

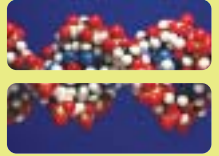
There's more to
biotechnology
than science and
business

BIOETHICS

FACING THE
FUTURE
RESPONSIBLY



Unlocking the swirl of genetic information that makes up the double helix of human DNA is only part of the challenge that faces us.



As scientists and citizens, we must address questions and controversies surrounding the use of biotechnology and make choices that will best serve humanity.

The Biotechnology Industry Organization (BIO) is committed to the socially responsible use of biotechnology in health care, food and agriculture, industry and the environment. As biotechnology reaches toward such benefits as treatments for intractable diseases such as cancer, Alzheimer's and Parkinson's; abundant, nutritious food; industrial sustainability; and a cleaner world, we encourage public discussion of the ethical, legal and social implications of biotechnology research.

BIO and the biotechnology industry respect the power of the technology we are developing. We believe in the need for regulation, and we insist that this technology — in its myriad of applications — be used to benefit patients and others.

Moreover, BIO supports responsible and ethical testing of new technologies and believes that decisions regarding whether and how to use medical products and technologies always must be made with profound respect for the rights of patients. In our view, appropriate regulation of biotechnology is solidly rooted in values such as autonomy, privacy, beneficence, social justice and intellectual freedom.

BIO's Statement of Ethical Principles demonstrates a comprehensive vision of how we can ensure that biotechnology is used for human good; we will add to these principles as the technology advances.

We respect the power of biotechnology and apply it for the benefit of humankind.

We listen carefully to those who are concerned about the implications of biotechnology and respond to their concerns.

We help educate the public about biotechnology, its benefits and implications.

We place our highest priority on health, safety and environmental protection in the use of our products.

We support strong protection of the confidentiality of medical information, including genetic information.

We respect the animals involved in our research and treat them humanely.

We are sensitive to and considerate of the ethical and social issues regarding genetic research.

We adhere to strict informed-consent procedures.

We will abide by the ethical standards of the American Medical Association and, where appropriate, other health-care professional societies to ensure that our products are appropriately prescribed, dispensed and used.

We develop our agricultural products to enhance the world's food supply and to promote sustainable agriculture with attendant environmental benefits.

BIO has a long-standing policy of opposing the use of biotechnology to develop weapons of any sort that contain pathogens or toxins aimed at killing or injuring humans, crops or livestock.

We continue to support the conservation of biological diversity.

BIOTECHNOLOGY INDUSTRY ORGANIZATION
STATEMENT OF ETHICAL PRINCIPLES

REGENERATIVE MEDICINE

Stem Cells

The discovery of pluripotent stem cells is an extremely important scientific and medical breakthrough. Researchers can now separate early, undifferentiated stem cells from blastocysts—the 5-day-old ball of cells that eventually develops into an embryo. Such embryonic stem cells can differentiate into any cell type found in the human body, and they also have the capacity to reproduce themselves. According to the National Institutes of Health, this ability to maintain stem cell lines in culture and direct their development into specific cell types holds the potential to save or improve many lives by controlling cancer, re-establishing function in stroke victims, curing diabetes, regenerating damaged spinal cord or brain tissue, and successfully treating many diseases associated with aging. BIO supports federal funding for research using embryonic stem cells.

Scientists have also learned that undifferentiated cells from other tissues (for example, adult stem cells) have value. BIO supports research using these cells.

Cloning

“Cloning” is a generic term for the replication in a laboratory of genes, cells or organisms from a single original entity. As a result of this process, exact genetic copies of the original gene, cell or organism can be produced.

BIO is opposed to human reproductive cloning—that is, using cloning technology to create a human

being. BIO was one of the first national organizations to support the voluntary moratorium on research into cloning a whole human being. Reproductive cloning is dangerous and raises far too many ethical and social questions.

But somatic cell nuclear transfer (SCNT, or therapeutic cloning) is another matter. SCNT uses cloning technology to generate new stem cells. It is an extension of basic embryonic stem cell research aimed at generating replacement cells, tissues and organs. Genetically matched cellular and tissue transplants could address some of humanity’s most vexing and devastating disorders, such as Alzheimer’s and Parkinson’s diseases, kidney failures and heart disease.

SCNT could also be used to create new stem cell lines for research purposes.

BIO supports the use of SCNT under a regulatory and ethical oversight system because of the remarkable potential to lead to cures for illnesses and restore function to diseased tissues.

PRIVACY/DISCRIMINATION

Medical information, including genetic information, must be treated responsibly. Patients’ privacy rights must be recognized, and they should be assured that their medical information will be treated responsibly. In addition, medical researchers must continue to have access to medical information so they can pursue research objectives that could lead to cures and treatments for currently unmet medical needs.

BIO companies abide by existing laws and regulations governing the use of patients' medical information, including genetic information.

BIO deplores any practices that might lead people to avoid accessing genetic tests and other products out of fear that they will be discriminated against, including with regard to health insurance, employment and education.

BIO continues to support national legislation that would prohibit health insurers from discrimination based on predictive genetic information.

LIMITS OF BIOTECHNOLOGY

BIO members operate within a regulatory and ethical framework that protects patients while allowing critical research to go forward. BIO embraces the values that these regulations embody—autonomy, privacy and social justice. BIO companies support an oversight structure based on sound science and these values.

BIO members share the belief that our lives are not preordained by genetics, but are shaped by the choices our parents made, our own choices and our environment and opportunities. Individual freedom is key to personal dignity.

BIO strongly supports education about biotechnology and genetics. We applaud the intellectual freedom of researchers to think and dream in the pursuit of greater understanding that could lead to a better life for all of us.

BIO AND THE FAITH COMMUNITY

The Biotechnology Industry Organization acknowledges its responsibility to consider the interests and ideas of all segments of society and to be sensitive to cultural and religious differences. In keeping with this and because of the fundamental questions raised by biotechnology's rapid advances, in 2001 BIO established a dialogue with members of the faith community.

BIO has hosted several forums across the country to foster a deeper understanding of differing viewpoints through frank, meaningful and respectful discussions. Participants come from seminaries, universities, religious institutions and religious organizations, representing a broad spectrum of religious perspectives. Catholics, Lutherans, Muslims, Presbyterians, Methodists, Baptists, Reform and Orthodox Jews, and Unitarians are among those who have made personal and professional contributions to the discussions.

These meetings have provided an informal forum for discussing bioethics issues and have touched on how the biotech and religious communities can broaden the dialogue within and between the two.



GLOBAL HEALTH

Infectious diseases are a global concern. BIO's goal must be to ensure the widest possible dissemination of biotechnology's benefits while respecting the diversity of the world's nations and peoples.

As of 2003, there are 300 million infections from malaria each year, a third of the world's population already carries the TB bacteria, and 42 million people are living with AIDS. The numbers continue to grow, but very little research is directed toward the diseases that overwhelmingly afflict the poor throughout the world.

Armed with new tools and information, biotech companies have demonstrated considerable interest and success in applying the latest biotech advances to these health problems. Scientists using biomedical technologies are exploring how to improve the way we diagnose, prevent, treat and control infectious diseases prevalent in the developing world.

To be a part of the world's response to this public health crisis, BIO has worked with the Bill & Melinda Gates Foundation and other organizations and governmental agencies. BIO worked to bring together leaders of biotech companies, government and international health agencies, and nongovernmental organizations to forge new partnerships and brainstorm new incentives to overcome the barriers to applying biotechnology to diseases plaguing the developing world.

OUTREACH

BIO works closely with a wide variety of organizations, groups and coalitions that represent patients, physicians, medical specialists, hospitals and other health-care providers, as well as those that are connected or advocate on behalf of those populations. BIO develops long-term relationships built on mutual respect and trust to improve communication and understanding between the providers and users of our products.

PLANTS AND ANIMALS

Biotechnology is used to modify plants and animals to meet consumer demand for more healthful, nutritious foods and to produce food in more environmentally sustainable ways. Crops and animals also are being modified to provide new, plentiful and safer sources of medicines for treatment of human disease. BIO is dedicated to open discussions with consumers, farmers, legislators and opinion leaders regarding ethical issues in the use of agricultural biotechnology.

Of the vast numbers of scientific findings made over the last century, perhaps none has improved human health and longevity more than the developments that have occurred through biomedical research using animals. BIO acknowledges that use of animals in research is a privilege and deserving of our care and respect. BIO strongly supports the



principles of refinement, reduction and replacement regarding use of animals in research and is proud that some of our members work to develop alternative testing methods that will actively encourage reduction in use of animals.

We affirm and uphold the coordinated science-based regulation and oversight of agricultural biotechnology by the Food and Drug Administration, the U.S. Department of Agriculture and the Environmental Protection Agency. This oversight ensures the safety and quality of the food supply and the everyday ethical treatment of animals.

We believe the public should fully participate in the introduction of these new products both through an open, accessible and accountable regulatory system and through the exercise of free choice via market mechanisms. We encourage increased awareness and understanding of how agricultural biotechnology is being applied, and its impact on agricultural practices, use of animals in research, the environment and biological diversity.

HUMAN SUBJECTS PROTECTION

Innovations that lead to the discovery and development of crucial treatments cannot come about without the willing participation of people who volunteer to be subjects in testing new products.

BIO has long advocated protection for research participants. We pledge adherence to strict informed-consent procedures to ensure that participants are fully aware of the potential risks and benefits of that research.

BIO has outlined principles that federal law should follow to protect human subjects involved in all research. These principles provide BIO with the basis for participation in legislative and regulatory debates to strengthen and standardize the federal laws protecting human subjects so that they apply to all research, regardless of funding sources. The five main points of these principles are:

- Human subject research is grounded in trust and respect.
- Protecting the contribution of research participants transcends national borders. Even where no local laws cover the issue, if a clinical trial involves more than minimal risk to a living human being, investigators and sponsors should seek review of their trial.
- Disclosure and oversight by institutional review boards provide critical support for participants' informed consent.
- Conflicts of interest should be identified and appropriately managed.
- Sponsors should disclose results that are of material significance for the health and health care of individuals, and sponsors should protect the research participants from unwanted publicity.



Bioethics Committee

Mission: BIO is committed to the socially responsible use of biotechnology to save and improve lives, improve the quality and abundance of food, and protect our environment. BIO's board of directors has adopted a Statement of Ethical Principles, and we continue to refine a comprehensive vision of ways to make sure that biotechnology is used for the betterment of humankind and not abused.

Issues: During the past few years, the bioethics committee has addressed such issues as stem cell research, cloning, global health, use of genetic information, medical records confidentiality and protection of human subjects.

Eligibility for Participation: To become a member of the Bioethics Committee, one must be employed by a company or organization that is a member of BIO.



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BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.