Medical Innovations
Biologics are complex medicines manufactured from living organisms. Unlike traditional small-molecule drugs, biologics are not chemically synthesized but are manufactured using living cells and tissues using highly controlled and optimized processes. Each manufacturer’s resulting biologic therapy is unique. Biosimilars are biologic products similar to—but not the same as—the innovator biologic.

America’s biopharmaceutical research companies are using biological processes testing 907 medicines and vaccines targeting more than 100 diseases. Many biologics are made from a variety of natural sources—human, animal or microorganisms. Like small-molecule drugs, some biologics are intended to treat or cure diseases and medical conditions. Other biologics are used to prevent or diagnose disease.

These medicines often represent cutting-edge research in which the latest scientific discoveries are translated into novel therapies that provide new treatment options for patients. Increased understanding of the molecular and genetic bases of disease has opened up the development of a range of targeted treatments.

Biologic Medicines in the Pipeline
Over the past decade, biologics have accounted for one-third of new medicine approvals. Key biologic medicines approved in the last decade include:

1. The first genetically engineered antibody approved to prevent the formation of new blood vessels that provide tumors with oxygen and nutrients—a process called angiogenesis. The medicine was approved for the treatment of metastatic colorectal cancer.

2. A first-in-class human monoclonal antibody that targets the cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23). IL-12 and IL-23 are naturally occurring proteins that are believed to play a role in the development of psoriasis.

3. A recombinant vaccine for the prevention of infection by human papillomavirus (HPV), which can lead to cervical and other cancers.

4. The first in a new therapeutic class called autologous cellular immunotherapy, approved for the treatment of metastatic, castrate-resistant (hormone-refractory) prostate cancer.

5. The first in a new class of antibody-drug conjugates (ADC) which utilizes a monoclonal antibody to target a therapeutic drug to cancer cells. It was approved to treat Hodgkin lymphoma and systemic anaplastic large cell lymphoma (ALCL), a rare type of non-Hodgkin lymphoma.
The Importance of Protecting Intellectual Property

The development of new biologics is a long, complex and costly endeavor. It takes about 10–15 years, on average, to bring a medicine through the discovery and clinical trial phases to patients, and, according to a 2007 study, the average R&D investment for each new medicine is $1.2 billion, including the cost of failures— with more recent studies suggesting an even higher costs. To recoup their investment, America’s biopharmaceutical companies rely on strong data protection—a specific period of time during which a biosimilar manufacturer cannot rely on data generated by the innovator to obtain marketing approval.

Strong protection for patents, copyrights, trademarks, trade secrets, and regulatory data allows our country’s top inventors to maintain their innovative advantage. In order to realize the full potential of biologics, it is essential that the U.S. maintain policy and regulatory environments that help foster the discovery and development processes.

Protecting data exclusivity, domestically and abroad, for biologics is critical to:

1. **Encourage further investment in biomedical innovations and save lives.** There are currently 907 biologic medicines in the pipeline to treat diseases such as Alzheimer’s disease and cardiovascular disease. Many of these are also being developed to address rare diseases that currently have no treatments or cures. Strong data protection, such as the current 12 years of exclusivity, provides U.S. biopharmaceutical companies a fair incentive to start or continue their important work on these promising therapies. Without these protections, companies will be less likely to participate in this life-saving research.

2. **Preserve the economic impact of a critical industry.** In 2009, every direct job in the biopharmaceutical sector supported 5 jobs in other sectors; the sector supported a total of nearly 4 million jobs across the economy. Additionally, the biopharmaceutical industry invests billions of dollars in research and development each year, and accounts for nearly 20 percent of all domestic R&D funded by U.S. businesses, generating high-quality, high-wage jobs, contributing to the U.S. economy, and developing critical new treatments for diseases.

A pathway for the approval of biosimilars in the United States was included in the Patient Protection and Affordable Care Act of 2010. The pathway, which received broad bipartisan support in both chambers of Congress, struck an appropriate balance between promoting increased competition and providing adequate incentives to support continued innovation of new treatments and cures through a 12-year period of data protection. This is critical to spurring the investment in research and development needed to seize the extraordinary opportunities for medical advances against our most costly and challenging diseases and the resulting jobs supported across the U.S. economy.

The collaborative ecosystem that exists in the United States between the government, academia, and biopharmaceutical companies is among our greatest strengths in moving medical advances forward and has helped position the United States as the worldwide leader in biopharmaceutical innovation.