Quantria Strategies, LLC

Increasing Investment and Jobs in Life Sciences in the United States Through Targeted R&D Tax Incentives

A White Paper Prepared For:

The Life Sciences Investment Act Coalition

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Overview

The United States leads the world in innovation and research and development (R&D). Spending on R&D in the United States exceeds that of any other country on an annual basis. R&D expenditures correspond to growth in the U.S. economy; many economists believe that R&D investments have made substantial contributions to U.S. productivity growth since World War II. Thus, there is a direct link between the leadership role of the United States in R&D and the leadership position of the United States in the world economy.

As one of the most research-intensive industries in the United States, the life sciences industry has made significant contributions to the U.S. economy. The life sciences industry supports millions of jobs, contributes to significant advancements in medical knowledge, and develops products that keep the United States at the forefront of world medical markets. In addition to the direct benefits to the economy, innovations in the life sciences industry have contributed to improved health outcomes for U.S. citizens, cures and treatments for chronic illnesses, better quality of life, and increased longevity.

Small and mid-sized businesses have made a particularly important contribution to R&D in the life sciences industry in the United States. Approximately 15,800 small and mid-sized businesses in the United States are engaged in R&D in the life sciences industry.[1] Many of the country's most important medical innovations begin with small companies owned by scientists or engineers with an idea.

The United States faces unprecedented challenges to its role as a world leader in medical innovation. Countries like China, India, and Korea are aggressively increasing their R&D capabilities, particularly in the life sciences fields. The costs and regulatory burdens of developing new medical products keep rising in the United States, making it more and more difficult for companies to compete in U.S. markets. The Federal government's share of total R&D expenditures has declined steadily over several decades. These challenges come at a particularly bad time as the U.S. economy struggles to recoup the substantial job losses suffered during the recession.

Economists generally believe that companies do not invest optimally in R&D activities the profits that companies receive for their products do not reflect the societal benefits from R&D. Thus, to achieve optimal levels of R&D activity in the United States, either the Federal government must invest directly in R&D activities or the return on investment for companies engaging in R&D must reflect not only the company benefits, but also the societal benefits, of R&D activities. Tax incentives are one way of increasing a company's return on investment for

[1] This estimate relies on the definition of life sciences as detailed in the legislative draft. Small and mid-sized businesses include those businesses with receipts of $50 million or less. These estimates rely on data from the Economic Census of the Census Bureau.

R&D activities. This paper explores the economic benefits of a proposal to provide temporary targeted tax incentives for companies engaged in life sciences R&D in the United States.

Importance of innovation and research and development

Technological advancements spurred by innovation and research and development (R&D) activities contribute significantly to long-term economic growth. In 2005, the Congressional Budget Office said, "there is little doubt that research and development – especially if defined broadly to include the invention of new products, the discovery of new ideas, and the improvement of business processes – is the root of all increases in productivity."[2] At least half of the growth in the U.S. gross domestic product in recent decades resulted from technological innovation from R&D spending.

Importance of R&D in the life sciences industry

The life sciences industry makes important contributions to the U.S. economy. The industry directly employs approximately 1.4 million workers, 20 percent of whom are scientists and engineers, making the life sciences industry one of the most important sources of employment for these professionals.

Private industry contributes at least 65 percent of all R&D spending in the United States; the life sciences industry contributes approximately 32 percent of all private industry R&D spending, making it the single most research intensive industry in the United States.

Small and mid-sized businesses make a significant contribution to R&D activity in the United States, including the life sciences sector. Approximately 98 percent of all businesses conducting life sciences R&D in the United States are either small or mid-sized businesses. In fact, 57 percent of businesses conducting life sciences R&D in the United States have annual revenue of less than $1 million. Small businesses tend to be more research intensive (i.e., conducting more research as a percentage of sales) than larger businesses. In addition, small businesses have a larger percentage of highly skilled workers engaged in R&D activities than large businesses.

Challenges facing the U.S. life sciences industry

The U.S. life sciences industry faces a number of challenges that threaten to derail its role as the world leader in life sciences R&D. These challenges include the following:

- Increasing costs have led to a decline in the amount of money available for R&D;
- Over the long-term, the Federal government's share of R&D spending in the United States has declined;
- Increased regulatory requirements have greatly lengthened the approval process for new products, slowing the number of innovative products making it to market; and

[2] *R&D and Productivity Growth*, Congressional Budget Office, June 2005, at p. 30.

- The United States is not training sufficient numbers of scientists and engineers.

Competition from other countries

As the costs of developing new products in the United States rise, companies feel greater pressure to find lower cost locations to conduct R&D. Other countries are competing aggressively for life sciences R&D spending. While life sciences R&D spending in the United States in 2011 is projected to remain below the level of spending in 2008, life sciences R&D spending globally for 2011 is expected to be 11.5 percent higher than 2008. Compared to 2008, , the share of life sciences R&D performed in the United States will decline in 2011 relative to the rest of the world.

Countries like China and India are rapidly increasing their life sciences R&D capabilities. While the United States struggles to recoup job losses that occurred during the recession, trends in life sciences R&D could result in the shifting of highly skilled jobs to these other countries.

Many countries provide tax incentives to encourage R&D spending because economists believe that tax incentives provide an effective tool to ensure that optimal R&D spending occurs in a country. Research shows that the United States ranks behind many OECD countries (including China and India) in terms of the level of tax incentives provided for R&D activities. All other things being equal, companies will prefer to locate their R&D activities in countries with more favorable tax incentives.

Temporary targeted tax incentives for life sciences R&D

Changing the tax incentives offered to life sciences R&D in the United States could help to reduce the shifting of life sciences R&D spending to other countries. The proposed legislation would do this by offering companies a choice between an enhanced R&D tax credit for life sciences R&D and a dividends-received deduction for foreign earnings returned to the United States and invested in life sciences R&D. The proposed tax incentives would be available through 2015 and would be limited to a maximum amount of R&D spending each year of $150 million per taxpayer. Small and mid-sized businesses comprise a substantial percentage of the companies benefiting from these tax incentives.

These two temporary tax incentives will stimulate new life sciences R&D investment in the United States. We estimate that this new investment will lead to an additional 683,000 jobs in the U.S. economy. In addition to jobs for highly skilled workers such as scientists and engineers, the indirect effects of this new investment will stimulate jobs in other sectors as well.

II. Importance of Innovation and Research and Development in the United States

Innovation is the process of creating new products, improving old products, or reducing the costs and efforts involved in producing goods and services. Research and development, commonly referred to as R&D, refers to the systematic efforts of researchers, such as scientists and engineers either to develop new knowledge or to find new applications of knowledge, often for developing commercial products or services.

A study by the National Academies of Science, originally published in 2005 and updated in 2010, addresses the importance of innovation and research and development in the United States.[3] This study, "Rising Above the Gathering Storm," concludes that a "primary driver of the future economy and concomitant creation of jobs" will be the innovation that comes from advances in science and engineering knowledge.[4] Workers in science and engineering disproportionately contribute to the creation of jobs in other sectors of the U.S. economy. As the updated report states,

> "Importantly, *leverage* is at work here. It is not simply the scientist, engineer, and entrepreneur who benefit from progress in the laboratory or design center; it is also the factory worker who builds items..., the advertiser who promotes them, the truck driver who delivers them, the salesperson who sells them, and the maintenance person who repairs them – not to mention the benefits realized by the user."[5]

R&D and Innovation Fuel Economic Growth and Create Jobs

Economists universally believe that the technological advancements spurred by innovation and R&D activities lead to economic growth. A great deal of empirical literature has been devoted to the question of the extent to which R&D spending increases productivity and contributes to economic growth. In general, the most common conclusion of these studies is that R&D spending, particularly R&D spending by private businesses, has a significantly positive effect on productivity growth.

A 2005 study by the Congressional Budget Office specifically examined the question of the contribution of R&D spending by private businesses to the nation's productivity.[6] The CBO concluded that "the consensus view of the link between R&D and productivity is probably the correct one: it is quite likely that R&D has a positive impact on productivity, with a rate of return that is at least equal to the return on other types of investment."[7] Further, R&D spending has spillover effects, in which there are benefits that accrue to firms, industries, and nations other than the entity performing the R&D. These spillover effects are very difficult to measure, but suggest that R&D activities create significantly broader benefits to an economy than the benefits

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[3] *Rising Above the Gathering Storm, Revisited, Rapidly Approaching Category 5,* Prepared for the Presidents of the National Academies of Sciences, National Academy of Engineering, and Institute of Medicine by Members of the 2005 "Rising Above the Gathering Storm" Committee. The National Academies Press: Washington, DC, 2010.

[4] *Id,* at 2.

[5] *Id,* at 3.

[6] *R&D and Productivity Growth.* Congressional Budget Office, Background Paper, June 2005.

[7] *Id,* at 2.

accruing to a single business performing the R&D. A Bureau of Labor Statistics (BLS) study found that the literature suggests private R&D nets private returns of 25 percent and social returns (i.e., indirect spillover effects) of 65 percent.[8]

Studies have found that R&D spending has made a steady contribution to economic growth in the United States during the post World War II period. [9] The CBO noted, "given that innovation is a fundamental source of technological change and therefore of productivity growth, there is little double that research and development – especially if defined broadly to include the invention of new products, the discovery of new ideas, and the improvement of businesses processes – is the root of all increases in productivity." [10]

The National Academies of Science study cited research that found that at least half of the growth in the U.S. gross domestic product (GDP) in recent decades has been the result of technological innovation resulting from R&D spending.

R&D Helps the United States Maintain a Competitive Position in World Markets

In addition to contributing to economic growth in the United States, R&D spending helps the United States maintain a competitive position with the rest of the world. The United States has been the long-time leader in R&D spending, accounting for approximately 33 percent of global R&D spending.[11]

Table 1 shows a comparison of international R&D spending in U.S. dollars and as a percentage of a country's GDP. The statistics show that the United States continues to invest the largest dollar amount on R&D. However, as a percentage of GDP, many countries are gaining on the United States and some countries, such as Japan and South Korea, have taken the lead.

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[8] Sveikauskas, Leo. *R&D and Productivity Growth: A Review of the Literature*. U.S. Department of Labor, U.S. Bureau of Labor Statistics, Office of Productivity and Technology, Working Paper 408, September 2007.

[9] *R&D and Productivity Growth, supra.*

[10] *Id*, at 30. After examining research on the issue of the contribution of R&D to productivity growth and acknowledging the difficulties in this measure, the CBO concluded the rate of return to R&D is slightly higher than that of other types of corporate spending. This analysis examined only R&D spending by businesses and does not consider R&D spending from other sources.

[11] Boroush, Mark. *New NSF Estimates Indicate that U.S. R&D Spending Continued to Grow in 2008*. National Science Foundation, Division of Science Resource Statistics, InfoBrief, NSF 10-312, January 2010.

Table 1 – International Comparisons of National R&D Expenditures and R&D Share of Gross Domestic Product, Most recent year, 2006-2008		
	Gross Expenditures R&D (GERD) ($ in millions)	**GERD/ GDP (%)**
United States (2007)	$368,799.0	2.68
OECD (2007)	886,347.1	2.29
European Union-27 (2007)	262,985.0	1.77
G-7 countries (2007)	715,329.6	2.53
Japan (2007)	147,800.8	3.44
China (2007)	102,331.0	1.49
Germany (2007)	71,860.8	2.54
France (2007)	43,232.6	2.08
South Korea (2007)	41,741.6	3.47
United Kingdom (2007)	38,892.8	1.79
Russian Federation (2007)	23,482.0	1.12
Italy (2006)	19,678.1	1.13
Taiwan (2007)	18,324.8	3.47
Spain (2007)	18,000.3	1.27
Australia (2006)	14,914.4	2.01
Sweden (2007)	12,076.3	3.60
Netherlands (2007)	10,949.8	1.70
Israel (2007)	8,845.8	4.68
Austria (2008)	8,530.1	2.66
Source: Boroush, Mark, *New NSF Estimates Indicate that U.S. R&D Spending Continued to Grow in 2008*. National Science Foundation, Division of Science Resources Statistics.		

Trends in R&D investments show that, while the United States continues to lead the world in absolute dollars of R&D investment, other countries, particularly countries like China and Korea, are making significant inroads in R&D and are poised to overtake the United States. R&D investments in Asia will exceed U.S. levels in absolute terms over the next five years.[12] Measures of R&D intensity, such as R&D investments as a share of GDP, show strong gains in India, China, Japan, and South Korea, while remaining relatively flat in the United States.[13]

In a recent report, Gilman reports troubling statistics that point to the decline of U.S. influence with respect to innovation and R&D:

- China is now second in the world in the publication of biomedical research articles;
- In 2009, 51 percent of patents issued in the United States were awarded to non U.S. companies;
- The United States is ranked 48th in the world in quality of mathematics and science education by the World Economic Forum;

[12] Gilman, Douglas. *The new geography of global innovation.* Goldman Sachs Global Markets Institute, September 20, 2010.
[13] *Id.*

- In 2009, the Information Technology and Innovation Foundation ranked the United States 6th in global innovation-based competitiveness and 40th in the rate of change over the last decade;
- China has replaced the United States as the world's number one *high-technology* exporter;
- In 2000, the number of foreign students studying the physical sciences and engineering in U.S. graduate schools exceeded the number of U.S. students; and
- 77 percent of global firms planning to build new R&D facilities indicated that they would build in China or India.[14]

While the United States currently retains its leadership position, it is important to develop incentives that encourage future innovation and reverse these trends.

[14] *Rising Above the Gathering Storm*, supra.

III. Importance of R&D in the Life Sciences Industry

A. Identifying the Life Sciences Industry

1. Defining life sciences research

Life science is a broad term encompassing the branch of science relating to the study of human organisms. The American Heritage Dictionary defines life sciences as "any of several branches of science, such as biology, medicine, anthropology, or ecology, that deal with living organisms and their organization, life processes, and relationships to each other and their environment."[15] In this broad sense, life science is the study of living organisms, compared to physical science, such as physics or astronomy, dealing with nonliving organisms. In this broad definition of life science, life science refers to the study of human organisms as well as the study of other living organisms, such as animals and plants.

Under the proposed legislation that is the subject of this paper, the proposed tax incentives would apply to a narrower definition of life sciences research.[16] Under the proposed legislation, qualified life sciences research would include research

> "(I) with respect to the branch of knowledge or study of biology, biochemistry, biophysics, bioengineering, biotechnology, microbiology, genetics, or physiology (in each case as such knowledge or study relates to human beings), and
> (II) that is considered scientific research and development for purposes of North American Industry Classification System code 5417."[17]

Under the proposed legislation, the term qualified life sciences research does not include sociology or psychology.

Pharmaceutical R&D constitutes an important part of the life sciences industry. However, life sciences R&D also contributes innovation to the knowledge and study of human beings, ranging from advancements in diagnostic techniques to improved joint replacement products and procedures.

There is no single definition of life sciences that applies for data collection purposes, despite a general understanding of the term. In some cases, overlaps occur between research that would qualify as life science research and other scientific research. Research conducted for one purpose may have applications in other branches of science. For example, researchers may discover a new substance with applications in the manufacture of artificial joints that may also

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[15] American Heritage Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2006.

[16] The definition of life science research is contained in S. 4018, introduced in the 111th Congress. The North American Industry Classification System code 5417 describes the type of research intended to be covered by the proposed legislation, as involving "…original investigation undertaken on a systematic basis to gain new knowledge (research) and/or the application of research findings or other scientific knowledge for the creation of new or significantly improved products or processes (experimental development). The industries within this industry group are defined on the basis of the domain of research; that is, on the scientific expertise of the establishment."

[17] S. 4018, proposed IRC sec. 41(h)(2)(B).

have applications in electronics or in the defense program. As a result, the line between life sciences research and other (closely related) research may depend on the initial purpose of the research and the type of firm that conducts the research, rather than on the ultimate results.

An examination of the industry codes used in the North American Industry Classification System (NAICS) helps to narrow the view of research that may qualify as life sciences research.[18] Using the specific industry subcategories, Table 2 shows the following types of establishments that may be engaged in life sciences research, based on the National Science Foundation reports identifying research activities and based on the type of research necessary per NAICS Code 5417, as explained in footnote 16.

[18] NAICS is a system of business classification adopted in 1997 for data collection purposes by the United States, Canada, and Mexico. In the United States, the NAICS system classifies business establishments to collect, analyze, and publish statistical data. Classifications under NAICS range from broad industry categories (2-digit NAICS) to fairly detailed industry subcategories (4-, 5-, and 6-digit NAICS). For purposes of the NAICS, an establishment is a single physical location where business is conducted or where services or industrial operations are performed. A business entity, such as a corporation, can consist of a single establishment or multiple establishments. Each establishment is assigned a NAICS code based on the primary business activity at that establishment.

Table 2 – Life Sciences Research Activities by NAICS (Source: National Science Foundation Reports, 2007 and 2008)
NAICS
3254 – Pharmaceuticals and Medicines Manufacturing
325411 – Medicinal and Botanical Manufacturing
325412 – Pharmaceutical Preparation Manufacturing
325413 – In-Vitro Diagnostic Substance Manufacturing
325414 – Biological Product (except Diagnostic) Manufacturing
3345 – Navigational, Measuring, and Electromedical and Control Instruments
334510 – Electromedical and Electrotherapeutic Apparatus Manufacturing
3391 – Medical Equipment and Supplier†
339112 – Surgical and Medical Instrument Manufacturing
339113 – Surgical Appliance and Supplies Manufacturing
339114 – Dental Equipment and Supplies Manufacturing
5417 – Scientific Research and Development Services
541711 – Research and Development in Biotechnology
541712 – Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)
5419 – Other Professional Scientific and Technical Services
541990 – All Other Professional, Scientific, and Technical Services
621- 623 Health Care Services[19]
622110 – General Medical and Surgical Hospitals
622310 – Specialty (except Psychiatric and Substance Abuse) Hospitals
†In addition to these subsectors, two additional classes (339115 and 339116) may engage in research. However, it appears that the vast majority of manufacturers in these subsectors are primarily manufacturing operations.

Approximately 60 percent of U.S. life sciences research occurs in establishments classified under NAICS code 33254 – pharmaceutical and medicine manufacturing and its subcategories (325411 through 325414). Establishments classified under 5471, 5419, and 3345 contribute approximately 35 percent to U.S. life sciences research, with lesser amounts conducted by establishments classified under the other codes (3391 and 621-623) listed above.

2. How firms conduct life sciences research

Three components comprise the research process (R&D) in the life sciences – basic research, applied research, and development. ***Basic research*** refers to research that is designed to advance knowledge without a specific commercial outcome as a goal. ***Applied research***, on the other hand, uses advancements gained through basic research to create practical solutions to problems.

[19] The vast majority (86 percent) of facilities in this industry sector are not subject to Federal income tax. Further, it is unlikely that hospital based research facilities would maintain significant foreign presence. Therefore, the analysis assumes that most of these facilities would not receive benefits from the enhanced tax incentives.

Applied research typically begins with a specific application in mind. For example, basic research encompasses research to map the human genome, while applied research would use the knowledge of this mapping to identify possible cures for genetic illnesses. ***Development*** activities use existing knowledge gained from research or practice experience to produce new products or processes. These may include both original and improved products and processes. Further, development activities usually have the goal of commercial production.

Basic research can be expensive and time consuming and often has the primary goal of advancing knowledge, rather than solving a specific problem. As a result, for-profit businesses are less likely to engage in such research because there is no clear commercial outcome. However, basic research remains an important step in the advancement of scientific knowledge. In the life sciences area, government funding of basic research helps to stimulate private sector funding on applied research and development through the scientific discoveries that expand scientific knowledge about the treatment of diseases and conditions.[20]

On the other hand, businesses engage in applied research (and some basic research) because there is a potential for profit from the knowledge gained. Firms undertake R&D activities that promise the largest possible financial gain, but not necessarily the R&D activities that promise the greatest benefit to society.[21]

Economists generally believe that the private sector alone will not perform the amount and type of research that provide the maximum benefit to society.[22] This occurs because the rate of return that businesses can earn with respect to their R&D activities does not take into account the inherent gains to society of the research conducted.[23]

Because of these concerns, a variety of entities conduct life sciences research in the United States, including the Federal government, universities, research consortia, nonprofit organizations, and private businesses. As Graphs 1 and 2 show below, businesses conducted 72.7 percent of U.S. R&D in 2008 and accounted for 67.4 percent of R&D expenditures. In comparison, the Federal government conducted 10.5 percent of R&D and accounted for 26.1 percent of the R&D expenditures.

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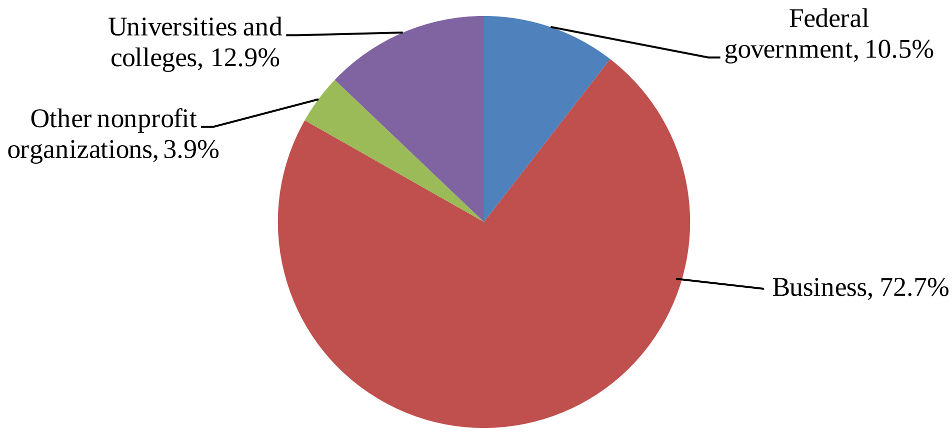
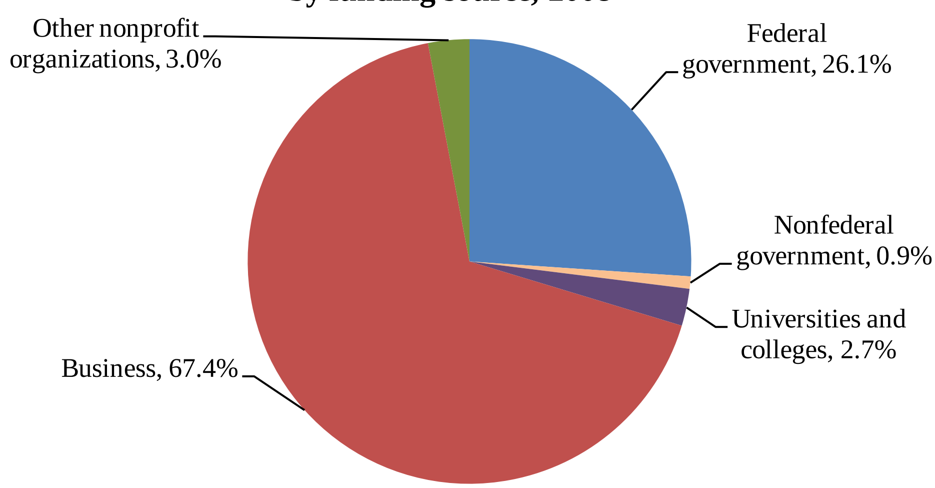
[20] *Research and Development in the Pharmaceutical Industry.* Congress of the United States, Congressional Budget Office, October 2006.
[21] *Federal Support for Research and Development.* Congress of the United States, Congressional Budget Office, June 2007.
[22] *Id.*
[23] *Id.*

Graph 1 – Share of U.S. R&D Expenditures, by performing sector, 2008



Source: National Science Foundation, Division of Science Resources Statistics, National Patterns of R&D Resources (annual series).

Graph 2 – Share of U.S. R&D Expenditures, by funding source, 2008



Source: National Science Foundation, Division of Science Resources Statistics, National Patterns of R&D Resources (annual series).

38 Federally funded R&D centers (FFRDCs) performed approximately four percent ($14.7 billion) of total R&D in the United States in 2008. These centers are privately operated R&D organizations financed almost entirely by the Federal government.[24] By design, FFRDCs help meet special long-term R&D needs not met effectively with existing R&D expenditures. Universities or university consortiums administer fourteen of the FFRDCs, nonprofit

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[24] Boroush, Mark. *NSF Releases Statistics on R&D Expenditures in FY 2008 by Federally Funded R&D Centers.* National Science Foundation, Division of Science Resource Statistics, NSF 10-325, August 2010.

organizations administer eight, and industrial organizations administer six.[25] Graph 1, above, depicts the R&D expenditures of FFRDCs in the category for the type of entity performing the R&D.

The sources of funding vary significantly by the type of research conducted. The following tables shows, for 2008, the sources of funding for basic research, applied research, and development.

Table 3 – Sources of Funding for R&D Expenditures in the United States, by type of activity, 2008 [dollar amounts in thousands]

Sources of Funding	All R&D	Basic Research	Applied Research	Development
All sources	$397,629	$69,146	$88,591	$239,891
Business	267,847	12,222	53,827	201,798
Federal government	103,709	39,379	28,661	35,669
Universities and colleges	10,600	7,685	2,390	525
Other nonprofit	12,020	7,357	2,934	1,729
Other government	3,453	2,503	779	171

Source: Boroush, Mark, *National Patterns of R&D Resources: 2008 Data Update.* National Science Foundation, Division of Science Resources Statistics, NSF 10-314, March 2010.

Table 3 shows that the Federal government funded approximately 57 percent of basic research in the United States in 2008, compared to 32 percent for applied research, and only 15 percent for development activities. The business sector funded a much larger percentage (84 percent) of development activities, which is consistent with the view that businesses are more likely to expend R&D for activities that are likely to lead to commercial products.

3. The life sciences R&D process

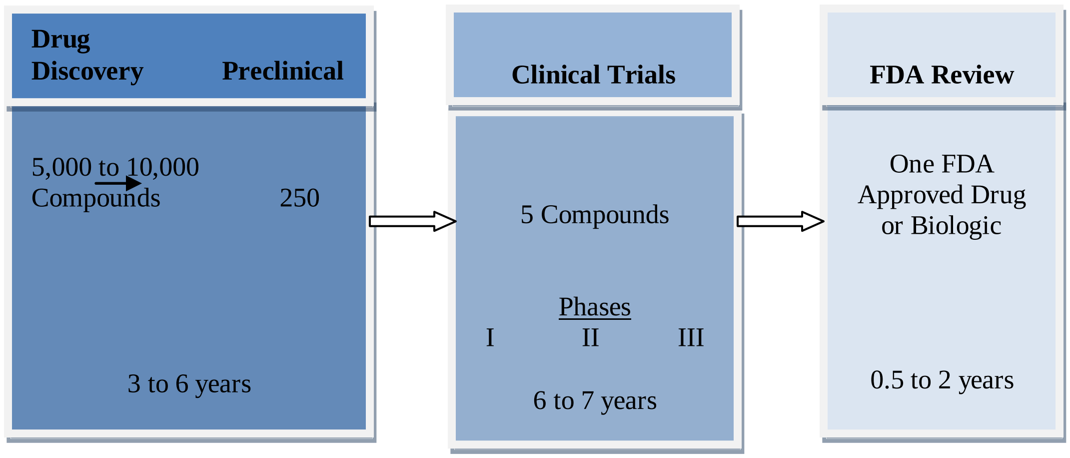
Generally, life sciences research brings new treatments to patients by developing an understanding of a disease. By identifying the basic causes of disease, the R&D process identifies a compound or molecular entity that will affect the causes (or treatment) of disease.

The R&D process for bringing new treatments to market often takes 10 to 15 years. While each stage of the R&D process advances the science with the goal of bringing to market promising new treatments for patients, there are considerable costs and challenges associated with each stage.

The R&D of new medical treatments is a complicated and time-consuming process. Each FDA approved product emerges as a single successful compound from many failed attempts. In other words, the final approved product must pass through a long process of research, testing, and more testing.

[25] *Id.*

Stages of R&D – The stages of R&D include discovery of the new compound or test, preclinical research, clinical trials, Food and Drug Administration review and approval, and the large-scale manufacture.[26] The following graphic provides an overview of this process.



1. Product Discovery – The product discovery process begins with a scientific understanding of human disease at the molecular level. Scientists develop a research process based upon this understanding and work to understand the causes of the disease or affliction. This work often involves research at the molecular level using such advanced techniques as genomics, proteomics and computational analysis.

The product discovery process may begin with thousands of compounds that will ultimately not contribute to the final product or compound from this research. The discovery process includes all early research to indentify a new molecular structure or compound. After identifying a viable approach, the compound must undergo testing it in the lab, which often takes 3 to 6 years.

2. Preclinical – The preclinical testing is a critical stage in the R&D process, as it relies on animal testing to determine if the product is safe enough for human testing. The preclinical phase often involves a small number of compounds – the candidate products – for the clinical trials. The purpose of these studies is to determine how the product works and develop a safety profile.

In addition, the researchers must develop a method for making quantities to satisfy clinical trials, should the compound or product make it to this next stage.

3. Clinical Trials – The clinical trials mark an important milestone in the R&D process, by moving from laboratory testing to human testing. However, before beginning clinical trials, the researchers must file an investigational new drug (IND) application.[27] This application provides all of the results from the preclinical work as well as the clinical trial plan. As the clinical trials progress, the research firm provides ongoing comprehensive reports to the FDA and IRB.

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[26] PhRMA, *Drug Discovery and Development*, February 2007.

[27] In addition to the IND, the research firm must ensure the safety of the human participants by seeking review from the Institutional Review Board. This process includes the development of appropriate informed consent, which will be required of all clinical trial participants.

Phase I Clinical Trial – (Initial human testing with about 20 to 100 healthy volunteers) Phase I testing relies on health individuals to determine if the drug creates any adverse reactions or has unintended effects.

Phase II Clinical Trial – (Testing to evaluate the benefits of the drug on 100 to 500 patients with the disease or illness under study) Phase II testing determines the effectiveness of the product on the specific condition or disease.

Phase III Clinical Trial – (Testing involving approximately 1,000 to 5,000 patients) Phase III trials produce statistically significant data on the drug's safety, effectiveness and the relative benefits to risk.

4. FDA Review – After completing the first three phases of clinical trials, the company may file a New Drug Application (NDA) with the FDA – assuming the research findings support this application. The NDA must incorporate all of the data and background information from the past R&D process. In many cases, this may represent many years (10 to 12) of work. In addition, the NDA includes both the proposed manufacturing process and detailed labeling plans.

From this information, the FDA reviews the application to determine if the new product is safe for final approval. The FDA has three options, following their review process -- to approve the product, indicate it is "approvable," but requires more information or studies before final approval, or deny approval.

5. Large-Scale Manufacture – Following FDA approval, the process moves from small-scale to large-scale production. In addition, even while the product is in the production process, the manufacturer must continue with clinical trials. The Phase 4 Trials involve a large patient base and require monitoring and reporting for adverse reactions to the newly approved drug. In addition, in some cases, the FDA may require such further studies as long-term safety or effects on target populations.

Costs and Barriers in the R&D Process – Each stage of the R&D process brings associated costs. The direct research phases (before clinical trials begin) may involve many years, but clinical testing and FDA approval may take even longer. Expenditures rise steadily with each stage, increasing the total direct research costs for successful product R&D.

Included in the direct research costs is the cost of failed research projects. These failed projects may include molecular entities that never attained final FDA approval as well as those abandoned during the various stages of the R&D process.[28] These rising costs force the research firm to evaluate carefully the viability of this research and curtail R&D if it appears that they would not recover their costs.

Therefore, depending upon the success rate of a firm's research, the average cost of R&D may be relatively higher (for a greater failure rate) or lower (for a greater success rate).

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[28] Researchers may abandon the R&D efforts for certain products or processes for a variety of reasons, but one important reason is insufficient patent protection.

It is also important to recognize the ***total*** R&D costs (which include opportunity costs) often are two to three times higher than the ***average direct*** costs (including failed research).[29] Opportunity costs include the indirect costs of devoting investment capital to this R&D, when instead they might have earned a greater return by using this capital for an alternative venture.

R&D costs are one important factor in the decision to abandon research efforts or continue those efforts through the approval process. Another important factor is the ability to recover the investment and realize a reasonable return. Part of the decision-making process involves predicting the return on a research product, assuming the product survives the approval process. The expectation of a reasonable period to recover costs and realize a profit influences the decision (early in the R&D process) to pursue the research. If an adequate return does not seem likely, the life sciences research firm may be compelled to abandon the research purely for economic reasons.

B. Life Science R&D Contribution to the U.S. Economy

1. Life sciences R&D spurs job growth and capital investments

Life sciences research provides an important source of employment in the United States, employing approximately 1.4 million workers.[30] Of these workers, nearly 20 percent are scientists and engineers, making the life sciences industry an important employer of highly skilled and educated professionals.

R&D employment relative to total employment in an industry provides an indicator of the R&D employment intensity. This ratio provides a sense of the importance of skilled professionals as well as the industry commitment to R&D. Industries heavily engaged in R&D activities have a higher than average R&D employment intensity relative to the 7.1 percent aggregate for all other industries. The pharmaceuticals and medicines (NAICS 3254) industry maintains an R&D employment intensity of approximately 14.7 percent, while the scientific R&D services industry (NAICS 5417) maintains an R&D employment intensity of 31 percent. [31]

The life sciences industry is not only important to stimulating demand for highly skilled researchers, but it is an important driver of private R&D investment. Currently, private industry contributes 65 percent of all R&D resources in the United States.[32] Life sciences R&D

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[29] For a detailed discussion, refer to DiMasi, Joseph A., Ronald W. Hansen, and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics,* vol. 22, no. 2 (March 2003), pp. 151-185.

[30] This estimate relies on the definition of life sciences used in the proposed legislation. According to the National Science Foundation survey data, broader definitions suggest that the broader industry definition employs approximately 2 million workers.

[31] Refer to Morris, Francisco and Nirmala Kannankutty, *New Employment Statistics from the 2008 Business R&D and Innovation Survey,* Info Brief, Science Resources Statistics, National Science Foundation, NSF-10-326, July 2010.

[32] Refer to *2011 Global R&D Funding Forecast*, by Battelle, 2010.

investment, as defined in the legislative proposal, contributes approximately 32 percent of the private industry resources.

Another important aspect of R&D spending is the measure of research intensity, defined as the ratio of R&D spending to total sales revenue. Research intensity measures business commitment to R&D. The pharmaceutical and medicines (NAICS 3254) industry's research intensity remains at 19 percent for 2009.[33] The life sciences industry maintains one of the highest R&D intensities of all industries in the United States and has been the most research-intensive industry for much of the past 25 years.[34]

2. Small and mid-sized businesses play a critical role in life science research

Small businesses contribute to job growth

Small businesses represent one of the key drivers of economic growth in the United States.[35] Indeed, small businesses account for:

- 98 percent of all businesses in the United States,
- approximately 50 percent of the private sector workforce, and
- a significant share of exports to some of the United States' most important trading partners.[36]

In addition, small businesses are the engines that generate new jobs, which ultimately expand economic activity. Small businesses contributed:

- almost 64 percent of all net new jobs created in the United States over the 1993-2008 period, and
- approximately half of the nonfarm, private real gross domestic product.

At the same time, small and mid-sized businesses tend to be more vulnerable than large businesses to the economic shocks of a recession. During the period from the fourth quarter of 2007 through the second quarter of 2009, firms with less than 500 employees accounted for

[33] Refer to Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Report 2010,* Released in 2010. Estimates (based on Economic Census and NSF data) suggest that the scientific R&D services industry (NAICS 5417) maintains a research intensity of approximately 19 to 20 percent.

[34] U.S. Congressional Budget Office, *Research and Development in the Pharmaceutical Industry,* October 2006 and U.S. Congressional Budget Office, *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998.

[35] A variety of definitions can be used to define small and mid-sized businesses and data are collected using different measures, including number of employees, total receipts, and total assets. The Small Business Administration uses a broad guideline for a small business as a firm with less than 500 employees, although this standard varies across industries. For purposes of this analysis, a small business is defined to include firms with less than 500 employees.

[36] *The Small Business Economy, 2010. A Report to the President.* Small Business Administration. United States Government Printing Office, Washington: 2010.

slightly more than 5 million (61 percent) of net job losses in the economy.[37] Even more important, the marked decline in gross job gains contributed significantly to the recent recession, suggesting that the economy is not generating new jobs and that employment is not returning to pre-recession levels. This decline in job gains is particularly significant for small firms, which saw average quarterly job gains decline to historic lows.[38]

Life sciences small businesses are innovators

In addition to being a critical source of job growth in the economy, small businesses contribute to economic growth by being innovators. A recent National Science Foundation issue brief states "U.S. small business is closely associated with the development of new technologies in many of the science-based industries likely to be important to future economic growth."[39] Small businesses in industries that focus on R&D tend to be more research intensive than larger businesses in those industries. In highly technical industries, such as the life sciences industry, new inventions and technologies originate with R&D activities. Among newly created businesses, which are likely to be small businesses, innovator firms create more net new jobs compared to new firms with less "innovation intensity."[40]

A key measure of innovation activity is R&D spending. From 2003 to 2007, R&D spending by small businesses grew faster than R&D spending by larger companies. The rate of growth in R&D spending for all companies was 4.5 percent (after adjustment for inflation) for the 2003-2007 period; small business R&D spending grew over the same period by 5.6 percent. In 2007, R&D spending by small businesses totaled approximately $50 billion and represented 18.7 percent of all U.S. industrial R&D.[41]

R&D intensity, which measures a firm's commitment to innovative activity as a core business activity, is noticeably higher for small businesses. One way of examining R&D intensity in the United States is to measure R&D expenses as a percentage of total revenues. In 2007 (the final year before the recession), small businesses spent 8.6 percent of sales revenue on research and development, compared to an overall percentage for all businesses of 3.8 percent of sales revenue.[42] By comparison, in 2008, small businesses spent 5.28 percent (worldwide) of total

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[37] *All firm sizes hit hard during the current recession.* U.S. Department of Labor, U.S. Bureau of Labor Statistics, Issues in Labor Statistics, Summary 10-02, March 2010.
[38] *Id.* For example, during the period from September 2003 through September 2007, the average quarterly gross job gains for small businesses was 4.9 million, while the average quarterly gross job losses was 4.7 million. This translates to net average quarterly job gains of 200,000 during the period. On the other hand, during the period from September 2007 through June 2009, the average gross quarterly job gains for small businesses was only 4.2 million, while the average quarterly gross job losses was 5.0 million; this translates to a net quarterly job loss of 800,000 jobs. The number of average quarterly gross job gains for small businesses for the September 2007 through June 2009 period is significantly lower than the averages for either the 1990-1991 recession (average quarterly gross job gains of 4.9 million) and the 2001 recession (average quarterly job gains of 5.3 million).
[39] Rausch, Lawrence M. *Indicators of U.S. Small Business's Role in R&D.* National Science Foundation, Science Resource Statistics, InfoBrief, NSF 10-304, March 2010.
[40] Kirchhoff, Bruce A. *Entrepreneurship and Dynamic Capitalism: The Economics of Business Firm Formation and Growth.* Westport, CT: Praeger, 1994.
[41] *Id.*
[42] Rausch, supra.

sales on R&D expenses, compared to an overall percentage for all businesses of 3.01 percent of sales.[43]

Another measure of innovation is the number of patents that a business receives. Small businesses in the United States produce 13 times more patents per employee than large businesses.[44] In addition, small business patents outperform the patents of large businesses on a number of measures used to measure the innovativeness of firms.[45] Further, small businesses tend to patent at a higher rate in certain industries, particularly health-related industries.[46]

Small businesses create jobs for highly skilled workers

Because small businesses, particularly in health-related industries, tend to be greater innovators, they also employ larger percentages of highly skilled workers like scientists and engineers.

More importantly, small businesses hire 40 percent of so-called "high tech" workers, such as scientists, engineers, and computer programmers.[47] During the 2003-2007 period, scientists and engineers performing R&D accounted for 13.1 percent, on average, of employees of small businesses, compared to a 6.1 percent average for medium and large companies.[48] Thus, small businesses represent an important source of employment for these highly skilled workers.

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[43] Wolfe, Raymond M. *U.S. Businesses Report 2008 Worldwide R&D Expense of $330 Billion: Findings from New NSF Survey*. National Science Foundation, Science Resource Statistics, InfoBrief 10-322, May 2010. It should be noted that the 2008 data are based on a new survey, the Business R&D and Innovation Survey (BRDIS), developed jointly by the National Science Foundation and the U.S. Census Bureau. The BRDIS collected more detailed information, which included a specific breakdown of R&D sales and expenses for the United States and worldwide. Thus, the numbers reported for the 2007 survey and the 2008 survey may not be comparable.

[44] Breitzman, Anthony and Diana Hicks. *An Analysis of Small Business Patents by Industry and Firm Size*. Under contract no. SBAHQ-07-Q-0010. U.S. Small Business Administration, Office of Advocacy, November 2008.

[45] *Id.* Patent scorecards compare patents based on the number of U.S. patents granted to a company during a period, the growth in U.S. patents from one period to another, the 2007 pipeline impact (which measures how often a set of patents is cited by subsequent 2007 patents), 2007 pipeline generality (which measures the breadth of the impact of a company's patent), pipeline originality (which measures the breadth of technologies cited by an organization's patents), and the citation index.

[46] *Id.*

[47] *The Small Business Economy, 2010. A Report to the President.* Small Business Administration. United States Government Printing Office, Washington: 2010.

[48] Rausch, supra.

IV. Challenges Facing the U.S. Life Sciences Industry

While the U.S. life sciences industry has long been a primary force in worldwide R&D, unprecedented challenges threaten to derail U.S. efforts to remain the world leader in life sciences R&D. The challenges facing the U.S. life sciences industry in coming years arise from the intersection of Federal budget deficits, less money available for R&D, the difficulties in getting innovative products to market in the United States, and growing competition from the rest of the world in the life sciences industry. While a thorough review of these problems is beyond the scope of this paper, a brief review of the major issues facing the industry demonstrates the need for U.S. policies that recognize the importance of life sciences R&D.

A. Funding Challenges

1. Fewer resources available for R&D

While life sciences industry investments in R&D rose significantly over the last decade, fewer products from which companies can derive profits reached the market. The estimated cost of bringing a single new product to market in the life sciences industry was $1.3 billion in 2005, compared to $800 million in 2000; some have estimated the cost to be as high as $2.0 billion.[49] Because of these increasing costs, companies in the life sciences industry can expect smaller profits for each dollar spent on R&D.

From 2003 to 2008, annual business spending in the United States on R&D increased from $186.2 billion to $267.8 billion; total annual R&D spending in the United States over the same period increased from $288.3 billion to $397.6 billion.[50] However, investments in R&D were not immune to the effects of the recession. Worldwide R&D spending declined 3.5 percent in 2009 for the world's largest innovation companies and revenue dropped by 11 percent.[51]

From 2008 to 2009, U.S. life sciences industry R&D declined by 11.5 percent, from $63.28 billion to $56.01 billion.[52] Over the same period, global R&D spending by the life sciences industry declined by only 1.2 percent, from $125 billion to $123.53 billion.[53] Projected U.S. life sciences R&D spending is $62.27 billion in 2011, which remains below the 2008 level.[54]

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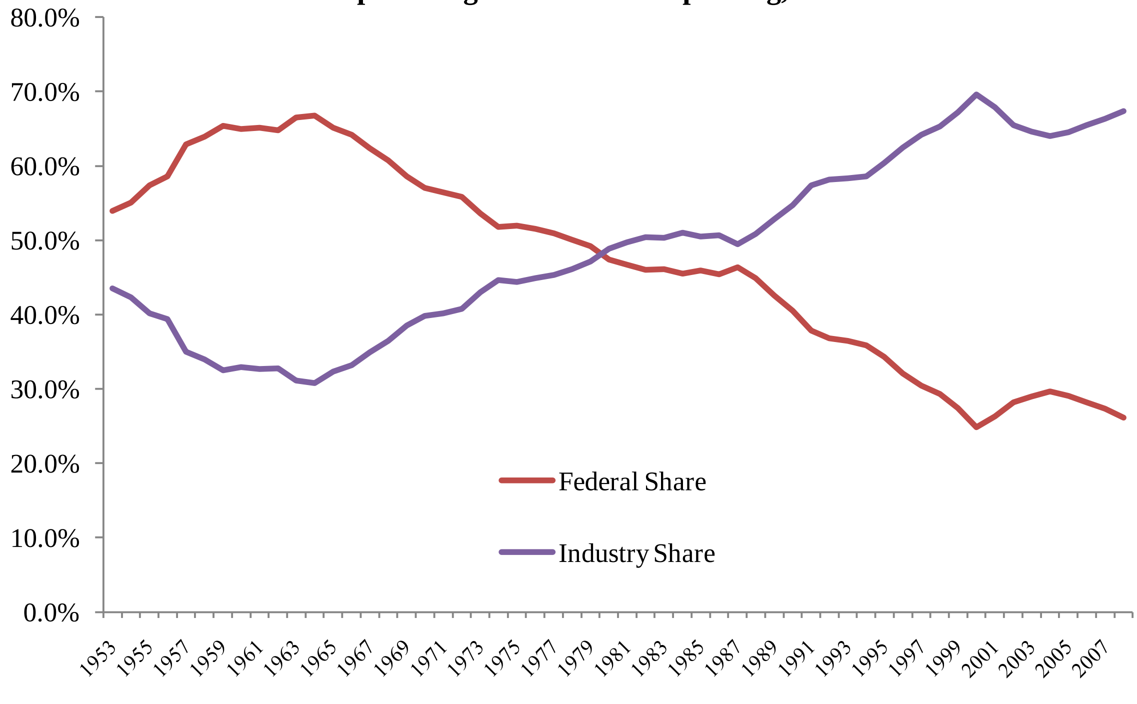
[49] DiMasi, Joseph A. and Grabowski, Henry G. *The Cost of Biopharmaceutical R&D: Is Biotech Different?* Manag. Decis. Econ. 28:469-479 (2007).
[50] *National Patterns of R&D Resources (annual series).* National Science Foundation, Division of Science Resources Statistics.
[51] Jaruzelski, Barry and Dehoff, Kevin. *The Global Innovation 1000. How the Top Innovators Keep Winning.* Booz&co., Issue 61, Winter 2010.
[52] *2011 Global R&D Funding Forecast.* R&D Magazine, December 2010. Available at: www.rdmag.com
[53] *Id.*
[54] *Id.*

2. Declining Federal Role in R&D

The current budget picture in the United States suggests that difficult decisions are necessary to reduce Federal spending levels. Cuts in discretionary spending large enough to help control budget deficits will threaten the ability of the Federal government to continue to support R&D activities at their current levels. Indeed from fiscal year 2007 to fiscal year 2008, Federal funds for R&D declined by $3.5 billion, reflecting an inflation-adjusted decrease of 4.8 percent.[55] The inflation-adjusted decline was 7.3 percent from fiscal year 2005 to fiscal year 2008.[56] By comparison, Federal spending for fiscal years 2001-2005 rose by 22.2 percent.[57] In fiscal year 2009, stimulus funding from the American Recovery and Reinvestment Act provided a one-time bump in this funding.

In addition, over the long term, the Federal government's share of R&D spending in the United States has declined relative to total spending on R&D. As Graph 3 shows, the Federal share of R&D spending in the United States has declined from more than 65 percent in the mid-1960's to approximately 26 percent in 2008. At the same time, the share of total R&D spending in the United States by industry has increased to nearly 70 percent of total R&D spending by 2008.

Graph 3 – Federal and Industry Shares of R&D Spending in the United States, as a percentage of total R&D spending, 1953-2008



Authors' calculations based on data contained in: Boroush, Mark. *National Patterns of R&D Resources, 2008 Data Update.* National Science Foundation, Division of Science Resources Statistics, NSF 10-314, March

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[55] Pollak, Melissa F. *FY 2008 Data Show Downward Trend in Federal R&D Funding.* National Science Foundation, Division of Science Resources Statistics, NSF 09-309, January 2009.

[56] *Id.*

[57] *Id.*

As of 2008, the United States ranked 6 out of the top 10 R&D performing countries based on Federal government spending as a percentage of all R&D spending (see Table 4 below). While the United States continues to outspend other countries on R&D in absolute terms, the long-term trends show a steadily declining Federal government contribution to the R&D process.

Table 4 – R&D Expenditures for Selected Countries by Funding Source, Percentage of total, Most recent year, 2006-2008

Country	Business	Government	Other Domestic	Foreign Sources
United States (2008)	67.4%	26.1%	5.8%	NA
Japan (2007)	77.7	15.6	6.3	0.3
China (2007)	70.4	24.6	NA	1.3
Germany (2006)	68.1	27.8	0.4	3.8
France (2006)	52.4	38.4	2.2	7.0
South Korea (2007)	73.7	24.8	1.3	0.2
United Kingdom (2007)	47.2	29.3	5.8	17.7
Russian Federation (2007)	29.4	62.6	0.7	7.2
Canada (2008)	49.5	31.3	10.3	9.0
Italy (2006)	40.4	48.3	3.0	8.3

NA = not available
NOTES: Top 10 R&D performing countries. U.S. data on R&D funding from abroad not separately identified but included in sector totals.
SOURCE: Organisation for Economic Co-operation and Development, Main Science and Technology Indicators (2009/1). *Science and Engineering Indicators 2010*.

Increases in Federal funding for life sciences research have also declined.[58] During the 1999-2003 period, Federal funding for life sciences research increased from approximately $13.9 billion to $26.0 billion.[59] However, during the fiscal year 2004-2008 period, Federal funding for life sciences research increased by only 6.1 percent and in two years, fiscal year 2004 and fiscal year 2006, Federal funding for life sciences research declined in actual dollar amounts.

B. Regulatory Challenges

Life sciences industry companies face increasing costs of developing new commercial products in the United States. The increasing costs and complexity of conducting clinical trials has added considerably to the costs of getting a new commercial product approved for sale to consumers. As knowledge of the safety and effectiveness of the clinical trial process improves, the FDA

[58] For this purpose, life sciences research is considered to exclude agricultural sciences and environmental biology, which are classified as life sciences for data collection purposes.
[59] National Science Foundation, Division of Science Resources Statistics, *Survey of Federal Funds for Research and Development: FY 2007, 2008, and 2009.*

continues to make regulatory changes to trial protocols. Between 1999 and 2005, the following changes occurred in the clinical trial process:

- the median number of unique procedures per trial protocol increased 46 percent;
- the median number of total procedures per trial protocol increased 65 percent:
- the clinical-trial staff work burden increased 67 percent;
- the length of clinical trials in days increased 70 percent;
- the clinical-trial participant enrollment rate declined 21 percent; and
- the clinical-trial participant retention rate declined 30 percent.[60]

Considerable variability in FDA approval of new products over the last 10 years translates into increasing variability for the companies developing these new products. In a 2006 report, the Congressional Budget Office (CBO) noted with respect to pharmaceutical companies:

> "Most manufacturers of brand-name drugs earn the majority of their revenue from drugs under patent. Wider fluctuations in revenue heighten companies' uncertainty about their main source of R&D funding. If that variability persists, firms may have to rely largely on external, more costly forms of financing. Such a change could make firms less likely to invest in drug projects with smaller, more uncertain, or more distant payoffs."[61]

C. Workforce Challenges

The United States faces a crisis in the training of new scientists and engineers. A July 2005 report provided the following sobering statistics:

- By 2010, more than 90 percent of all scientists and engineers in the world will be living in Asia;
- South Korea, with one-sixth the U.S. population, graduates as many engineers as the United States;
- More than 50 percent of all engineering doctoral degrees awarded in the United States are awarded to foreign nationals;
- Security concerns have reduced the number of foreign students in the United States at the same time that competition for this talent has increased in other countries;
- The number of engineering degrees awarded in the United States is down 20 percent from 1985 (the peak year); and
- U.S. fourth graders score well against international competition, but by 12th grade fall near the bottom in mathematics and science.[62]

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[60] *Growing Protocol Design Complexity Stresses Investigators, Volunteers,* Tufts Center for the Study of Drug Development, Tufts CSDD Impact Report 10, no. 1 (2008).

[61] *Research and Development in the Pharmaceutical Industry,* Congressional Budget Office, October 2006.

[62] *Tapping America's Potential. The Education for Innovation Initiative,* Published by AeA, Business Roundtable, Business-Higher Education Forum, Computer Systems Policy Project, Council on Competitiveness, Information Technology Association of America, Information Technology Industry Council, Minority Business Roundtable, National Association of Manufacturers, National Defense Industrial Association, Semiconductor Industry

The United States produces fewer qualified research scientists than other countries. As a result, the cost of labor for these scientists is higher in the United States than in other countries, leading many companies to outsource a growing percentage of their R&D activities.

In the life sciences industry, this problem is particularly acute as companies outsource R&D activities to emerging market countries to try to reduce the overall costs of R&D. By 2016, an estimated 84 percent of life sciences organizations will conduct R&D activities outside the United States, in countries with emerging markets, such as China and India.[63] In 2009, the combined market value of India and China drug outsourcing markets were $7.3 billion. By 2011, this projected market value will be $19.1 billion.[64]

D. Competition from Other Countries

As the costs of developing new products in the United States rise due to these ongoing challenges, companies feel greater pressure to locate lower cost locations to conduct R&D. Projections for spending on life sciences R&D in the United States in 2011 ($62.27 billion) suggest that it will not recover to the 2008 levels ($63.28 billion). On the other hand, estimates suggest that global life sciences R&D spending in 2011 will increase 11 percent ($138.74 billion) over 2008 levels ($125 billion).[65] Clearly, the share of life sciences R&D spending in other countries, particularly Asia, is growing relative to the U.S. share of R&D spending.

The trend toward a larger role for R&D outside the United States result from a variety of factors, including lower costs for labor outside the United States and easier regulatory hurdles. Above all other factors, the U.S. tax system undeniably increases the incentives to conduct R&D outside the United States. The corporate tax structure in the United States creates incentives for businesses to conduct operations outside the United States. In the case of R&D, the United States provides less indirect support of R&D through R&D tax incentives than many countries.

Economists generally believe that businesses will not invest enough in R&D because there are external benefits not reflected in the profits that businesses can expect from these investments. Furthermore, the levels of taxes on R& D investments in a country affect the profits that companies can earn. The higher the taxes, the lower the rate of return for an R&D investment and the less likely a business will make the investment.

As a result, one way that countries commonly induce additional R&D investments is through tax incentives that reduce the taxes that apply to the investments. If one country provides generous tax incentives for R&D investments relative to another country, all other things being equal, a business should prefer to invest in R&D in the country with more generous tax incentives.

Association, Software and Information Industry Association, TechNet, Telecommunications Industry Association, and U.S. Chamber of Commerce, July 2005.

[63] *Life Sciences R&D talent strategies. Remaining competitive in the emerging markets talent pool.* Deloitte Development LLC, 2009.

[64] *Id.*

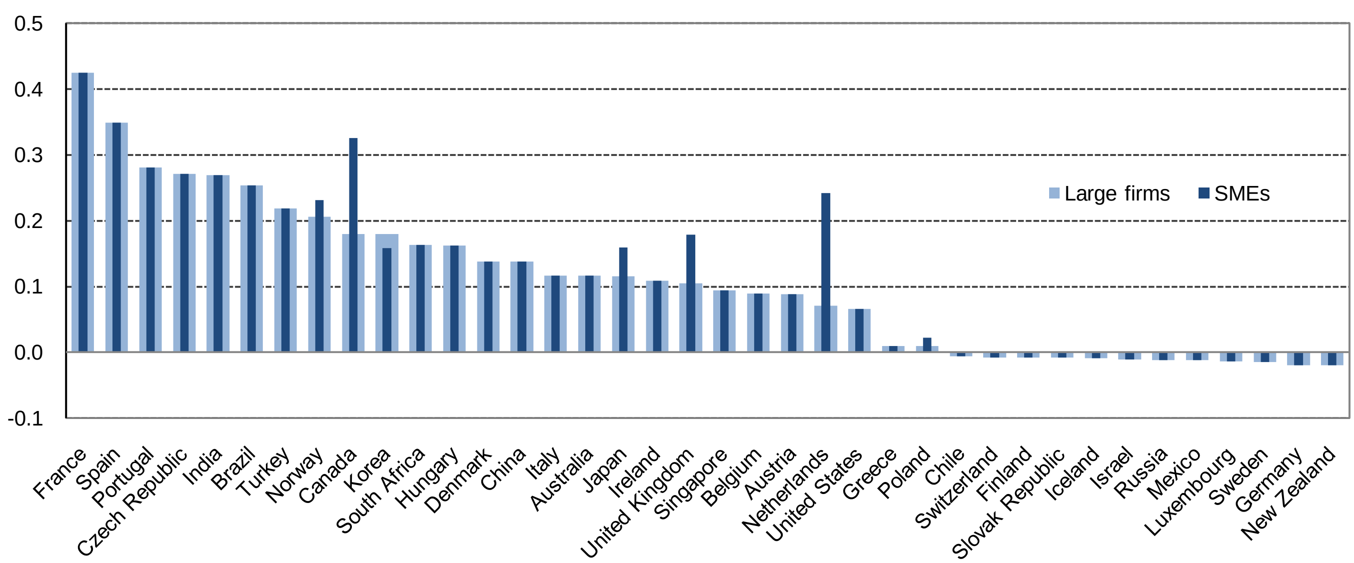
[65] *2011 Global R&D Funding Forecast*, supra.

Despite the budget problems facing many countries throughout the world, many analysts believe that the competition for R&D investment dollars will continue to drive countries to offer significant tax incentives for these investments. Countries recognize that a key to long-term job and economic growth is a robust and stable environment for R&D investments. As competition for life sciences R&D continues to grow around the world, the United States cannot ignore the tax treatment of life sciences R&D investments relative to the tax treatment in other countries. As one recent analysis notes with respect to life sciences R&D:

> "Despite the need to replenish depleted public coffers, the competition to attract companies engaging in R&D will intensify. Some countries will offer generous tax incentives and credits – and several will be new competitors keen to build knowledge-based economies."[66]

The United States currently lags most OECD countries in terms of the tax subsidy provided to R&D investments (see Graph 4, below). Countries that are aggressively pursuing life sciences R&D investments, like China, India, and Korea, provided significantly greater tax subsidies than the United States. Graph 4 shows that some countries, like Canada, Japan, the United Kingdom, and the Netherlands, offer even greater benefits for small and mid-sized businesses (SMEs in Graph 4).[67]

Graph 4 – Tax Subsidy for $1 (USD) of Investment in R&D in OECD Countries, 2008



Source: OECD Science, Technology, and Industry Scorecard, 2009.
The amount of tax subsidy for R&D is calculated as 1 minus the "B index." The B index was designed by Jacek Warda to compare tax subsidies in different countries and is the present value of before tax income needed to cover the inital cost of R&D investments and to pay corporate income taxes.

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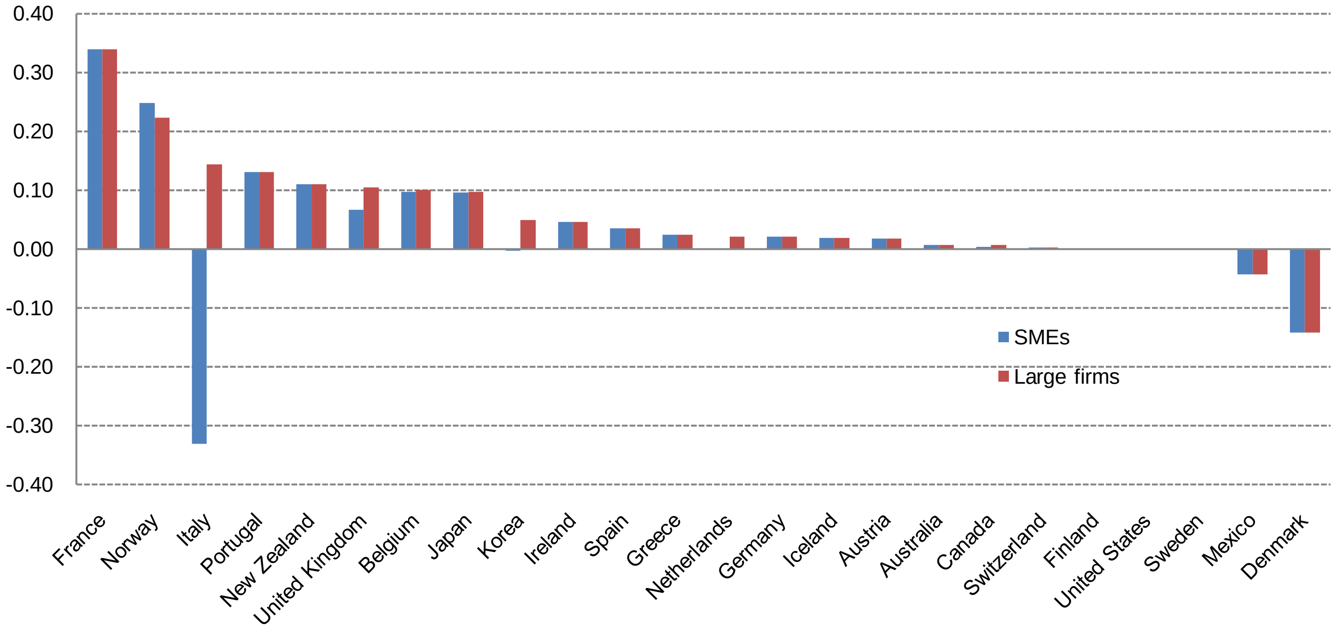
[66] *Phama 2020: Taxing times ahead. Which path will you take?* PricewaterhouseCoopers, available at www.pwc.com/pharma2020.

[67] As of 2009, Canada offered a refundable R&D credit available at a higher rate for small businesses. Japan offered a higher credit rate for small and mid-sized businesses. The United Kingdom offered a higher credit rate and partial refundability for small and mid-sized businesses.

Even more illuminating is a look at the trend in tax subsidies over the 1999-2008 period (Graph 5). While the tax subsidies provided for R&D investments in the United States have remained essentially static, most OECD countries have increased, in some cases substantially increased, the tax subsidies provided for R&D investments.

Graph 5 – Changes in Tax Subsidies Offered for $1 (USD) of R&D Investment in OECD Countries, 1999-2008



Source: OECD Science, Technology, and Industry Scorecard, 2009.

Thus, tax incentives for R&D have a significant and positive effect on business R&D spending. A 2005 study found that a $1 increase in R&D tax incentives leads to 90 cents of additional R&D spending.[68]

[68] Falk, Martin. *What Drives Business R&D Intensity Across OECD Countries?* Paper presented at the DRUID Tenth Anniversary Summer Conference 2005 on Dynamics of Industry and Innovation: Organizations, Networks and Systems.

V. Targeted R&D Tax Incentives Can Help the U.S. Life Sciences Industry Remain Competitive

A Federal policy that recognizes the challenges the U.S. life sciences industry faces from other countries for R&D dollars can help the United States remain the world leader in life sciences R&D. The following section discusses a legislative proposal to provide temporary targeted tax incentives to help the U.S. life sciences industry invest more in R&D in the United States. This proposal would allow taxpayers a choice between two temporary tax incentives – an enhanced R&D credit and a deduction for foreign earnings invested in life sciences research in the United States.

These temporary tax incentives will lead to increased investment in life sciences research in the United States. This increased investment leads directly to increased jobs in the United States and particularly to increased jobs for the highly skilled workers that conduct life sciences R&D.

A. Targeted R&D Tax Incentives

1. Enhanced R&D tax credit

The proposal provides a temporary enhanced R&D tax credit for amounts invested in qualified life sciences research. This enhanced credit would be available through December 31, 2015.

The proposal increases the R&D credit to 40 percent (from the current law 20 percent) of the amount by which qualified life sciences research exceeds a base amount. The proposal increases the Alternative Simplified Credit for qualified life sciences research from 14 to 28 percent (from 6 to 12 percent in the case of taxpayers with no qualified research expenses in the three preceding taxable years). Under the proposal, no more than $150 million of qualified life sciences research would be eligible for the enhanced credit in any year.

Taxpayers can claim the credit with respect to their qualified life sciences research expenses, which includes any research relating to human beings in the fields of biology, biochemistry, biophysics, bioengineering, biotechnology, microbiology, genetics, or physiology, but does not include research in the fields of sociology or psychology. In addition, the research must be considered scientific research and development under Code 5417 of the North American Industry Classification System, which includes "establishments engaged in conducting original investigation undertaken on a systematic basis to gain new knowledge (research) and/or the application of research findings or other significantly improved products or processes (experimental development)."[69]

Qualified life sciences research expenses include in-house research expenses and certain contract research expenses. Under current law, only 65 percent of contract research expenses can be taken into account in computing the credit (except for amounts paid for energy research to eligible small businesses (averaging500 or fewer employees during either of the preceding two

[69] See, http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=5417&search=2007

years), universities, and Federal laboratories) (75 percent in the case of payments to certain research consortia). In the case of contract research expenses, the proposal permits taxpayers to claim 100 percent of qualified life sciences research expenses, if paid to certain research consortia, certain tax-exempt organizations, eligible small businesses, universities, and Federal laboratories for qualified life sciences research. Qualified life sciences expenses do not include payments (1) to certain highly compensated employees, (2) to pay dividends to shareholders of the taxpayers, or (3) to pay interest or principal on any debt security of the taxpayer.

Taxpayers who claim the enhanced life sciences R&D credit are not entitled to utilize the provision to allow limited repatriation of foreign earnings to invest in life sciences jobs and investment in the United States (described below).

The bill requires taxpayers to provide substantiation of their compliance with the bill's requirements and certification of such compliance by the corporate CEO and the independent director serving as head of the taxpayer's audit committee.

Table 5 – Comparison of R&D Credit for Life Sciences Research to Current Law R&D Credit

Provision	Current Law	Proposed Legislation
Base Credit Percentage	20%	40%
Credit Percentage for Basic Research Payments	20%	40%
Alternative Simplified Credit Percentage	14%	28%
Alternative Simplified Credit If No Qualified Research Payments in Any of 3 Preceding Years	6%	12%
Percentage of life sciences expenses qualifying for research credit	100 percent of in-house expenses; 65 percent of contract expenses, unless certain exceptions apply; 75 percent of contract expenses paid to a certain research consortia	100 percent of in-house expenses; 100 percent of contract expenses paid to certain research consortia, certain tax-exempt entities, qualifying small businesses, universities, and Federal research labs for life sciences research

2. Limited deduction for foreign earnings invested in U.S. life sciences research

In lieu of the enhanced R&D credit, the proposal allows taxpayers to claim a limited deduction for cash dividends received from a controlled foreign corporation, as long as the dividends received are invested in life sciences research. Thus, companies that have financial statement earnings permanently reinvested outside the United States can repatriate these earnings without paying U.S. Federal taxes on the amounts repatriated. The deduction in any year is limited to the lesser of $150 million or the amount of financial statement earnings permanently reinvested outside the United States.

For purposes of the repatriation deduction, life sciences research includes:

1. the new hiring of scientists, researchers, and comparable personnel engaged in qualified life sciences research,
2. payments to certain tax-exempt entities, small businesses, universities, and Federal research laboratories for qualified life sciences research, and
3. the building and leasing of new facilities used primarily to conduct life sciences research.

The taxpayer may not use the amounts to make payments:

1. to certain highly compensated employees,
2. to pay dividends to shareholders of the taxpayers, or
3. to pay interest or principal on any debt security of the taxpayer.

In addition, the proposed legislation requires the taxpayer to hold the repatriated dividends in a separate account, trust, or other arrangement to segregate the amounts until they use the funds for qualified life sciences research.

The proposed legislation requires taxpayers to provide substantiation of their compliance with the bill's requirements and certification of such compliance by the corporate CEO and the independent director serving as head of the taxpayer's audit committee.

B. Benefits of the Proposed Legislation

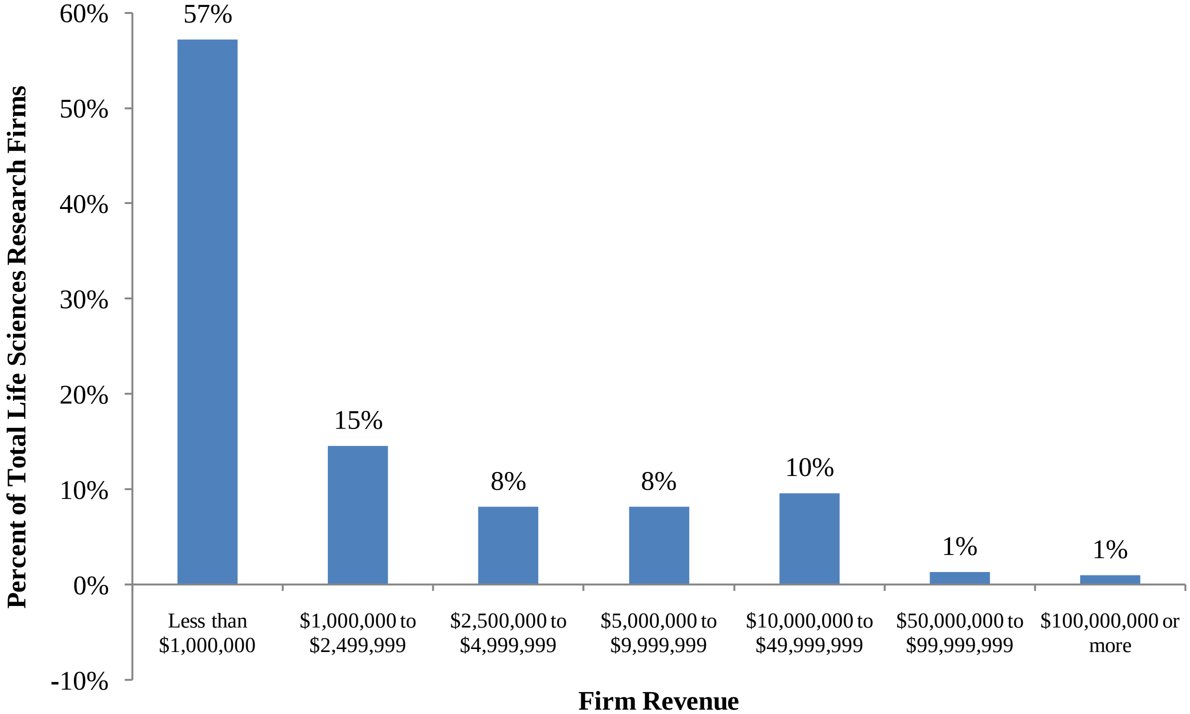
The proposed legislation will stimulate additional investment in life sciences research in the United States. By improving the tax benefits for life sciences R&D conducted in the United States, companies will prefer to increase their investments in life sciences R&D relative to their planned levels of R&D investments. In addition, the proposal will encourage companies to invest more in life sciences R&D in the United States compared to their planned life sciences R&D investments outside the United States.

By stimulating investment in the United States that would not have otherwise occurred, the number of jobs for workers in the life sciences industry, particularly skilled workers like scientists and engineers, will increase. This additional investment will also contribute indirectly to the creation of other jobs in the U.S. economy as the beneficial effects of the increased life sciences R&D contribute to improvements in other industries.

While all taxpayers in the life sciences industry are eligible for the tax incentives in the proposed legislation, the incentives are relatively more meaningful to small and mid-sized taxpayers. Graph 6 shows the estimated distribution of eligible life sciences taxpayers by size of receipts.

Graph 6 – Life Sciences Research Taxpayers Distributed by Size of Firm Revenue

Source: Author's estimates based on Economic Census and IRS SOI data sources



The vast majority (98 percent) of taxpayers eligible for these incentives are small to mid-sized firms.[70] However, in addition to the absolute number of eligible firms, the tax incentives also provide a greater relative incentive to small and mid-sized taxpayers.

Effects of the proposed changes – To understand the relative stimulative effects to small and mid-sized firms of the enhanced credit, consider the example in Table 6. Since the R&D credit applies only to amounts above a base R&D activity, dollar-for-dollar, the incremental increases provide a greater percentage return to total investment for small or mid-sized firms.[71]

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[70] Small and mid-sized firms are those firms with $50 million or less in receipts.

[71] However, it is important to note that if large firms increase their investment proportionately, they will also realize a higher relative return on that investment. The table attempts to demonstrate that small and mid-sized firms will have a greater sensitivity to increasing investment (dollar-for-dollar) relative to larger firms.

Table 6 – Relative Stimulative Effects of the Enhanced R&D Tax Credit *(dollar amounts in thousands)*				
Small Firm				
Base Investment	$50,000	$50,000	$50,000	$50,000
Investment Eligible for the Credit	$20,000	$30,000	$40,000	$50,000
Total Investment	**$70,000**	**$80,000**	**$90,000**	**$100,000**
Enhanced Credit	$8,000	$12,000	$16,000	$20,000
Enhanced Credit as a Percentage of Total R&D Investment	11.4%	15.0%	17.8%	20.0%
Large Firm				
Base Investment	$ 500,000	$ 500,000	$ 500,000	$ 500,000
Investment Eligible for the Credit	$ 20,000	$ 30,000	$ 40,000	$ 50,000
Total Investment	**$520,000**	**$530,000**	**$540,000**	**$550,000**
Enhanced Credit	$8,000	$12,000	$16,000	$20,000
Enhanced Credit as a Percentage of Total R&D Investment	1.5%	2.3%	3.0%	3.6%

These provisions will enable small and mid-size businesses to increase their R&D investments in the United States as well as to help counter the effects of the recent recession.

Since the provisions provide tax incentives for domestic research activity, it is likely that they will encourage firms to conduct more research in the United States. This enhanced credit makes domestic research less expensive relative to research conducted outside the United States.

In addition, the recent recession dampened spending on R&D in the United States. Firms faced economic uncertainty and were reluctant to embark on new research ventures, given the inherent risks associated with new research. Further, much of the available venture capital was not available after the financial market collapse in 2008. Many firms were unable to gain private funding that was once readily available.

While the enhanced credit addresses the relative cost of new R&D research, the ability to repatriate foreign permanently reinvested earnings provides a considerable source of new capital for life sciences research.

Just as with the enhanced credit, the ability to return foreign earnings provides a relatively greater benefit to small and mid-sized firms. Using the above example of a firm that invests $50 million each year in life sciences R&D, allowing the taxpayer to return up to $150 million in foreign earnings represents a tripling of current resources available for investment for the small taxpayer.[72]

[72] The comparable increase is 30 percent for the larger firm that invests $500 million each year.

Analysis of these two provisions suggests that these tax incentives will make available approximately $28 billion in new investment over the five-year period.[73] These increased resources provide an infusion of capital dedicated to life sciences research in the United States. As with any increase in investment capital, there is the potential to increase jobs as well as stimulate new capital expenditures.

The jobs estimates shown in Table 7 include direct and indirect jobs creation or retention. For purposes of this analysis, the job creation estimates rely on the RIMS II final-demand employment multiplier provided by the U.S. Department of Commerce's Bureau of Economic Analysis. The RIMS employment multipliers used in this analysis are specific to the life sciences industry.

Table 7 – Estimated Potential Job Creation Potential and Economic Stimulus from Increased Investment, Attributable to the Enhanced R&D Credit and the Repatriation of Foreign Dividends, **2011 to 2015**
(Numbers of Jobs)

	Total
New Jobs Resulting from Increased R&D Investment	**683,000**
Average per year from Increased R&D Investment	**136,600**

[73] This estimate includes only induced investment and investment that accelerated into the early years of the budget window (encouraged to take place sooner). It does not include investment that receives a windfall from the current provisions.

VI. Conclusions

The life sciences industry is one of the most important to the U.S. economy. The industry provides jobs for highly skilled workers and makes significant contributions to long-term economic growth through the technological advancements gained from R&D activities. However, the U.S. life sciences industry faces a variety of challenges, such as regulatory barriers and increasing costs, which threaten to derail the role of the United States as the world leader in life sciences R&D.

At the same time that the United States struggles to recoup jobs lost during the recession, other countries are competing aggressively for life sciences R&D. While life sciences R&D in 2011 is expected to be below 2008 levels in the United States, it is projected to be 11.5 percent higher than 2008 levels worldwide. Countries like China and India are rapidly increasing their life sciences R&D capabilities. If these trends continue, additional job losses in the United States could occur.

A legislative solution that provides targeted, temporary tax incentives to increase life sciences R&D in the United States could help to stem this tide. Such targeted tax incentives could contribute as many as 683,000 new jobs to the U.S. economy over the next five years. In addition, as many other countries are increasing the tax incentives they offer for R&D activities, these types of targeted tax incentives could help the United States maintain its competitive position in the world life sciences R&D market.