

# Biotechnology Medicines

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*ENGR 300: Societal Issues in Technology*

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## **Technology Assessment Form**

### **References:**

1. [Genentech, Inc. http://www.genentech.com.](http://www.genentech.com)

### **Technology Name:**

Biotechnology Medicines

### **Category:**

Biotechnology

### **Keywords:**

Biotechnology Medicines, Technology in Society

### **Technology Background:**

This information is mostly adapted from [Genentech, Inc.](http://www.genentech.com)

Research, clinical development, and process all contribute to the development of a new medicine. Each stage performs specific tasks that the other areas count on. Making medicine requires a sustained process at each stage right up to the final manufacturing process, where scientists collaborate to assure that ample amount of high quality pure product is made to meet the needs of clinical testing.

Research is square one: where investigation begins into how proteins -- the basic building blocks of the body -- might be used as is, modified or mimicked in an effort to treat or cure disease.

The clinical development scientists and medical professionals understand disease

and how it affects patients, their lives and their families; and they understand the role potential new medicines may play. There are a couple of criteria to look for in clinical development: a) Scientific Confidence - a potential medicine must have a solid scientific basis; b) Critical Medical Need - The disease or ailment targeted must be critical and currently unmet by existing medical technologies.

Regulatory authorities require pre-clinical testing and three phases of human clinical trials of increasing complexity and cost to prove the safety and efficacy of every new medicine. Before testing a new medicine in humans, researchers conduct extensive pre-clinical testing of the molecule. They perform various experiments in vitro (i.e. in the petri dishes, vials and beakers of the laboratory) or in animal models. They examine the activity of the potential drug carefully and under many different conditions before moving it into human testing in medical clinics.

Phase I clinical trials are principally designed to examine the safety of a drug. Further trials and development cannot take place unless Phase I trials show the drug to be reasonably safe when administered to humans. (Some side effects may be acceptable in relation to the severity of the disease targeted). Participants in this trial are closely scrutinized for the smallest indication of harm caused by the medicine. Because safety is as yet a question, these trials are necessarily small in scope. But they also give researchers an opportunity to begin to understand how the drug will work in humans.

Phase II clinical trials are designed to confirm safety, determine efficacy in humans over the short term, and help set up parameters (e.g. dosage) of the longer-term Phase III trials. Phase II trials are typically placebo-controlled and double-blinded: neither the patient nor the medical personnel know whether the patient is receiving the drug or a dummy placebo. These trials are larger in scope than Phase I and tend to take more time. In an effort to save time and money, some companies try to minimize the size and scope of Phase II trials.

Phase III trials are designed to prove the efficacy and safety of a drug over the long term. They are usually double-blinded and placebo-controlled and can involve hundreds or even thousands of patients over many months or even years. Though the numbers of patients involved can be great, the risks are relatively minimal because of the earlier testing to establish safety. The large scope of these trials gives researchers opportunity to prove efficacy and overall safety of the medicine as well as to identify rare side effects of treatment, if any.

Once all phases of clinical testing have been completed, if the data warrants it, an application is then submitted to the Food and Drug Administration for regulatory approval to market the medicine. If the FDA agrees that the data proves the safety and efficacy of the drug, approval may come in several months or years, with those medicines with the most urgent medical need typically approved more quickly.

It is important to monitor the medical community and the important health problems of the public, and to consider which diseases have a good chance of finding successful treatment or cure in the science of biotechnology. With all the attention biotechnology medicines receive, rarely discussed is what happens physically to the product between the initial discovery and the eventual market launch of a new medicine. How does a tiny vial of liquid in a laboratory become hundreds of thousands of bottles of medicine on shelves all over the world? How does a test tube of crude, delicate protein at a research bench become a dependable product that is pure and stable enough to withstand manufacturing, packaging, shipping and storage?

Manufacturing protein medicines is fabulously complicated, yet brilliantly simple: Cells are harnessed to do what they do naturally -- produce proteins. Manufacturing is essentially a process of coaxing the cellular reproduction process, recovering the desired proteins, and formulating and packaging those proteins into a stable medicine. It sounds simple, but the host cells and the proteins require perfect conditions at all points in the manufacturing process -- from the production of raw material to the packaging of the medicine for distribution. The FDA monitors closely the production of protein pharmaceuticals to ensure that the product delivered to patients is exactly what it is supposed to be.

### Technology Description:

This information is mostly adapted from [Genentech, Inc.](#)

Molecular biology -- the basic science underlying biotechnology -- may be the least romantic of any scientific discipline. After all, it views humans and other living organisms as but intricate collections of molecules. Its application to medicine is based on the premise that, since we have the tools to understand the body in molecular terms, we can understand diseases in molecular terms. Add to that recombinant DNA technology: the ability to alter the very definition of living organisms and, as a result, the kinds of proteins they produce. Suddenly the possibilities for medical advancement are tremendous.

Many scientists seek to use the body's own proteins -- or molecules that block or mimic them -- to treat or cure disease. Discovery is often a matter of systematically identifying which protein is causing problems in the body (either because it is absent, defective or present in excess) and then identifying or building a protein or related molecule to correct or counteract the problem. In this sense, biotechnology research relies on a singularly rational approach to discovery.

On the other hand, Louis Pasteur's view that "chance observation favors the prepared mind" still applies. The complexity of the human body and of human disease, even as it is increasingly understood in molecular terms, calls for all the creativity, imagination, insight and leaps of faith a scientist can muster. But a

rational approach drives the hunt for a solution: find the molecular basis of the problem, and use that knowledge and the increasingly powerful tools at hand to find a potential solution.

The following are three major defined therapeutic areas of medicine research:

- ✖ Cardiovascular Medicines
- ✖ Endocrinology
- ✖ Oncology

A primary tool for discovery remains the technology at the foundation of the biotechnology industry: recombinant DNA technology -- recombining DNA from different organisms to produce new organisms that can make proteins that may provide medical benefit. Many newer technologies also come into play. New methods of modeling and visualizing molecules on computers, integrated with increasingly powerful microscopes, allow researchers to understand the molecular workings of the body. Experiments with organisms lacking a specific gene, and therefore a specific protein, unmask the roles of individual proteins in disease states.

Ever more sensitive assays and instruments let researchers quickly and accurately characterize proteins, so they can be certain when the invisible stuff in their test tubes is indeed the protein they are looking for. Each advance in technology and each improvement in the relationship between computer science and bioscience helps spur research advances toward important new medicines.

## Technology Evaluation:

### 1. Social Impact

- a. Who are the stakeholders?

Biotechnology medical companies, numerous patients, physicians, medical doctors, hospitals, and governments around the world.

- b. Who will benefit?

Most beneficiaries would be the numerous patients. Commercially, the following will have some material or monetary benefits: biotechnology medical companies, physicians, medical doctors, and hospitals.

- c. How are the poor affected?

The costs associated with biotechnology medical care are initially

prohibitive for most middle-class and below without insurance, which is essentially most people in the world. However, as most other technologies, the price usually come down over time.

d. Does it bring society together?

Yes, I believe so. If the advances in the biotechnology medicine is shared and controlled in such manner that it does not become over-commercialize, this can improve the lives of many patients. Healthy and happy people would always bring society together.

e. What effects will it have on employment?

The effects on employment are mostly those in the biotechnology medical field, such as the biotechnology medical company's engineers and employees, the physicians, the medical doctors, nurses, and other hospital employees. Biotechnology medicine is a relatively new field and it will have much bigger employment effects in the future.

## 2. Ethical Questions

a. Does it violate rights?

Biotechnology medicine offer medical treatments to patients, this should actually improve their quality of life, not violate their rights.

b. Is it fair?

Yes, for the most part. The only exception is that to those who are not able to afford biotechnology medical care. However, as with other technologies, the cost for biotechnology medicine decrease dramatically over time so that more people will be able to realize the benefits of biotechnology medicine. Also, some biotechnology medical companies, endowment organizations, hospitals, and government agencies offer assistance program for indigent patients.

c. Does it produce the maximum good?

Yes, definitely. As cost comes down for biotechnology medical treatment and more poor people be able to receive treatment, this will produce the maximum good to most patients requiring medical treatments.

d. Does it promote the common good?

Yes, in the long run. Many patients have been helped by biotechnology medicines.

- e. Should we pursue this?

Yes, definitely, for the above reasons of producing the maximum good and promoting the common good.

- f. How do you weigh factors / make decisions?

I am always all for technologies those produce the maximum good and promote the common good. Technologies can always be good or bad; it is a matter on how a person uses the technology and how a technology company markets their products. However, I truly believe that any technology will do more good than bad and over the long haul, it will be for the greater good.

### **3. Legal Implications**

- a. Is it legal?

Yes, I believe so. The only danger that I can think of is that if new biotechnology medicine has been discovered and not sufficient tests have been done to prove the discovery and the companies who discovered the medicine pushed it to the market to commercialize the product for quick profits (i.e., biotechnology medicine that actually causes cancer instead of treating a particular disease or ailment).

- b. Does it promote law (or assist law breaking)?

In most cases, biotechnology medicine promotes law as this gives medical treatment to countless patients. I am not aware of any case where it may assist law breaking. However, if and when, in the future, someone figures how to create a biotechnology medicine that can essentially wipe out a particular people, race, gender, etc., this will definitely be used by the wrong people to assist law breaking.

- c. Does it assist (or hinder) law keeping?

This is the same situation as promoting law and assisting law breaking above.

### **4. Economics**

- a. Is it desirable for the country, region, company, and people?

It is economically desirable for patients as biotechnology medicines will give them much needed medical treatments and continue working to live. It is definitely economically desirable to those who commercialize and make profit and to those who earn living from biotechnology medical services, such as the biotechnology medical companies, the physicians, the medical doctors, and the hospitals. The country and the region may have to fund high cost research in the biotechnology medicines. In the short term, it has a negative impact to their economy; however, in the long run, they will benefit as the patients return to work and continue to pay taxes.

- b. Is it globally desirable?

Biotechnology medicine is definitely desirable globally. Some countries may not be able to fund such research, but they can certainly use and definitely need the biotechnology medicines to help their ailing citizens.

- c. What is the impact on economic stability?

I do not believe there is much impact on economic stability. It is a small part of the U.S. government research budget and probably much smaller or non-existent in other countries' budgets.

- d. Is it economically feasible?

Developed nations and biotechnology medical companies can certainly fund the research of biotechnology medicines. Hopefully, major inroads and advancements continue to evolve rapidly and bring down the cost of biotechnology medicines quickly so that the poor worldwide can have equal access to the biotechnology medicines and treatments.

## **5. Environmental Issues**

- a. How does it affect our environment (short term and long term)?

There is not much affect to our environment in the short term and long term; unless if biotechnology medical disposals have any side effect to the environmental plants and animals (no such cases reported yet).

## **6. Unanticipated Consequences**

- a. How might it be used?

Biotechnology medicines provides medical treatments to numerous patients that would hopefully fully or close to fully recover them. This will allow most patients, for the most part, to prolong their lives and continue almost a full and perfectly normal life. They can go back to work and continue to earn a living; they can now do most everything that they used to do, exercising, camping, etc.

- b. What alternate paths might it take?

I hope that biotechnology medicine will continue to evolve and improve further that it will give all patients restore their lives completely. This technology has the potential to prolong our life forever as we can avoid all kinds of sickness, disease, etc. I also hope that the biotechnology medical field advance very rapidly and the cost lowered very quickly so that everyone in the world will have equal chance to access the biotechnology medicines.

- c. Can you think of any uses of this technology other than the one proposed here?

As mentioned above, if and when, in the future, someone figures out how to create a biotechnology medicine that can essentially wipe out a particular people, race, gender, etc., this would definitely be used by the wrong people to assist law breaking.

- d. Are there any historical examples of developments analogous to this one that might serve as a guide to ways in which this technology might evolve?

If biotechnology medicine can be crossed with prosthetic technology and science, for example, in growing prosthetic tissues for implants in humans and children, this will have a huge impact to the society and human kind.

- e. Are there any other consequences that have not been mentioned?

Many unforeseen consequences of this biotechnology medicines have not had a chance to be developed yet; there may be many consequences that we do not yet know today. For example, the biotechnology medicine that can essentially wipe out a particular people, race, gender, etc. as mentioned above will also have a huge impact to the society.