The Biopharmaceutical Research and Development Enterprise:

GROWTH PLATFORM FOR ECONOMIES AROUND THE WORLD

Prepared by Battelle Technology Partnership Practice

Prepared for Pharmaceutical Research and Manufacturers of America (PhRMA)

May 2012

Battelle
The Business of Innovation

Battelle is the world's largest independent research and development organization, providing innovative solutions to the world's most pressing needs through its four global businesses: Laboratory Management, National Security, Energy, Environment and Material Sciences, and Health and Life Sciences. It advances scientific discovery and application by conducting $6.5 billion in global R&D annually through contract research, laboratory management and technology commercialization. Battelle's Technology Partnership Practice (TPP) assists local, state, and regional organizations, universities, nonprofit technology organizations, and others in designing, implementing, and assessing technology-based economic development programs.

PhRMA

The **Pharmaceutical Research and Manufacturers of America (PhRMA)** represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $49.5 billion in 2011 in discovering and developing new medicines.

Contents

EXECUTIVE SUMMARY

The innovative biopharmaceutical industry, which includes pharmaceutical and biotechnology companies developing cutting-edge prescription medicines, is an important driver of economic growth not only in the United States (U.S.) but increasingly around the world. Biopharmaceuticals and related industries, including biotechnology and the life sciences, are frequently the focus of economic development, innovation, and science and technology strategic plans in countries across the globe. This growing global focus is being driven by the recognition that these research-intensive, knowledge-based industry sectors produce important new treatments to fight the most costly and challenging diseases, generate high-quality and high-wage jobs, contribute to economic sustainability and growth, and generate exports for the countries where these companies' research and development (R&D) and manufacturing facilities are located.

The U.S. biopharmaceutical sector is one of the nation's most dynamic innovation and business ecosystems contributing substantially to national, state, and local economies. The industry sector directly and indirectly supported approximately four million U.S. jobs in 2009, including more than 650,000 direct jobs[1] with the average wage being more than twice the U.S. private sector wage, $118,690 versus $64,278, respectively. Furthermore, the U.S. biopharmaceutical sector's economic "output" totaled more than $917 billion on an annual basis in 2009, and the industry invested significant resources in R&D that yielded new treatments and potential cures that improve the health and well-being of individuals and reduce the socioeconomic burdens for society as a whole. As a result, **the overall economic impact of the biopharmaceutical sector on the U.S. economy is substantial.**

Building a World-Class Biomedical Innovation Ecosystem

The U.S. biopharmaceutical sector has held a dominant leadership position globally over the past 30 years, which is a direct result of the world-class biomedical innovation ecosystem that the nation developed and the policies in place to foster innovation.[2] The U.S. earned its global leadership across the continuum from research to innovation to industry development based on a well-balanced approach involving key roles for both the public and private sectors. Studies of the industry have attributed the sustained competitive advantage of the U.S. to a variety of factors, including, but not limited to, robust intellectual property (IP) protection and enforcement; a strong science-based regulatory system with the U.S. Food and Drug Administration (FDA), often viewed as the gold standard globally; public and private funding for biomedical research; healthcare payment and coverage polices that provide access to innovative therapies; and the presence of a competitive free market system that provides the potential for innovative biopharmaceutical companies to earn a return on their substantial R&D investments.

However, it is becoming clear that the U.S. can no longer take its leadership in biopharmaceuticals or other knowledge-based industries for granted. U.S. economic leadership is now being challenged by international competitors who are increasingly competing on the basis of technological innovation and scientific talent. Countries all over the world—from developing countries, emerging economies, and developed economies—are implementing policies and programs to foster innovation and grow knowledge-based industries; many of which are targeted to the biopharmaceutical industry and related industries.

In 2011, PhRMA engaged Battelle to examine the policies and programs that other countries are implementing to attract and grow the biopharmaceutical sector and related industries that comprise the life sciences or biosciences. For purposes of this study, Battelle focused on 18 countries and the European Union (E.U.). These countries were selected because of their interest in growing an innovation economy through pro-innovation policies and programs that can be applied to the biopharmaceutical sector and other R&D-intensive sectors. Countries selected include a mix of developed countries with an existing biopharmaceutical presence (Australia, Canada, France, Germany, Ireland, Israel, Italy, Japan, Sweden, the United Kingdom [UK], and the E.U. as a whole) and emerging countries that are targeting the biopharmaceutical sector (Brazil, Chile, China, Russia, Saudi Arabia, Singapore, South Africa, and South Korea).

Countries Profiled:

- AUSTRALIA
- BRAZIL
- CANADA
- CHILE
- CHINA
- FRANCE
- GERMANY
- IRELAND
- ISRAEL
- ITALY
- JAPAN
- RUSSIA
- SAUDI ARABIA
- SINGAPORE
- SOUTH AFRICA
- SOUTH KOREA
- SWEDEN
- UNITED KINGDOM

This report summarizes key findings regarding the efforts being implemented to attract and grow innovative bioscience industries across the selected countries. It is designed to help gauge how the global environment is changing and the extent to which the nation's global competitors are actively seeking to attract and grow this sector. The findings suggest potential initiatives that might be explored in the U.S. to sustain and grow its biopharmaceutical industry. The policies and initiatives described in this report highlight efforts specific to the biopharmaceutical sector where available. As noted above, a favorable environment for innovation also requires other elements such as strong intellectual property rights and a dynamic, science-based regulatory system. These aspects are not specifically addressed in the following analysis.

Biopharmaceutical Development Strategies Around the World

Not surprisingly given the key role of innovation in driving economic growth, all but two of the countries examined have in place a national plan or strategy to guide investment designed to cultivate a knowledge-based economy. The vast majority of these plans include biotechnology, health care, or the life sciences as sectors targeted for growth and development. In addition, half of the countries examined have a separate strategy focused solely on the development of the biopharmaceutical or biotechnology sector.

About half of the countries examined have a specific strategy to attract and grow the biotechnology and/or biopharmaceutical industry; the rest have innovation strategies targeted to growing technology-based industries, including biopharmaceuticals.

By and large, these innovation strategies are aimed at building the type of infrastructure found in the U.S. and other countries with well-developed biopharmaceutical and other high-technology industry sectors. Other countries' efforts have generally focused on the following:

- **Building R&D excellence and seeking to accelerate commercialization of research findings** by constructing an R&D infrastructure, e.g., increasing public funding of R&D; encouraging greater public/private collaborations, often with international partners; attracting the R&D operations of global companies through a range of tax and other financial incentives; adopting policies to encourage universities to commercialize research findings; investing in R&D infrastructure; and implementing a range of policies to encourage private firms to invest in R&D, from flexible immigration laws to tax and other policies.
- **Ensuring access to financial capital for companies**, particularly start-ups and emerging companies, by using tax incentives to encourage private investment in venture capital funds and/or technology-based companies and investing public funds directly in private venture capital funds and/or companies.
- **Attracting, retaining, and developing talent** by offering programs that encourage and enable students to study math, science, and engineering and that provide incentives to draw world-class researchers and scientists to national universities and research institutes.

"Pharmaceuticals are knowledge products. Drugs are physically small but their effects are targeted and potent and they command high value. That is how Singapore must be. Ours is a small island with no natural resources. We must therefore invest in knowledge and R&D, recruit and groom talent, and focus our efforts to excel in niche areas. Then we can transcend the limitations of physical size and punch above our weight class among the global competition."

Lee Hsien Loong
Singapore, Prime Minister
Speech given during the opening of a
GSK Vaccine Manufacturing Plant, 2009

Most strategies being pursued to attract R&D investment and grow the biopharmaceutical sector include a range of initiatives that cover the continuum of activities, including investing in R&D and human capital, supporting new enterprise development, and offering tax incentives. The most commonly pursued strategy focuses on investing in R&D excellence, often at universities but also at independent research institutes. While tax policies are commonly used to encourage innovation, they are not necessarily targeted specifically to the biopharmaceutical industry. In countries in which the biopharmaceutical industry is at an early stage of development, such as Singapore, South Africa, and South Korea, their strategies tend to be more broad, covering more industry sectors and a broader range of companies from start-ups through mature operations. The strategies of countries with well-established biopharmaceutical industries may be more targeted focusing more on how to further encourage the development of new medicines. Several countries are targeting the development of new medicines and treatments to address local health needs.

"Europe needs an innovative R&D oriented and responsible biotech industry. An industry which is rooted in the middle of our societies, because it offers concrete solutions to its many challenges, because it offers high-quality employment, because it drives economic growth."

José Manuel Barroso
President, European Commission
Eropabio Meeting, December 2010

Perhaps the most striking finding of this analysis is the similarity found across countries in terms of policies and programs countries are implementing. While developed countries are more able to leverage their own intellectual and financial resources and developing economies are more likely to focus first on attracting foreign direct investment and talent from abroad before turning to development of indigenous resources of technology, talent, and capital, all of the countries examined are focusing on strategic components to grow their biopharmaceutical economy. Table ES-1 compares the U.S. to the benchmark set of countries on key aspects of pro-innovation policies examined.

Table ES-1: Comparison of U.S. and International Practices to Support the Development of the Biopharmaceutical and Other Knowledge-Intensive Industries

	International Practice	U.S. Practice
Presence of national innovation and/or biopharmaceutical development strategy	Nearly all countries have innovation strategies that include focus on biopharmaceuticals Half of the countries have an explicit biotechnology/biopharmaceutical development strategy Greater coordination of national and regional strategies	Many state-level bioscience/life science strategies No tradition of national innovation or competiveness strategy; some modest efforts under way No coordinated national or regional strategy focused on promoting the sustainability and growth of the biopharmaceutical and related industries
Formal economic development and industrial policies focused on supporting "industry clusters"	National funding to regions to support cluster development National support for development of science and technology parks and other infrastructure to promote industry-university collaborations	U.S national policy has not traditionally focused on cluster development Limited activities recently initiated but not focused specifically on the life sciences Much more activity at the state and regional level but little support from national level for regional efforts

(Table continues on following pages)

	International Practice	U.S. Practice
R&D and Commercialization	Significant increases in public support for R&D, with most countries committing to invest a certain percentage of GDP in R&D, albeit for many countries starting from a low base compared to the U.S.	Select legislative proposals call for doubling investment in basic research but funding for basic research at the national level is flat or declining Administration has set a goal of increasing R&D as percentage of GDP to three percent, but no specific strategy has been outlined
	Reforming university and public R&D systems to encourage greater interaction and collaboration between universities and private industry	Strong U.S. public /private innovation ecosystem remains a competitive advantage but increasingly faces barriers States are facing increasing budgetary pressures which are resulting in reduced public funding for universities, community colleges, and other educational and training programs
	Creating mechanisms to accelerate commercialization of university-developed technologies Learning from the U.S., other countries are implementing Bayh-Dole-type policies	Implementation of Bayh-Dole continues to have positive economic impacts U.S. universities continue to develop new mechanisms to move discoveries into the marketplace, including seeking partnerships with companies Biopharmaceutical and other innovative industries are embracing open innovations, thus making university collaboration even more important, but barriers to public-private partnerships are increasing, e.g., conflicts of interest provisions Creation of the NIH National Center for Advancing Translational Sciences (NCATS) seeks to catalyze innovative methods to spur the development, testing and implementation of diagnostics and therapeutics.
	Increasing public investment in R&D infrastructure, including research facilities, research parks, and incubators	Public investment in basic research through National Institutes of Health, National Science Foundation, and other federal agencies has remained stable and/or declined slightly in recent years Very modest public funding support through U.S. Economic Development Administration (EDA) More activity at the state and regional level but little coordination between national and state efforts especially as EDA awards often go directly to counties or municipalities
	Accelerating use of tax policies to encourage investment in R&D	U.S. first to offer R&D tax credit but today incentive is much less than that of other countries R&D tax credit has not been expanded or made permanent with the lack of certainty likely impacting R&D investment decisions

	International Practice	U.S. Practice
Tax Policies	Offering significant tax incentives to help start-up companies	State-level incentives are available but as public budgetary pressures increase, incentives are being reduced in some states Few national-level incentives
	Increasingly globally competitive corporate tax rates	The U.S. now has the highest corporate tax rate among developed nations
Capital	Venture capital investment increasing, particularly in Europe and Asia, where some countries are establishing publicly backed venture capital funds	U.S. continues to dominate bioscience venture capital market globally, but becoming more difficult for bioscience firms to raise financing with investment shifting to later-stage deals and large declines seen in overall venture capital market in U.S. in recent years
	Many countries offer incentives for private investment in venture capital partnerships and/or in technology-based companies	Many state governments provide programs that catalyze private investment in venture capital funds and/or in technology-based companies Limited direct national level policies focused on promoting venture capital and other private capital investments. There are tax policies and other specialized mechanisms, such as SBIR/STTR
	Most countries have development banks that can invest directly in companies	At the national level, no vehicle for making equity investments in firms
Talent	Increasingly competitive incentives to attract and retain foreign talent and to encourage those trained and working in other countries to return to home country	U.S. immigration policies increasingly restrictive, limiting the nation's ability to attract skilled scientists and engineers
	E.U. countries encouraging mobility	More foreign graduates returning to their home countries due to increasingly restrictive immigration policies
	Emerging countries working to raise education levels, including in science, technology, engineering and mathematics (STEM) fields, and for targeted industries	U.S. students increasingly not proficient in and/or not interested in STEM careers with other countries ranking higher on many STEM measures The U.S. lacks a coordinated approach to STEM education
	Increased emphasis on improving STEM rankings at all education levels	The April 2012 Bioeconomy Blueprint calls for enhancements to STEM education and incentives for academic institutions to enhance entrepreneurship and restructure training programs Limited national- and state-level investment aimed at improving STEM performance at all educational levels

Conclusion

The biopharmaceutical industry has been an important contributor to U.S. economic growth and sustainability. While the U.S. has dominated globally over the past three decades, other developed and developing countries have been making substantial investments via new policies and programs to increase the economic footprint of the biopharmaceutical and related sectors in their own countries. The U.S. has been characterized by strong public and private R&D investments, a free market system that supports innovation, a robust IP and regulatory system, as well as access to venture and other private capital and a well-educated and highly-skilled workforce. Increasingly, other countries are seeking to develop knowledge-based economies to not only spur economic growth but also increase their ability to compete effectively in a global economy. Many of these countries are borrowing effective pro-innovation practices that have worked in the U.S. and building on them at the same time that the U.S., in some respects, is becoming less favorable to innovation. While the U.S. is still a world leader in biopharmaceutical R&D investment and the introduction of new medicines, as the President, his Council on Jobs and Competitiveness and others have stated, a range of factors underpin national competitiveness. In an increasingly global economy, the future of U.S. global biopharmaceutical leadership is not assured.

Ever more, other countries are recognizing that a long-term commitment to science, technology, and biomedical innovation is vital to enabling the biopharmaceutical industry to establish the foundation for economic growth and jobs of the future. It is clear that the U.S. still leads in many of the components required to support knowledge- and innovation-based industries, including the biopharmaceutical industry. But, it should be recognized that international competition is rising and retaining U.S. leadership will require the U.S. to not only maintain but expand investments in R&D and commercialization, education and workforce development, financial capital, and the nation's science and technology infrastructure, as well as consider overall favorability of the environment for innovation in the U.S. A range of other factors also impact the degree to which a country has a favorable environment for innovation, including many which were beyond the scope of this report.

For example, America's innovative biopharmaceutical companies face increasing challenges, ranging from the cost and increased complexity of bringing new medicines to patients, the prospect of attracting and sustaining the capital needed to develop tomorrow's new treatments and cures, the increasing uncertainty related to coverage and payment of innovative medicines, and intensifying competition from other countries. Continued innovation is fundamental to U.S. economic well-being and the nation's ability to compete effectively in the global economy. Just as other countries have drawn lessons from the growth of the U.S. biopharmaceutical sector, so too can the U.S. learn from other countries that are strategically and effectively creating a more favorable environment for R&D investment.

INTRODUCTION

The innovative biopharmaceutical industry, which includes pharmaceutical and biotechnology companies developing new prescription medicines, is an important driver of economic growth not only in the United States (U.S.) but increasingly around the world. Biopharmaceuticals and related industries, including biomedicine and the life sciences, are frequently the focus of economic development, innovation, and science and technology strategic plans in countries around the globe. This growing global focus is being driven by the recognition that these research-intensive, knowledge-based industry sectors produce important new treatments against the most costly and challenging diseases, generate high-quality and high-wage jobs, contribute to economic sustainability and growth, and generate exports for the countries where these companies' research and development (R&D) facilities are located.

The U.S. biopharmaceutical sector is one of the nation's most dynamic innovation and business ecosystems. A large part of the modern biomedical economy is built upon a robust foundation of biopharmaceutical companies that perform and support advanced biomedical and technological R&D and act as the funnel and distribution engine for getting life-saving and quality-of-life-improving therapeutics to the marketplace. In accomplishing the mission of bringing new medical treatments to patients, the biopharmaceutical sector sustains a large-scale supply chain—both in R&D and in support of the production and distribution of biopharmaceutical and biotechnological products. As a result:

- **The U.S. biopharmaceutical sector contributes substantially to national, state, and local economies.** It directly and indirectly supported approximately four million U.S. jobs in 2009, including more than 650,000 direct jobs.[3] Prior analysis by Battelle found that in 2009 the U.S. biopharmaceutical sector generated nearly $33 billion in state and local taxes and more than $52 billion in federal tax revenues. Furthermore, the average wage in 2009 for biopharmaceutical workers was more than twice the U.S. private sector wage, $118,690 versus $64,278, respectively.
- **The overall economic impact of the biopharmaceutical sector on the U.S. economy is substantial.** The U.S. biopharmaceutical sector economic "output" totaled more than $917 billion on an annual basis in 2009. This impact comprises $382 billion in direct impact of biopharmaceutical businesses and $535 billion in indirect and induced impacts. Every $1 in output generated by the biopharmaceutical sector generates another $1.4 in output in other sectors of the economy. This significant multiplier is due to the high value-added nature of the sector, its extensive supply chain relationships, and high-wage jobs. As a result, gains and losses in the biopharmaceutical sector cascade across many important economic sectors in the U.S.
- **The U.S. biopharmaceutical industry is a major export generator for the U.S. economy**, providing valuable foreign trade and income for the nation. In the seven-year period, 2005–2011, the U.S. exported more than $277.6 billion in biopharmaceuticals. Moreover, despite the recession, U.S.

biopharmaceutical exports have continued to rise for each of those seven years, with volume exported increasing from $29.1 billion in 2005 to $45.6 billion in 2011 (about a 60 percent increase over seven years).[4] The export of biopharmaceutical goods is one of the few bright spots in U.S. exports as most other sectors saw declines in exports over the same period.

The U.S. biopharmaceutical sector provides significant R&D investments, yielding new treatments that improve the health and well-being of individuals and reduce the socioeconomic burdens for society as a whole. The U.S. biopharmaceutical sector continues to lead the world in the discovery of new medicines, with more than 3,200 compounds in development in 2011 and an estimated $49.5 billion in R&D investments by Pharmaceutical Research and Manufacturers of America (PhRMA) members alone.[5] According to data from the National Science Board (NSB), the U.S. pharmaceutical industry spends more on R&D than any other subsector in the U.S. economy, representing 19.4 percent of total domestic R&D funded and performed by U.S. businesses in 2008, the latest year for which comparable data exist. Other traditionally research-intensive industries such as software ($27.7 billion), semiconductors ($21.6 billion), aerospace products and parts ($10.4 billion), and automobiles ($12.2 billion) spend significantly less on R&D, both in absolute terms and in proportion to the size of their industries.[6]

However, it is becoming clear that the U.S. can no longer take its leadership in biopharmaceuticals or other knowledge-based industries for granted. As noted by President Barack Obama, "A half century ago, this nation made a commitment to lead the world in scientific and technological innovation; to invest in education, in research, in engineering; to set a goal of reaching space and engaging every citizen in that historic mission … [O]ther countries are now beginning to pull ahead in the pursuit of this generation's great discoveries."[7] For the first time, U.S. economic leadership is being challenged by international competitors who are increasingly competing on the basis of technological innovation and scientific talent. Countries all over the world—from developing countries, emerging economies, and developed economies—are implementing policies and programs to foster innovation and grow knowledge-based industries; many of which are targeted to the biopharmaceutical industry and related sectors.

In 2010, PhRMA commissioned Battelle to examine the types of policies and programs U.S. states have put in place to create a climate favorable to sustaining and growing the biopharmaceutical sector and larger biomedical and/or life sciences sector. That study found that states in every region of the U.S. are investing in biopharmaceutical development, not only because the industry is a source of high-value, high-wage jobs and contributes to local and state economies, but also because the sector brings benefits to citizens in terms of having access to the latest medical discoveries, diagnostics, and treatments.

But, just as the U.S. has recognized the economic contributions and potential for growth offered by the presence of a robust biopharmaceutical sector, so too have other countries and regions of the world. More and more, the U.S. is competing globally to maintain its leadership position in biopharmaceuticals. In recognition of this growing trend, PhRMA engaged Battelle in 2011 to produce this report examining the policies and programs that other countries are implementing to attract and grow the biopharmaceutical sector and related industries that comprise the life sciences or biosciences.

For purposes of this study, Battelle examined policies and programs being implemented to promote the bioscience sector in 18 countries and the European Union (E.U.). These countries were selected because of their interest in growing an innovation economy. In addition, countries selected include a mix of developed countries with an existing biopharmaceutical presence (Australia, Canada, France, Germany, Ireland, Israel, Italy, Japan, Sweden, the United Kingdom [UK], and the E.U. as a whole) and emerging countries that are targeting the biopharmaceutical sector (Brazil, Chile, China, Russia, Saudi Arabia, Singapore, South Africa, and South Korea).

Countries Profiled:

- AUSTRALIA
- BRAZIL
- CANADA
- CHILE
- CHINA
- FRANCE
- GERMANY
- IRELAND
- ISRAEL
- ITALY
- JAPAN
- RUSSIA
- SAUDI ARABIA
- SINGAPORE
- SOUTH AFRICA
- SOUTH KOREA
- SWEDEN
- UNITED KINGDOM

This report summarizes key findings regarding the efforts being implemented across this mix of countries. It is designed to help gauge how the global environment is changing and the extent to which global competitors are actively seeking to attract and grow this sector. The findings suggest potential initiatives that might be explored in the U.S. to sustain and grow its biopharmaceutical industry.

The policies and initiatives described in this report focus on attracting and growing innovative bioscience industries in a number of developed and emerging countries, and highlights pro-innovation efforts specific to the biopharmaceutical sector where available. A favorable environment for innovation also requires other elements such as strong intellectual property rights and a dynamic, science-based regulatory system. These aspects are not specifically addressed in the following analysis.

Overall, while the U.S. biopharmaceutical industry's contributions are substantial and of great importance to the U.S. economy, the industry faces real challenges, from navigating the clinical development and regulatory processes to ensuring adequate coverage and payment for new treatments. At the same time, international competition to attract R&D investment has grown more robust as more countries around the world recognize the potential of the sector to grow and sustain their economies and, as a result, are exploring how they can attract and nurture a vigorous, innovative biopharmaceutical sector not only for its economic contributions but also to address the health needs of its people.

> ***"The UK life sciences industry is a high-tech and innovative industry which is vital to the economic prosperity and growth of the UK. Life sciences businesses will help us to meet the big societal challenges of our age from addressing the needs of an ageing population through developing advanced diagnostics and medicines, to improving our sustainability and ability to feed a growing population."***

The Rt. Hon. David Willetts MP
United Kingdom, Minister of State for Universities and Science,
Department of Business, Innovation and Skills, Annual Update on the
Bioscience & Health Technology Database, December 2010.

U.S. Leadership in Biopharmaceutical R&D

During the past 30 years, the U.S created a world-class biomedical innovation ecosystem that helped to make it a world leader in biopharmaceutical development. The U.S. earned its global leadership across the continuum from research to innovation to industry development based on a well-balanced approach involving key roles for both the public and private sectors. Studies of the industry have attributed the sustained competitive advantage of the U.S. to a variety of factors, including but not limited to, robust intellectual property (IP) protections and enforcement; a strong science-based regulatory system with the U.S. Food and Drug Administration (FDA) often viewed as the gold standard globally; public and private funding for biomedical research; healthcare payment and coverage polices that provide access to innovative therapies; and the presence of a competitive free market system that provides the potential for innovative biopharmaceutical companies to earn a return on their substantial R&D investments.

As we entered the second decade of the 21st century, the world leadership of the U.S. in the biopharmaceutical sector could clearly be measured. The U.S. accounted for 27 percent of the world net output in pharmaceuticals in 2010, a broad measure of economic activity after the cost of inputs to production. This stands well above the 18 percent share of total world manufacturing net output that the U.S. makes up. Pharmaceutical net output also continues to grow in the U.S. The 2010 level of pharmaceutical net output in the U.S. increased by eight percent from the level reached in 2007, the peak year before the recent recession, and stood 72 percent higher than in 2000.[8]

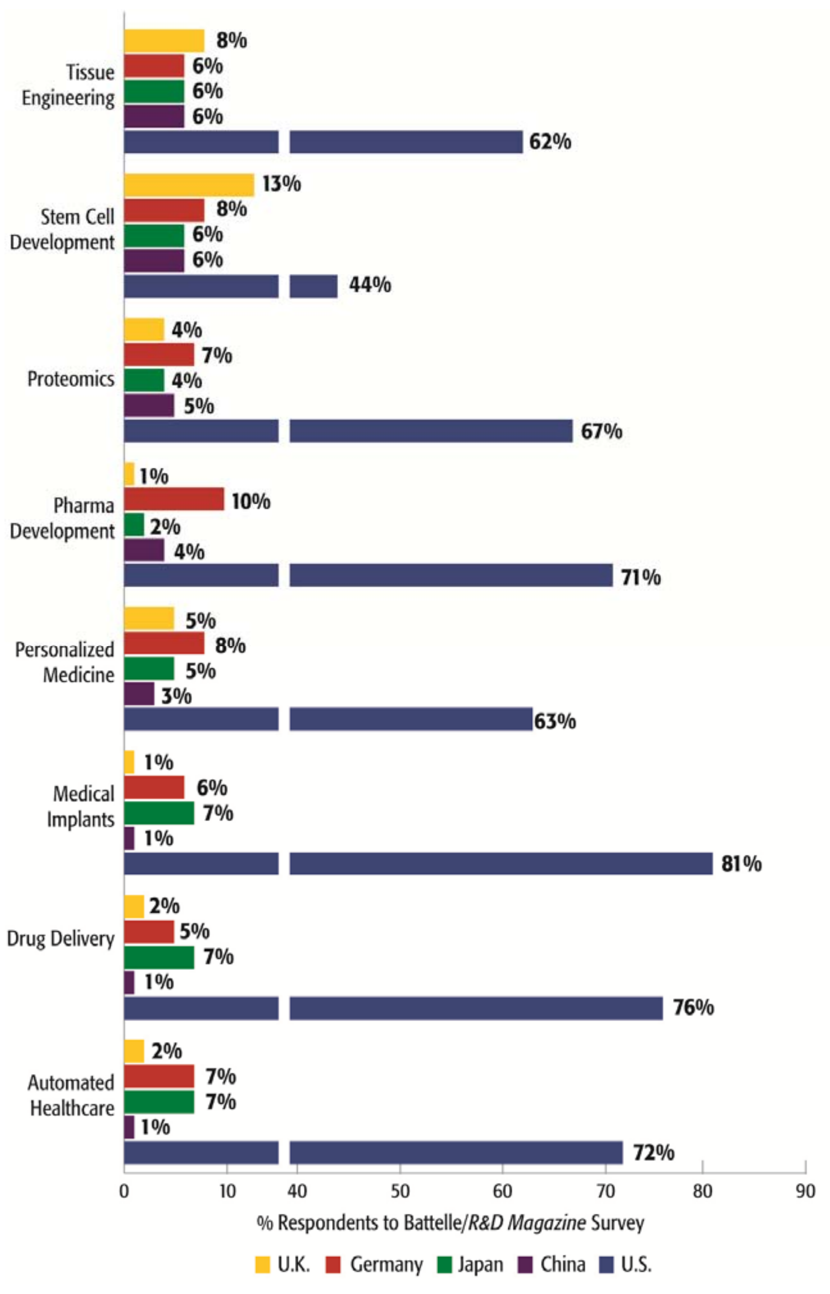
The U.S has outstanding strengths in biopharmaceutical research and innovation, a distinct advantage that helps fuel its world leadership in pharmaceutical economic activity. Just consider that in 2010 the U.S. represented:

- 33 percent of all medical science publications generated worldwide[9]
- 52 percent of all industrial R&D spending in the life sciences[10]
- 47 percent of all medical science patents filed under the World Intellectual Property Organization[11]
- 70 percent of all biopharmaceutical-related venture capital deals.[12]

The strength of this research and innovation ecosystem has allowed the U.S. biopharmaceutical sector to stand out in advancing new biopharmaceutical innovations, which has been a key driver of the industry's success in the U.S. It is important to keep in mind that the U.S. has not always been the leader in biopharmaceutical innovation. The revolution in molecular biology in the 1980s that changed the playing field for drug discovery and development helped the U.S. position itself to capitalize on these new advances. As the Milken Institute explains: "During the 1970s, the four large European countries (France, Germany, Switzerland and the United Kingdom (UK)) were responsible for 55 percent of NCEs (new chemical entities) produced by major nations, while the U.S. held a 31 percent share. But over the decade from 2001 to 2010, the U.S. share jumped to 57 percent while France, Germany, Switzerland, and the UK saw their share of NCEs plummet to 33 percent."[13]

Looking to the future, the "2011 Global R&D Funding Forecast" prepared by *R&D Magazine*/Battelle surveyed corporate and academic research leaders on the perceived leaders in life science technologies and found that the U.S. is viewed as the leader across the board in health/biopharmaceutical technologies compared with four benchmark nations, three of which represent nations with well-established biopharmaceutical sectors (Germany, Japan, and the UK) and the fourth is China (Figure 1).

Figure 1: Perceived Leaders in Life Science Technologies



Source: 2011 Global R&D Funding Forecast, R&D Magazine and Battelle, December 2010

Other Countries Challenge U.S. Leadership

While the U.S. is still the world leader with a growing biopharmaceutical base, a closer look at the trends suggests that U.S. dominance in the biopharmaceutical sector is facing broad international competition, with U.S. market share of worldwide activity declining. One good way to consider this shifting global competition is to examine key performance measures across economic activity and innovation in biopharmaceutical development.

In economic activity, two measures are considered. One is net output of pharmaceutical manufacturing, and the other is export of pharmaceutical goods. Table 1 shows both the levels and changes over the past decade in these two measures of economic activity for the world, the U.S., the E.U., and the 18 comparison nations for this study. While the size of the U.S. pharmaceutical economic activity remains substantial and is growing, it is not keeping pace with overall world growth. Of particular note is that other nations, while at a substantially lower base, are making major gains well above world growth rates.

In pharmaceutical net output, while the world grew by 109 percent from 2000 to 2010, the U.S. grew a sizable, though lagging, 72 percent. The fastest-growing nations in pharmaceutical net output from 2000 to 2010 are China at 719 percent, Russia at 359 percent, Israel at 278 percent, and Singapore at 274 percent.[14] Similarly, in exports of pharmaceutical goods, the U.S. is a significant player, though not dominant given the size of its internal market. The U.S. grew at a substantial 240 percent from 2000 to 2010, but still behind the hefty world growth rate of 325 percent. The fastest-growing nations in the export of pharmaceutical goods from 2000 to 2010 include Israel at 1,410 percent, Ireland at 548 percent, Singapore at 503 percent, China at 498 percent, and Brazil at 412 percent.[15]

It is interesting to note that the position of the U.S. is similar to that of the overall E.U. in terms of pharmaceutical net output level and growth—both accounting for slightly more than a quarter of world pharmaceutical net output but lagging world net output growth rates. However, the overall E.U. connection to global markets appears substantially stronger than the U.S. as shown in total export levels—even when accounting for intra-E.U. trade. Germany is an exception among the leading developed nations as it continues to outpace world growth rates in pharmaceutical net output and exports.

It is also important to note that the faster growth of economic activity in pharmaceuticals, particularly by emerging nations, is similar to the overall growth expected in the demand for pharmaceuticals across the world. Datamonitor reports that the global pharmaceuticals market is expected to grow from $733 billion in 2010 to $981 billion by 2015, an increase of 33.8 percent. This healthy growth of the pharmaceuticals market is largely driven by emerging nations, with demand for pharmaceuticals expected to grow from 2010 to 2015 in China by 109 percent, and Brazil by 67 percent. By contrast, the U.S. is expected to increase its demand for pharmaceuticals from 2010 to 2015 by 31 percent, slightly below the world growth rate. This demonstrates a major market opportunity going forward in the demand for pharmaceuticals among many emerging nations with rising populations and incomes.[16]

Table 1: Biopharmaceutical Economic Activity Measures, by Country

Country	Pharmaceuticals, Net Output 2010 Level (U.S., $M)	Pharmaceuticals, Net Output Percentage Change 2000–2010	Exports of Pharmaceutical Products 2010 Level (U.S., $M)	Exports of Pharmaceutical Products Percentage Change 2000–2010
World	345,994	108.6%	461,267.8	324.5%
United States	91,903	72.3%	44,582.9	239.8%
European Union*	90,418	95.6%	295,144.4	326.1%
Australia	2,597	191.1%	3,584.0	207.4%
Brazil	11,683	191.6%	1,360.4	412.1%
Canada	4,215	138.8%	5,703.6	364.6%
Chile	370	70.5%	128.3	258.5%
China	63,316	718.5%	10,688.8	497.6%
France	11,324	49.7%	34,479.8	229.6%
Germany	19,546	129.7%	66,937.7	386.7%
Ireland	5,035	151.1%	32,178.1	547.5%
Israel	949	278.1%	6,475.1	1,409.9%
Italy	9,379	52.2%	17,675.8	177.0%
Japan	30,015	-3.4%	4,324.0	58.3%
Russia	1,784	358.6%	583.0	289.2%
Saudi Arabia	73	82.5%	47.7	113.8%
Singapore	6,510	274.4%	6,097.4	503.1%
South Africa	1,439	196.7%	167.6	55.4%
South Korea	6,813	113.9%	1,215.0	260.6%
Sweden	5,687	86.9%	9,191.6	134.6%
United Kingdom	14,744	84.6%	34,340.0	218.9%

Source: Pharmaceutical Net Output from the National Science Foundation, 2012 Science and Engineering Indicators. Exports from World Trade Organization—Note that intra-exports for the E.U. nations and China are included in the levels of exports.
*The European Union includes Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the UK.

In innovation activity, as measured by medical science publications, medical science patents, and biopharmaceutical-related venture capital funding, the U.S. currently has an especially strong share of worldwide activity. In particular, the U.S. accounted for 66 percent of the world's biopharmaceutical-related venture capital funding in 2010, suggesting that the U.S. has a substantial advantage in its more established capital and entrepreneurial development infrastructure. The U.S. innovation strength also remains strong in medical science, where the U.S. represented 47 percent of worldwide activity in 2010. The rest of the world seems to be challenging the U.S. in one notable area—medical science publications—suggesting that other nations are laying the foundation of knowledge and discovery needed to advance biopharmaceutical innovation.

In terms of growth rates for innovation, similar to economic activity, the U.S. has grown in scientific publications, patents, and venture capital funding since 2000, but it is not keeping pace with world growth rates in these areas, demonstrating that other nations are moving forward aggressively. A closer examination of medical science publications suggests that China and Brazil have been emphasizing growth of their academic health research activities over the past decade, with each more than doubling its output of medical science publications. Meanwhile, in patents, South Korea and Israel crossed the 1,000 patent level in medical sciences in 2010 and realized strong growth over 2000 to 2010. In biopharmaceutical-related venture capital funding, emerging nations, such as Brazil and China are laying the groundwork of a venture capital industry, making enormous gains from 2000 to 2010 to put their nations on the map of venture-backed new company formation in biopharmaceuticals. By contrast, more developed nations across the E.U. and Japan recorded a significant decline in biopharmaceutical-related venture capital from 2000 to 2010.

Table 2. Biopharmaceutical Innovation Activity Measures, by Country

	Medical Science Publications		Medical Science WIPO Patents		Biopharmaceutical-related Venture Capital Investments ($ USD Millions)	
Country	2010 Level	Percentage Change 2000–2010	2010 Level	Percentage Change 2000–2010	2010 Level	Percentage Change 2000–2010
World	179,021	15.6%	34,151	64.4%	$12,478	15%
United States	58,664	10.6%	15,932	54.1%	$8,229	5%
European Union*	61,774	4.0%	10,518	47.7%	$1,710	-9%
Australia	4,960	29.9%	493	44.6%	$98	-31%
Brazil	3,131	167.4%	186	353.7%	$189	57,103%
Canada	7,356	25.0%	843	1.8%	$862	87%
Chile	403	29.2%	26	44.4%	–	-100%
China	7,429	373.0%	856	48.9%	$491	6,649%
France	6,100	-12.5%	1,939	73.9%	$370	108%
Germany	11,779	-0.2%	3,014	31.7%	$399	-50%
Ireland	614	41.5%	199	41.1%	$54	889%
Israel	1,602	-7.8%	1,037	141.2%	$197	8%
Italy	7,698	22.1%	881	75.8%	–	-100%
Japan	10,666	-20.1%	2,729	106.3%	$7	-50%
Russia	153	-25.1%	157	-10.8%	–	–
Saudi Arabia	503	51.5%	16	1,500%	$12	-65%
Singapore	521	14.1%	162	800%	$8	–
South Africa	4,227	226.5%	76	46.2%	$89	21%
South Korea	546	7.4%	1,232	592.1%	$48	-53%
Sweden	2,959	-10.4%	534	8.3%	$2	–
United Kingdom	12,518	-10.6%	1,897	-2.0%	$370	108%

Sources: National Science Foundation, 2012 Science and Engineering Indicators for Medical Science Publications.
Thomson One for Venture Capital Funding in Biopharmaceutical-Related Technologies.
WIPO Medical Science Patents, World Intellectual Property Organization.

The findings revealed in Tables 1 and 2—that the U.S. is a world leader in biopharmaceutical innovation, but is not keeping pace with rising competition—are similar to the conclusions in the most recent *Medical Technology Innovation Scorecard* prepared by PricewaterhouseCoopers (PwC), which focused on both general medical innovation measures and those more specific to medical device innovation. PwC compared the U.S. with eight other benchmark nations from across the developed and developing world, including Brazil, China, France, Germany, India, Israel, Japan, and the UK. The selection of these benchmark nations, along with the measures for medical technology innovation, was guided by consultations with corporate leaders from Boston Scientific, Medtronic, Johnson & Johnson, and MEDEC (Canada's national association for medical device technology companies). PwC in its *Medical Technology Innovation Scorecard* considers where each country stands relative to five innovation pillars: (1) financial incentives, including health care spending and reimbursement; (2) leading resources for innovation, including the number of researchers, academic medical centers, and research output; (3) regulatory and legal environment, based on a survey of major medical device companies, including the time, cost, and ease of regulatory approvals; (4) patient demand, including access to care and infrastructure; and (5) the investment environment, including the availability of venture capital and attractiveness of market commercialization opportunity.

Altogether, PwC considered 86 metrics, some data based and others survey based, to assess each country's capacity to adapt to the changing nature of medical innovation. The U.S., with a score of 7.1 out of a maximum of 9, ranked first among the countries; but, its score declined from 7.4 to 7.1 between 2005 and 2010. Germany, the UK, France, Japan, and Israel, whose scores fell in the 4.7 to 5.8 range, also experienced declines, while China (2.9) and Brazil (2.3)experienced gains, albeit starting from low levels. While the developing countries experienced gains, they still have a long way to go to reach the level of innovation found in the U.S. and other developed countries.

A more policy-oriented, economy-wide look at innovation is provided by the recently released *Global Innovation Policy Index* by the Information Technology and Innovation Foundation and the Kauffman Foundation. This report assessed 55 nations, including all members of the Organisation for Economic Co-operation and Development (OECD), all E.U. members, and 19 of the 21 nations that are members of the Asia-Pacific Economic Cooperation, as well as the large developing nations of Argentina, Brazil, India, and South Africa. The report assessed seven specific core innovation policy areas, including the following:

- Open and nondiscriminatory market access and foreign direct investment policies
- Science and R&D policies to spur innovation
- Openness to domestic competition and new firm entry
- Effective IP rights protection policies
- Digital policies enabling the robust deployment of information and communications technology (ICT) platforms
- Open and transparent government procurement policies
- Openness to high-skill immigration.

Overall, the U.S. ranked among the upper-tier countries across the seven core focus areas, along with 17 of the 55 nations considered. Only one nation—Singapore—was rated in the upper tier across all seven core focus areas. The U.S. ranked only upper- to mid-tier in two of the seven areas involving science and R&D policies to spur innovation and openness to high-skill immigration. The factors shaping the lower performance of the U.S. in science and R&D policies were the nation's low scores in the value of its R&D tax incentives and nondefense government R&D expenditure as a share of gross domestic product (GDP), where for each measure the U.S. fell below the average of all other nations in the study. The U.S. also stood well behind the top nations in the study in higher education R&D performance as a share of GDP. In the core focus area of openness to high-skill immigration, the U.S. fell short compared with the top-rated nations in the ratio of selection rate of high-skill immigrants to low-skill immigrants in its policies.

In summary, the U.S. remains the global leader in biomedical and biopharmaceutical innovation, as well as in broader innovation measures. However, the U.S. is not keeping pace with improvements in key pro-innovation indicators whereas a number of other countries are seeing substantial improvements (Table 3). In fact, the U.S. environment for innovation is showing signs of relative weakening compared with other nations in such areas as net output, exports, publications, and patents.

Table 3: Measures of Biopharmaceutical Economic & Innovation Activity

	U.S. Share of World Activity	
	2000	2010
Pharmaceutical Net Output	32.2%	26.6%
Pharmaceutical Exports	12.1%	9.7%
Medical Science Publications	34.3%	32.8%
Medical Science WIPO Patents	49.8%	46.7%
Biopharmaceutical-related Venture Capital Investment	72.3%	65.9%

Sources: 2012 NSF Science and Engineering Indicators, except Venture Capital data from Venture One and Exports from World Trade Organization

BIOPHARMACEUTICAL DEVELOPMENT STRATEGIES AND POLICIES AROUND THE WORLD

This section reviews various components of biopharmaceutical development strategies, policies, and programs from around the world, being implemented to promote the bioscience sector in 18 countries and the E.U. All but two of the countries examined have in place a national plan or strategy to guide investment designed to grow a knowledge-based economy. The vast majority of these plans include biotechnology, health care, or the life sciences as a sector targeted for growth and development. In addition, half of the countries examined have a separate strategy focused solely on the development of the biopharmaceutical or biotechnology sector. Table 4 outlines the various innovation and targeted sector strategies of each of the countries examined.

> About half of the countries examined have a specific strategy to attract and grow the biotechnology and/or biopharmaceutical industry. Nearly all have innovation strategies targeted to growing technology-based industries, including biopharmaceuticals.

> ***"Europe needs an innovative R&D oriented and responsible biotech industry. An industry which is rooted in the middle of our societies, because it offers concrete solutions to its many challenges, because it offers high-quality employment, because it drives economic growth."***

José Manuel Barroso
President, European Commission
Eropabio Meeting, December 2010

Table 4: Innovation Strategies and Targeted Sectors

Country	Innovation Strategy	Biopharmaceutical/biotechnology sector targeted	Explicit biopharmaceutical/ biotechnology strategy
Australia	*Powering Ideas, 2009*		Pharmaceuticals Industry Advisory Group convened in 2008
Brazil	*Action Plan on Science, Technology and Innovation for National Development: 2007–2010*	Biopharmaceuticals and 12 other technology sectors	
Canada	*Mobilizing Science and Technology to Canada's Advantage(2007)*	Health and related life science technologies	
Chile	*Innovation and Competitiveness Agenda 2010–2020*	Biotechnology	
China	*Medium and Long-term Plan for Science and Technology Development*	Biotechnology	
European Union	Innovation Union		
France	*National Research and Innovation Strategy, 2009–2010*	Health care, nutrition, and biotechnology	
Germany	*High Tech Strategy* (adopted 2006)		Pharmaceuticals Initiative for Germany
Ireland	*Strategy for Science Technology and Innovation (2006–2013)*	Biotechnology	
Israel		Biotechnology	Bioplan 2000–2010
Italy	*National Reform Plan*	Health care, pharmaceutical and biomedical	
Japan	*New Growth Strategy* (released in 2008 and updated annually)	Biopharmaceuticals	Maintains a Biotechnology Strategy Council
Russia		Biotechnology/life sciences	Pharma 2020 Initiative
Saudi Arabia	*National Science and Technology Plan*	Biotechnology, health care	
Singapore	*Research, Innovation and Enterprise Plan (2011–2015)*	Biomedical sciences	Biomedical Sciences Initiative
South Africa	*Innovation Towards a Knowledge-Based Economy: Ten-Year Plan for South Africa (2008–2018)*	Biopharmaceuticals	"Farmer to Pharma" Initiative
South Korea	577 Initiative—basic science and technology strategic plan	Biopharmaceutical	*Bio-Vision 2016: 2007–2016*
Sweden	Research and innovation target budget 2009-2012	Biotechnology	
United Kingdom	*The Plan for Growth*, 2011	Life sciences	Life Science Strategy, 2011
United States	*A Strategy for American Innovation: Securing Our Growth & Economic Prosperity*, 2011	Biotechnology, health care technology, biologics research, biomanufacturing	National Bioeconomy Blueprint, 2012

By and large, these innovation strategies are aimed at building the type of infrastructure found in the U.S. and other countries with well-developed high-technology industry sectors. Other countries' efforts have generally focused on the following:

- **Building R&D excellence** by increasing public-sector investment in R&D and providing incentives to attract new private-sector investment in R&D activities and facilities.
- **Ensuring access to venture and other private capital for companies** by investing public funds directly in start-ups or through venture capital funds and by providing tax incentives to encourage private investment in venture capital funds and in emerging technology companies.
- **Developing, attracting, and retaining talent** by offering programs that encourage students at all levels to study math, science, and engineering and by providing incentives to attract world-class researchers to national universities and research institutes.

In general, the areas of focus are similar in all countries. Developed countries are able to leverage their own intellectual and financial resources, while developing economies are more likely to focus first on attracting foreign direct investment and talent from abroad before turning to development of indigenous resources of technology, talent, and capital.

"As Canada enters the 21st century, strategic investments in biopharmaceuticals will be increasingly important in improving the health and quality of life for Canadians, maintaining national prosperity and even dealing with issues of national security…."

The Canadian Biopharmaceutical
Industry Technology Roadmap
Letter of Transmission, 2006

Most strategies being pursued to specifically grow the biopharmaceutical sector include a range of initiatives that cover a full continuum of activities, including investing in R&D and human capital, supporting new enterprises/start-ups development, and offering tax and other financial incentives. Nine of the countries examined have formal biopharmaceutical/biotechnology strategies. Table 5 shows the primary focus areas for each of the biopharmaceutical strategies examined. The absence of a checkmark in a table cell does not suggest that the country is not pursuing any activities in this area, just that it is not a key emphasis of the country's strategy.

Table 5: Primary Focus of Select Biopharmaceutical/Biotechnology Strategies

Country	R&D Excellence/ University Infrastructure	Human Capital	Capital Formation for Investment in Emerging Enterprises	Tax Policies	Drug Discovery and Development as a General Capacity	Development of New Medicines/Treatments for Specific Diseases
Australia	X	X		X		
Germany						X
Israel			X		X	
Japan						
Russia	X					
Singapore	X	X	X		X	
South Africa	X	X				X
South Korea	X	X			X	
United Kingdom	X			X		

Clearly, the most commonly pursued biopharmaceutical/biotechnology strategy focuses on investing in R&D excellence, often at universities but also at independent research institutes. While tax policies are commonly used to encourage innovation, they are not necessarily targeted specifically to the biopharmaceutical industry. In countries in which the biopharmaceutical industry is at an early stage of development, such as Singapore, South Africa, and South Korea, their strategies tend to be more comprehensive, covering more industry sectors and a broader range of companies from start-ups through mature operations. The strategies of countries with well-established biopharmaceutical industries may be more targeted, e.g., targeting the development of new medicines and treatments to address local health needs.

Examples of Strategies to Foster Biopharmaceutical Development

Germany and the EU are among those that have initiatives aimed at accelerating the development of new medicines. **Germany's €100 million ($144.1 million) Pharmaceuticals Initiative** is awarding funds on a competitive basis to support drug-development consortia that bring together large and small companies and academic partners from science and clinical practice.

The **EU's Innovative Medicines Initiative (IMI)**, is a €2 billion ($2.9 billion) initiative that supports precompetitive R&D collaboration on drug discovery, development, and approval. Funding for the IMI is shared equally by the European Commission and the European Federation of Pharmaceutical Industries and Associations.

South Africa and Saudi Arabia are seeking to promote external and internal investment in innovative biopharmaceutical development in part to address the health needs of their citizens. South Africa, through its "Farmer to Pharma" initiative, sees opportunities to not only create quality jobs, but also to ease the burden of diseases like HIV/AIDS, tuberculosis, and malaria for its residents. Focusing on these diseases has provided opportunities for South Africa to enter into international R&D collaborations. One such collaboration is the Institute for Tuberculosis and HIV between the Howard Hughes Medical Institute and the University of KwaZulu-Natal Nelson R. Mandela School of Medicine in Durban. The Kingdom of Saudi Arabia is making major, long-term investments in science, technology, and innovation to develop better strategies for management or prevention of diseases that are common in the Kingdom, such as diabetes, which affects almost one in three Saudis.

An examination of innovation strategies and specific biotechnology programs and initiatives being increasingly implemented around the world reveals a number of areas of growing focus, including the following:

- Developing regional industry clusters
- Building R&D excellence
- Accelerating the commercialization of university research
- Fostering R&D investment via tax policies
- Increasing access to investment capital
- Building human capital.

These six strategic components to growing a biopharmaceutical economy are discussed in detail below.

> ***"Pharmaceuticals are knowledge products. Drugs are physically small but their effects are targeted and potent and they command high value. That is how Singapore must be. Ours is a small island with no natural resources. We must therefore invest in knowledge and R&D, recruit and groom talent, and focus our efforts to excel in niche areas. Then we can transcend the limitations of physical size and punch above our weight class among the global competition."***

Lee Hsien Loong
Singapore, Prime Minister
Speech given during the opening of a
GSK Vaccine Manufacturing Plant, 2009

Developing Regional Industry Clusters

The innovation and biopharmaceutical strategies examined across the 18 countries commonly focus on developing industry clusters, often in partnership with regional governments. Clusters are geographic concentrations of interconnected companies, specialized suppliers, service providers, and associated institutions in a particular field. Clusters develop because they create efficiencies and synergies that build thriving productive ecosystems from which companies can compete in an increasingly more competitive global market. As a result, clusters are an important source of jobs, income and, export growth. The philosophy behind clusters is that large and small companies and institutions in a similar industry contribute more economically when they work together than they would individually. Clusters give businesses an advantage by providing access to a broader range of suppliers and customized support services, skilled and experienced labor pools, and knowledge transfer through informal and formal exchanges. Strong clusters foster innovation through dense knowledge flows and spillovers; strengthen entrepreneurship by boosting new enterprise formation and start-up survival; enhance productivity, income-levels, and employment growth in industries; and positively influence regional economic performance.

> Other countries have formal economic development and industrial policies focused on supporting the development of "industry clusters," often in partnership with regional entities. The U.S. has modest efforts underway to support the development of regional industry clusters.

Battelle's 2010 report, *Driving State Economic Growth in the 21st Century: Advancing the Biopharmaceutical Sector,* cited the following as key attributes of a robust biopharmaceutical sector:

- World-class bioscience programs
- A thriving risk capital community (e.g., angel investors and access to venture capital)
- The capacity to grow, attract, and retain talented workers
- The ability to commercialize research findings
- A business climate that supports the growth and sustainability of biopharmaceutical industry.

While biomedical development has much in common with other technology sectors, it stands apart in particular specialized characteristics, capital requirements, unique talent needs, and long-term business commitment required for sustained growth. Biomedical cluster development calls for especially close ties between industry, clinical care, and academic research communities and also operates in a highly regulated environment. For these reasons, biopharmaceutical and other bioscience firms are good candidates for cluster development.

The U.S. is home to a number of biopharmaceutical and bioscience-focused clusters that are at various stages of development. Boston, the San Francisco Bay area, the New York/New Jersey region, Maryland/Washington DC region, Philadelphia, and North Carolina's Research Triangle Park are all recognized as leading bioscience clusters. These clusters generally develop in a region with strong research institutions, a high quality of life, access to venture capital, and a highly skilled and mobile workforce. The Boston life sciences cluster, for example, depends on a highly skilled workforce associated with Harvard and the Massachusetts Institute of Technology (MIT) and on a clinical network of Harvard-affiliated hospitals to facilitate the research enterprise. The growth of these and other clusters has long been supported by favorable public policies, including the following:

- State funding and financial incentives to support the construction of high-tech labs and other research facilities
- Financial incentives to enable companies to expand or locate within the state (e.g., refundable or tradable R&D tax credits and bioscience investment tax credits)
- State investment in training, education, and workforce development programs (e.g., faculty recruitment programs)
- Support from state government, universities, and regional organizations to play a role in the development of bioscience clusters in North Carolina's Research Triangle Park, Maryland, and San Diego.

While individual states in the U.S. have a history of seeking to build industry clusters, particularly in the biosciences, until recently there have been few national-level programs to support such regional development efforts. Among these are the "i6" and Jobs and Innovation Accelerator Challenge competitions coordinated by the U.S. Economic Development Administration and involving also the participation of several science agencies. To date, both programs have made relatively small awards, in the range of $1 million to $2 million each from a total national pool of less than $50 million. This total level of funding is much smaller than that being provided by many other countries. Germany's Leading-Edge Cluster Competition, for

Examples of Initiatives to Build Regional Biopharmaceutical Industry Clusters

In **France**, the national government has provided funding to support the development of eight regional innovation clusters focused on biopharmaceuticals. Such efforts seek to integrate regional universities, large companies, and small and medium enterprises (SMEs) in directed joint R&D, education and training, and infrastructure development. Two (in Paris and Lyons) are designated for global leadership, and one (in Alsace) represents a tri-national cluster also involving academic and industrial participants in Germany and Switzerland. Each cluster has a 3-year performance contract and roadmap.

In **Germany** starting in the early 1990s, the federal government ran a series of competitions (BioRegio and BioProfile) to encourage the development of regional bio-clusters. They have been succeeded by several programs that provide funding for R&D projects (funded at least half by industry), business incubators, joint marketing, and other networking/linkages. For example, the Heidelberg cluster focuses on personalized medicine, and the Munich cluster on clinical trials. Public funds up to €40 million ($53.4 million) each are matched by private industry, with about a third of the total going to research and education institutions and 40 percent reserved for projects of SMEs.

In **Italy**, many regional governments, with support from the national government, have created nonprofit foundations to support cluster formation, often giving these foundations responsibility for research and science park development.

example, is funded at $865 million with each cluster being awarded $57.5 million through 2013. In addition, only one of the most recent Accelerator Challenge awardees, the St. Louis Bioscience Jobs and Innovation Accelerator Project, was focused on the biosciences.

Internationally, there appears to be greater coordination of national and regional strategies. Nine of the countries examined have formal policies to support the development of regional industry clusters, often targeted to the biopharmaceutical and/or biomedical sector. Some of these countries provide funding to regional governments to support cluster development, others focus on infrastructure investments to develop science parks and incubators, while others may create special zones in which various tax and other financial incentives are available to attract particular types of companies (Table 6).

Table 6: Examples of Support for Development of Industry Clusters

Country	National Funding to Regions to Support Cluster Development	National Support for Development of Science Parks and Other Infrastructure	Designation of Special Zones
China		X	X
France	X		
Germany	X		
Italy	X	X	
Japan	X		
Russia		X	
Saudi Arabia		X	X
Singapore		X	
European Union	X		

"With such vast market opportunities, it is little wonder that many Asian countries are developing biomedical manufacturing and R&D activities. In Singapore's case, our plans for the development of a biomedical cluster began ten years ago. Since then over S$5 billion have been invested. With excellent connectivity to key Asian markets, a stable and skilled workforce and our well-developed and robust Intellectual Property (IP) regime, Singapore has attracted leading global companies from the pharmaceutical and biomedical sciences industries to establish operations here."

Lee Yi Shyan
Singapore, Minister of State for Trade, Industry and Manpower
Biospectrum Asia Pacific Life Sciences Industry Awards
March 12, 2010

Building R&D Excellence

A prerequisite for any country or region seeking to grow a knowledge-based economy is to ensure that the country has a robust overall R&D base or infrastructure that can benefit multiple industries by focusing on generating new knowledge and understanding. The first step for a country seeking to develop a biopharmaceutical industry cluster is to ensure that its universities and research institutions have the necessary resources to develop world-class bioscience R&D strengths, which includes building labs and other research facilities. It is therefore not surprising that countries committed to growing the biopharmaceutical sector and other knowledge-based industries are greatly increasing their investment in R&D.

> U.S. competitors are significantly increasing their investment in R&D at the same time that funding for U.S. R&D is flat or declining. Other countries also are funding more multidisciplinary, multi-institutional R&D and focusing more on translational research.

Examining R&D spending as a percentage of GDP is one measure used to gauge a country's R&D intensity. In fact, many countries that are pursuing innovation strategies set a goal of achieving a certain level of R&D as a percentage of GDP.

Among the countries examined, the U.S. spent 2.8 percent of GDP on R&D in 2008, ranking fifth behind Israel, Sweden, Japan, and South Korea (Table 7). It should be noted, however, that total U.S. spending on R&D of $398.2 billion is more than double that of China, which has the second-highest level of funding at $154.1 billion on total R&D. U.S. spending on R&D also exceeds that of the E.U. by more than $100 billion.

Israel, first in the world in its percentage of GDP that is invested in R&D at 4.9 percent, has long sought to build its technology industries by investing in R&D. South Korea has also made a very strong commitment to growing its economy by investing in R&D. South Korea's national plan calls for increasing its already impressive 3.4 percent to five percent by 2012. President Obama has set a goal for America to invest more than three percent of GDP in public and private R&D. The E.U. has set a goal of three percent for each of its member countries; currently, E.U. member countries are investing 1.8 percent of GDP in R&D.

Another difference among countries is the extent to which R&D receives funding from the private or public sectors. In Israel, Japan, South Korea, and the U.S., a high percentage of total R&D is financed primarily by the private sector. In other countries, particularly in developing nations but also in some European nations, the public sector supports a greater share of R&D. A strong industry R&D base is likely to lead to commercialization more quickly. As a result, many innovation strategies include providing incentives to encourage businesses to increase their investment in R&D. Alternatively, public investment in R&D is needed to support more basic research that can help build the basic R&D infrastructure and attract additional public- and private-sector investment.

Table 7: Research and Development Spending, by Country, by Gross Domestic R&D Expenditures

Country*	Domestic R&D Spending as a Share of GDP	Business R&D Expenditures as Share of Gross Domestic R&D Expenditures	Gross Domestic R&D Expenditures (Million Current Purchasing Power Parity $)**
United States	2.8%	72.6%	$398,194
European Union***	1.8%	N/A	$281,556
China	1.5%	73.2%	$154,147
Japan	3.4%	75.8%	$137,908
Germany	2.6%	67.5%	$82,730
France	2.0%	61.9%	$47,953
South Korea	3.4%	75.4%	$43,906
United Kingdom	1.8%	60.4%	$40,279
Russia	1.1%	62.4%	$33,368
Italy	1.2%	51.5%	$24,752
Canada	1.8%	51.7%	$24,551
Australia	2.0%	60.8%	$18,754
Sweden	3.8%	70.4%	$12,494
Israel	4.9%	79.9%	$8,810
Singapore	2.6%	N/A	$5,626
South Africa	0.9%	58.6%	$4,689
Ireland	1.4%	65.4%	$3,164
Chile	N/A	40.4%	$963

Notes: Data are for the most recent year available as reported by individual countries (2005–2009). Gross Domestic R&D Expenditures data for Israel exclude defense.

*Data for Brazil and Saudi Arabia are not available.

**Purchasing Power Parity rates used to convert GDP to international dollars.

***European Union = Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the UK.

Source: Main Science and Technology Indicators, OECD Science, Technology and R&D Statistics.

> ***"We have decided to massively invest in research and higher education because they are the drivers of growth. E1 billion are being added to the university budget and E800 million to the research budget every year for a period of five years. Additional resources, though necessary, are not, however, sufficient: we needed to … restructure our publicly funded research ... professionalize the structures that translate research findings into practice (and) learn to better cooperate with privately funded research. A great nation must attract and retain the best research scientists and the most dynamic companies."***

French President Nicolas Sarkozy
Speech at the Elysée Palace
June 5, 2009

An examination of R&D investment programs and initiatives being implemented reveals a number of commonalities among the countries studied, including the following:

- Increasing public investment in R&D
- Seeking to raise the quality of their R&D enterprise by attracting world-class researchers and engaging in international partnerships
- Funding multidisciplinary, multi-institutional R&D
- Focusing on translational research.

These four components, which are contributing to the growing global trend in building R&D excellence, are discussed in detail below.

Increased Public Investment in R&D

The current U.S. administration has committed to raising combined public and private expenditures on R&D to three percent of GDP, in line with the European "Barcelona Agreement" targets. However, U.S. government expenditures outside the physical sciences have been stagnant for almost a decade. Between 1998 and 2003, a commitment to double the NIH budget was accomplished. However, since 2004, NIH funding has been flat or declining in real terms. If not for stimulus funding, it would have declined by more than five percent between 2005 and 2010. It is anticipated that many federal agencies will see declines in their R&D budgets in 2013 and

Examples of Increased Public Investment in R&D

China has increased its R&D investment by ten percent each year for the past ten years. At this level of investment, China's R&D spending will reach $154 billion in 2011, the second-highest total R&D investment of any country in the world. As a result, China's share of global R&D investment will increase from 11 percent in 2009 to 13 percent in 2011. China currently is investing about 1.75 percent of GDP in R&D. China's leaders have set a goal of 2.5 percent.

Since 2008, the government of **Saudi Arabia** has been investing heavily in science and technology (S&T). S&T spending jumped from about 600 million Saudi riyals ($160 million) annually in previous years to 2 billion riyals ($533 million) in 2008. Plans are to increase annual funding to 8 billion riyals ($2.1 billion) over the next five years.

beyond in response to increased budgetary pressures. Meanwhile, many U.S competitors are greatly increasing their investments in R&D.

Brazil, which increased the budget of the Science Ministry from $600 million to $4 billion during the past decade, now accounts for more than 60 percent of all research spending in South America. China and Saudi Arabia have also greatly increased their investment in R&D (see text box). Other countries, such as Israel and Japan, which have a long history of investing in R&D, have continued to commit to investing an even larger share of GDP in R&D.

Policies to Raise the Quality of the R&D Enterprise

States in the U.S. realize that building a strong biopharmaceutical R&D base and, subsequently, a strong innovative biopharmaceutical industry, requires world-class researchers who are able to attract funding and are willing and able to see their research discoveries turned into commercial products and services. In order to recruit such individuals, they have created programs that provide funding to attract established scientists and researchers to their universities and provide them with the necessary infrastructure to conduct their research. Countries that are seeking to grow their innovative biopharmaceutical industry have taken a similar approach.

Countries are also seeking to bolster their talent base by entering into international partnerships that allow their researchers to interact with leading experts from around the world. In Israel, the Office of Chief Scientist (OCS) and Matimop, a separate government agency of OCS,[17] [18] vigorously promote participation by small and medium-sized Israeli companies in international collaborations, especially those that qualify for financial support from the E.U. through its "Framework Programme" that provides funding for industrial innovation.[19] Israel pursues such partnerships to accelerate commercialization, encourage the competitiveness of Israeli companies through transfer of knowledge and technology, and promote Israel's R&D assets.

Examples of Policies to Attract World-Class Researchers

Canada has several programs aimed at recruiting "star" faculty with industrial and entrepreneurial orientation to its universities. The Canada Research Chairs program offers universities $200,000 annually for seven years to attract outstanding researchers.

Singapore has been very aggressive in recruiting foreign researchers to come to its research institutes. Its National Research Foundation Fellowship Scheme offers newly recruited fellows grants of up to $2 million over five years (over and above salary support at the assistant professor level at one of Singapore's universities).

Funding for Multidisciplinary, Multi-Institutional R&D

It is generally recognized that the production of scientific knowledge is shifting from single disciplines to broader interdisciplinary collaborations that often reach beyond single institutions, and from a national to an international scope. As the *Chronicle of Higher Education* notes, "[interdisciplinary] partnerships are proliferating in academe—and slowly changing the face of science—because they offer the best hope for answering some of the thorniest research subjects including climate change, biodiversity and cancer."[20]

In biopharmaceutical development, these broader multidisciplinary and multi-institutional approaches are taking hold. Battelle and *R&D Magazine*'s "2012 Global R&D Funding Forecast" highlights the changes underway in life science R&D and explains:

> *[There are] "significant R&D opportunities for universities, non-profits and governments … consider the Pfizer example, while reducing internal R&D, it has expanded its presence in Cambridge, MA, specifically to have better collaborative access to the great research institutions of the area and to adopt an open innovation posture. In a larger example intended to accelerate drug development, GlaxoSmithKline, Novartis, Pfizer, and Eli Lilly have joined the Structural Genomics Consortium, a public-private partnership that supports the discovery of new medicines through open access research … At the same time, the federal government has become oriented to a larger role in early-stage drug R&D with initiatives like the National Center for Advancing Translational Sciences and the NIH's Common Fund. Foundations are also taking a more active role in funding and R&D toward treatments for the often difficult diseases in which they have an interest. This convergence of public and private life science R&D toward open innovation and open source information—especially in areas needing considerable fundamental research—is a major change in the approach to funding and performing life science R&D."*[21]

It is not surprising, therefore, that as countries seek to build their R&D enterprise, they are investing in programs and initiatives that aim to foster multidisciplinary and multi-institutional approaches. For those countries that are members of the E.U., the E.U.'s Framework Programme generally favors multidisciplinary, transnational projects that involve both academic and industry scientists.

Examples of Mechanisms to Foster Interdisciplinary and Inter-institutional Collaboration

France has created a new national program to designate "Carnot Institutes" to support organized collaborations between one or more national research organizations and private industry. For example, the Pasteur Infectious Diseases Carnot Institute is a collaboration among large and small biopharmaceutical companies, the Pasteur Institute (one of France's nongovernmental, nonprofit research "foundations"), the national Institute of Health and Medical Research, and the biological-science division of the publicly-funded National Center for Scientific Research. It has an overall budget of €61 million ($82.4 million), of which €28 million ($37.8 million) comes from research contracts with industry.

Ireland's Centres for Science, Engineering and Technology are major university-industry collaboratives that carry out cutting-edge research programs for which Science Foundation Ireland pays 75 percent of the costs up to €25 million ($33.8 million) over five years. Each has large industrial partners from the respective sectors that pay the required 25 percent cost share and participate in the research program.

Promoting Translational Research

To drive economic growth, scientific discoveries must be translated into practical applications. In the biomedical arena, the complexities of conducting clinical research make it particularly difficult to translate new knowledge into new drugs and therapeutics. Around the globe, as well as in the U.S., people are undertaking initiatives designed to support translational research that bridges the gap between bench and bedside. A key element of the UK's Life Sciences Strategy is a focus on building, maintaining, and extending research excellence into "translational research partnerships."[22]

Examples of Efforts to Encourage Translational Research

In **Ireland**, the Higher Education Authority (the planning and development agency for higher education) and the Health Research Board (the main agency for health research) have jointly funded a consortium of Irish universities and hospitals to create **Molecular Medicine Ireland** (MMI), a translational research consortium among seven academic institutions that host advanced biomedical research institutes and associated academic hospitals. The goals of MMI's Irish Clinical Research Infrastructure Network are to harmonize clinical protocols and operating procedures within Ireland and in concert with EU partners, to improve training for clinicians and nurses (including those outside the academic setting), and to present a common reform agenda to regulators and other stakeholders.

Singapore's A*STAR and its Biomedical Research Council have created a series of **research institutes** and industrial consortia designed to focus on relatively applied problems that are capable of attracting industrial collaboration and to contract their services on an international basis. Consistent with the priorities of the second phase of their Biomedical Sciences Initiative, the more recently established research institutes are more heavily oriented to translational research.

To strengthen **South Korea's** ability to serve as a hub for international clinical trials, the government has established a **Korea National Enterprise for Clinical Trials** (KoNECT), which has recently created five new regional centers to train clinical-research personnel, bringing the total to 14 nationwide. In addition, the Research Hospital Program has selected two hospitals to become comprehensive sites for translational research institutes in partnership with industry.

Accelerating the Commercialization of University Research

The U.S. has seen rapid growth in commercialization of basic bioscience discoveries since the passage in 1980 of the Bayh-Dole Act, which allowed universities to retain title to discoveries made with federal research funding, and then to execute exclusive licenses with private-sector companies that intend to commercialize those discoveries. Today, many technology transfer offices at U.S. universities are becoming even more proactive in terms of commercialization—providing funding to support proof-of-concept activities, creating commercialization centers to help faculty and students launch new companies, operating incubators, and even directly investing in new ventures. The Association of University Technology Managers (AUTM), which represents more than 300 universities, research institutions, and teaching hospitals, reported in the *AUTM U.S. Licensing Activity Survey: FY2010* that universities:

- Introduced 657 new commercial products
- Formed 651 new companies
- Executed 4,284 new licenses
- Had 3,657 start-up companies still operating at the end of fiscal year (FY) 2010.

> Similar to the U.S., competitors are seeking new ways to accelerate commercialization of university-developed technologies to increase their global competitiveness and promote economic growth.

A similar focus on encouraging the commercialization of university research findings is seen in Europe. Since the 1990s, most French universities that conduct any significant amount of research have been equipped with technology transfer offices and regional innovation centers, often including linkage to a business incubator. Enterprise Ireland, the nation's agency to promote industrial innovation, has provided €30 million ($40.5 million) over 2007–2012 to create and staff technology transfer units at Irish universities that provide technical assistance, hold annual technology

Examples of Programs to Encourage Commercialization of University-Developed Technologies

Singapore is an example of a country that has become very proactive in terms of promoting commercialization. In Singapore, A*STAR, the country's science and technology agency, has established a dedicated technology transfer and commercialization arm called "Exploit Technologies" to serve its research institutes. In addition to its intellectual property (IP) licensing operations, the program offers counseling and funding designed to prepare start-up ventures for formal financing. Commercialization of Technology grants provide up to S$1 million ($780,000) per "incubator-stage" project for up to one year to develop prototypes. Flagship projects qualify for a higher level of support, up to S$3 million ($2.3 million) over three years. Additionally, Singapore's National Research Fund offers proof of concept grants up to S$250,000 ($192,000) and translational R&D grants, which support its higher education institutions that offer 3-year diploma courses in subjects such as information technology, engineering, and other vocational fields, as vehicles for carrying out translational work on research output from the universities and research institutes.

showcase events, and provide support for developing spin-out companies.

An examination of commercialization programs and initiatives being implemented reveals a number of commonalities among the countries, including the following:

- Enhancing public and private collaboration
- Attracting biopharmaceutical R&D investment
- Investing in R&D infrastructure.

These three components to the growing global trend in commercialization are discussed in detail below.

> ***"By speeding up drug development across Europe, the investments made by the IMI will ultimately save and improve lives, as well as making a major contribution to the Innovation Union and to growth and jobs."***
>
> Máire Geoghegan-Quinn
> E.U. Commissioner for Research, Innovation and Science
> IMI Press Release, August 2011

Enhancing Public and Private Collaboration

One factor that has enabled the U.S. to become a global leader in biopharmaceutical R&D is the unique and complex research ecosystem characterized by strong collaborative relationships between industry, government, and academic researchers. The public sector invests primarily in basic life science research, both directly and through grants to academic research institutions, and the private sector primarily focuses on translating these findings into new treatments for patients.

Historically, other countries have not had as strong or robust a collaborative model for commercialization as the U.S. However, many other countries are now implementing polices designed to emulate the U.S. model by encouraging universities and other public research institutions to work more collaboratively with the private sector to accelerate the commercialization of discovery. A key goal of the E.U.'s Innovation Union, for example, is "[to] revolutionize the way the public and private sectors work together, notably through European Innovation Partnerships between the European institutions, national and regional government authorities and business." [23]

> U.S. competitors are reforming their university and public R&D systems to encourage greater interaction and collaboration between universities and the private industry. Such interactions and collaborations have given the U.S. a competitive advantage in the past; but, other countries are increasing their investments in this area.

Actions being undertaken to promote greater interaction between universities and private industry outside of the U.S. in the countries examined include the following:

- Expanding the mission of public universities to include working with industry

- Granting universities greater autonomy regarding research investments but requiring greater accountability
- Privatizing formerly public research institutions
- Creating new research centers to support collaborations between university researchers and private industry researchers
- Implementing IP policies that clarify the rights and obligations of universities to license new discoveries for commercialization in the private sector.[24]

Examples of Increasing Collaboration

Japan is focused on fostering industrial collaboration with universities through the creation of "SuperZones", which offer reductions in regulatory burdens as a way of promoting university/industry collaborative research. The first competition specified a focus on R&D in state-of-the-art medicine.

Under **Russia**'s current government, there has been increased emphasis on reforming the university system to infuse a responsibility for research and innovation into a system that had formerly been focused only on higher education.

During the past decade, **France** has sought to refocus its innovation system on encouraging academic-industrial collaboration (including in translational research), which had not previously been emphasized in the university sector. There also has been a parallel "reinvention" of the university sector, with passage of a 2007 Law on University Reform that allowed for increased autonomy for individual universities, more competition for resources between universities, and better integration into regionally based, cluster development initiatives. The government has expressed commitment in the strongest terms to reforms of both universities and research organizations.

China began economic reforms more than three decades ago. Traditionally, China had a highly centralized and risk-averse R&D system, in which virtually all research was conducted by the state-owned Chinese Academy of Sciences. Universities were restricted to teaching and instruction. Under a "Knowledge Innovation Programme" in place since 1995, the Chinese government has sought to divest itself of research institutes better run in the private sector and to upgrade the quality and interdisciplinary capability of those that remain.

Attracting Biopharmaceutical R&D Investment

Another way in which countries seek to grow their biopharmaceutical industry and commercialize a larger percentage of their academic and public R&D base is to attract the R&D operations of global innovative biopharmaceutical companies. Many countries, particularly those with less well-developed economies, offer tax incentives and subsidies to attract foreign capital. Because foreign direct investment (FDI) contributes to a country's external financing and economic growth, it increases technological know-how, higher-paying jobs, entrepreneurial and workplace skills and new export opportunities. Many countries are offering tax and other incentives to attract FDI. A number of countries, including Ireland, China, and South Korea, have built a biopharmaceutical industry base by attracting biopharmaceutical manufacturing plants and are now seeking to also attract biopharmaceutical R&D operations.

Because FDI contributes to a country's external financing and economic growth, it increases technological know-how, higher-paying jobs, entrepreneurial and workplace skills, and new export opportunities. Many countries are offering tax and other incentives to attract FDI.

In the U.S., there is also discussion of encouraging inward investment. President Obama's Council on Jobs and Competitiveness, an advisory council composed of business, labor, and academic leaders, has recommended that the U.S. undertake "a national investment initiative to boost job-creating inward investment in the United States, both from global firms headquartered elsewhere and from multinational corporations headquartered here."[25]

Examples of Encouraging Private Investment in R&D

One country that has a unique approach to commercialization is **Germany**, which has developed an elaborate system of overlapping intermediaries dedicated to moving technology into the marketplace. Under the German system, some research is done in universities; but, much of the most elaborate research—and almost all research in collaboration with industry—is done in a series of independent associations for which support is shared among the federal and state governments. These associations each employ more than 10,000 staff and operate dozens of separate research centers or institutes. One of the associations, the **Fraunhofer Society**, which conducts applications-oriented research for industry and government, operates eight centers in the U.S. Each of these centers is affiliated with one of 60 Fraunhofer Institutes in Germany. They also work in partnership with U.S. universities.

Investing in R&D Infrastructure

The U.S. is home to the world's first research park, launched in 1951 at Stanford University. In the 60 years since, another 170 university-related research parks have sprung up across the country, promoting innovation, incubating technology, and stimulating economic growth.[26] Today, however, the U.S. has lost its lead. China and South Korea are now home to some of the world's largest research parks, developed by their national governments, attracting global R&D companies from afar to their shores. In the U.S, while the federal government invests heavily in university research, it has not had a history of investing in research parks or other infrastructure to support commercialization, with the exception of small investments made by the U.S. Economic Development Administration.

Competitors to the U.S. are increasing their investments in R&D infrastructure, including research park-type developments, while the U.S. investments in such facilities are flat or declining.

Examples of Investment in R&D Infrastructure

In the Soviet era, **Russia** had a tradition of developing "science cities," or residential communities surrounding specific scientific or engineering laboratories. Mostly, these were small communities of 10,000 to 15,000 residents. Today, the state is seeking to build a massive "Silicon Valley"-style city near Moscow known as the **Skolkovo Project**, which will include a biopharmaceutical component and is directed, in part, at attracting major overseas technology-based firms.

Singapore is developing the 2-million-square-foot **Biopolis Research Park** (established 2003), itself one component of the multidisciplinary One-North research park complex. Biopolis was designed specifically to co-locate A*STAR's bioscience research institutes is side-by-side with the R&D operations of their industry partners. As of 2008, there were 30 companies with significant biomedical research interests at Biopolis, many of them well-known multinationals. In all, some 4,000 researchers are scattered across seven buildings, while multinational manufacturing operations are situated separately in the Biomedical Park. Biopolis is currently expanding by 400,000 square feet.

"Korea's biotechnologies still fall behind advanced countries. However, if Korea fully utilizes [its] well maintained information infrastructure and excellent human resources, the industry is highly likely to grow into a core growth industry. Accordingly, the government is providing aggressive support for bio-R&D and infrastructure building."

InvestKorea Web site

Fostering R&D Investment Via Tax Policies

It has become increasingly common for countries to offer tax incentives to both attract and spur private investment in R&D and thus boost economic growth. These polices range from reducing the overall corporate tax rate and providing R&D tax credits to patent "tax boxes," which provide additional tax breaks for revenue derived from commercialization of IP.

While the U.S. was the first country to implement an R&D tax credit, it has never been permanently authorized and in recent years other countries have implemented R&D tax credits which are more expansive and favorable.

While the U.S. was the first country to create an R&D tax credit in 1981, tax incentives have not been a key focus of federal policy. In fact, the Tax Credit for Research and Experimentation (Internal Revenue Code Section 41) has never been permanently authorized, although related public debate continues. As of 2011, 26 out of 34 OECD countries offer R&D tax incentives. Brazil, China, Russia, Singapore, and South Africa also offer R&D tax incentives. Of the 18 countries examined in this analysis, 15 offer some type of R&D tax incentive. Only Germany, Saudi Arabia, and Sweden do not (Table 8).

The R&D tax incentives of the various nations differ significantly in terms of their size, design, and whether they explicitly target certain types of firms or specific locations. Some credits are provided based on the total volume of R&D conducted, whereas others, as in the U.S., are based on increases in R&D spending above a particular base year. Many countries offer larger credits for small and medium-sized companies. In some instances, credits are provided for capital investments to support R&D.

To make the credits more useful to small, early-stage companies that may not yet be profitable, eight countries offer tax credits that are refundable," i.e., the firm, if it has no tax liability, may receive a cash grant for all or a portion of the credit.[27] In the U.S., 38 states reported offering R&D tax credits in 2010, a small number of which are refundable,[28] but the federal credit is not refundable.

"The R&D Tax Credit will act as a beacon to attract more firms, particularly small and medium firms, to undertake research and development in Australia."

Senator Kim Carr, Innovation Minister, Australia
August 24, 2011

Countries with the Largest R&D Tax Credits for Large Firms, 2008

1. SPAIN
2. MEXICO*
3. PORTUGAL
4. CZECH REPUBLIC
5. FRANCE
6. NORWAY
7. KOREA
8. CANADA
9. NEW ZEALAND*
10. HUNGARY

Countries with the Largest R&D Tax Credits for Small Firms, 2008

1. SPAIN
2. MEXICO
3. FRANCE
4. CANADA
5. PORTUGAL
6. CZECH REPUBLIC
7. NETHERLANDS
8. NORWAY
9. UNITED KINGDOM
10. NEW ZEALAND

*Have since eliminated their R&D tax incentive

"Generation of R&D Tax Incentives"
Presentation by Jacek Warda
Paris, December 12, 2007
http://www.oecd.org/dataoecd/40/33/40024456.pdf

The U.S. offers a traditional R&D tax credit of 20 percent and an alternative simplified credit of 14 percent. According to OECD data and U.S. analysts such as the Information Technology and Innovation Foundation,[29] this level is less than that of many other nations. In 2008, the U.S. ranked 17th among OECD nations in terms of the level of its R&D tax credit. In the UK, the super-deduction for a small or medium-sized company is 200 percent and is refundable;[30] the current government has proposed increasing the credit to 225 percent in 2012. Large firms can receive a 130 percent credit, which is not refundable. Australia passed legislation creating a refundable R&D tax credit of 45 percent for small companies and a 40 percent nonrefundable credit for larger companies in 2011.[31] China and Singapore offer a 150 percent tax credit for R&D.

Singapore provides a 400 percent deduction for R&D as well as for IP acquisition or protection, training and approved design or automation project.[32] As illustrated in Table 8, a number of countries offer R&D tax incentives with the objective of inducing multinational companies to locate or to expand R&D operations in their country.

Table 8: Key R&D Tax Credits, by Country, as of July 2011

Country	R&D Credit	Refundable
Australia	• 125% immediate super deduction for expenses incurred • 175% enhanced super deduction is offered for expenditures exceeding a 3-year rolling average.	Yes
Brazil	• 160% super deduction of the total R&D expenditures • The super deduction increases to 170% of the qualified expenses if the entity increases the amount of researchers by up to 5% in a given year • The super deduction increases to 180% of the qualified expenses if the entity increases the amount of researchers by more than 5% in a given year • Enhanced R&D tax super deduction for patents is an extra 20% deduction when a patent is registered • Other excise and withholding tax exemptions available	No
Canada	• 20% federal tax credit for all qualifying R&D costs. Enhanced refundable credits (35%) are available for Qualified Canadian controlled private corporations. Tax credits are also available from provincial authorities	Yes
Chile	• 35% credit against corporate income tax if applicable to activities carried out in conjunction with pre-approved universities and research institutes; remaining 65% may be deducted from taxable income	No
China	• 150% super deduction of the qualifying R&D expenses • Business Tax Exemption for the transfer of qualified technology • Corporate tax rate for companies granted High and New Technology Enterprise (HNTE) status is reduced from 25% to 15% • Newly established Technology and Software companies receive a tax holiday (and new established HNTEs in certain provinces may receive tax holidays) • Enterprise Income Tax exemptions for certain qualified technology transfers.	No
France	• 30% tax credit for the first €100M of qualified R&D expenditures incurred during the tax year; plus an additional 5% of any amount in excess of the €100M threshold • Increased credits are available for new credit applicants - 50% for the first year of application (subject to limitation), 40% for the second year (subject to limitation), and 30% thereafter • Cash grants for R&D and acceleration of depreciation deductions for fixed assets used in qualified research.	Yes

(Table continues on following page)

Country	R&D Credit	Refundable
Ireland	• 25% incremental credit for all expenditures exceeding the “base amount” • 25% credit for expenditures incurred for buildings or structures used in the conduct of qualified R&D activities • R&D grants are also offered	Yes
Israel	• Tax rate reductions though the Alternative Tax Program and Strategic Program • Several grant programs are available.	NA
Italy	• 10% on expenditures for in-house research • 40% for expenditures on research connected by contract with European universities or other public research entities	Yes
Japan	• The credit equals 8% to 10% of qualifying expenditures for large companies • The credit equals 12% of qualifying expenditures for SMEs • Both SMEs and Large Companies are eligible for an Additional Incremental Credit	No
Russia	• Value added tax (VAT) —Full VAT exemption for new products and technologies development or conceptual improvements of existing products and technologies • 150% super deduction for certain R&D expenses	No
Singapore	• 100% base deduction for qualifying R&D expenses incurred • Additional 50% deduction for certain R&D expenses incurred in Singapore • Additional 250% or 300% enhanced deduction on the first S$400K of certain R&D expenses • 200% super deduction for certain expenses approved by government	Yes
South Africa	• 150% volume-based super deduction • Accelerated depreciation for R&D related capital expenditures	No
South Korea	• Tax credits for SMEs and large companies • Investment tax credits • 3% deduction of revenue from taxable income	No
United Kingdom	• 130% volume-based super deduction for large companies • 175% volume-based super deduction for SMEs • Cash credits for loss position SMEs	Yes
United States	• Incremental tax credit of 20% • Accelerated Simplified Credit of 14%	No

Source: Deloitte *Global Survey of R&D Tax Incentives*, July 2011, http://www.deloitte.com/assets/Dcom-Canada/Local%20Assets/Documents/Tax/EN/2011/ca_en_tax_RD_Global_RD_Survey_TaxIncentives_111011.pdf

Another way in which countries are encouraging R&D and its commercialization is to allow corporate income from the sale of patented products to be taxed at a lower rate than other income. This is sometimes referred to as a patent box (so called because income derived from domestic patents is isolated and taxed at a lower rate than the taxpayer's net income). A patent box is intended to encourage commercialization domestically by lowering the effective corporate tax rate for knowledge-based companies. Eight nations (Belgium, China, France, Ireland, Luxembourg, the Netherlands, Spain, and Switzerland) offer this incentive (Table 9). The UK government recently completed a "consultation" on the detailed regulations for a ten percent patent box (versus the corporate rate of 26 percent) due to come into effect in April 2013.

Table 9: Overview of Corporate Tax Rates and Impact of Patent Box Tax Policies on Tax Rates, by Country

Country	Regular Corporate Tax Rate	Patent Box Rate	Qualifying Income
Belgium	20%	6.8%	Patents and supplementary protection certificates
China	16%	0–12.5%	Registered patents and know-how
France	34%	15%	Patents and supplementary protection certificates, industrial fabrication processes, and patentable inventions
Ireland	10%	<10%	Most IP
Luxembourg	17%	5.9%	Software, copyrights, patents, trademarks, design, or models, and domain names
The Netherlands	17%	5%	Patents or IP from qualifying and approved R&D
Spain	25%	15%	Most IP
Switzerland	21%	0–12%	Most IP

Source: Information Technology and Innovation Foundation, http://www.itif.org/files/2011-pb-atkinson.pdf.

In addition to using tax incentives to encourage R&D and commercialization, a number of countries offer tax incentives to help start-up companies and to encourage investment in start-ups.

Examples of Tax Incentives

Singapore offers an extremely broad array of tax incentives including ones targeted for start-up companies. Under the R&D Incentive for Start-Up Enterprises, start-ups with few shareholders engaged in at least S$115,000 ($91,441) in R&D annually can convert their losses into tax grants up to S$15,000 ($11,926) for each of their first three years of operations. Singapore also exempts the first S$77,000 ($61,225) of taxable income and half the next S$200,000 ($159,056) from corporate income tax for qualifying start-ups and offers an angel investor tax credit.

The UK allows individual purchasers of shares in qualifying companies to deduct 20 percent of the value of their investment of up to £500,000 ($794,887) in relief against income-tax liability. Gains on subsequent sale of shares are free of capital-gains tax. If shares are disposed at a loss, the loss is deductible. The government has proposed increasing the deduction from 20 percent to 30 percent.

Italy exempts gains from investment in start-ups less than seven years old from taxation, provided ownership was held for at least three years, and the gains are reinvested within two years on start-ups in the same sector.

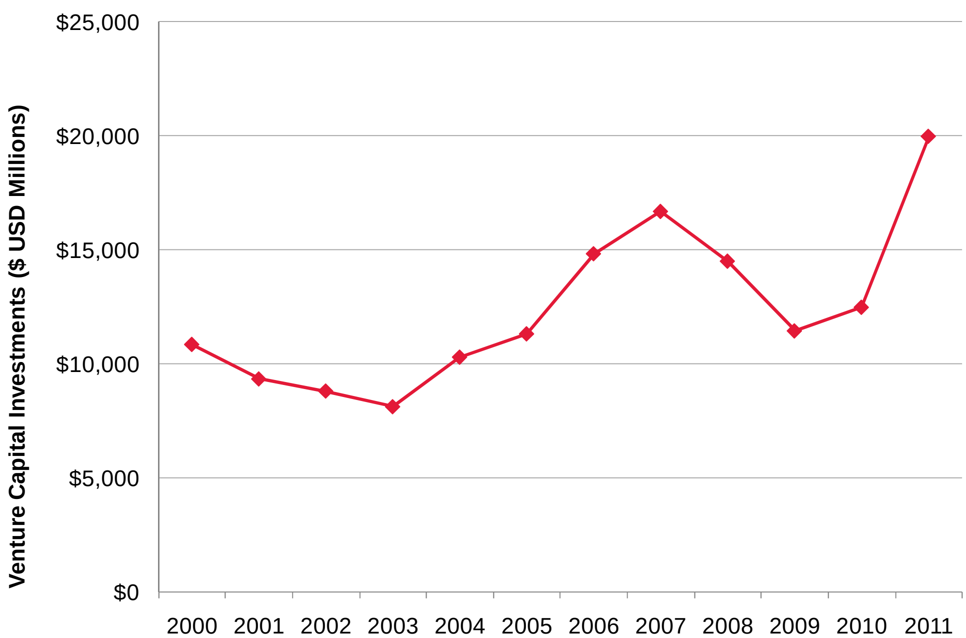
To attract R&D investment in **Canada**, the Scientific Research and Experimental Development Tax Credit offers corporations a 35 percent credit on the first C$3 million ($3 million) in qualified expenditures and 20 percent on excess, and the credit is refundable for smaller Canadian-controlled private corporations. Additional credits are available at the provincial levels.

Under **France**'s Young Innovative Companies program, companies less than eight years old with R&D at least 15 percent of revenue can be exempted from social insurance contributions and profit tax for the first three years of profitability and then at a scale that declines over 12 years. In addition, for such companies, the R&D credit is refundable, and investors can be exempted from capital gains tax on shares or options held at least three years.

Increasing Access to Investment Capital

The ability of firms to access venture and other sources of private capital is a prerequisite for countries and regions seeking to grow an innovation and knowledge-based economy. "A great deal of research suggests that venture capital plays an absolutely critical role in stimulating innovation. Indeed, outside the United States, where venture capital is less well developed, governments see the formation of a vibrant venture capital sector as one of the keys to stimulating innovation."[33] As shown in Figure 2, worldwide venture capital funding steadily rose from 2003 through 2007, took a significant drop through 2009 during the recent economic downturn, but picked up in 2010 and 2011 and stands well above earlier levels.

Figure 2: World Biopharmaceutical-Related Venture Capital Funding, 2000 to 2011



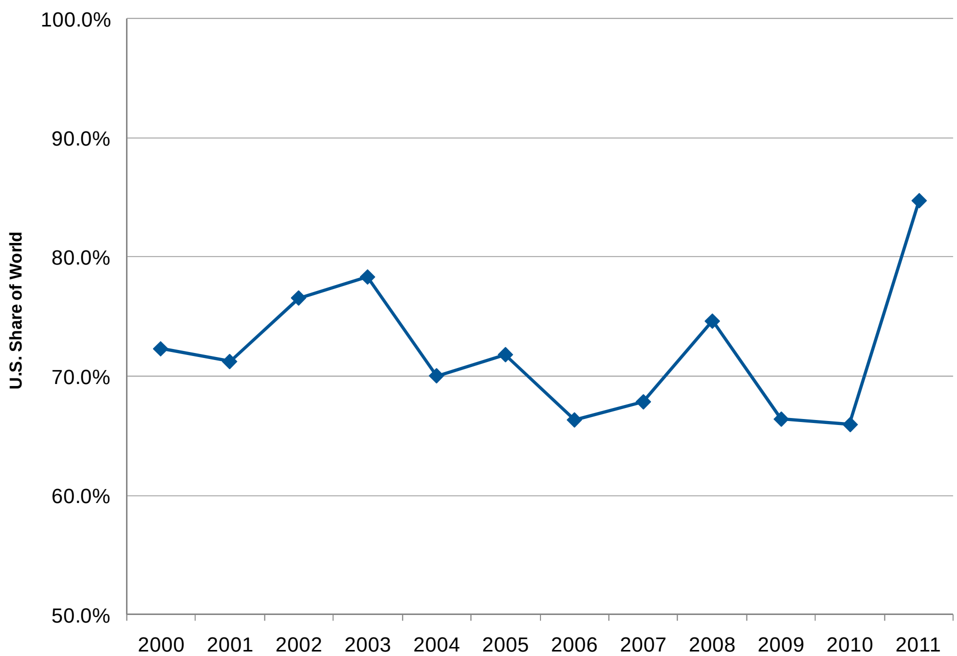
Source: Thomson Reuters Thomson One database.

The U.S. has historically led the world in terms of venture capital investment, and that advantage grew significantly in 2011, demonstrating that the U.S. continues to have the advantage of the most established capital markets and entrepreneurial development infrastructure. As a share of worldwide biopharmaceutical-related venture funding, the U.S. has hovered in the high 60 percent to high 70 percent range through the past decade, but leaped to over 80 percent in 2011 as venture capital funding rose sharply overall, suggesting that the best positioned young biopharmaceutical companies are found disproportionately in the U.S.

The U.S. continues to have the advantage of the most established capital markets and entrepreneurial development infrastructure; however, emerging nations are laying the foundation of an infrastructure for venture-backed new biopharmaceutical companies, with significant gains made in establishing a venture capital market over the past decade.

Still, as the earlier data on country-by-country venture capital funding suggests (see Table 2), emerging nations are laying the foundation of an infrastructure for venture-backed new biopharmaceutical companies, with significant gains made in establishing a venture capital market over the past decade. In particular, major gains in biopharmaceutical-related venture capital investment from 2000 to 2010 were recorded in China, which increased from $7 million in 2000 to $491 in 2010, and in Brazil, which rose from under $1 million in 2000 to $189 million in 2010. While these gains by China and Brazil are significant, the levels of biopharmaceutical-related venture capital pale in comparison to the $8.2 billion invested in the U.S. in 2010.[34]

Figure 3: U.S. Share of World Biopharmaceutical-Related Venture Capital Funding, 2000 to 2011



Notes: European Union = Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the UK.

Source: Thomson Reuters Thomson One database.

In terms of the outlook for the future, findings from a survey of more than 500 venture capital professionals and chief executive officers (CEOs) of venture-backed companies in the U.S. suggest that it will be increasingly difficult to raise funding moving forward, particularly at the seed and early stage.[35] Fifty-eight percent of the venture capitalists surveyed believe that there will be a seed and early-stage funding shortage and 67 percent of the CEOs expect that it will be difficult to raise follow-on money. Fifty percent of the survey respondents will invest outside the U.S. next year, with China and Western Europe being the most cited global region at 19 percent each, followed by Canada (14 percent), India (12 percent), Latin America (ten percent), Eastern Europe (seven percent), Middle East (six percent), Africa (four percent), and Japan (three percent). It may also be particularly difficult for bioscience firms to raise financing. Fifty-eight percent of the venture capital industry respondents indicated that they expect investment decreases in the biopharmaceutical and medical device sectors. About half of the venture capital fund managers indicated that they plan to invest outside the U.S., with China and Western Europe among the most likely destinations. Similar findings were identified by the National Venture Capital

Association in its October 2011 survey of its members, which found decreasing investments being made in biotechnology and medical device start-ups, with FDA regulatory challenges identified by 61 percent as having the highest impact on their investment decisions.[36]

Governments can seek to ensure that firms have access to the capital needed for sustainability and growth by creating incentives to encourage private investment in companies or venture capital funds and/or by directly investing in companies. While few programs exist at the national level in the U.S. aimed at increasing the availability of early-stage capital, state governments have employed a variety of tools to encourage the establishment of in-state venture funds or to encourage funds located out-of-state to consider investments within their states. Some states have provided resources to create a "fund of funds," a fund that invests in private venture capital funds that agree to make a good faith effort to invest in firms within the state. Other states have encouraged state pension funds to invest in venture capital funds, and still other states have created public venture capital funds. States also offer tax incentives to encourage investment in technology companies and in private venture capital funds. Examples of state programs include the following:

- The Connecticut BioSeed Fund provides early-stage capital designed to sustain a company until it is able to secure its first round of private investment. The BioSeed Fund is a $5 million fund managed by Connecticut Innovations, a nonprofit organization that promotes technology-based economic development in the state.
- The Pennsylvania Life Sciences Greenhouses make pre-seed and seed-stage investments in life science start-up companies. These capital pools are supplemented by several other programs to stimulate the formation of locally managed venture capital funds.
- Wisconsin has enacted a number of venture investment tax credits under which qualifying angel and venture capital investors may receive tax credits of 25 percent. Another way in which Wisconsin has tried to increase the availability of early-stage capital is the State of Wisconsin Investment Board, the state's pension fund, which has invested $200 million in venture funds that are managed by four Wisconsin firms, two of which invest in health care and life science firms.

Again, although individual states have actively invested in state-specific venture funds and programs, there are few national programs in the U.S. Conversely, the analysis indicated that many competing countries have taken similar actions at the national level. An examination of investment capital programs and initiatives being implemented reveals a number of commonalities among the countries, including the following:

- Policies to encourage private investment in companies and/or investment funds
- Direct investment in innovative, technology-based companies.

These two components to the growing global trend in providing access to investment capital are discussed in detail below.

Policies to Encourage Private Investment in Companies and/or Investment Funds

One way to build capital markets is to encourage investment in private venture funds either by using public dollars to leverage private investment or by offering tax advantages for investing in privately managed funds. The E.U.'s European Investment Fund (EIF) is an example of a fund that leverages public sector funding to raise private funds. EIF makes equity funding available by purchasing interest in privately managed venture capital partnerships specializing in a region of the E.U. Each investee partnership secures other limited partner investors, thus using public investment to attract and leverage private capital. The EIF manages member-nation interests in 28 venture funds of which 11 include a life science focus.

The UK's Capital for Enterprise is a state-affiliated investment fund that also invests public money in privately managed venture capital partnerships. In 2009, the government announced the creation of a new UK Innovation Investment Fund comprising two 10-year funds that will pool public and private investment to create a fund targeted at more than $500 million.

> While the U.S. government at the national level does not provide direct venture capital or other investment in companies, the EU and UK are among those providing such incentives, in some cases investing directly in innovative, technology-based companies.

In Australia, the AusIndustry development agency offers flow-through tax benefits (including eligibility of foreign investors for complete exemption from capital gains taxes) to eligible venture capital firms. Also, the Innovation Investment Fund has directly invested more than $A500 million ($516.4 million) in federal funds (alongside private co-investors) in the creation of at least 16 new venture capital funds that target early-stage investing across several sectors.

Direct Investment in Innovative, Technology-Based Companies

Nearly all of the countries examined have development banks or publicly supported investment vehicles that make direct investments in companies. Germany's national development bank, KfW, has a High-Tech Start-Up Fund that makes equity investments in partnership with several of its largest industrial companies. About a third of the companies in which Germany's start-up fund has invested since 2005 are biotechnology or life science companies. Sweden has several state-owned or quasi-state entities that provide equity capital to early-stage enterprises and small and medium-sized enterprises (SMEs). One program uses E.U. "structural funds" to make minority investments in start-ups, matched by private investors. Industrifonden,[37] a foundation established by the German government in 1979, invests directly in SMEs with international-growth potential in three areas, including life sciences. InnovationBridge[38] is a national pre-seed commercialization fund that invests in companies established around university-developed technologies.[39]

China's Innovation Fund for Small Technology-Based Firms offers more than $600 million in start-up capital in the form of grants, subsidized loans, and equity investments up to 20 percent of a company's capital base to companies engaged in technology commercialization and innovation.

The U.S. government in contrast does not have a vehicle for making direct equity investments in companies, although various federal programs can provide grants, loans, and loan guarantees. One source of early-stage capital in the U.S. is the Small Business Innovation Program (SBIR) and related Small Business Technology Transfer (STTR) Program. The SBIR program reserves a certain percentage of federal agencies' R&D budgets for small firms; in FY 2010, $2.1 billion went to small firms through the 11 federal agencies that participate in the program. The STTR program requires the five agencies that spend more than $1 billion on outside research to set aside 0.3 percent of their budgets for partnerships between small firms and nonprofit institutions, which amounted to $276 million in 2009.[40] The program was reauthorized in December 2011 for six years, and a change was made to allow companies in which venture funds are the majority investors to compete for up to 25 percent of the funds available from the NIH, Department of Energy, and National Science Foundation and for 15 percent of funds available from other agencies. In addition, the SBIR allocation will increase from 2.5 percent of agency extramural R&D budgets to 3.2 percent over the course of the most recent reauthorization.

Building Human Capital

Developing an innovative biopharmaceutical cluster requires access to well-educated, highly skilled talent. Yet this is an area in which the U.S. is falling behind—both in terms of the level of proficiency of its graduates in science, mathematics, and engineering and in the number of highly educated and talented individuals in these fields. As the National Academies warned in its 2007 report, *Rising Above the Gathering Storm*, "Having reviewed trends in the U.S. and abroad, the committee is deeply concerned that the scientific and technological building blocks critical to our economic leadership are eroding at a time when many other nations are gathering strength. In particular, the interest of students to pursue science, technology, engineering and mathematics (STEM) skills and careers seems to be diminishing."[41] In a September 2010 update by the members of the highly influential 2005 report from the National Academies, *Rising Above the Gathering Storm,* the unanimous view on STEM education is that "in spite of sometimes heroic efforts and occasional very bright spots, our overall public school system—or more accurately 14,000 systems—has shown little sign of improvement, particularly in mathematics and science."[42]

Early exposure to math and science can help foster student achievement and interest in STEM-related fields. Unfortunately, results from the National Assessment of Educational Progress (the nation's only ongoing representative sample survey of student achievement in core subject areas) show that while there were marked improvements in student achievement in math and science between 2000 and 2009, the percentage of U.S. students that scored at the "proficient or above" level of achievement in these subjects remains relatively low:

- Student achievement in math has improved in the U.S. over time. In 2009, 47 percent of U.S. 4th graders, 43 percent of 8th graders, and 26 percent of 12th graders scored proficient or higher in math. These scores reflect an improvement from 2000 scores which were 26 percent, 27 percent, and 17 percent, respectively.

"In spite of sometimes heroic efforts and occasional very bright spots, our overall public school system—or more accurately 14,000 systems—has shown little sign of improvement, particularly in mathematics and science."

September 2010 update by the members of the highly influential 2005 report from the National Academies, *Rising Above the Gathering Storm*

- Student scores in science have also risen over time. In 2009, 35 percent of 4th graders, 32 percent of 8th graders, and 22 percent of 12th graders scored proficient or higher in science, compared with 29 percent, 32 percent, and 18 percent, respectively, in 2000.
- While better student achievement in math and science may reflect progress in the U.S. education system, there is still significant room for improvement as less than half of 4th and 8th graders are proficient in math and about a third are proficient in science. Even more alarming is the fact that only a quarter of U.S. students are proficient in either subject by the time they reach the 12th grade. [43]

Poor early preparation is a likely contributor to the lack of student interest in pursuing STEM degrees. As a study by the Business-Higher Education Forum found, only 17 percent of American students in their senior year of high school have math proficiency and an interest in pursuing a career in the STEM disciplines.[44] McKinsey & Company concludes that if United States' youth could match the performance of students in Finland, America's economy would be between nine and sixteen percent larger. That equates to between $1.3 and $2.3 trillion each year.[45]

While U.S. students are underperforming, other countries are ramping up their STEM education efforts, further widening the gap between the achievement of U.S. students and their foreign counterparts. One metric that is often used to assess how well a country is succeeding in educating students is the Programme for International Student Assessment (PISA), a test administered by the OECD. In 2009, Shanghai students scored first and Hong Kong students scored third in both science and math scores among nearly 65 countries that participated. Singapore, South Korea, Japan, and Canada all scored among the top 10. U.S. students scored below nearly 30 other countries in math and more than 20 other countries in science (Table 10).[46]

Table 10: PISA Math and Science Scores for selected countries, 2009

Country	PISA Math Ranking, 2009	PISA Science Ranking, 2009
China	1	1
Singapore	2	4
South Korea	4	6
Japan	9	5
Canada	10	8
Australia	15	10
Germany	16	13
France	22	27
Sweden	26	29
United Kingdom	28	16
Ireland	31	19
United States	31	23
Italy	34	35
Russia	38	39
Israel	42	42
Chile	49	44
Brazil	57	53

Another important indication that the U.S. is falling behind other countries in building a STEM workforce is the low number of people completing science and engineering degrees and the number of researchers working in R&D compared to other countries. In terms of science-related graduates between 25 and 34 years old, the U.S. ranks last among the OECD countries. In terms of the number of researchers employed in R&D, Singapore ranks highest with 6,088 researchers per million population, followed by Japan and Sweden. The U.S. ranks fourth with 4,663 researchers per million population, similar to Australia, Canada, and South Korea (Table 11).

An examination of human capital development programs and initiatives being implemented reveals a number of commonalities among the countries, including the following:

- Policies to build the STEM talent pool
- Development and implementation of talent attraction programs
- Development and implementation of talent development programs.

These three components to the growing global trend in building human capital are discussed in detail below.

Another important indication that the U.S. is falling behind other countries in building a STEM workforce is the low number of people completing science and engineering degrees and the number of researchers working in R&D compared to other countries.

Table 11: Science-Related Graduates and Number of Researchers in the Workforce

Country	Science-related Graduates Among 25–34-Year-Olds (2009)	Researchers in R&D per Million People
Singapore*	N/A	6,088
Japan*	1,643	5,573
Sweden	1,596	5,573
United States*	1,472	4,663
South Korea*	3,555	4,627
United Kingdom	2,380	4,269
Canada*	2,146	4,260
Australia*	2,362	4,224
Germany*	1,796	3,532
France*	2,717	3,496
Russia	N/A	3,191
Ireland	2,172	3,090
European Union**	1,770	2,876
Italy	N/A	1,616
China*	N/A	1,071
Chile*	1,745	833
Brazil	N/A	694
South Africa*	N/A	393

*Researchers in R&D per Million People Data are for the most recent year available where 2008 data are unavailable. 2004=Chile, France; 2006=Australia, Canada, United States; 2007=China, Germany, Japan, South Korea, Singapore, South Africa,

**E.U.-15 = Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the UK

Note: Science-related fields include life sciences; physical sciences, mathematics and statistics, computing; engineering and engineering trades, manufacturing and processing, architecture and building. Data represents the number of S&E graduates divided by the total number of 25–34-year-olds in employment per 100,000.

Sources: *Education At a Glance*, OECD, 2011. OECD, PISA 2009 Database; United Nations Educational, Scientific, and Cultural Organization (UNESCO) Institute for Statistics

Policies to Build STEM Talent Pool

An examination of the policies and programs being pursued to attract, develop, and retain talent show that countries are competing for talent as aggressively as they compete for industry locations and R&D operations. Countries are seeking to build their talent pools by both recruiting scientists and researchers and educating and encouraging their citizens to pursue careers in STEM fields.

Almost all of the countries reviewed for this report have policies designed to both develop talent from within as well as to attract talent from abroad (Table 12). Policies and programs range from:

- Offering scholarships and fellowships to attract students to study science, math, and engineering
- Subsidizing doctoral wages

- Recruiting world-class talent by offering incentives targeting both foreign and native scientists and researchers to relocate
- Making it easier for skilled workers to immigrate
- Subsidizing overseas study.

Table 12: Select Initiatives to Develop, Attract, and Retain Talent

Country	Fellowships/Scholarships/ Upgrading Universities	Incentives to Attract Researchers, Faculty and Students	Eased Immigration Policies for Skilled Workers	Overseas Study for Residents
Brazil	X			
Canada	X	X	X	
Chile				X
China	X	X		
France		X		
Germany		X	X	
Ireland	X			
Israel		X	X	
Italy			X	
Japan	X	X		
Russia	X	X		
Saudi Arabia	X			X
Singapore	X	X	X	X
South Africa				X
South Korea		X		
Sweden	X			
United Kingdom		X		

Talent Attraction Programs

While in the past, the U.S. attracted large numbers of entrepreneurial, highly educated people, recent restrictions on immigration have made it harder to entice skilled workers. In 2011, only 65,000 H-1B visas were reserved for scientists, engineers, and technological experts. (The H-1B visa program allows U.S. businesses to employ foreign workers in specialty occupations that require theoretical or technical expertise in specialized fields, such as scientists, engineers, or computer programmers.) This is one-third less than the number reserved between 1994 and 2004. This immigration policy change is significantly different than many of nation's competitors.

> The nation's competitors are placing more emphasis on attracting talent than the U.S., offering incentives to attract world-class researchers implementing favorable immigration policies, and encouraging former residents who are working abroad to return.

For instance, European nations have been particularly active in trying to attract highly skilled people to relocate to their countries. France's National Center for Scientific Research places considerable emphasis on recruiting non-French researchers, and the Agency for National Research supports university-based Chairs of Excellence (eminent scholar professorships) allowing both national research organizations and universities to recruit foreign researchers.[47] Germany lowered the income level at which a foreign highly skilled worker can receive an "unlimited settlement permit" and has eased access for academics from new E.U. member states. For academics from outside the E.U., the German labor market has been opened up to all disciplines, provided that no domestic job seekers can be found to fill the post.[48]

The E.U. also actively promotes mobility, i.e., the free circulation of researchers within the E.U. nations as a method of encouraging further "cohesion" among member-nation economies. In addition, E.U. policy seeks to make science and engineering occupations uniformly attractive across all member nations. Under the European Charter for Researchers and the Code of Conduct for Recruitment of Researchers,[49] member nations, universities, and other research-performing institutions commit to meeting the needs of researchers for social insurance, portable retirement options, good working conditions, and enhanced opportunities for further education and training.[50] The E.U.'s EURAXESS program is a one-stop portal for researchers seeking to advance their careers by moving to other countries. [51]

Furthermore, while some attention has been paid in the U.S. to very senior academic recruitments, an equally serious challenge comes from more routine programs countries use to attract large numbers of early and mid-career scientists who have earned doctoral degrees in the U.S. but have not become U.S. citizens or settled here permanently. These scientists are increasingly provided incentives to return to their native countries where they may head up R&D units for innovative companies or conduct clinical research. At the same time, the U.S. continues to place onerous requirements on these U.S. trained foreign scientists to stay and work in the U.S.

Examples of Talent Attraction Programs

The **Thousand Talents Program,** commonly known as the "sea turtle" strategy, recognizes that many of **China**'s most talented science and engineering students have gone abroad and found places in Western academic and industrial career tracks and, as a result, have not returned to China to pursue their careers. The goal of the program is to attract 1,000 of the most talented expatriate scientists back to well-funded, prestigious positions (deanships, department chairmanships, etc.) with universities and research institutes of the Chinese Academy of Sciences.

The **Israel Science Foundation** offers funding under the "**Morasha" program**, which is designed to encourage Israelis who pursued postdoctoral training overseas to return and work in Israeli universities. Morasha provides funding, which must be matched by the university, for one-time lab and other start-up costs and 3-year follow-up research support for postdoctoral students in the life sciences as well as in physics, chemistry, and other sciences. Experimental scientists can receive up to $600,000 for start-up costs and $50,000 annually for three years for research support. Theoretical scientists can receive $100,000 for start-up costs and $25,000 annually for three years for research projects. More generally, the Israeli government offers tax exemptions on certain income classes for up to ten years to new immigrants and returning residents and additional exemptions to foreign investors under certain circumstances.

Talent Development Programs

Countries are also providing education and training opportunities for students in order to grow their indigenous workforce. Brazil, which set a goal of producing 16,000 PhDs and 45,000 master's degrees, provides scholarships through several programs. These efforts include programs that send students abroad to broaden their research experience and subsequently attract them back with opportunities at universities and research institutions at home

U.S. competitors are providing a wide array of education and training opportunities for students in order to grow their indigenous workforce.

Singapore works on parallel tracks of recruiting talent at all levels and developing indigenous talent, including offering a very broad array of scholarships and fellowships. Many of the advanced-degree programs are aimed either at inward recruits or at providing graduates of Singapore's universities with significant, multiyear doctoral or postdoctoral experiences at major universities abroad and then re-integrating them into the country's research institutes as scientific staff. Other fellowships assure that those on a traditional academic career track in Singapore also gain experience in the more targeted environment of the research institutes. It is also worth noting that Singapore has developed a new graduate school of medicine that stands a strong chance of creating active "physician scientists" largely because it follows the American concept of medicine as a graduate/professional program with at least some exposure to research, replacing the British and Continental model of the medical degree as an undergraduate one aimed at practice.

To encourage entrepreneurship, the National University of Singapore offers an Overseas Colleges Program that sends bright undergraduate students to entrepreneurial hubs, including Silicon Valley and Philadelphia, to work as interns in high-technology start-up companies while taking entrepreneurship courses at partner universities (Stanford University in Silicon Valley and the University of Pennsylvania in Philadelphia). The Philadelphia program is focused on the life sciences. The university also places students as interns with start-up companies in Singapore.

Ireland has also implemented new programs aimed at developing its bioscience workforce. For example, to meet the needs of its biopharmaceutical sector, the Industrial Development Agency (IDA) provided €72 million ($97.3 million) in funding to the National Institute for Bioprocessing Research and Training (NIBRT),[52] a consortium of four Dublin universities that coordinates training curriculum in bioprocessing, while also offering industry access to a 6,500-square-meter pilot plant fully equipped to scale up mammalian cell-based cultures.

CONCLUSION

The innovative biopharmaceutical industry has been an important contributor to U.S. economic growth and sustainability. While the U.S. has dominated globally over the past three decades, many developed and developing countries have been making substantial investments via new pro-innovation policies and programs to increase the economic footprint of the biopharmaceutical and related sectors in their own countries. The U.S. has been characterized by strong public and private R&D investments, a free market system that supports innovation, a robust IP and regulatory system, as well as access to venture and other private capital and a well-educated and highly skilled workforce. Increasingly, both developed and developing nations are creating the type of innovation ecosystem that allowed the U.S. to seize global leadership in biopharmaceutical R&D from Europe in the 1990s. Other countries are borrowing effective practices that have worked in the U.S. and building on them at the same time that the U.S., in some respects, is becoming less favorable to innovation. While the U.S. is still a world leader in biopharmaceuticals, as the President and his Jobs Council and others have stated, a range of factors underpin national competitiveness. In an increasingly global economy, the future of U.S. global leadership is not assured.

Perhaps the most striking finding of this comparison of policies and programs being enacted by other nations to grow their innovation biopharmaceutical industry is the similarity in approaches found across both developed and developing nations. While developed countries are more able to leverage their own intellectual and financial resources and developing economies are more likely to focus first on attracting foreign direct investment and talent from abroad before turning to development of indigenous resources of technology, talent, and capital, all of the countries examined are focusing on similar strategic components to grow their innovative biopharmaceutical industry.

This report highlights that a range of countries have identified knowledge-based industries, particularly the biopharmaceutical and related industries that make up the biomedical field, as providing potential to speed job creation by boosting R&D investment in-country, building a strong talent pool, enhancing economic growth and sustainability, and increasing the ability to compete globally to improve a particular country's long-term economic position. This examination of policies and programs being implemented around the world to attract and grow the biopharmaceutical industry revealed that most of the countries examined, both those with developed economies and those that have emerging economies, are making investments to grow a knowledge-based economy, often targeting the biopharmaceutical or biotechnology sector. Perhaps the most striking finding of this analysis is the similarity found across countries in terms of policies and programs being pursued. The range of strategies being employed across the 18 countries and the E.U.

that are seeking to build their own innovation economies, including their biopharmaceutical sectors, include the following:

- **Building R&D excellence and seeking to accelerate commercialization of research findings** by increasing public funding of R&D; encouraging greater public/private collaborations, often with international partners; attracting the R&D operations of global companies through a range of tax and other financial incentives; adopting policies to encourage universities to commercialize research findings; investing in R&D infrastructure; and implementing a range of policies to encourage private firms to invest in R&D from flexible immigration laws to tax and other policies.
- **Attracting, retaining, and developing talent** by offering programs that encourage and enable students to study math, science, and engineering and that provide incentives to attract and retain world-class researchers and scientists to national universities and research institutes.
- **Ensuring access to venture and other private capital for companies**, particularly start-ups and emerging companies, by using tax incentives to encourage private investment in venture capital funds and/or technology-based companies and investing public funds directly in private venture capital funds and/or companies.

Table 13 compares the U.S. to the benchmark set of countries on key areas addressed in the innovation policies examined.

Table 13: Comparison of U.S. and International Practices to Support the Development of the Biopharmaceutical and Other Knowledge-Intensive Industries

	International Practice	U.S. Practice
Presence of national innovation and/or biopharmaceutical development strategy	Nearly all countries have innovation strategies that include focus on biopharmaceuticals Half of the countries have an explicit biotechnology/biopharmaceutical development strategy Greater coordination of national and regional strategies	Many state-level bioscience/life science strategies No tradition of national innovation or competiveness strategy; some modest efforts under way No coordinated national or regional strategy focused on promoting the sustainability and growth of the biopharmaceutical and related industries
Formal economic development and industrial policies focused on supporting "industry clusters"	National funding to regions to support cluster development National support for development of science and technology parks and other infrastructure to promote industry-university collaborations	U.S national policy has not traditionally focused on cluster development Limited activities recently initiated but not focused specifically on the life sciences Much more activity at the state and regional level but little support from national level for regional efforts

(Table continues on following pages)

	International Practice	U.S. Practice
R&D and Commercialization	Significant increases in public support for R&D, with most countries committing to invest a certain percentage of GDP in R&D, albeit for many countries starting from a low base compared to the U.S.	Select legislative proposals call for doubling investment in basic research but funding for basic research at the national level is flat or declining Administration has set a goal of increasing R&D as percentage of GDP to three percent, but no specific strategy has been outlined
	Reforming university and public R&D systems to encourage greater interaction and collaboration between universities and private industry	Strong U.S. public /private innovation ecosystem remains a competitive advantage but increasingly faces barriers States are facing increasing budgetary pressures which are resulting in reduced public funding for universities, community colleges, and other educational and training programs
	Creating mechanisms to accelerate commercialization of university-developed technologies Learning from the U.S., other countries are implementing Bayh-Dole-type policies	Implementation of Bayh-Dole continues to have positive economic impacts U.S. universities continue to develop new mechanisms to move discoveries into the marketplace, including seeking partnerships with companies Biopharmaceutical and other innovative industries are embracing open innovations, thus making university collaboration even more important, but barriers to public-private partnerships are increasing, e.g., conflicts of interest provisions Creation of the NIH National Center for Advancing Translational Sciences (NCATS) seeks to catalyze innovative methods to spur the development, testing and implementation of diagnostics and therapeutics.
	Increasing public investment in R&D infrastructure, including research facilities, research parks, and incubators	Public investment in basic research through National Institutes of Health, National Science Foundation, and other federal agencies has remained stable and/or declined slightly in recent years Very modest public funding support through U.S. Economic Development Administration (EDA) More activity at the state and regional level but little coordination between national and state efforts especially as EDA awards often go directly to counties or municipalities
	Accelerating use of tax policies to encourage investment in R&D	U.S. first to offer R&D tax credit but today incentive is much less than that of other countries R&D tax credit has not been expanded or made permanent with the lack of certainty likely impacting R&D investment decisions

	International Practice	U.S. Practice
Tax Policies	Offering significant tax incentives to help start-up companies	State-level incentives are available but as public budgetary pressures increase, incentives are being reduced in some states Few national-level incentives
	Increasingly globally competitive corporate tax rates	The U.S. now has the highest corporate tax rate among developed nations
Capital	Venture capital investment increasing, particularly in Europe and Asia, where some countries are establishing publicly backed venture capital funds	U.S. continues to dominate bioscience venture capital market globally, but becoming more difficult for bioscience firms to raise financing with investment shifting to later-stage deals and large declines seen in overall venture capital market in U.S. in recent years
	Many countries offer incentives for private investment in venture capital partnerships and/or in technology-based companies	Many state governments provide programs that catalyze private investment in venture capital funds and/or in technology-based companies Limited direct national level policies focused on promoting venture capital and other private capital investments. There are tax policies and other specialized mechanisms, such as SBIR/STTR
	Most countries have development banks that can invest directly in companies	At the national level, no vehicle for making equity investments in firms
Talent	Increasingly competitive incentives to attract and retain foreign talent and to encourage those trained and working in other countries to return to home country	U.S. immigration policies increasingly restrictive, limiting the nation's ability to attract skilled scientists and engineers
	E.U. countries encouraging mobility	More foreign graduates returning to their home countries due to increasingly restrictive immigration policies
	Emerging countries working to raise education levels, including in science, technology, engineering and mathematics (STEM) fields, and for targeted industries	U.S. students increasingly not proficient in and/or not interested in STEM careers with other countries ranking higher on many STEM measures The U.S. lacks a coordinated approach to STEM education
	Increased emphasis on improving STEM rankings at all education levels	The April 2012 Bioeconomy Blueprint calls for enhancements to STEM education and incentives for academic institutions to enhance entrepreneurship and restructure training programs Limited national- and state-level investment aimed at improving STEM performance at all educational levels

Ever more, competing countries are recognizing that a long-term commitment to science, technology, and innovation is vital to enabling the biopharmaceutical industry to establish the foundation for economic growth and jobs of the future. It is clear that the U.S. still leads in many of the components required to support knowledge- and innovation-based industries, including the biopharmaceutical industry. But, it should be recognized that international competition is rising and retaining U.S. leadership will require the U.S. to not only maintain but expand investments in R&D and commercialization, education and workforce development, financial capital, and the nation's technology infrastructure. A range of other factors also impact the degree to which a country has a favorable environment for innovation, including many which were beyond the scope of this report. For example, America's innovative biopharmaceutical companies face increasing challenges, ranging from the cost and increased complexity of bringing new medicines to patients, the prospect of attracting and sustaining the capital needed to develop tomorrow's new treatments and cures, the increasing uncertainty related to coverage and payment of innovative medicines, and intensifying competition from other countries. Continued innovation is fundamental to U.S. economic well-being and the nation's ability to compete effectively in the global economy. Just as other countries have drawn lessons from the growth of the U.S. biopharmaceutical sector, so too can the U.S. learn from other countries that are strategically and effectively creating a more favorable environment for R&D investment.

Endnotes:

[1] Battelle Technology Partnership Practice. "The U.S. Biopharmaceuticals Sector: Economic Contribution to the Nation," July 2011.

[2] Arthur Daemmrick. "Where is the Pharmacy to the World? International Regulatory Variation and Pharmaceutical Industry Location," Harvard Business School, Working Paper 09-118, 2009, http://www.hbs.edu/research/pdf/09-118.pdf. Accessed December 11, 2011.

[3] Battelle Technology Partnership Practice. "The U.S. Biopharmaceuticals Sector: Economic Contribution to the Nation," July 2011.

[4] U.S. International Trade Commission Trade Data database.

[5] Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry 2012 Profile*, April 2012.

[6] National Science Board. Science and Engineering Indicators, 2012, National Science Foundation.

[7] President Barack Obama, National Academy of Sciences, April 27, 2009.

[8] See National Science Foundation 2012 Science and Engineering Indicators, Table 6–16.

[9] See National Science Foundation 2012 Science and Engineering Indicators, Table 5–36.

[10] *R&D Magazine*. 2012 Global R&D Funding Forecast, prepared by *R&D Magazine* and Battelle, December 2011.

[11] Thomson Reuters Delphion patent analysis database. U.S. and world total patents applications to the World Intellectual Property Organization classified under International Patent Class A61.

[12] Thomson Reuters ThomsonOne venture capital database. U.S. and world venture capital deals classified as "Medical/Health/Life Science" by Thomson Reuters.

[13] Ross C. DeVol, Armen Bedroussian, and Benjamin Yeo. *The Global Biomedical Industry: Preserving U.S. Leadership*. Milken Institute, 2011.

[14] See National Science Foundation 2012 Science and Engineering Indicators.

[15] See World Trade Organization.

[16] Datamonitor. Global Pharmaceuticals, December 2011, with separate country reports issued from December 2011 and January 2012.

[17] See http://www.moital.gov.il/NR/exeres/802D8E02-473D-4449-801A-694E47CDDB87.htm. Visited May 5, 2011.

[18] See http://www.matimop.org.il/. Visited May 5, 2011.

[19] The EU's program that funds research, technology development, and commercialization is known as the Framework Program for Research and Development. It is currently in its seventh 5-year iteration.

[20] Jeffrey Brainard. "U.S. Agencies Look to Interdisciplinary Science," *Chronicle of Higher Education,* June 14, 2002.

[21] Battelle and *R&D Magazine*, "2012 Global R&D Funding Forecast," December 2011, page 15.

[22] See http://www.bis.gov.uk/assets/biscore/innovation/docs/s/11-1429-strategy-for-uk-life-sciences.pdf. Visited March 13, 2012.

[23] Bullet quoted from http://ec.europa.eu/research/innovation-union/index_en.cfm?pg=intro. Visited March 4, 2011.

[24] This project did not include a review of IP policies, and only notes IP policies when explicitly indicated by a country as part of their innovation strategy.

[25] *Taking Action, Building Confidence*, Jobs Council Report to the President, www.jobs-council.com. Visited November 18, 2011.

[26] Brian Darmody. "The Power of Place 2.0: The Power of Innovation," Association of University-Related Research Parks, 2010.

[27] Deloitte *Global Survey of R&D Tax Incentives*, July 2011, http://www.deloitte.com/assets/Dcom-Canada/Local%20Assets/Documents/Tax/EN/2011/ca_en_tax_RD_Global_RD_Survey_TaxIncentives_111011.pdf.

[28] Battelle/BIO State Bioscience Initiatives 2010.

[29] See http://www.itif.org/files/2011-pb-atkinson.pdf. Visited March 13, 2012.

[30] See http://www.hmrc.gov.uk/ct/forms-rates/claims/randd.htm#2. Visited March 31, 2012.

[31] See http://www.ato.gov.au/taxprofessionals/content.aspx?doc=/content/00193778.htm. Visited March 31, 2012.

[32] See http://iras.gov.sg/irashome/PIcredit.aspx#About_Productivity_and_Innovation_Credit. Visited March 31, 2012.

[33] G. Pisano "Science Business: The Promise, The Reality and the Future of Biotech." Harvard Business School Press, 2006:115.

[34] Thomson One for Venture Capital Funding in Biopharmaceutical-Related Technologies.

[35] "Optimism Wanes for Start-Up Ecosystem as Venture Capitalists and CEOs Face Economic Realities in 2012," http://www.fiercebiotech.com, December 15, 2011.

[36] National Venture Capital Association, Vital Signs: The Crisis in Investment in U.S. Medical Innovation and the Imperative of FDA Reform, Survey Findings, October 2011.

[37] See http://www.industrifonden.se/en. Visited May 17, 2011.

[38] See http://www.innovationsbron.se/Om-Innovationsbron/Innovationsbron-in-English/. Visited May 17, 2011.

[39] See report on state-owned companies, available at http://www.sweden.gov.se/content/1/c6/08/94/86/187a4344.pdf. Visited May 17, 2011.

[40] Robb Mandelbaum. "Congress Reaches Deal to Reauthorize and Revamp Small-Business Programs," *The New York Times*, December 14, 2012.

[41] Committee on Science, Engineering, and Public Policy. Rising Above the Gathering Storm: Energizing and Employing America for a Brighter Economic Future, The National Academies, 2007.

[42] National Academies of Science, *Rising Above the Gathering Storm, Revisited: Rapidly Approaching Category 5*, September 2010, page 4.

[43] U.S. Department of Education, Institute of Educational Sciences, National Center for Education Statistics. National Assessment of Educational Progress, 2009.

[44] Business-Higher Education Forum. "Creating the Workforce of the Future: The STEM Interest and Proficiency Challenge," August 2011, http://www.bhef.com/publications/documents/BHEF_Research_Brief-STEM_Interest_and_Proficiency.pdf.

[45] McKinsey & Company. The Economic Impact of the Achievement Gap in America's Schools. April 2009. Available at: http://www.mckinsey.com/App_Media/Images/Page_Images/Offices/SocialSector/PDF/achievement_gap_report.pdf.

[46] See http://nces.ed.gov/surveys/pisa/.

[47] See program announcement at http://www.agence-nationale-recherche.fr/documents/aap/2010/aap-chex-2010-en.pdf or http://www.agence-nationale-recherche.fr/fileadmin/user_upload/documents/aap/2011/aap-chex-en-2011.pdf . Visited January 30, 2011.

[48] See http://www.hightech-strategie.de/en/883.php. Visited July 17, 2011.

[49] See http://ec.europa.eu/euraxess/pdf/brochure_rights/rights_leaflet_highres_en.pdf. Visited March 4, 2011.

[50] See http://ec.europa.eu/research/era/areas/researchers/researchers_en.htm. Visited March 4, 2011.

[51] See http://ec.europa.eu/euraxess/links/about_en.htm. Visited March 4, 2011.

[52] See http://www.nibrt.ie/. Visited April 8, 2011.