# Healing, Fueling, Feeding: How Biotechnology Is Enriching Your Life.

reduce $CO_2$ emissions by 32 million tons annually by lowering temperatures for washing clothes and dishes?

prevent 241 million people annually from suffering from malaria?

ensure no child ever goes to bed hungry?

stop chronic disease from resulting in 7 out of 10 deaths each year?

make farming more Earth-friendly?

cut the cost of inputs for producing nylon by 50%?

# How do we...

shrink the waste from making vitamin B-2 by 95%?

eliminate 78% of cervical cancer?

Reduce by 50% food crops in developing countries lost to pest and disease?

reduce greenhouse gas emissions by 86%?

feed 7 billion people?

decrease water use by the textile industry by 50%?

save 2.1 million people annually from dying of diarrheal diseases?

# Executive Summary

## What is the biggest, most alarming challenge facing society today?

Is it how to feed 7 billion people and ensuring no child ever goes to bed hungry?
Or is it how to reduce greenhouse gas emissions and help stop human-induced climate change?
Or is it how to help save lives by eliminating the threat of cancer, HIV/AIDS, and rare diseases?
Or is it some combination of all these things?

## What about you, personally—what's the biggest hurdle in your life?

Is it how to eat more healthily and live greener while saving money?
Or is it how to conserve energy and minimize your own carbon footprint?
Or—maybe it's how to ensure your mother survives breast cancer?

## We all face challenges, each and every day. Some are personal, and some are much grander in scale.

So—how do we tackle them? How do we solve them—from the mundane problems of day-to-day living to the bigger-picture problems that define a generation?

## These are the questions we ask ourselves every day: *how do we live better, and what tools do we need?*

**We believe biotechnology has a central role in meeting these and other urgent challenges.** Biotechnology is all around us and is already a big part of our lives, providing breakthrough products and technologies to combat disease, reduce our environmental footprint, feed the hungry, and make useful products. Even though we may not recognize it, we see it every day in our homes and workplaces, and everywhere in between. At its simplest, biotechnology harnesses cellular and biomolecular processes and puts them to work for us.

The science of biotechnology isn't easy. Nature does not readily yield her secrets. Still, every day in nearly every country on Earth our brilliant scientists decode a bit more of the language of life. The science continues to astonish and amaze. Today, there are more than **250 biotechnology health care products** and vaccines available to patients, many for previously untreatable diseases. More than **13.3 million farmers** around the world use agricultural biotechnology to increase yields, prevent damage from insects and pests and reduce farming's impact on the environment. And more than

**50 biorefineries** are being built across North America to test and refine technologies to produce biofuels and chemicals from renewable biomass, which can help reduce greenhouse gas emissions.

Most of us don't realize that humans have used biotechnology for literally thousands of years; fermenting beer, aging cheese, and baking bread are just a few examples. These rudimentary forms of biotechnology often relied on fermentation, capitalizing on yeasts and other microorganisms to enhance our food supply and make other lifestyle improvements.

Today, biotechnology continues to help improve the way we live, and it helps us do so more responsibly. In the last 40 years, we have seen many important breakthroughs that enable us to:

- harness bacteria and yeasts as nature's microscopic workhorses;
- leverage genetic markers; and
- deploy a more sophisticated, systematic use of enzyme-based production processes.

The result is a diverse and nearly endless set of practical biotechnology products helping us live longer and healthier lives, have a more abundant and sustainable food supply, use safer and more efficient industrial manufacturing, and reduce our greenhouse gas footprint.

## Confronting the Challenges of Today and Tomorrow

We face many challenges in the near future. Globally, the population is expected to **increase 38%** by 2050, **from 6.8 billion** in 2009 **to 9.4 billion** in 2050, with the U.S. population growing **43%** and the population of Africa projected to **double** during that same period.

The population is also aging, especially in more developed countries including the United States, Canada, and Japan—and at increased risk for developing age-related degenerative diseases and other health conditions. Left unchecked, this threatens our economic stability and social infrastructure.

Against this backdrop, we face a dwindling supply of fossil fuels, limited arable land for food production, a scarcity of clean water, the looming impact of climate change, and constantly evolving threats to our health and nutrition. Even so, recent advances in biotechnology are helping us prepare for and meet these challenges today.

New medicines have helped reduce the debilitating impacts of multiple sclerosis and cystic fibrosis, drastically improving life expectancy for those suffering from them. For other diseases, including many cancers and hereditary conditions, important new diagnostic tools leverage genetic testing and other biomarkers to help physicians determine whether a patient is likely to respond to a medication and choose the right dosage.

To address the challenges of climate change and resource scarcity, biotechnology is helping us become more environmentally sustainable. New manufacturing processes leveraging biotechnology reduce waste, minimize water use, prevent pollution from harmful chemicals, and reduce the generation of greenhouse gases. For example, using biofuels cuts greenhouse gas emissions by **52%** or more , while lowering the temperature for laundering clothes could potentially save **$4.1 billion** annually.

The development of new biofuels and other renewable fuels has helped enhance our energy sustainability while reducing dependence on foreign oil, while new biodegradable plastics are reducing the need for landfills.

Agricultural applications of biotechnology have helped create a more sustainable food supply by increasing crop yield, reducing agriculture's environmental impact, and enhancing resistance to destructive pests. For example, through modern biotechnology corn plants resist the dreaded corn borer, resulting in healthier plants, more corn for food, feed and fuel and fewer insecticide applications.

## Promise for the Future

We have only tapped a small fragment of the many potential uses—and benefits—of biotechnology. Everyday, research scientists explore new ways to improve our quality of life using biotechnology applications.

In health care, researchers are capitalizing on genetic information to develop promising new cures for cancer, including therapeutic vaccines, and—through personalized medicine—working to help the right patients get the right treatment at the right time. And promising new work on malaria, tuberculosis, and dengue fever could prove the key to developing vaccines for deadly diseases that have plagued the globe for centuries.

While great progress has already been made to improve our food supply and reduce the environmental footprint of our farms, further positive impacts are not far off. Through new biotechnological innovations, scientists are in the process of developing salt-tolerant and drought-resistant crops and opportunities for leveraging currently non-productive land. New applications will also improve the nutritional value of our food, the health of our forests and the sustainability of livestock production.

Biotechnology is also paving the way for a 21st century industrial revolution that moves our economy away from a petrochemical-based economy to a more green and cleantech focused, bioprocessing-based economy. This could lead to the emergency of a new "home grown" value chain, giving every state the opportunity to sustainably leverage local biological resources.

## Raising the Bar: Enhancing Our Competitiveness

The last 40 years have seen an explosion of innovation and creativity within the biotechnology industry. The life-changing applications we've come to rely on today were made possible by a highly skilled workforce with extensive training in science and math. Ensuring a steady supply of that same talent is critical to ensuring we fully

## THE BOTTOM LINE

Biotechnology has a long history of helping create a better, more sustainable way of life, and continues to provide tremendous value by leveraging cutting edge technology to address looming challenges and help create a brighter future.

- We've used biotechnology for thousands of years, and it continues to help improve the way we live—and to live more responsibly. The diversity of its applications is nearly endless.
- Biotechnology is all around us, helping solve problems and make useful products. We see it every day in our homes and workplaces—and everywhere in between.
- Biotechnology helps us answer the world's most pressing challenges: resource scarcity, climate change, clean water shortages, an aging population, and cancer, to name just a few.
- The biotech industry continues to be a powerful economic growth engine, providing high-quality jobs for researchers and scientists, and generating employment for millions of workers in other industries.

realize the untapped potential of biotechnology, and that the prospective biotech applications we envision today become tomorrow's reality.

Today, the biotechnology industry employs 1.3 million workers, and the industry continues to be a key growth engine for our economy. These high quality, talent-rich jobs enjoy a portability experienced by few other industries.

The boosts to our competitiveness don't stop with biotech's workforce. Biotech applications themselves yield many economic advantages—from reducing the cost of raw materials and operating costs to increasing rural economic development through higher incomes from higher crop yields using fewer inputs.

Our national workforce is stronger, too, from better availability of more nutritious food, longer life expectancies, and increased productivity due to reduced disability and mortality from diseases such as diabetes and rheumatoid arthritis.

By continuing to invest in biotech companies and in training a skilled workforce with high aptitudes for science and math, we can help ensure the biotech industry is fully equipped to carry on its investigations into helpful new biotech applications that address looming challenges while improving our quality of life far into the future.

# Heal

Biotech is helping to heal the world and make it a healthier place by developing new medicines that dramatically reduce rates of infectious disease and save millions of children's lives.  Biotech is improving the odds for millions of patients around the world with serious, life-threatening conditions, and is providing tailored treatments to individuals to minimize health risks and side effects. These medicines also create more precise tools for disease detection, while combating serious illnesses and everyday threats confronting the developing world.

To bring these new discoveries to patients, the biotech industry has harnessed nature's own toolbox and looked inside our bodies, to use our own genetic makeup to heal and guide lines of research.

In the process, the biotech health sector has helped spur economic growth by creating millions of jobs across the U.S., helped disabled workers rejoin the workforce and become productive members of society, and kept the U.S. competitive in a rapidly advancing, high-tech global economy.

# Biotechnology: Saving and Extending Lives

In every stage of life, biotechnology can help us live longer, healthier lives more fully than ever before by preventing and treating illness. In the United States and around the globe, countless breakthroughs in biotechnology, such as vaccines, medications, and diagnostic testing, have revolutionized health care and changed the way we think about and treat disease.

## Jump Start to a Healthy Life

Infants and children are among of the most vulnerable when it comes to disease susceptibility. Biotech vaccines help prevent and treat some of the most dangerous childhood conditions—increasing life expectancy, reducing costs of care and avoiding immeasurable suffering. In the U.S., the recommended immunization series prevents approximately **10.5 million cases** of infectious illness each year and **33,000 deaths**.[1] Worldwide, **2.5 million child deaths** are prevented each year by immunization.[2]

Rotavirus is one of the most devastating childhood diseases, especially in developing nations. Typically, it causes severe diarrhea and is often accompanied by vomiting and fever. The leading rotavirus vaccines, RotaTeq® (Merck) and Rotarix® (GlaxoSmithKline), have seen tremendous success in treating the disease and reducing related hospital visits.

DR. PAUL OFFIT, M.D.

### **Case Study 1.** Killing Old Foes

Since the development of the first vaccine by Edward Jenner in 1796, we have seen tremendous progress in our ability to prevent deadly childhood infections, effectively assuring health and wellness for our children and a foundation for a healthy adulthood. Jenner's discovery in 1796 marked the beginning of the end of many diseases that had caused suffering around the world for centuries, especially in children at their most helpless age. A century later, by the beginning of the 20th century, vaccines had been developed for rabies, diphtheria, typhoid fever, and plague; by the 1990s, deadly infections like smallpox and polio had been eradicated or nearly eradicated worldwide.

Today, vaccines have been developed for more than 20 infectious diseases, and many are given to our children at a young age. "Vaccines have virtually eliminated a number of childhood diseases and have prevented millions of deaths worldwide," says Dr. Paul Offit, M.D., co-inventor of a rotavirus vaccine. "With the development of vaccines, children are no longer threatened by deadly infection at their most vulnerable stage, and instead are given a foundation for health and wellness to last a lifetime." As a result of continuous development and innovation, today's vaccines not only protect our society's most important generation, our children, throughout early life, but give them increased longevity and quality of life for years to come.

**Case Study 2.** Protecting 1 Million Newborns

By age two, almost all children are infected by respiratory syncytial virus (RSV). For most, RSV results in a simple cold. But for some more vulnerable infants—such as those born prematurely and those with heart and lung problems—it can quickly progress from a low-grade fever, coughing, and difficulty breathing to life-threatening conditions, including bronchiolitis and pneumonia.

For Ariel Doggett, this became all too real in 2004. "My son Will was born four weeks early, at 36 weeks gestational age. When he was one month old, I noticed Will was breathing abnormally and his lips were turning blue. I took him to my local emergency room, and after observation they took him via Medivac to Children's Hospital Boston, where he required a ventilator," recalls Ariel. "Over the next few weeks, Will's condition continued to deteriorate, so doctors placed him on ECMO, a machine that functions as both the heart and lungs when they won't operate on their own. While on ECMO, Will suffered a stroke in his occipital lobe, causing him to lose all his right-sided vision and suffer permanent weakness throughout the right side of his body.

"It was almost three months before he was finally discharged," Ariel continues. "And, Will still holds the record for the longest stay and sickest infant due to RSV-related illness at Children's Hospital Boston."

Synagis® (MedImmune), protects high-risk infants from RSV—helping to reduce hospitalizations that cause an emotional and financial burden on patients and their parents. It works by giving high-risk newborns passive immunity; their immune systems are too immature to produce antibodies on their own, so Synagis steps in. Since FDA licensed Synagis, over 1 million infants have received protection from serious RSV.


WILL DOGGETT

- RSV accounts for up to **1.7 million** physician office visits, **400,000** emergency-room visits, **125,000** infant hospitalizations, and about **500** infant deaths every year in the United States.[3]
- Synagis has a **78% to 80% efficacy** in preventing RSV hospitalization in premature infants without chronic lung disease and has been shown to reduce recurrent wheezing in infants.[4]
- The estimated direct medical cost of RSV-associated hospital care is **$750 million** annually.[5]

"My doctor told me about RSV when Will was first born, but didn't recommend Synagis," notes Ariel. "It is possible that if Will had initially received Synagis following birth, he may never have contracted RSV. It is conceivable that all of his medical conditions could have been avoided. Instead, my son will live with the consequences for the rest of his life."

RSV infection does not cause long-lasting immunity, so re-infection is common and children may be infected up to three or four successive RSV seasons.[6]

"Per his doctor's recommendations, Will received Synagis every month during his second and third RSV seasons," says Ariel. "Luckily, he has not contracted the virus again."

- In Latin America, Rotarix vaccination decreased hospitalizations for diarrhea among children under one year of age by **42%,** and in the United States and Finland, by **63%** during the first year of life.[7]
- In 2009, deaths due to rotavirus in Mexico dropped by more than **65%**.[8]
- In the United States, RotaTeq reduced the number of lost workdays from rotavirus by nearly **87%**.[9]

The vaccines are so successful, it is estimated that their widespread use has the potential to prevent about **2 million deaths** over the next decade.[10] In the United States alone, rotavirus vaccination has the potential to prevent annually:

- **344,000** physician office visits;
- **188,000** emergency department visits; and
- as many as **67,000** rotavirus-related hospitalizations.[11]

Similarly, the introduction of a vaccine for pneumococcal meningitis in 2000 led to a significant reduction in infection rates, particularly among society's most vulnerable populations: incidence declined by **64%** among children 2 and under and by **54%** among those 65 and older.[12] An early cost-effectiveness analysis of the vaccine Prevnar® (Pfizer) projected that an infant vaccination program would save **$342 million** in medical expenses and **$415 million** for work-loss and other costs, before accounting for vaccine costs, by preventing:

- more than **12,000 cases** of meningitis;
- **53,000 cases** of pneumonia;
- **1 million episodes** of middle ear infections; and
- **116 deaths** from pneumococcal infection.[13]

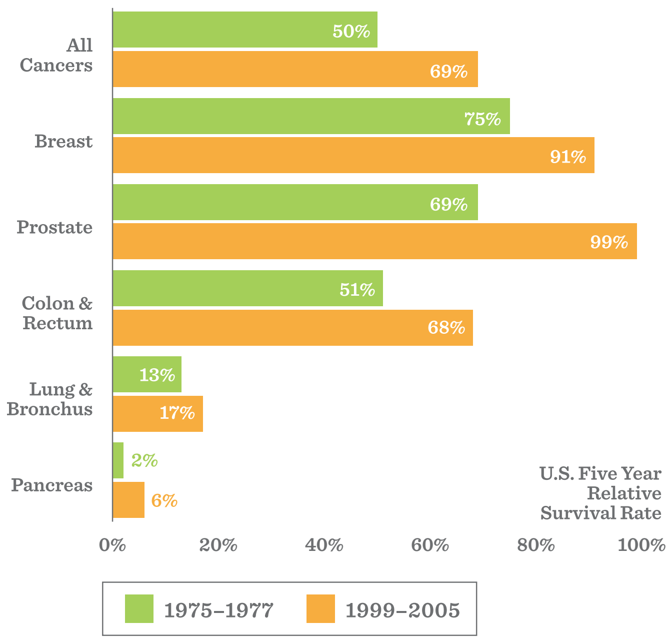
Prevnar13® (Pfizer), a new vaccine that protects against six additional strains of pneumococcal meningitis, was approved by the FDA in December 2009.[14]

## Changing the Odds

Some advances in biotechnology have changed more than disease prevention and treatment. The outlook for cancer diagnoses, for example, has changed drastically: no longer a death sentence, cancer survival rates have increased significantly for a number of types of cancer (see Figure 1) and treatments are more effective than ever.[15]

Innovative treatments are also changing the outlook for multiple sclerosis (MS), an autoimmune disease that affects the brain and spinal cord. Because of nerve damage, patients can suffer severe symptoms in all parts of the body, including muscle loss, loss of bladder and bowel control, and vision loss. In addition to causing

**Figure 1.** Surviving Cancer[16]




emotional and physical suffering for the 250,000 to 300,000 patients in the U.S., MS also exerts a significant toll on our economic competitiveness:

- Employees with MS need an average of **25.3 more disability days** per year.[17]
- Total annual indirect costs for employees with MS are **$4,352** more on average.[18]

While a cure remains elusive, treatments like Tysabri® (Biogen Idec/Elan) and Betaseron® (Bayer) are helping MS patients fight disease progression and stay healthier longer; new treatments like Ampyra® (Acorda) help improve walking ability by **25%** and treatment convenience.[19]

Other biotech innovations are changing how we think about disease by moving us away from treatment and toward prevention. For example, **70%** of cervical cancer stems from two strains of the human papillomavirus.[20] The cancer vaccines Gardasil® (Merck) and Cervarix® (GlaxoSmithKline) provide protection against these viruses. The U.S. currently spends an estimated **$2 billion** each year treating cervical cancer;[21] a widespread vaccination campaign could save the health care system as much as **$1.4 billion** annually—in addition to thousands of lives.

RICE UNIVERSITY UNDERGRADUATE ELIZABETH NESBIT HOPS ON A BIKE TAXI TO MAKE THE 6 KILOMETER TRIP FROM NAMITONDO TO NAMITETE TO DEMONSTRATE THE DIAGNOSTIC LAB-IN-A-BACKPACK TO HEALTH CARE PROVIDERS AT ST. GABRIEL'S HOSPITAL IN MALAWI.

### **Case Study 3.** Lab-in-a-Backpack[22]

Bioengineering design students at Rice University have partnered with Baylor International Pediatric AIDS Initiative (BIPAI) and Baylor Shoulder to Shoulder physicians to develop a portable Diagnostic Lab-in-a-Backpack, which includes a power source and tools specific to the needs of the developing countries where it's used, most often Central America and Sub-Saharan Africa.

"These students are brilliant and are making a difference in the world," said Ruth Bush, a physician who has used the backpack on her medical service trips to Mayette, Haiti, since 2008.

For physicians treating patients in rural, hard-to-reach, or even war-torn communities in developing countries, timing means everything. Follow-up visits can become impossible, and innovative and creatively engineered tools become essential to make an accurate diagnosis.

"I'm better able to treat my patients, who often walk for six to nine hours for medical treatment, because of the backpack," said Bush. "Having the capability to test for illnesses, such as diabetes, and urinary tract infections and being able to check blood levels is essential to correctly diagnosing patients. Before the backpack I often had to guess, risking the patients' health."

## Faster Detection, Better Accuracy, Greater Mobility

Biotech diagnostic tools have enhanced our ability to detect and diagnose conditions faster and with greater accuracy—helping improve patient prognosis.

There are more than **1,200** biotechnology diagnostic tests in clinical use today.[23] These types of diagnostics range from faster and more accurate strep throat tests to tests that pinpoint specific cancer cells in order to select treatment options. Many of these tests require only a simple blood sample or mouth swab—eliminating the need for costly invasive surgery.

Many biotech diagnostic tools are now portable, allowing physicians to conduct tests, interpret results and determine treatment on-the-spot. These tools have had a profound effect on access to health care in developing countries, many of which lack a health care delivery infrastructure.

## Personalized Medicine: Cures Designed Just for You

Today, biotechnology is helping personalize medicine by tailoring treatments to the individual patient and the specific circumstances necessitating treatment. This is known as personalized medicine: leveraging information about individual genetic make-up to guide health care decisions, rather than treating every individual like the anonymous statistical average.

The use of genetic information can help determine:

- which treatment will likely work best;

> We are on the leading edge of a true revolution in medicine, one that promises to transform the traditional "one size fits all" approach into a much more powerful strategy that considers each individual as unique and as having special characteristics that should guide an approach to staying healthy.
>
> *— Francis S. Collins, **Director, U.S. National Institutes of Health**[24]*

- the safest and most effective dosage; and
- whether a person is predisposed to develop a specific disease later in life.

Biotech diagnostic tools have helped drive the personalization of medicine in our health care system. Genetic tests identify patients predisposed to developing various cancers, osteoporosis, emphysema, type II diabetes, and asthma. This gives patients an opportunity to take preventive steps by avoiding disease triggers such as poor diet, smoking, and other behavioral factors.

Other biotech diagnostic tests look for specific genetic markers that determine whether a patient is likely to benefit from a certain treatment. For example, new tests have been launched recently that identify patients likely to respond to the following cancer treatments:

- Iressa® (Astra Zeneca, for non-small cell lung cancer);
- Tarceva® (Genentech, non-small cell lung and pancreatic cancers);

### **Case Study 4.** Tailoring Breast Cancer Treatment

Some of the most exciting new biotech diagnostic tests help improve breast cancer treatment and care. One of these diagnostic tests determines whether a breast cancer patient has an aggressive form of breast cancer associated with the human epithelial growth factor receptor-2 (HER-2). This form of breast cancer strikes quickly, spreads aggressively, and is often deadly. However, patients treated with Herceptin® (Genentech) experience extremely positive outcomes: two recent clinical trials found that chemotherapy plus Herceptin **cut the chance of cancer recurrence in half** compared to chemotherapy alone.[25]

Judy Kayse, a breast cancer survivor and patient, knows firsthand the power of the latest breast cancer treatments and diagnostic tests. "I was first diagnosed with breast cancer 15 years ago. At the time there was no testing for HER-2 or a treatment for people with that type of breast cancer, so I was treated with a lumpectomy and radiation and went into remission," recounts Judy. "But at my annual exam in late 2009, we found a tumor. The cancer was back, and it was invasive. But this time my doctors had a new weapon in their arsenal: they were able to test for the HER-2 factor. They determined I was HER-2 positive, meaning I was eligible for Herceptin. It's now part of my treatment program, and doesn't come with the debilitating side effects of other breast cancer treatments. My doctor told me if Herceptin had been available the first time around, I probably would not have had a recurrence."

Herceptin is a tailored treatment that works by blocking the HER-2 receptor, stopping the cancer tumor from growing and eventually killing the cancer cells. Only patients with HER-2 positive breast cancer are eligible for Herceptin—making the HER-2 diagnostic test critical to determining the appropriate breast cancer treatment.

- Gleevec® (Novartis, chronic myeloid leukemia and gastrointestinal stromal tumor); and
- Campath® (Genzyme, B-cell chronic lymphocytic leukemia).

A recent study showed that hospitalization rates **dropped 30%** when genetic information was used to determine the best dosing for heart patients taking warfarin (the world's most prescribed blood thinner).[26]

One diagnostic test shows whether patients are developing resistance to Gleevec®, while yet another enables selection of the correct dosage of a powerful chemotherapy drug for pediatric leukemia. These tests have saved lives by preventing overdose fatalities.

Research has also shown that a woman's risk of developing breast and/or ovarian cancer is greatly increased if she inherits a specific harmful genetic mutation. A simple blood test can now determine if a man or woman has inherited these genes. Many research studies are being conducted to find newer and better ways of detecting, treating, and preventing cancer in individuals who carry the gene mutation.[27]

In December 2004, the FDA approved AmpliChip CYP450 Genotyping Test (Roche/Affymetrix), a blood test that allows physicians to consider unique genetic information from patients in selecting both the choice and dose of medications for a wide variety of common conditions such as cardiac disease and cancer. The test analyzes the enzyme cytochrome P4502D6, which plays an important role in the body's ability to metabolize commonly prescribed antidepressants, antipsychotics, beta-blockers, and some chemotherapy drugs, among others.

New, personalized applications of biotech tools and therapies continue to emerge as new discoveries about human genetics unfold. As our understanding of the human genome improves, so too will our ability to develop targeted treatments. For example, oncology may soon enter an era when cancer treatment will be determined as much or more by genetic signature than by location in the body.[28]

# How Bean Curds and Snails Improve Your Health

Biotechnology and health have been closely intertwined throughout history, with some of the most exciting advances arriving in the last 40 years. In health care alone, the diversity of applications is virtually endless—with nature and the human genome itself often providing the inspiration for what's next.

Biotech medicines diagnose, treat, and even prevent a host of illnesses—from some of the most deadly and disabling chronic diseases, including cancer, diabetes and cardiovascular disease, to the rarest disorders that afflict only a few thousand people worldwide—and new products tackling unmet medical needs are being investigated every day.

## A Long History of Curing Deadly Disease

Modern biotechnology may find its origins thousands of years ago, but today's biotech solutions are a far cry from those ancient remedies.

Anchored in the science of discovery and development, biotechnology-based therapies have helped to improve quality of life while reducing death and disease rates and, in some cases, eradicating disease altogether. Vaccines, for example, have played a critical role in drastically reducing the imprint of some of the deadliest and most debilitating infectious diseases in human history (Figure 3).

**Figure 2.** Ancient Biotechnology-Based Remedies

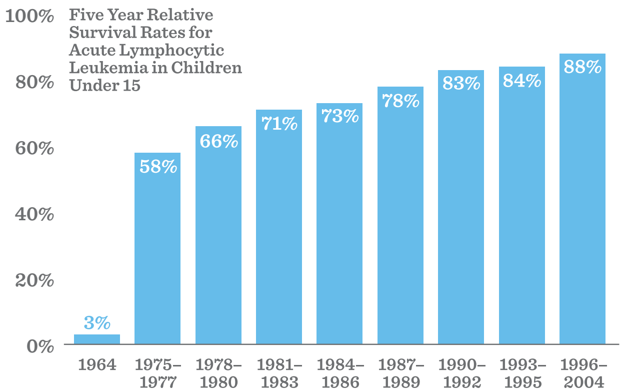
In 500 B.C., the first antibiotic—moldy soybean curds, similar to tofu—was used to treat boils in China.[29] The ancient Egyptians applied yeast to leg ulcers and swellings, and took yeast internally for digestive disorders.[30]

# Heal

**Figure 3.** Injections of Hope[31]

| | AVG. ANNUAL U.S. CASES, BEFORE VACCINE | PEAK ANNUAL U.S. DEATHS, BEFORE VACCINE | DECLINE IN U.S. CASES | DECLINE IN U.S. DEATHS |
|---|---|---|---|---|
| Diphtheria | 21,053 | 3,065 | 100% | 100% |
| Measles | 530,217 | 552 | 99% | 100% |
| Mumps | 162,344 | 50 | 96% | 100% |
| Polio | 16,316 | 5,865 | 100% | 100% |
| Rubella | 47,745 | 2,184 | 99% | 100% |
| Tetanus | 580 | 511 | 93% | 99% |
| Whooping cough | 200,752 | 7,518 | 92% | 99% |
| Chickenpox | 4,085,120 | 138 | 85% | 82% |
| Hepatitis A | 117,333 | 298 | 87% | 87% |
| Acute hepatitis B | 66,232 | 267 | 80% | 80% |
| Invasive pneumococcal disease | 63,067 | 7,300 | 34% | 25% |

**Figure 4.** The Life-Saving Impact of Biotech Therapies[32,33]




## How It Works: Biotechnology Drug Discovery and Development

To understand how biotech products are made, picture biotechnology as a scientific method that uses nature's toolbox to create life-saving therapies. The "tools" are thousands of living cells and their component molecules, and biotech scientists must explore different ways to use them to create the medicines we use today.

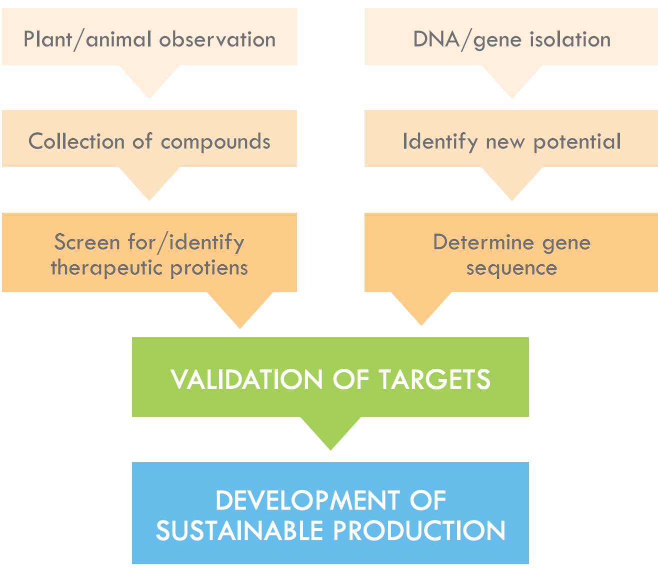
There are three basic ways that biotech scientists develop therapies:

- working with cells, the smallest unit of life;
- working with proteins, one type of molecule found in cells; and
- working with genes, the molecules responsible for inherited traits.

The diversity of applications is virtually endless. Often, biotech scientists find inspiration in two main sources: they look inside the human body, to our DNA, and outside, to the plants and animals around us.

**Figure 5.** The Steps of Biotech Research and Discovery

The biotechnology research and development process is constantly evolving as technology advances. The process below is illustrative; certain steps may occur simultaneously or at different points depending on the specific application under development.




## Cracking the Code: Deciphering Your DNA

Healthy or not, our cells are guided by DNA instructions that tell them what to do. But how do we transition our knowledge of DNA behavior to therapeutic discovery and production? It all begins with understanding how our genetic code works. Recent developments, such as the completion of the human genome sequence, have rapidly increased our understanding of human genetics.

Through genetic research like the Human Genome Project—a thirteen year public-private collaboration that paved the way for leveraging genetic information in preventing, diagnosing, and treating disease—we have learned how to change the code in DNA molecules, meaning that we can give cells new instructions. Biotech scientists are using this knowledge to help correct defective genes that cause a disease. In time, it may be possible to use gene therapy to cure hereditary conditions.

Gene therapy focuses on finding ways to introduce corrective genes into cells in order to:

- correct a cell malfunction;
- add a new function to a cell; or,
- in the case of cancer, add a gene to a cancer cell that causes that cell to die.

A variety of different types of gene delivery systems are used to deliver genes into target cells, including:

- modified viruses, which appear to be very efficient at getting genetic information into cells;
- "naked" DNA containing the corrected genes; or
- artificial lipids carrying new DNA.

The goal is to match the appropriate delivery system with the gene, the target cell, and the disease, in order to develop effective therapeutics.

The wealth of information made available through the Human Genome Project and subsequent genetic research has enabled more targeted research, even for traditional small molecule drugs. This not only saves valuable time and resources, but vastly improves the likelihood of success.

# Heal

## From Mother Nature to You

Next time you're outside, take a look around you. Chances are that some of the living organisms you observe—plants and animals alike—possess compounds or qualities with health care applications. Biotechnology helps us tap into these qualities to create nature-inspired therapies.

The years-long process is time and resource intensive, requiring:[34]

- collecting a diverse array of organisms from land and marine habitats all over the world, in accordance with local, national, and international laws and regulations;

- bringing them back to labs for analysis of the potential biological and pharmaceutical activity of their natural products;
- isolating promising compounds;
- testing them ("proof of concept");
- finding a clinically meaningful application;
- determining how to sustainably synthesize the compound in large quantities;
- testing the product in patients for safety and efficacy; and
- gaining regulatory approval.

However, the reward is worth the effort. Scientists have already had success developing some plant and animal-inspired therapies that have been approved and are in clinical use (see Figure 6), and many more hold promise:

- In the ocean, organisms contain compounds that could heal wounds, destroy tumors, prevent inflammation, relieve pain and kill microorganisms.

### **Case Study 5.** Giving Sight to the Blind

Born with a rare retinal disease called Leber's congenital amaurosis, Corey Haas had lost most of his sight by the time he was 7 and was legally blind. He often clung to his parents when going out, and depended on a teacher's aide, Braille, a large-type computer screen, and cane while at school. Corey expected to eventually lose his vision entirely.

But just two years later his prognosis has undergone a 180 degree turn. He now enjoys the same activities as any active, healthy 9 year old boy: go-karting, hiking, and playing baseball.

Corey's miraculous recovery was due to an experimental gene therapy procedure. In fall 2008, he received an injection in his left eye. The injection contained a virus specially engineered to replace DNA containing a defective version of the gene responsible for his debilitating condition, RPE65, with a normal version of that same gene.

In fact, Corey was one of 12 patients in a groundbreaking study on the potential applications of gene therapy for patients suffering from Leber's congenital amaurosis; all patients showed significant improvement in both subjective and objective measures of their vision.[35]

**Case Study 6.** Medicine from the Sea: Can a Snail Cure Pain?

No bigger than your thumb, the cone snail Conus magus has venom that packs a punch: it enables the cone snail to paralyze and swallow a whole fish its own size. "The cone snail caught the attention of researchers in the late 1970s, who began investigating its venom to help better understand how our nervous systems work. But it was several years before it became clear the venom held potential for pain relief, too," recounts George Miljanich, Ph.D., former Senior Director of Research at Elan. "We broke the venom into its components, called peptides. I collaborated with the team responsible for isolating the peptide, ziconotide, that had the potential to block pain signals, and led the original investigations into understanding its potential pain-mitigating properties. We set about finding a way to sustainably manufacture ziconotide, and then began the long process of clinical development and testing the synthetic peptide in patients. Even in the early days, it was extremely motivating and encouraging to see the impact of what would become Prialt® on patients."

Manufactured by Elan, Prialt® helps manage severe chronic pain in adults who have failed other therapies.

- On land, field trials with protein-producing plants are providing the essential building blocks that may one day yield treatments for cancer, HIV, heart disease, Alzheimer's disease, diabetes, and many other debilitating illnesses.

## After Discovery: Manufacturing Biotechnology-Based Therapies

Producing biotech drugs is a complicated and time-consuming process (see Figure 7). Many years can be spent just identifying the therapeutic protein, determining its gene sequence, and working out a process to make the molecules using biotechnology.

Once the method is devised and scaled up, the biotech medicines can be produced in large batches. This is done by growing host cells that have been transformed to contain the gene of interest in carefully controlled conditions in large stainless-steel tanks. The cells are kept alive and stimulated to produce the target proteins through precise environmental conditions.

After careful culture (the duration varies depending on the protein produced and the nature of the organism), the proteins are isolated from the cultures, stringently tested at every step of purification, and formulated into active products for clinical use. All of these procedures are in strict compliance with U.S. Food and Drug Administration (FDA) regulations and good manufacturing practices.

# Heal

**Figure 6.** From Nature to Medicine: Biotechnology Drug Therapies[36,37]

| CONDITION | COMPOUND | SOURCE ORGANISM | GEOGRAPHIC ORIGIN |
|---|---|---|---|
| Cancer | Aplidine | Tunicate | Mediterranean |
| | Bryostatin 1 | Bryozoan | Gulf of California |
| | Didemnin B | Tunicate | Caribbean |
| | Dolastatin 10 | Sea Hare | Indian Ocean |
| | Ecteinascidin-743 | Tunicate | Caribbean |
| | Halichondrin B | Sponge | Japan |
| | Kahalaide F | Gastropod | Hawaii |
| | Mycaperoxide B | Sponge | California |
| | Taxol | Bark of a Pacific yew tree | |
| HIV | Cyclodidemniserinol trisulfate | Tunicate | Palau |
| | Lammellarin a 20 sulfate | | Australia |
| Asthma | Contignasterol | Sponge | New Guinea |
| Pain | Conotoxins | Gastropod | Tropical Pacific |
| Diabetes | Byetta | Gila monster saliva | Southwestern U.S. |
| Chronic Pain | ziconotide | Cone snail | Philippine Islands |

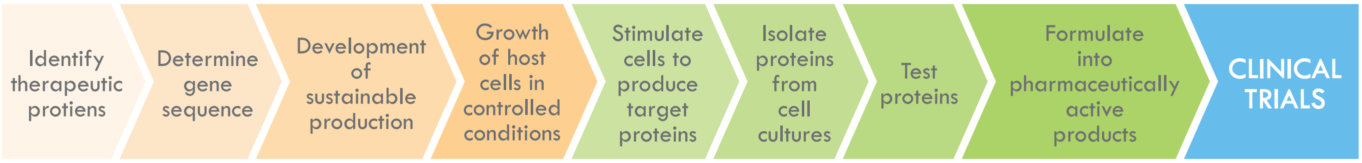

SPONGE


GILA MONSTER


CONE SNAIL

**Figure 7.** Biotech Manufacturing Process

This manufacturing process describes a typical recombinant biotechnology product, and may be different for other biotechnology based therapies.



# Malaria, Cancer, and Diabetes: New Hope Against Old Enemies

From infectious diseases and cancer to bioterrorism and chronic disease, our health—and health care systems—are at risk. New advances driven by the biotechnology health care sector are helping tackle current and looming challenges by confronting them head on. By preparing us today, biotechnology is helping ensure we have a better tomorrow.

## Global Diseases in the Crosshairs

Every day, researchers work to harness the power of biotechnology for the fight against global infectious diseases. Tremendous progress has already been made to treat and eliminate these diseases: globally, significant declines have been seen in the rates of certain infectious diseases, including a 78% decline in measles since 2000,[38] the complete global eradication of smallpox by 1980,[39] and the eradication of polio in the Americas by 1994.[40]

Despite this progress, infectious diseases are still the second leading cause of death worldwide each year,[41] and new strains of infectious diseases continue to emerge. Through close collaboration with governments and non-governmental organizations, there is hope that biotech companies may develop better treatments for neglected diseases such as Chagas, Dengue, African Sleeping Sickness, and Leishmaniasis.

**Figure 8.** Worldwide Burden of Selected Infectious Diseases[42]

| DISEASE | DESCRIPTION | GLOBAL INCIDENCE (2004) | GLOBAL DEATHS (2004) |
|---|---|---|---|
| Chagas | A parasitic, often chronic disease that can result in damage to the heart, brain, and digestive tract[43] | 100,000 | 47,000 |
| Dengue | A virus transmitted by mosquitoes that can result in a high fever and other serious complications[44] | 8.9 million | 18,000 |
| Diarrheal Diseases including Rotavirus | Infections that result from enteric parasites found in water and food[45] | 4.6 billion | 2.1 million |
| HIV/AIDS | HIV/AIDS is a serious viral disease that attacks the immune system[46] | 2.8 million | 2 million |
| Leishmaniasis | A parasitic disease that can result in skin sores or swelling of the organs[47] | 1.7 million | 48,000 |
| Malaria | A parasitic disease spread by mosquitoes that can causes a serious fever and flu-like illness[48] | 241 million | 900,000 |
| Tuberculosis | A serious bacterial disease that often affects the lungs and can be transmitted through the air[49] | 7.8 million | 1.5 million |

## Addressing Future Threats to World Health

Biotechnology plays an important role in helping proactively address serious threats to global health. This includes both visible threats, such as increasing rates of cancer, as well as unseen threats, such as pandemics and bioterrorism.

### *Cancer*

Cancer is the third leading cause of worldwide deaths each year, and cancer rates in the U.S. and elsewhere are only predicted to increase—potentially exacting a harsh toll on our health and economy:

- From 1975 to 2000, rates of cancer doubled, and rates are expected to double again by 2020 and to triple by 2030, with 2030 cancer rates resulting in **17 million deaths**.[59]
- Cancer costs are expected to take an increasingly large toll on the U.S. economy, with cancer cost estimates at **$147.6 billion** in 2020.[60]

Biotechnology is helping us better understand the molecular and genetic basis of cancer, fueling the development of new therapeutics and vaccines to treat some of the world's most common cancers:

- Gardasil® (Merck) and Cervarix® (GlaxoSmithKline) protect again human papillomavirus, the cause of 70% of cervical cancer.
- Therapeutic cancer vaccines under development by EMDSerano, Bavarian Nordic, Pfizer, and others leverage immunostimulant technology to help the body eradicate cancer cells on its own.

### **Case Study 7.** Combating Malaria

Malaria kills nearly 1 million people and puts half of the world's population at risk each year.[50] The disease has proven difficult to control and prevent, and strategies to combat malaria must involve multifaceted solutions in order to provide any hopes for success at controlling this deadly disease.[51]

**Prompt and Accurate Diagnosis:** The biotech industry has developed malaria tests that can detect the disease rapidly, allowing physicians to get quick and accurate disgnoses so that treatment, if needed, can begin as soon as possible.

**Cost-Effective Treatment:** Current effective treatment for malaria often involves the use of Artemisinin Combination Therapy (ACT). Artemisinin, a compound found in the Chinese wormwood plant,[52] is in short supply and hard to procure, therefore making it is a very expensive treatment for those populations most vulnerable to malaria.[53] Thanks to efforts from the biotechnology industry, however, this problem may soon be eliminated. Biotech scientists have discovered that artemisinin can be artificially synthesized in a fast and cost-efficient manner using yeast and ***E.coli*** cells.[54] The Artemisinin Project, a partnership between Amyris, sanofi-adventis, the University of California, Berkeley, One World Health, and the Bill and Melinda Gates Foundation, is currently working to develop this new biotechnology.[55]

**Preventative Measures:** Biotechnology scientists have been working in partnership with governments and organizations for years to develop a malaria vaccine, and are getting closer every day. Recently, Sanaria received a grant from the U.S. National Institutes of Health to begin Phase II trials of a malaria vaccine currently in development.[56] Additionally, scientists at GlaxoSmithKline are developing two different vaccines for the disease, one of which boosts the immune system to target malaria parasites in the blood stream and, in recent studies, has been shown to be highly successful at producing immunity to malaria in children.[57,58]

- Stimuvax® (Merck/Oncothyreon), a cancer vaccine in Phase III trials stimulates the immune system to attack cancer cells common to lung cancer, breast cancer, prostate cancer and colorectal cancer cells, all while leaving healthy cells unharmed.[61]

### *Bioterrorism*

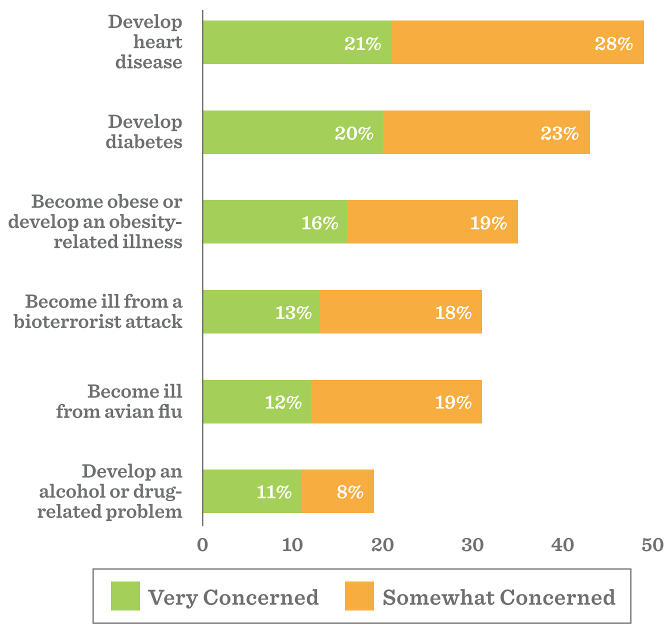
Security experts have repeatedly highlighted the reality and likelihood of bioterror threats, stating that a biological attack on the U.S. is more likely than a nuclear attack.[62] Public opinion data echoes this anxiety: after chronic diseases such as diabetes, heart disease and obesity, bioterrorism ranks as Americans' most urgent health concern.[63]

### **Case Study 8.** The Urgent Need for Biopreparedness

U.S. security experts view a bioterrorism attack as an increasingly likely possibility and a greater threat than even a nuclear attack. In their June 2009 report, former U.S. Senators Bob Graham and Jim Talent reiterated the urgency and reality of this threat: "[T]he lethality of a biological weapon could rival a nuclear bomb, but it is much less expensive to produce, the starting materials are accessible, and the diversity of technological expertise required is not nearly as great. For these and many more reasons, in our commission report, World at Risk, we stated that terrorists are more likely to obtain and use a biological weapon than a nuclear weapon."

Former U.S. deputy secretary of Health and Human Services Tevi Troy was responsible for overseeing U.S. bioterrorism and emergency preparedness: "U.S. biopreparedness is an increasingly important component of our national security. We need to continue to develop medical countermeasures to help minimize the impact of a bioterrorism attack. In addition, our military and first-responders—essential personnel like paramedics, police officers, and firemen—need to be appropriately equipped to face these challenges."

**Figure 9.** How concerned are you that each of the following will happen to you or an immediate family member during the next 12 months?[64]



ANGIE STONE

**Case Study 9.** Biotech: Helping Achieve Your Dreams

Angie Stone—the Grammy-nominated singer-songwriter and actress best known for her R&B, soul, and neo-soul music—is partnering with Eli Lilly and Company on the Fearless African-Americans Connected and Empowered (F.A.C.E.) Diabetes Initiative to share her story and be a part of a movement of African-Americans, just like her, who face diabetes on a daily basis.

"I'm just like a lot of people living with the disease—getting my diabetes under control wasn't so easy at first.

"Ten years ago, I was diagnosed with diabetes after I started experiencing a few common symptoms associated with high blood sugar like, frequent urination and unquenchable thirst. I couldn't stop going to the bathroom and no matter how much water I drank, I couldn't get enough. Despite having a family history of the disease, my diagnosis came as a shock because I didn't think I was a candidate for diabetes.

"Even after I was diagnosed and my doctor prescribed medication, I didn't truly take the disease as seriously as I should have. I was in denial about my condition and the importance of taking my medication, changing my diet and getting more exercise. Through trial and error and working with my health care team, I know now, it's important for me to take control and face my disease fearlessly so I can be healthy for myself, my family and my fans."

Biotechnology manufacturers are working with government agencies in the U.S. and around the globe to develop vaccines and therapeutics for potential bioweapons—including smallpox and anthrax.

### *Diabetes*

The number of Americans diagnosed with diabetes—the seventh leading cause of death in the U.S.—has risen by epidemic proportions, from less than 1% of the U.S. population in 1958 to 5.9% in 2007.[65] This is of serious concern, as diabetes can cause serious health complications like heart disease, blindness, kidney failure, and lower-extremity amputations. Annually, treatment of diabetes costs the U.S. **$174 billion**—of which **$58 billion** covers indirect costs like disability payments, time lost from work, and premature death.[66]

Lifestyle choices like diet and exercise and other environmental factors often serve as the trigger for chronic diseases like diabetes, but it's often our own genetic make-up that loads the gun and predisposes us to developing the disease.

Regardless of how diabetes manifests, biotech therapies and tools are helping fight its devastating impact. For example, insulin has a critical role in controlling glucose in many diabetes patients; each percentage point drop in the blood test measuring glucose levels can reduce the risk of microvascular complications (eye, kidney, and nerve disease) by **40%**.[67] Less quantifiable but as important are the quality of life improvements lent by these therapies and tools—such as how new insulin pumps and meters are enabling young athletes to continue competing in their chosen sport.

# 3.2 Million Jobs and Counting

The biotech health sector has a vital role in enhancing our competitiveness, serving as an engine of growth and helping foster a highly skilled workforce that excels in math and science. The need for a highly skilled workforce in the biotech health sector creates investments in education and rewarding, portable, high paying jobs:

- The biotech health sector depends on a unique and highly skilled workforce. Bioscience workers must possess exceptional skills, including knowledge of advanced sciences like molecular biology, and knowledge of how to operate and interpret data from advanced scientific instrumentation.[68]
- The need for this expert workforce means that the United States must continue to make investments in educational programs in science and math, as the biotech industry provides an important, steady supply of jobs, especially important in times of economic hardship, and represents one of the most important segments of our economy today, both in its current output and in its potential for growth.[69]
- The skill set needed for biotech jobs is incredibly transferable and portable, so biotech workers have job security without being confined to one geographic area, one company, or one specialty.

The biotech health sector provides an important impact to state employment rates and economic output, and significant investments in biotech research and jobs will only continue to increase these impacts to state and national economies.

- **1.3 million** people were employed by the biotech industry in 2006, and these jobs generated **6.2 million** related jobs throughout the rest of the economy, a job multiplier of **5.8**.[70]
- Investment by biotech firms in research and development is highly important not only to industry growth, but also to the creation of new medicines and technologies to improve our health. Biotechnology firms in the United States spent **$25.1 billion** on biotechnology research and development, accounting for **75%** of the total biotechnology R&D expenditures.[71]

**Figure 10.** Employment Supported by the U.S. Biopharmaceutical Sector, 1996–2006[72]

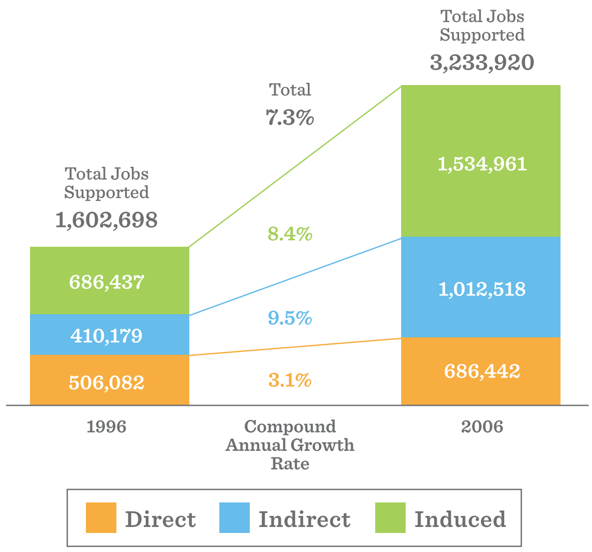
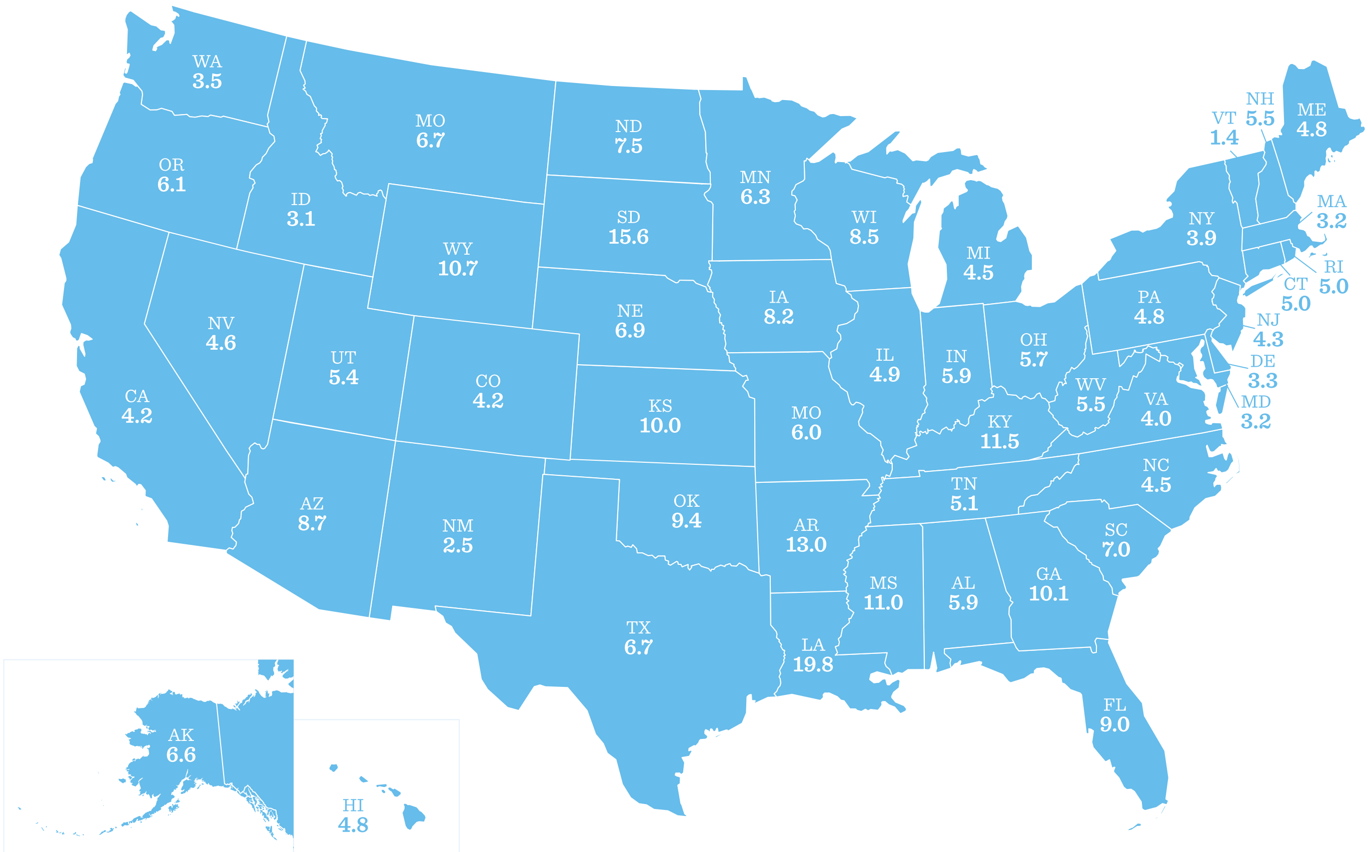


**Figure 11.** State Biopharmaceutical Sector Employment Multipliers (2006)[73]

Every new job in the biopharmaceutical sector also generates new jobs in other industries. This is called the employment multiplier. For example, an employment multiplier of 4.5 would mean that each new biopharmaceutical job would generate 3.5 new jobs in other industries. Below, we capture the biopharmaceutical employment multiplier for each individual state.



## Workforce Productivity

In addition to providing high paying jobs and broad economic impact, the biotechnology industry also has a distinct impact on our workforce productivity across the country through the therapies it produces. The economic impact of disabling chronic disease is considerable for employers and immense for those that are unable to work as a result of these diseases.

For example, rheumatoid arthritis (RA), a painful autoimmune disease, causes **66%** of employed rheumatoid arthritis patients to experience work absences.[74]

- The median work absence for RA patients is **39 days** per year.[75]
- Costs of rheumatoid arthritis consequences, such as lost productivity, total **$10.9 billion** annually.[76]

However, new biotech therapies such as Enbrel® (Amgen/Pfizer), Humira® (Abbott), Remicade® (Johnson & Johnson), and Simponi® (Johnson & Johnson) for debilitating rheumatoid and autoimmune diseases like RA and Crohn's disease can:

- Help employees remain active, productive, and healthy for a longer period of time;
- Decrease rates of absenteeism and presenteeism;
- Improve workforce efficiency and productivity;
- Enhance quality of life by making treatment more convenient; and
- Minimize painful treatment side effects.

DEBRA LAPPIN

### **Case Study 10.** Out of Bed and Back to Work

Autoimmune rheumatic diseases are among the most debilitating known to humankind. Left untreated, they rob individuals of quality of life and keep them from becoming a productive contributing member of society.

One such disease is ankylosing spondylitis (AS). This form of rheumatic disease primarily affects the spine and leads to inflammation that causes it to fuse, resulting in severe chronic pain and discomfort. Debra Lappin, a lawyer and president of the Council on American Medical Innovation, is an AS patient:

"I was practicing law when I was diagnosed with AS in 1978. We didn't know much about the disease at the time, and there weren't many therapies available. By 1984, I had an autoimmune response throughout my joints and eyes that became completely disabling. Ultimately, I was forced to take disability from my job as a partner at an international law firm. It was devastating. I was young, loved my job and enjoyed working—but it became clear that my immune system could not handle the challenge of work," Debra recalls. "For 15 years, I was out of the workforce. But during this time I became active in the arthritis community, advocating for research and better access to care. I had an excellent rheumatologist who became a true partner in my care. When Enbrel® [Amgen/Pfizer], the first biological treatment for rheumatoid arthritis, came to market in 1999 I was one of the first AS patients in line to test this drug. Within a few short months, my health was improving. My mobility and energy levels returned. Imagine the day when I knew I could return to work. Enbrel didn't just change my life—it saved it. You can't place a value on being able to return to work and productivity—for oneself, one's family, and society!"

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# Fuel

Producing exciting new biofuels, and fueling the economy with new and better products, industrial and environmental biotechnology is creating a brighter and more sustainable future. Today, industrial biotechnology is streamlining manufacturing, reducing the steps needed to make certain chemicals by up to 80%, and reducing the energy required in manufacturing processes by upwards of 50%. Using biological feedstocks, industrial biotechnology is reducing dependence on foreign oil and opening the way to a sustainable, home-grown biobased economy.

The biotechnology industry is using natural biological processes such as fermentation and harnessing enzymes, yeasts and microbes as high-productivity microscopic manufacturing plants. In doing so, industrial and environmental biotechnology is producing a wide range of everyday products—biodegradable plastics, "green" chemicals, energy-saving low temperature detergents, pollution-eating bacteria, multi-vitamins and renewable biofuels are just some of the myriad products produced and enhanced by biotechnology.

Whether applied to the needs of the developed or developing world, industrial and environmental biotechnology is generating sustainable and responsible economic development, using renewable and local natural resources to create a brighter economic and environmental future for all of humankind. Industrial biotechnology is helping manufacturers operate more efficiently, to save energy, reduce resource consumption, and bring new and improved products to the market—and, in doing so, biotechnology is keeping industry competitive and creating quality jobs. What makes industrial biotechnology unique is that its technologies enable critically important business and economic goals to be met within a model of resource and environmental sustainability. Industrial biotechnology is thus both a fundamental force for modern economic growth and a platform for sustainable U.S. and global development.

# What if we could...

## transform manufacturing with biobased resources and technologies?

## do so in an environmentally sustainable way?

## do all this while generating new high-paying, high-quality jobs?

# We can.

For over 8,000 years, humans have used enzymes, microbes and other biological building blocks to improve quality of life and increase economic prospects. But it was Louis Pasteur's invention of pasteurization in the mid 1800s that ushered in a new age of enlightenment as scientists discovered the role of microbial activity in fermentation.

Modern biotechnology is now expanding the application and engineering of microbes and enzymes into a broad variety of industrial processes, serving to construct products faster and in a resource- and environmentally-sustainable manner at reduced cost and using less energy.[1] Today, microbes, enzymes and their bioengineering form the basis of a suite of technologies and processes that together are termed "industrial biotechnology."

### Industrial Biotechnology: Flexible Tools for a Better World

The application of industrial biotechnology is benefitting a diverse range of industries, including:

- food processing;
- pharmaceuticals manufacturing;
- plastics;
- fuels and specialty chemicals manufacturing;
- textiles and paper;
- advanced materials and beyond.

Industrial biotechnologists are leveraging the complexity and refinement of the natural world, building upon biological structures and processes to create a new paradigm of efficient, sustainable and environmentally-benign industrial tools for both the developed and developing world.

Modern industrial biotechnology is grounded in biocatalysis and fermentation technology. Typically using a controlled environment (termed a "bioreactor"), original and genetically engineered microorganisms or cell lines are used to convert raw materials into commodity chemicals and higher-value processed chemicals, pharmaceuticals, biobased materials, bioplastics and biofuels.

The application of industrial biotechnology is driven by fundamental business models: the desire to add value, increase efficiency, reduce production costs and introduce new and improved products to the marketplace. Industrial biotechnology is made unique, however, by its ability to meet these business goals within a model of resource and environmental sustainability. In this way, industrial biotechnology is both a fundamental tool of modern economic growth and a central platform for sustainable global development.

## Touching Nearly 7 Billion Lives

The momentum for industrial biotechnology is driven by global needs. For both the developing and developed world, industrial biotechnology is a route to more equitable and evenly geographically distributed economies. By converting locally-produced biomass and biological resources into value-added manufactured products and energy, people from all parts of the globe have the opportunity to participate in this new economy—not just places rich in fossil resources, or those with the financial wherewithal to acquire scarce resources.

For the United States, industrial biotechnology represents a solution to key national imperatives:

- **Economic Development**: The U.S's position as a global bioscience leader is being leveraged for new business development, job creation and economic growth via new industrial biotechnologies and applications. Industrial biotechnology is improving the competitiveness of existing industry and providing a platform for new business development and growth.
- **Economic Security**: Industrial biotechnology has opened a pathway to a U.S. economy rooted in home-grown renewable biological resources, as opposed to a petroleum-based economy heavily dependent on foreign crude oil and other finite, non-sustainable fossil resource imports. High—and highly volatile—crude oil prices can have dramatic destabilizing influences on economies, whereas the use of home-grown renewable resources means reliable and predictable feedstocks to fuel the economy.
- **Environmental Sustainability**: Resource inputs and outputs for industrial biotechnology are generally biodegradable and non-polluting. The use of organic materials provides a route to green manufacturing and new tools and technologies that improve process efficiencies, reduce process energy consumption and limit the production of waste. Industrial biotechnology goes even further, providing technologies for environmental remediation—cleaning up the legacy of a previously non-sustainable industrial process.

# The Role of Industrial Biotechnology in Sustainable Development

Industrial biotechnology represents a key link in the chain of sustainable production, from the production of green inputs to market use and post-use recycling. As Figure 1 illustrates, industrial biotechnology provides multi-faceted solutions to the sustainability challenge of traditional industrial manufacturing, as well as a broad range of valuable products for consumers in the marketplace.

## GLOSSARY TERMS

**Industrial biotechnology** applies tools such as microbes and enzymes to traditional manufacturing and chemical processes to produce biobased products and materials from renewable feedstocks.

**Biocatalysis** is the use of natural catalysts, such as protein enzymes, to perform chemical transformations on organic compounds.

**Commodity chemicals** are chemicals such as ethanol that have low monetary value and are thus sold primarily in bulk.

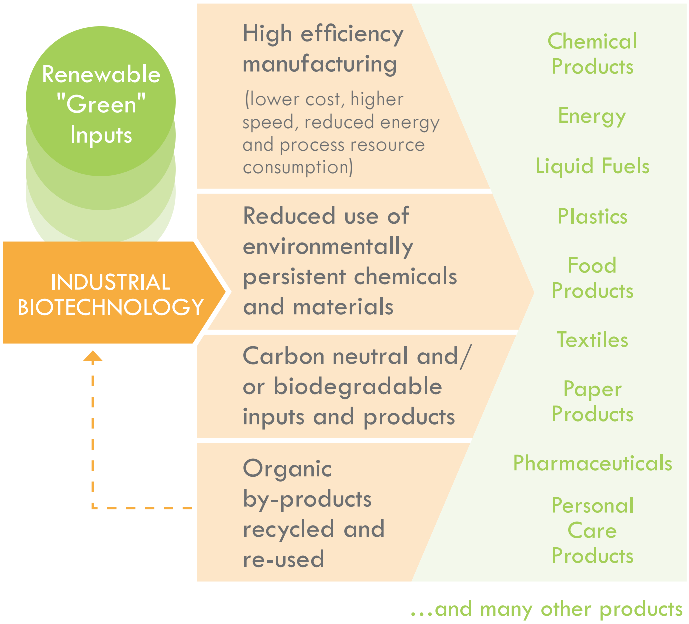
**Polymer** refers to a large class of natural and synthetic materials with a wide variety of properties.

**Biopolymers** are polymers that are produced from renewable biomass feedstock.

**Feedstock** is the raw material required for an industrial process.

Industrial biotech products have a significant market footprint today and are anticipated to constitute a **$228 billion to $547 billion** market by 2025.[2] Within this global industry, a broad variety of products and processes are making substantial current contributions to environmental preservation and sustainable development.

**Figure 1.** Industrial Biotechnology Solutions to Sustainable Production of Key Goods and Commodities



## Household Products Stabilizing Our Climate

Global energy consumption in 2010 stood at 508 quadrillion (quad) BTUs,[3] the equivalent of over 4 trillion gallons of gasoline or 492 trillion cubic feet of natural gas.[4] Clearly these numbers are staggering—as demonstrated by the number of zeros in Table 1.

With global energy consumption anticipated to rise to 637 quads by 2025, energy conservation must be seen as a key goal for the world, our nation and individual households. Every day, industrial biotechnology is providing solutions to energy conservation and climate stabilization, as the examples below illustrate.

## Detergents That Could Save Us $4.1 Billion Each Year

Small things can make a big difference. Laundry and dish washing, for example, are among the most energy intensive household activities—requiring the heating of large quantities of water and the consumption of electricity to drive the wash process. Reducing the temperature required to effectively clean soiled clothes or dishes can result in significant savings for the consumer, and biotechnology has made that a reality.

**Table 1.** Global Energy Consumption Equivalency by Energy Type

| FUEL TYPE | 1 QUADRILLION BTUS EQUIVALENT | 2010 GLOBAL CONSUMPTION OF 508 QUADS EQUIVALENT |
|---|---|---|
| Gasoline | 8,007,000,000 gallons | 4,067,556,000,000 gallons |
| Coal | 45,000,000 tons | 22,860,000,000 tons |
| Natural gas | 970,000,000,000 cubic feet | 492,760,000,000,000 cubic feet |

The difference in the cost of energy required to heat water to 140°F (60°C) for a traditional non-biotech detergent versus 86°F (30°C) for a biotech enzyme enriched detergent adds up quick. Novozymes, a leading biotechnology company in the development and production of industrial enzymes, notes that by washing at 86°F (30°C) rather than 140°F (60°C), the $CO_2$ savings potential in the U.S. and Europe alone is around **32 million tons** annually—equivalent to the **emissions of 8 million cars**.[5]

With products like these, we can achieve not only energy savings, but also savings for the consumer. The Rocky Mountain Institute calculates that on average a household spends $72 per year on electricity for washing laundry[6]—so reducing this by half through lower temperature, biotech-enhanced detergents would save the average household **$36 per year**. With 115 million households in the United States, this would equate to a total household energy savings of **$4.1 billion annually** in the U.S. alone.

## Nylon Production—Minus 80% of the Steps

Manufacturing is an energy-intensive business, but industrial biotechnologies have empowered leaner and greener approaches. The production of many of the chemicals and materials used to make everyday products typically requires numerous energy-intensive steps, often at high temperatures and high pressures. However, industrial biotechnology is enabling entire processing steps to be shortened—or omitted altogether—and undertaken at lower temperature and pressure levels (thereby conserving energy).

For example, producing dodecane dioic acid—a chemical ingredient required for producing nylon—requires four synthesis steps and four isolation steps in the traditional petro-chemical non-biotech process. The industrial biotechnology approach reduces this to just one synthesis and one isolation step—a reduction of 4:1 (or **80%**) in processing requirements to produce the same product. The resulting savings for this one chemical alone are estimated to be **75%** in terms of capital equipment and a **50%** cut in operating costs.[7]

## Lowering Greenhouse Gas Emissions

Biotechnology is unlocking pathways to a low carbon future, finding ways to produce our fuels, chemicals, materials and other products in ways that greatly reduce greenhouse gas emissions. World Wildlife Fund notes that industrial biotechnology today already reduces $CO_2$ emissions globally by a factor of 16.5:1, meaning for every one ton of $CO_2$ emitted by industrial biotech processes, on average 16.5 tons of $CO_2$ emissions are prevented from the non-green processes that biotech replaces.[8]

### **Case Study 1.** Brewing Technology Saves $CO_2$ Equivalent of 85,000 Car Emissions

Malting barley for use in brewing is an energy and water intensive process. The barley has to be soaked in water to allow it to germinate and then has to be heated for drying. Brewers and biotechnologists wondered if this entire step could be removed and a great tasting beer produced with un-malted barley. The answer is "yes"—made possible with the use of an enzyme. Consumer tests show the new beer to be comparable in taste to the original. By removing the malting process, the application of this biotech enzyme to brewing is estimated to save 350,000 tons of $CO_2$ for every 10% of global beer production that is converted to un-malted barley—a $CO_2$ savings equivalent to the emissions of 85,000 cars.

One of the best ways to reduce greenhouse gas emissions is to replace fossil fuels with biofuels. The burning of fossil fuels releases concentrated carbon into the environment—carbon that was safely locked away deep within the earth for millions of years. Biofuels, on the other hand, typically use plant materials that absorbed carbon dioxide from the atmosphere in order to grow. Burning a plant only releases the same absorbed carbon back into the atmosphere for recycling—a process called "carbon neutral."

At present, fossil fuel resources are used in the agricultural and production processes that make biofuels, so they are not truly carbon neutral—but even the first generation of biofuels improved with biotechnology processes, such as corn ethanol, are noted by the U. S. Department of Energy to produce between **19%** and **52%** less greenhouse gas emissions than gasoline.[9]

## Reducing the Use of Petrochemicals in Production Processes

Pick up the average product—a telephone or a TV remote for example—and you will be holding a product that required many chemicals to produce. As the American Chemistry Council points out:

> *Chemistry provides the raw materials for more than 70,000 products that help keep you safe, warm, cool, on time, in motion, and connected. From heart monitors to satellites to cell phones to microwave ovens to synthetic fibers, chemistry makes the things that make modern life possible.*[10]

While chemicals have a tremendously important economic and social impact, persistent, non-biodegradable chemicals present disposal and environmental challenges. Biotechnology is currently being applied in many ways to reduce the volume of chemicals, number of process steps, and variety of chemicals needed for everyday manufacturing processes.

### *Revolutionizing Chemical Consumption in the Pulp and Paper Industry*

Pulp and paper production in the U.S. is a $7.7 billion industry and uses more than 40 chemicals in its production processes.[11] Data shows that industrial biotechnology applied in the pulp and paper industry has resulted in a **90% reduction** in the use of chlorine and reduced the industry's energy consumption by **32%**.[12] Some examples of biotech companies providing valuable solutions for the pulp and paper industry include:

- **Novozymes.** Use of Novozymes enzymes has made it possible to reduce the amount of chlorine chemicals used by **10%** to **15%**, and reduced energy consumption during the bleaching process by **40%**.
- **Leykam.** Using fungus that releases enzymes to selectively degrade lignin as opposed to chemical treatment has resulted in **30%** to **40%** less energy input and results in savings in energy costs and chemical use.

Biofuels production is proving to be an economic driver for the developing world. In 2010, the U.S. EPA has designated Brazilian sugarcane ethanol as an advanced biofuel due to its 61% reduction of total life cycle greenhouse gas emissions.

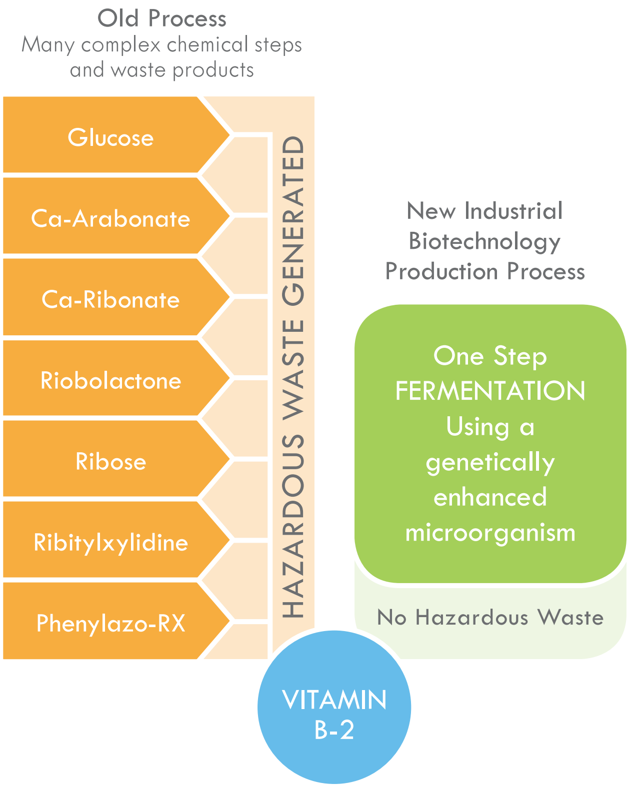
With energy demand projected to grow by 50% by 2025, with much of the demand increase coming from the developing world, a move to biobased, renewable, low-carbon or carbon neutral fuels, enabled by industrial biotechnology, is of central importance to the health of the planet.

### *Simplifying Vitamin B-2 Production*

Vitamin B-2, also known as riboflavin, plays a very important role in maintaining human and animal health. Vitamin B-2 is central to energy metabolism, and is required for the metabolism of fats, carbohydrates, and proteins.

Biotechnology has revolutionized and simplified the production of vitamin B-2 (Figure 3). The industrial biotechnology process, developed by Hoffman La-Roche,

**Figure 3.** From Seven Steps to One: Production of Vitamin B-2




DSM, and others for the production of vitamin B-2 took a laborious and costly traditional multi-chemical synthesis and purification process and reduced it to a one-step fermentation process whereby a fungi micro-organism directly transforms vegetable oil into the required vitamin. This highly efficient process now produces over 1,000 metric tons of vitamin B-2 annually. Evaluation of the benefits of the one-step process shows a reduction of $CO_2$ emissions of **30%** and a **95%** reduction in waste production.[13]

### *Fish Friendly: Eliminating Phosphate Chemicals in Detergents*

Sodium tripolyphosphate used to be a key ingredient in most detergents and a major contributor to phosphate water pollution and harmful algae blooms, both of which upset the balance of aquatic ecosystems. Biotechnology companies like Novozymes and Genencor developed enzymes to remove clothing stains more effectively than phosphates, replacing a polluting chemical with a non-polluting biobased additive while improving the performance of the end product.

**Case Study 2.** Streamlining the Production of Antibiotics

Biochemie, a subsidiary of Novartis, uses an enzyme-catalyzed manufacturing process for producing cephalosporin, a commonly prescribed antibiotic. This has resulted in significant reductions in chemicals usage.

Using genetic modification of microorganisms producing the process enzymes, the company has developed a manufacturing process that produces 100 times less waste solvent to be incinerated—reducing the environmental emissions and energy usage associated with waste incineration.

The European Commission's Joint Research Centre reports that biotechnologies applied to the production of 7-Aminodeacetoxycephalosporanic acid, a key intermediate for the synthesis of cephalosporin, have resulted in 37% less electricity use, $CO_2$ reductions of 75% and a 90% reduction in wastewater.[14]

## Finding Solutions for 14 Million Tons of Plastic Waste

One of the most exciting sustainability impacts of industrial biotechnology has come via the production of biodegradable plastics and associated materials.

The developed world generates substantial volumes of waste. In the U.S. alone, the Environmental Protection Agency (EPA) reports that **132 million tons** of municipal solid waste goes to landfills every year—the equivalent of half of all the automobiles in the U.S. being buried every year. Of these 132 million tons, **10.5% (14 million tons)** are estimated by the EPA to be plastics.[15]

Despite environmental controls and close regulation, a significant amount of plastic and other waste is not properly disposed of in landfills and instead makes its way into the environment. These misplaced petrochemical based plastics don't break down well—meaning their careless disposal remains an environmental problem for centuries. Industrial biotechnology, however, has brought highly effective alternative and biodegradable plastic materials to the market to replace traditional non-degradable petrochemical plastics.

### *PLA Plastics: From Sugar Beets to Biodegradable Plastic*

Polylactic acid (PLA) is a biopolymer that uses corn or sugar beet as a renewable process feedstock. Unlike traditional plastics, PLA is recyclable, biodegradable, and can be composted.[16]

NatureWorks (a Cargill company) is producing PLA products under the Ingeo™ brand label. The biopolymer is being used in fabrics, plastic films, food and beverage containers, textiles, coated papers and boards, and many other packaging applications. NatureWorks reports that Ingeo™ requires **68% less** fossil fuel to produce than traditional plastics while being completely biodegradable.

### *PHA Plastics: A Polymer Fighting Pollution*

Telles, a joint venture between ADM and Metabolix, Inc., is producing Mirel® bioplastics—a line of Polyhydroxyalkanoates (PHA) biopolymers. PHA production uses a biotech enabled fermentation process to convert sugar into plastics that have a wide range of uses. Biodegradable PHA can displace many petroleum-based plastics such as ABS, polycarbonate and styrenes. The ability of PHA to biodegrade in an ocean environment is a particularly important asset in tackling the growing global ocean pollution challenge.

Industrial Biotechnology can also help the environment and the economy by converting organic waste into valuable products. As noted previously the U.S. pours 132 million tons of waste into landfills annually, and **66.4%** of this is "organic waste":[17]

- 38.1% paper;
- 10.9% food waste;
- 12.1% yard trimmings; and
- 5.3% wood.

In addition to this municipal waste, many industries produce organic waste streams that now, using biotechnology, can be converted into valuable products and energy.

*Glycerin: From a Growing Problem to an Economic Opportunity*

Glycerin is a colorless, odorless, thick and sticky liquid that is widely used in soaps and cosmetics, food additives, industrial foams and transportation fluids. Despite glycerin's many uses, there is currently a large-scale oversupply of it. Biodiesel production, which generates glycerin as a byproduct, has further saturated the market.

Industrial biotechnology is helping solve the glycerin glut. Biotech divisions of companies such as Glycos Biotechnologies Inc., Dow, Huntsman, Davy Process technology (DPT), and Solvay have developed conversion technologies producing value-added chemicals from glycerin. Microbes have been developed that efficiently convert glycerin to valuable chemicals like ethanol, succinic acid, propanediols, and lactates. Glycos Biotechnologies, for example, uses non-pathogenic microorganisms to convert glycerin into ethanol.

## Environmental Remediation and Clean-Up

Industrial biotechnology can also be used for environmental remediation, that is, to clean up the environment after disasters and accidents such as oil spills. These include two primary biotechnology product groups:

1. "phytoremediation" which uses genetically optimized plants to absorb pollution and toxic substances from the ground and groundwater; and
2. "microbial bioremediation" which uses microorganisms to digest pollutants.

The first genetically engineered organism for bioremediation was a pseudomonas (a type of bacteria) capable of breaking down oil hydrocarbons. Since the development of the original pseudomonas bioremediation microbe, several other microbes have been developed through genetic engineering for treatment of oil spills. Biotechnology is also being used in the production of nutrient capsules used to speed the bacterial digestion process of pollutants.

# Creating renewable fuels needed for energy sustainability and security

Some renewable energy technologies—such as solar and wind power—have only one use: to produce electricity. In contrast, biological materials, or biomass, are renewable resources with many uses, including:

- fuels for generating electricity;
- liquid transportation fuels; and
- biobased chemicals and materials.

Biomass is the most globally available and most versatile renewable energy asset. It uses sunlight and $CO_2$ absorbed from the atmosphere to produce green energy.

Biotechnology is a vital tool in unlocking this "biological" energy for human use. Industrial biotechnology supplies enzymes that drive the process of converting plant starches and sugars into alcohols via fermentation. These enzymes are called "biocatalysts" and are critical to achieving high levels of process efficiency and productivity.

Biotechnology is also paving the way for new second-generation advanced biofuels. It now allows us to efficiently and cost-effectively convert non-food biomass (such as crop residues, switchgrass, and hybrid wood plants) into ethanol and valuable co-product chemicals, polymers, and materials. Industrial biotechnology is also making possible a variety of new "drop in" biofuel molecules (such as biobutanol and "green gasoline") that can be directly substituted for petroleum-based fuels. For example:

- **Enzymes** are used to break down starch into fermentable sugars. The sugars are then fermented by yeast to produce ethanol or other fuels and products. Biotechnology companies such as Verenium, Novozymes, Dyadic, Genencor, and Iogen, are active in the development and production of advanced enzymes for improved fuel production from a variety of non-food sources.

## UNLOCKING THE FUEL POTENTIAL OF CELLULOSIC MATERIALS

Cellulases are enzymes that break down cellulose. Biotechnology has enabled the identification of cellulases produced by microbes and fungi—and their production at industrial scales. Within North America cellulosic ethanol plants have been developed by companies such as Abengoa, Iogen, Lignol, Mascoma, POET, Verenium, and Western Biomass using enzymatic conversion processes. The industrial biotechnology investments being made by these and other companies are rapidly bringing cellulosic biofuels to a market reality with all its economic, energy security, and environmental benefits.

# Fuel

- **New strains of yeast**—engineered using biotechnology to tolerate high levels of alcohol—have improved the productivity and speed of ethanol fermentation processes.
- **Algae**—some of the world's most productive organisms—are also being developed as a source of biofuels and other bioproducts. Several algae demonstration projects are now under way.

Industrial biotechnology unlocks the many benefits of using home grown biomass for energy and biofuels, including:

- providing a pathway to energy independence and security;
- creating a more geographically distributed and equitable opportunity for fuels production across the United States and the developed and developing world; and
- helping protect the environment and combat global climate change.

While first-generation corn-to-ethanol plants reduce greenhouse gas emissions by **as much as 52%** over petroleum-based fuels, ethanol made from cellulosic feedstocks (e.g., switchgrass), agricultural residues (e.g., corn stover), or wood forest residues has the potential to reduce greenhouse gas emissions by **as much as 129%**, compared to gasoline.[18]

Beyond these benefits, cellulosic biofuels represent a game-changing technology. Never before has society been poised to so effectively harness what have traditionally been regarded as waste products. Potential sources of this "cellulosic biomass" (the inedible cellulose fibers that form the stems and branches of most plants) include:

ON NOVEMBER 3, 2009, POET HELD A PROJECT LIBERTY FIELD DEMONSTRATION OF BIOMASS HARVESTING EQUIPMENT, INCLUDING THIS COMBINE, WITH MORE THAN A DOZEN AGRICULTURAL EQUIPMENT MANUFACTURERS IN EMMETSBURG, IOWA.

### **Case Study 3.** Transforming Small Town Iowa

Biofuel production is one of the most promising new industries for promoting rural economic development. Traditionally, the production of fuel has necessitated tremendous capital investment and elaborate infrastructure, making it difficult for rural communities to enter the market. With the advent of biofuels and the need for ethanol producers to be located near biomass supplies, the landscape is changing.

Emmetsburg, a small Iowa town with a population under 4,000, is one such community being transformed by bioethanol. The Emmetsburg ethanol plant, operated by POET Ethanol, LLC, is a 60 million gallon per year facility with 40 full-time employees. As a result of plant expenditures for goods and services as well as wages paid to employees, the ethanol plant has contributed an additional $60 million per year to the local economy.

New businesses have been attracted to Emmetsburg since the POET plant opening, including chain stores, a casino/resort, and the town's first McDonald's franchise. According to Craig Brownlee, a third-generation corn farmer, "The town was dying a slow death. The farm community wasn't making any money and was living on crop subsidies. Now people are spending money like they haven't in a long time."[19]

In 2007, POET announced its plan to expand the Emmetsburg plant to become one of the nation's first commercial cellulosic biorefineries. Project Liberty, as the plan is known, calls for increasing the plant's capacity to 125 million gallons per year and is anticipated to be in operation by 2011. Although it will still produce corn based ethanol, 25% of the feedstock will be derived from corn cobs and fibers.

- crop residues (such as corn stalks, wheat straw and rice straw);
- wood waste;
- municipal solid waste; and
- dedicated energy crops (such as switchgrass, miscanthus or fast-growing hybrid trees like poplar and willow).

Despite the wide abundance of cellulose-containing natural resources (cellulose is estimated to make up half of all organic carbon on the planet), cellulosic biomass remains a highly undervalued and underused energy asset in the United States and around the world. A 2005 analysis by the Natural Resources Defense Council found that ethanol from cellulose could supply half of U.S. transportation fuel needs by 2050 without decreasing production of food and animal feed.[20]

# The Economic Growth Engine: From Trade Surpluses to High-Quality New Jobs

From saving energy to reducing water usage and waste generation, applied industrial biotechnology is doing right by the planet. But just as exciting—it is doing it while fostering economic growth and creating new jobs.

Research, innovation, creativity and the high technologies that result from these inventive activities are the most valuable assets in the U.S. economy. These high technologies—including industrial biotechnologies—have a long history of delivering for the U.S. economy: between 1990 and 2003 U.S. high-technology generated a **$243 billion trade surplus** in high-tech goods—compared to a $3.4 trillion deficit in all other U.S. goods combined. The development, commercialization and deployment of advanced technology drives economic growth and opportunity.

The 21st Century is being called "The BioCentury" by many. Providing solutions to identified needs is a fundamental force behind business and economic growth, and industrial biotechnology is all about providing solutions to needs—whether those needs are global (like fighting climate change), national (such as economic development), or personal (having the products that make life easier and more enriching). Ultimately, biotechnology is about efficiently bringing useful products to market.

A well known multinational's corporate slogan captures the essence of industrial biotechnology best: "We don't make a lot of the products you buy. We make a lot of the products you buy better.®" Biotechnology is being applied to the needs of industry to:

- make industry more efficient;
- help introduce new and improved products; and
- generate business growth.

Biotechnology is at the cutting-edge of American scientific and technical innovation, producing a host of new and exciting products and technologies that keep American business competitive. The net societal impact of this is economic development: real productivity and economic gains that foster job and wealth creation. Biotechnology gives industry better ways of doing things—and generating better ways of doing things forms the platform of a successful and growing economy. Whether at home, in the workplace, or on the go, the full range of industrial biotechnology products and applications for consumers is virtually limitless (see Figure 4 and Table 2).

**Figure 4.** Industrial Biology at Home

Industrial and environmental biotechnology is clearly a powerful innovation engine for the U.S. economy, a fact illustrated by the broad range of examples of some current applications of biotechnology to making manufactured products for consumers across the nation.

# Fuel

**Table 2.** Taking Industrial Biotech Home

| CONSUMER PRODUCT | OLD NON-BIOTECH MANUFACTURING PROCESS | NEW INDUSTRIAL BIOTECH PROCESS | ENVIRONMENTAL SUSTAINABILITY BENEFITS | CONSUMER BENEFIT |
|---|---|---|---|---|
| Bread | Potassium bromate, a suspected cancer-causing agent at certain levels, added as a preservative and a dough strengthening agent | Genetically enhanced microorganisms produces baking enzymes to<br>• Enhance rising<br>• Strengthen dough<br>• Prolong freshness | Reduces $CO_2$ emissions in grain production, milling and baking and transportation | • High-quality bread<br>• Longer shelf life<br>• Eliminates suspected carcinogen potassium bromate |
| Personal Care | Chemical ingredients such as propylene glycol and butylenes glycol from petroleum used as solvents to mix ingredients | Genetically enhanced microbe produces 1,3 propanediol from renewable feedstocks, which can function as a solvent, humectant, emollient or hand-feel modifier | 20% reduction of greenhouse gas emissions compared to petroleum PDO | • High purity<br>• Environmentally sustainable and renewable process<br>• Non-irritating for sensitive skin<br>• Enhanced clarity |
| Cosmetics | Mineral oil and petroleum jelly from fossil sources used as ingredients | Metathesis chemistry applied to convert renewable vegetable oils to replacement ingredients | • Reduction of process temperatures<br>• Low toxicity products and byproducts | • Smoother, less greasy feel<br>• Semi-occlusive film former<br>• Enhanced hair-care properties |
| Detergent | Phosphates added as a brightening and cleaning agent | Microbes or fungi genetically enhanced to produce biotech enzymes, which are added as brightening and cleaning agents<br>• Protease enzymes remove protein stains<br>• Lipases remove grease<br>• Amylases remove starch | Elimination of water pollution due to phosphates | • Brighter, cleaner clothes with lower wash temperature<br>• Energy savings |
| Textiles | New cotton textiles prepared with chlorine or chemical peroxide bleach | Use of biotech cellulose enzymes to produce peroxides<br>• allows low-temperature bleaching of textiles, at 65°C, and<br>• at a neutral pH range | • 25% reduction in greenhouse gases<br>• 25% reduction in non-renewable energy use | New fabrics have<br>• lower impact on the environment<br>• better dyeing results<br>• a permanent soft and bulky handle |
| Paper | Wood chips are boiled in a harsh chemical solution to yield pulp for paper making | Wood bleaching enzymes produced by genetically enhanced microbes to selectively degrade lignin and to break down wood cell walls during pulping | Reduces use of chlorine bleach and dioxins in the environment | Cost savings from lower energy and chemical use |
| Diapers | Woven fabric coverings made from petroleum-based polyesters | Bacillus microbe ferments corn sugar to lactic acid, which is heated to create a biodegradable polymer for woven fabrics | 50 to 70 % reduction in $CO_2$ emissions | • Biodegradable.<br>• End of life options include composting, rather than landfills |

| | | | | |
|---|---|---|---|---|
| Carpet | Nylon fibers made from petroleum in a chemical reaction | Genetically enhanced microbe produces 1,3 propanediol, which is a building block for other polymers such as Nylon | 20% reduction of greenhouse gas emissions compared to petroleum PDO | Fibers have<br>• durability, elasticity and softness<br>• permanent stain and ultraviolet ray resistance |
| Furniture | Polyurethane foam produced from petroleum | Polyols (such as Cargill's BiOH or Dow's Renuva) derived from soy and other renewable feedstocks are chemically mixed with other ingredients to create a flexible foam | • 60% reduction of non-renewable energy<br>• 23% reduction in total energy demand | Comparable quality and properties to polyurethane foam |
| Synthetic Rubber | Isoprene used in synthetic rubber produced from petroleum | Genetically enhanced microorganisms ferment BioIsoprene™ from sugars derived from renewable resources. BioIsoprene™ polymerized to synthetic rubber and other elastomers | Reduced use of petroleum | • High purity and low cost<br>• Predictable raw material cost and availability |
| Biofuels | Petroleum is cracked and distilled into gasoline and byproducts, some of which are flared into atmosphere | Novel enzymes convert starches and cellulose in biomass into sugars. Genetically enhanced microbes convert sugars to a growing range of alcohols and esters | • 16% to 128% fewer greenhouse gas emissions<br>• Cleaner burning: 30% fewer tailpipe emissions of nitrogen oxides and carbon monoxide | • Reduced volatility in raw material cost and availability<br>• The ethanol industry created 240,000 domestic jobs in 2008 |
| Plastic Films | Polyethylene made from natural gas liquids | Chemical building blocks fermented from sugar. Heat processing and mixing converts ethanol to a polyethylene | • 80% reduced use of fossil energy<br>• Plastics can be fully biodegradable or recyclable | Comparable quality and properties to petroleum-based polyethylene |
| Food Serviceware | Polystyrene products based on petroleum | Bacillus microbe ferments corn sugar to lactic acid, which is heated to create a biodegradable polymer (such as NatureWorks' Ingeo) | • 62% reduction in GHG emissions<br>• 51 % reduction in non-renewable energy usage | Compostable serviceware eliminates contamination of food waste with petro-based plastics |
| Beverage Packaging | Polyester, a synthetic polymer fiber, produced chemically from petroleum feedstock | Bacillus microbe ferments corn sugar to lactic acid, which is heated to create a biodegradable polymer (such as NatureWorks' Ingeo) | • 59% reduction in GHG emissions<br>• 47 % reduction in non-renewable energy usage | Enables feedstock recovery (versus typical 'downcycling' that occurs with existing PET-based bottles) |

## Harnessing the Biobased Economy: Improving Economic Development

**What if we could move away from overdependence on foreign oil?**

**What if we could use homegrown natural resources to power our economy?**

**What if the production of these natural resources and their conversion into value-added manufactured products could be distributed all across the country to benefit every state and almost every community?**

With industrial biotechnology the answer to these questions is, "We can."

As the U.S. Government itself has pointed out, the U.S. economy is hostage to global oil prices:

> *"Cheap oil fuels America's economy—most of which is imported. Small changes in crude oil prices or supplies can have an enormous impact on our economy—increasing trade deficits, decreasing industrial investment, and lowering employment levels. Developing a strong industry for biomass fuels, power, and products in the United States will have tremendous economic benefits including trade deficit reduction, job creation, and the strengthening of agricultural markets."*[21]

The U.S.'s huge landmass and world-leading agricultural and forestry productivity provide the raw material and potential raw material for a new economy—a biobased economy built around home-grown, sustainably produced, natural biomass resources. By using agricultural biotechnology to increase yields and processability of biomass in concert with industrial biotechnology to efficiently and cost-effectively convert that biomass into energy, liquid fuels, plastics, materials, chemicals and fibers the biotechnology industry sets the stage for a bold new future.

The U.S. Department of Energy emphasizes the benefits of moving to a biobased resource and industrial

**Case Study 4.** I Scream, You Scream, We All Scream for Ice Cream

Ice cream and frozen treats are something enjoyed by just about everyone, but these tend to be "guilty treats" because of high levels of fat and sugar content. A new food biotechnology discovery by Unilever, however, called "ice structuring protein" (ISP), is helping to produce products that are lower in fat, sugar, and calories, and the technology has the added benefit of slowing melting and allowing more fruit to be incorporated into the product. ISP is produced from a modified baker's yeast using fermentation and the technology is approved for use in lower fat ice cream, popsicles, and other frozen treats in the U.S., Europe, and other major regions of the world.

**Case Study 5.** Synthetic Biology—A New Approach to Engineering Biology

Synthetic biology is a new biotechnology tool enabling biotechnologists to go far beyond manipulation of one or two genes, and instead into engineering changes in entire genetic pathways. In effect scientists can now "write" DNA code, rather than making simple modifications to an existing code. Such biotechnology brings some astounding opportunities to the industrial biotech sphere—most notably an ability to custom engineer microbes, such as bacteria or yeast, to produce specific chemical compounds (compounds that the microbe never previously made).

Examples of synthetic biology successfully applied in manufacturing processes already exist in pharmaceuticals manufacturing with production processes for the anti-malarial drug artemisinin and the widely-prescribed cholesterol lowering statin Lipitor® (Pfizer).

Codexis is a biotech company active in synthetic biology and novel biocatalyst development from enzymes. Codexis biotechnology is being used to synthesize the chiral side chain of atorvastatin, the active ingredient in Lipitor. The new process has reduced the cost of producing the statin by up to 70% and capital expenditures by 35%.[20]

Synthetic biotechnologies and biocatalysts have the advantage of reducing process steps and operating at lower temperatures and pressures than their chemical-process competition. The net result is less consumption of energy in processing and reduced capital costs for equipment (since the equipment need not withstand high temperatures and pressures).

biotechnology economy, noting that many benefits will be associated with it, including:[23]

- Improved national energy security
  - Reduced reliance on foreign sources of energy
  - Decreased threat of supply disruptions due to natural disasters, political instability, and price volatility
- Increased economic growth
  - Economic opportunities for domestic, rural economies
  - Decreased petroleum trade deficit
- Broad-based environmental benefits
  - Reduced greenhouse gas emissions
  - Reduced petroleum use in fuel production.

The petroleum-based economy has tended to concentrate value-added economic activity around the huge infrastructure of very large-scale refinery complexes and chemical facilities—often at big coastal ports, the ports of call for supertankers bringing in foreign oil. In contrast, under the biobased model, value-added activity will be distributed all across the nation.

How is this possible? In short, the reason is three-fold:

- Agricultural and forest land is distributed widely across the nation;
- Cellulosic materials including woody biomass, perennial grasses, and other biomass are able to be grown over a wider area than current row crops; and
- The comparatively low-bulk density of biomass means it cannot be shipped very far before it needs to be converted into a higher-value, higher-density product.

# Fuel

Studies show that the supply radius for biorefineries will vary between 15 and 50 miles,[24] depending on the agronomic and transportation characteristics of a region—and that this would support individual refineries of up to **100 million gallons per year** capacity. The net result is, and will increasingly be, new jobs and economic opportunity.

Despite the biofuel industry's relative infancy, 189 ethanol biorefineries operate in the U.S.[25]—already exceeding the 141 total petroleum refineries operating in the U.S.[26]

Industrial biotechnology is bringing new high paying, high quality jobs to communities and will underpin future economic growth across the developed and developing world. Ultimately though, the positive impacts of industrial biotechnology come down to the everyday life benefits of the jobs and products produced via biotechnology.

### **Case Study 6.** The U.S. Economic Impact of Advanced Biofuels Production

An analysis by Bio Economic Research Associates (bio-era) calculates the projected economic impacts of building an advanced biofuels economy by 2022—meeting the U.S. Renewable Fuel Standards requirement for 21 billion annual gallons of production by 2022.[27]

The projected economic impacts benefits of this biotech-enabled industry will be substantial, with bio-era estimating impacts at:

- 29,000 direct jobs created by 2012, 94,000 by 2016 and 190,000 by 2022. Total job impacts in the economy (comprising direct and indirect employment via the employment multiplier effect) could reach 123,000 in 2012, 383,000 in 2016, and 807,000 by 2012.
- Total (direct and indirect) economic output generated by the advanced biofuels industry could reach $20.2 billion by 2012, $64.2 billion by 2016, and $148.7 billion by 2022.
- Anticipated cumulative reduction in petroleum imports over the period 2010-2022 would exceed $350 billion.

AFTER LEARNING ABOUT FERMENTATION IN BIOPROCESS TRAINING AT THEIR LOCAL COMMUNITY COLLEGE, LAURA AND THAD CRANE FOUND JOBS WITH CARGILL AND, IN THEIR SPARE TIME, OPENED THE CRANE WINERY.

### **Case Study 7.** A Personal Story: A Midwest Couple Enters the Bioeconomy

When ArvinMeritor decided to close its doors in 2000, one Iowa family's lives were forever changed. Laura and Thad Crane, both machinists, were left unemployed with a young daughter to support. With limited employment opportunities for machinists in their region, both Laura and Thad opted to enter into the Bioprocess Technology Program at Indian Hills Community College. The two-year program prepares workers to enter the bioeconomy by offering courses designed to teach skills in large scale fermentation, bioprocessing equipment, and the application of scientific principles and technical skills.

In 2002, Laura and Thad both completed the Bioprocess Technology Program and graduated with an Associate of Science. Since graduating, Laura and Thad have both found jobs with Cargill, a major biotechnology company producing products and services for the food, agricultural, financial, and industry sectors. Thad works as a Production Technician and Laura works as a Lab Technician, a position she credits the Bioprocess Technology Program for helping her secure. According to Laura: "I would never have gotten into a lab position without completing the bioprocess training at Indian Hills Community College."

Bioprocess Training impacted their life in another important way: in 2007 the Cranes opened a small winery. Recounted Laura, "We took the knowledge we learned in fermentation [through bioprocess training] and opened our own winery. So, in addition to being employed at Cargill, we're entrepreneurs as well!"

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# Feed

With a global population of nearly 7 billion expanding every day, feeding the world with nutritious foods via sustainable agriculture is an intense challenge. Agricultural biotechnology is leading the charge in meeting this challenge—providing solutions that increase crop yields, preserve and improve soils, enhance the control of pests, weeds and harmful diseases, and produce more healthful food with enhanced vitamin and nutrient levels.

Since their introduction in the 1990s, biotech crops have been grown on more than 2.3 billion acres of farmland worldwide, helping to improve farmer incomes, food security, and the sustainability profile of agricultural production. Biotechnology inventions such as herbicide tolerant crops, insect resistant crops and disease resistant plants have revolutionized modern agriculture while greatly reducing the need for a diverse range of agricultural chemical pesticides. Furthermore, agricultural biotechnologists are bringing to market the next wave of biotech plants with a host of new and exciting production characteristics such as drought tolerance, cold tolerance, saline tolerance, and plants with enhanced nitrogen-use efficiency—reducing the amount of fertilizers needed for high levels of productivity.

While feeding the world, agricultural biotechnology is also on the front lines of fueling the world—providing grain and biobased feedstocks such as crop residues and energy crops, for the production of high-value, environmentally friendly biofuels, bio-based chemicals, biopolymers, and bio-based materials.

# What if...

## we could feed the world?

## we could do so in an environmentally sustainable way,

## and the foods we consume were safer and healthier?

## Not only is this possible—it's happening now with the help of modern biotechnology.

The use of biotechnology to enhance our food supply isn't anything new. The fact is we've been using it ever since humans first attempted to cultivate the environment surrounding us some ten or twelve thousand years ago.

When humans first started to plant crops it marked progress away from a nomadic hunter-gatherer culture and made possible the formation of settlements, towns, and then cities. By farming and herding, our early ancestors built farms that generated a surplus of food. This freed many people to take up specialized crafts such as weaving, metal-working, pottery making, and stone-masonry. These crafts, in turn, formed the basis for the trade of goods for food and other necessities thus creating the first commercial economy. [1]

### Crop Improvement: Empowering Human Progress

Over the centuries agriculture improved and farmers noticed that certain plants and animal offspring had superior characteristics to others. They saved the seeds of superior plant varieties to plant the next year (the foundation of selective breeding) and they used superior livestock to breed healthier and better yielding herds. In effect, farmers were the first experimental scientists—using observation of their crops, livestock, and agronomic conditions to improve their yields and the quality of food.

Despite humanity's long history with agriculture, it was only recently that "modern" biology experiments began applying bioscience to plant improvement:

- 1700 to 1720: Thomas Fairchild creates Europe's first hybrid plant.[2]
- 1866: Austrian monk Gregor Johann Mendel publishes the first study on heredity describing how plant characteristics are passed from generation to generation.[3]
- Late 1800s: Researchers crossbreed cotton to develop hundreds of varieties with superior qualities.[4]
- 1908: G. H. Shull of the Carnegie Institute produces the first U.S. hybrid corn through self-pollination techniques.[5]
- 1930s: Hybrid corn varieties became commercially available,[6] leading to a **tripling of corn yields** over the next 50 years.[7]
- 1960s: Norman Borlaug's development of dwarf wheat increases wheat yields by **70%**, launching what has been termed the "Green Revolution."

Together with the discovery of DNA's double-helix structure in 1953 and techniques for splicing genes in 1973, bioscience developments have paved the way for a "Second Green Revolution," a revolution using the tools of biotechnology to generate crops with enhanced agronomic traits including resistance to diseases and insect pests, and engineered resistance to herbicides allowing more efficient weed control.

In the 1990s the era of biotechnology-enhanced agriculture began with government authorization for commercial deployment of biotech soybeans, corn, cotton, canola, and papaya. Because of tremendous production advantages, biotech crops have become the most rapidly adopted technology in the history of agriculture.

**Figure 1.** Teosinte

The original wild grass ancestor of modern corn bears little resemblance to modern corn because of humankind's selective breeding and hybridization of the plant.

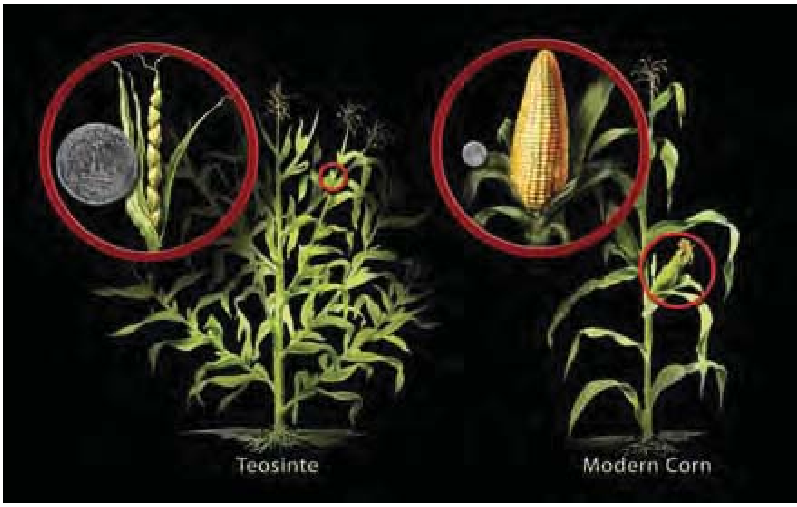



*Illustration by Nicolle Rager Fuller, National Science Foundation.*

## Biotech Crops: Feeding Human Progress Around the World

The phenomenal growth of biotechnology-enhanced crops across the globe is a testament to the positive results observed by the pragmatic farmers who grow them.

- In 1996 farmers in six countries planted biotech crops on **4.2 million acres**.
- By 2000, this had grown to farmers in 13 countries planting on **109.2 million acres**—a **25-fold increase** in just five years.[8]
- In 2009 more than **330 million acres** of biotech crops were grown in 25 countries and 14 million individual farmers chose to grow biotech crops.[9]

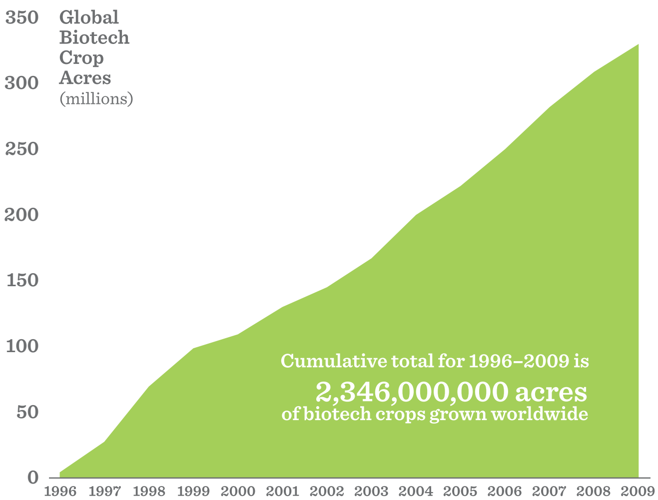
# Feed

The adoption of biotech crops has not been limited to farmers in the developed world:

- 2009 data indicate that almost **93% (13 million)** of the 14 million farmers growing biotech crops in 2009 were "small and resource-poor farmers from developing countries such as China, India, Philippines and South Africa."[10]
- In terms of total acreage of biotech crops planted, the developed world (with its larger farms) planted 40% of the acreage, while developing countries accounted for 60%.[11]

Between 1996 and 2009 more than **2.3 billion acres** of biotech crops "have been successfully grown as a result of approximately **70 million** repeat decisions by farmers to grow these crops."[12]

**Figure 2.** Total Acres of Biotech Crops Grown in 2009.[13]




Countries on all six settled continents have authorized biotech crops for their farmers. As Figure 3 shows, in 2009 the Americas had the largest number of countries and total biotech crop acreage, followed by Asia where India and China combined grew biotech crops on nearly 30 million acres.[14] In Africa, three key agronomic regions of the continent now contain nations that serve as an example of biotech crop advantages (North Africa with Egypt, Southern Africa with South Africa, and Burkina Faso in West Africa). East Africa is expected to soon be represented in biotech crops by Kenya.

**Figure 3.** Nations of the World Growing Biotech Crops in 2009[15]

# Biotechnology in Agriculture—Multiple Technologies Meet Widespread Needs

It is generally recognized that the growth of global population, in combination with rising incomes and associated food demands, mean that by **2030 global food supply may need to be doubled**.[16] As the Council for Agricultural Science and Technology (CAST) notes:[17]

> *This growth is a staggering challenge for agriculture because most of the world's usable farmland is already in production. In 1991, 0.81 acres of farmland was available to feed each person. By 2050, only 0.37 acres of farmland will be available for each person. It means that the productivity of each unit of land must be increased.*

The United Nations Millennium Project estimates that 50% of the world's population consists of farmers cultivating small land-holdings—farmers who use the food they produce to feed their families.[18]

Clearly, we face many challenges in ensuring the productivity and sustainability of the global food supply. Fortunately, the scope of beneficial impacts generated by biotechnology in agriculture and food production is extremely broad and capable of meeting these challenges. Key categories of benefits from biotechnology in agriculture include, for example:

- Increased agricultural yields and agricultural productivity;
- Reduced environmental impacts of agricultural production;
- Increased farmer incomes;
- Enhanced food safety, nutrition, and health; and
- Opportunities for new and expanding industries in the sustainable production of biobased fuels, chemicals, plastics and materials from agricultural and forest biotech crops.

Biotechnology is on the frontlines generating new and brighter futures for humankind. The application of biotechnology in agriculture and food production promises global agriculture that is both more productive and environmentally sustainable.

Philippines being the first country in Asia to have a biotechnology crop for food and feed approved for commercialization generated significant development for farmers by attaining higher yield, thereby becoming profitable, reducing pesticide use and helping the country attain sufficiency in grain. Adoption of biotech corn in particular has increased consistently since it was first commercialized delivering economic, environmental, health and social benefits to all kinds of farmers in the country.

***—Rosalie Ellasus, Farmer in the Philippines***

## TOOLS FOR FEEDING THE WORLD: KEY BIOTECHNOLOGIES IN AGRICULTURE

**Molecular Breeding and Marker Assisted Selection**—rapidly identifies the genes associated with positive traits, speeding their integration into crop lines for farmers.

**Tissue Culture**—producing copies of desirable plants without the need of seeds, this technology allows the production of disease-free, high quality planting material and the rapid production of uniform plants

**Genetic Engineering**—Engineering improved plants by altering their genetic make-up using recombinant DNA technology. This assures that only desirable genes with known positive benefits are incorporated in crops. Genetic engineering can accomplish in one year what would take 25 years with selective breeding. In many cases the benefits derived from genetic engineering of transgenic plants would be impossible via any other route.

**RNA Interference (RNAi)**—is a method of blocking the function of specific genes and is being used in producing plants with pest resistance, novel traits and increased yield.

**Diagnostics Development**—Biotechnology is producing highly refined diagnostic tools for early identification of plant and livestock diseases.

# How to Feed 7 Billion People

With global population increasing rapidly and the vast majority of farmable land already in production, the future of humankind depends on increasing agricultural yields. Biotechnology today is unlocking dramatic productivity increases.

Independent research data indicate that biotech crops are at the forefront of increasing agricultural yields. Table 1 highlights yield improvement data for four biotech crops—soybeans, corn, cotton and canola—with soybeans, for example, seeing an additional biotech-related yield totaling **74.7 million tons** between 1996 and 2007. [19]

U.S. Department of Agriculture (USDA) data on annual corn yields dramatically illustrate the extent to which crop improvements, via selective breeding and hybridization, led to large-scale yield increases from the 1960s through the mid-1990s, and how (starting in 1997) biotechnology has allowed the trend in yield gains to continue.[20] As shown in Figure 4, during the "biotech corn era", which began in 1997, yield has increased from the 1996/97 production year yield of 127.1 bushels per acre to 165.2 bushels/acre in 2009/10 (a substantial 30% yield increase).[21]

### THE NUMBERS IN PERSPECTIVE

It takes one-third of a ton of grain to sustain one person for one year (current global average). Therefore an additional 16 million tons of corn produced by biotech crops could potentially **feed 48 million people.**

**Table 1.** Additional Crop Production Arising from Positive Yield/Production Effects of Four Biotech Crops

| | 1996-2007 ADDITIONAL PRODUCTION [MILLION TONS] | 2007 ADDITIONAL PRODUCTION ALLOCABLE TO BIOTECH CROPS [MILLION TONS] | PERCENT CHANGE IN 2007 PRODUCTION ON AREA OF LAND PLANTED WITH BIOTECH CROPS |
|---|---|---|---|
| Soybeans | 74.7 | 15.9 | 32.8 |
| Corn | 68.8 | 16.6 | 8.4 |
| Cotton | 7.5 | 2.2 | 21.8 |
| Canola | 4.9 | 0.6 | 9.4 |

The trend in yield increases allocable to biotech is likely to continue into the future—with crop yields even better than they are now. This optimism is driven by biotech companies' recent field trial results and the expanding ability to "stack traits" (i.e., introducing more than one transgene into a crop to add multiple input or output trait benefits).[22] The projections for U.S. soybean and corn yield through 2030 in Figure 5 show the significantly enhanced yield from biotech crops versus a continuation of the historic yield increase trend line.

Such conclusions are certainly reasonable given the actual data for corn reported in the journal *Crop Science* and reproduced in Figure 6: corn yields for biotech corn have grown at a significantly greater pace than for corn produced via traditional breeding and hybridization techniques.[23]

**Figure 4.** USDA ERS Data Show Substantial Growth in Corn Yields Via Selective Breeding, Hybridization, Marker Assisted Breeding and Biotech Crops

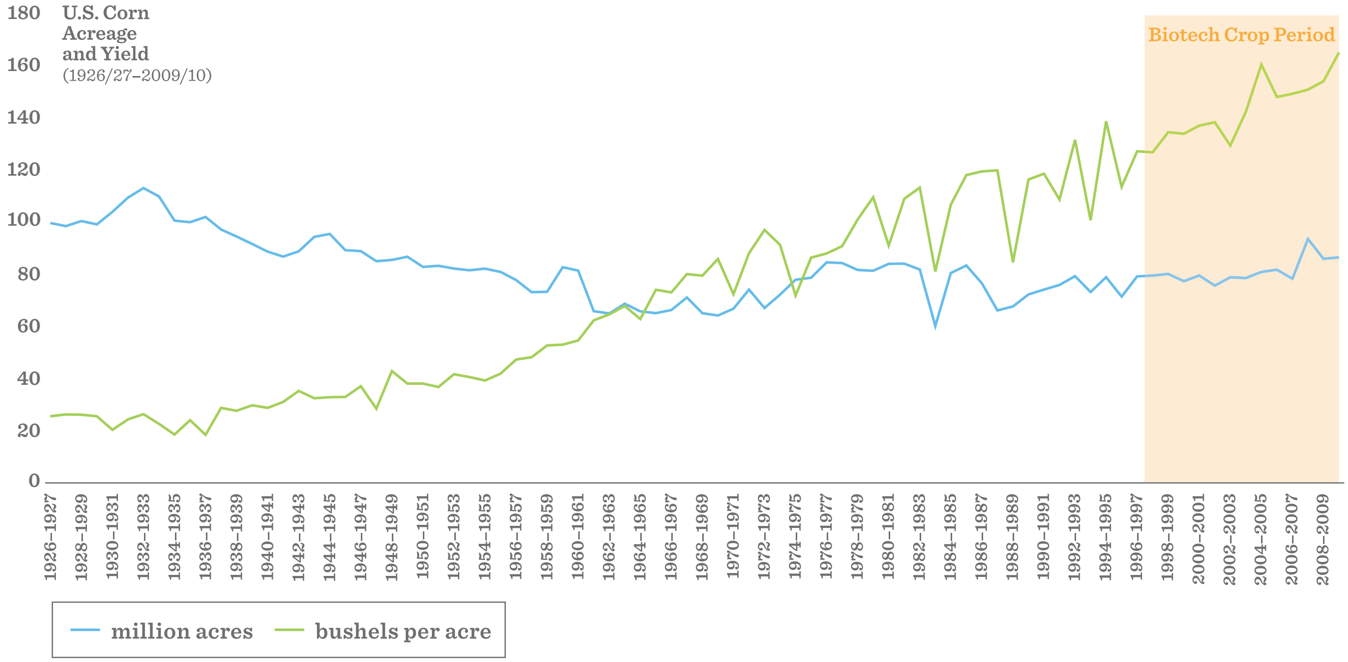



**Figure 5.** United States Historic Data and Projections of Crop Yield Increases from Biotechnology in Corn and Soybeans [24]

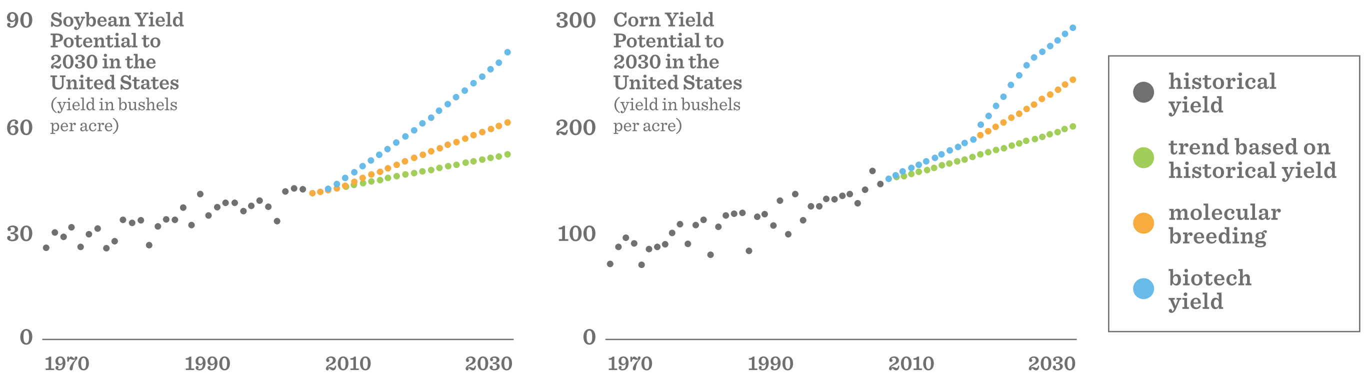
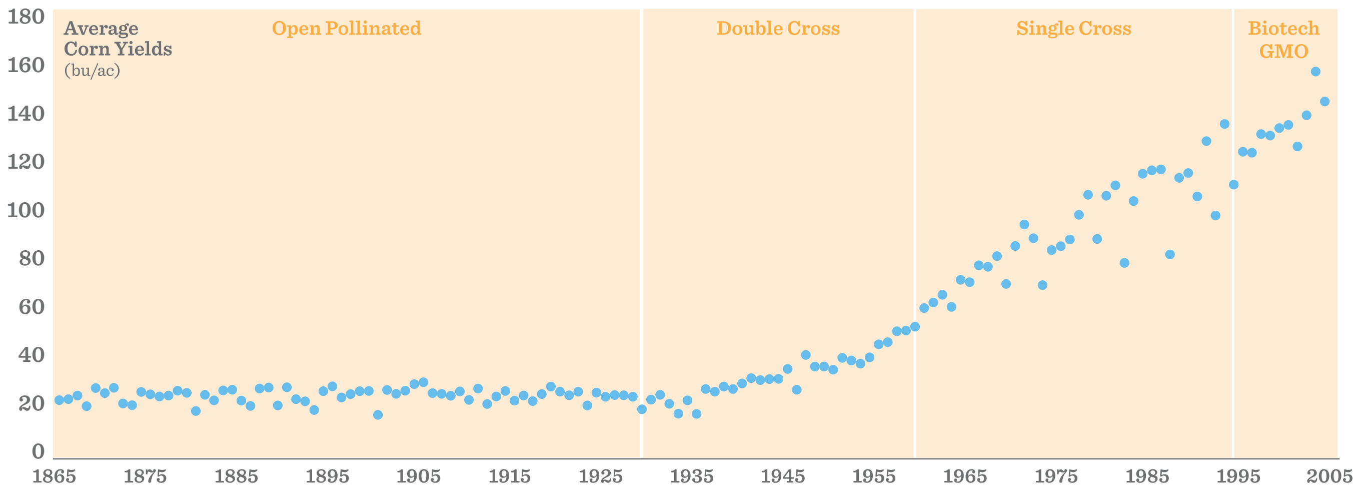


**Figure 6.** Average U.S. corn yields and kinds of corn, 1865 to 2004.[25]




## So how is biotechnology helping to achieve these yield increases?

Well, like many complex issues the answer is multi-faceted. Several biotechnology innovations are generating agricultural yield increases—but especially notable are those producing traits that reduce crop damage and destruction due to pests, weeds, and diseases. Together, these crop threats reduce yield, hurt farmer incomes, and increase the cost of food globally.

Each of these threats is responsible for similar levels of crop losses (pathogens causing 12% losses, insects 13%, and weeds 12%).[26] It is estimated that diseases and pests together reduce global production of food by **more than 35%**—a cost estimated at **more than $200 billion per year**.[27] Using biotechnology to limit these losses is of critical importance to global food security.

## How a Common Soil Bacterium Improves Insect Resistance and Crop Yields

One of the keys to achieving crop yield increases has been the development of biotech crops containing insect resistance (IR) traits. Biotech crops developed with IR traits are reducing crop losses to insect pests and reducing the use of various pesticides associated with risks to health and the environment.

### *The Miracle of Bt*

Take, for example, Bacillus thuringinesis (Bt). Imagine a common soil bacterium that would destroy the larvae of some of the most destructive crop pest insects, and you'll have what biologists found in Bt.

How does it work? Bt produces a protein that effectively paralyzes the larvae of Asian and European corn borers and the cotton bollworm—the most destructive pests to corn and cotton crops. But the power of Bt doesn't end here:

- There are **more than 200** Bt produced proteins with varying effects on a broad range of insects; and
- Bt is widely used by organic growers for pest control.

Leveraging the characteristics of Bt, crop biotechnologists have taken the Bt gene coding for the desired insecticidal proteins and incorporated it into the genome of crop plants. The result is quite astounding—crops that have a built-in defense against their most threatening insect enemies. The Bt proteins are highly specific, only affecting the targeted pest insects, and have no deleterious effects on humans, livestock, or wildlife that eat the crop output.

## THE BOON OF Bt BIOTECHNOLOGY[28]

Bt crops have many advantages for farmers and society:

**Increased Yield.** By effectively combating the damage and loss of crops from targeted insects, Bt biotech crops generate higher yields. Field studies in India, for example, showed Bt cotton increased yield by 45% in 2002 and 63% in 2003.

**Improved Pest Management.** Bt crops provide no-maintenance or limited maintenance, providing ongoing protection throughout the complete life-cycle of the crop.

**Reduction in Pesticide Applications.** If the plant has engineered protection from the Bt gene produced proteins then the need to spray insecticides is greatly reduced. USDA analysis show reductions of between 2.4 and 8.6 percent depending on region of the U.S.

**Improved Field Conditions for Non-Target Organisms.** The specificity of Bt in targeting only specific pests means that broader spectrum insecticides are not needed. The result has been proliferation of other beneficial organisms in farmer's fields.

**Safer Corn.** By reducing insect damage, Bt corn provides less opportunity for fungi and microbial pathogens to infect damaged crops—the result has been reduction in corn mycotoxins that harm both livestock and humans.

**Less On-Farm Energy Use.** With reduced spraying, tilling and other insect control activities required, farmers save time, energy consumption and wear-and-tear on equipment. Tractors need to make less passes on fields and energy is saved.

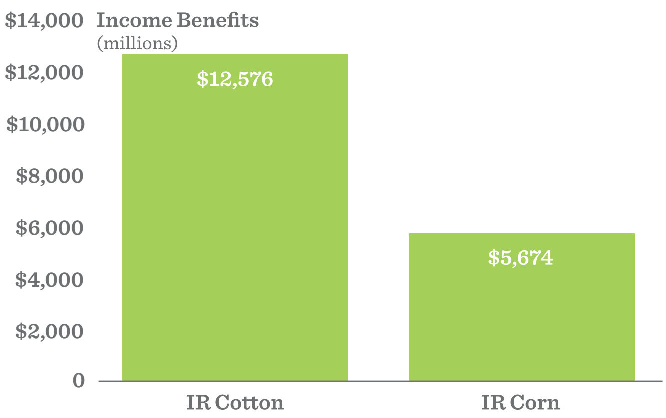
Across the globe, farmers using Bt cotton and corn are applauding this key application of biotechnology to agriculture:[29]

> With the old seed, I used to plant it, and then when it was knee-high, I had to go and buy chemicals to control the insects. With this new seed, I don't have to buy the chemicals anymore...so I just plant it and leave it. And my life is now easier and better.
>
> —***Elizabeth Jele, South African Cotton farmer***

> One thing that has helped by using Bollgard is that there has been a reduction in the number of times of spraying pesticides...This cotton had to be sprayed only once. Since I had to spray only once, my expenses have reduced. And the bollworms that come, have vanished
>
> —***Keshavrao Bhaurao Pawar, Indian farmer***

> I have spent less energy on the farm and less money on inputs and other costs with Bt cotton compared to the conventional one I have been planting that require up to 12 sprays of pesticides and fungicides to get a decent harvest.
>
> —***El-Hadji Karim Ouedraogo, Cotton farmer, Burkina Faso, West Africa.***

**Figure 7.** Cumulative Farm Income Benefits of Insect Resistant Cotton and Corn: 1996-2007[30]




Since 1997, the use of pesticides on biotech crop areas has been reduced by **790 million pounds** of active ingredient (395,000 tons).[31] Overall:

- The environmental impact of insecticide use on IR crops decreased by **27.8%** in cotton and by **6%** in maize (corn); and
- The positive impact on farm incomes over the 1996 to 2007 time period was **$12.6 billion** for IR cotton and **$5.7 billion** for IR corn.[32]

In sum, insect resistant crops have proven to be a win-win-win application of biotechnology:

- Global food security is increased through greater crop yields;
- Farmer incomes are increased via higher yields and lower input costs; and
- Environmental gains are realized via more limited applications of chemical insecticides.

## The Helping Hand of Herbicide Tolerance.

Herbicide tolerant (HT) crops are biotech crops that have been improved through the addition of genetic traits that make them immune to herbicides that previously would have destroyed the crop along with targeted weeds. The most common herbicide-tolerant crops (cotton, corn, soybeans, and canola) are crops resistant to glyphosate, an herbicide effective on many species of grasses, broadleaf weeds, and sedges. Other genetically modified herbicide-tolerant crops include corn resistant to glufosinate-ammonium, and cotton resistant to bromoxynil.[33]

Not surprisingly farm incomes have also benefited significantly from HT biotechnology. As Figure 8 shows, between 1996 and 2007:

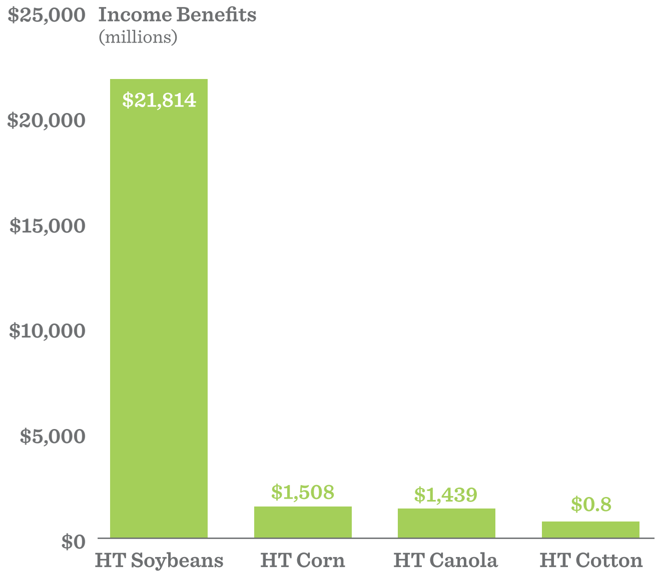
- HT soybean technology generated over **$21.8 billion** in farm income benefits;
- HT corn generated **$1.5 billion**;
- HT canola generated **$1.4 billion**; and
- HT cotton generated **$848 million**.[34]

## Leading the Fight Against Plant Diseases

Plant diseases can be particularly devastating. The Irish Potato Famine which began in September 1845 is one of the most well-known historic events of a plant disease ravaging a nation; that famine was caused by a fungal pathogen—but it is just one event among thousands that have plagued agriculture and society.

Today plant diseases remain a leading cause of crop loss. As with insect and weed issues, however, biotechnology is providing solutions to plant diseases.

**Figure 8.** Cumulative Farm Income Benefits of Herbicide Tolerant Soybeans, Corn, Canola, and Cotton: 1996-2007[35]




### KEY ADVANTAGES OF HERBICIDE TOLERANCE

**Increased Yield.** One approach used herbicides applied before crops and weeds were well-established—a technique that reduced crop yield via "knock-back" side-effects of the herbicides. HT crops however are treated with one key herbicide to which the crop is tolerant and it is applied when crops are established and better able to avoid knock-back.

**Reduced Costs for Farmers.** Easier weed control is more cost effective weed control, saving farmer's time. Improved weed control has also reduced harvesting costs and provided a "cleaner crop" able to achieve market price premiums. U.S. farm income benefits from 1996-2007 are estimated at nearly $20 billion resulting from enhanced productivity and efficiency gains from agricultural biotechnology.[36]

**Environmental Benefits from No-Till Agriculture.** Plowing (tilling) is a traditional approach to weed control. HT crops, however, facilitate adoption of no-tillage systems reducing labor and fuel costs associated with tilling, improving soil moisture retention, holding carbon in the soil and reducing soil erosion. Analysis performed in Canada, for example found a 44.3% reduction in fuel-use on farms allocable to no-till practices.[37]

**Time for a Second Crop.** Brookes and Barfoot note that biotech HT soybeans "have also facilitated the adoption of no tillage production systems, shortening the production cycle. This advantage enables many farmers in South America to plant a crop of soybeans immediately after a wheat crop in the same growing season. This second crop, additional to traditional soybean production, has added 67.5 million tonnes to soybean production in Argentina and Paraguay between 1996 and 2007."[38]

### *The Great Hawaii Papaya Comeback*

Papaya is a tropical and subtropical crop grown in small back yard plots as well as in large-scale commercial farms. It produces year round and is one of the most nutritious fruit crops, rich in both vitamins A and C. It is a healthy staple food for many people around the globe. In the United States, however, the plant disease Papaya ringspot virus (PRSV) broke-out in 1992 in the Puna district of Hawaii and all but wiped out the production of papaya—a major export crop for the state. As CIMMYT, the International Maize and Wheat Improvement Center, reports:[39]

> *Up until 1992, Hawaii enjoyed steady production of papaya with greater than 80% of their crop being exported out of state. In 1992, Hawaii accounted for more than 75% of the papaya imported to mainland U.S. In May 1992, PRSV was discovered in Puna, the main papaya*

Transgenic papaya plants show resistance (right) while non-transgenic plants (left) are susceptible to papaya ringspot virus under field conditions.

*Photograph Courtesy of Dr. Stephen Ferreira, University of Hawaii, and Dr. Dennis Gonsalves, USDA/ARS, Hilo, Hawaii.*

*growing area where 95% of Hawaii's papaya was being grown, and by 1995, PRSV was widespread throughout the area. The papaya production steadily dropped from 53 million pounds in 1992 to 26 million pounds in 1998. The papaya industry in Hawaii was on the way to virtual extinction.*

Biotechnology literally came to the rescue with a transgenic PRSV-resistant papaya that fortuitously had been developed by Cornell University and University of Hawaii researchers beginning in 1991. Approved for growing in 1998, the transgenic papaya varieties "Rainbow" and "Sun-up" have replaced infected papaya in Puna and other areas of Hawaii, bringing production back-up to pre-PRSV outbreak levels. Biotechnology effectively saved the Hawaiian papaya industry. Today papaya is Hawaii's second-largest fruit crop with an estimated value of **$18 million** grown on 178 farms.[40]

## Biotechnology, Increasing the Yield of the Livestock Sector

According to the United Nations Food and Agriculture Organization (UN-FAO) livestock contributes 40% of the global value of agricultural output and directly supports the livelihood and food security of almost one billion people. Rapidly rising global incomes and urbanization, combined with underlying population growth, are driving rising demand for meat and other animal products in many developing countries.[41] In addition livestock agriculture is part of a vertically integrated value-adding agricultural industry; for example, fully **80%** of corn and **70%** of the soybeans produced in the U.S. are used for livestock feed.

### **Case Study 1.** Biotech for Animal Health

"Development of improved vaccine and diagnostic-based disease control strategies has benefited considerably from advances in biotechnology, particularly those relating to recombinant DNA technology. Efficiency of the vaccine development process has been increased at all levels, from the analysis of immune responses to the production and delivery of protective antigens to the target species. Serological analysis of antibody prevalence has also become more straightforward as a result of the availability of recombinant pathogen proteins. However, greatest advances arising from biotechnological development relate to the detection and characterization of pathogens in infected hosts."[67]

—D. J. McKeever

Biotechnology contributes to animal agriculture in a range of positive ways, with some leading areas of application being:

**Metabolic Modification.** Advances in bioscientists' knowledge of the regulation of nutrient use in livestock have led to the development of biotechnology-based metabolic modifiers. These modifiers have become a key biotech tool for increasing yield in animal agriculture. As noted by the Council for Agricultural Science and Technology, metabolic modifiers are a group of compounds that "have the effect of improving production efficiency (weight gain or milk yield per feed unit), improving composition (lean:fat ratio) in growing animals, increasing milk yield in lactating animals, and decreasing animal waste per production unit."[43] The major metabolic modifiers used are produced using the biotechnology process of recombinant DNA technology.

# Feed

**Livestock Health Products.** Biotechnology helps diagnose, treat, and prevent animal diseases in both livestock and companion animals. Infectious diseases are the leading cause of livestock output loss, and a number of significant disease events (such as foot and mouth disease and BSE) have had large-scale impacts on farmers and consumers. Some livestock diseases are also "zoonotic" in nature, meaning they have the ability for transmittal from animals to humans. Biotechnology has developed rapid diagnostic tests for diagnosis of disease and vaccines against viral and bacterial livestock diseases. The biotech based test for BSE, for example, gives results in just one day instead of the three to five days previously required.

**Reproduction, Selection, and Breeding.** In the field of livestock reproduction, new biotechnologies such as embryo transfers, in vitro fertilization, cloning, and sex determination of embryos have been developed for multiple livestock species. The tools and technologies of genetics and biomarkers are used to identify genetic traits associated with positive production and animal health attributes and to help producers raise livestock with optimized production characteristics, such as leaner or more tender and flavorful meat.

**Animal Nutrition.** Biotechnologists have successfully developed enzyme-based treatments for livestock feed products that increase the digestibility of feed and reduce any anti-nutritive factors. One of the key biotechnologies being used in animal nutrition is technology to decrease the amount of phosphorus, an environmental pollutant, contained in livestock manure. Similar work is taking place to limit nitrogen excretion also.

Agricultural biotechnology has long been a source of innovation in production and processing, profoundly impacting the sector. Rapid advances in molecular biology and further developments in reproductive biology provide new powerful tools for further innovation.

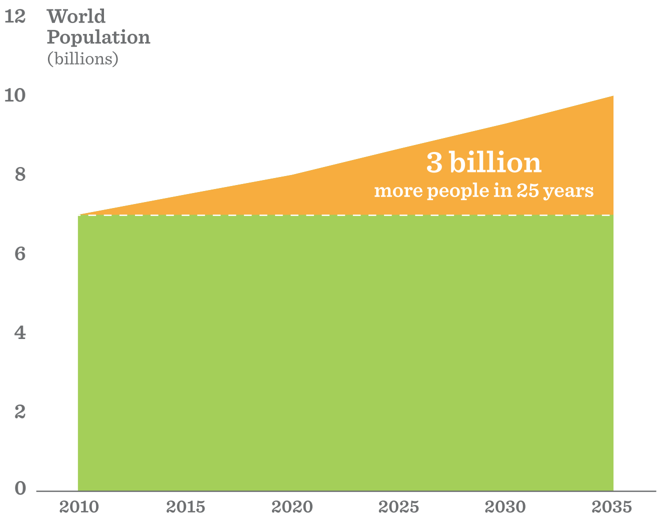
*—United Nations FAO*[44]

# Making Food and Agriculture Planet-Friendly

As of May 2010, the world population stood at just under **7 billion people**. By 2025 this is projected to grow to **8.7 billion**, by 2030 **9.3 billion** and by 2035 it is expected to exceed **10 billion**.[45] The expanding population will increase demands on agricultural land, water, energy, and natural resources—and the use and consumption of these resources impact the global environment.

As population grows, so does pressure to force marginal lands into production—lands with fragile soils and poor water resources.

**Figure 9.** Projected Growth of World Population 2010-2035[46]




Already upwards of **2 billion** people are malnourished, and the need to sustain **3 billion** more people by 2035 places a global imperative on finding ways to meet the daily life needs of this huge population. But, this need must be met in an environmentally sustainable way. It is an immense challenge.

> Cropland and population are not evenly distributed. China has only 1% of the world's productive land but 20% of the world's population.[47]

Biotechnology provides tools and technologies that provide solutions to many of these global environmental challenges. The key areas in which biotechnology does and can provide environmental benefits include:

- Increasing agricultural yields, thereby reducing pressures to force more land, often marginal and highly erodible land, into production;
- Using biotech herbicide tolerant crops that allow the use of no-till farming practices—practices which enhance soil moisture content, reduce erosion and limit carbon dioxide emissions;
- Using biotech crops that need fewer applications of pesticides and herbicides, and that thrive in a no-till environment, greatly reducing on-farm energy consumption and associated environmental impacts; and
- Reducing waste production from livestock feedlots and concentrated animal agriculture operations via biotechnology-improved feed products and biotech nutritional supplements for livestock.

## Biotechnology and the Conservation Tillage Revolution

Traditional methods of row crop cultivation have required regular plowing, also known as tillage, of the soil. The primary purpose of tillage has been to turn over the top layer of soil, in part to bury weeds and the remains of previous crops, and also with a goal of bringing fresh nutrients to the surface. Unfortunately, this practice also serves to expose the soil to erosion and associated nutrient losses. In dry conditions soil is lost to wind and, of course, the process of plowing is also energy and labor intensive.

Since the mid-1990s, however, farmers have been able to choose an alternative to tillage. There is a strong movement into no-till or limited-till agriculture. By leaving soil undisturbed, and by leaving some crop residues on the soil surface, farmers are actually recreating the natural type of robust prairie soils that once covered the nation 200 years ago.

> Where we went away from the tillage and went to the no till, we've cut the amount of fuel use dramatically. Because it's fewer trips over the field....And, in the fall when we are able to plant earlier with the newer genetics we're harvesting at a much nicer time of the year...We definitely do not spend the amount of gas...to dry this crop as we did a number of years ago. It allows us to harvest in much better weather...which means less field loss.
>
> *—Gordon Wassenaar, U.S. Corn and Soybean Farmer*[48]

As the Conservation Technology Information Center (CTIC) notes, "there is a strong association between the use of herbicide-tolerant biotech crops and recent improvements in tillage reduction."[49] Farmers are more confident in achieving good levels of weed control under no-till with the use of HT crops and CTIC reports that "nearly all the growth has occurred in crops where herbicide-tolerance technology is available," most notably in soybeans, cotton and canola.

The environmental benefits of conservation tillage and no-till agriculture are multifaceted and have been shown to include:

- reduced soil erosion;
- improved soil moisture content;
- healthier, more nutrient-enriched soil;
- more beneficial soil microbes and earthworms;
- reduced consumption of fuel for farming equipment;
- the return of beneficial insects, birds and other wildlife in and around fields;
- less sediment and chemical runoff entering streams and ecosystems;
- reduced flooding potentials;
- less dust and smoke pollution;
- less carbon dioxide released into the air; and
- carbon sequestration.

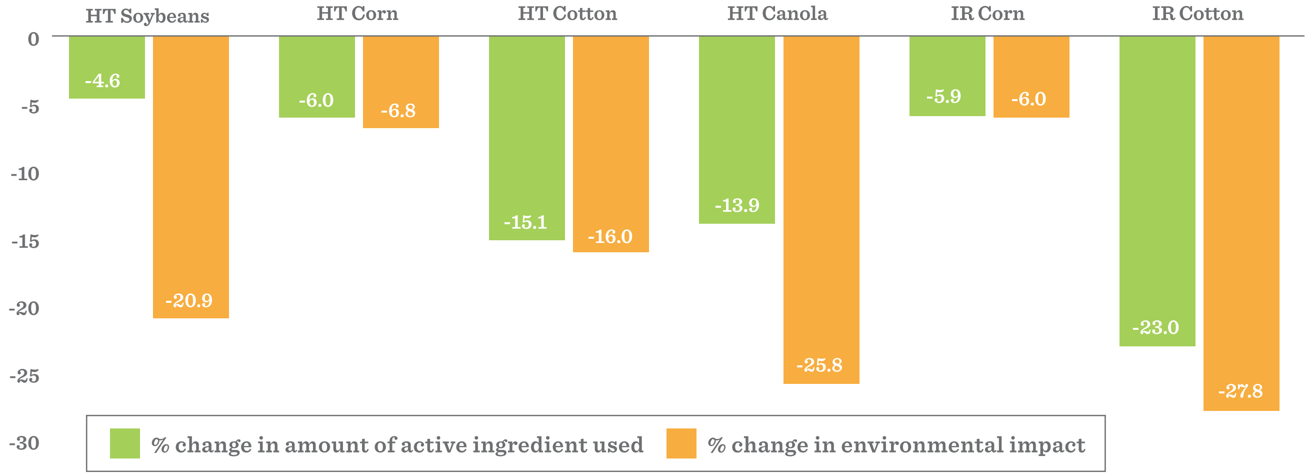
## Biotechnology and Reduced Greenhouse Gas Emissions

Biotech crops have resulted in significant reductions in greenhouse gas emissions, the gases associated with global warming and negative climate change consequences. In 2007, for example, the **274 million acres** of biotech crops resulted in a **31.3 billion pound reduction** in carbon dioxide emissions—the equivalent of removing **6.3 million cars** from the road for a year.[50]

And…it's not just a small benefit to the environment through this new technology. It's—it really is huge. There's no-till and minimum-till operations have just overtaken the landscape. Things that we just couldn't do before without these technologies….There's less soil erosion, wind erosion…which is a great advantage to our water supply and a whole host of other things. So I think the environment is probably one of the greatest benefactors.

***—Al Skogen, U.S. Soybean Farmer***[51]

**Figure 10.** Significant Reductions in Global Herbicide and Insecticide Use From Growing Biotech Crops: 1996-2007[52]




## Biotechnology: Key to Limiting Agricultural Chemicals Entering the Environment

Achieving high levels of agricultural productivity and yield depends on the use of fertilizers, insecticides, fungicides, herbicides, and other highly-effective agricultural input chemicals. As farming is largely an open-air open-field activity, the flow of water through agricultural fields eventually leads to some of these agricultural chemical inputs moving out into the environment.

One of the key environmental benefits of biotech crops is the reduction in insecticide applications and herbicide applications with these crops. In countries where biotech crops have been planted, pesticide use on four biotech crops—soybeans, corn, cotton, and canola—has fallen by **791 million pounds (8.8%)**. This has resulted in a **17.2% reduction** in the associated environmental impact.[53]

# Safer, Healthier, More Nutritious Foods for Consumers

Beyond producing more agricultural output, biotechnology in agriculture is being applied to producing healthier, more nutritious, and safer foods.

World prices of corn, soybeans and canola would be higher, on average, than 2007 baseline levels if biotech crops were no longer available to farmers.

## Biotech Crops and Healthier Food

Whether in the developed world (where obesity is at epidemic levels) or the developing world (where malnutrition takes a huge global toll) human nutrition is a matter of great public health concern:[54]

- One-sixth of the world's population suffers from hunger; and
- Over half of the global population suffers from "hidden hunger" due to the poor nutritional quality of available staple foods.

Billions of people in the developing world simply do not have access to a well-rounded and diverse diet. What is needed, in lieu of such a diet, is an approach to fortifying their staple crops with the nutrients that are typically missing from their diets. Biotechnology is helping achieve this goal:

- **Vitamin A Enrichment.** Vitamin A deficiency is a leading cause of blindness in the developing world and is particularly prevalent among children. To combat this deficiency, biotech processes are being used to enrich staple crops with β-carotene (provitamin A). β-carotene is produced naturally in rice plants, but only in their green tissues, not in the rice grain that people eat. The development of the biotech crop "Golden Rice," however, used genetic engineering to get β-carotene expressed in rice grains. At its current stage of development, Golden Rice could provide half the required daily intake of Vitamin A for a 1 to 3 year old child in a 2.5 ounce serving. Biotechnologists are also working to incorporate increased expression of β-carotene in potatoes, canola, tomatoes, carrots and cauliflower.[55]
- **Iron for Fighting Anemia.** Insufficient iron in the diet has led to anemia in **2 billion people** worldwide. Anemia, which reduces the capacity of blood to carry oxygen, is a silent plague for those afflicted, sapping their strength, causing weakness and fatigue and shortness of breath on exertion. Exhausted and weak, those impacted by anemia have a hard time meeting the demands of daily life. Biotechnologists have worked on two fronts to increase iron availability in staple crops: (1) by increasing iron content in crops such as rice, and (2) by decreasing the level of phytate in the crop (which inhibits the body's ability to uptake iron).

## Biotech Foods: A Tool for Fighting Obesity

In the diet of those in the developed world, the consumption of oils and fats is associated with many negative health conditions, not the least of which is obesity. The World Health Organization (WHO) reports that "obesity has reached epidemic proportions globally, with more than **1 billion adults** overweight—at least **300 million** of them clinically obese—and is a major contributor to the global burden of chronic disease and disability."[56]

> Saturated fatty acids are commonly judged to have a negative health impact as they lead to increased serum cholesterol levels and a higher risk of coronary heart disease. Therefore, all recommendations stress the importance to limit the intake of saturated fatty acids. Monounsaturated fatty acids, on the other hand, have a positive impact on the serum lipid profile, lead to decreased LDL-oxidation and favorably influence the metabolism of diabetics. However, it is essential that monounsaturated fatty acids be mainly supplied by plant oils like rape seed or olive oil and not by foods that are simultaneously rich in saturated fatty acids.
>
> ***—Ursel Wahrburg***[57]

Fats and oils are an essential part of the human diet, but in the developed world, especially the western hemisphere, we consume far too many of them and the wrong type:

- Saturated fats and trans-fats are associated with increased levels of cholesterol and cardiovascular disease.
- Monounsaturated fatty acids, however, are associated with positive health effects when derived from plant oils.

Biotechnology is enabling the production of modified plant oils optimized for promoting human health—by changing the abundance of individual "bad" fats or by producing "good" fats not normally found in crop plants.[58] Indeed, these biotech oilseed crops are already a market reality:

- In soybeans, the normally nominally expressed fatty acid oleic acid has been greatly enhanced in crops grown on thousands of acres.
- In other food crops, biotechnology is being used to express positive oil traits, such as Omega-3 fatty acids, associated with improved cardiovascular health.

In addition to work on the plant side, biotechnologists and animal scientists are also using biotechnology to create healthier meat products, such as beef with lower fat content and pigs with a higher meat-to-fat ratio.[59]

# Powering the Emerging Bioeconomy

There are clear and powerful imperatives—environmental, strategic and economic—that make alternative, non-fossil resource economic development models of central importance to our planet.

Plant-based biofeedstocks (dedicated energy crops, crop residues, tree branches, *etc.*) add limited carbon to the environment, since they absorbed carbon from the atmosphere in order to fuel their growth process. Plant biomass now represents the clearest hope for a sustainable economic future—a future built around green, renewable resources for fuels, chemicals, plastics, materials, and fibers.[60]

First generation biofuels (including corn ethanol and soy-based biodiesel) have already had a positive impact on the U.S. economy and the economies of many individual states and U.S. communities. More than 100 communities across the U.S., for example, are home to ethanol plants with the vast majority using locally grown biotech corn as the feedstock.

The impact of ethanol in the corn-belt has been a boon to rural communities and state economies. For example, the Minnesota Department of Agriculture reports that 14 ethanol plants in the state:

- Generate almost **$1.4 billion** in annual economic impact; and
- Are responsible for **5,300 jobs** in the state.

In Nebraska, the Nebraska Ethanol Board reports that 11 plants there have generated almost **3,000 jobs** across the state. The Chief Economist of the Nebraska Public Power District notes that "I don't know of a single industry that has had a more positive impact on rural economies than ethanol."[61]

Importantly, because biotech corn has such strong yields, corn ethanol production has grown in the U.S. without negatively impacting corn for food and feed applications. As the National Corn Growers Association notes:

> *There is no shortage of corn. In 2007, U.S. farmers produced a record 13.1 billion bushel corn harvest—and some 2.3 billion bushels (about 13 percent) were used in ethanol production. In other words,*

*there is still room to significantly grow the ethanol market without limiting the availability of corn. Steadily increasing average corn yields and the improved ability of other nations to grow corn also make it clear that ethanol production can continue to grow without affecting the food supply.*[62]

Ultimately, the great promise of biofuels and the bioeconomy depends on two things:

- The availability of high productivity biomass feedstocks with characteristics that suit them to sustainable production and economic processing (the application for agricultural and forestry biotechnology); and
- The development of biotechnology-enabled processes for the industrial processing of biomass into value-added fuel, chemical, plastics, materials, fiber and other products (the application of industrial biotechnology).

**Case Study 2.** Big Economic Impacts from First Generation Corn Ethanol Plants[63]

The Nebraska Public Power District (NPPD) undertook analysis of the economic impact of a "typical" 40 million gallons per year corn ethanol plant and found the impacts to be substantial, generating:

- $71 million in construction phase economic impacts
- Annual recurring economic output impacts on the local economy of $70.2 million
- Creation of 33 full-time direct jobs and a total of 120 jobs in the local economy
- Increasing local household incomes in the community hosting the plant by $6.7 million annually.

## Plant Biotechnology a Key to Unlocking the Bioeconomy

A critical challenge for agricultural biotechnology is to increase biomass yields so that both food and bioeconomy demands can be met. It's not an easy challenge, but biotechnology is proving up to the task.

For example, a key focus of plant and agricultural biotechnologists is the development of "Dedicated Energy Crops" (DECs). DECs are non-food, low-carbon footprint crops (such as switchgrass, eucalyptus, and miscanthus) developed specifically as raw materials for biofuels. Biotechnology is being used in the development of these specialized crops.

The OECD's International Energy Agency states that "biomass is the most important renewable energy source today."[64] Biotechnology is, and will continue to be, a key contributor to realizing maximum energy value through biomass feedstocks:

*Plant-based systems capture solar energy and can be produced in a renewable manner. However, the harvestable parts are not well optimized for energy transfer and this has been a significant limitation to the development of economically viable and sustainable biomass energy systems. Biotechnology has provided a new toolset that can be used to design and optimize the capture of solar energy through crops. Further development of biotechnology and genomics tools will enable the development of crops with specific traits that are optimized for biofuels and bioenergy. The implementation of such a system will enable a sustainable platform for centuries to come and should be given a high priority in society.*[65]

# Looking Forward: The Promise of Future Food, Agriculture, and Forest Biotechnologies

Today, biotechnology provides widespread benefits in food and agricultural applications. Biotech crops:

- Have generated undeniable benefits in terms of increased yield in both developed and developing economies;
- Have significant environmental and sustainability benefits attached to them; and
- Are providing healthier, safer and more nutritious food and feed products.

In the near future we can expect biotechnology to be at the forefront in providing solutions to the world's most pressing issues—feeding a significantly expanding global population with sufficient volumes of healthful and nutritious foods; promoting environmental sustainability; and providing a central path to an industrial bioeconomy built upon renewable biofuels, biobased chemicals and biobased materials.

Some of the exciting prospects for agricultural and food biotechnology in the near future include:

- **Drought Tolerant Crops.** Drought stress is the primary challenge to high levels of crop production for many crops and many regions of the world. Even temporary moisture deficits reduce yields in crops such as corn, and such deficits are commonplace in almost any non-irrigated growing environment each year. Crop biotech companies are using marker-assisted selection and plant transgenic technology to engineer drought tolerant corn and other crops.
- **Flood Tolerant Crops.** Flooding of cropland is a serious issue in much of the world. As researchers at the University of California Davis note: "Globally,

> Genetically modified crops are proving to be an unmitigated environmental miracle. Herbicide-tolerant plants are now grown with minimum tillage, which reduces the soil erosion that results from ploughing. Drought-tolerant plants are nearing the market and salt-tolerant ones are not far behind. Within a decade there may be crops that are no-till, insect-resistant, omega-3-enriched, drought tolerant, salt-tolerant and nitrogen –efficient. If they boost yields, then the 21st century will see more and more people better and better fed from less and less land.
>
> —***Matt Ridley, science writer for*** The Economist[66]

rice is the most important food for humans, and each year millions of small farmers in the poorest areas of the world lose their entire crops to flooding."[67] As with drought tolerance, crop biotechnologists and geneticists are using marker-assisted selection and plant transgenic technology to engineer flood tolerant rice, the staple crop for three billion people.

- **Nitrogen Use Efficiency.** Nitrogen fuels plant growth, and so soil enrichment through the application of nitrogen fertilizer has been a major contributor to high-agricultural yields across the world. However, fertilizers are expensive and their overuse has contributed to nitrogen fertilizer being washed out of soils and into water supplies. A number of biotech companies are focusing on nitrogen use efficiency (NUE) and are using transgenics to insert genes associated with high-levels of nitrogen use efficiency into rice, corn, wheat and other crops. It is also important to note that some existing biotech crops have already been found to have enhanced nitrogen use efficiency characteristics. For example, scientists at the University of Illinois have found that Bt corn hybrids have "a higher NUE and yield primarily due to higher nitrogen uptake efficiency of **71%** in Bt hybrids versus **55%** in non-Bt hybrids."[68]
- **Salinity Tolerance.** Many areas of the globe have groundwater that has a high salt content rendering it unusable for irrigation. Compounding the problem, evaporation of poor quality irrigation water leaves salt solutes that have accumulated over time in many soils, ruining their agricultural productivity. Increased salinity presently affects about **20%** of the world's area under irrigation, without taking into account arid areas or deserts, which comprise a quarter of the total land area on the planet. If crops with high levels of salinity tolerance can be developed it may allow salt-impacted land to be returned to production and new marginal lands to be brought into production. Genetic engineering is being used in pursuit of several salinity-tolerance strategies, including: "increasing a crop's ability to limit the uptake of salt ions from the soil; increasing the active extrusion rate of salt ions; and improving the compartmentalization of salt ions in the cell vacuole where they do not affect cellular functions."[69] These approaches are leading to successes being reported with experiments in rice, canola, and tomato.

- **Release of Nutritionally Enhanced Crops.** Crops to fight Vitamin A deficiency, iron deficiency, and other micronutrient deficiencies are already developed and nearing commercial release. Transgenic rice grains have been produced that increase both iron intake and iron bioavailability—promising a solution to iron deficiency that plagues **30%** of the world population. Golden Rice stands ready to do the same thing with Vitamin A. Similar near-term opportunities exist across a range of crops, such as corn, potatoes, tomatoes and lettuce. In addition, biotechnologists are working to increase the expression of naturally occurring pro-health substances in foods, an approach termed "functional foods." Work is taking place here to enhanced protein quality and level, expression of essential amino acids, production of healthy oils and fatty acids, and more dietary fiber, in addition to minerals and vitamins.

- **Forest Biotechnology.** Diseases and insect pests have ravaged some tree species and continue to cause widespread forest losses. The American Elm almost disappeared as a result of Dutch Elm Disease, and today the Emerald Ash Borer is similarly destroying Ash trees, while the pine beetle threatens the loss of the Rocky Mountain region's pine trees. Biotechnology is being applied to produce transgenic trees with resistance to plant pathogens and insect pests. Those working with transgenic "heritage trees" such as Elm and Chestnut are optimistic regarding the potential to restore these trees to the American landscape via the application of biotechnology. Biotechnology and transgenics also holds promise for introducing yield enhancement and other traits to commercial soft and hardwood species—doing for forest productivity what has already been started in biotech crops.[71] Biotechnology is also being used to expand the range of useful trees into areas where cold temperatures limited their growth. Cold tolerant Eucalyptus represents the first of these range-enhanced trees.

> ...the coming decades will be unparalleled and will place plant researchers in the position of being able to modify the nutritional content of major and minor crops to improve many aspects of human and animal health and well-being.
>
> ***—Martina Newell-McGloughlin, Director, University of California Systemwide Biotechnology Research and Education Program (UCBREP) and Co-Director, NIH Training Program in Biomolecular Technology[70]***

- **Molecular Farming and Plant Made Pharmaceuticals.** Plants express a wide-range of chemical compounds called "phytochemicals" and biotechnologists are leveraging plants as small-scale chemical "factories" for the production of chemicals useful to humans. Plants have been used to produce pharmaceuticals since the 1990s. Today, however, biotechnology has advanced to enable the production of complex technical therapeutic proteins via plant pathways, with examples including antibodies, blood products, cytokines, growth factors, hormones, recombinant enzymes and human and veterinary vaccines. Molecular farming will likely bring several products to market in the near future with applications to the treatment of diseases and conditions such as cystic fibrosis, non-Hodgkin's lymphoma, hepatitis, Norwalk virus, rabies, and a range of gastrointestinal illnesses.[72] In some instances, the chemicals may not need to be extracted to be of use. For example, researchers have successfully vaccinated volunteer patients against Norwalk virus in clinical trials by having them eat transgenic potato that expresses the vaccine.[73] Biotech companies are using plants for development of both pharmaceutical and non-pharmaceutical products and are using plants to produce bulk therapeutics, such as insulin and lactoferin, in a far more cost-effective manner than other techniques—helping make the therapies more affordable and widely available to meet global health needs.

- **Genetically Engineered Animals.** Animal biotechnology is a highly promising field, likely to be associated with multiple public health benefits. Genetically engineered animals will improve human health via production of novel proteins, vaccines, drugs and tissues for prevention and therapeutic application. Livestock animals are being engineered that will have improved food production traits, enabling them to help meet growing food needs worldwide. Genetically engineered livestock can also be produced that use feed more efficiently and produce less manure. For example, Enviropig™ is a genetically engineered line of Yorkshire pig that is uniquely able to digest the phosphorus in cereal grain, which limits the amount of phosphorus in pig manure.[74] Genetically engineered animals may also be used to produce industrial products such as spider silk used in medical and other applications.[75]
- **Growth of the BioEconomy.** The development of dedicated energy crops and other custom engineered biomass crops will facilitate a revolution in economic development—particularly in rural areas across both developed and developing nations. Advancements, in particular, in regards to lignocellulosic biomass yields, storage and processability will be key drivers of the development of an economy increasingly powered by highly distributed rural biorefineries producing not only biofuels but also a range of value-added chemical, biodegradable plastics and other high value materials.

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