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Bioethics Consultation in the Private Sector

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Abstract
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[Introduction]

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The members of a task force on bioethics consultation report their conclusions. The task force was convened by the American Society for Bioethics and Humanities and the American Society for Law, Medicine and Ethics, although these organizations do not endorse the group's conclusions. Two commentaries follow, and an essay by science reporter Nell Boyce sets the scene.

Bioethics consultation is flourishing in the private sector. The corporate clients are aware that their work raises substantive ethical issues, and often they are concerned about how their response to these issues may affect their public image and their financial standing. Many are prepared to compensate ethics consultants at substantial rates.

This is a new phenomenon for the field of bioethics. Traditionally, most requests for comment and analysis arose within the academic setting, where compensation for consultation is generally modest, if it is offered at all. But consultations are not new. Bioethicists have provided clinical consultations on individual cases and on policy development within academic medical centers, health care delivery systems, and community health care institutions.[1] They have consulted about the design and conduct of clinical trials for public and private funding agencies and have participated on institutional data and safety monitoring boards for those trials.[2] They have also participated as consultants for governmental, quasi-public, and private-foundation working groups developing guidelines for the ethical practice of medicine, biomedical research, and health policy.[3]

What distinguishes this newest form of bioethics consultation are several features:

- the consultation is sought by a for-profit client, not by an academic institution (although this distinction loses force as patents, profits, and biotechnology come increasingly to characterize the academy);

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- the issues have potential financial implications for the clients;

- the consultant is offered a substantial fee and perks for the consultation; and

- the consultant is not a full-time employee of the client (full time consultancy relations raise still other issues, beyond the scope of this report).

Examples of the types of arrangements considered in this report include:

- serving as a member of an ongoing bioethics board such as the Geron Ethics Advisory Board or the DNA Sciences Ethics Advisory Board;[4]

- serving as an ad hoc advisor about a company's research programs or product development, as in the AbioCor Independent Patient Advocacy Council and Pfizer's Advisory Panel on Viagra;[5] and,

- developing background analyses that identify ethical issues and possible corporate responses, as has been done for Framingham Genomic Medicine and by Dupont's Advisory Panel on Biotechnology.[6]

Educational sessions, public performances, and agent-negotiated after-dinner speaking engagements fall outside this list and are not reached by this text. But as academic institutions and not-for-profit corporations begin acting more like for-profit firms, they will fall within the guidelines suggested below.

There are those who have thoughtfully and seriously challenged this new role of bioethicists.[7] In part, these commentators are concerned about the appropriateness of ethicists who should have broader interests, such as concerns about social justice, serving clients whose primary interest is profit-maximizing. This concern is heightened when it is suspected that the consultation is not a genuine request for advice, but rather just an effort to justify what is planned anyway.

In part, too, the critics are concerned about the increased conflicts of interest created by the substantial fees available in the private sector. Finally, they are concerned about the effect that these new consultations may have on both the integrity of the field and its reputation for objectivity, independence, and impartiality. Some are worried about the effect that even the appearance of a conflict might have on the reputation of the field. While some might regard these concerns as inherent in the process of bioethics consultation, others see these problems as unique to this new type of consultation.

It is a premise of this report that the effort of these clients to seek out bioethics consultation as part of their ongoing planning process should be encouraged. The effort of business to become more ethically conscious should be promoted, and since it is unlikely that corporations will have the internal resources to deal with these issues, consultation will be required. Moreover, much of the activity that raises the most complex bioethical issues is now conducted in the private sector (where the majority of research now takes place), and bioethics can have an impact on that activity only if bioethicists can be part of the dialogue.

It is another premise of this report that appropriate compensation is acceptable. Ethics consultation is as deserving of compensation as other types of expertise the client needs. Moreover, while pro bono consultation is often laudatory, affluent for-profit clients do not seem to be the appropriate recipients of pro bono service. Yet compensation poses real risks to the individual and to the field, and the critics are correct to point them out.

The purpose of this report is to identify these risks and to develop strategies to manage them. (While our focus is on consultation in the private sector, some of these risks arise in the more traditional activities of bioethicists, raising the same need for strategies to manage them there.) In some cases we recommend a specific way of managing the risk. In other cases we discuss a range of alternative approaches and identify the strengths and weaknesses of each.

One of our goals in all of this is to minimize threats to independence and objectivity and maximize trust in bioethics consultation. Another goal is to provide context and guidance to those entering into these relations. A third goal is to encourage discussion and debate about this type of consultation in the field.

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Advertising and Soliciting

Until the latter part of the twentieth century, there had been a longstanding agreement in medicine and the law that advertising was not compatible with either the appearance or the reality of professionalism. This agreement seemed particularly impor-

tant in areas where there was no consensus on the credentialing and licensing of experts. In recent years, it has come to be seen that advertising serves two legitimate functions: enabling consumers to be aware of available services and encouraging differentiation between providers.[8]

False or misleading advertisements are still held to be unprofessional, of course. Examples of these include unsubstantiated claims of expertise and experience, promises of outcomes that cannot be guaranteed, and claims to uniqueness. Many professional organizations have already established fuller criteria for appropriate and inappropriate advertising.[9] We believe that those criteria are helpful for evaluating advertising about bioethics consultations and that bioethics consultants should become familiar with the issues and established standards. Examples of reasonable advertisements are newsletters and brochures that describe the consultant's resources and accomplishments.

Soliciting business, which is the targeted approach to individual potential clients, augments concerns about inappropriate advertising and presents the appearance of a "hired-gun" who is not acting in accordance with standards of integrity. Those engaging in soliciting business should therefore exercise diligent care to ensure that professional standards are met. They should also recognize that some in the field will find their behavior inherently objectionable.

The Consultation

The most important technique for minimizing the risks of this sort of consultation is negotiating appropriate terms for the consultation at the outset. Those inexperienced in negotiating contracts, or unsure about the appropriateness of a particular contract, should seek the advice of more experienced colleagues.

When negotiating terms, among the issues it is important to address are the appropriateness of the client, individual versus group consultation, the consultative process, the standards to be used in formulating recommendations, how the results and outcomes will be presented, and the rate of compensation. What approach to these issues is best will necessarily vary depending upon such factors as whether the consultation concerns a single issue or is ongoing, the complexity of the issues, and the possible public impact of the consultative process.

The appropriateness of the client. The consultant has an obligation to find out enough about the client and its history and current projects—the products and services it is developing, for example—to feel comfortable about working with the client. Moreover, the consultant must be con-

A View from the Fourth Estate

by Nell Boyce

Last summer, a colleague stopped by my office with a juicy rumor. Word on the street had it that "bioethics has been co-opted by industry, that all these 'experts' we see in the media are being paid by the very corporations that people are raising questions about."

I began poking around and soon learned that bioethicists themselves were debating this issue. Suddenly I felt naïve. I've been writing about science and medicine for years and I've talked with hundreds of researchers and physicians. I've always known to ask about their funding, but it never occurred to me to ask "ethicists" about conflicts of interest.

At the same time, I wondered: What's the big deal? Other professionals get research money from industry or act as consultants—it's the rare scientist who has no corporate ties. And the arguments of those bioethicists who'd rather work closely with companies than snipe at them from the sidelines certainly made sense. To gauge how the public might react, I began telling friends and colleagues about this "ethicists struggle with their ethics" story, which eventually ran in *U.S. News & World Report.*

The vast majority of them expressed dismay at the idea that someone described as an academic bioethicist and quoted in the national media might benefit in some way from corporate money. They seemed as shocked as if I'd said that I was moonlighting for a biotech company myself.

Obviously, I could never do that; journalists have a well-defined public role that comes with fairly clear rules for ethical behavior. (I've received no money for this piece, by the way, and ran it by two other reporters to see if it would compromise me. They didn't think so, and I hope not.) Money and gifts aren't the only influences that journalists have to avoid, but they're the most quantifiable. It's no mystery why the public got mad when CNN anchor Lou Dobbs took $30,000 for giving a speech to Ford Motor Company just days after his program featured the company's CEO.

Why should the public care if a bioethicist solicits $30,000 from a biotech company? Perhaps it shouldn't. But many people do seem to care. The disapproval that

Nell Boyce, "A View from the Fourth Estate," *Hastings Center Report* 32, no. 3 (2002):

cerned about whether consulting on these projects generates a conflict of interest, since the consultant may already be working on the same set of issues for other corporate clients or for government agencies. Unless all of these other parties are informed and have agreed that the consultant may accept the new consultation, it should not be undertaken. Transparency about the full range of the individual's consultations avoids problems with the use of confidential or proprietary information and protects the consultant's ability to separately examine the issue in each individual setting.

Individual versus group consultation. The benefits of a group process may include a diversity of viewpoints and disciplines and an intrinsic peer review process. On the other hand, an individual consultation may offer the benefits of clarity of result and speed of process. The respective advantages of these options will depend on the complexity of the issues, the timetable dictated by circumstances, and the client's needs. If it is agreed that a group process is preferable, then each candidate for the group should have information about the other members' qualifications and affiliations when deciding whether to participate in the group. Regardless of which arrangement is suggested by the client, those approached should consider whether they are the appropriate experts to be included in that process. Possibly others are more skilled on the particular issues and should be recommended to the client.

The consultative process. The structure of the consultative process may vary considerably. Among the issues to be addressed in the agreement:

- Who convenes and chairs the process?
- Is the agenda already identified or will it be developed, and if so, by whom?
- Will reports be approved by a simple majority, a super-majority, unanimity, or consensus (and will there be room for the presentation of minority and dissenting opinions)?
- Under what conditions (including substantial modifications of the process without prior agreement) do the consultants or the client have a right to terminate the process, and what are the implications of that termination?
- How can the client be a useful participant in the discussions without risking the independence of the consultative process?
- What documentation of the activities will be kept to protect the integrity of the process?

The client must provide accurate, complete, and timely information rel-

they have expressed to me implies that they see bioethicists as having a public service role akin to that of a journalist, a government official, or a judge. For professions like these, disclosure of conflicts isn't usually enough—their mere existence threatens the public's trust.

Maybe you never asked for this kind of public role, and maybe you don't want it. Many scholars reject the title "bioethicist" because of its "secular priest" connotation, despite the fact that they work at bioethics centers, write for bioethics journals, and attend bioethics conferences. If the diverse community of philosophers, lawyers, scientists, physicians, and others who study bioethics can't even agree on what to call themselves, how will they reach consensus on their proper public role and their corresponding obligations regarding conflicts of interest? My guess is: They won't.

I hope that they'll at least agree on the need for full, meaningful disclosure of anything potentially compromising when they speak or write publicly about their opinions. If bioethicists can't go along with that, then I as a journalist have a slight problem.

My colleagues and I researched many prominent bioethicists and their academic centers last year. We found some corporate money, to be sure, but not vast amounts. Was that because it wasn't there or because we had no way to find it through public records? As much as reporters might long for subpoena powers, they don't have them. A bioethicist could take a large gift or a grant from a corporation, either for personal use or for a center, and reporters would have no way to know.

So journalists must rely on people to self-disclose. I recently wrote a story on pet cloning, for example, and spoke with a bioethicist who had visited Genetic Savings & Clone, one of the firms pursuing this potential business. This firsthand experience with the company's work probably made her views seem fairly compelling to readers, and the company's CEO says that it paid only her travel expenses.

Hypothetically, imagine that the company said it had given her a large research grant. (I have no reason to think that it did.) Would readers dismiss her views? I don't know, but I'd certainly want to include that information so they could draw their own conclusions.

Now consider another scenario: a bioethicist talks to me about, say, genetically modified crops and neglects to mention that he got a $100,000 grant from an agricultural biotech company. If I found out about that omission, I'd definitely want to write about it. I think my readers would feel that it raised all sorts of fascinating ethical questions—the kind of questions that they could ask and answer without needing help from a professional ethicist.

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evant to the issues raised by the consultation, and in ongoing consultations, to the development of client products and policies. The consultant or team must therefore have access to individuals who can provide this information as needed. The contract must specify that a failure to provide requested either information or access to requested individuals is grounds for the consultant to terminate the contract.

Issues of transparency and confidentiality are particularly difficult to balance. The client might choose to make the entire consultative process confidential as part of its strategic planning process, since even the fact that a company feels it may be confronting an ethical dilemma may reveal a portion of its strategic plan. The ethicists might prefer to keep the process confidential to avoid the appearance of endorsing a particular corporation's effort or product. In high profile cases, especially in cases involving patients or research subjects who request confidentiality, both parties may want to keep the fact of ethics consultation private to avoid undue pressures and the intrusion of the press. Finally, individuals may wish to keep their financial affairs private.

These considerations need to be weighed against the desirability of transparency in a democratic society, the professional benefit to be derived from peer review and criticism, and the corporate need to meet regulatory requirements for disclosure. Full disclosure also allows the field as a whole to understand the substantive and procedural issues. The assessment of these factors is particularly complex in ongoing consultative relationships, such as with standing corporate ethics boards. These issues need to be fully addressed, and a decision about them reached, before the consultant agrees to participate. In any case, if the consultant has an academic appointment, institutional conflict of interest policies may require that the relations at least be disclosed to the institution. Moreover, consultative funding must be disclosed in any public presentation or publication.

Standards for formulating recommendations. A good consultation should contain the following components:

1) a review of the competing relevant positions and principles found in the literature, the reasoning behind them, and their implications for the issues being examined in the consultation in light of relevant empirical data;

2) an identification of that position, if any, which has found widespread acceptance in professional standards, regulations, and government or foundation reports, and a history of the evolution of that standard; and

3) the position of the consultant and the reasons for holding that position, especially if the position differs from the consensus.

The expertise of the bioethics consultant consists in his or her ability to develop these three components. In doing so, too, the consultant may need to refer to international discussions and debates, not only to material developed in the context of United States policy and regulations. This is true both because it's good to listen to alternative voices, and because the corporate response may extend beyond the United States.

It is crucial to carry out consultative obligations with integrity. In this context, that requires a fair and honest analysis involving all of the above components, not a selective opinion that anticipates the corporate interests and identifies only the material that supports the client's interests. It also requires a reasoned presentation, not merely the articulation of conclusions.

Presentation of results and outcomes. The product to be produced must be carefully defined and agreed upon in advance. Is there to be an interim or final report? Is there room for contrasting professional opinions? To whom will the report go? In order to keep the advice from being manipulated, consultants should insist that the report as authored by the consultant be sent to that level of corporate authority that has the power to consider and act on the recommendations, and that the consultant be informed about the decisions reached in response to that report. If there is to be no formal report, then what is the goal of the activity—identifying problems, or developing a greater awareness of ethical issues?

The rate of compensation. Because the rate of compensation may be high and cumulative, concerns about its effect on integrity are real, and compensation needs to be structured to minimize potential conflicts of interest. This means:

1) The rate of compensation must not depend on the conclusions reached. There should be no contingency fees. Nor should compen-

Both the client and the consultant might have reasons for keeping the consultation confidential. Against these stands the desirability of transparency in a democratic society, the benefit of peer review and criticism, and corporate regulatory requirements for disclosure.

sation involve any equity interest whose value might depend on the conclusions.

2) While it is difficult to quantify these issues, a good rule of thumb is that the rate of compensation should not be so great as to compromise the ability of the consultants to drop out of the process if they are not comfortable with either the process or the product. Another good rule is that the rate of compensation should not be so great that the consultant would be uncomfortable if the rate became publicly known. A third rule is that the compensation should be commensurate with the consultant's compensation from other clients, and/or with the compensation offered by that client to other experts.

3) The compensation should be paid only for work actually performed, or as a retainer against work to be performed.

In any case, in computing the rate of compensation, perks such as gifts and payment for attractive subsidized travel should be considered along with direct payments. Finally, consultants may wish to consider arranging their compensation so that at least part of it goes toward socially worthwhile projects and activities.

Post Consultation

Other issues may arise after the formal consultation is completed. Among these are the consultant's obligations as an advocate and as a whistle-blower, the publications and presentations permitted by the contract, and the consultant's role as an educator.

Responsible advocacy and whistleblowing. In the normal consultative process resulting in recommendations, the consultant remains available to meet with decisionmakers, at their request, but has no further obligations to advocate for the positions presented in the recommendations. In certain circumstances, however, where the harm to affected and unaware others resulting from disregarding advice may be great, the ethics consultant, as any other consultant, retains a role of continued advocacy within the corporate context. This role may entail going beyond submitting the recommendations and beyond remaining available for further discussion; it may require that the consultant take the initiative to approach higher level managers within the client corporation to identify the danger posed by the client's project and to advocate for the recommendations. Documenting these efforts is essential.

On occasion, the consultant may judge that continued advocacy within the client context is inadequate. In such cases, public disclosure may be required, even though it may violate the terms of the contract. One way to lessen the problem posed by the contract is to include a "whistleblowing" clause in it—although the obligation may remain whether or not the clause is there. In fairness to the client and to honor the contract as best as possible, however, the consultant should offer the client, at the highest level, the opportunity to respond before, and in place of, public disclosure.

The prudent consultant will obtain independent legal advice before taking any action involving public disclosure. Bioethics consultants who are themselves attorneys should be certain that public statements do not breach the attorney-client privilege and subject the consultant to possible professional discipline or civil liability.

Publication and public presentations. Public discussion of ethical issues, prompted by publications and public presentation, is vital both for the professional and public understanding of the issues and for informed public policy. Discussion is particularly important both about the conduct of ethics consultation and about the often contentious issues addressed in consultations.

As a general rule, then, the consultant should try to persuade the client to incorporate into the agreement between them the right to publish the results of the consultations after it is completed, subject to protection of client secrets, to review but not censorship by corporate officials, and to the protection of the interests of other consultants involved in the consultation. This last condition means that the product of a group consultation should not be published by any individual without the permission of the group. In addition to these public benefits, this policy enables academic consultants to contribute to the development of the field. In offering these presentations and publications, any consultative relations relevant to the presentation or publication should be fully disclosed.

Educating for a developing field. Further discussion of these issues within our field is essential. We see this report not as the final word but as the beginning of public debate. As part of that process, discussion of these issues should also be part of graduate education in bioethics and cognate fields.

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Disclaimer

The views and opinions contained in this article/report are those of the members of the American Society for Bioethics and Humanities (ASBH) and the American Society of Law, Medicine and Ethics (ASLME) Task Force on Bioethics Consultation in the Private Sector, and should in no way be construed as representing official policies of the ASBH or the ASLME, their membership, or their boards of directors.

Disclosures

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formed consultations of the type described in this article.

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1. American Society for Bioethics and Humanities, *Core Competencies for Health Care Ethics Consultation* (Glenview: American Society, 1999).

2. A good example is the National Institutes of Health Recombinant DNA Advisory Committee. The NIH Guidelines call for members who are knowledgeable in "standards of professional conduct and practice." Section IV-C-2 of "NIH Guidelines for Research Involving Recombinant DNA Molecules," *Federal Register*, (5 January 2001) 66FR1146. The presence of bioethicists on data safety monitoring boards is endorsed in the 10 June 1998 NIH Policy for Data and Safety Monitoring, available at www.nih.gov/grants/guide/notice-files/not98-084.html. A committee on which bioethicists have consistently played a major role is described in D.L. Demets et al., "The Data and Safety Monitoring Board and Acquired Immune Deficiency Syndrome (AIDS) Clinical Trials," *Controlled Clinical Trials* 16 (1995), 408-21.

3. Prominent governmental examples in the United States include the National Commission, the President's Commission, and the National Bioethics Advisory Commission. This phenomenon is not unique to the United States, nor is it that new. See D. Wikler, "Bioethics Commissions Abroad," *HEC Forum* 6 (1994), 290-304. The Nuffield Council on Bioethics is an excellent example of one of the many quasi-public, private foundation-sponsored panels on which bioethicists have served (www.nuffieldbioethics.org/); many more examples exist in the United States and elsewhere.

4. Geron Ethics Advisory Board, "Research with Human Embryonic Stem Cells: Ethical Considerations," *Hastings Center Report* 29 (1999), 31-36. The DNA Sciences board is described on the company's website as follows: "As with all important studies, there are people we depend on to keep us on track. DNA Sciences draws upon the knowledge, expertise and guidance of two boards, a Bioethics Advisory Board to advise us on ethical issues and a Scientific Advisory Board to advise us on scientific matters. Our boards comprise the most highly respected scholars, scientists and practitioners in their respective fields. Because of the nature of our work, we feel it is necessary to put together boards that will serve as objective third parties. They are here to look out for your interests and to make sure that our work stays true to our original mission." The website is www.DNA.com.

5. The Abiomed board is briefly described in the company's 2001 annual report, found at www.abiomed.com: "For the AbioCor clinical trial, we have supported the creation of an Independent Patient Advocacy Council. This group of experienced patient advocates and ethicists, operating completely independent of Company control, is available to supplement the information and counseling provided by the clinical team, and will help to assure a truly informed decision about trial participation. The Council will also serve as an independent source of commentary to the company on ethical issues raised by the AbioCor trial." On Pfizer's board, see J. Timpane, "Hope Takes on Hype," *Philadelphia Inquirer*, 11 May 1998; and L. Weeks, "Viagra Debate Vigorous: Drug Sparks Question of Sexual Politics," *The Washington Post* 26 April 1998.

6. Some of the issues raised by this company's activities, and a brief indication of some of the ethics advice they got, is found in R. Rosenberg, "Questions Still Linger on Heart Study Access," *Boston Globe*, 21 February 2001. DuPont's advisory panel is described on the company's web site (www.dupont.com/biotech/difference/advisory.html) as follows: "Dupont formed an independent panel to guide our actions, help us consider and address important issues, and guide and challenge us in the development, testing and commercialization of new products based upon biotechnology. The advisory panel will audit DuPont's progress and provide a public report on a regular basis."

7. R.J. Neuhaus, "The Best Bioethicists That Money Can Buy," *First Things* (March 2002): 71-72; C. Elliot, "Pharma Buys a Conscience," *The American Prospect,* 24 September 2001.

8. This history is summarized in B. Brody, "Commercial Relations," chapter 5 of B. Brody et al., *Medical Ethics: Analysis of the Issues Raised* (Washington, D.C.: BNA, 2001).

9. Useful discussions are found in the Code of Ethics and three advisory opinions of the American Academy of Ophthalmology, a 1998 statement of the American Academy of Orthopedic Surgeons, and the Code of Ethics of the American Society of Plastic and Reconstructive Surgeons. All of these documents are collected in Brody et al., *Medical Ethics: Codes, Opinions, and Statements* (Washington, D.C.: BNA, 2000).