

Ethics in Biotechnology – An Executive Guide (version 1.0)

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A concise guide to recognizing, evaluating, & resolving key ethical issues in the biotech industry.

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Why ethics is important

The biotechnology industry faces challenges unlike those faced in other sectors. Few industries conduct research so likely to become front-page news, or so likely to face intense scrutiny by press, academics, government, and consumers. Managers in biotechnology must necessarily think carefully about ethical issues if their companies are to survive.

Almost no one believes any longer that a corporation's *only* obligations are to its shareholders. A high percentage of successful corporations now acknowledge that they need to think of themselves as having responsibilities to a wide range of interested parties. "Social responsibility" is no longer a buzzword; rather, it is accepted as best practice.

Ethics is the attempt to render coherent our thoughts and principles regarding how we behave when our actions affect other people. Ethics is important because doing the right thing is important. It affects how others feel about us and how we feel about ourselves. In addition, there's good reason to think that there are competitive advantages in being able to position your company as the kind of company that is trustworthy and operates with integrity.

Recognizing ethical issues

The first – and perhaps most difficult – element of ethical decision-making is recognizing an issue as an *ethical* issue. It pays to think broadly and imaginatively, here.

Some biotech executives will want to assume that their company's work is unlikely to involve ethical issues or to attract public scrutiny. Such an attitude risks being both naïve and dangerous because the people affected by corporate practices are the very people who decide its propriety and its social / market context – from the regulatory and financial agencies that oversee business practices to the consumers who decide which competitor creates the most desirable products.

Signs of the potential for ethical problems can be spotted by asking yourself the following questions:

- Is anyone to be harmed or helped by this decision?
- Is there a question of trust?
- Are there fiduciary obligations at stake? Other kinds of obligations?
- Is someone's autonomy – their right to choose – at risk?
- Is there a question of fairness?
- How will the costs and benefits of this research and/or product be distributed?
- Are important relationships in jeopardy?
- Do my products meet a social need?
- Are there popular arguments in society (the press, social activists, etc.) that relate to my core research?

Triage, first-aid and long-term care

Once an ethical issue has been recognized as such, you need to begin to think in terms of time frame. Is the issue here a) an ethical crisis, b) an ongoing ethical debate, or c) a distant possibility of ethical controversy?

a) Ethical crises require that companies act quickly. Experience shows that when scandals or other crises arise, openness and honesty are key. The touchstone example here is the Tylenol poisoning case, in which Johnson & Johnson quickly increased its market share, arguably because their response was immediate, honest, and put public safety first.

b) Ongoing ethical debate – such as the debate over stem cell research or somatic cell nuclear transfer – requires that companies understand that the ethical context of their research is sensitive in the here-and-now, despite the lag time before products are developed. Stem cell technologies are roughly five to ten years away from product release; however, ethical considerations are affecting corporate bottom lines *today*. Debates over cloning and stem cells have created a wary investment community, while government organizations like the National Institutes of Health (NIH) are unlikely to provide funding to firms or research labs developing these technologies, especially if those firms and labs do not have strong oversight guidelines. Because revenues are so

far down the line, sustainable funding sources are a critical component of this revolutionary therapeutic tool. Those companies that have engaged in ethical reflection as a long-term project, one that requires immediate and ongoing consideration rather than post-marketing public relations, are better positioned vis-à-vis the investment community and other sources of funding.

c) Issues perceived as involving the possibility of *eventual* ethical controversy require a different kind of planning. If any lesson has been learned from the genetically modified foods sector, it is that regulatory agencies are not the sole decision makers regarding the marketability of new bioscience-related products. When regulatory policies lag behind technological trends, it is likely that corporations will have to form their own, responsible policies to oversee the introduction and continued evaluation of their technologies; for instance, reflective information management procedures provide a firm grounding for strategic planning and ethical deliberation (see Fig. 1). Further, as the technologies grow, expand and revolutionize, corporations will need to continue to involve themselves in that process, as well as to interact with the consumers and intermediaries affected by and affecting the technology.

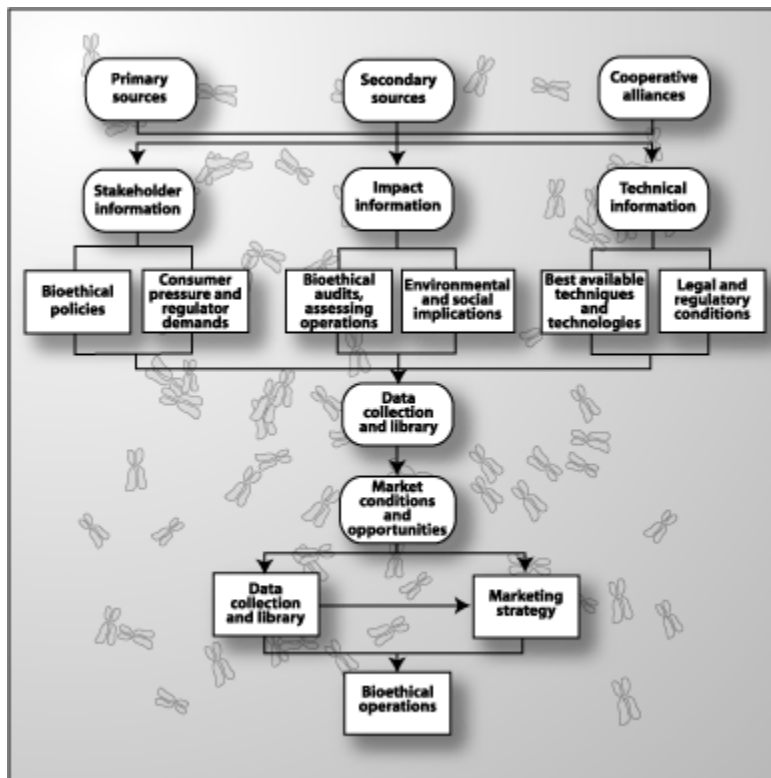


Fig. 1

Strategic / Marketing Considerations

Corporate behaviour is increasingly under the microscope. Nowhere is this more true – and more likely to increase – than in the biosciences. These companies have as their

stock-in-trade the very building blocks of all life – DNA, RNA, proteins, stem cells, etc. Many of their activities have implications for (or are seen as having implications for) quite an expansive range of interested parties.

This may be cause for worry, but managers who succeed in getting their companies “ahead of the curve” with regard to dealing with ethical issues may be able to market that special capacity. This is not a question of public relations; rather, it is a comment on the likelihood that markets – and investors – will reward those companies that show themselves as being sustainable over long term periods because they are capable of dealing with the complex ethical issues that are endemic to the field of biotech.

Tests & principles

From an ethical point of view, there is no one right way to evaluate your options. Some advocate a principle-based approach, evaluating ethical issues in terms of social benefit, avoidance of harm, respect for autonomy, and justice. Others favor a “stakeholder” approach, advising companies to think imaginatively about the range of groups and individuals who might have a “stake” – a legitimate ethical interest – in the decisions they take.

While these issues are too important to leave to gut reactions, our instincts can be important guides in identifying potential problems. Ask yourself the following questions:

- Would I be pleased to see this work reported – honestly and fairly – on the front page of my local newspaper?
- Would I be worried if the relevant regulatory agencies knew about the decision we’re making?
- Would I be happy to explain to my children the sort of work I do?
- Would I trust my products with my own health? My family’s health?
- Is the information that I keep confidential kept that way because of proprietary considerations or because I am afraid of the repercussions if word of it was released?

Sensitivity Analysis

Finally, we advise performing a sensitivity analysis on any proposed course of action. Ask yourself: which variables in this situation would have to be different in order for my *decision* to be different? Would we choose differently if this issue were a front-page story? Would our view on this be any different if this decision were being made by a competitor? If the competitor made these decisions instead of us, would we want those actions to gain publicity so that they would be viewed as irresponsible? Would we do this differently if we were an industry leader? Would we do this differently if we were trailing the industry?

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Appendix 1: Where to Find Out More

Websites:

<http://www.GuidingIcarus.com>

<http://www.BiotechEthics.ca>

<http://www.StemCells.ca>

<http://www.Genethics.ca>

<http://www.BusinessEthics.ca>

Books:

Rahul K. Dhanda, [*Guiding Icarus: Merging Bioethics with Corporate Interests*](#) (Wiley, 2002).