HUMAN GENETIC ENGINEERING

FIELDS OF STUDY

Biotechnology; genetics; cytogenetics; molecular genetics; biochemical genetics; genomics; population genetics; developmental genetics; clinical genetics; genetic counseling.

SUMMARY

Human genetic engineering is a branch of genetic engineering focusing on the understanding of human genes to produce applications that can improve human life. Genes, formulated by DNA (deoxyribonucleic acid), determine genotype–the complete genetic information carried by an individual, even if not expressed. Visible human characteristics, by contrast, are formed as the result of human genes interacting with the environment and are called the phenotype. Human genetic engineering aims to alter genotypes to cause changes in phenotypes; also, and more often, the knowledge of human genetics is used to engineer products, such as medications, that can cure or improve the quality of human life by addressing genetic disorders. Many of the applications of what is now known as human genetic engineering arose out of the mapping of the human genome during the Human Genome Project, completed in 2003.

KEY TERMS AND CONCEPTS

- **Bioinformatics:** Science of compiling and managing genetic and other biology data using computers, requisite in human genome research.
- **Biologics:** Medicines produced using genes and genetic manipulations.
- **Clones:** Genetically identical living organisms produced via genetic engineering.
- **DNA (Deoxyribonucleic Acid):** Molecule, found in all living organisms, that by reproducing itself allows for the inheritance of characteristics from one generation to the next.
- **Dysmorphology:** Abnormal physical development resulting from a genetic disorder.
- **Forensic Genetics:** Application of genetics, particularly DNA technology, to the analysis of evidence used in criminal cases and paternity testing.
- **Gene:** Specific DNA sequence that codes for a specific protein.
- **Gene Therapy:** Use of a viral or other vector to incorporate new DNA into a person's cells with the objective of alleviating or treating the symptoms of a disease or condition.
- **Genetic Screening:** Use of the techniques of genetics research to determine a person's risk of developing, or his or her status as a carrier of, a disease or other disorder.
- **Gene Transfer:** Using a viral or other vector to incorporate new DNA into a person's cells; used in gene therapy.
- **Genetic Testing:** Process of investigating a specific individual or population of people to detect the presence of genetic defects.
- **Genomics:** Branch of genetics dealing with the study of the genetic sequences of organisms, including the human being.
- **Pharmacogenomics:** Branch of human medical genetics that evaluates how an individual's genetic makeup influences his or her response to drugs.
- **Proteomics:** Study of how proteins are expressed in different types of cells, tissues, and organs.
- **Recombinant DNA:** DNA that has been transferred from one cell to another. Genes are recombined from a human chromosome to another cell, usually from bacteria; if the transferred human genes code for insulin, the bacteria accepting the transferred genes will now produce human insulin.
- **Stem Cell:** Progenitor cell that has the capability to become a more specialized cell, such as a kidney, liver, or heart cell. Once a cell becomes a specific kind of cell, it cannot change to another type of cell.
- **Toxicogenomics:** Science of evaluating ways in which genomes respond to chemical and other pollutants in the environment.

Definition and Basic Principles

Human genetic engineering is the science and technology of manipulating or changing human genes to alter or control visible characteristics of a human newborn or adult. Genes, formulated by DNA (deoxyribonucleic acid), are called the genotype. Visible human traits or characteristics, formed from the interaction of genes and the environment, are called

the phenotype. Human genetic engineering aims to change genotypes to cause change in the phenotype. To understand human genetic engineering capabilities, it is important to understand basic genetic principles.

Background and History

Human genetic engineering is a scientific endeavor, and as such this field builds on the information and knowledge gained from the decades of experimentation accomplished in years past. Without this foundation, human genetic engineering would not exist. This foundation brings the prospect of human cloning and the use of human genetics for therapeutic purposes.

A keystone event in modern genetics occurred in 1953, when American biologist James D. Watson and English physicist Francis Crick deduced the double-helical structure of DNA. This structural information enabled effective study of how genetic material codes for life. In 1968, the DNA genetic code was deciphered. Armed with this important genetic information, geneticists undertook the first recombinant DNA experiments on bacteria in 1973. The ambitious Human Genome Project started in 1990, with the goal of mapping out the entire human genetic sequence. In June, 2000, the first working draft of the human genetic sequence was produced from the efforts of this project. April, 2003, saw the announcement of the first complete human genetic sequence–breakthrough information for human genetic engineering.

Cloning, a subdiscipline of bioengineering, is the reproduction of genetically identical living organisms. In 1996, the first mammal was cloned, a sheep named Dolly. Other animals have been cloned since this pioneering event, including a bull in 1999 and a pig in 2000. The year 2003 saw the cloning of a mule, a horse, and a rat, followed by the cloning of a dog in 2005. Attempts at pet cloning have occurred: John Sperling, a wealthy and influential American educator, has funded pet-cloning projects, and researchers at Texas A&M University successfully cloned a cat in 2002. Commercial attempts at pet cloning started in April, 2004, with a company called Genetics Savings and Clone (now defunct) offering pet gene banking and cloning. Korean researchers published claims of successful human embryonic cloning in 2004, but these claims were later retracted because of fabricated data and other problems with the research. In May, 2010, the journal *Science* reported that scientists J. Craig Venter, Clyde Hutchison III, and Hamilton Smith had created a living creature in the laboratory. This new life-form, a bacterium, was artificially produced using genetic-engineering techniques. It had no ancestor and it reproduced, a key ability of living organisms.

Milestones in other areas of human genetic engineering—with more practicable and practical results—occurred in the areas of medicine, pharmaceuticals, forensics, and even psychology, as identified below in Applications and Products. Many, if not most, of these blossomed shortly after the mapping of the human genome was completed in 2003. Many more will be developed as scientists and researchers continue to investigate the data that were gathered through that monumental accomplishment.

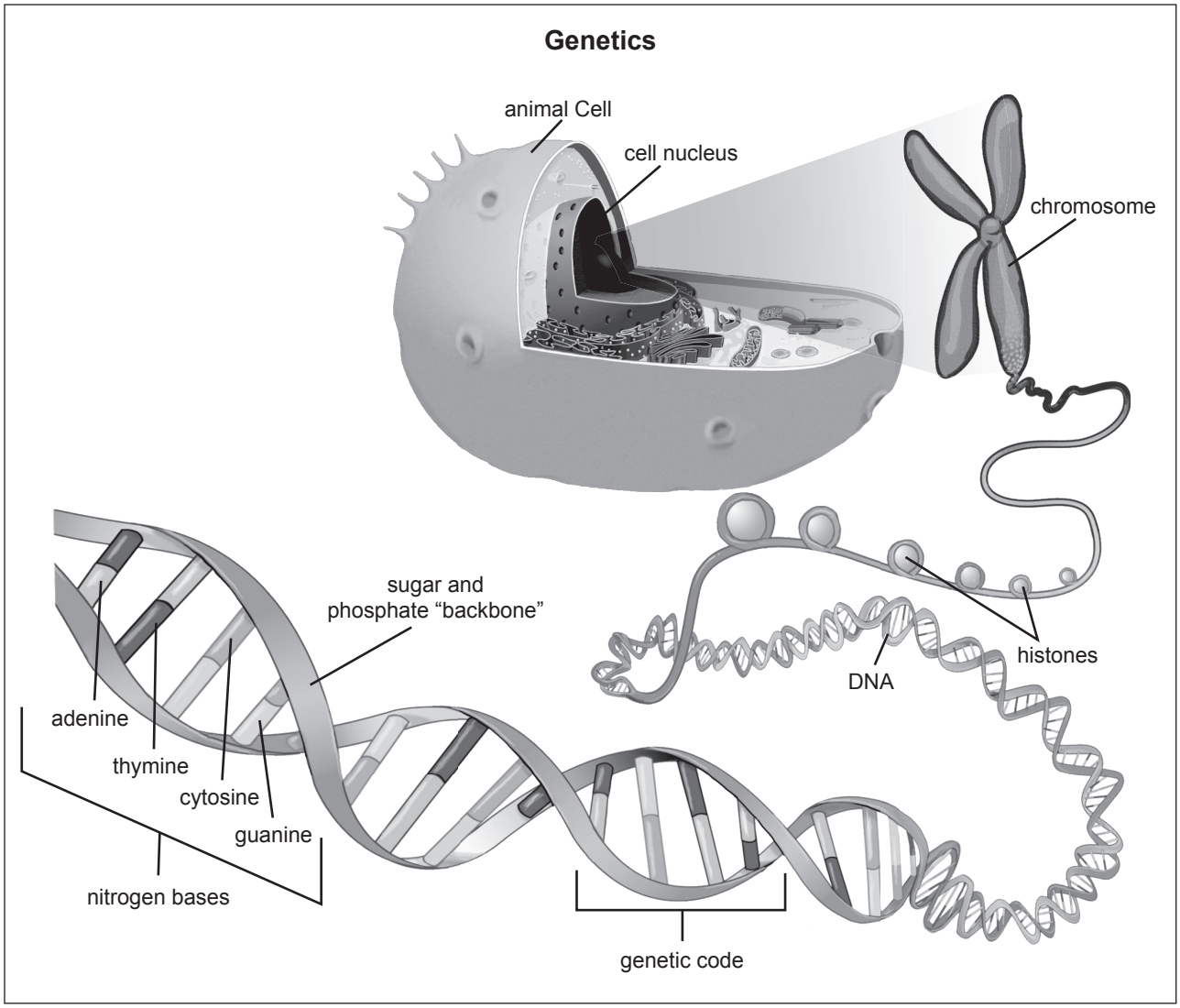
How It Works

Until the middle of the eighteenth century, most biologists believed in spontaneous generation—that life arises from combinations of decaying matter, as if flies arose from garbage. It is now known that DNA genetically codes for many physical characteristics.

The story of genetics starts with DNA and ends with protein. DNA, the genetic material found in the nucleus of every cell, codes for (that is, creates instructions for the building of) various proteins by means of components of the DNA molecule called nucleotides, which form the building blocks of DNA. The nucleotides establish the code. Proteins make up the structural elements of the body, including collagen, ligaments, tendons, and muscles; some hormones, such as insulin, are made of protein as well. Perhaps most important, however, are the protein enzymes.

All the enzymes in the body are made up of protein and protein alone. Enzymes are key because they accelerate chemical reactions. Thousands of chemical reactions occur in human bodies all the time. Protein enzymes catalyze all these reactions. DNA, by dictating the production of enzymes, controls these chemical reactions.

DNA dictates which proteins are produced by living and staying in the cell nucleus during the entire protein-making process. Much like a general in a command center, the DNA sends out orders but does not leave the nucleus. DNA is made up of nucleotide



bases, and the first step in protein production involves the reading of the nucleotide code in the DNA. When the nucleotides are read, a strand of messenger ribonucleic acid (mRNA) is produced and sent from the nucleus into the cytoplasm of the cell. The DNA stays in the nucleus, while the mRNA leaves the nucleus. This process of reading the DNA nucleotide code and producing mRNA is called transcription.

The next step involves reading the nucleotide code on the mRNA in the cytoplasm of the cell. The cytoplasm is the liquid environment inside the cell where all the cellular organelles float. Transfer RNA (tRNA) reads the code on the mRNA, and this process is called translation. tRNA is called transfer because it transfers a specific amino acid when it reads the appropriate code on the mRNA. The basic building blocks of protein are called amino acids. About twenty-two different amino acids build all the various proteins the body uses. It is like the English alphabet: Twenty-six letters and vowels comprise the English alphabet, and combining these various letters and vowels results in tens of thousands of different combinations and all the various words in the English language. Likewise, the body uses the different amino acids to form the tens of thousands of different proteins in the body.

During translation, a specific amino acid is coded for and carried by the transfer RNA to a ribosome. Ribosomes (along with the rough endoplasmic reticulum) are where the cell's proteins are produced. Along ribosomes, different amino acids are transported by tRNA and linked, forming a protein molecule. Some proteins may be only eighty or ninety amino acids long, whereas others, such as hemoglobin, may have more than 300 amino acids as their amino acid backbone.

The way DNA codes for all this involves the nucleotide bases that make up DNA. Four nucleotide bases make up DNA: adenine, cytosine, guanine, and thymine. Adenine will chemically bind with thymine, and cytosine always chemically binds with guanine. When DNA is transcribed to form mRNA, if the nucleotide sequence in the DNA reads cytosine-cytosine-guanine, these nucleotide bases will code for guanine-guanine-cytosine in the mRNA. Then when mRNA is translated by tRNA, the code goes back to the original DNA code, cytosine-cytosine-guanine. Cytosine-cytosine-guanine can code for a specific amino acid, and in that fashion DNA codes for the amino acid sequence of all protein molecules. The nucleotide base sequence in the mRNA is called the codon and the complimentary base sequence found in tRNA is called the anticodon.

The example of how Dolly the sheep was cloned demonstrates how genetic engineering in mammals works, and, hence, how human cloning could work. Cloning is an ultimate example of genetic engineering because cloning produces an entire living organism via genetic engineering. Dolly was a Finn Dorset sheep, which is all white. A Blackface ewe, named because of the distinctive black face these sheep have, was used as an egg donor and as a surrogate mother.

Cells taken from a Finn Dorset ewe were grown in a tissue culture. An egg cell, from the Blackface ewe, had the nucleus removed. The nucleus contained the genes and DNA. The nucleus and genetic information from the Finn Dorset ewe were placed in the enucleated Blackface ewe egg cell. The Blackface ewe egg cell, now containing genetic information from the Finn Dorset ewe, was placed in the uterus of the Blackface ewe after an electric pulse is applied to stimulate growth and duplication of the cells. The Blackface ewe gave birth to Dolly, the all-white Finn Dorset ewe. The newborn Finn Dorset ewe was an identical genetic copy of the Finn Dorset ewe originally used to harvest the genetic information found in the nucleus.

Recombinant DNA refers to DNA transfer from one cell to another. In human genetic engineering, genes transfer from a human chromosome to another cell, usually bacteria. If the transferred human genes code for insulin, the bacteria accepting the transferred genes will now produce human insulin.

In this process, the desired genes are isolated and removed from the human cell. Bacterial cells have small, circular strips of DNA called plasmids. These circular plasmids are removed from the bacterial cells and opened up. Various enzymes are used to cut the human DNA and bacterial DNA sequences at specific points. Restriction enzymes cut the original DNA in specific locations. DNA ligase pastes strips of DNA together. Scientists mix isolated human genes with the opened bacterial plasmids, along with DNA ligase. The human genes are spliced into the bacterial plasmid and the circle of genetic information in the bacterial plasmid closes.

The bacterial plasmid with the spliced human genes is now called a vector. The plasmid vectors are taken up by the bacterial cells. Once inside the bacterial cells, the bacteria multiply and reproduce the spliced human genes. Whatever specific human genes were selected for splicing, for example, human insulin genes, are now functioning in the reproduced bacteria, and human insulin is harvested from the bacterial clones.

APPLICATIONS AND PRODUCTS

Early Medical Applications. Recombinant DNA techniques are remarkable biological life adaptations, and many medicines based on this technology are used. Medications generated through human genetic engineering techniques have been in use since 1982, with the production of human insulin using recombinant DNA techniques. Human genes are inserted into a bacterial host that then makes human insulin. Prior to this type of genetic manipulation, diabetics needing insulin had to rely on insulin harvested from pigs or cows. Genetic techniques produce human growth hormone, previously only available from human cadavers. A genetically engineered hepatitis B vaccine has been in use since 1987.

Since these first human genetic medicines and vaccines, many types of biological products have

been introduced or are under current investigation and development. These new medicinal products are called biologics to distinguish them from chemically synthesized medicines. Genes and genetic manipulations produce biologics. Major types of biologics include hormones, antibodies, and cell-receptor proteins.

Insulin and human growth hormone, discussed above, are classic protein hormones produced with recombinant DNA technology. The immune system produces protein antibodies that attack disease causing-agents such bacteria and viruses. Genetic antibody production interferes with or attacks entities associated with diseases such as psoriatic arthritis and Crohn's disease. Recombinant DNA technology produces proteins binding with specialized white blood cells to reduce inflammation associated with rheumatoid arthritis.

Bioinformatics. The purpose of bioinformatics is to help organize, store, and analyze genetic biological information in a rapid and precise manner, dictated by the need to be able to access genetic information quickly. In the United States the online database that provides access to these gene sequences is called GenBank, which is under the purview of the National Center for Biotechnology Information (NCBI) and has been made available on the Internet. In addition to human genome sequence records, GenBank provides genome information about plants, bacteria, and animals other than humans.

Proteomics. Bioinformatics provides the basis for all modern studies of human genetics, including analyzing genes and gene sequences, determining gene functions, and detecting faulty genes. The study of genes and their functions is called proteomics, which involves the comparative study of protein expression. That is, it studies the metabolic and morphological relationship between the protein encoded within the genome and how that protein works. Geneticists are now classifying proteins into families, superfamilies, and folds according to their configuration, enzymatic activity, and sequence. Ultimately proteomics will complete the picture of the genetic structure and functioning of all human genes.

Toxicogenomics. Another newly developing field that relies on bioinformatics is the study of toxicogenomics, which is concerned with how human genes respond to toxins. As of 2011, this field is specifically concerned with evaluating how environmental factors negatively interact with mRNA translation, resulting in disease or dysfunction.

Gene Testing. In a gene-testing protocol, a sample of blood or body fluids is examined to detect a genetic anomaly such as the transposition of part of a chromosome or an altered sequence of the bases that comprise a specific gene, either of which can lead to a genetically based disorder or disease. As of 2011, more than 600 tests are available to detect malfunctioning or nonfunctioning genes. Most gene tests have focused on various types of human cancers, but other tests are being developed to detect genetic deficiencies that cause or exacerbate infectious and vascular diseases.

Fascinating Facts About Human Genetic Engineering

- In 2011, researchers at Brigham and Women's Hospital in Boston identified a self-renewing human lung stem cell. This particular stem cell is also able to form and integrate a variety of biological lung structures, including bronchi, alveoli, and pulmonary vessels.
- DNA fingerprints, used in forensic genetics, are made by using enzymes splitting the genetic sequence up into patterns unique to an individual. DNA fingerprinting used to require test tubes of blood for analysis. Polymerase chain reaction technology now allows the reproduction of DNA (and subsequent analysis) from a sample as small as dried saliva from the back of a stamp.
- Synthetic biology aims to produce life-forms. Life-forms reproduce, by definition. An invention such the atomic bomb cannot reproduce itself, but biologics can.
- Dolly the sheep, the first cloned mammal, lived six years, half the normal life expectancy. The sheep originating the cloned DNA was six years old at the time of donation, raising speculation about the genetic age of the donor DNA.
- Genetic engineering techniques could resurrect life for extinct animals, such as mammoths, or extinct human species, such as Neanderthals. Although "farming" DNA that is viable for such use is difficult, theoretically such feats could be accomplished. A film that was based on this possibility is *Jurassic Park* (1993), based on a novel of the same name by Michael Crichton.

The emphasis on the relationship between genetics and cancer lies in the fact that all human cancers are genetically triggered or have a genetic basis. Some cancers are inherited as mutations, but most result from random genetic mutations that occur in specific cells, often precipitated by viral infections or environmental factors not yet well understood.

At least four types of genetic problems have been identified in human cancers. The normal function of oncogenes, for example, is to signal the start of cell division. However, when mutations occur or oncogenes are overexpressed, the cells keep on dividing, leading to rapid growth of cell masses. The genetic inheritance of certain kinds of breast and ovarian cancers results from the nonfunctioning tumor-suppressor genes that normally stop cell division. When genetically altered tumor-suppressor genes are unable to stop cell division, cancer results. Conversely, the genes that cause inheritance of colon cancer result from the failure of DNA repair genes to correct mutations properly. The accumulation of mutations in these "proofreading" genes makes them inefficient or less efficient, and cells continue to replicate, producing a tumor mass.

If a gene screening reveals a genetic problem several options may be available, including gene therapy and genetic counseling. If the detected genetic anomaly results in disease, then pharmacogenomics holds promise of patient-specific drug treatment.

Gene Therapy. The science of gene therapy uses recombinant DNA technology to cure diseases or disorders that have a genetic basis. Still in its experimental stages, gene therapy may include procedures to replace a defective gene, repair a defective gene, or introduce healthy genes to supplement, complement, or augment the function of nonfunctional or malfunctioning genes. Several hundred protocols are being used in gene-therapy trials, and many more are under development. As of 2011, trials are focusing on two major types of gene therapy, somatic cell gene therapy and germ-line gene therapy.

Somatic cell gene therapy concentrates on altering a defective gene or genes in human body cells in an attempt to prevent or lessen the debilitating impact of a disease or other genetic disorder. Some examples of somatic cell gene therapy protocols now being tested include ones for adenosine deaminase (ADA) deficiency, cystic fibrosis, lung cancer, brain tumors, ovarian cancer, and AIDS.

In somatic cell gene therapy a sample of the patient's cells may be removed and treated and then reintegrated into body tissue carrying the corrected gene. An alternative somatic cell therapy is called gene replacement, which typically involves insertion of a normally functioning gene. Some experimental delivery methods for gene insertion include use of retroviral vectors and adenovirus vectors. These viral vectors are used because they are readily able to insert their genomes into host cells. Hence, adding the needed (or corrective) gene segment to the viral genome guarantees delivery into the cell's nuclear interior. Nonviral delivery vectors that are being investigated for gene replacement include liposome fat bodies, human artificial chromosomes, and naked DNA (free DNA, or DNA that is not enclosed in a viral particle or any other "package").

Another type of somatic gene therapy involves blocking gene activity, whereby potentially harmful genes such as those that cause Marfan syndrome and Huntington's disease are disabled or destroyed. Two types of gene-blocking therapies being investigated include the use of antisense molecules that target and bind to the mRNA produced by the gene, thereby preventing its translation, and the use of specially developed ribozymes that can target and cleave gene sequences that contain the unwanted mutation.

Germ-line therapy is concerned with altering the genetics of male and female reproductive cells (gametes) as well as other body cells. Because germ-line therapy will alter the individual's genes as well as those of his or her offspring, both concepts and protocols are still very controversial. Some aspects of germ-line therapy now being explored include human cloning and genetic enhancement.

Clinical Genetics. Clinical genetics is that branch of medical genetics involved in the direct clinical care of people afflicted with diseases caused by genetic disorders. Clinical genetics involves diagnosis, counseling, management, and support. Genetic counseling is a part of clinical genetics directly concerned with medical management, risk determination and options, and decisions regarding reproduction of afflicted individuals. Support services are an integral feature of all genetic counseling themes.

Clinical genetics begins with an accurate diagnosis that recognizes a specific, underlying genetic cause of a physical or biochemical defect following guidelines outlined by the National Institutes of

Health (NIH) Counseling Development Conference. Clinical practice includes several hundred genetic tests that are able to detect mutations such as those associated with breast and colon cancers, muscular dystrophy, cystic fibrosis, sickle-cell disease, and Huntington's disease.

Genetic counseling follows clinical diagnosis and focuses initially on explaining the risk factors and human problems associated with the genetic disorder. Both the afflicted individual and family members are involved in all counseling procedures. Important components include a frank discussion of risks, of options such as preventive operations, and of options involved with regard to reproduction. All reproductive options are described along with their potential consequences, but genetic counseling is a support service rather than a directive mode. That is, it does not include recommendations. Instead, its ultimate mission is to help both the afflicted individuals and their families recognize and cope with the immediate and future implications of the genetic disorder.

Pharmacogenomics. That branch of human medical genetics dealing with the correlation of specific drugs to fit specific diseases in individuals is called pharmacogenomics. This field recognizes that individuals may metabolically respond differentially to therapeutic medicines based on their genetic makeup. It is anticipated that testing human genome data will greatly speed the development of new drugs that not only target specific diseases but also will be tailored to the specific genetics of patients.

Forensic Genetics. Forensic genetics is the use of human genetics in criminal or paternity cases. For example, DNA testing on blood, saliva, or other tissue can be used to determine the source of evidence, such as blood stains or semen, left at a crime scene. Forensic DNA analysis is also used to determine paternity and other kinship. Finally, with the increasing use of forensic genetics since the 1990's, some incarcerated prisoners have been released after it was clearly determined that they could not possibly have been guilty of crimes they were convicted of, as DNA evidence eliminated them from suspicion.

Potential for Human Cloning. Human therapeutic cloning involves the production of cloned human embryos, with the idea of harvesting embryonic stem cells. The hope is that the stem cells can be grown into a wide variety of cells to replace or repair organs, such as liver, kidney, or heart cells. Although human cloning has not yet reached this potential, future applications could offer identically matched kidneys for people with failing kidneys or even a genetically duplicate heart for someone in severe heart failure.

Impact on Industry

The many applications of our knowledge of human genetics have had a revolutionary impact on industry, spawning entirely new industries as well as new product lines. Three main areas on which these industries focus is research, or the analysis of the human genome to identify new and potentially profitable areas of investigation; pharmaceutical applications–many of the large pharmaceutical companies produce medications based on human genetic research, such as the aforementioned synthetic insulin hormones; and finally, genetic counseling, which the National Society of Genetic Counselors defines as the practice of "health care professionals with specialized graduate training in the areas of medical genetics and counseling" who "work as members of a health care team, providing information and support to families who have members with birth defects or genetic disorders and to families who may be at risk for a variety of inherited conditions."

Genentech, established in 1976, is considered the founder of the biotechnology industry, with special focus on human genetics. Its stated mission is "using human genetic information to discover, develop, manufacture, and commercialize medicines to treat patients with serious or life-threatening medical conditions . . . to create, produce, and market innovative solutions of high quality for unmet medical needs." Other leading companies in the field include Amgen, Genzyme, Gilead Sciences, Biogen Idec, Cephalon, and MedImmune in the United States; Merck Serono in Switzerland; CSL in Australia; and UCB in Belgium.

Careers and Course Work

A variety of career paths exist for people interested in genetics. Educational requirements vary from bachelor's to doctorate degrees. Research scientists, working at major universities, companies, and government agencies such as the NIH usually need a Ph.D. or M.D. A clinical geneticist who treats patients typically completes medical school and

specialty training. Geneticists or research scientists usually have Ph.D. training in fields such as molecular genetics, cytogenetics, or the burgeoning field of synthetic biology. Genetic counselors complete a master's degree program in genetic counseling. Research assistants in genetics laboratories usually have a master's degrees in genetics or biological sciences. Genetic laboratory technicians work in forensic or research labs with a bachelor's degree in science-related fields.

Select engineering schools, such as the University of Michigan, have biomedical engineering programs. Biomedical engineers interface with medical device and drug industries. Biomedical engineers will play an important role bringing genetic therapies into clinical practice. Tissue engineering involves the manipulation of genes to affect changes in phenotypes, the essence of genetic engineering.

Social Context and Future Prospects

The Human Genome Project painstakingly mapped out the human DNA sequence in 2003, after a decade and a half of meticulous multicenter collaboration. Genetic databases are now rapidly filling with genetic detail because of technological advances in the speed of analyzing DNA sequences. While the speed of this analysis has increased considerably, the price of such investigations has dropped significantly. Genetic databases currently hold information on a wide variety of life-forms, and significant amounts of new generic information is added frequently.

The DNA sequencing found in genetic databases provides the burgeoning field of synthetic biology with important basic information needed for human genetic engineering. This information can be used for modeling and as supply depots for the mixing and matching of genes. As the speed of genetic analysis has increased significantly and the price of genetic investigations has dropped considerably, the process of DNA synthesis is much less expensive and faster than it was in the beginning of the twenty-first century.

More genetic information, faster artificial DNA synthesis, and significant technological cost savings result in more feasible human genetic engineering projects. Genes are the stuff of life, and the field is on the verge of changing life and even making new life-forms, via genetic engineering. How and what changes are made will present significant bioethical and societal challenges, along with potentially fantastic and beneficial results.

Richard P. Capriccioso, M.D.

Further Reading

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Web Sites

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http://www.ashg.org

Center for Genetics and Society
http://www.geneticsandsociety.org

Genetics Education Center
University of Kansas Medical Center
http://www.kumc.edu/gec

Human Genome Project
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National Institutes of Health
Stem Cell Information
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National Society of Genetic Counselors
http://www.nsgc.org

See also: Bioengineering; Cell and Tissue Engineering; Cloning; DNA Analysis; DNA Sequencing; Genetically Modified Food Production; Genetic Engineering; Proteomics and Protein Engineering.