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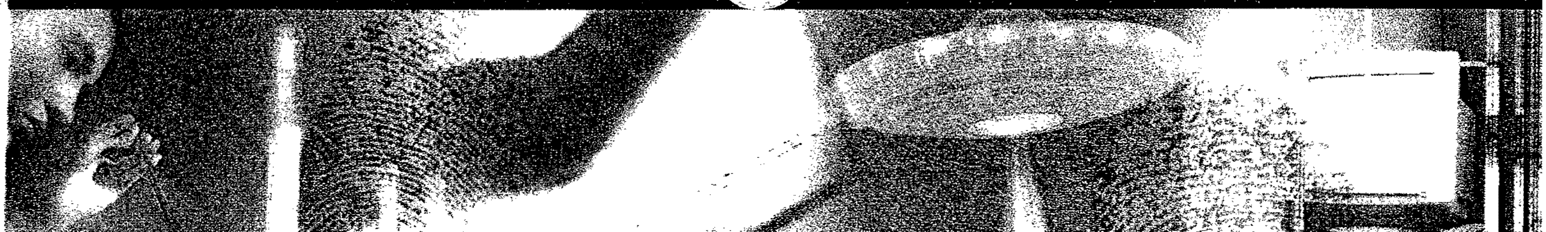

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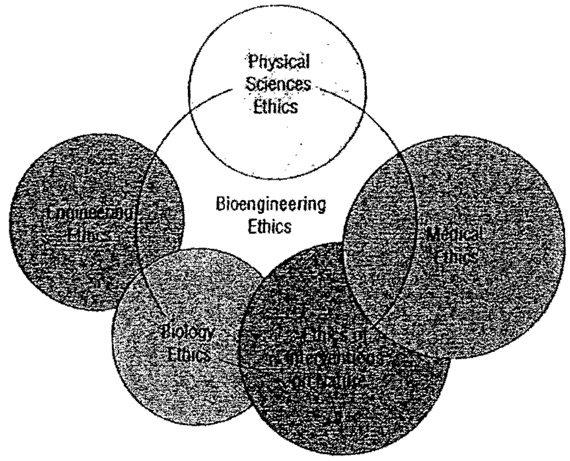
TABLE 1

The Interaction of Various Disciplines with Bioengineering Ethics



SOURCE: Courtesy of George Bugliarello.

The intersection of Bioengineering Ethics with Cognate Ethics.

BIOENGINEERING ETHICS

All of engineering can be viewed as a continuation of biology by other means—a metabiological activity. Bioengineering arose relatively recently with specific focus on living systems, for medical purposes in a close alliance with medicine, for scientific and industrial purposes and for other purposes.

A vast array of specializations and subfields have emerged, not always closely related and sometimes predating the overall recognition of bioengineering as a field. An ever expanding and at times confusing and overlapping taxonomy includes biomechanics (encompassing also biorheology and biofluid mechanics), instrumentation, biochemical engineering, bioastronautics, environmental engineering, biomaterials, tissue engineering, biological systems engineering, engineering of drug design and delivery, biotechnology instrumentation, bionanotechnology, and bioinformatics (Blanchard and Enderle 1999, Bronzino 1999, Fung 2001).

Bioengineering, as a field of research and applications, brings to bear not only engineering on medicine and biological organisms, but also a knowledge of biology on engineering designs. This helps assessing the meaning of engineering as the extender of biology and ultimately helps engineering develop a clearer sense of its own nature and address the ethical issues involved in its modification of nature and the creation of machines, that is, artifacts.

Biomechanics

Biomechanics began to flourish in the 1960s, but interventions on the human body through artifacts have a long history that originated with prehistoric supports for fractured bones and skin decorations such as scarification, implanted rings, and tattoos. Daedalus with his mythical wings and the Tailor from Ulm with his arm-extending wings for gliding (Eyth 1885) were precursors of biomechanics, one in legend and the other in reality. After medieval times this process progressed to encompass eyeglasses, artificial teeth, and rudimentary artificial limbs. Eventually the interventions on the human body fulfilled other needs through diagnostic and curative tools and processes, from the application of bioengineering to bioastronautics starting in the 1960s (Konecci 1968) to X-ray visualization through computed tomography (CT), ultrasound scans, and magnetic resonance imaging (MRI), to hearing aids, surgical robots, autoanalyzers, DNA-sequencing machines, tissue engineering, and the application of engineering knowledge to the understanding of biological (Bejan 2000) and therapeutic processes. Most of these developments were strongly interdisciplinary, blending engineering, physiology, physics and mathematics. Interdisciplinarity continues to characterize the field.

Other bioengineering milestones include the first artificial organs. The artificial kidney was given practical form through the application of engineering principles by the Dutch physician Wilhelm Kolf in the 1940s, and the first heart pacemaker was implanted in 1958 in Sweden through the collaboration of the surgeon Åke Senning and the physician-inventor Rune Elmquist.

Pioneering studies of the brain were conducted by John Von Neumann and Walter Roseblith, and the study of neurons was initiated by Walter Pitt and Warren McCullogh. They opened a new domain for bioengineering, and also provided significant insight for the design of new kinds of computers.

An early example of the application of biology to engineering that has had an immense impact on human health is biological water and waste-water treatment processes. Biomimesis—the mimesis of biological designs, materials and processes—is another aspect of engineering applications that range from the creation of artifacts for medical and industrial purposes to genetic engineering and to ergonomics.

Other developments include the embryonic emergence of biomachines, as in the case of cardiac pacemakers and of bioelectrical sensors (biological sensors implanted on an electronic platform), and the biosoma concept of the integration of biological organisms and their two metabiological offshoots: society and machines (Bugliarello 2003).

Toward an Ethics of Bioengineering

Harmonization of the comprehensive ethical canons needed to address modifications of nature through the design and operation of artifacts and respond to conflicting views of the public good that engineering is committed to serve presents limitations and contradictions, as occurs when engineers develop products in which commercial motivation overshadows social goals. As a consequence, the flourishing of bioengineering as an offshoot of engineering has outpaced a focus on the ethical issues that confront it.

The complexity of formulating a bioengineering ethics arises from the need of bioengineering to be coherent not only with the ethics of engineering but also with those of biology, medicine, and the physical sciences, the fields with which bioengineering interacts most strongly (see Figure 1). Those specialized ethics, which are congruent with general ethics but distinct from it and complementary, must be rooted in the fundamental philosophical issues of each field: In the physical sciences, how do researchers obtain and verify knowledge? In biology, how can this be done in the context of living organisms and what is the nature of life, including the body-mind problem of consciousness? In medicine, what is the nature of disease? In engineering, what is the nature of the machine, why are there machines, and how far can humankind go with machines, for example, in making them self-reproducing?

The associated key ethical issues in physics and biology are concerned primarily with the purpose and conduct of research and the impacts and limits of research as exemplified by controversies in nuclear energy and cloning. In medicine, those issues relate to the limits of therapy, safety and risk, the Hippocratic imperatives, informed consent, and the role of the patient as well as the dilemma of individual versus societal benefit. In engineering, they have to do with the purposes and benefits of machines and interventions in nature, biosocial and environmental impacts, and risk and appropriate safety factors. The host of specific ethical issues associated with bioengineering arises from the need to incorporate the ethical questions of physics, medicine, and biology in addressing the domain, focus, and impact of bioengineering; its risks and safety factors; the views of nature that govern its activities; and the issues of activism and intellectual responsibility.

Domain, *focus*, and *impact* questions start with the positioning of the biomachine interface: Where should it be placed in the polarity between biological organisms and machines? To what extent should biomachines retain the essential characteristics of biological organisms *versus* those of machines? Also, should there be limits to biomimesis, the imitation of biology in creating devices? Are there potential dangers as well as benefits, and if so, what should guide the bioengineer? Should the ethical responsibility of bioengineering be exclusively humancentric, or should it extend to a broader biocentric domain with responsibility to other advanced life forms?

Relevant to urgent social needs are questions of prevention versus therapy. Historically, many medically oriented bioengineering activities have focused on therapy and very costly devices. This has improved medical capabilities, but to what extent should escalation of medical costs and principles of social equity make it an ethical imperative for bioengineering to focus more on prevention? Indeed, what should be the appropriate interface with medicine; what should be the specific role and responsibility of the bioengineer in a clinical environment? The dilemma of the individual versus society affects medicine and bioengineering alike and is at the core of the debate about health care: Should the focus be exclusively on the individual? To what extent should the cost to society also be taken into account?

The issues of medical versus industrial purposes, with their different motivations, also can be a source of contradictions and conflicts for bioengineers: Should they participate in a medical procedure or in the development of an industrial process merely for the technical challenge, without a clear understanding of the ultimate consequences? Should the imperative ethical requirement for bioengineers be to act as independent-minded professionals regardless of the pressure that may be put on them by a hospital, research laboratory, factory, or granting agency?

A closely related issue is the depersonalization of health care brought about by its increasing technicization. To what extent should bioengineers focus on the design of the clinical environment in which bioengineering machines are placed and processes are carried out and endeavor to reduce that depersonalization by taking into account the emotional component of human nature (a component that depends in turn on physiological factors, themselves amenable to medical and bioengineering research)?

What are acceptable *risks* and appropriate *safety factors* of bioengineering designs (a meeting point of the ethics of medicine and engineering with political, economic, and legal theories)? Do the efforts expended and the risks generated by a solution produce benefits that justify its development? A correlate ethical issue is the bioengineer's responsibility to follow up on the performance of a design or process, communicate the results whether they are positive or negative, and strongly advocate the adoption of satisfactory, safe, effective designs or processes and the elimination of dangerous and counterproductive ones.

Bioengineering interventions in natural processes must take into account the many basic and often conflicting values involved in *different views of nature*. These views range from utilitarian (an emphasis on the way in which humans derive benefits from nature) to the doministic (the drive to dominate nature for the sake of doing so) (Kellert 1996). Each view involves ethical dilemmas for bioengineering, starting with the basic issue of whether or to what extent to accept nature as is or to modify it teleologically; this can be thought of as an aspect of the conflict between biology (and at times religion) and engineering or medicine. The dilemma leads to different ethics—the ethics of discovery (science) versus that of design (engineering)—and to contemporary debates about genetic engineering (under what conditions should discovery lead to design?).

Activism and Intellectual Responsibility

In terms of *activism and intellectual responsibility*, to what extent should bioengineers intervene in the philosophical dialogue about the modification of nature, the future of humans and the human responsibility for other species? Should they participate actively in the political arena by pressing for new visions and their realization rather than seeing their role as a purely technical one? What is the ethical responsibility of bioengineers in projecting the potential modifications of nature that bioengineering can make possible and to inform society as to how beneficial modifications can be safely accomplished?

Provisional Answers

Even a cursory view such as the one presented here conveys the broad, complex, and fundamental nature of the ethical questions involved in bioengineering. Like all of ethics, bioengineering ethics deals with questions that are beyond the realm of the legal responsibility of bioengineers and may conflict with it. However, these are issues for which bioengineers should seek to define and enhance a professional conscience and behavioral guidance. So far only some of these questions have been addressed, and often only in a rudimentary way. Until a comprehensive bioengineering ethics has been formulated, a provisional set of tenets is needed. Those tenets might include the following:

- The *harm avoidance tenet* (essentially a restatement of the Hippocratic oath): to minimize the side effects of a design or intervention and devise something that bioengineers would use on themselves if necessary
- The *professional tenet:* to act as independent-minded professionals regardless of pressure from the environment in which bioengineers operate and intervene in professional and public discussions about engineering, medical, biological, and societal issues that bioengineering could illuminate
- The *approval tenet:* not to participate in medical procedures or in the development of industrial or military processes of which bioengineers do not personally approve no matter how technically challenging those procedures or processes are
- The *conflict of interest tenet:* not to advocate an unsafe, ineffective, or inferior design because one has a vested interest in it

- The *risk tenet:* to weigh the risks to human society and the environment of a bioengineering device or process
- The *effectiveness tenet:* to make the cost and risk of a design or intervention commensurate with the expected benefits
- The *responsibility tenet:* to assume the responsibility to follow up the performance of a design or process and communicate the results whether they are positive or negative
- The *finality tenet:* to attempt to expand the capabilities of humans, and, where appropriate, other biological organisms, being mindful of the metabiological nature of bioengineering as an activity that synthesizes two human drives: understanding nature and modifying it to preserve and enhance life

It is unrealistic to believe that a consistent and comprehensive bioengineering ethics will emerge rapidly from all the disparate elements and concerns that will contribute to its formation. A bioengineering ethics cannot be independent from the fundamental philosophical conceptions and ethics of the society in which bioengineering is embedded. These issues in turn are shaped and modified by advances in knowledge, social and political events, and the progress of bioengineering. It is, however, realistic and necessary to endeavor to establish some ethical principles that can guide the actions of bioengineers beyond their contingent legal obligations or at least to increase bioengineers' awareness of the ethical dilemmas that may confront them.

Ultimately, all forms of engineering are involved—directly or indirectly—in the modification of the biological world: For example, a highway, by bisecting a habitat, affects the ecology of that habitat and hence its biology. In the future, greater awareness and knowledge of biological processes resulting from advances in bioengineering will blur some of the boundaries between bioengineering and other fields of engineering, as in the creation of biomachines—intimate combinations of machines and biological organisms. This will add to the complexity of the ethical issues confronting the bioengineer and society.

GEORGE BUGLIARELLO

SEE ALSO *Bioethics; Biotech Ethics; Engineering Ethics; Medical Ethics.*

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BIOETHICS

Bioethics is a broad subject connecting advances in biological and medical science with moral concerns. Medical ethics is one large part of bioethics but by no means the only part. Bioethics has grown as a discipline precisely as science and technology have increasingly demonstrated that human beings are biological beings. Scientists have mapped the human genome and scanned the human brain. Researchers have evermore precisely