JOBS TODAY: CURES TOMORROW
INNOVATION AND THE PHARMACEUTICAL INDUSTRY

Introduction

Our nation's biopharmaceutical industry is vital to the personal health of our people and the economic health of our country. The unions and companies of the Pharmaceutical Industry Labor-Management Association (PILMA) recognize that, especially in the current economy, America needs a sustainable and growing biopharmaceutical industry. Directly and indirectly, our industry provides jobs for 3.2 million people who live in all 50 states. But, without changes to our nation's trade- and industry-related policies, these jobs may ultimately be moved overseas, where policies are friendlier.

Such a loss would be a blow to the economy, but it would mean an even worse fate for Americans' health care and quality of life. The industry's biopharmaceutical research creates treatments that reduce the need for hospitalizations, and lessen the length and intensity of rehabilitations. But, perhaps most importantly, our industry provides hope for patients whose lives depend upon our discovering breakthrough treatments, and we must remain mindful of preserving — and even improving — patients' access to them.

Over the last 10 years, more than 300 new medicines have been approved by the U.S. Food and Drug Administration (FDA). These medicines are helping people live longer, healthier lives. They are transforming many kinds of cancer into treatable conditions, reducing the impact of cardiovascular disease, offering new options for patients with such hard-to-treat diseases as Alzheimer's and Parkinson's, and fighting even the rarest conditions.

> "Many examples exist of major therapeutic gains achieved by the industry in recent years … anecdotal and statistical evidence suggests that the rapid increases that have been observed in drug-related R&D spending have been accompanied by *major therapeutic gains* in available drug treatments."
>
> — Congressional Budget Office, 2006

New medicines have been credited with advances in treating a variety of diseases:

- Disabilities among seniors have been reduced, and the chances of an elderly patient surviving a cardiovascular disease event have increased by 50 percent.[1]
- Nine of the 12 major treatment innovations the American Society of Clinical Oncology identified as being important "to the way cancer is understood or had an important impact on patient care" were "related to new medicines, better ways to use existing medicines, or newly discovered benefits or approved medicines."[2]

- For a 2008 study on rheumatoid arthritis the "primary outcome was to achieve actual clinical remission of disease activity, rather than an incremental percentage improvement in a standard outcome measure — a primary outcome that would have been unthinkable in the 20th century."[3]

- A 2009 review reported, "Protein enzymes, receptors, or channels identified by the pharmaceutical industry as 'drugable targets' have led to striking, remarkable, and repeated achievement."[4]

These are but a few of the creative innovations that have helped improve health, prevent diseases, and save lives. The men and women of PILMA, who work at jobs within America's biopharmaceutical industry, are proud to play a vital part in supporting these health achievements. And, we know our industry can continue to lead the world in discovering and manufacturing future breakthroughs. But, we also know that unless there is a sustained commitment to strategic investments and policies, global leadership will be ours to lose.

We must ensure that we prevent other countries from using their friendlier economic and tax policies to entice American biopharmaceutical companies to relocate overseas. Further, since we are in an environment where tax revenues are a central focus of policymakers, we must guard against tax policies that would diminish or erode our already fragile competitive position. We believe America's global leadership position will be in danger unless we establish policies that encourage sustained innovation and growth.

"Scientifically, we have never been in a better position to advance cancer treatment. … We now understand many of the cellular pathways that can lead to cancer. We have learned how to develop drugs that block these pathways. And increasingly, we know how to personalize therapy to the unique genetics of the tumor, and the patient."

— Richard L. Schilsky, MD
President, ASCO

SOURCE: American Society of Clinical Oncology, "Clinical Cancer Advances 2008: Major Research Advances in Cancer Treatment, Prevention and Screening," *Journal of ClinicalOncology,* 22 December 2008.

Currently, the playing field is not level between America's biopharmaceutical industry and its global competitors. But we need to do more than just make the field level; we must tilt the field to our advantage, so that America's biopharmaceutical companies will stay here, providing jobs and health solutions.

The industry directly provides hundreds of thousands of good paying jobs for America's working families. To retain those jobs — or even to create new ones — the success and growth of the industry's basic research efforts, as well as innovations in effective treatments and associated technology advancements, must remain in the U.S., where they contribute mightily to our nation's future economic growth and international competitiveness.

Competitiveness

Medical innovations in general and biopharmaceutical advancements in particular, have traditionally been drivers in the knowledge-based economy. The U.S. maintains global leadership in biopharmaceutical development,[5] in part because of the American biopharmaceutical industry's research and development achievements, but also because American biotechnology employment represents more than half of all such jobs worldwide.[6] Clearly, if steps aren't taken to maintain this leadership position, good jobs and the health of the American people are at stake.

While the biopharmaceutical industry is firmly positioned to continue its contribution to America's economic growth and health, other countries are offering strong challenges to America's preeminence. Other countries' dramatic growth can be inferred from their domestic research and development expenditures, their share of new U.S. patents, and the number of new doctorates in science and engineering being awarded to their citizens. A recent study found that the U.S. ranked last among 40 countries and regions when it comes to progress made over the last decade toward the "new knowledge-based innovation economy." In terms of overall competitiveness, the study ranks America sixth, behind Singapore, Sweden, Luxembourg, Denmark and South Korea.[7]

Our need to address global competition for innovation is noted in the Obama Administration's National Economic Council report, "A Strategy for American Innovation: Driving Towards Sustainable Growth and Quality Jobs," which states: "We must redouble our efforts to give our world-leading innovators every chance to succeed. We cannot rest on our laurels while other countries catch up."[8]

New medicines are one area identified by the administration as addressing the "Grand Challenges of the 21st Century" and helping "improve our quality of life and establish the foundation for the industry and jobs of the future."[9] Included in the report as examples are[10]:

- Smart anti-cancer therapeutics that kill cancer cells and leave their normal neighbors untouched;
- Nanotechnology that delivers drugs precisely to the desired tissue;
- Personalized medicine that enables the prescription of the right dose of the right drug for the right person;
- A universal vaccine for influenza that will protect against all future strains; and,
- Regenerative medicines that can end the agonizing wait for an organ transplant.

As the National Economic Council states, "Other countries understand that innovation is fundamental to their economic well-being and are finding new ways to advance their innovation agendas." Innovation is the key to global competitiveness, new and better jobs, a resilient economy, and the attainment of essential national goals."[11]

A review of our competitors' efforts testifies to the challenges we face:

China

In May 2009, China's State Council approved policies to foster its biotechnology sector investment. The pro-biotechnology policy guidelines include enhancing government financial support, establishing national hubs, and improving intellectual property protection. China's National Development and Reform Commission also launched 20 venture capital funds, in partnership with seven provincial governments, to develop China's burgeoning technology sector. Biomedicine is one of the primary sectors targeted by these funds.[12]

Additionally, the Chinese government has earmarked about $9.2 billion for new technology, including biotechnology, to stimulate economic growth.[13] The government's investment is "in line with the government's increasing support to drug innovation in China."[14] The biotechnology sector was one of five sectors identified by the Chinese government as key to the nation's economic growth.[15]

A recent RAND study also notes that fostering research and development (R&D) in biopharmaceuticals and nanotechnology may help China provide more effective medical treatments to improve public and individual health, bolster its national R&D policies, improve modern traditional Chinese medicine, and enhance the nation's capabilities for inventing and producing new drugs.[16]

India

The government of India wants to make sure biopharmaceutical companies have everything they need to encourage them to shift operations to India, which is building more than 20 biotechnology parks throughout the country,[17] and allocating about $1.7 billion over 5 years to grow the nation's biotechnology industry.[18] According to Burrill & Company, the Indian government's "major revenue generator" for 2008 was the biopharmaceutical sector.[19]

Singapore

According to the Singapore Economic Development Board, "Singapore aims to capture a share of the fast growing global biotech pie."[20] In 2008, Singapore's biomedical sciences industry output grew by 33 percent, to reach $9.4 billion.[21]

Singapore's vision is to be "the biopolis of Asia," which is described as "an international biomedical sciences cluster advancing human health." In 2003, the government of Singapore unveiled a 46-acre bioscience complex called Biopolis. The

$328 million development project, along with $1 billion in funding for translational research, has helped Singapore recruit major pharmaceutical companies and Western scientists.[22]

United Kingdom

The U.K. is following an announced strategy to become a global leader in life sciences (including biopharmaceuticals) by attracting foreign companies.[23]

"The life sciences is a global business and companies take a global view when choosing where to locate activity and jobs. … Only by making the most of its strengths will the U.K. be able to achieve its vision for a diverse and integrated life sciences sector that sustains high-value-added employment, drives economic growth, and improves well-being."[24]

They have already established an Innovation Investment Fund, which, along with private sector investment, aims to build an estimated $1.6 billion 10-year venture capital fund.

They have also created the "Innovative Medicines Initiative" with approximately $2.9 billion in funding "to find solutions to overcome research bottlenecks in the drug development process"[25] in collaboration with biopharmaceutical companies.

France

In 2009, the French government launched its Strategic Investment Fund — which totaled about $8.7 billion — in partnership with the biotechnology industry to promote growth of the French economy. They have also created a collaborative approach with biopharmaceutical firms to foster the creation and development of new innovative biotech firms that find it difficult to raise funding from other sources.[26]

The government will team with France Biotech (the country's professional association for life sciences companies) to aid life sciences companies. Philippe Pouletty, president of France Biotech, stated that without the investment fund to aid life sciences companies "France cannot have economic growth."[27]

Germany

Germany's Federal Ministry of Education and Research (BMBF) created a Pharmaceuticals Initiative to give new impetus to Germany's biotechnology and pharmaceuticals industries. The initiative seeks to fund entrepreneurial biotech research teams with a sound business plans.[28] Germany is also home to a number of bio-clusters, which formed as a result of the BMBF and the private sector's partnering to encourage new competitive bio-industry hubs.[29]

In addition, Germany has established four multi-institute centers to conduct research and drug discovery work. To ensure that promising discoveries made in academic

settings are transmitted to industry, several technology transfer institutions have also been organized.[30]

Australia

The Australian government increased its annual budget for science and innovation by 25 percent.[31]

Australia has eight Cooperative Research Centers working in various areas of medical science and technology, and matching publicly-funded researchers with private companies. The National Health and Medical Research Council currently funds 23 Centers of Clinical Research Excellence throughout the country.[32]

Recently, Australia was ranked first as an attractive clinical trials location, based on lower costs compared to other countries, due to the large number of recognized trial sites, and the ability to complete the majority of clinical trials within the allocated time.[33]

Brazil

In 2007, the Brazilian government outlined its National Policy for Biotechnology, a development policy for the biotechnology industry aimed at making Brazil a global leader in the sector in 10 to 15 years. The plan calls for investments of $5.8 billion over the next decade.[34]

The Brazilian Ministry of Science and Technology has also launched strategic programs to support research projects, development, and innovation in Brazil.[35] Further, Brazil created a Biotechnology Sector Fund to fuel investment into its biotechnology and biopharmaceutical sectors. The fund has invested resources in the organization of genome networks and biotechnological projects relevant to health and agriculture.[36]

Mexico

The Mexican Congress created the National Institute of Genomic Medicine to expand Mexico's participation in the development of the personalized medicine field, as well as genomic medicine.[37] Mexico provides one of the most favorable tax treatments for R&D through its Organization of Economic Cooperation and Development, with one unit of R&D expenditure resulting in 0.37 units of tax relief.[38]

America must similarly support innovation and strengthen our global competitiveness. We need to find ways to give stability to the biopharmaceutical innovation development process, encourage investment, protect intellectual property rights, and encourage free and fair trade.

Many states have created strategic plans to strengthen their capacity to maintain and compete for future biopharmaceutical jobs.[39] Frequently crafted within a broader overall

strategy, including life science innovations, these efforts demonstrate both richness of approaches and the need for a coordinated national policy. The states are competing with other countries that have national recruitment and development policies.

The experience of California is a prime example of the current scene.

California is the birthplace of biotechnology, and the state's biomedical innovation delivers not only global advances in health care, but the accompanying jobs that drive our economy. While the biomedical industry has weathered the recession, it faces unprecedented challenges, with access to capital, the educational funding crisis, and uncertainty surrounding health care reform. Now, more than ever, the sustainability of California's biomedical industry depends on decisions made in Sacramento and Washington. [40]

Intellectual Property Rights

Intellectual property (IP) rights protections are essential for maintaining and improving America's position within the global, knowledge-based economy. A recent study contrasted the importance of intellectual-property intensive industries (IPIs) with non-intellectual property intensive industries (non-IPIs), in terms of innovation, job creation, and exports. The study concluded that IPIs[41]:

- Created jobs and spurred economic growth due to high investments in R&D;
- Spent nearly 13 times more than non-IPIs on research and development per employee, driving innovation;
  - *The pharmaceutical sector, an IPI, is a leader as an economic engine, alone spending more than 10 times the average in research and development expenditures across all sectors.*
- Were more resilient, recovering more quickly from economic downturns and driving U.S. global competitiveness, with exports at more than three times the rate of non-IPIs.
- Averaged $91,607 in exports-per-employee between 2000 and 2007 — more than three times the average for non-IPIs.

According to one expert, American intellectual property is worth between $5 trillion and $5.5 trillion, and is "one of America's competitive strengths that must be defended at all levels, domestically and globally."[42]

Intellectual property is protected in the U.S. not only by patent protections but also through data exclusivity. These safeguards on intellectual property are complementary.

Data exclusivity is critical for ensuring continued research and development advances throughout the biopharmaceutical sector, but specifically in the field of new and innovative biologics.

Data exclusivity prevents competitors from obtaining and relying on an innovator's clinical trial results on drug safety and efficacy that were used to obtain FDA approval during a specified period of time. Patent protections complement the innovative protections afforded through data exclusivity by preventing others from producing and selling a copy of the patented product. Both are necessary to provide an adequate incentive for innovators to invest the time and resources in developing new biopharmaceuticals.

More medicines are in the development pipeline in America than in the rest of the world combined, nearly 3000.

SOURCES: U.S. Food and Drug Administration, Office of Orphan Product, "Cumulative List of Designated and Approved Orphan Products" (Washington, D.C.: FDA, 4 October 2007), www.hhs.gov/orphan/disignat/allap.rtf; B. Silverman,"FDA First-Cycle Approval Rate is silver Lining in Cloud of Low NME Count," The Pink Sheet 70.no.2 (14 January 2008); and, B. Silverman, "Year in Review: New Biologics Total Seven in 2007, But Only Four Will See Market," The Pink Sheet 70, no.3 (21 January 2008). Food and Drug Administration, www.fda.gov.

Because of the complex nature of new products being developed, traditional patent protections are no longer sufficient to protect the intellectual property of innovators. In order to foster continued development and ensure the right incentives for innovation, manufacturers in the research-intensive biopharmaceutical sector must be able to rely on the certainty afforded to them through data exclusivity, as well. These two protections are not mutually exclusive, but rather genuinely complementary. They provide certainty upon which research-based companies can rely as they decide to invest significant sums of money and years of effort to discover and manufacture new products.

As a nation, in order for us to sustain a healthy research commitment to the innovative biopharmaceutical industry, there must be significant intellectual property protections. America's workers and their families depend on the progress of biopharmaceutical innovations for both their personal health and the good paying jobs that research and manufacturing provide. We must work to ensure that exclusivity rights are not eroded.

In 2009, PILMA passed a resolution calling on Congress to pass legislation to strengthen intellectual property protections for innovators by providing for 12 years of data exclusivity for innovator biologics. Congress heard our call, and as part of health care reform, passed a provision that will provide certainty for innovators and encourage the right incentives for future innovation.

IP protections and their enforcement ensure inventors and innovative companies that their investments in time, money, and human capital will be protected if they are successful, and that they will have the opportunity to earn a potential return on their investment. For the biopharmaceutical sector, investments in R&D require certainty, security, and predictability, as well as a clear and stable legal environment.

Reforming the patent application and approval process must protect the integrity of the system and ensure appropriate exclusivity for creators, so that their creations may drive innovation and create jobs. We must be vigilant that America's patented innovations are protected and strengthened. The biopharmaceutical industry is among the most advanced technological sectors in the world economy, and is heavily dependent on strong, vigorously enforced intellectual property rights as a means to balance the substantial risks involved in R&D with the promise of appropriate rewards for success. Unless such rights are protected from infringement, we are in danger of losing one of America's foremost industries.

Other countries are studiously observing our developing patent reform policy. We need to be careful that we don't improve our competitors' positions rather than strengthening our own. Public policy changes that would allow public access to patented information early in a patent's protected period, coupled with early non-court-based patent challenges, would facilitate international competitors' challenges of our patent rights. Further, such action would be costly and tie up the patent holder with challenges during a substantial portion of the use-and-sell period.

President of the Manufacturing Policy Project and noted economist Pat Choate points out, "As to the question of whether such legislation would strengthen or weaken the capacity of the patent system, technology writers at the *India Times* and the former Chief Judge of China's patent courts have independently concluded that the proposed legislative changes would make infringement easier and less costly. Many U.S. analysts, including me, agree."[43]

Today some have calculated that patent infringement is an acceptable cost of doing business; the cost of a civil fine or legal settlement is worth the business revenue generated. Referred to as "breach theory" or "efficient infringement," such practices undermine the integrity of our inventors' intellectual property. We must find ways to strengthen patent protections and their enforcement. [44]

The "2010 Joint Strategic Plan on Intellectual Property Enforcement" offers hope for America's workers and their families. It provides significant insight into the problems involved in enforcing intellectual property rights, and offers several policy recommendations to address them. A letter to President Obama and Congress transmitting their report sums up the issues[45]:

> *Intellectual property laws and rights provide certainty and predictability for consumers and producers in the exchange of innovative and creative products, and for investors shifting capital to their development. Where there are insufficient resources, ability, or political will to appropriately enforce these rights, exchanges between investors, producers and consumers may be inefficient, corrupt or even dangerous.*

In a knowledge-based globally competitive economy, the enforcement of intellectual property rights is critically important. The Joint Strategic Plan further identifies the fundamental reasons underlying the need to strengthen enforcement[46]:

- Growth of the U.S. economy, creation of jobs for American workers and support for U.S. exports;
- Promotion of innovation and security of America's comparative advantage in the global economy;
- Protection of consumer trust and safety;
- National and economic security; and,
- Validation of rights, as protected under our Constitution

The policy recommendations offered are comprehensive and pragmatic, from calling for U.S. government officials and contractors to lead by example — by purchasing products and services that do not infringe on IP protections — to coordination of U.S. federal, state, and local enforcement efforts, with particular focus on counterfeit biopharmaceutical and medical products.

Recommendations also include enforcing our rights internationally by using trade policy tools and working in cooperation with foreign law enforcement and other international organizations, and, in cooperation with our private sector, securing our supply chains against counterfeit products.

PILMA Supports …

> *Wide dissemination of the interrelated, complex problems that are inhibiting effective support for our intellectual property rights and the laws that protect them, as identified in the 2010 Joint Strategic Plan on Intellectual Property Enforcement*

> *Monitoring and enforcing IP obligations under international trade rules, including bilateral and regional free-trade agreements and multilateral agreements, such as the World Trade Organization Agreement*

Similar IP issues in other industries also affect American jobs. For example, the AFL-CIO recently issued a statement detailing the harm done to U.S. workers in the entertainment industry through the piracy of copyrighted works and the sale of illegal CDs and DVDs. Billions of dollars are lost each year, resulting in reduced industry activity, lost jobs, and lost compensation and benefits.[47]

But, as the AFL-CIO points out, "Intellectual property right infringement by our trading partners isn't limited to movies, music and other copyrighted products — it affects all sectors of our economy."[48] The organization points out that "counterfeit goods flood world markets, depriving us of the sales necessary to maintain good wages and benefits. In addition, we've seen substandard counterfeit products sold overseas and here that jeopardize the health and safety of people in all countries."[49]

Further, "Our domestic manufacturing sector is among the most innovative in the world. … Strong intellectual property rights protection is vital to ensure that our companies are willing to make the capital investments in plant and equipment here in America to create good jobs."[50]

When a biopharmaceutical company seeks FDA approval of a new drug, it receives intellectual property rights protection in the form of a period of time during which the company has exclusive rights to safety and efficacy data, called "data exclusivity." Data exclusivity prevents other manufacturers from using an innovator's data to gain FDA approval for one of their products. And, it encourages investment in the research and development of new drugs.

Without such protection, the financial incentive to invest in R&D is lost, as are innovation and jobs. Why would an innovator company invest funds and effort in the development of new products if they had to turn over their research results to others immediately, without benefit of an adequate period of property-rights protection?

Importation

There are serious well-documented concerns related to the quality, safety and efficacy of unregulated, illegally imported biopharmaceuticals into our country.[51]

The Partnership for Safe Medicines, of which PILMA is a member, has detailed the health problems resulting from illegally imported medicines and provided educational programs across the country and around the world on how patients, providers, and government officials can protect the supply chain. One expert says "the continuing trade in counterfeit products results in the loss of hundreds of thousands of jobs annually."[52]

To be clear, counterfeit medicine is fake medicine. It may be contaminated or contain the wrong or no active ingredient.[53] The Partnership for Safe Medicines offers a concise answer to how counterfeit drugs can be dangerous, in the organization's *Principles for Drug Safety*.[54]

Not only do counterfeit medicines defraud consumers, they deny patients the therapies that can alleviate suffering and save lives — and in too many cases, counterfeit drugs cause great harm and fatalities. They can cause allergic reactions or heavy metal

poisoning, and they can promote drug-resistant strains of diseases. These fake medicines may consist of anything from chalk or powdered concrete to boric acid (or worse), and are sold as if they were real medicines. Because counterfeiters are very good at making their product look like the real thing, it is easy to confuse these harmful products with the real thing. This issue has even attracted the attention of the White House, with Vice President Joe Biden recently noting that "we need to protect our citizens from unsafe … counterfeit pharmaceuticals that put lives at risk."[55]

And, the situation is getting worse. A report by the Center for Medicines in the Public Interest projects counterfeit drug sales to reach $75 billion in 2010, nearly doubling 2005 sales.[56] "The business of selling fake prescription drugs to unsuspecting consumers is burgeoning, and is a global industry. This underground industry represents a major public health risk for citizens of the world,"[57] the organization said.

In fact, among European Union countries, counterfeit medicine seizures more than doubled in 2008, with nearly 9 million medicine articles seized.[58]

As we seek opportunities to address the counterfeiting of medicines, it is important to distinguish such efforts from protection of intellectual property rights. Counterfeiting and delivering counterfeit medicines involves illicit manufacture and illegal sales by unregulated sellers. It's a crime of a far greater magnitude than trademark violations involved in the sale of counterfeit handbags or watches. The personal and public health issues of medicines set them apart.

While we must address these health issues, we cannot ignore the major impact illegal importation has on both our national economy and on job security among American biopharmaceutical industry and workers.

America has a vibrant yet potentially fragile innovation-centered biopharmaceutical industry. Importation of price-controlled products sets up a severely negative situation. Yet, price controls on foreign manufactured products are continuing and growing, and our incentive to innovate trails our competition. Noël Renaudin, an official in France's health ministry, has a tough message for the pharmaceutical companies: "We have to stop the infinite growth in prices for drugs."[59]

These pricing pressures can be witnessed in countries around the globe. This year, Greece unilaterally imposed a 25 percent price cut on two pharmaceutical companies' medicines, sparking a boycott. Britain imposed an average price cut of 5 percent in 2009, and the new Conservative-Liberal Democrat coalition has signaled fresh price controls are on the horizon. Germany has proposed mandatory rebate increases on patented medicines from 6 to 16 percent. Spain plans 10 to16 percent price reductions for patented products. And, Greece instituted cuts of 20 to 27 percent on patented medicines, with prices similar to other countries.[60]

The list goes on: Ireland recently reduced generics' prices by up to 40 percent. Denmark and Sweden have introduced their price control approaches. And, a recent research note by Citi predicted "5 to 10 percent drug price cuts in Europe's five largest economies." Many European countries link medicine prices to those established by their neighbors, "a cut by one government can quickly translate into reductions elsewhere."[61]

The American biopharmaceutical industry invests heavily in R&D — spending an estimated $65.3 billion in 2009 alone[62] — in its effort to discover, test, and develop new medicines, but only a small portion of products obtaining FDA approval actually make it to the market.

"Only one of every 10,000 potential medicines investigated by America's research-based pharmaceutical companies makes it through the research and development pipeline and is approved for patient use by the United States Food and Drug Administration. Winning approval, on average, takes 15 years of research and development and costs over $1.3 billion dollars per drug."[63]

With appropriate investment incentives and protections of intellectual property rights in patents and data exclusivity, profits can be made. Introduce a *de facto* price control mechanism in the form of price-controlled imports, and the revenue picture turns grim quickly. The innovation-investment process dries up, and quickly, jobs are lost.

There is another significant benefit to having a strong biopharmaceutical industry R&D presence in America. Successful clinical trials are an essential part of the FDA approval process. Thousands of Americans with severe advanced stage health problems have gained early access to potential breakthrough treatments because of their participation in clinical trials.

Trade

America must insist on free trade that is fair trade. Trade policies are major determinants of the competitiveness of Americas' biopharmaceutical industry. We cannot allow the continuation of trade policies that have hampered, and ultimately destroyed, other industries, such as steel, automobiles, and textiles.

The Trade-Related Intellectual Property Aspects (TRIPS) portion of the World Trade Agreement is a minimal building block of what should be included in negotiations of pending free trade agreements. Yet, despite the existence of TRIPS and the availability of dispute resolution panels operated by the World Trade Organization, within the last decade, the U.S. has only filed two intellectual property cases. This is despite annual reports by the Office of the U.S. Trade Representative listing numerous violations of American intellectual property rights. Clearly, more aggressive attention is needed.

As the AFL-CIO states, “we need to strengthen and effectively enforce our trade laws so when foreign governments and companies engage in anti-competitive trade actions they are held accountable, so America’s workers and businesses can compete fairly on a level playing field. We must ensure that WTO negotiations and actions do not undermine our ability to use our trade laws effectively.”[64]

There is a significant fairness problem in our free trade arrangements with other countries. Other nations do not accept and treat direct taxes in the same manner as they do indirect taxes. The Value-Added Tax (VAT), imposed by other nations is trade compatible, while the corporate taxes used in the U.S. are not. For example, a European manufacturer that exports products to America gets a tax rebate on the VAT they paid at home. However, an American company exporting to Europe does not get a rebate of their corporate taxes paid here. And, the European country will impose a VAT on U.S. products sold there. Our exports cost more there and their imports cost less here. [65]

President Obama has made achieving substantial increases in America’s exports a top federal priority. The president established a National Export Initiative (NEI) to double U.S. exports and support 2 million new jobs. The NEI will help American firms expand sales of their goods and services abroad by creating a new Cabinet-level focus on exports, expanding export financing, prioritizing government advocacy on behalf of American exporters, providing new resources to our businesses seeking to export, and ensuring a level playing field for our exporters in global markets.[66]

The success of this initiative will go a long way to enhance our nation’s global economic competitiveness and create high-paying, long-term jobs. U.S. Trade Representative Ron Kirk recently said, "The link between increased exports and high-quality jobs is significant enough to demand a smart, concerted effort to maximize this economic opportunity. We aren't going to leave any jobs on the table. ... The U.S. Trade Representative's mission is to tear down foreign barriers to American exports and to open up new markets for U.S. goods and services. And with our partners across the government, we'll work to ensure that job-creating export opportunities are available around the world to American businesses of every size and type."[67]

Corporate Tax Treatments

The U.S. maintains corporate tax rate that makes foreign competition difficult. In fact, among trading nations, only Japan has a higher rate, and it is introducing tax rate cuts that will make us No. 1 in this unenviable competition. Policymakers should consider this situation when exploring ways to improve our nation’s global competitiveness.

Other countries are taking advantage of the situation and improving their own tax rates and structure. For example, Belgium has implemented a highly favorable corporate tax approach for intellectual property income. It established a “patent income deduction,”

which results in an effective tax rate of 6.8 percent. This 6.8 percent can be further reduced by R&D expense deductions and tax credits.[68]

Other countries, like the Netherlands, are following similar approaches. The Dutch government introduced a "patent box" approach, which allows a reduced corporate tax (an effective rate of 10 percent) on revenue generated from patented intellectual property, excluding trademarks, designs and models.[69]

Activities like these provide an important opportunity in the U.S. to create jobs and strengthen our global competitiveness by expanding biopharmaceutical industry investment in R&D and manufacturing in this country. Simultaneous to that, we need to ensure that we are not instituting tax policies that eliminate the incentive or opportunity for companies to create the newest therapeutic breakthroughs. Presently, United States-based biopharmaceutical companies pay corporate tax on any foreign earnings brought back into our country. This situation acts as a disincentive for investment and job creation in America, and an incentive for investment abroad, given the relatively lower corporate tax rates in other countries. Further, many competitive nations, in fact, don't tax most of such "repatriated" earnings at all, significantly adding to the imbalance.

We need to find ways to encourage investment in America. Bringing home offshore revenues would provide the necessary capital infusion to fund new R&D efforts, innovation, construction and jobs. Further, if we don't provide incentives — in the form of globally competitive tax treatment on foreign revenue — we will encourage foreign investment that will ultimately undermine American jobs. Of course, we need to assure that the favorable tax treatment is tied to a verifiable monitoring process that shows companies are actually investing in job-creating innovations within our borders. Balance in this regard is extremely important to labor and management.

Competitor countries are developing substantial incentives for R&D investment and the resulting patented innovations. A number of countries have identified supporting innovation as a way to increase their global competitiveness. Economic and tax incentive policies vary across countries, but generally, they include various forms of tax incentives and favorable corporate tax rates. As just one example, as a way to attract R&D investment, several European countries have adopted innovation tax boxes, which provide lower corporate tax rates for patent and other IP-related income for innovation based in the particular country .[70]

"The United States is unique among major industrial nations in taxing a company's global income. … This feature of the U.S. tax code poses special challenges when it comes to global investment decisions and the return of foreign profits to the United States."

SOURCE: National Association of Manufacturers," Manufacturing Strategy For Jobs and a Competitive America," June 2010.

The Information Technology and Innovation Foundation recently indicated that expanding the R&D tax credit from 14 percent to 20 percent would result in the creation of more than 160,000 jobs, increase economic output by $90 billion, and provide a net increase of $11 billion in federal tax revenues.[71]The Milken Institute concurs, reporting that a 25 percent increase in the federal R&D tax credit would result in 316,000 jobs created, with a net federal deficit reduction of $22.7 billion.[72]

The Council for American Medical Innovation recently released the consensus views of nationwide experts representing, "the diverse stakeholders involved in advancing medical innovation."[73] Altogether, this agenda was informed by 72 experts representing the diverse stakeholders involved in advancing medical innovation, including all sectors of the biomedical industry — from medical device manufacturers to contract research organizations — as well as experts in medical academia, executives from research organizations, disease-focused patient advocates, leaders of foundations and nonprofits, state officials, and capital investment executives.

The experts' identified key challenges that directly apply to the future success of America's biopharmaceutical innovations:

Lack of consistency and predictability in review and approval of new products

American workers and their families *need* the bounty of new biopharmaceutical breakthroughs. As science drives forward with new discoveries that can potentially ameliorate critical personal medical problems, regulatory oversight must keep pace. There is increasing concern regarding the U.S. Food and Drug Administration's capacity to deal with the unprecedented demand for an efficient review-and-approval process that can respond to the explosion of potential scientific breakthroughs, while still protecting patient safety.

Further, certainty and regulatory timeliness are essential to the business of researching and developing new biopharmaceuticals. Action is needed to adequately and immediately fund the FDA so that it may overcome backlogs and delays, while policymakers develop an appropriate, efficient, longer-term approval process. Long-term sustained funding is needed, and should reflect the FDA's expanded responsibilities and workforce requirements.

PILMA Supports …

> *Adequately funding the FDA to address both its immediate critical needs and its sustained and expanded responsibilities longer term*
>
> *Building on the FDA's proposed "Advancing Regulatory Science Initiative" to implement a science-based benefit/risk framework, which includes the active participation of patient advocates and industry, representatives.*

Insufficient recognition that biopharmaceutical breakthroughs save money while improving Americans' health

In addition to the obvious health benefits for patients, satisfying previously unmet medical needs provides a significant economic benefit. For example, recent research from the Alzheimer's Association has estimated that delaying the onset and progression of Alzheimer's could save Medicare and Medicaid $210.5 billion in 2030 alone.[74]

Other breakthroughs offer similar opportunities:

- In Medicare, each properly used prescription saves $57 in avoidable hospital costs.[75]
- Overall in America, each dollar spent on diabetes medicines results in $7.10 saved on other services.[76]
- A study reported in *Health Affairs* showed antihypertensive medications prevented 833,000 hospitalizations for stroke and heart attack, saving $16.5 billion in medical costs within the yearlong study period.[77]
- For osteoporosis, total health care spending was recently shown to be $1,273 less for patients with the highest medication adherence.[78]
- Further, only a 10 percent increase in adherence to asthma medicines in elderly patients has been shown to result in a 5 percent decrease in total annual medical spending.[79]

Despite these kinds of significant savings, we find that some policymakers focus only on the cost of the biomedical innovations. Describing its perspective on health care cost increases, the Congressional Budget Office's (CBO) "Long-Term Outlook" states[80]:

> *A crucial factor underlying the rise in per capita spending for health care in recent decades has been the emergence, adoption, and widespread diffusion of new medical technologies and services. Major advances in medical science allow providers to diagnose and treat illnesses in ways that previously were impossible. Many of those innovations rely on costly new drugs, equipment, and skills. Other innovations are relatively inexpensive, but their costs add up quickly as growing numbers of providers and patients make use of them. Although technological advances can sometimes reduce costs, in medicine such advances and the resulting changes in clinical practice have generally increased spending.*

Rather than recognizing the numerous documented health improvements and related cost-reductions and -avoidance medical innovations can provide, the CBO calls, in

effect, for implicit rationing of medical innovations, or at least for removing the already insufficient incentives for their development. Importantly, beyond the personal health improvements and the direct and indirect cost savings, the CBO statement ignores the overall positive economic impact biomedical innovations can have on the economy through job creation and increased exports. Again, rather than limiting R&D for innovation, the U.S. should be supporting R&D investment.

Recall that the Obama Administration identified new medicines as part of addressing our country's greatest issues in its report, "Grand Challenges of the 21st Century." One of the goals of the report was to help "improve our quality of life and establish the foundation for the industry and jobs of the future."[81]

The recently enacted *Patient Protection and Affordable Care Act* includes many provisions designed to reduce health care spending (relative to prior projections), and it will be important to monitor the effects and outcomes of its pilot programs as they will be particularly useful in developing and refining future policies.

Included in the legislation are some initial steps toward modifying incentives for patients and providers to reduce costs. In many cases, the current health care system does not provide incentives for doctors, hospitals, and other providers of health care — or their patients — to control costs. Making appropriate changes in financial incentives will be critical in developing successful policies to restrain spending growth.

The past several years have seen shifts among private health benefits plans to base their payments to medical professionals and hospitals on quality measures and actual medical outcomes, rather than on the quantity of medical services provided. Under health care reform, these efforts (often referred to as "pay-for-performance," "value-based benefit designs," or "accountable care") offer great hope for the improved health of Americans.

The foundation of this new focus is an expanded emphasis on chronic disease prevention/management and health promotion. Biopharmaceutical innovations have long demonstrated their critical role in the success of such efforts, and new treatments will be needed to sustain and improve Americans' health into the future.

Additional substantial changes will probably be needed to significantly lower the future trajectory of health care spending, however. For example, given the key role of medical technology in contributing to spending growth, slowing the growth of spending over the long term will probably mean decreasing the pace of adopting new treatments and procedures, or limiting the breadth of their application. Such changes need not involve explicit rationing but could occur as a result of market mechanisms or policy changes that affect the incentives to develop and use more costly treatments.[82]

We need to remember that a critical dimension in investing, researching and bringing innovative biopharmaceuticals to market is the market itself. Unless there is a reasonable expectation that a new, innovative treatment will actually be used, the pipelines for new breakthroughs will not meet Americans working families' medical needs into the future. As our nation develops new health care delivery standards and reimbursement structures, we must "keep pace with the development and diffusion of new technologies and treatment options and allow for flexibility in addressing diverse patient needs."[83]

These needs can be addressed through the emerging science of "personalized medicine." Advances in personalized medicine offer great hope for future cures of millions of Americans. Considering the ethnic and racial diversity among residents of the U.S., understanding personal heritage variations among diseases and targeting treatments beyond a "one size fits all" approach will offer hope to countless people.

American workers and their families are relying on our nation's health care system to embrace innovation in biopharmaceutical treatments for their personal care. But while we recognize and celebrate advances in medicines' efficacy, we must not overlook the overall direct and indirect economic cost savings' opportunities such innovations offer.[84]

PILMA Supports …

> *National health policies that recognize that biopharmaceutical and biomedical innovations not only improve health and save lives, they save money, as well*
>
> *National health policies and developing standards of care lead by medical professionals that encourage and include evolving biopharmaceutical innovations to address Americans' critical health needs*
>
> *National reimbursement policies that emphasize the diversity of individual patient medical needs as part of decisions regarding access to care, quality of care, and cost*

There are limitations on the availability of an educated and trained workforce

There is a significant need to renew efforts to ensure that America has the talent to research, discover and manufacture biopharmaceutical innovations well into the future. We need to address the full formal education pipeline in science, technology, engineering and mathematics from kindergarten through 12th grade, in vocational/technical schools, college, and graduate university programs.

To meet the future health care needs of Americans, we must consider: curricula development, as part of an industry-education partnership; ways to encourage students to prepare for and enter science fields; new continuing education programs, and; funding support for the total effort.

It can be said that America is receiving a wake-up call, similar to the one received with the launch of Sputnik in the late 1950s — although this one comes from another part of Asia: China has already fully recognized that the future will be a competition of talent. Its national "Talent Development Plan" emphasizes graduating domestic high-tech researchers over the next ten years, with a goal of having 3.8 million researchers and 40,000 high-level scientists leading the nation's drive to innovate.[85]

While developing domestic talent, China is also focusing on recruiting top-level foreign scientists to work with Chinese researchers, and continuing a program to bring home Chinese scientists who trained and are employed abroad. Some 1,300 scientists and researchers have already returned to China, and plans are to bring home 600 more each year.[86] In addition, China has well-established programs to train skilled workers to construct technology-based manufacturing operations.

Because America cannot afford to lose this competition, we must ensure that, in addition to researchers and scientists, we also have a skilled workforce that can construct, maintain, and retrofit the research, testing, and manufacturing facilities needed to keep up with demand.

The trade union movement has led the way in establishing and maintaining skill-training and continuing education programs that graduate fully prepared workers to meet industry demands. Annually, the trade union movement spends $700 million dollars to support workers' bettering their skills and improving their lives.

One such program is offered by the Center for Construction Research and Training (formerly known as "CPWR," the Center to Protect Workers' Rights), which builds on the existing infrastructure of the fifteen Building Trades unions and the 2,000 joint apprenticeship and training programs in all 50 states and in Canada. These multiemployer apprenticeship and training programs invest more than $700 million annually to train union construction workers in construction skills, including safety and health. More than 500,000 workers are trained annually in this system. Building on this existing training infrastructure optimizes the Center for Construction Research and Training's ability to reach all sectors of the construction industry.[87]

Either on their own or in conjunction with industry/contractors through trust-fund arrangements, these programs should play a key role in assuring the strength of America's knowledge-based economy. Because we are now confronted with losing the leadership position we have, our response now requires national attention and support.

PILMA Supports …

> *Federal funding in support and coordination of America's biosciences education pipeline, including continuing workforce education*

> *The coordination of vocational and technical schools, community colleges and union-based trust fund programs in training and retraining efforts, including financial support as appropriate*

Energy Efficiency and Job Creation

The U.S. Department of Labor has initiated a coordinated effort to ramp up layoff prevention and job creation strategies at the national level, and build upon innovative state and regional job training and economic development initiatives to accelerate our national economic recovery.[88]

The biomedical industry can be central to the success of such efforts.

Many industries today — clean energy and technology, efficient transportation, green construction, and other innovative sectors — are poised for growth. At the crossroads of this transition is an opportunity to strengthen and convert existing industries so they may become part of the new system. We need robust new federal policies, strategic partnerships, capital incentives and initiatives, and resource realignment to turn this potential into reality.

The Obama Administration has already launched many of the starting initiatives to accomplish these long-term aims. The Administration has set a goal of doubling America's exports over the next five years, and called for boosting investments in R&D, increasing funding for biomedical research, investing in the next generation of scientists and engineers, and creating a national infrastructure-innovation and -finance fund.[89]

National and state policymakers have a stake in seeing the industry develop innovative solutions that will keep our citizens healthy and maintain America's position as the global leader in biopharmaceuticals. Understanding what policies and programs will create a climate that supports the development of this sector requires understanding the environment in which biopharmaceutical firms operate.

State-level policies that have helped attract and grow the sector and the jobs it offers include:

- Policies aimed at ensuring capital is available to support R&D enterprise, including programs to attract private, venture capital funding, bioscience investor and angel investor tax credits, and refundable and tradable R&D tax credits;
- Policies designed to attract facilities, including state tax policies, workforce development programs, and research parks; and,
- State R&D grants for bioscience research and other efforts to attract and retain R&D

jobs and spur construction of key infrastructure.[90]

Some existing state programs and policies demonstrate ways to achieve our industry's goals:

Maryland

"Maryland's biotechnology industry is at the forefront of medical innovation and continues to make groundbreaking discoveries because of the [state's] continued investments in our workforce, our higher education system and in the programs that have helped our emerging companies to succeed. … Medical innovation has the proven ability to generate economic growth by sustaining and creating new jobs in the highly desirable, knowledge-based economy and providing significant health advances that benefit individuals and society as a whole."[91]

Illinois

For many years, Illinois has focused on developing the state's technology industry sectors, including the biopharmaceutical industry.

- In 2007, the University of Illinois opened the state's signature bioscience R&D facility — the 186,000-square-foot, $75 million Institute for Genomic Biology — on the Champaign-Urbana campus. Some 400 researchers from diverse university departments now work in this building.[92]

- In 2009, the governor approved "Illinois Jobs Now," a capital and infrastructure program that includes $300 million for science and technology investments, and several hundred million more for university-based construction projects.[93]

Pennsylvania

A study of Greater Philadelphia's life science cluster found the sector accounted for 15 percent of all economic activity, and one in every six jobs in the region.[94]

Arizona

An economic impact analysis found that Arizona's bioscience sector, including bioscience R&D firms, hospitals and health care institutions, directly contributed $12.5 billion in economic activity and employed 87,415 workers in 2007. The total economic impact was more than $21 billion, taking into account the additional jobs (indirect and induced) that were created in the economy as a result of activity in the overall bioscience sector.[95]

Building STAR, Industrial STAR and CHP

We have a significant opportunity to address two critical national problems, jobs and energy efficiency, while protecting and improving the environment. The results will include the creation of good paying jobs and the establishment of a "green" biopharmaceutical industry.

Toward this effort, PILMA believes in jumpstarting construction and retrofitting projects throughout the country and, in particular, within the biopharmaceutical industry by using general economic incentives combined with "green credits". An example of this could be seen with the Energy STAR label approach, and the resulting "Building STAR" plan, which will provide much needed job growth, while meeting the U.S. Environmental Protection Agency's energy standards. This has the possibility to result in manufacturing plants that use less energy, are less expensive to operate, and emit less greenhouse gas.

Current policy discussions point to the critical role a Building STAR approach could play in putting hundreds of thousands of people to work improving the energy performance of commercial and apartment building infrastructure. Building STAR would create 150,000 to 200,000 good jobs in construction and related industries over the next 18 months, which would go a long way toward restoring the 2 million construction jobs lost in this recession.[96]

Further opportunities exist through expansion of Combined Heat and Power (CHP) systems. In a recent communication to Congress, representatives of business and labor and environmental groups urged action, because Congress has an opportunity to make American manufacturers more competitive and create jobs by developing incentives to expand the use of efficient CHP and clean recycled energy. America needs an industrial energy-efficiency policy now, because the nation's industrial sector is the engine for wealth creation, economic growth, and manufacturing investments, and benefits the entire economy.[97] In fact, every industrial job supports three jobs elsewhere.

As opportunities are created to construct and retrofit manufacturing operations within the innovation-driven, knowledge-based biopharmaceutical industry, we believe consideration could be given toward exploring innovations in workforce relationships, as well. Construction projects require planning, coordination, and anticipation of potential concerns, so planned business relationships are essential.

It may make sense to arrive at prearranged understandings with the construction workforce to increase the opportunities for high-quality, efficient, and cost-effective projects, for example. Uniform pre-hire, project-specific agreements known as "Project Labor Agreements" or PLAs could be a potential vehicle to this end. PLA's "have been demonstrated to be a very useful construction management tool for cost savings, for on-time, on-budget, and quality construction."[98] Covering all the crafts on a project, and lasting only as long as the project, PLAs have the ability to maximize project stability, efficiency and productivity.[99]

A typical PLA also includes no-strike, no lock-out agreements and procedures for settling quickly any problems or disputes that might develop during a project. Consequently, PLAs eliminate hidden costs and cost overruns by eliminating unexpected wage demands or disputes during the life of the project. [100]

Bristol-Myers Squibb's construction of a new biopharmaceutical manufacturing and research facility in Fort Devens, Mass., is a good example of the major contribution a PLA might offer in a biopharmaceutical company's facility construction. Being home to a biopharmaceutical plant that will produce an injectable drug means that Bristol-Myers Squibb has to adhere to very strict building standards set forth by the FDA. Workers have to follow a clean construction protocol that demands a high level of experience and training. The union trades people have been meeting and often exceeding goals to deliver a quality facility for the manufacture of a product that will enhance and save lives.[101]

With construction of six structures, including flagship office buildings and quality-control labs totaling 72,000 square feet, and a 190,000 square-foot manufacturing plant, at any one time there have been as many as 950 craftsmen onsite, and the union workers and contractors have surpassed 2.2 million man-hours on the job. Despite the challenges associated with such a monumental undertaking — and the potential for disaster — Bristol-Myers Squibb said the project is testimony to how things go well when all interests align.

Similarly, Pfizer has established a set of principles to guide workforce relations during construction and retrofitting it operations. Pfizer's "Responsible Contracting Policy Principles" are:

- Pay close to the hourly base-wage rate for the work classifications utilized in the geographic area of the work.
- Provide employer-subsidized family health insurance for all employees.
- Provide craft training and upgrading programs.
- Classify workers as employees, and not as "independent contractors."
- Comply with all workers' compensation and other insurance for employees as may be required by Pfizer and/or local law.
- Comply with any residency and/or affirmative action requirements.
- Comply with *all* applicable laws and statutory requirements in the locale where the work is performed.

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