Is there a bioethicist in your company? Should there be?

'Companies should consider bioethics to deal with the minefields that current dilemmas and future technologies create.'

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When bioethics first showed up on the scene in the 1970s, it was driven by several concerns. On the clinical front, the most prominent concerns were over issues at the end of life: withdrawal of life support, allocation of dialysis and organs, and the role of medicine in ending life. At the same time, there was a crisis in confidence over the regulatory system for protecting human research subjects. Henry Beecher's 1966 article demonstrated that prominent and successful researchers routinely ignored many of the lessons from Nuremberg [1]. In 1972 it was revealed that researchers studying the natural history of syphilis had denied treatment to black men and lied to them about their condition (claiming they had 'bad blood' that needed treatment, to get them to come in for spinal taps) for over 40 years [2]. The Willowbrook scandal revealed that researchers had intentionally infected retarded children with hepatitis [3]. A great deal of important work was done on research ethics and the basic regulatory structure that we have today was put in place during the first decade or so of the existence of bioethics. Through the 1980s and most of the 1990s, bioethics was dominated by clinical concerns, as well as new technologies that could greatly impact on clinical medicine. In the early days of bioethics, most bioethicists were either clinicians, philosophers or theologians; however, the field gradually became more inclusive and came to include law, and especially various empirical, social science methods.

Bioethics today is different in many ways. The media attention devoted to bioethics has exploded, especially since the cloning of Dolly the sheep in 1997 [4]. It is hard to read a newspaper or watch a news show on TV without seeing someone from the field expounding on whatever the current issue is. Bioethics scholars publish more than ever, and it is now common to find bioethics articles (often empirical) in medical and scientific journals.

At the same time, there are many ways in which we are witnessing a similar period to the birth of bioethics. For perhaps the first time since the 1970s, there is a growing concern over several research scandals that have shaken confidence in the regulatory system. The death of Jesse Gelsinger at the University of Pennsylvania (Philadelphia, PA, USA) [5], other revelations of failure to report adverse events in gene therapy trials around the country [6–8], the lead abatement study at Johns Hopkins University (Baltimore, MD, USA), and the problems at the Hutchinson Cancer Center at the University of Washington (North Seattle, WA, USA) [9], follows the temporary shutdown of a Veterans Administration Hospital (Los Angeles CA, USA), as well as shutdowns at Duke (Durham, NC, USA) and the University of Illinois at Chicago (IL, USA). Although it is unclear what the results of all of this attention will be, it is obvious that we are going through an upheaval in the way research is conducted and perhaps at no other time has there been greater interest in using bioethics for compliance support.

What can bioethics do for the pharmaceutical industry?

Bioethics can offer a great deal to the pharmaceutical industry. The benefits can range widely depending on the model of interaction. Compliance officers are often so focused on legal and regulatory issues, that they miss the larger context in which research occurs. Bioethics can provide some of that context. First, companies must be committed to the value of good science. Bioethics is an important part of insuring that the research sponsored by companies or conducted by them is done in an ethically responsible, scientifically rigorous manner. Second, a great deal of thought and literature has gone into exploring some of the tough issues that arise in the drug development process. These include the problems of doing research in developing nations that have different standards of care and different conceptions of individual autonomy

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and consent; placebo versus active control trials; problems with research on 'vulnerable populations'; conflicts of interest; various informed consent problems; and the morass that DNA banking is likely to cause for the industry. Some of these problems are systemic in character and, through input from bioethics, it is possible that companies could become a positive force for change, helping to educate the researchers they sponsor and generally raising the ethical level of research. One final benefit to the companies is that ethicists can act as 'hackers' to deduce areas where companies have problems that need addressing and where they are likely to be criticized. This is essentially the function played by 'research ethics audits', which are becoming increasingly common, although these often have too much focus on compliance. At the same time, bioethicists can benefit from learning more about the nitty gritty of the work that goes on and can gain access to information in a more timely way. It would certainly have been nice to know (before the public announcement) that a cloned mammal was on the way. This can be a benefit to both the bioethicists and to companies.

What are the problems with introducing bioethics into companies?

Perhaps the single biggest drawback to bringing bioethics within a company is the problem of a conflict of interest. Bioethicists who are affiliated with and paid by a company might be perceived as failing to have sufficient independence to address the primary concerns of the company credibly. And there are certainly risks to an employee in telling the company that hired them that there are problems with the way they conduct business. By contrast, simply telling them that everything is fine undermines any value that the bioethicist might have to offer. It is important to recognize that conflicts are inherent in these kinds of relationships and to consider ways of assessing the extent to which they are a problem and ways to minimize and mitigate those problems. Employees who already work for the company and go on to get bioethics training would seem to represent little problem – they were working for the company before receiving bioethics training and it is hard to see how additional education added to existing personnel could be a problem. For outside bioethicists hired by companies there are ways of minimizing conflicts by limiting the amount of support and insuring that there are enough sources of support for that individual or institution that they are in a position to easily walk away from any one source of support.

A second problem with hiring a bioethicist is a related one – that they will simply be 'rubber stamps' that are used for public relations purposes. This is a double-edged sword. For the bioethicist, there is the risk of being used by the company, rather than providing genuine input. For the company there is the risk that an outside bioethicist who feels he or she is being used as a rubber stamp will resign in protest. This has caused a great deal of controversy for at least one company, with attendant media scrutiny.

Who are the bioethicists? What exactly is their role?

There are actually several different roles for bioethicists in companies. One possibility is to have companies hire academic bioethicists (e.g. people with doctorates in philosophy or theology or social science) to work for them. They could help with reviewing protocols, provide educational programs for employees and provide input into company policies. At the same time, the conflict of interest problem is probably more acute for this approach than for any other. A second, related model is to provide bioethics training and education for employees who already work for the company. Masters programs in bioethics are being developed all over the USA and several pharmaceutical companies are sending some of their employees to receive training so that they can bring some expertise back to the companies. We have several representatives from the pharmaceutical industry enter our program each year, funded by their companies. A third model is to create advisory boards of ethicists to advise the company on controversial issues. A number of companies [especially in the biotech arena, such as Geron (Menlo Park, CA, USA) and Advanced Cell Technology (Worcester, MA, USA)] have adopted this model. One of the major drawbacks to this approach is that these board members do not have access to the workings of the company on a day-to-day basis and, therefore, they could be limited in what they can offer. There is clearly a great risk that these kinds of boards largely serve as window dressing rather than substantive help. A fourth model is the 'hacker model'. Companies can bring in outside bioethics consultants to provide criticism of their operations, so that they can improve them. Finally, there is contract work, where outside bioethicists are charged with particular tasks, such as providing educational material or services, addressing particular ethical issues that the company faces, or developing a code of ethics to govern a particular area.

Conclusion

Bioethics is now a part of the cultural landscape. But more than that, bioethics is a field that is a repository of knowledge about issues of concern to the industry. It would be wise for companies to take advantage of this expertise as they deal with the minefields that current dilemmas and future technologies combine to create.

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