

# Ethical Issues Arising in Biotechnology

Evelyn S. Becker

Biotechnology has been defined by the Food and Drug Administration (FDA) as any technique that uses living organisms to make or modify products, improve plants or animals, or develop microorganisms for specific purposes. The technology itself is about twenty-five years old and involves the excision of the gene of interest and its insertion into a suitable host, thus the term, recombinant deoxyribonucleic acid (DNA). Isolation of enzymes to excise genetic material proved to be the key to the subsequent identification of human gene fragments and human genes.

Although recombinant DNA technology was originally intended to produce large quantities of previously unobtainable proteins, a much wider range of applications has emerged. These include the manufacture of new classes of therapeutic agents, new diagnostic tools, an understanding of the precise structure of drug receptor sites, and ultimately the sequencing of the entire human genome. Knowledge about genes and genetic markers will provide opportunities for genetic intervention. Many ethical dilemmas are posed by the rapid proliferation of knowledge and products that have resulted from biotechnology. This chapter describes and addresses some of them.

These dilemmas may be divided into two categories. Both are concerned with the morality of the development and utilization of this technology. The first dilemma concerns the development of recombinant DNA products and their allocation. The second deals with the pursuit of

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the unraveling of the human genome, gene therapy, and the reproductive choices it will afford.

### ***BIOTECHNOLOGY PRODUCTS***

Biopharmaceutical agents currently marketed include antiviral agents, diagnostics, thrombolytic agents, immunomodulators, hematopoietic agents, vaccines, and tissue repair agents. Investigational uses for these and new drugs will further expand the market (1). Biotechnology companies posted sales of over \$1.4 billion in the first quarter of 1996—a 19% increase over 1995. By the year 2000, the biotechnology industry is projected to have sales reaching \$50 billion (2).

These drugs find use in both the preventative and curative aspects of medical care. They are, however, exceedingly expensive. The high costs are generally attributed to high research and development costs. Many represent entirely new therapeutic modalities which cannot be used instead of some other, less expensive therapy. Questions of cost and allocation raise major ethical concerns. Pharmacists are and will be involved in these types of ethical decisions.

### ***ALLOCATION OF THE HEALTH-CARE DOLLAR***

#### ***Macroallocation***

Macroallocation looks at the distribution of goods and services among all members of society. Beneficence would require us to provide the best health care for all and contain its cost. It is difficult, if not impossible, to maintain freedom of choice while containing overall health-care costs. Therefore, pharmacists in collaboration with other health-care professionals will be called upon to decide which drugs for which diseases to include in the institutional or managed-care formulary. This is an inherently ethical decision making process because it involves allocation of scarce resources.

Macroallocation decisions involve the utilitarian concern over investment in a technology whose products may benefit only the few. Many biotechnology products were produced and marketed under the Orphan Drug Act (3). Companies which participate in this program benefit from tax credits which are designed to stimulate development of medications for treatment of illnesses afflicting fewer than 200,000 people in this

country. Other parameters to consider in allocation of research dollars include the severity of the disease being treated and the chance of improvement. For example, many of the new immunomodulators are utilized in the treatment of already severely ill patients with poor prognoses. Do the sickest have the greatest right to health care?

The allocation of health-care dollars for the purchase, distribution, and reimbursement of biotechnology products will undoubtedly have significant impact on the practice of pharmacy. The cost of some of these drugs is comparable to surgery. For many institutions, these products will represent a 10% to 20% increase in the drug purchasing budget but will be administered to only 1% to 2% of the patients (4).

Hospitals have developed a variety of strategies to manage the utilization of biotechnological agents (5). Some hospitals have established biotechnology subcommittees of the traditional pharmacy and therapeutics (P&T) committee to develop usage guidelines for newly released products. Patient care, ethical, financial, and formulary issues are considered (6).

### ***Microallocation***

Because funds may be limited, some may be denied care. Such microallocation decisions raise the issue of the sacrifice of one for the benefit of others. Deontological theories generally assign an intrinsic value to all human life. Patients have the right to be treated as ends, not merely as a means to an end. Thus, there is an intrinsic right to the best possible care. Indeed, there is a duty on the part of health-care professionals to preserve life. In light of this duty, it becomes questionable as to whether medical or financial criteria alone constitute an ethical basis for allocation.

Access to expensive medication regimens may be evaluated in the same way as one might view the provision of any other extraordinary, life-saving technology. Constituency factors, the likelihood of success, and life expectancy are common criteria for inclusion of individuals in exotic protocols (7).

Additional criteria for selection might include family role, prospect of future societal contribution, or previous record of service. Rawls' principles of justice would seem to rule out the distribution of scarce resources based upon such social worth. Under a "veil of ignorance," all should have equal opportunity. A random procedure whereby each individual has an equal chance has been suggested as the most equitable means of choosing among selected individuals (7).

Some of the more common criteria used in the allocation of scarce resources to individuals may be applied by using an equation. Multiply the

probability of success by the quality of success by the length of life remaining and divide by the cost (8). This allows one to determine the comparable reasonableness of the investment and the consequent duty to invest. It should be noted that the quality of success is determined by a review of previous patient progress, whereas other parameters in this equation are patient specific. Thus a debilitated patient with a low life expectancy would not qualify for a therapy with a proven record of success unless the cost was sufficiently low.

The assessment of quality of success will surely change as new therapeutic modalities are tested and developed. Not all new drug regimens will result in a clearly beneficial outcome. Erythropoietin, a drug used to treat chronic anemia resulting from end stage renal disease, is a good example of a modality which has, according to most reports, resulted in a dramatic improvement in the quality of life. Many drugs benefit some patients in uses not approved by the FDA. Increasingly, pharmacists and physicians are called upon to act as patient advocates by convincing insurance companies to bear the cost of an investigational use of a biotechnology product. Is there an obligation to make these therapies available to all who might benefit? If so, the cost would be borne by the medically best off.

The ethical dilemmas relating to the selection criteria for candidates seeking a particular therapy are perhaps best exemplified by the allocation of growth hormone. This product was originally intended for use in children with potential pituitary dwarfism. Increased availability of growth hormone has led to increased demand even though the number of pituitary dwarves has not increased. This raises questions about its use and entitlement to therapy. Should growth hormone be supplied to children of potentially short (but normal) stature? Allen has proposed that the use of growth hormone be limited to those for whom height is not merely a disadvantage (9).

Further concerns have been raised by the use/abuse of erythropoietin by athletes to improve oxygen carrying capacity. Does this constitute an unethical advantage over the competition? The use of medication to correct nonmedical conditions looms as a future ethical dilemma.

Distributive justice might require allocation on the basis of need with the sickest being treated first. Should private insurers and/or the federal government make such decisions? In an increasingly cost-conscious society, competition for a piece of the health-care pie becomes fierce.

Utilitarian theory does not answer the question of who should receive exotic therapy so long as the distribution policy creates the greatest good. Thus, social worth and contribution might be employed as criteria in assessing the long-term outcome of a therapeutic modality. One could look

at socioeconomic status, family, and compliance in making a decision about the consequences of drug therapy. A utilitarian calculus may also be employed in doing a cost-benefit analysis.

### ***THE ROLE OF THE PHARMACIST IN ALLOCATION DECISIONS***

Pharmacists' roles in the distribution of biotechnology drugs will vary according to practice setting. As indications for and availability of biotechnology drugs expands, the community pharmacist will become increasingly involved in allocation decisions. Betaseron® (interferon-1-beta) for the treatment of multiple sclerosis is an example of a medication for which demand by far exceeded supply, thus necessitating decisions about its distribution (10).

The Code of Ethics for Pharmacists approved by the American Pharmaceutical Association stipulates that pharmacists seek justice in the distribution of health resources. Therefore, when health-care dollars are allocated, a pharmacist must "be fair and equitable, balancing the needs of patients with those of society." In this era of managed health care with its emphasis on cost efficacy, these needs may conflict. Thus, the covenantal relationship whereby the pharmacist assumes responsibility for patients' welfare may be adversely affected by third-party payers' strategies to cut costs for all insureds by limiting the availability and use of certain medications.

It has been suggested that developments in biotechnology may require a shift from an individual-oriented ethic that emphasizes autonomy to a community ethic that emphasizes distributive justice (11). Does the cost of a drug justify its use in this or any patient? Are there other, less expensive therapies that are equally efficacious? These are questions that will increasingly be left to pharmacists to decide.

It has been suggested that pharmacoeconomic analysis be used to develop management strategies for the safe, cost-efficient, and cost-effective use of biotechnology products (4). Pharmacists will be involved in the pharmacoeconomic analyses used to develop formularies for a variety of health-care providers. Such decision-making processes will invoke the ethical principles of justice, utility, beneficence, and autonomy. Some expensive drug entities may be included in a formulary but their use may be restricted in certain patient categories. Use of biopharmaceuticals such as erythropoietin and filgrastim have only recently been covered for use in AIDS patients. Thus, a pharmacist may be faced with balancing conflicting duties in looking out for an individual patient's best interest and providing the best, most cost-effective medication regimen for all patients.

**THE HUMAN GENOME PROJECT**

A more global concern brought about by advances in biotechnology is the result of the explosion of information about human genetic makeup. Some of this research will elucidate the exact nature of drug receptor sites, thus making possible the design of drugs that are very specific and have few side effects.

The human genome will be sequenced by the year 2005, a little over half a century since the elucidation of the structure of the hereditary material by James Watson and Francis Crick. The human genome project will cost an estimated \$3 billion and is already generating oceans of data (12). The information about the actual sequence of the genetic code will be known long before science discovers how to correct defects thus revealed. For example, recent advances in the detection of the BRCA1 gene which is responsible for one form of inheritable breast cancer will provide risk information, although no therapeutic intervention is currently available (13).

Ethical issues attendant to the unraveling of the human genome have perhaps received more attention than any others. Tampering with the human genetic constitution raises the specter of eugenics. The Human Genome Project has generated a constant stream of data and a flood tide of questions about the potential use and abuse of this data.

The emergence of the debate over the use of genetic information was signaled in 1967 by Marshal Nirenberg, a Nobel prize winner who first "cracked" the genetic code. He cautioned that man should refrain programming his own cells until he has sufficient wisdom to use this knowledge for the benefits of mankind (14).

Ethical discussions surrounding early attempts at gene therapy concerned the choice of subjects (they were terminally ill and had few alternatives), the efficacy of the procedure, and its oversight. Basic scientific criteria needed to be met. "Slippery slope" arguments against such work were often cited in the 1980s. There was concern that somatic cell (body cell) therapy would lead to germ cell (sex cell) therapy with inheritable harms ensuing. During this period, social activist Jeremy Rifkin became the leader in the opposition to recombinant DNA research. It may be argued that technology itself does not create moral problems and that moral lines can be drawn.

Current research efforts are coordinated by the Department of Energy (DOE) and the National Institute of Health (NIH). In 1988, these agencies established a joint working group to examine the ethical, legal, and social issues related to the mapping and sequencing of the human genome. Areas of concern included: education about potential applications of research

data, privacy, medical insurance, impact of research data on provision of clinical services, and commercialization of genome technologies (15).

Areas of genetic manipulation include diagnosis of carriers and fetuses with genetic defects, probing of gene function, replacement of defective genes (somatic cell gene therapy), modification of gene expression, and germ line (inheritable) gene alteration.

### ***DIAGNOSIS OF GENETIC DISORDERS***

The ability to manipulate genes will facilitate treatment of a medical problem before the appearance of actual symptoms. A \$2 million market is predicted for diagnostic genetic test kits (16). Once a gene or markers for a gene are identified physicians can use relatively simple tests to provide individuals with genetic information about themselves, their children, and their fetuses. This will further expand the reproductive choices available to prospective parents.

Prenatal testing will give prospective parents control over their pregnancies by expanding their ability to choose the kinds of children they will bear (17). Will certain conditions be deemed so intolerable so as to require abortion? Dilemmas regarding the morality of abortion for genetic abnormalities will escalate. On a continuum, how severe must a genetic defect be for abortion to be morally justifiable? "Slippery slope" arguments hold that permitting abortion for even severe defects will inexorably lead to abortion for seemingly trivial reasons such as gender preference or physical appearance. If one's consideration of the personhood status of the fetus is a biological one, then genetic aberrations do not diminish the rights of the fetus. Considerations of the social and financial consequences of bringing an affected child into the world might lead to a different conclusion. Despite passage of the Americans with Disabilities Act, society is often reluctant to accept individuals with disabilities (17). With increased information about potential afflictions will parents feel compelled to abort a less than perfect fetus? And will this ultimately lead to a devaluation of life itself?

Utilitarian arguments may be made such that the overall benefit of supplying information to those who wish it outweighs the potential harm of seeking such information. Since the expression of some mutations is affected by environmental factors, knowledge about one's genetic fate would permit one to make life style and environmental changes that could ameliorate a genetic disease.

The ultimate dissemination and use of our knowledge about our genetic

potentials and liabilities constitutes an important ethical issue which may best be examined through application of ethical principles.

### ***Autonomy***

An argument may be made that autonomy requires the provision of information to interested patients so that their right to informed consent is not abrogated. Consequently, health-care professionals have a duty to inform their patients about genetic alternatives. Scientists have an obligation to pursue the unraveling of the genome in order to make such information available.

A faulty gene for an enzyme, alpha-1-antitrypsin, leaves the lining of the lungs sensitive to destruction and may result in emphysema. Should patients with this gene avoid such obvious hazards as smoking? One in every 500 individuals lacks a protein which enhances the removal of low density lipids (bad cholesterol) from the blood stream. Ought such individuals be required to adhere to diets which minimize the risk?

Once a genetic liability has been identified, a person might become genetically unemployable. Some insurance companies already reward health-promoting behavior such as exercise. Should people who carry tumor suppressing genes be rewarded with lower premiums? Since some private insurers operate as for-profit corporations, they may withhold coverage from individuals who carry disease genes. Thus, freedom of choice may be limited.

### ***Veracity***

There are many questions about the ethical and legal liability of clinicians who fail to provide patients with genetic counseling. Is there a duty to identify patients at risk? Disclosure of information regarding genetic liability may be harmful. Presymptomatic testing for Huntington's disease may yield information about risks of other family members or provide information a patient chooses not to be made aware of.

In a futuristic scenario, a pharmacist verifying a new prescription is alerted by the computer data system of a potential interaction between the new medication and the patient's genetic predisposition to a particular disease state. The genetic information was made available through a federal genetic data bank. Should the pharmacist alert the physician? the patient?

Inherent in making patients aware of medical options are questions concerning the accuracy and availability of genetic tests. Pharmacists, as potential distributors of such test kits, should be particularly sensitive to this concern.



### ***Confidentiality***

Protection of an individual's right to privacy about his genetic record is probably the area of greatest concern regarding the human genome. It has been suggested by the joint ethics working committee of the NIH-DOE that guidelines be established regarding responsible use of computerized records (15). Availability of human genetic information will be limited by passage of federal legislation. The Medical Privacy in the Age of Technology Act protects genetic information as well as family histories (18).

Increased availability of genetic test information may identify large groups of people who may be predisposed to certain disorders. There is concern as to how this information might be used by insurers in financial risk calculations.

An additional area of concern is the use of confidential genetic information by potential employers to screen applicants for particular positions. For example, someone with a preponderance of oncogenes might be denied a position that would expose him to carcinogens (e.g., a pharmacist involved in chemotherapy preparation). The use of genetic information for use in determining job candidate suitability has been deemed inappropriate by the NIH-DOE working group (19).

Increased computerization of patient records and increased access to that information makes the duty of confidentiality more important. Access could be limited to a "need to know" basis. Thus, medical information could be separated from financial records. The need for information to provide the best therapeutic outcome must be weighted against the potential violation of confidentiality.

### ***Justice***

The potential for discrimination on the basis of genetic liability looms because alleles for mutations occur in varying frequencies in different ethnic populations. For example, alpha-1 antitrypsin deficiency is more prevalent among those of Scandinavian descent. Sickle cell anemia and hypertension occur with greatest frequency in those with African-American heritage. Tay Sachs disease is most frequently found among Jews of Eastern European extraction. Are genetic tests, like other predictors of the need for health care, good reasons for treating people differently (20)?

### ***Genetic Research Implications for Pharmacy***

Pharmacists will be involved in counseling and delivery decisions about drugs which affect gene expression. Such drugs would work in

much the same way that lipid soluble drugs such as corticosteroids are thought to interact with DNA. Thus, aberrant oncogenes could be "turned off" or modulated. Similar interactions with the genetic material could influence a drug's metabolism by enzymes in the body.

Gene therapy itself could be viewed as a form of drug delivery (21). Additionally, drug therapy may be administered as an adjunct to gene therapy. Pharmacists will need to be knowledgeable about the use of such therapies and potential interactions. Genetic information about a patient may enable a pharmacist to steer a patient away from a potential adverse drug interaction. Pharmacists with access to patient genetic records must be bound by the ethical principles described above. Confidentiality, justice, beneficence, and autonomy will be a necessary part of the pharmaceutical care of the future.

### *Ethical Issues in Somatic Cell Therapy*

The ability to introduce recombinant genes into somatic (body) cells is being tested in more than 100 different trials involving patients with a host of disorders including AIDS, severe combined immune deficiency syndrome (SCIDS), cancer, cystic fibrosis, atherosclerosis, and Duchenne's muscular dystrophy (22). One technique involves introduction of a gene into a tumor cell in order to render that cell more susceptible to attack by drug. Another application uses altered cells to target drug delivery to particular cells. Additionally, viral vectors are used to deliver normal genes through aerosolized sprays.

Pharmacists may become involved in the delivery of gene therapy to patients. The FDA is responsible for the development of regulatory standards for products used in somatic and gene therapy. Pharmaceutical and biotechnology firms submit product license applications for their products (23).

Patient selection is an important point to consider with such novel therapy. Patients must give informed consent for such procedures. It is unclear how free of duress terminally or severely ill patients and their families might be. All possible side effects may not be known. For many of the diseases currently under investigation, there are no conventional therapies to which patients might turn. Although harms may befall patients risking such procedures as a last resort, potential benefits may be reaped by future generations.

Current attempts at gene manipulation may be viewed as therapeutic. However, somatic cell techniques could be used to enhance genetic make-

up (24). Limiting gene therapy to curing debilitating disease rather than enhancing human ability avoids the issue of eugenics.

### ***Germ-Line Therapy***

Germ-line therapy involves the insertion of genetic material into the egg or sperm. Alterations of the genome achieved in this manner would be inheritable. The use of preimplantation diagnosis in the procedure for *in vitro* fertilization is increasing. Sickle cell anemia, Duchenne's muscular dystrophy, and several trisomies may be identified in this way. Gene therapy could be undertaken to correct these defects or the conceptus could be discarded. Alternately, potential parents with known defects could have their gametes genetically altered.

These types of procedures are not yet technically feasible but the debate about the social and ethical implications of germ-line therapy is already raging. Such procedures might be the only way to treat certain genetic diseases. Does beneficence obligate scientists to investigate such options? Should such techniques be confined to severe diseases (so the benefits outweigh the harms)? Any errors that result from such technology would be passed on to the offspring. Indeed, evolution could be affected if mutations induced by such procedures were passed on in the human gene pool. Current generations would be consenting to a procedure that would affect not only themselves, but all subsequent generations. For this reason, some view germ-line therapy as a line that ought not to be crossed (25).

### ***FUTURE CONSIDERATIONS***

Yesterday's science fiction is already today's reality. The greatest defense against potential misuse of biotechnology is an informed public. Only through recognition of the ethical issues involved can a reasonable public debate ensue. The following case studies in Appendixes A and B highlight some of the ethical problems in biotechnology.

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## APPENDIX A

## BIOTECHNOLOGY DISCUSSION SCENARIOS

1. John Musclebound lives in the small town where you practice pharmacy. He is a high-school senior and a star on the track team. His only hope for going to college is to win a track scholarship. In a few weeks, scouts will come to watch him compete. John has heard from his sister, who works in a local dialysis unit, that a new drug will increase endurance in athletes. Your pharmacy currently supplies this drug for dialysis. John's sister has obtained some of the drug for him (by sweet-talking a physician) but he is unsure how to administer it. John asks for your advice.
  - What are the pharmacist's duties in this case?
  - What ethical principles are involved?
  - In general, what role, if any, should pharmacists play in the use and distribution of drugs for unapproved use?
2. As a hospital pharmacy director and chair of the P & T committee, it is your responsibility to decide which drugs should be on formulary. Physicians want the hospital to have available a new drug which has been shown to be efficacious in reducing mortality from infection among cancer chemotherapy patients. Placing this drug on formulary and stocking it for anticipated use will require 15% of your total budget and requires elimination of some other more frequently used medications. How should this dilemma be resolved?
  - Should such (biotech) drugs be available to all patients regardless of ability to pay? Are indigent patients entitled only to standard (as opposed to extraordinary) care?
3. Adena O. Seen is a young woman of 24 who is seeking a high-paying job in a factory that manufactures batteries. She hopes to be able to provide for her two-year-old son now that she is divorced from her husband who beat her. Applicants for these jobs must submit to a genetic screen for oncogenes. Adena is tested and it is determined that she is too high a risk to warrant employment.
  - What ethical principles are involved here?
  - What are the rights of the employee and the duties of the employer?

4. In the future, routine blood analysis will be able to detect genetic abnormalities. Is it ethical for insurance companies to deny coverage for people at risk? Is it ethical for insurers, employers, or society to require life style changes on the part of patients who are at high risk? Is there a difference if the disease is preventable or curable?

## APPENDIX B

### BIOTECHNOLOGY AND ALLOCATION

1. Tay Sachs, Gaucher's, and cystic fibrosis are all severe, recessive genetic disorders for which adult carriers and fetuses with the disease can be diagnosed. In the Orthodox Jewish community of Brooklyn, marriages are arranged and rabbis provide close spiritual supervision and guidance. The community elders agreed that all children in the community should be tested, with information provided to parents. Carriers will be "urged" not to marry. Education about genetic testing will be provided in the high schools. Birth control within marriage is discouraged.
  - a. Why is this an allocation issue?
  - b. Identify all relevant ethical principles.
  - c. Give a rule utilitarian argument both for and against such intervention.
  - d. Is the argument affected by the fact that Tay Sachs and Gaucher's are fatal?
2. Huntington's disease is a dominant genetic disorder causing severe mental dysfunction and ultimate death. Symptoms do not manifest themselves until after child-bearing years. The gene can now be identified. There is no treatment or cure. People who have the gene will have the disease.
  - a. Should all members of high risk families be tested? Should testing be voluntary or mandatory?
  - b. Why is this an allocation issue?
  - c. Identify all relevant ethical principles.
  - d. Give a deontological and utilitarian argument for such testing.
  - e. If the disease were treatable would it affect your decision? Why?
3. Risk of developing late-onset Alzheimer's disease (the most prevalent type) is positively associated with the inheritance of a gene,

Apo E4. Not all people with the mutated Apo E4 gene develop the disease. Alzheimer's disease is common, affecting 4 million Americans. Who should be tested? Who should know?

- a. Why is this an allocation issue?
  - b. Identify all ethical principles involved.
  - c. Give a rule utilitarian argument for and against this type of testing.
  - d. Would the argument be different if there were effective treatment for Alzheimer's? Is the argument affected by the disease?
4. A genetic marker associated with increased risk for breast cancer, BRCA1 has been identified. While having the marker doesn't absolutely mean an individual will get breast cancer, the risk is high. Women in their twenties with this gene are at risk. What are the issues involved in such testing?
- a. Is this an allocation issue? Why or why not?
  - b. Is this a women's rights issue?
  - c. What ethical principles are involved?
  - d. If a woman opts for mastectomy, does she become uninsurable or unemployable?
  - e. What is a deontological argument for testing high risk women?
  - f. Should life style changes be enforced? (i.e., smoking, oral contraceptives, caffeine.)
  - g. What is a utilitarian argument for and against testing?