The future looks brighter for business than for basic research. Shannon Stewart and Stacy Springs

A nurse uses a light therapy device to treat the side-effects of chemotherapy and radiotherapy in a cancer patient, during a trial at Birmingham Hospital in 2011 run by the University of Alabama. This High Emissivity Aluminiferous Luminescent Substrate (HEALS) technology uses 288 powerful light-emitting diodes (LEDs) to provide intense light. HEALS light therapy was developed from experiments carried out at the International Space Station. Photo ©: Jim West/Science Photo Library

Shannon Stewart and Stacy Springs

INTRODUCTION

A fragile recovery

The US economy has recovered from the 2008–2009¹ recession. The stock market has hit new heights and GDP has been on the upswing since 2010, despite having stuttered in a few quarters. At 5.5%, the 2015 unemployment rate is well below its 2010 peak of 9.6%.

After a sharp deterioration in 2008, the USA's public finances are on the mend. The combined federal and state fiscal deficit should improve to 4.2% of GDP in 2015, thanks to increasingly robust economic growth, even though it will remain one of the highest among G7 countries (Figure 5.1). The federal budget deficit (2.7% of GDP) will make up just under twothirds of the total deficit, according to projections² by the Congressional Budget Office. This is a big improvement on the situation in 2009, when the federal deficit peaked at 9.8% of GDP.

1. According to the US National Bureau of Economic Research, the USA was in recession from December 2007 to end June 2009.

2. See: https://www.cbo.gov/publication/49973

Since 2010, federal investment in research and development (R&D) has stagnated in the wake of the recession. Despite this, industry has largely maintained its commitment to R&D, particularly in growing, highopportunity sectors. As a result, total R&D spending has dipped only slightly and the balance of spending has shifted further towards industrial sources since 2010, from 68.1% to 69.8% of the total. Gross domestic expenditure on research and development (GERD) is now rising, as is the share performed by the business enterprise sector (Figures 5.2 and 5.3).

The recovery remains fragile, however. Despite the decline in unemployment, there are still 8.5 million job-seekers. The long-term unemployed - those out of a job for 27 weeks or more - still number about 2.5 million. A further 6.6 million are employed part-time but would prefer fulltime employment and 756 000 have given up looking for work. Wages remain stagnant and many of those who lost their jobs during the recession have since found positions in growth areas but with lower salaries. The average hourly wage rose by just 2.2% over the 12 months ending in April 2015.

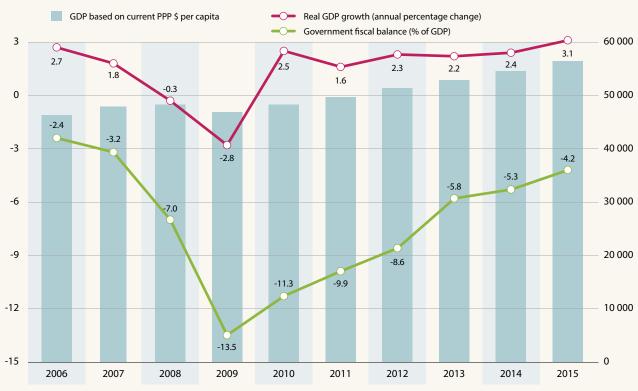
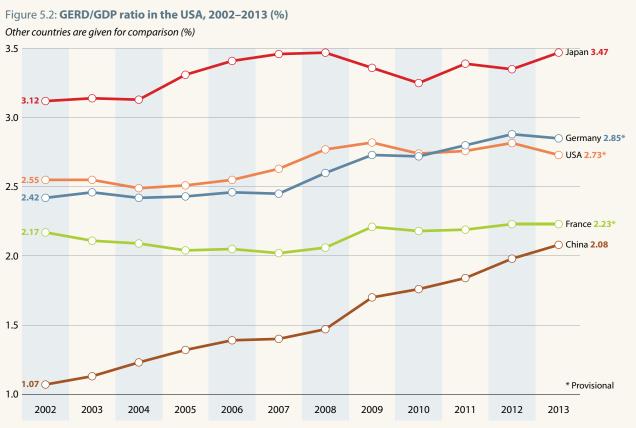


Figure 5.1: GDP per capita, GDP growth and public sector deficit in the USA, 2006–2015

Note: Data for 2015 are estimates. General government fiscal balance is also known as net lending/borrowing. The fiscal balance covers both the federal and state governments. Source: IMF Data Mapper online, August 2015



Source: UNESCO Institute for Statistics, August 2015. USA data for 2013 from OECD Main Science and Technology Indicators, August 2015

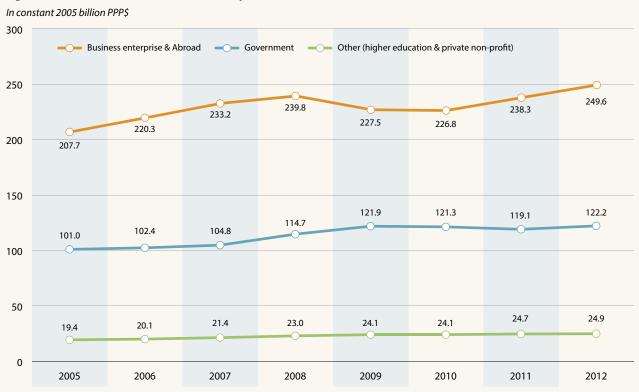


Figure 5.3: Distribution of GERD in the USA by source of funds, 2005–2012

Source: UNESCO Institute for Statistics, August 2015

Funding from the economic stimulus package of 2009, formally known as the American Recovery and Reinvestment Act, may have buffered immediate job losses for those working in science and technology, since a significant portion of this stimulus package went to R&D. A study by Carnivale and Cheah (2015) showed that students who had majored in science, technology, engineering and mathematics were less affected by unemployment than the average American: only 5% were unemployed in 2011–2012. Those graduates having studied physical sciences were the least affected of all. However, average salaries for recent graduates have declined across all disciplines. Moreover, although the Industrial Research Institute indicates that businesses plan to hire people with experience and new graduates - albeit fewer than last year - cutbacks looming in the federal budget for R&D in 2015 and 2016 throw a pall over the economic future of publicly funded R&D funding.

Flat federal research budgets

Although the president makes an annual budget request, the ultimate authority on federal funding of science in the USA is Congress (bicameral parliament). Control of Congress was divided between the two main political parties from 2011 onwards, with Republicans controlling the House of Representatives and Democrats the Senate, until the Republicans gained control over the latter in January 2015. In spite of the efforts made by the government to increase allocations to research, congressional priorities have largely prevailed (Tollefson, 2012). Most federal research budgets have remained flat or declined in inflation-adjusted dollars over the past five years, as part of the congressional austerity drive to trim US\$ 4 trillion from the federal budget to reduce the deficit. Since 2013, Congress has withheld approval of the federal budget presented by the government several times. This bargaining chip has been possible since 2011, when Congress passed a law stipulating that about US\$ 1 trillion in automatic budget cuts across the board would start to take effect in 2013 if Congress and the White House could not agree on a plan to reduce the deficit. The deadlock over the budget in 2013 led to an administrative shutdown for several weeks, effectively putting federal employees on leave without pay. The effects of budgetary austerity and sequestration linger in federal investment, making it difficult for young scientists to establish a career, as we shall see later.

This austerity drive may be explained, at least in part, by the perception of there being a lesser need for R&D than before. With two lengthy interventions in Afghanistan and Iraq winding down, the focus of research has shifted away from military technologies, causing defence-related R&D to decline accordingly. On the other hand, federal research investment in the life sciences has failed to keep pace with inflation, in spite of the emerging needs of an ageing population; in parallel, federal investment in energy and climate research has been modest.

In his 2015 State of the Union address, President Obama set forth his policy priorities for the future as being the pursuit of the fight against climate change and a new Precision Medicine Initiative. The executive's priorities are being taken forward largely thanks to collaboration between the government, industry and non-profit sectors. Some milestones built on this collaborative model are the BRAIN Initiative, the Advanced Manufacturing Partnership and the American Business Act on Climate Pledge that recently received a US\$ 140 billion commitment from its partners in industry. These three initiatives are discussed in the next section.

On the international scene, the USA is having to contend with the gradual, inexorable shift from a monopolar structure to a more pluralistic and globalized playing field for science. This shift is mirrored at many levels of US science, ranging from education to patent activity. For instance, the Organisation for Economic Co-operation and Development (OECD) projects that China will exceed the USA in R&D spending by about 2019 (see also Chapter 23). Although the USA is the current world leader in R&D, its lead is narrowing and is projected to narrow further or even disappear in the near future.

GOVERNMENT PRIORITIES

Climate change: the science policy priority

Climate change has been the Obama administration's top priority for science policy. One key strategy has been to invest in alternative energy technologies as a way of reducing the carbon emissions that lead to climate change. This includes increasing the availability of funding for basic research in the field of energy at universities, loans for businesses and other incentives for R&D. In the aftermath of the financial crisis, the White House effectively leveraged the ensuing economic crisis as an opportunity to invest in science, research and development. Since then, however, political difficulties have forced the president to scale down his ambitions.

In the face of Congressional opposition, the president has taken steps to address climate change to the extent that his executive powers allow. For instance, he vetoed a congressional bill in March 2015 that would have authorized construction of the Keystone XL pipeline to carry oil from tar sands in Canada across the USA to the Gulf of Mexico. He has also overseen the creation of ambitious new fuel standards for cars and trucks, for instance. In 2014, his top scientist, John Holdren, Director of the Office of Science and Technology

Policy and Co-Chair of the President's Council of Advisors on Science and Technology,³ organized and issued the *National Climate Assessment*, a thorough, peer-reviewed examination of the effects of climate change on the USA. On the grounds that the USA needs to maintain its energy independence, the president has nevertheless authorized fracking and, in 2015, approved oil drilling in the Arctic Ocean.

The government has elected to use the power of the Environmental Protection Agency to regulate greenhouse gas emissions. The Environmental Protection Agency wishes to reduce power plants' carbon emissions by 30% across the USA. Some states are also supporting this policy, since each state is free to fix its own emission targets. California is one of the most rigorous, in this regard. In April 2015, the state governor imposed a 40% carbon emissions reduction target by 2030 over 1990 levels. California has been experiencing severe drought for several years.

The USA will only be able to reach its emissions reduction targets with the involvement of industrial stakeholders. On 27 July 2015, 13 large US companies committed to investing US\$ 140 billion in low carbon emission projects, as part of the American Business Act on Climate Pledge announced by the White House. Six of the signatories have made the following pledges:

- Bank of America undertakes to increase its investment in favouring the environment from US\$ 50 billion at present to US\$ 125 billion by 2025;
- Coca-cola undertakes to reduce its carbon footprint by one-quarter by 2020;
- Google, the world leader for the purchase of renewable energy to run its data centres, pledges to triple its purchases over the next decade;
- Walmart, the world leader in distribution (supermarket chains) pledges to increase its production of renewable energy by 600% and double the number of its supermarkets running on renewable energy by 2020;
- Berkshire Hathaway Energy (Warren Buffett group) will double its investment in renewable energy, currently US\$ 15 billion; and
- Alcoa, the aluminium manufacturer, undertakes to halve its carbon emissions by 2025.

Better health care: the Patients' Bill of Rights

Better health care has been a priority of the Obama administration. The Patient Protection and Affordable Care Act was signed into law by the president in March 2010 and upheld by the Supreme Court in a decision rendered in June 2012. Touted as the 'Patients' Bill of Rights,' it sets out to give a maximum of citizens health care coverage.

The Biologics Price Competition and Innovation Act is part of this law. It creates a pathway for abbreviated licensure for biological products that are shown to be 'biosimilar' to, or 'interchangeable' with, an approved biological product. The act was inspired by the Drug Price Competition and Patent Restoration Act (1984), more commonly known as the Hatch-Waxman Act, which encouraged development of generic drug competition as a cost containment measure for high-priced pharmaceuticals. Another inspiration for the act was the fact that the patents for many biologic drugs will expire in the next decade.

Although the Biologics Price Competition and Innovation Act was passed in 2010, the first biosimilar was only approved in the USA by the Food and Drug Administration (FDA) in 2015: Zarxio, made by Sandoz. Zarxio is a biosimilar of the cancer drug Neupogen, which boosts the patient's white blood cells to ward off infection. In September 2015, a US court ruled that the Neupogen brand manufacturer Amgen could not block Zarxio from being sold in the USA. Neupogen costs about US\$ 3 000 per chemotherapy cycle; Zarxio hit the US market on 3 September at a 15% discount. In Europe, the same drug had been approved as early as 2008 and has been safely marketed there ever since. The lag in development of an approval pathway in the USA has been criticized for impeding access to biological therapies.

The true cost savings from the use of biosimilars is difficult to assess. A 2014 study by the Rand Institute estimates a range of US\$ 13–66 billion in savings over 2014–2024, depending upon the level of competition and FDA regulatory approval patterns. Unlike generics, biosimilars cannot be approved on the basis of minimal and inexpensive tests to prove bioequivalence. Since biological drugs are complex, heterogeneous products derived from living cells, they can only be shown to be highly similar to the appropriate reference product and therefore require demonstration that there are no clinically meaningful differences in safety and efficacy. The extent to which clinical trials are required will largely determine the cost of development.

The Affordable Care Act included financial incentives for health care providers to adopt electronic health records: up to US\$ 63 750 for a physician whose practice includes a minimum of 30% of patients covered by Medicaid, a federally funded, state-run programme for those with limited income. According to an annual report submitted to Congress in October 2014,

^{3.} This group of distinguished scientists advises the president through written reports. Recent topics include individual privacy in big data contexts, education and work training and health care delivery issues. The council's reports tend to focus more closely on the president's policy agenda than those of the national academies of science.

more than six of ten hospitals electronically exchanged patient health information with providers outside their organization and seven out of ten health-care providers electronically prescribed new prescriptions. One of the benefits of electronic health records is that this system makes it easier to analyse swaths of patient health data to individualize and personalize care. It was President George W. Bush who, in 2004, initiated a plan for Americans to have electronic health records by 2014, in order to reduce medical errors, optimize treatment and consolidate medical records for better, more cost-efficient care.

Cures for the 21st century

The goal of the 21st Century Cures bill is to streamline drug discovery, development and approval by relaxing barriers to information-sharing, increasing regulatory transparency and modernizing standards for clinical trials. The bill includes an innovation fund of US\$ 1.75 billion per year for five years for one of the USA's main science agencies, the National Institutes of Health (NIH), and US\$ 110 million per year for five years for the FDA. Endorsed by a number of industry groups, it enjoys strong support. In a rare moment of bipartisanship, the bill passed the House on 10 July 2015. At the time of writing in August 2015, the bill has not yet been taken up by the Senate.

Were the bill to pass into law, it would alter the way in which clinical trials are conducted by allowing new and adaptive trial designs that factor in personalized parameters, such as biomarkers and genetics. This provision has proven controversial, with doctors cautioning that overreliance on biomarkers as a measure of efficacy can be misleading, as they may not always reflect improved patient outcomes. The bill also includes specific provisions to incentivize the development, and facilitate the approval, of drugs for rare diseases and new antibiotics, including the prospect of limited release to special populations – the first time that an identified subpopulation for a particular disease will be treated differently from a regulatory perspective. (For another approach to speeding up the process of drug approval through pre-competitive collaboration, see the Accelerating Medicines Partnership, Box 5.1.)

The BRAIN Initiative: a 'grand challenge'

In 2009, the Obama administration published its *Strategy for American Innovation*, which was updated two years later. This strategy emphasizes innovation-based economic growth as a way of raising income levels, creating better-quality jobs and improving quality of life. One element of this strategy are the 'grand challenges' introduced by the president in April 2013, three months into his second term of office, to help catalyse breakthroughs in priority areas, by combining the efforts of public, private and philanthropic partners.

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative is one of the 'grand challenges' announced by the president in April 2013. The goal of this project is to leverage genetic, optical and imaging technologies to map individual neurons and complex circuits in the brain, eventually leading to a more complete understanding of this organ's structure and function.

So far, the BRAIN Initiative has obtained commitments of over US\$ 300 million in resources from federal agencies (NIH, FDA, National Science Foundation, etc.), industry (National Photonics Initiative, General Electric, Google, GlaxoSmithKline, etc.) and philanthropy (foundations and universities).

The first phase is focusing on the development of tools. The NIH has created 58 awards totalling US\$ 46 million, guided by the scientific vision of the chairs Drs Cori Bargmann and William Newsome. For its part, the Defense Advanced Research Projects Agency has focused on tools to create electrical interfaces with the nervous system to treat motor damage. Industrial partners are developing improved solutions that the project will require in terms of imaging, storage and analysis. Universities across the country have committed to aligning their neuroscience centres and core equipment with the objectives of the BRAIN Initiative.

A Precision Medicine Initiative

Defined as delivering the right treatment to the right patient at the right time, precision medicine tailors treatments to patients based on their unique physiology, biochemistry and genetics. In his 2016 budget request, the president asked for US\$ 215 million to be shared by the NIH, National Cancer Institute and FDA to fund a Precision Medicine Initiative. As of August 2015, the budget had not yet been voted upon. Between 2005 and 2010, pharmaceutical and biopharmaceutical companies increased their investment in precision medicine by roughly 75% and a further increase of 53% is projected by 2015. Between 12% and 50% of the products in their drug development pipelines are related to personalized medicine (See Box 5.2).

A focus on advanced manufacturing

One of the federal government's major priorities has been to steer advanced manufacturing towards enhancing US competitiveness and job creation. In 2013, the president launched the Advanced Manufacturing Partnership Steering Committee 2.0 (AMP 2.0). Based on recommendations of the co-chairs representing the industrial, labour and academic sectors, he also called for the creation of a Nationwide Network for Manufacturing Innovation, a series of connected institutes for manufacturing innovation to 'scale up advanced manufacturing technologies and processes.' Congress approved this request, enabling the president to sign the Revitalize American Manufacturing Act into law in September 2014 for an investment of US\$ 2.9 billion. These funds, which are to be matched by private and non-federal partners, will be used to create an initial network of up to 15 institutes, nine of which have already been determined or established.

Box 5.1: The Accelerating Medicines Partnership

The Accelerating Medicines Partnership was launched by the National Institutes of Health (NIH) in Washington DC on 4 February 2014. This public–private partnership involves the NIH and the Food and Drug Administration on the government side, 10 major biopharmaceutical companies and several non-profit organizations. Government bodies and industry are sharing the US\$ 230 million budget (see Table 5.1).

Over the next five years, the partnership will develop up to five pilot projects for three common but difficult-totreat diseases: Alzheimer's disease, type 2 (adult onset) diabetes and the autoimmune disorders, rheumatoid arthritis and lupus. The ultimate goal is to increase the number of new diagnostics and therapies for patients and reduce the time and cost of developing them. 'Currently, we are investing too much money and time in avenues that don't pan out, while patients and their families wait,' said NIH director Francis S. Collins, at the launch. 'All sectors of the biomedical enterprise agree that this challenge is beyond the scope of any one sector and that it is time to work together in new ways to increase our collective odds of success.'

Developing a new drug takes well over a decade and has a failure rate of more than 95%. As a consequence, each success costs more than US\$1 billion. The most expensive failures happen in late phase clinical trials. It is thus vital to pinpoint the right biological targets (genes, proteins and other molecules) early in the process, so as to design more rational drugs and better tailored therapies.

For each pilot project, scientists from NIH and industry have developed research plans aimed at characterizing effective molecular indicators of disease, called biomarkers, and distinguishing those biological targets most likely to respond to new therapies (known as targeted therapies). They will thus be able to focus on a small number of molecules. Laboratories will share samples, such as blood or brain tissue from deceased patients, to identify biomarkers. They will also participate in NIH clinical trials.

The partnership will be managed through the Foundation for the NIH. One critical component is that industry partners have agreed to make the data and analyses arising from the partnership accessible to the broad biomedical community. They will not use any discoveries to develop their own drug until these findings have been made public.

Source: www.nih.gov/science/amp/index.htm

Table 5.1: Parameters of the Accelerating Medicines Partnership, 2014

Government partners	Industrial partners		Partners among non-profit organizations		
Food and Drug Administration	AbbVie (USA)		Alzheimer's Association		
National Institutes of Health	Biogen (USA)		American Diabetes Association		
	Bristol-Myers Squibb (USA)		Lupus Foundation of America		
	GlaxoSmithKline (UK)		Foundation for the NIH		
	Johnson & Johnson (USA)		Geoffrey Beene Foundation		
	Lilly (USA)		PhRMA		
	Merck (USA)		Rheumatology Research Foundation		
	Pfizer (USA)		USAgainstAlzheimer's		
	Sanofi (France)				
	Takeda (Japan)	ıkeda (Japan)			
Research focus	Total project (US\$ millions)	Total NIH (US\$ millions)		Total industry (US\$ millions)	
Alzheimer's Disease	129.5	67.6		61.9	
Type 2 Diabetes	58.4	30.4		28.0	
Rheumatoid Arthritis and Lupus	41.6	20.9		20.7	
Total	229.5	118.9		110.6	

These include institutes focusing on additive manufacturing like three-dimensional (3D) printing, digital manufacturing and design, lightweight manufacturing, wide band semiconductors, flexible hybrid electronics, integrated photonics, clean energy and revolutionary fibres and textiles. The goal for these innovation hubs will be to ensure sustainable collaborative innovation among industry, academia and government stakeholders in order to develop and demonstrate advanced manufacturing technologies that increase commercial productivity, bring together the best talent from all sectors to demonstrate cutting-edge technology and create a talent pipeline for advanced manufacturing.

A shift away from human spaceflight

In recent years, the focus of the National Aeronautics and Space Administration (NASA) has shifted away from human spaceflight, as part of a cost-cutting drive. In a reflection of this trend, the showpiece space shuttle programme was retired in 2011 and its successor cancelled. US astronauts now rely on Russian-operated Soyouz rockets to transport them to and from the International Space Station. In parallel, a partnership between NASA and the privately owned US company SpaceX is gaining traction but SpaceX does not yet have human flight capabilities. In 2012, SpaceX's Dragon became the first commercial spacecraft to fly cargo to and from the International Space Station.

In 2015, the US spacecraft New Horizons achieved a flyby of the dwarf planet Pluto in the Kuiper belt, 4.8 billion km from Earth, which astrophysicist Neil deGrasse Tyson likened to 'a hole-in-one on a two-mile golf shot.' John Holdren, the president's top scientist, noted that the USA had become the first nation to explore our entire Solar System.

CONGRESSIONAL PRIORITIES

A drive to cut research funding

The Republican leadership of the House Committee on Science, Space and Technology has been vocally sceptical of the Obama administration's climate change agenda. It has also striven to reduce funding for geosciences and alternative energy research, while intensifying political oversight. Individual members of Congress have criticized specific grants for being wasteful and unscientific, a strategy that resonates with the public.

Congress is able to set science-related policy directly through the passage of legislation that affects both matters of funding and law. The topics can vary widely: Congress takes up bills ranging from flood preparedness to nanotechnology, from offshore drilling to treatments for addiction. Below are three examples of enacted legislation that is having a large impact on US science policy: the America COMPETES Act, budgetary sequestration and the Food Safety Modernization Act.

Greater congressional control over grant funding

The America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act (America COMPETES Act) was first passed in 2007 before being reauthorized and fully funded in 2010; it will be taken up again before the end of the current legislature in January 2017. The aim of this act is to bolster US research and innovation through investment in education, teacher training, loan guarantees for innovative manufacturing technologies and scientific infrastructure. It also requires periodic assessment of progress in these areas and the general competitiveness of US science and technology. Its primary focus is education and its effects on this sector are discussed in detail in the section on Trends in Education (see p. 148).

At the time of writing in August 2015, the America COMPETES Reauthorization Act of 2015 has been passed by the House but not by the Senate. If passed, the new act will create a level of congressional control over the grant schemes funded by the National Science Foundation. The law would require every grant funded by NSF to be 'in the national interest' and each grant announcement to be accompanied by a written justification from the agency indicating how the grant meets any of the seven subsets of 'national interest' outlined by the bill. These seven subsets are defined as having the potential to:

- increase economic competitiveness in the USA;
- advance the health and welfare of the American public;
- develop an American labour force trained in science, technology, engineering and mathematics that is globally competitive;
- increase public scientific literacy and public engagement with science and technology in the USA;
- increase partnerships between academia and industry in the USA;
- support the national defence of the USA; or
- promote the progress of science in the USA.

Sequestration has squeezed research budgets

As we saw in the introduction, sequestration is a set of automatic budget reductions aimed at reducing the federal deficit. Since 2013, the agencies that fund R&D have received blanket cuts ranging from 5.1% to 7.3% and can expect their budgets to remain flat through 2021. Made outside the normal budget appropriations schedule, these cuts caught many institutions by surprise, particularly the universities and government laboratories that depend on federal funding.

Since most research universities depend heavily on federal grants to fund their activities, sequestration forced an immediate and significant across-the-board cut to their

Box 5.2: Industrial trends in the USA in life sciences

Industrial investment on the rise

The USA carries out 46% of global R&D in life sciences, making it the world leader. In 2013, US pharmaceutical companies spent US\$ 40 billion on R&D inside the USA and nearly another US\$ 11 billion on R&D abroad. Some 7% of the companies on Thomson Reuters' Top 100 Global Innovators list for 2014 are active in life science industries, equal to the number of businesses in consumer products and telecommunications.

Pharmaceutical companies pursued mergers and acquisitions actively in 2014 and 2015. In the first half of 2014, the value of this type of activity totalled US\$ 317.4 billion and, in the first quarter of 2015, the drug industry accounted for a little more than 45% of all US mergers and acquisitions.

In 2014, venture capital investment in the life sciences was at its highest level since 2008: in biotechnology, US \$6.0 billion was invested in 470 deals and, in life sciences overall, US\$ 8.6 billion in 789 deals. Two-thirds (68%) of the investment in biotechnology went to first-time/early-stage development deals and the remainder to the expansion stage of development (14%), seed-stage companies (11%) and latestage companies (7%).

Astronomic rise in prescription drug prices

In 2014, spending on prescription drugs hit US \$374 billion. Surprisingly, this hike in spending was fuelled by the costly new drugs on the market for treating hepatitis C (US\$ 11 billion) rather than by the millions of newly insured Americans under the Patient Protection and Affordable Care Act of 2010 (US\$ 1 billion). About 31% of this spending went on specialty drug therapies to treat inflammatory conditions, multiple sclerosis, oncology, hepatitis C and HIV, etc., and 6.4% on traditional therapies to treat diabetes, high cholesterol, pain, high blood pressure and heart disease, asthma, depression and so on.

From January 2008 to December 2014, the price of commonly prescribed generic drugs decreased by almost 63% and the price of commonly used branded drugs increased by a little more than 127%. However, a new trend in the USA, where drug consumer prices are largely unregulated, has been the acquisition of pharmaceuticals through licensing, purchase, a merger or acquisition, thus raising consumer prices astronomically. The *Wall Street Journal* has reported increases of as much as 600% for some branded drugs.

Costly orphan drugs

Orphan diseases affect fewer than 200 000 patients per year. Since 1983, over 400 drugs and biologic products for rare diseases have been designated by the FDA (2015), 260 alone in 2013. In 2014, sales of the top 10 orphan drugs in the USA amounted to US\$ 18.32 billion; by 2020, orphan drugs sales worldwide are projected to account for 19% (US\$ 28.16 billion) of the total US\$ 176 billion in prescription drug spending.

However, orphan drugs cost about 19.1 times more than non-orphan drugs (on an annual basis) in 2014, at an average annual cost per patient of US\$ 137 782. Some are concerned that the incentives given to pharmaceutical companies to develop orphan drugs by the FDA's orphan drug products programme is taking the companies' attention away from developing drugs that will benefit more of the population.

Medical devices: dominated by SMEs

According to the US Department of Commerce, the market size of the medical device industry in the USA is expected to reach US\$ 133 billion by 2016. There are more than 6 500 medical device companies in the USA, more than 80% of which have fewer than 50 employees. Observers of the medical device field foresee the further development and emergence of wearable health monitoring devices, telediagnosis and telemonitoring, robotics, biosensors, 3-D printing, new in vitro diagnostic tests and mobile apps that enable users to monitor their health and related behaviour better.

Biotechnology clusters

Biotechnology clusters are characterized by talent from top-notch universities and university research centres; firstrate hospitals, teaching and medical research centres; (bio)pharmaceutical companies ranging from start-ups to large companies; patent activity; NIH research grant funding and state-level policies and initiatives. The latter focus on economic development but also on creating jobs within states, support for advanced manufacturing and publicprivate partnerships to meet demand for talent (education and training). Statelevel policies also invest public monies in R&D and the commercialization of the resulting product or process, in addition to boosting state-led exports.

One overview classifies the USA's biotechnology clusters by region: San Francisco Bay Area; Southern California; the mid-Atlantic region (Delaware, Maryland and Virginia and the capital, Washington, DC); the mid-West (Illinois, Iowa, Kansas, Michigan, Minnesota, Missouri, Ohio, Nebraska and Wisconsin); Research Triangle Park and the State of North Carolina; Idaho; Montana; Oregon and Washington State; Massachusetts; Connecticut, New York, New Jersey, Pennsylvania and Rhode Island; and Texas.

Another overview ranks clusters by city or metropolitan area: San Francisco Bay area, Boston/Cambridge, Massachusetts, San Diego, Maryland/suburban Washington, DC, New York, Seattle, Philadelphia, Los Angeles and Chicago.

Source: compiled by authors

research budgets. As a result, universities scrambled to reduce the budgets of projects already under way by reducing staff and student positions, delaying equipment purchases and cancelling fieldwork. Federal grants that were already funded – as well as those being solicited – all suffered from cuts to their budgets. In general, the crisis has reduced morale among young and even established scientists and encouraged many to switch career paths. Some are even moving overseas to places where there appears to be more research money available.

A major law to limit food contaminants

Since the UNESCO Science Report 2010, the largest single piece of legislation covering scientific issues to pass into law has been the Food Safety Modernization Act (2011). This law introduced a major overhaul of the food safety system and includes a new focus on imported foods, in particular. The overriding goal is to move from coping with contamination to preventing it.

The passage of the Food Safety Modernization Act coincided with growing consumer awareness of food safety and purity. Regulation and consumer demand are leading to some reforms within the food industry to limit the use of antibiotics, hormones and some pesticides.

TRENDS IN R&D INVESTMENT

R&D intensity has been sustained

Generally speaking, US investment in R&D rose with the economy in the first years of the century before receding slightly during the economic recession then rising again as growth resumed. GERD amounted to US\$ 406 billion (2.82% of GDP) in 2009. After dipping briefly, R&D intensity recovered to 2009 levels in 2012, when GERD reached 2.81% of GDP, before dropping again in 2013 (Figure 5.2).

The federal government is the primary funder of basic research, at 52.6% in 2012; state governments, universities and other non-profits funded 26%. Technological development, on the other hand, is primarily funded by industry: 76.4% to the federal government's 22.1% in 2012.

Comparing them directly, the development phase is significantly more costly; therefore, private industry provides the largest input in absolute terms. Business enterprises contributed 59.1 % of US GERD in 2012, down from 69.0 % in 2000. Private non-profits and foreign entities each contribute a small fraction of total R&D, 3.3% and 3.8%, respectively. GERD figures are derived from the UNESCO Institute of Statistics R&D data, which were, themselves, derived from OECD statistics.

Figure 5.3 shows trends in GERD by funding source from 2005 to 2012 in current billions of dollars and constant 2005 dollars. Business sector funding of R&D (including R&D from abroad),

which had contracted by 1.4% during 2008-2010, has since rebounded by 6% (between 2010 and 2012). In global terms, R&D funded by government has remained fairly stagnant since 2008, despite the Recovery Act funding of 2009 and some political talk on fostering innovation-led recovery (Figure 5.4). However, the global picture masks the sharp drop in defence R&D; that carried out by the Department of Defense contracted by 27% in real terms between 2010 and 2015 (budget request).

A steep decline in defence spending

Among the 11 agencies that conduct the majority of federally funded R&D, most have seen flat R&D budgets over the past five years, the Department of Defense even experiencing a steep decline. At its peak in 2010, the Department of Defense spent US\$ 88.6 billion on R&D; in 2015, it is expected to spend only US \$64.6 billion. This reflects the winding down of the interventions in Afghanistan and Iraq and the reduced need for military technologies.

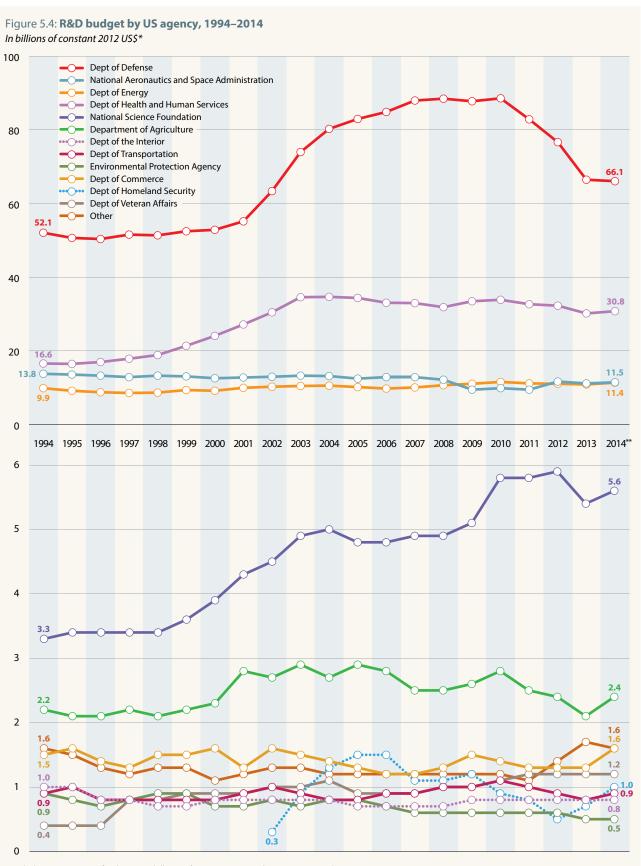
According to testimony given in February 2015 by Andrew Hunter (2015) of the Center for Strategic and International Studies before the US House of Representatives Committee on Small Business, the Department of Defense contracted US\$ 36 billion in R&D through industry in 2012 but only US\$ 28 billion in 2013. Hunter noted that 2014 defence contract obligations appeared to show a 9% decrease over the previous year, consistent with the US army's gradual withdrawal of troops from Afghanistan by 2016.

Non-defence federal R&D contracts were slightly above US\$ 10 billion in 2014, a drop of 6% over the previous year. Hunter suggested that this trend was due to a combination of decreasing federal budgets for specific research and the budget sequester instigated by Congress in 2013, which has enacted US \$1 trillion in automatic cuts to the federal budget to reduce the budget deficit.

Alternative energy a priority

The main areas of non-defence R&D are public health and safety, energy, basic science and the environment. The Department of Health and Human Services saw a major increase in its budget as a result of a doubling of the NIH budget between 1998 and 2003. Since then, the department's budget has failed to keep pace with inflation, resulting in a gradual squeeze on the newly expanded pipeline of researchers and trainees.

Consistent with its focus on climate change, the government has energetically funded alternative energy initiatives. The new Advanced Research Projects Agency – Energy (ARPA-E) is modelled on the highly successful Defense Advanced Research Projects Agency programme. The latter was established in 2009 with US \$ 400 million in funding from a federal stimulus package; its budget appropriations depend on the needs of the projects selected, ranging from



* excluding Recovery Act funding (20.5 billion US\$ in 2009) ** 2014 data are provisional

Source: American Association for the Advancement of Science

US\$ 180 million in 2011 to US\$ 280 million in 2015. Projects are organized around seven themes, including efficiency, grid modernization and renewable energy.

The Department of Energy's budget has remained relatively stable over the past seven years. It rose fairly steeply between 2008 and 2010 from US\$ 10.7 billion to US\$ 11.6 billion but had fallen back to US\$ 10.9 billion by 2013 (Figure 5.4).

Wrangling ahead over the 2016 research budget

The president's planned 2016 budget for science and technology comprises small cuts to defence but an increase for all other R&D under the Department of Defense. It also proposes a small increase for the NIH, cuts in defence-related nuclear energy R&D, a 37.1% cut in Homeland Security R&D, a 16.2% cut in R&D in the field of education and a few other small cuts. The National Science Foundation would receive a 5.2% increase. The Department of Energy's Office of Science would receive US\$ 4.9 billion, an increase over the past two years, within the department's wider budget of US\$ 12.5 billion. Overall, this budget would result in a 6.5% increase in total R&D: 8.1% for defence and 4.7% for non-defence (Sargent, 2015).

Congress has agreed to small increases for the National Science Foundation, National Institute of Standards and Technology and some Department of Energy programmes for 2016 but insists on flat funding in 2017 that would actually translate into a decrease when adjusted for inflation. Although this would only mean a slight decrease in funding for the National Science Foundation under the Congressional budget, Congress also plans to cut funding to the foundation's Social Science Directorate by 44.9%.

Congress also intends to cut funding for environmental and geoscience research, to curb the study of climate change. Congress plans to decrease R&D funds for renewable energy and advanced energy projects under the Department of Energy, while raising funds for fossil fuel energy research. Moreover, future R&D budgets will only be allowed to grow in concert with GDP. Political wrangling will determine the actual budget but, at this point, the chances of seeing significant increases in federal R&D budgets look slim, even if there is some agitation on the part of Republicans to increase NIH's budget. Figure 5.5 shows a breakdown of funding allocations by discipline.

Federal funding: a roller coaster ride

Research funding has grown at an unpredictable rate for many scientific disciplines, a trend which is ultimately disruptive to training and research. In boom times, the pipeline of trainees swells but, often, by the time they complete their training, they are facing a period of austerity and unprecedented competition for grants. Declining federal support for R&D has the greatest impact on public good science, where there is little incentive for industry to step in. A 2015 paper published in *Science Translational Medicine* by deans of US medical schools noted that 'support for the research ecosystem must be predictable and sustainable both for institutions and individual investigators' (Levine, *et al.*, 2015). They pointed out that, without greater spending, biomedical research would contract, the ability to address patient health would recede and the biomedical field would make a smaller contribution to the national economy.

An uncertain future for the NIH budget

The NIH is the government's flagship biomedical research funding organization. Since 2004, NIH funding has remained flat and is even decreasing when inflation is taken into consideration. The only brief respite came from the government's stimulus package in 2009 to reboot the economy after the subprime crisis, the American Recovery and Reinvestment Act. The NIH budget today is lower than in 2003– 2005, when it peaked at *circa* \$35 billion per year. Since 2006, the success rate for grant proposals has hovered around 20%.

Furthermore, the average age of a researcher obtaining an NIH grant⁴ for the first time is now 42 years. This raises the question of whether institutions are in a position to promote young faculty or give them tenure, as obtaining grants tends to be a pre-requisite for obtaining tenure. After reviewing the problems facing both the NIH and biomedical researchers, four top US scientists and administrators declared that the country was under the misconception 'that the research enterprise would expand forever' (Alberts et al., 2014). They noted that, after 2003, 'the demands for research dollars grew much faster than the supply' with the notable exception of the boost from the American Recovery and Reinvestment Act. The problem of dwindling funds has been exacerbated by the 2008 recession and the 2013 sequester of government funds. In 2014, NIH financial resources were 'at least 25% less in constant dollars than they were in 2003' (Alberts et al., 2014).

It is estimated that the NIH's 2016 budget will increase by 3.3% to US\$ 31.3 billion, \$1 billion more than in the FY2015 budget. Although this sounds promising, inflation of 1.6% and an increase in the Biomedical Research and Development Price Index⁵ of 2.4% will eat into the budget increase. It will be worth watching to see whether there are moves in Congress to increase the NIH's budget. For now, the American Association for the Advancement of Science estimates that the FY2016 rate of grant funding will average 19.3%, a huge drop from the rate of 33.3% over the past decade but better than the FY2015 rate of 17.2%.

^{4.} The majority of these grants correspond to what is known as the R01 mechanism, which limits the grant to US\$ 250 million per year in direct costs for a circumscribed study of 1–5 years.

This index offers an estimate of inflation for goods and services purchased on the NIH's budget.

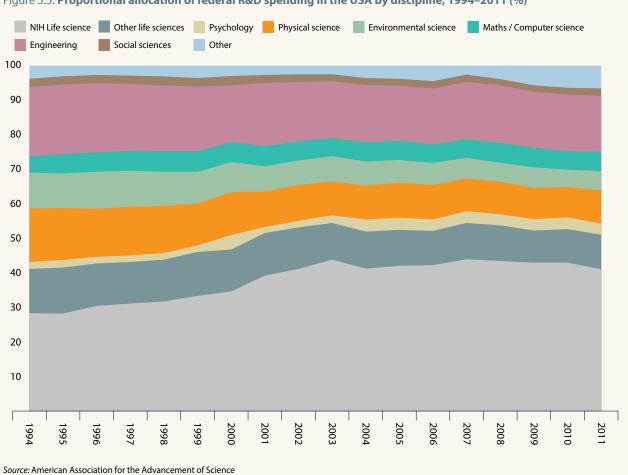


Figure 5.5: Proportional allocation of federal R&D spending in the USA by discipline, 1994–2011 (%)

NSF budget likely to remain flat

The National Science Foundation (NSF) is the USA's largest source of research grants for non-medical sciences. It funds most non-medical biological research and research in mathematics. At the time of writing in August 2015, the 2016 and 2017 NSF budgets have not yet been approved by Congress. Current estimates are that they will be flat for both years. The NSF has requested US\$ 7.723 billion for 2015 in its submission to Congress, a 5% increase over the estimated budget. However, in the latest version of the America COMPETES Reauthorization Act of 2015, the House Committee on Science, Space and Technology has recommended an annual appropriation of US\$ 7.597 billion for the 2016 and 2017 financial years, a mere 3.6% increase (US\$ 263 million) over the current budget.

Although the NSF indicates an overall 23% success rate among grant applicants, some directorates have higher success rates than others. The average NSF grant runs to about US\$ 172 200 per year for three years on average, which includes institutional overheads. A 23% success rate is considered fairly low, although success rates for some NSF programmes have been as low as 4–5% in some years.

Targeted cuts in 2016 to the Geosciences Directorate of 16.2% may have unintended consequences: in addition to climate change, the Geosciences Directorate also funds public interest research that is critical to tornado, earthquake and tsunami prediction and preparedness.

With the notable exception of the Departments of Defense and Energy, most government departments have much smaller research budgets than either the NIH or NSF (Figures 5.4 and 5.5). The Department of Agriculture requested a US \$4 billion budget increase for 2016 but only a small portion of this department's US\$ 25 billion in discretionary funds goes to research. Moreover, most of the research conducted by the Forest Service research is likely to be cut. As for the Environmental Protection Agency, it faces strong opposition from many Congressional Republicans who consider environmental regulations to be anti-business.

Six million work in science and engineering

The occupation of nearly six million US workers involved science or engineering in 2012. Over the period of 2005–2012, the USA had, on average, 3 979 full-time equivalent R&D researchers per million inhabitants. This is lower than some countries of the European Union (EU), Australia, Canada, Iceland, Israel, Japan, Singapore or the Republic of Korea but the USA also has a much larger population than any of these countries.

In 2011, GERD per researcher amounted to US\$ 342 500 (in current dollars). In 2010, research and/or development was the primary or secondary activity of: 75.2 % of biological, agricultural and environmental life scientists; 70.3% of physical scientists, 66.5% of engineers, 49.4% of social scientists and 45.5% of computer and mathematical scientists.

The Bureau of Labor Statistics maps the distribution of jobs related to science and engineering across all 50 US states (Figure 5.6). Geographically speaking, there is a broad correlation between the proportion of inhabitants employed in these fields and the state's share of national GERD, although there are some stark differences. Depending on the location, these differences reflect the greater prevalence of academics in some states, or a heightened business focus on R&D. In some cases, the two are combined, since high-tech companies tend to gravitate towards those regions with the best universities. The State of California is home to the prestigious Stanford University and University of California, for instance, which rub shoulders with Silicon Valley, the name given to the area hosting the leading corporations (Microsoft, Intel, Google, etc.) and start-ups in information technology. The State of Massachusetts is known for its Route 128 around the city of Boston, which is home to numerous high-tech firms and corporations. Harvard University and the Massachusetts Institute of Technology are found within this state. Differences from one state to another may also reflect the budget available to each researcher, which varies according to sectorial specialization.

Only three states fall into the top category for both R&D spending as a share of GDP and the share of jobs in science and engineering: Maryland, Massachusetts and Washington. One can speculate that Maryland's position reflects the concentration of federally funded research institutions there. Washington State has a high concentration of high-tech firms like Microsoft, Amazon and Boeing. Taken together, the six states that are well above the mean in terms of GERD/GDP ratio account for 42% of all R&D in the USA: New Mexico, Maryland, Massachusetts, Washington, California and Michigan. The State of New Mexico is home to the Los Alamos National Laboratory but may otherwise have a relatively low GERD. As for Michigan, the engineering functions of most automobile manufacturers are located in this state. At the other end of the scale, Arkansas, Louisiana and Nevada are the only states that fall into the lowest category for both maps (Figure 5.6).

US supremacy in R&D gradually eroding

The USA invests more funds in R&D in absolute terms than the other G7 nations combined: 17.2% more in 2012. Since 2000,

GERD in the USA has increased by 31.2%, enabling it to maintain its share of GERD among the G7 nations at 54.0% (54.2% in 2000).

As the home country of many of the world's leading hightech multinationals, the US remains in the league of large economies with a relatively high GERD/GDP ratio. That ratio rose moderately since 2010 (which marked a moderate rebound from the 2008-9 contraction), albeit with a GDP growing slower than the average of last several decades.

China has overtaken the USA as the world's largest economy, or is about to do so, depending on the indicator.⁶ China is also rapidly approaching the USA in terms of R&D intensity (Figure 5.5). In 2013, China's GERD/GPD ratio amounted to 2.08%, surpassing the EU average of 1.93%. Although it still trails the USA for this indicator (2.73% according to provisional data), China's R&D budget is growing fast and will 'surpass that of the USA by about 2022', according to a prediction by Battelle and *R&D Magazine* in December 2013. Several convergent factors cast doubt over the accuracy of Battelle's prediction: the deceleration in China's rate of economic growth to 7.4% in 2014 (see Chapter 23), the considerable drop in industrial production since 2012 and the major stock market slide in mid-2015.

The USA's R&D effort peaked in 2009 at 2.82% of GDP. Despite the recession, it was still 2.79% in 2012 and will slide only marginally to 2.73% in 2013, according to provisional data, and should remain at a similar level in 2014.

While investment in R&D is high, it has so far failed to reach the president's target of 3% of GDP by the end of his presidency in 2016. American supremacy is eroding in this respect, even as other nations – China, in particular – are carrying their own investment in R&D to new heights (Chapter 23).

TRENDS IN BUSINESS R&D

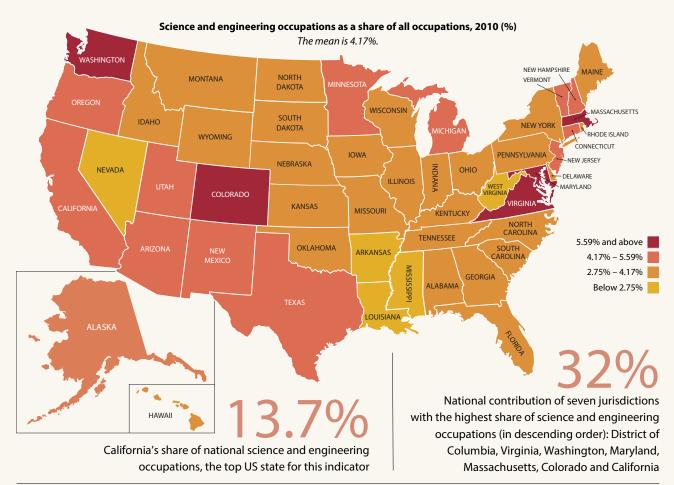
A rebound by business

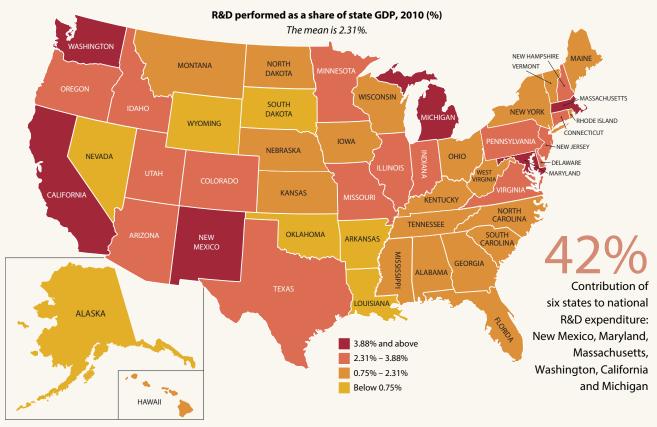
The USA has historically been a leader in business R&D and innovation. However, the economic recession of 2008–2009 has had a lasting impact. While the major performers of R&D largely maintained their commitments, the pain of the US recession was felt mainly by small businesses and start-ups. Statistics released by the US Census Bureau showed that, in 2008, the number of business 'deaths' began overtaking the number of business 'births' and that the trend continued at least through 2012, the last year for which data are available (Figure 5.7). However, more recent data collected by the Kauffman Foundation suggest that the trend reversed in 2015.

^{6.} By 2015, the Chinese economy had overtaken the USA in terms of purchasing power parity (GDP in international dollars) but was still far from doing so in terms of GDP at market prices and exchange rates.

Figure 5.6: Science and engineering in the USA by state, 2010

Three states fall into the top category in both maps: Maryland, Massachusetts and Washington





Source: Bureau of Labor Statistics, Occupational Employment Statistics Survey (various years); National Science Foundation (2014) Science and Engineering Indicators

In 2012, business R&D activity was mainly concentrated in the States of California (28.1%), Illinois (4.8%), Massachusetts (5.7%), New Jersey (5.6%), Washington State (5.5%), Michigan (5.4%), Texas (5.2%), New York (3.6%) and Pennsylvania (3.5%). Science and engineering (S&E) employment is concentrated in 20 major metropolitan areas, comprising 18% of all S&E employment. The metropolitan areas with the greatest share of jobs in science and engineering in 2012 were all situated in the northeast, in Washington DC, Virginia, Maryland and West Virginia. Second was the Boston metropolitan area in the State of Massachusetts and third was the Seattle metropolitan area in Washington State.

Retiring baby boomers may leave jobs unfilled

Concern about the retirement of the 'baby boomers⁷' leaving R&D jobs unfilled is a major worry of company executives. The federal government will, thus, need to provide adequate funding to train the next generation of employees with skills in science, technology, engineering and mathematics.

Many of the initiatives announced by the president focus on public–private partnerships like the American Apprenticeship Grants competition. This scheme was announced in December 2014 and is being implemented by the Department of Labor with an investment of US\$ 100 million. The competition encourages public–private partnerships between employers, business associations, labour organizations, community colleges, local and state governments and NGOs to develop high-quality

7. Those born between 1946 and 1964 in the aftermath of the Second World War, when there was a surge in the birth rate.

apprenticeship programmes in strategic areas, such as advanced manufacturing, information technology, business services and health care.

Signs of inertia rather than a return to growth

The recession has been bad for US business research spending. From 2003 to 2008, this type of expenditure had followed a generally upward trajectory. In 2009, the curve inverted, as expenditure fell by 4% over the previous year then again in 2010, albeit by 1–2% this time. Companies in high-opportunity industries like health care cut back less than those in more mature industries, such as fossil fuels. The largest cutbacks in R&D spending were in agriculture production: -3.5% compared to the average R&D to net sales ratio. The chemicals and allied products industry and electronic equipment industry, on the other hand, showed R&D to net sales ratios that were 3.8% and 4.8% higher than average. Although the amount of R&D spending increased in 2011, it was still below the level of 2008 expenditure.

By 2012, the growth rate of business-funded R&D had recovered. Whether this continues will be contingent on the pursuit of economic recovery and growth, levels of federal research funding and the general business climate. Battelle's 2014 *Global R&D Funding Forecast* (published in 2013) had predicted a 4.0% increase in R&D funded by business in the USA from 2013 to 2014 to US\$ 307.5 billion – about one-fifth of global R&D.

The industry information provider, IBIS World, shows business R&D expenditure increasing in 2015, decreasing in 2017–2018 then rising again, but only slightly, in 2019 (Edwards, 2015). IBIS attributes this to the transition from dependence on



Chapter 5

federal investment to a more self-sustained model. Although research expenditure will keep rising, the rate of increase is likely to be in the 2% per year range and, with decreases in some years, overall growth may be relatively flat. The Industrial Research Institute's forecast for 2015 is based on a survey of 96 research leaders: it forecasts that companies will maintain flat growth of R&D budgets over 2014 levels. The IRI report states that 'data on 2015 is indicative of inertia, not a return to growth' (IRI, 2015).

Venture capital has fully recovered

The one bright spot in the financial picture for technologyrelated companies is the burgeoning venture capital market. The National Venture Capital Association (NVCA) reported in 2014 that venture capital investment totaled US\$ 48.3 billion for 4 356 deals. This, says NVCA, is 'an increase of 61% in dollars and a 4% increase in deals over the prior year....' The software industry dominated these deals, with US\$ 19.8 billion having been invested in 1 799 deals. Second came internet-specific companies, which garnered US\$ 11.9 billion in investment through 1 005 deals. The life sciences, including biotechnology and medical devices, received US\$ \$8.6 billion in 789 deals (Box 5.2). The *STI Outlook 2014* published by the Organisation for economic Co-operation and Development estimates that venture capital investment in the USA 'has fully recovered.'

Mergers, acquisitions and moves offshore

In the quest for talent, access to new markets and unique products, some traditional performers of R&D have been actively engaging in mergers and acquisitions. In the 12 months from 30 June 2014 to 30 June 2015, 12 249 deals were concluded in the USA, 315 of which represented more than US\$ 1 billion. Notable among them was a flurry of acquisitions by technology giants Yahoo, Google and Facebook, each seeking to add new talent and products to its stable. On the other hand, several pharmaceutical companies have made strategic mergers in recent years to relocate their headquarters overseas to order to gain a tax advantage, including Medtronic and Endo International. Pfizer's own attempt to take over the British pharmaceutical company Astrazeneca aborted in 2014, after Pfizer admitted plans to cut research spending in the combined company (Chapter 9).

Some US companies are taking advantage of globalization to move their R&D activities overseas. Some multinational companies specializing in pharmaceuticals, in particular, may be moving at least some of their R&D to Asia on a large scale. The Industrial Research Institute actually notes in its report a decrease in the number of foreign-supported laboratories in China but this finding stems from a small sample of business executives (IRI, 2015).

Factors that can influence the decision to move R&D offshore include tax advantages but also the availability of local talent,

streamlining the speed to market and the opportunity to adapt products to a local market. However, offshoring comes with a potential drawback: the added organizational complexity can make the company less adaptive and flexible. Experts from the *Harvard Business Review* have suggested on several occasions that there is an optimal point of offshoring for any given business that depends on the industry and market.

High R&D spending fosters greater sales

Does high corporate R&D spending result in greater net sales? The answer is yes. The financial benefits seem to be highly contextual and selective. Bloomberg estimated in March 2015 that US corporate R&D grew by 6.7% in 2014, the biggest growth since 1996. Bloomberg estimates that 18 big companies catalogued in Standard & Poor's 500 Index increased R&D by 25% or more from 2013 and that these straddle a range of sectors from pharmaceuticals to hospitality and information technology. Bloomberg also considers that the 190 companies in this index that declare R&D outperform the index.⁸

On the other hand, Hesseldahl (2014) discussed a report from Bernstein Research on technology companies that arrived at the opposite conclusion. It claimed that 'companies that spent the most on R&D tended to have shares that underperformed the markets over time and also relative to those companies that spent less.' In fact, companies spending the most on R&D relative to sales saw their average share price decline by 26% after five years, not precluding growth in the interim. Those technology companies that invested a middle amount of R&D also saw a decline (15%) after five years. Only some of the companies that invested the least in R&D saw their share price rise after five years, although many of those companies experienced share price losses. John Bussey (2012) of the Wall Street Journal has noted that those companies investing the most in R&D are not necessarily the best innovators with the best financial performance for each R&D dollar spent. From this, we can conclude that corporate investment in R&D should be primarily determined by a fundamental need for specific R&D.

Tax credits undermined by uncertainty

The federal government and most of the 50 states that make up the USA offer R&D tax credits for particular industries or companies in particular areas. Congress usually renews a federal R&D tax credit every few years. According to Emily Chasan (2012) from *The Wall Street Journal*, since companies cannot rely on these credits being renewed, they do not factor them in when making decisions about investing in R&D.

A report by Rubin and Boyd (2013) for the State of New York on its numerous business tax credits stated that 'there is no conclusive evidence from research studies conducted since the mid-1950s to

8. See: www.bloomberg.com/news/articles/2015-03-26/surge-in-r-d-spendingburnishes-u-s-image-as-innovation-nation show that business tax incentives create net economic gains to the states above and beyond what would have been attained in the absence of the incentives. Nor is there conclusive evidence from the research that state and local taxes, in general, have an impact on business location and expansion decisions.'

Indeed, companies decide to invest in R&D based on a single factor: the need for R&D. Tax incentives tend to reward these decisions after-the-fact. Furthermore, many small companies fail to recognize that they are eligible to claim the credit and, thus, fail to take advantage of it.

Transition to a 'first to file' model

In 2013, US residents filed 287 831 patents, almost the same number as non-residents (283 781). In China, on the other hand, just 17% of patents were filed by non-residents and there were as many as 704 836 resident applications to the State Intellectual Property Office (see Figure 23.5). Likewise, in Japan, non-residents accounted for just 21% of patent applications. The picture changes somewhat when one examines the number of patents in force. Although China is catching up fast, it still trails the USA, Japan and the EU for this indicator (Figures 5.8 and 5.9).

The America Invents Act of 2011 moved the USA from a 'first to invent' system to a 'first to file' model, the most significant patent reform since 1952. The act will limit or eliminate lengthy legal and bureaucratic challenges that used to accompany contested filings. However, the pressure to file early may limit the inventor's ability to exploit the period of exclusivity fully. It may also disadvantage very small entities, for which the legal costs of preparing an application are the main barrier to filing. This legislation has also fostered the rise of what are familiarly known as patent trolls (Box 5.3).

A post-industrial country

The USA has run a negative trade balance since at least 1992. The balance for trade in goods is consistently negative. The deficit reached a high of US\$ 708.7 billion in 2008 before falling precipitously to US\$ 383.8 billion the following year. In 2014, the balance stood at US\$ 504.7 and will remain negative into 2015. High-tech imports have been lower in value than exports and led mostly (in terms of value) by computers and office machines, electronics and telecommunications (Figure 5.10).

The USA lost its world leadership for the volume of high-tech exports to China some time ago. However, up until 2008, it was still the largest exporter of high-tech goods excluding computing and communications equipment. Much of the latter has become commoditized and is now assembled in China and other emerging economies, with high-tech, value-added components being produced elsewhere. The USA imported US\$ 105.8 billion worth of computers and office machines in 2013 but exported just US\$ 17.1 billion worth of the same. Since the crisis of 2008–2009, the USA has also fallen behind Germany for high-tech exports (Figure 5.10). The last year in which the USA showed a positive trade balance for aerospace technology was 2008, the year it exported nearly US\$ 70 billion worth of aerospace products. In 2009, the value of aerospace imports overtook that of exports, a trend that lasted through 2013. The USA's trade in armaments managed to conserve a slight positive balance between 2008 and 2013. The USA's trade in chemistry products has been near-equal, with greater value in imports in 2008 and 2011-2013. Trade in electrical machinery has been fairly constant, with imports representing nearly double the value of exports. The USA also lags far behind its competitors in electronics and telecommunications, with imports worth US\$ 161.8 billion in 2013 and exports worth just US\$ 50.5 billion. Until 2010, the USA was a net exporter of pharmaceuticals but has become a net importer since 2011. The other area where the USA's exports are slightly higher in value than its imports is scientific instruments but here the difference is slight.

When it comes to trade in intellectual property, however, the USA remains unrivalled. Income from royalties and licensing amounted to US\$ 129.2 billion in 2013, the highest in the world. Japan comes a distant second, with receipts of US\$ 31.6 billion that year. The USA's payments for use of intellectual property amounted to US\$ 39.0 billion in 2013, exceeded only by Ireland (US\$ 46.4 billion).

The USA is a post-industrial country. Imports of high-tech products far exceed exports. New cellphones, tablets and smart watches are not manufactured in the USA. Scientific instruments that were once made in the USA are increasingly being made overseas. However, the USA profits from a technologically skilled workforce that, second to China in size, still produces a large volume of patents and can still profit from the license or sale of those patents. Within the USA's scientific R&D industries, 9.1% of products and services are concerned with the licensing of intellectual property rights.

Together with Japan, the USA remains the largest single source of triadic patents, which are a proxy for an economy's ambition and its effort to pursue technology-driven competitiveness in the principal advanced country markets. Since the mid-2000s, the USA has falling triadic patenting numbers, along with other large advanced economies, but triadic patenting resumed growth in the USA in 2010 (Figure 5.8).

Five corporations in top 20 for R&D spending

The top 11 USA-based multinational corporations for R&D funding in 2014 were responsible for a total of US\$ 83.7 billion in R&D expenditure (see Table 9.3). The top five have figured among the world's top 20 for at least 10 years: Intel, Microsoft, Johnson & Johnson, Pfizer and IBM. The top international firm for R&D investment in 2014 was the German corporation Volkswagen, followed closely by the Korean Samsung (see Table 9.3).

Box 5.3: The rise (and fall?) of patent trolls

'Patent troll' is a term used widely to designate firms that are formally called patent assertion entities. These firms make no products but rather focus on buying dormant patents from other firms, often at a low price. Ideally, the patent they purchase is broad and vague. The troll then threatens high-tech firms with litigation for infringement of its patent, unless the firm agrees to pay a licensing fee that may run into the hundreds of thousands of dollars. Even if the firm is convinced that it has not infringed the patent, it will often prefer to pay the licensing fee rather than risk litigation, as cases can take years to settle in court and entail exorbitant legal costs.

Patent trolls have become a nightmare for companies in Silicon Valley, in particular, including giants Google and Apple. However, trolls also harass small start-up companies, some of which have been forced out of business.

The business is so lucrative that the number of patent trolls has grown

exponentially in the USA: in 2012, 62% of patent litigation was brought by patent trolls.

The America Invents Act of 2011 set out to limit the power of patent trolls by preventing ligitators from attacking several companies at once in a single lawsuit. In reality, this has had the opposite effect by multiplying the number of lawsuits.

In December 2013, the House of Representatives passed a bill that would have required a judge to determine early on in the legal process whether a given patent was valid. However, the bill failed to pass into law after being shelved by the Senate Judiciary Committee in May 2014 following intense lobbying by pharmaceutical and biotech companies and universities, which feared the new law would make it hard for them to defend their own patents.

Ultimately, reform may come not from Congress but from the judiciary. A decision by the US Supreme Court on 29 April 2014 should make patent trolls think twice in future before bringing frivolous lawsuits. The decision departs from the so-called American Rule, which generally requires litigants to bear their own legal costs. It brings litigation closer to the English rule of 'loser pays,' whereby the unsuccessful litigant is forced to bear the legal costs of both parties – which may explain why patent trolls are much less common in the UK.

In August 2014, US judges cited the Supreme Court judgment in their decision on an appeal filed by Google against patent troll Vringo, which was claiming hundreds of millions of US dollars. The judges found against Vringo in the appeal on the grounds that neither of its two patents was valid.

Source: Fisher, D. (2014) Patent trolls face higher risks as Supreme Court loosens fee-shifting rule. Forbes.com 29 April; Wyatt, E. (2014) Legislation to protect against 'patent trolls' is shelved. NY Times Online, 21 May; Chien, C. (2013) Patent Trolls by the Numbers. Santa Clara Law Digital Commons. Compiled by Susan Schneegans, UNESCO.

Google was included in this list for the first time in 2013 and Amazon in 2014, which is why the online store does not appear in Table 9.3, despite having spent US\$ 6.6 billion on R&D in 2014. Intel's investment in R&D has more than doubled in the past 10 years, whereas Pfizer's investment is down from US\$ 9.1 billion in 2012.

The technological ambitions of the new giants of information and communications technology (ICTs) can broadly be described as smoothing the interface between information technology and the physical world. Amazon has optimized the consumer experience by developing services like Prime and Pantry to meet consumer needs in almost real time. Amazon recently introduced a limited pilot of the Dash Button, an extension of Amazon Pantry that allows a user to re-order a household consumable by pressing a physical button. Google has made several acquisitions of products at the interface of computation and the physical world, including autonomous thermostats, and has developed the first operating system specifically for such low-power devices. Perhaps the most ambitious project is Google's self-driving car, which is scheduled for commercial release in the next five years. Conversely, Facebook is developing virtual reality technology based on their acquisition of Oculus Rift, an approach that will integrate people into the digital environment, rather than vice versa.

The small sensors that facilitate this connectivity are also being applied in industry and health care. Since it relies on service contracts for much of its revenue, General Electric is currently investing in sensor technology to collect more information about the performance of its aeroplane engines in flight. Meanwhile, in health care, a few new enterprises are experimenting with the use of data from personal activity trackers to manage chronic diseases like diabetes.

Massachusetts a hotspot for non-profit R&D

Private non-profit organizations account for about 3% of GERD in the USA. In the 2013 fiscal year, federal obligations to non-profits for R&D totalled about US\$ 6.6 billion. Among non-profits, those in the State of Massachusetts received the greatest share of federal funding: 29% of the total in 2013, driven primarily by the cluster of research hospitals near Boston.

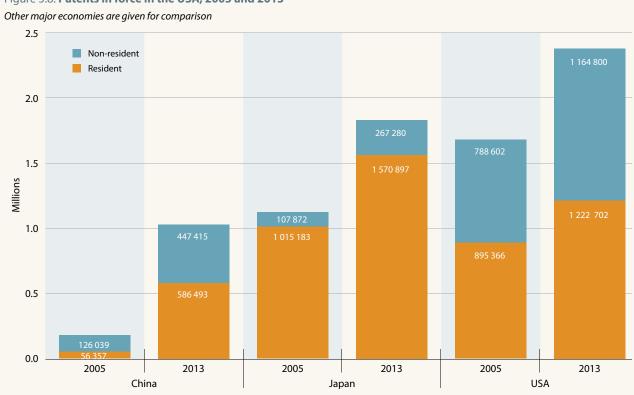
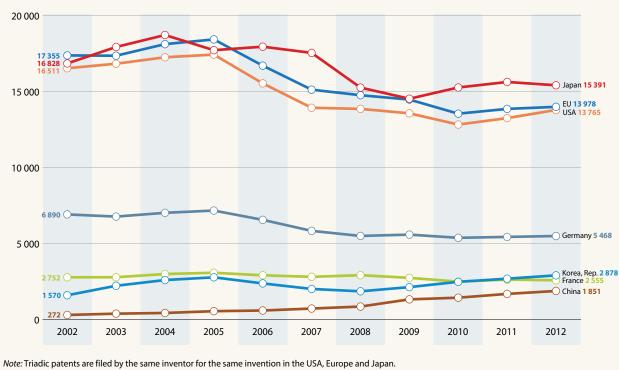


Figure 5.8: Patents in force in the USA, 2005 and 2013

Source: WIPO statistics online, accessed on 27 August 2015; patents held by the primary patent office for each economy: China's State Intellectual Property Office, Japan Patent Office, European Patent Office, US Patent and Trademarks Office for the USA

Figure 5.9: Triadic patents of the USA in the USPTO database, 2002–2012

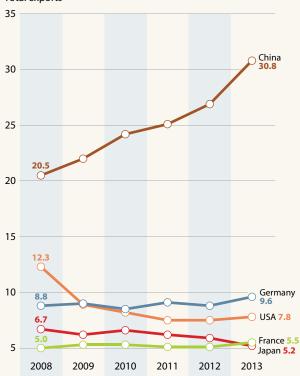


Number of triadic patents (nowcasting) for the world's largest economies for this indicator

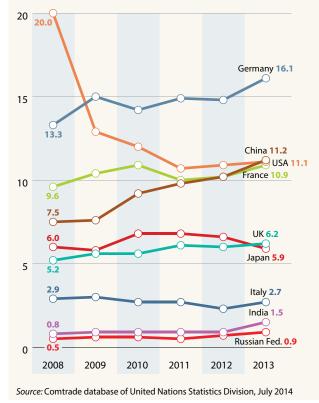
Figure 5.10: High-tech exports from the USA as a world share, 2008–2013 (%)

Other large exporters are given for comparison

Total exports



Exports excluding computers, office machines, electronics and telecommunications



Half of all federal obligations to non-profits are distributed within Massachusetts, California and the District of Columbia, three states which also happen to account for a sizeable share of the nation's R&D expenditure and science and engineering occupations (Figure 5.6). The institutions that receive the lion's share of funding are the national security-oriented MITRE Corp., research hospitals and cancer centres, Batelle Memorial Institute, the R&D generalist SRI International and RAND Corporation. Non-profits can also raise money for R&D from private sources, such as philanthropic donations (Box 5.4).

TRENDS IN EDUCATION

Common core standards to improve science teaching To prepare for the projected growth in jobs in science, technology, engineering and mathematics in the coming years, the Department of Education has focused on improving the proficiency of students and teachers in these subjects. To that end, a group under the aegis of the National Governors Association created the Common Core State Standards in 2009 for proficiency in English and mathematics.

These are national standards, as opposed to state ones. The US education system is highly decentralized, however, so federal policy may not be fully implemented in practice. In anticipation of this, the Obama administration has created incentives like the US\$ 4.3 billion Race to the Top, a competition for funding designed to encourage states to engage in educational reform.

Common Core Standards are highly controversial, as they require very difficult standardised testing, with tests produced by major academic publishing houses. It remains to be seen whether schools that embrace the Common Core Standards will prepare students any better for a career in science and engineering.

A drive to improve the quality of education

The America COMPETES Act is intended to bolster US competitiveness in science, technology, engineering and mathematics through education. It places strong emphasis on improving this type of education at all levels through teacher training. This has resulted in the creation of a STEM Master Teacher Corps. Additionally, the administration has formed a loose coalition of government and non-profit groups with an interest in teacher education called *100Kin10*, the explicit goal of which is to prepare 100 000 excellent teachers of these subjects and, in turn, one million qualified workers within 10 years.

The America COMPETES Act also mandates programmes to retain undergraduates majoring in S&T fields, with an emphasis on underrepresented minorities, such as African Americans, Latinos and Native Americans. In addition, it provides scientific institutions with funds to stimulate

Box 5.4: American billionaires driving more R&D

America's billionaires have increased their influence on R&D in both forprofit and non-profit contexts and are having a major impact on research priorities. Critics suggest that this influence is skewing research activities towards the narrow interests of wealthy, predominantly Caucasian patrons and the elite universities where most of these billionnaires received their education.

Some projects do, indeed, focus explicitly on the personal interests of their patrons. Eric and Wendy Schmidt founded the Schmidt Ocean Institute after an inspiring diving trip in the Caribbean, for instance, and Lawrence Ellison founded the Ellison Medical Foundation after a series of salons held at his home that had been led by Nobel laureate Joshua Lederberg. Conversely, the Bill and Melinda Gates Foundation, perhaps the most high-profile philanthropic research organization of all, has consistently defied that trend by instead focusing on the diseases that most affect the world's poor.

Philanthropic and other privately funded R&D has a complex relationship with federal priority-setting. Some privately funded groups have stepped in when political will is weak. For example, executives from eBay, Google, and Facebook are funding the development of a space-based telescope to search for asteroids and meteors that threaten to strike Earth for far less money than a similar project would require at NASA. SpaceX, the private venture of Elon Musk, has achieved similar savings for the federal government by acting as a contractor. SpaceX has received more than US\$ 5.5 billion in federal contracts from the US Air Force and NASA. It received a US\$ 20 million subsidy from the State of Texas to build a launching facility to foster the state's economic development.

Other philanthropy-driven R&D priorities have become federal priorities, as well. Before President Obama announced his BRAIN initiative, Paul G. Allen and Fred Kavli had established privately funded brain institutes in Seattle in the State of Washington and at the three Universities of Yale, Columbia and California, with scientists at those institutes helping to develop the federal agenda.

Source: compiled by authors

student interest through informal education. It also prioritizes vocational training in advanced manufacturing at the secondary school and community college levels. Lastly, it requires that the White House Office of Science and Technology Policy draw up a strategic plan for science, technology, engineering and mathematics education every five years.

A drop in revenue for state universities

Since the recession of 2008–2009, public research universities have experienced a decline in state appropriations, federal research funds and other grants, while enrolment has increased. The result has been a major decline in the amount of funding per student at these universities, despite dramatic increases in tuition fees and deferrals of facility maintenance. The National Science Board predicted in 2012 that this costsaving drive would have a lasting impact on the educational and research capacities of public research universities. (The pattern of growth in scientific publications does seem to have become more irregular since 2011, see Figure 5.11). This prospect is particularly troubling because demand for public education is rising fastest among historically disadvantaged groups who would otherwise choose two-year degree programmes at for-profit institutions; public universities provide educational opportunities in science and engineering that their for-profit competitors do not (National Science Board, 2012).

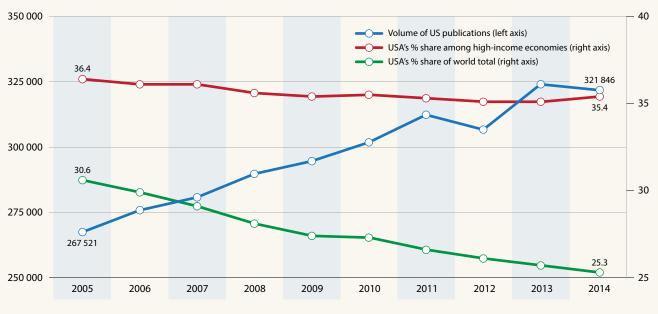
Universities have responded to the constrained funding environment by looking for new ways to diversify revenue and decrease costs. This includes seeking new sources of funding from industry, relying heavily on temporary contract or adjunct workers for both teaching and research and the adoption of new teaching technologies that allow bigger class sizes.

Too many researchers competing for academic posts

In the latter half of the 20th century, scientific departments at US universities went through a growth phase. Each investigator would train several people who could then reasonably expect to obtain an academic research position themselves. Recently, science departments have stopped expanding. As a result, the pipeline has dramatically narrowed at the postdoctoral phase, creating a bottleneck that effectively stalls the career of many researchers.

A 2015 National Academy of Sciences report suggests that, as tenure-track positions become scarcer, academic postdoctoral fellowships are being extended. In parallel, the fraction of graduates who pursue a fellowship before obtaining their first faculty position is increasing, a practice that is spreading to new fields. As a result, the number of postdoctoral researchers climbed by 150% between 2000 and 2012. Although postdoctoral fellowships were originally conceived as advanced research training, in practice, evidence suggests

Figure 5.11: Scientific publication trends in the USA, 2005–2014

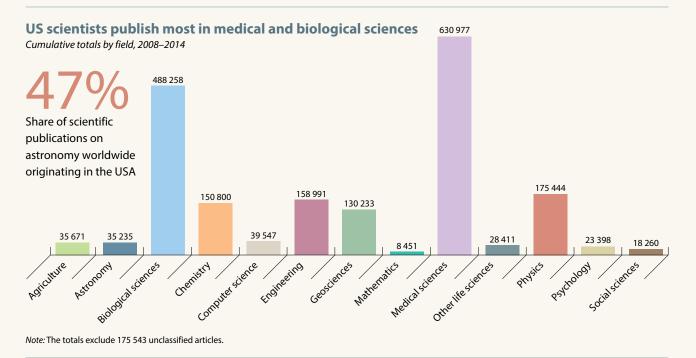


The USA has maintained its share of publications among high-income economies

1.32 Average citation rate for US publications, 2008–2012; the OECD average is 1.08

Share of US papers among 10% most cited papers, 2008–2012; the OECD average is 11.1% 34.8% Share of US papers with

foreign co-authors, 2008–2014; the OECD average is 29.4%



The USA's main partner is China, followed closely by the UK, Germany and Canada

Main foreign partners, 2008–2014 (number of papers)

	1st collaborator	2nd collaborator	3rd collaborator	4th collaborator	5th collaborator
USA	China (119 594)	UK (100 537)	Germany (94 322)	Canada (85 069)	France (62 636)

Source: Thomson Reuters' Web of Science, Science Citation Index Expanded; data treatment by Science-Metrix

that not all postdoctoral fellowships provide consistent and thorough mentoring and professional development. Often, hopeful academics will stall professionally in postdoctoral fellowships while providing high-quality research for low pay on indefinite terms.

Open innovation: a marriage of reason

Realizing that it had a lot of gain from encouraging the adoption of technologies developed with federal grant money, Congress passed the Bayh Dole Act in 1980. The act allowed universities to retain intellectual property rights from federally funded R&D and launched a trend in the university system towards the patenting and licencing of new technology.

As a result, some universities have become foci of innovation, where small start-ups developed from oncampus research add value and, usually, partner with a larger established industrial partner to bring its product(s) to market. Having observed the success of these universities in seeding local innovation ecosystems, a growing number of universities are developing internal infrastructure like technology transfer offices, to support start-ups based on research, and incubators for faculty inventors that are designed to support embryonic companies and their technologies (Atkinson and Pelfrey, 2010). Technology transfer supports the university mission in disseminating ideas and solutions that can be put into practice. It also supports job growth in their local economies and increases ties to industry that form the basis for sponsored research. However, owing to its unpredictable nature, technology transfer is not a reliable supplement to the university's revenue compared to other sources of revenue, such as federal grants and tuition.

From the industrial perspective, many companies in technology-heavy industries are finding that partnering with universities is a more effective use of their R&D investment than developing technologies internally (Enkel, *et al.*, 2009). By sponsoring university research, they benefit from the broad expertise and collaborative environment within academic departments. Although industry-sponsored research accounts for only 5% of academic R&D, leading universities are increasingly relying on research dollars from industry as alternatives to federal and state dollars. Incentives are not always directly aligned on sponsored research, however. The career of academic researchers is dependent on publishing their results, whereas industrial partners may prefer not to publish to prevent competitors from benefiting from their investment (see also Chapter 2).

An 8% rise in foreign students since 2013

In the 2013/2014 academic year, over 886 000 international students and their families living in the USA supported

340 000 jobs and contributed US\$ 26.8 billion to the US economy, according to a 2014 report by the National Association of Foreign Student Advisers.

The number of US citizens studying overseas was much lower, just under 274 000. The top five destinations for US students were the UK (12.6%), Italy (10.8%), Spain (9.7%), France (6.3%) and China (5.4%). These statistics belie the sheer numbers of students enrolled outside the country of their citizenship: 4.1 million in 2013, 53% of whom came from China, India and the Republic of Korea (see also Chapter 2).

The top five foreign student populations in the USA in 2014 were from China (28%), India (12%) and the Republic of Korea (*circa* 8%), Saudi Arabia (*circa* 6%) and Canada (*circa* 3%), according to the July 2014 quarterly review of the Student and Exchange Visitor Information System published by US Immigration and Customs Enforcement (ICE). Some 966 333 foreign students were following a full-time academic or vocational programme at a certified tertiary institution (F-1 and M-1 visas).⁹ According to ICE, the numbers of F-1 and M-1 visa-holders increased by 8% from 2013 to 2014. An additional 233 000 students were J-1 visa holders.

More than half of the F-1 and M-1 visa students were men (56%), according to statistics collected by ICE. Almost one in four of the women (58%) were from Eastern Europe and threequarters (77%) of the men from Western Asia. A little less than half of students with this type of visa had chosen California as their destination, followed by New York and Texas.

The bulk of these students are pursuing degrees in the following fields: business, management and marketing; engineering; computer and related sciences; and education-related studies. Among those studying science, technology, engineering or mathematics, three-quarters (75%) had opted for engineering, computer and information sciences and support services, or biological and biomedical sciences.

In 2012, the USA hosted 49% of the world's international doctoral students in science and engineering (See Figure 2.12). The National Science Foundation's 2013 *Survey of Earned Doctorates* compared doctoral degrees awarded to US citizens with those awarded to students with permanent residence and temporary visa-holders. The study found that temporary visa-holders earned 28% of the doctoral degrees awarded in the life sciences, 43% of those in the physical sciences, 55% in engineering, 10% in education, 14% in humanities, and 33% in non-science and engineering fields. These percentages have increased slightly for all fields since 2008.

9. J-1 visas are conferred on foreign nationals selected by a Department of Statedesignated programme to participate in an exchange visitor programme.

More foreign students being wooed back home

Historically, a large majority of trainees from overseas who came to the USA have stayed on indefinitely. As the countries of origin develop increasingly sophisticated R&D sectors, students and trainees are seeing more opportunities open up at home. As a result, the rate of return migration among foreign students and postdoctoral scholars is rising. Twenty years ago, around one in 10 Chinese doctoral graduates returned to China after completing their degree but the current rate is closer to 20% and the trend is gaining momentum (see also Box 23.2).

The drivers of this trend are a push-pull phenomenon in which the US research environment seems increasingly competitive, even as foreign enterprises are offering skilled workers more opportunities. For instance, the scarcity of visas for skilled workers creates tough competition for those wishing to work in sophisticated US industries; in 2014, the lottery for these visas closed after just one week because it was oversubscribed. US business executives are strongly in favour of increasing the number of visas for skilled workers, particularly in the software industry. At the same time, countries such as China, India and Singapore are investing heavily in building world-class research facilities, a potent lure for US-trained foreign students to return home.

SCIENCE, TECHNOLOGY AND THE PUBLIC

Americans positive about science

Several recent surveys have found that Americans' attitudes towards science are generally positive and optimistic (Pew, 2015). They value scientific research (90% support maintaining or increasing research funding) and have high confidence in scientific leaders. In general, they appreciate the contributions of science to society and believe that scientific and engineering work is a worthy enterprise: 85% consider that the benefits of scientific research outweigh or match the harm it can do. In particular, they believe science has had a positive impact on medical treatments, food safety and environmental conservation. Furthermore, the great majority of Americans see investment in engineering, technology and research as paying off in the long term. Most Americans report being generally interested in new scientific discoveries. More than half have visited a zoo, aquarium, natural history or science museum in 2012.

Public sceptical of some scientific issues

The biggest differences of opinion between the general public and the scientific community concern acceptance of genetically modified foods (37% of the public versus 88% of scientists consider them generally safe) and animal research (47% of the public versus 89% of scientists in favour). There is a comparably large scepticism about whether humans

are responsible for global climate change: 50% of the public agrees with this statement, compared to 87% of scientists.

Americans are less concerned about climate change than residents of other countries and more likely to attribute observed trends to non-human causes. Addressing the causes of climate change is not a high policy priority for most Americans. However, momentum may be building in this area, as evidenced by the People's Climate March 2015 in New York City, which attracted about 400 000 participants from civil society.

In general, Americans view nuclear energy more favorably than residents of other countries. Support for both oil and nuclear power has gradually rebounded after high-profile accidents in those industries in the Gulf of Mexico and Japan, although support for nuclear energy production has not completely recovered.

One point on which both the general public and scientists agree, according to a survey of the public and the American Association for the Advancement of Science, is that science teaching at the primary level in the USA lags behind that of other countries, despite US science being highly regarded abroad.

Public's factual grasp of science is tenuous

In spite of a broad enthusiasm for science and discovery, the American public's factual grasp of science shows room for improvement. Respondents to a factual questionnaire scored an average of 5.8 correct answers to nine questions, which is comparable to results from European countries. These scores have been stable over time.

In addition, the way in which a question is asked may affect a person's answer. For instance, only 48% of survey respondents agreed with the statement that 'human beings, as we know them today, developed from earlier species of animals' but 72% agreed with an identical statement that first specified 'According to the theory of evolution...'. Likewise, 39% of Americans agreed that 'the Universe began with a huge explosion' but 60% agreed with the statement that 'According to astronomers, the Universe began with a huge explosion.'

Public consulting open access scientific literature

The America COMPETES Act established the goal of making all unclassified research results produced at least partly with federal funding publicly available. By the time the act was passed in 2007, a similar requirement was already in the pipeline at the NIH requiring funded investigators to submit accepted manuscripts to PubMed Central within 12 months of publication. PubMed Central is a free full-text archive of literature from biomedical and life science journals at the NIH's National Library of Medicine. The 12-month embargo has successfully protected the business models of scientific journals, since the number of publications has risen since the policy entered into effect and has made a wealth of information available to the public. Estimates suggest that PubMed Central receives 500 000 unique visits every weekday, the average user accessing two articles, and that 40% of users are members of the general public, rather than from industry or academia.

The government generates about 140 000 datasets¹⁰ in a host of areas. Each of these datasets is a potential application for a mobile phone or could be cross-referenced with other datasets to reveal new insights. Innovative businesses have used these data as a platform for the provision of useful services. For example, home price estimates on Realtor.com® are based on open-source data on housing prices from the Census Bureau. Bankrank.org provides information on banks based on data from the Consumer Financial Protection Bureau. Other applications are built on the Global Positioning System or the Federal Aviation Administration. President Obama has created the position of Chief Data Scientist to promote the use of these datasets, with Silicon Valley veteran DJ Patil the first person to serve in this office.

TRENDS IN SCIENCE DIPLOMACY

An agreement with China on climate change

Consistent with the president's overarching priorities, the most important goal of science diplomacy at the moment and in the near future will be to address climate change. His *Climate Action Plan* (2013) articulates both a domestic and international policy agenda aimed at quickly and effectively reducing greenhouse emissions. To that end, the administration has entered into a variety of bilateral and multilateral agreements and will be participating in negotiations at the United Nations Climate Change Conference in Paris in November 2015 for a universal legally binding agreement. In the run-up to the conference, the USA has provided developing countries with technical assistance in preparing their Intended Nationally Determined Contributions.

During a visit to China in November 2014, the USA agreed to reduce its own carbon emissions by 26–28% over 2005 levels by 2025. In parallel, the US and Chinese presidents issued a Joint Announcement on Climate. The details of the agreement had been ironed out by the USA–China Clean Energy Research Center. This virtual centre was established in November 2009 by President Obama and President Hu Jintao and endowed with US\$ 150 million. The joint workplan foresees public-private partnerships in the areas of clean coal technology, clean vehicles, energy efficiency and energy and water.

An historic agreement with Iran

Another major diplomatic success has been the negotiation of a nuclear agreement with Iran jointly with the other four permanent members of the United Nations Security Council and Germany. The agreement signed in July 2015 is highly technical. In return for the lifting of sanctions, the Iranians have made a number of concessions with regard to their nuclear programme. The agreement was endorsed by the United Nations Security Council within a week of adoption.

Building diplomacy through science

Scientific collaboration is often the most durable type of peace-building programme, owing to the high level of personal investment. For instance, the Middle East Research Cooperation programme run by the US Agency for International Development (USAID), which establishes bilateral or trilateral scientific collaboration with Arab and Israeli partners, has operated without interruption since its establishment in 1981 as part of the 1978 Camp David Accords, in spite of periods of violent conflict in the Middle East. In a similar spirit of peace-building, individual scientists in the USA have been working with Cuban colleagues for over half a century, despite the embargo. The restoration of US–Cuban diplomatic relations in 2015 should lead to new export rules for donated scientific equipment that will help to modernize Cuban laboratories.

Universities are also a major contributor to science diplomacy through international scientific collaboration. In the past decade, a number of universities have set up satellite campuses abroad that focus specifically on science and technology, including the University of California (San Diego), the University of Texas (Austin), Carnegie Mellon University and Cornell University. A School of Medicine is due to open at Nazarbayev University in 2015, in partnership with the University of Pittsburgh; another fruit of this US–Kazakh partnership is the *Central Asian Journal of Global Health*, which first appeared in 2012 (see Box 14.3). For its part, the Massachusetts Institute of Technology has helped to establish the Skolkovo Institute of Science and Technology in the Russian Federation (see Box 13.1).

Other projects involving the Russian Federation have stalled or lost momentum. For instance, as diplomatic tensions grew between the USA and the Russian Federation in 2012, Bilateral Presidential Commission meetings bringing together scientists and innovators from the two countries were quietly suspended. Projects such as the USA–Russia Innovation corridor have also been put on hold. The Russian Federation has also enacted a number of policies since 2012 that have

^{10.} These datasets are available online at www.data.gov.

had an adverse effect on foreign scientific collaboration, including a law on undesirable organizations. The MacArthur Foundation recently pulled out of the Russian Federation after being declared an undesirable organization.

For its part, the USA has introduced new restrictions on Russian scientists working in the USA in sensitive industries but, for now, the longstanding collaboration in human space flight is proceeding as usual (see Chapter 13).

A focus on Africa in health and energy

The Ebola epidemic in 2014 highlighted the challenge of mobilizing funds, equipment and human resources to manage a rapidly evolving health crisis. In 2015, the USA decided to invest US\$ 1 billion over the next five years in preventing, detecting and responding to future infectious disease outbreaks in 17 countries,¹¹ within its Global Health Security Agenda. More than half of this investment will focus on Africa. The USA is also partnering with the African Union Commission for the establishment of African Centers for Disease Control and Prevention. It is also supporting the development of national public health institutes.

The USA and Kenya signed a Cooperative Threat Reduction agreement during President Obama's visit to Kenya in July 2015. The aim is to enhance biological safety and security through 'real-time biosurveillance, rapid disease reporting, research and training related to potential biological threats, whether posed by naturally occurring diseases, deliberate biological attacks or the unintentional release of biological pathogens and toxins.'

In 2014, USAID launched the Emerging Pandemic Threats 2 Program with more than 20 countries in Africa and Asia to help 'detect viruses with pandemic potential, improve laboratory capacity to support surveillance, respond in an appropriate and timely manner, strengthen national and local response capacities and educate at-risk populations on how to prevent exposure to these dangerous pathogens.'

A year later, President Obama launched Power Africa, which is also being spearheaded by USAID. Rather than being an aid programme, Power Africa provides incentives to foster private investment in the development of infrastructure in Africa. In 2015, Power Africa partnered with the United States African Development Foundation and General Electric, for instance, to provide African entrepreneurs with small grants to develop innovative, off-the-grid energy projects in Nigeria (Nixon, 2015).

CONCLUSION

The future looks brighter for business than for basic research

In the USA, the federal government specializes in supporting basic research, leaving industry to take the lead in applied research and technological development. In the past five years, federal spending on R&D has dipped as a consequence of austerity and changing priorities. Industry spending, on the other hand, has picked up. The result is that R&D spending has flagged only somewhat over the past five years before returning to modest growth.

Business has generally maintained or augmented its R&D commitment over the past five years, particularly in newer high-opportunity sectors. R&D tends to be considered a long-term investment in the USA that is essential to fuel innovation and build resilience in times of uncertainty.

Although most R&D spending enjoys broad bipartisan support, public-interest science stands to suffer the most from the current austerity and political targeting.

The federal government has been able to wield some influence through partnerships with industry and nonprofit organizations in the field of innovation, in particular. Examples are the Advanced Manufacturing Partnership, the BRAIN Initiative and the more recent Climate Pledge. The federal government has also fostered greater transparency and made government data available to potential innovators. Regulatory reforms offer a promising new era in precision medicine and drug development.

The USA has also maintained its commitment to science and engineering education and job training. The stimulus package adopted in 2009 to conjugate the financial crisis provided a one-time opportunity for the federal government to foster high-tech job growth at a time of burgeoning demand for skilled workers. Only time will tell if this massive injection of funds in education and training will pay off. Within universities meanwhile, the pipeline of trainees has been squeezed by the austerity drive, resulting in a build-up of postdoctoral fellows and greater competition for funding. Thanks to a heavy investment in technology transfer, leading universities and research institutes are making their ivory tower more porous to their surrounding communities in the hope of seeding robust local knowledge economies.

What does the future look like for US science? Indications are that opportunities in federally funded basic research are likely to stagnate. Conversely, the future looks bright for innovation and development in the business enterprise sector.

^{11.} The 17 partners are (in Africa): Burkina Faso, Cameroon, Cote d'Ivoire, Ethiopia, Guinea, Kenya, Liberia, Mali, Senegal, Sierra Leone, Tanzania and Uganda; (in Asia): Bangladesh, India, Indonesia, Pakistan and Viet Nam.

KEY TARGETS FOR THE USA

- Raise GERD to 3% of GDP by the end of 2016;
- Prepare 100 000 excellent teachers of science, technology, engineering and mathematics and, in turn, one million qualified workers in the ten years to 2021, through a loose coalition of government and non-profit groups with an interest in teacher education dubbed 100Kin10;
- Reduce the USA's carbon emission by 26–28% over 2005 levels by 2025;
- Reduce the carbon emissions of the State of California by 40% over 1990 levels by 2030.

REFERENCES

- Alberts, B.; Kirschner, M. W.; Tilghman, S. and H. Varmus (2015) Opinion: Addressing systemic problems in the biomedical research enterprise. *Proceedings of the National Academy of Sciences*, 112(7).
- Atkinson, R. C. and A. P. Pelfrey (2010) *Science and the Entrepreneurial University*. Research and Occasional Paper Series (CSHE.9.10). Center for Studies in Higher Education, University of California: Berkeley (USA).
- Bussey, J. (2012) Myths of the big R&D budget. *Wall Street Journal*, 15 June.
- Chasan, E. (2012) Tech CFOs don't really trust R&D tax credit, survey says. *Wall Street Journal* and The Dow Jones Company: New York.
- Edwards, J. (2014) *Scientific Research and Development in the USA*. IBIS World Industry Report No.: 54171, December.
- Enkel, E.; Gassmann, O. and H. Chesbrough (2009) Open R&D and open innovation: exploring the phenomenon. *R&D Management*, 39(4).
- Hesseldahl, A. (2014) Does spending big on research pay off for tech companies? Not really. *<re/code>*, 8 July.
- Hunter, A. (2015) US Government Contracting and the Industrial Base. Presentation to the US House of Representatives Committee on Small Business. Center for Strategic and International Studies. See: http://csis.org/ files/attachments/ts150212_Hunter.pdf

- Industrial Research Institute (2015) 2015 R&D trends forecasts: results from the Industrial Research Institute's annual survey. *Research–Technology Management,* 58 (4). January–February.
- Levine, A. S.; Alpern, R.J.; Andrews, N. C.; Antman, K.; R. Balser, J. R.; Berg, J. M.; Davis, P.B.; Fitz, G.; Golden, R. N.; Goldman, L.; Jameson, J.L.; Lee, V.S.; Polonsky, K.S.; Rappley, M.D.; Reece, E.A.; Rothman, P.B.; Schwinn, D.A.; Shapiro, L.J. and A. M. Spiegel (2015) *Research in Academic Medical Centers: Two Threats to Sustainable Support*. Vol. 7.
- National Science Board (2012) Diminishing Funding and Rising Expectations: Trends and Challenges for Public Research Universities. A Companion to Science and Engineering Indicators 2012. National Science Foundation: Arlington (USA).
- Nixon, R. (2015) Obama's 'Power Africa' project is off to a sputtering start. *New York Times*, 21 July.
- OECD (2015) *Main Science and Technology Indicators*. Organisation for Economic Co-operation and Development Publishing: Paris.
- Pew Research Center (2015) Public and Scientists' Views on Science and Society. 29 January. See: www.pewinternet.org/ files/2015/01/PI_ScienceandSociety_Report_012915.pdf
- Rubin, M. M. and D. J. Boyd (2013) *New York State Business Tax Credits: Analysis and Evaluation*. New York State Tax Reform and Fairness Commission.
- Sargent Jr., J. F. (2015) *Federal Research and Development Funding: FY 2015*. Congressional Research Service: Washington DC.
- Tollefson, J. (2012) US science: the Obama experiment. *Nature,* 489(7417): 488.

Shannon Stewart (b. 1984: USA) is a Research Scientist at the Center for Biomedical Innovation within the Massachusetts Institute of Technology. She holds a PhD in Molecular, Cellular and Developmental Biology from Yale University (USA).

Stacy Springs (b. 1968: USA) is Director of Programmes at the Center for Biomedical Innovation within the Massachusetts Institute of Technology (MIT), where she heads a programme on biologics manufacturing. Dr Springs holds a PhD in Organic Chemistry from the University of Texas at Austin (USA).