potential solution to this debate, a review in the *New England Journal of Medicine* recently set forth suggested guidelines for scientific authors to prevent financial incentives from generating corporate influence.¹⁴⁶ The two-fold solu-

¹³⁸ *Id.* at 327.

¹³⁹ See, e.g., Elliott, *supra* note 64, at 11; Stuart J. Youngner and Robert Arnold, *Who Will Watch the Watchers?*, HASTINGS CENTER REP., May-June 2002, at 21.

¹⁴⁰ See Sharpe, *supra* note 119, at 23-26.

¹⁴¹ See Brody et al., *supra* note 20, at 15.

¹⁴² Youngner & Arnold, *supra* note 139, at 21.

¹⁴³ Baruch Brody et al., *The Task Force Responds*, HASTINGS CENTER REP., May-June 2002, at 22, 23 [hereinafter *Task Force*] (responding to Youngner’s accusations that the Task Force did not follow the guidelines it proposed within their article).

¹⁴⁴ Gregory E. Kaebnick, *Difficulties with Disclosure*, HASTINGS CENTER REP., May-June 2002, at 3.

¹⁴⁵ *Id.*

¹⁴⁶ See Zoloth, *supra* note 65, at 16.

tion consists of disclosing all financial relationships and limiting those relationships to “de minimus levels.”¹⁴⁷ Unfortunately, “[m]ost bioethics journals do not even require conflict-of-interest disclosures. And even when a financial relationship is disclosed, the amount of money that has changed hands [has] not [been disclosed].”¹⁴⁸ This view has begun to change recently and journals such as *Nature*, *Science*, and the *Hastings Center Report* are requiring disclosure of financial ties from their contributors.¹⁴⁹ One final proposal for journal disclosure requirements consists of transparency with regards to sources of funding for the published topic; author’s financial relationships with other companies and associations that could benefit or be harmed as a result of the publication; and the specific contributions of each author to the published work.¹⁵⁰

In addition to individual disclosure within journal publications, there has been a call for bioethics centers, many of which do not release their financial information to the public, to increase their disclosure of financial ties of the center itself and those bioethicists in residence.¹⁵¹ This proposal consists of setting a policy such that a bioethics center should provide through its website or annual statements a “clear statement[] on external funding and consultancy; the types of affiliation that are unacceptable; and procedures for conflict-of-interest management.”¹⁵² Finally, centers should make funding information of faculty, other staff, and any other relevant information available for full public disclosure on their website.¹⁵³

While disclosure is often good, some believe that it can be “not only unnecessary but destructive.”¹⁵⁴ The rationale for this viewpoint is that there are a limited number of scenarios when disclosure is required, but in other situations disclosure can be harmful.¹⁵⁵ One scenario where disclosure is necessary occurs when a bioethicist is presented as an expert in support of a topic that the public is unable to

¹⁴⁷ *Id.*

¹⁴⁸ See Elliott, *supra* note 90.

¹⁴⁹ See Zenit, *Corporate Bioethicists: Watchdogs . . . Or Show Dogs?*, CULTURE LIFE FOUND. & INST., Aug. 4, 2001, at <http://www.christianity.com> (last visited Feb. 20, 2005).

¹⁵⁰ Sharpe, *supra* note 119, at 25-26.

¹⁵¹ E.g., Letter from Virginia A. Sharpe, Ph.D., to Colleagues of the Center for Science in the Public Interest (June 7, 2002), available at http://www.cspinet.org/new/pdf/letter_to_bioethics_orgs.pdf.

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ Lynn A. Jansen & Daniel P. Sulmasy, *Bioethics, Conflicts of Interest, and the Limits of Transparency*, HASTINGS CENTER REP., July-Aug. 2003, at 40, 40.

¹⁵⁵ E.g., *id.* at 41.

critically analyze or evaluate.¹⁵⁶ Therefore, the expert's conclusions must be taken as authoritative. To combat excessive reliance on the bioethicist, disclosure of financial ties and incentives is an appropriate mechanism to evaluate the reliability of the bioethicist.¹⁵⁷ An example of a situation where a bioethicist is taken as an authoritative source occurs when a biotechnology company releases a statement of study results endorsed by its bioethicist and the public has no access to the actual data or research protocol.¹⁵⁸ Here, the public has no choice but to rely on the endorsement of the bioethicist that performance of the study fits within ethical boundaries. Additionally, bioethicists often appear on television commenting on research, and news reporters should seek disclosure information to be made available to the viewing public.¹⁵⁹

The alternative to the argument that disclosure is appropriate in specific contexts is that disclosure is altogether unnecessary. Similar to court proceedings where judges often prevent specific evidence from being heard by the jury in fear that it might bias their opinion, disclosure of information could also affect a reader's opinion.¹⁶⁰ For example, readers that are aware that an author has received corporate funding could be biased either consciously or subconsciously to discredit the arguments and claims within a specific report.¹⁶¹ Thus, there are specific situations in which disclosure is harmful. However, looking at this argument from the alternative perspective, disclosure is often necessary to try to avoid blind reliance by the public on the advice that a consultant gives. Therefore, it is necessary to strike a balance between when public disclosure is necessary and unnecessary.

V. RECOMMENDATIONS

The bioethics community, the biotechnology and pharmaceutical industries, and the government can take several actions to ensure that the relationship between bioethicists and corporate entities is one that looks towards the protection of the safety of human research subjects. Furthermore, bioethicists and industry should have the similar goal of maintaining that the pursuit of scientific research falls within ethical boundaries. The focus of this Note has been to examine problems from the perspective of the bioethicist, and therefore the following recommendations are centered on what means could be utilized to

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.* at 42.

strengthen the requirements for bioethicists who wish to consult for biotechnology and pharmaceutical companies.

First, bioethicists need to achieve and prove a level of competency to adequately reassure the public and industry that they are capable of advising companies on controversial scientific research. The methods employed by the states in establishing licensing requirements for educators, stockbrokers and investment advisers could provide a framework for the establishment of a registration and licensing bureau for individuals seeking to function as bioethics consultants. Registration requirements for bioethics consultants would ensure that the public could obtain information on bioethicists from a central location. Each bioethicist would fill out a form stating his educational background, practical experience, and appointments or achievements. In addition, registration could ensure adequate education and minimize problems such as conflicts of interest since they would require full disclosure from the applicant.

While licensing regulations such as those for teachers and stockbrokers would be an ideal method to begin to standardize the requirements of bioethics consultants, it does not have to be driven by the state regulatory system. A private licensing bureau, similar to the National Association of Securities Dealers,¹⁶² governed through an association affiliated with academic universities could provide the appropriate standardization necessary.

If one were to require licensing, the argument remains whether an agency or standardized test can adequately test bioethics knowledge. The requirements set out by the licensing bureau should include an advanced degree consisting of a minimum number of bioethics courses. Simply having an undergraduate degree is not enough. Since many universities now have bioethics departments, it would not be an undue hardship to require individuals to enroll in courses specifically designed to deal with issues that one might confront in the profession. From there it is difficult to determine what other skills should be required for a bioethicist.¹⁶³ A requirement for a specific number of clinical training hours overseen by a faculty member is also necessary, since such training is integral to the education of social workers and physicians.¹⁶⁴ While a standardized exam could prove useful to test basic knowledge of ethics and the current and ever-changing doctrines in existence, the answers to the questions would be

¹⁶² See *supra* note 48 and accompanying text.

¹⁶³ See Hoffmann et al., *supra* note 23, at 30-31.

¹⁶⁴ For a general discussion of the residency requirement for physicians, see Jennifer F. Whetsell, *Changing the Law, Changing the Culture: Rethinking the "Sleepy Resident" Problem*, 12 ANNALS HEALTH L. 23 (2003).

too subjective because individuals will wind up providing their own ethical ideas and not those of others.¹⁶⁵ Thus, the proposal for a licensing requirement remains limited by the ability to define the means of applying such a system. An alternate solution might be to adopt a registration system similar to that utilized by investment advisers. As mentioned before, this system would not test specific knowledge, but would allow the public to examine a bioethics consultant's background and affiliations, allowing society to reach its own conclusions.

Second, compensation should be commensurate with an industry standard and limited to avoid the inclusion of high consultation fees, additional gifts, stock options, or guarantees. As professionals, bioethicists have a right to compensation for their work, but the level of compensation should reflect the work and expertise required for the position. Setting an industry standard would lessen concerns that bioethicists are advising biotechnology companies for the sole reason of the potential to receive exorbitant salaries.¹⁶⁶ This could help to increase objectivity and independence, two growing concerns that many bioethicists believe are being lost to those individuals who worry that they will be replaced as consultants if they do not provide the advice that companies want to hear.¹⁶⁷ Furthermore, compensation should never be dependent on the results reached.¹⁶⁸ To promote independent thought and ensure that bioethicists advise with the goal of the public safety in mind, consultants should receive compensation regardless of whether they provide advice the company wants to hear, or recommends that the scientific research not be performed.

Third, bioethicists need to reach a consensus on disclosure requirements. Many bioethicists have suggested disclosure requirements and the need for transparency in dealing with corporate consultations,¹⁶⁹ yet adoption and use of these suggestions is minimal within the bioethics community.¹⁷⁰ Bioethicists need to disclose their financial conflicts of interests for the benefit of the public. As mentioned in an earlier section, without disclosure, the public will not be able to discern whether a bioethicist publishing a paper in a journal or making a public statement criticizing controversial research is funded by a company or foundation to express its views.¹⁷¹ Therefore, the need for bioethicists as well as bioethics centers to disclose their financial

¹⁶⁵ See Hoffmann et al., *supra* note 23, at 37.

¹⁶⁶ See Brody et al., *supra* note 20, at 15.

¹⁶⁷ See Donaldson, *supra* note 70, at 13.

¹⁶⁸ See Brody et al., *supra* note 20, at 18.

¹⁶⁹ E.g., Zoloth, *supra* note 65, at 18; Sharpe, *supra* note 119, at 25-26.

¹⁷⁰ See, e.g., Youngner & Arnold, *supra* note, 139 at 21; Task Force, *supra* note 143, at 22-23.

¹⁷¹ See Zoloth, *supra* note 65, at 18.

resources is essential to maintaining the necessary level of objectivity so the public can feel confident relying on the advice given to clients of bioethics consultations.

Finally, bioethicists need to continue to contract for use of the "power of the pen." This has proven to be an effective means of preventing biotechnology companies from seeking a bioethicist's advice and failing to use it.¹⁷² The field of bioethics wants to avoid criticism that portrays them solely as "corporate window dressing" or a public relations tool. Therefore, being able to speak out against management is an effective tool to ensure that bioethicists do not mislead the public into thinking that they are puppets for the biotechnology industry to use to soften news of controversial research.

VI. CONCLUSION

The intersection between bioethics and corporate science has the potential to be a powerful alliance. The importance of biotechnology to address the need for ethics will aid in the elimination of future accidents that never should have occurred because of ethical reasons. Bioethicists are one key to ensuring this future, but they must create standards and maintain their own value systems to avoid losing their credibility in the eyes of the public they are seeking to protect. Bioethicists must begin with adequate education and obtain sufficient experience before entering the corporate world as a bioethics consultant. Then, once they have entered the consulting business, they must maintain diligence to prevent being swayed towards crafting their advice to obtain money rather than protect the public welfare. If this can be achieved, then the union between bioethics and biotechnology stands a chance of maintaining credibility in an overly critical society.

¹⁷² Green et al., *supra* note 20, at 29.