

Virtual Mentor

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Bioethics Consultation for Pharmaceutical Corporations

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It is a good time to be a bioethicist. Medicine, pharmaceutical development, and the culture wars combine to provide urgency and public interest regarding the traditional questions of moral philosophy in which bioethicists are trained. A fairly recent addition to the repertoire of bioethics is consultation for pharmaceutical corporations, which might involve, among other possible consulting engagements, offering an opinion on contemplated research, participation in an ongoing ethics board overseeing research activities, or preparation of analyses on particular bioethics issues.

Currently, there is no agreement within the field on whether this consultation ought to be a permissible activity or what the guidelines and standards would be if it were. In fact, there is neither a general accreditation procedure nor an accreditation body for bioethicists, though this seems likely to change in the not-too-distant future, based on current debate within the discipline. So for now, the field lacks even broad standards from which for-profit consultation might borrow. Part of the work that must be done prior to formulating standards is identifying the potential problems in for-profit bioethics consultation and who may be harmed by wrongdoing.

Forsaking Our Purpose

Some argue that there is a set of concerns on which bioethicists ought to focus that does not include for-profit consultation [3]. There are 2 aspects to this claim. First, if there are specific activities bioethicists ought to engage in, then time spent away from these makes one, in a sense, less of a bioethicist. Second, the nature of bioethics activities may be in tension with for-profit consultation. For example, many in the field see bioethics as an altruistic or advocative calling, consisting of a duty to help the worse off and to fight inequities in health care. To those who perceive for-profit pharmaceutical companies to be part of the inequality problem, taking money from corporations can be seen as a betrayal of bioethics, harming its reputation and, by extension, the reputation of its practitioners.

Naturally, anyone committed to this position is free not to consult for profit-making companies. The salient issue is whether the alleged harms preclude anyone from engaging in such practice under the label “bioethicist.”

Unseemliness

Another argument, put forward most prominently by Carl Elliott [1, 2], is that it is “unseemly” for ethicists to take money from for-profit corporations. Though it is difficult to articulate exactly what this unseemliness is, it may be the proximity between

what is sometimes perceived of as an ignoble, unethical, or avaricious field (the pharmaceutical industry) and a field that either purports to or is understood to offer moral advice (bioethics). In other words, working for a pharmaceutical corporation gives what ought to be an unsullied profession dirty hands. The harm done by this unseemly proximity would redound exclusively to the profession, since the damaged credibility could lead to diminished opportunities for its practitioners.

Conflict of Interest and Credibility

Especially troubling for some is that bioethics consultants are being paid by the very companies that stand to benefit when their products are viewed favorably by the public, the investment community, and the Food and Drug Administration (FDA). The additional fact that for-profit companies must closely guard the confidentiality of ongoing research projects (and hence the ethical oversight of them as well) means that if a company and an ethics consultant made an agreement that a specific opinion would be delivered for a sum of money, no one might be the wiser. As Elliott summarizes the problem, it may be difficult to trust bioethics consultants who “...are on the payroll of the very corporations whose practices they are expected to assess...” [2].

Conflicts of interest pose a potential danger to the public because the opportunity for personal gain might tempt a bioethics consultant to deliver the answer the pharmaceutical company wants. There is the chance that an individual might be harmed by the medical treatment under question, but, since bioethicists are not the only layer of protection between pharmaceutical corporations and the public (the FDA primarily serves this purpose), this sort of harm is unlikely. Moreover, the likelihood of such fraud is small because, while a bioethicist’s favorable opinion might be worth *something* to a pharmaceutical corporation, it is not clear how much. It certainly would not seem to warrant the chance of being caught, with the adverse publicity that would entail.

Instead, conflict of interest is more likely to harm the profession through a loss of credibility. It is important to note that the most scrupulously ethical consultant may suffer this loss of credibility regardless of the fact that she has done nothing to deserve it, for the mere *appearance* of conflict of interest is sufficient to cast doubt on the profession in the minds of many.

Cherry Picking

A more insidious problem is the possibility of a corporation “cherry picking” bioethical opinion without a consultant’s knowledge. Because bioethics literature comprises a wide variety of reasonable arguments, a corporation need only research those positions and, knowing an individual’s opinion on the ethical issues at stake in the company’s research, approach a bioethicist who has a congenial view. The bioethicist might be unaware of this tactic. All he knows is that his opinion is being solicited. Because he offers his honest opinion, he has done no moral wrong by consulting for the corporation. But has the corporation done wrongly by soliciting the opinion that serves its interest best?

Answering this question requires us to identify the wrongdoing. There is genuine, well-argued disagreement about many principles and issues in bioethics. Is a pharmaceutical corporation duplicitous if it simply seeks someone with similar views? The alternative is

to require corporations to use bioethicists with opposing views, but it is not clear what this would achieve, other than constant disagreement. If for each expert opinion an opposing one can be found, what is ethics expertise and how does the field adjudicate among its experts?

Expertise

When a bioethicist offers an opinion on moral matters, what authority does that opinion possess? Most authors agree that a moral philosopher can be an ethics expert because, due to her training, she can accurately present the moral geography of a case, including the various moral positions available, the consequences of making particular decisions or holding certain moral values, and so on. What remains an area of disagreement is whether a bioethicist can be an expert in the sense of knowing the *right* answer to a moral question, by virtue of her training.

The challenge in assessing moral expertise lies in determining the very standards of evaluation. In the sciences, published results of reproducible experimentation and analysis offer a reasonably solid (though of course evolving) knowledge base against which scientific experts can be assessed. Those who are more familiar with the literature will be more expert than those who are not. In bioethics, a body of literature exists concerning moral argument, and there is consensus on some broad principles (such as the importance of autonomy). And to be an expert in bioethics one needs to command this literature in much the same way as will a science expert. But 2 important features distinguish scientific expertise from ethics expertise. First, the body of knowledge in science is subject to verification by a variety of empirical methods. If there is doubt about some fundamental piece of this knowledge, such as the mechanism of disease or success of treatment, there is a clear means for resolving the doubt. In moral philosophy, very little is subject to empirical testing. Even a moral realist (ie, one who believes that there are objectively correct and incorrect moral values and solutions) cannot offer a reproducible method for ascertaining those values. Disagreement about core moral values fuels a great deal of the tension over answers to moral questions and will not be resolved by future empirical testing.

Second, the experts' recommendations in the sciences can usually be verified post hoc. While it is true that, even in the age of evidence-based medicine, there is still an art to some medical treatment, one physician's application of his art can be shown to have desired outcomes, while that of another does not. In bioethics, there is no means for post hoc evaluation. Some solutions may leave the parties more satisfied than others, but this is not necessarily evidence that a morally correct answer has been reached.

Conclusion

What expertise are pharmaceutical corporations buying when they hire bioethicists, and what authority do these bioethicists have? It is certainly true that bioethics training will impart, in varying degrees, the ability to identify moral issues at stake in a particular case, facility with the major moral arguments, and a familiarity with particular belief systems and their likely implications in particular instances. This can be very helpful in clinical consultations where the patient's or family's wishes are decisive. In pharmaceutical research, on the other hand, there is not always a unique set of values upon which a

bioethics consultant might draw to offer a conclusive answer about the moral rightness of a clinical trial or research agenda. There are often federal or state laws and moral principles generally accepted within the bioethics community that are decisive—for example, no bioethicist ought to condone a clinical trial which would deceive participants. Yet there are also many questions, such as the moral permissibility of embryonic stem cell research, that hinge on one's core moral values. With this kind of question, a bioethicist can only illuminate possible arguments, not offer a conclusive answer.

References

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