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[drugpricing@ita.doc.gov](mailto:drugpricing@ita.doc.gov)

Kristie Mikus  
Department of Commerce  
14th and Constitution Avenue  
Room 4039  
Washington, D.C. 20230

**RE: Comments for the Department of Commerce's Consideration for its Report of Trade in Pharmaceuticals.**

In response to the International Trade Administration's request for stakeholder input, the Biotechnology Industry Organization's ("BIO") comments focus on the impact that price controls and intellectual property laws have on international fair pricing systems, innovation and research and development ("R&D"). BIO appreciates the opportunity to submit the following comments.

**Background**

There are over 1,400 biotechnology companies in the United States employing more than 190,000 people. The industry has produced an estimated 200 biotech drug products and vaccines helping more than 325 million people worldwide. The biotechnology industry depends on scientific research; spending more than \$20.5 billion on research and development in 2002, with the top five companies expending an average of \$101,200 per employee on R&D. Biotechnology is responsible for hundreds of medical diagnostic tests, ranging from maintaining blood safety to home pregnancy testing. The biotechnology industry is also a dynamic one as Erythropoietin, Herceptin<sup>®</sup> and Xigris<sup>®</sup> have revolutionized the way patients with cancer and other chronic diseases are treated.

While excited about these accomplishments, the biotechnology community knows that this is just the beginning with many more revolutionary products in the pipeline. The biotechnology industry is one of the most innovative industries and an essential player in a growing economy. BIO members have developed and will continue to develop products that have great impact on patients and consumers. However, these

1225 EYE STREET, N.W., SUITE 400  
WASHINGTON, D.C. 20005-5958

202-962-9200  
FAX 202-962-9201  
<http://www.bio.org>

accomplishments are the result of the disproportionate contribution of patients residing in the United States as over 80% of R&D costs are absorbed by patients in this country as a result of certain international pricing policies. This unsustainable model must be changed and BIO looks forward to working with the Department of Commerce to convince the members of the Organization for Economic Cooperation and Development (“OECD”) to contribute their fair share to R&D costs by loosening price restrictions.

### **Strong Intellectual Property Laws Promote Innovation**

Biotechnology companies operate in a complicated environment balancing funding requirements, solving scientific research challenges and complying with federal intellectual property laws, particularly patent law. Patent law provides the innovator exclusive rights to sell their product recouping initial investments and making a profit. Therefore, patent law protections serve as a stimulus for innovation and investment because inventors know that patent law protections will ensure a return on their personal and financial investment in a successful product.

Indeed, many start-up biotechnology companies have been created based solely on the promise of their patent estates. The vast majority of biotechnology companies do not have products on the market; rather, they have only patents on what may eventually become a commercially viable product or technology. Intellectual property laws protect the assets that entice investment for further innovation of a promising technology or product. The capital generated as a result of this intellectual property supports companies as they invest the hundreds of millions of dollars and the decades necessary to develop a commercial biotechnology product.

But other nations are not as enthusiastic as the United States about the benefits of intellectual property protections. Therefore, many countries are not strong proponents of these rights, and they allow these rights to be greatly compromised. This systematic weakening of intellectual property protections in the international arena contributes to the continued exodus of foreign based biotechnology companies. The strong protective patent laws are one reason why the United States is the world’s biotechnology leader.

Confidence in the patent system by the innovation sector, the investment community and the consuming public is especially important. The United States government has recognized the value of intellectual property protection and has done much to provide the essential strong domestic intellectual property protections for biotechnology inventions. In turn, these strong intellectual property laws promote innovation.

### **Strong Intellectual Property Laws Promote Research and Development**

The average cost of developing a single biopharmaceutical can exceed \$800 million and take 10 to 14 years. Approximately 98 percent of this initial capital comes from the private sector. The flow of private capital is greatly affected by threats to domestic and international intellectual property rights. Strong domestic intellectual property laws encourage R&D; whereas, weak international IP laws open the door for the foreign

companies to expropriate innovative biopharmaceuticals discouraging R&D in foreign markets. Foreign-based companies can inexpensively replicate innovative biotechnology products in countries with weak patent systems to avoid the massive R&D costs incurred by U.S. companies. Therefore, strong intellectual property laws provide necessary protections for investors to fund expensive initial R&D costs.

### **Fair Pricing (Price Controls) Weaken Intellectual Property Laws**

Certain members of the OECD use a “fair pricing” system to institute governmental price controls on pharmaceutical products sold in their country. Basically, each OECD country sets the price or price range that a manufacture must abide by in order to sell their product in that country. This price setting mechanism eviscerates patent law protections because it removes the innovators’ ability to establish their own price for their product. Patent laws allow and provide the innovator the exclusive right and necessary protections to determine the economic outcome of their invention. This right is an essential aspect of patent law and is the engine that drives innovators. However, government instituted price controls remove this fundamental right from the innovator as the government determines a drug’s price and removes any input from the innovator or manufacturer.

BIO supports world-wide strong and predictable intellectual property law, especially patent protections. Strong intellectual property law protections serve as the impetus for innovation and its absence via price controls will chill scientific exploration.

### **Price Controls**

For several years, international pricing differentials for drugs and biologics have been a highly contested subject in the policy arena and marketplace. Various studies comparing drugs show that patients in America pay a disproportionately higher cost for drugs than international consumers because of international price control systems. For example, in France and most EU countries, specific authorities set prices for pharmaceutical products, creating formal price controls. Similarly, Canadian drug prices are set by a government body. Germany’s price control system is more complex, albeit hardly less dominant: some drug prices must be discounted by a fixed amount while others are subject to a reference pricing system.

The United States does not have price controls, drugs are priced based upon an open market system. Therefore, manufacturers are forced to recoup their expensive R&D costs in America’s free market. Thus, patients in the United States subsidize the R&D costs of foreign countries’ price controls.

BIO is concerned that foreign price controls prevent the market from reflecting the true value of drugs. BIO believes that if foreign countries would allow drug prices to reflect the true value of drugs, a free and open market will adjust accordingly. BIO strongly supports efforts to remove artificial price controls in other countries so that the prices reflect the true value of medicines.

## **Price Controls Stunt Innovation**

The biotechnology industry is a growing creative force on the U.S. economic landscape. The industry provides many jobs and a thriving tax base for communities throughout the country. National and state policies encourage biotechnology innovation and foster the growth of the industry because innovators know that the free market system allows them to recoup start-up costs. These domestic policies provide an economic boost and a fertile ground for the development of treatments and cures. Biotech innovation has led to the development and FDA approval of more than 200 products that have helped at least 325 million people worldwide. Policies such as price controls stunt innovation because they stymies the innovator from recouping initial costs and therefore will slow or end scientific progress.

BIO urges other countries to amend their own policies to promote innovation and balance the price of pharmaceuticals in the marketplace. This initiative will provide a better solution than seeking to impose domestic price controls with the corresponding delays and market distortions that will stunt the innovator's desire to develop new and revolutionary therapies.

## **Price Controls Chill Research and Development**

Investment in the U.S. biotechnology industry is based on an expectation that a product's success will reap benefits not only for patients but also for future industry projects and investors. The vast majority of biotechnology companies across the United States are small companies with no products on the market and without significant revenue or profits. To fund costly and lengthy periods of R&D, biotechnology companies rely heavily on three primary sources of capital: (1) private (i.e., institutional or venture investors); (2) public (i.e., the stock markets — mutual fund investors and individual investors); and (3) capital obtained from partnerships with other companies.

The capital markets are acutely sensitive to factors that threaten to limit current or future profitability for any company or industry sector. We see examples of this on a daily basis: if a public company unexpectedly announces an event that could adversely impact future earnings, the stock price plummets, resulting in millions, sometimes billions, in lost market value. Frequently, depending on the nature of the event, an announcement by one company also will have a negative effect on other stocks in the same sector, because of the fear that something similar could happen to those companies. Broader pronouncements that threaten to limit the profitability of an entire sector have even greater significant adverse consequences.

To illustrate this phenomenon, one need only recall the early nineties, when the call for widespread health-care reform with government price controls caused a precipitous decline in health-care stocks, in aggregate valuations, and in the subsequent flow of investment capital into the health-care sector. It is worth remembering that this tide was reversed only when the threat of price controls subsided. Another example of the capital markets' quick response to a perceived threat to future profitability was the Clinton-Blair

gene patent pronouncement, when a misstatement by a White House press secretary caused the immediate loss of billions of dollars in market value for the biotech industry. There was no policy change, yet the bottom fell out of the biotechnology market as stock prices plunged within a few hours.

Biotechnology development is an extremely high-risk venture. Of the many wonderful ideas this creative industry generates, only a small handful result in FDA-approved new products. Our member companies are dedicated to finding the next biologically based treatment or cure. They are willing to devote enormous energy, creativity, and resources to this endeavor, even though they know success is difficult and elusive. This research and development cannot be undertaken without the commitment of substantial financial resources, most of which come from the highly sensitive capital market that will be significantly limited under a price control system.

### *The Orphan Drug Act*

Price controls will have a disproportionate effect on products designed for orphan diseases, which are important to many BIO members and the patients they serve. Even a free market economy could not provide enough economic incentives for the development of orphan drugs. Congress recognized this market place insufficiency and enacted the Orphan Drug Act to create incentives, via tax breaks and market exclusivity, for the development of treatments for rare diseases. Consequently, many orphan products were developed improving the lives of thousands who suffer from rare diseases. Implementing price controls will completely reverse the positive effects of the Orphan Drug Act. Without the proper economic incentives, scientists and investors will not dedicate resources to discovering cures for rare diseases.

### **Conclusion**

United States companies depend on the free market system and strong intellectual property laws to recoup their R&D investment. Without the potential to recoup initial investment, investors will not support innovators and scientific research will suffer significantly. If the United States does not sustain a free market approach—if companies are repressed by inadequate intellectual property laws and restricted by price controls—financing of biotechnology R&D will fade to less risky and resource-intensive endeavors choking the development of the next generation of miracle cures.

Sincerely,

/s/

Michael Werner  
Chief of Policy  
Biotechnology Industry Organization