In a culture where words like "artificial," "synthetic," and "man-made" are often used as slurs and the masses increasingly applaud so-called natural healing, a revolution in what might reasonably be termed "unnatural healing" is proceeding almost full blast yet so quietly that the public has scarcely noticed it.

This revolution the "biopharm" revolution stems from major advances in biotechnology, or biotech, a field that encompasses such disparate processes as winemaking, bioconversion (a means of recycling organic waste), and cloning. The medical repercussions of advances in biotech have been impressive, but the implications of those advances for human well-being are no less than staggering.

"Biotherapy" refers to any treatment that involves the administration of a microorganism or other biologic matter. Biotherapy's name may be spanking new, but biotherapy itself is not: Administering living things or biologic matter is an ancient approach to disease. Crude vaccines were used in antiquity in China, India, and Persia. Vaccination with scabs that contained the smallpox virus had been a practice a dangerous one in the East for centuries when, in 1798, English country doctor Edward Jenner demonstrated that inoculation with pus from sores due to infection by a related virus could prevent smallpox far less dangerously. Humankind has benefited incalculably from the implementation of vaccination programs.

Another form of biotherapy, insulin replacement therapy, has been in use for decades. Before Canadian physiologists Frederick Banting and Charles Best discovered and isolated insulin in 1921, nearly all persons diagnosed with diabetes died within a few years after the diagnosis. In the mid-1960s several groups reported synthesizing the hormone.

Virtually all biotherapeutic agents in clinical use are biotech pharmaceuticals. A biotech pharmaceutical is simply any medically useful drug whose manufacture involves microorganisms or substances that living organisms produce (e.g., enzymes). Most biotech pharmaceuticals are recombinant that is, produced by genetic engineering. Insulin was among the earliest recombinant drugs.

Genetic engineering also known as bioengineering, gene splicing, and recombinant DNA technology comprises altering genetic (DNA) molecules outside an organism and making the resultant DNA molecules function in living things. Many-celled organisms that have been genetically engineered to produce substances that are or may be medically useful to humans include cows, goats, sheep, and rats and corn, potato, and tobacco plants.

In general, recombinant drugs approved by the U.S. Food and Drug Administration (FDA) are safer than comparable natural-substance derivatives: Recombinant-DNA processes are precision
techniques that inherently limit contamination. Moreover, many biotech agents are identical to, or differ only slightly from, proteins the human body produces naturally; thus, biotech pharmaceuticals tend to have a lower potential for adverse reactions. In contrast, most conventionally produced pharmaceutical agents designed for treating humans are foreign to, or not normally present in, the human body.

Genetic engineering is central to modern biotherapy’s backbone: pharmaceutical biotechnology. Pharmaceutical biotechnology involves using microorganisms, other organisms (e.g., sheep), or hybrids of tumor cells and white blood cells:

to create new pharmaceuticals;
to create safer and/or more effective versions of conventionally produced pharmaceuticals; and
to produce substances identical to conventionally made pharmaceuticals more cost effectively than the latter pharmaceuticals are produced.

For example, before the development of recombinant human insulin which became the first manufactured, or commercial, recombinant pharmaceutical in 1982 animals (notably pigs and cattle) were the only nonhuman sources of insulin. Animal insulin, however, differs slightly but significantly from human insulin and can elicit troublesome immune responses. Recombinant human insulin is at least as effective as insulin of animal origin, is safer than animal-source insulin, and can satisfy medical needs more readily and more affordably.

The FDA approved more biotech drugs in 1997 than in the previous several years combined. The laundry list of human health conditions for which the FDA has approved recombinant drugs includes AIDS, anemia, certain cancers (Kaposi’s sarcoma, leukemia, and colorectal, kidney, and ovarian cancers), certain circulatory problems, certain hereditary disorders (cystic fibrosis, familial hyper-cholesterolemia, Gaucher’s disease, hemophilia A, severe combined immunodeficiency disease, and Turner’s syndrome), diabetic foot ulcers, diphtheria, genital warts, hepatitis B, hepatitis C, human growth hormone deficiency, and multiple sclerosis.

Pharmaceutical biotechnology’s greatest potential lies in gene therapy. Gene therapy is the insertion of genetic material into cells to prevent, control, or cure disease. It encompasses repairing or replacing defective genes and making tumors more susceptible to other kinds of treatment.

Genetic engineering is revolutionizing medicine: enabling mass production of safe, pure, more effective versions of chemicals the human body produces naturally. Through gene therapy, the potential of biotech pharmaceuticals for curing chronic and "incurable" diseases and improving the human condition is limitless. With sensible regulatory requirements and expeditious product review by the FDA, biotech pharmaceuticals can within decades become unprecedented relievers of human suffering.

Biotech Pharmaceuticals and Biotherapy [1]