

Will US Leadership in Biopharmaceutical R&D Continue?

Consequences of Price Controls and Other Anti-Innovation Policies

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Executive Summary

Innovation most successfully occurs in regions around the world that allow inventors to operate in a public policy framework that rewards risk taking and investment. This is especially so for the biopharmaceutical industry, which requires an average of over \$2.6 billion and between 10 and 15 years on average to bring a new drug to market, which occurs in only about 12% of the compounds tested in clinical trials.² Because of the high risk, high cost, and long research timelines associated with biopharmaceutical development, innovative manufacturers tend to conduct R&D in countries with supportive public policies that promote a skilled workforce, efficient regulatory system, foster competition, and let the market and the value of medicines drive pricing and access.

The positive and negative impacts that public policies can have on biopharmaceutical innovation can be seen in the movement in the balance of R&D investment from Europe to the U.S. in the late 1990s, and perhaps again with the rise of Asia as a biopharmaceutical innovation center very recently. Price controls and other interventions in the European medicines market decades ago – and the adoption in the U.S. of more market-friendly drug policies – corresponded with the shift to the U.S. as the world leader in biopharmaceutical R&D. As the Information Technology & Innovation Foundation (ITIF) wrote, “The United States was once a global also-ran in biomedical innovation, but it’s become the world leader thanks to the adoption of a broad set of public policies including increases in public investment in biomedical research; effective technology transfer and commercialization mechanisms; robust intellectual property (IP) protections; a pricing system that allows innovators to earn sufficient revenues to reinvest in innovation; tax incentives to encourage investment; and an effective drug approval system.”³

In the 1980s and 1990s, as European governments adopted stringent drug price control policies, the U.S. took the opposite tack to maintain and enhance its market-based system. As a result, the biopharmaceutical industry in the U.S. gained momentum, increased R&D investment, jobs and drug innovation, while European biopharmaceutical innovation began to lag. By the late 1990s, the total amount of biopharmaceutical R&D

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² DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen. 2016. “Innovation in the pharmaceutical industry: New estimates of R&D costs.” *Journal of Health Economics*.

³ Ezell, Stephen. 2020. “Ensuring U.S. Biopharmaceutical Competitiveness.” Information Technology & Innovation Foundation. <https://itif.org/publications/2020/07/16/ensuring-us-biopharmaceutical-competitiveness>

investment in the U.S. surpassed Europe, and the U.S. benefited from significant job expansion in the sector. Since then, the U.S. has enjoyed the position as the global leader in biopharmaceutical innovation. Currently, the U.S. hosts half of the biopharmaceutical companies worldwide, provides half of the clinical trials, and accounts for half of the global market for medicines.⁴ Patients in the U.S. also have more medicines available to them than in other countries, and they are available sooner. However, some in the U.S. have initiated a policy debate that could undermine the U.S. market-based system of medicines pricing through the imposition of price controls.

The U.S. cannot take its position as a global leader for granted. Over the last decade, various Asian nations have been advancing policy reforms to grow that region's biopharmaceutical sector, including seeking to implement more science-based regulatory systems for the review and approval of new medicines, pricing and access reforms, and other policies to incent increases in biopharmaceutical R&D investments. For example, in 2017, China updated its National Reimbursement Drug List (NRDL) for the first time since 2009 to include additional new innovative medicines,⁵ and is seeking to establish an innovative biopharmaceutical industry as a key development goal.⁶

Although equaling one-tenth of the R&D invested in the U.S, total biopharmaceutical R&D expenditure in some Asian countries has been growing by 19.3% per year, with a cumulative growth of more than 310% since 2008, compared to 3.8% per year in the U.S. and 3.3% in Europe.⁷ The difference between some Asian countries and the U.S. is even more pronounced. Consequently, countries such as China and Korea are increasingly important players in global R&D.⁸ Shanghai has become a global bioscience hotspot along with Boston, San Francisco, and London. Global biopharmaceutical companies have shifted some R&D operations to Asia and also participate in direct investment in local biotech startups.⁹

Public policies are powerful tools that can foster or hinder a country's industrial development, job growth and innovation. In the case of the biopharmaceutical industry, companies allocate R&D investments, hire workers and conduct clinical trials in countries with science-based regulatory systems and strong IP protections, as well as the opportunity to earn returns on inventions commensurate with the investments and risks undertaken and value delivered. While outside the scope of this paper, where biopharmaceutical firms locate R&D operations also carries implications for advanced manufacturing, as R&D and associated advances in manufacturing often go hand-in-hand. A strong R&D presence carries with it a strong manufacturing presence in countries that pursue sound policies.

⁴ Milne, Christopher-Paul. 2019. "U.S. continues to lead new drug R&D, but Asia-Pacific is starting to rise." Impact Report. Tufts Center for the Study of Drug Development.

⁵ Atkinson, Robert. 2019. "China's Biopharmaceutical Strategy: Challenge or Complement to U.S. Industry Competitiveness?" Information Technology and Innovation Foundation. August; McKinsey & Company. 2018. "Building Bridges to Innovation." Presented at China Healthcare Summit. November 13-14. Shanghai, China.
<https://www.bioindustry.org/uploads/assets/uploaded/72fb6652-6307-4d9e-8eaab4088c4ecb92.pdf>

⁶ People's Republic of China, State Council Statement, February 15, 2016.

⁷ European Federation of Pharmaceutical Industries and Associations, survey data, Table 6. R&D Conducted (by National and Foreign Companies) in the Country; Organization for Economic Co-operation and Development "Business enterprise R&D expenditure by industry," Research and Development Statistics; Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2020.

⁸ Milne, Christopher-Paul. 2019. "U.S. continues to lead new drug R&D, but Asia-Pacific is starting to rise." Impact Report. Tufts Center for the Study of Drug Development.

⁹ Gautam, Adam. 2016. "The Changing Model of Big Pharma: Impact of Key Trends." Drug Discovery Today. 21(3).

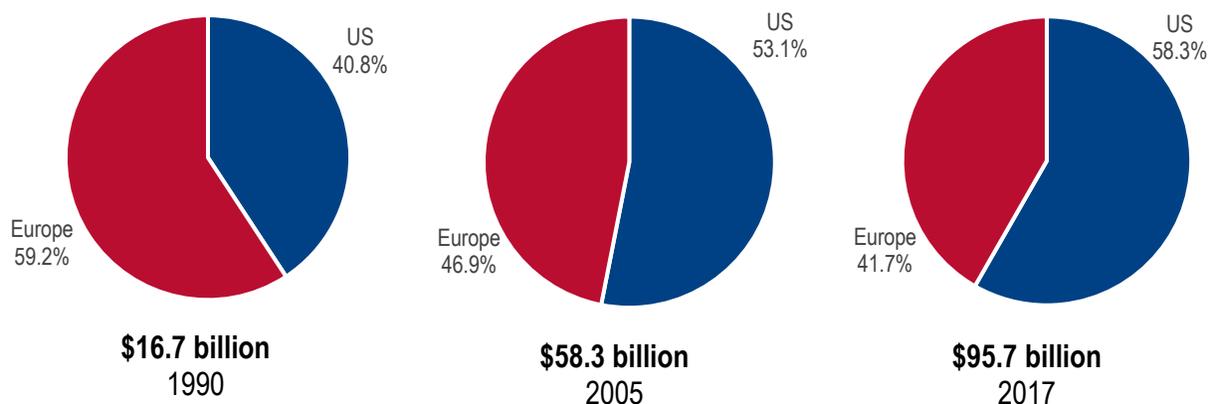
Biopharmaceutical R&D Investment Shifted from Europe to the United States

Biopharmaceutical R&D investment in Europe was consistently higher than R&D investment in the U.S. until the late 1990s. In 1990, biopharmaceutical R&D investment in Europe was over 45% higher than similar investment in the United States. However, in the 1990s, European countries increasingly adopted public policies that failed to recognize the full value of new medicines by adopting price controls and other negative policies, while the United States began adopting market-based policies (such as strengthening IP protections, tech transfer and market pricing mechanisms). As shown below, while various European governments implemented suppressive public policies to control medicine prices, the U.S. government maintained and enhanced the market-based pricing system. In addition, the U.S. government introduced a series of policies to encourage innovation and to protect IP. As a result, total biopharmaceutical industry R&D investment in the U.S. surpassed R&D investment in Europe in the late 1990s. European industrial biopharmaceutical R&D investments have lagged the U.S. ever since.

While overall biopharmaceutical R&D investment in Europe and the U.S. increased nearly 3.5 times, from \$16.7 billion in 1990 to \$58.3 billion in 2005, by 2005, the U.S. was responsible for the majority of biopharmaceutical R&D investment. In 1990, investment in the U.S. accounted for nearly 41% of the total. By 2005, as the intercontinental shift in the preponderance of R&D was underway, investment in the U.S. accounted for over 53% of the total. (Figure 1)

Figure 1.

The balance of biopharmaceutical R&D investment shifted from Europe to the U.S. over the past several decades¹⁰



The shift in biopharmaceutical R&D investment from Europe to the United States drew the attention of policymakers and health system researchers. Notably, the European Union analyzed the industry changes and concluded that the European biopharmaceutical industry had lost its competitiveness to the U.S. after

¹⁰ OECD, EFPIA and PhRMA *op cit*. Note: Because R&D data dating back to 1990 is incomplete for many European countries, we use EFPIA and PhRMA data to compare the development between the U.S. and Europe during 1990-2005. We use OECD data to compare the development between the U.S. and Asian countries during 2008-16.

dominating the global market in the 1980s and 1990s.¹¹ In its 2006 competitiveness report, the European Commission (EC) noted, “Since 2000, the U.S. has consolidated its central role as a locus of innovation in pharmaceuticals.” Further, the EC observed, “Europe is lagging behind the U.S. in its ability to generate, organise, and sustain innovation processes and productivity growth in pharmaceuticals. Moreover, a disproportionate share of pharmaceutical R&D is performed in the U.S., with negative consequences [for Europe] in terms of both high value-added employment and complementary investments in clinical research.”¹² Günter Verheugen, Vice-President of the European Commission for Enterprise and Industry, stated “[W]e are confronted with a move of research and production of innovative drugs outside Europe.”¹³

This shift in the locus of R&D activity is also shown in various data that measure innovation in biopharmaceuticals, including:

- **Geographic origin of new medicines:** Günter Verheugen, Vice-President of the European Commission for Enterprise and Industry, asserted that in the late 1980s, 41% of the top 50 innovative drugs were of American origin while 18% were of European origin. By the late 1990s, the U.S. percentage climbed to 62% while Europe’s share remained more or less static at 21%. (Figure 2) Furthermore, he stated, “in 1990, the pharmaceutical industry spent 50% more on research in Europe than in the United States. In 2001, the situation was reversed with 40% spent more in the United States. In 1992, six out of the top ten medicines in worldwide sales were European, while in 2002 this figure had fallen to just two.”¹⁴
- **Patents:** According to the European Commission (EC), “From the period 1984-1993 to the period 1994-2003, the share of biopharmaceutical patents held by U.S. inventors has risen by approximately 7% (from 50.8% to 57.3%).”¹⁵
- **Patent citations:** Further, the EC stated, “[O]n average patents assigned to US institutions have a much greater impact on future innovative activity. U.S. biopharmaceutical patents received 5.56 citations on average between 1994 and 2003, far more than European (2.92) and Japanese (2.07) ones.”¹⁶
- **New drug applications:** According to data from the Tufts Center for the Study of Drug Development’s Kenneth Kaitin, “Of the 71 drugs receiving marketing clearance both in the European Union and the U.S. between 2000 and 2005, 73% (that is, 52 drugs) received approval first from the U.S. FDA. On average, the FDA approval came one year ahead of clearance by the European Medicines Agency (EMA).”¹⁷

¹¹ Gambardella, Alfonso, Luigi Orsenigo, and Fabio Pammolli. 2000. “Global competitiveness in pharmaceuticals: A European perspective.” Prepared for the Enterprise Directorate-General of the European Communities.

¹² European Commission. 2006. “Economic reforms and competitiveness: key messages from the European Competitiveness Report 2006.” Staff Working Document accompanying the Communication from the Commission. Brussels, November 14.

¹³ Günter Verheugen, Vice-President of the European Commission for Enterprise and Industry. 2005. “Biotechnology’s contribution to an innovative and competitive Europe.” Lyon. April 14.

¹⁴ Günter Verheugen, Vice-President of the European Commission for Enterprise and Industry. 2005. “Biotechnology’s contribution to an innovative and competitive Europe.” Lyon. April 14.

¹⁵ European Commission. 2006. “Economic reforms and competitiveness: key messages from the European Competitiveness Report 2006.” Staff Working Document accompanying the Communication from the Commission. Brussels, November 14.

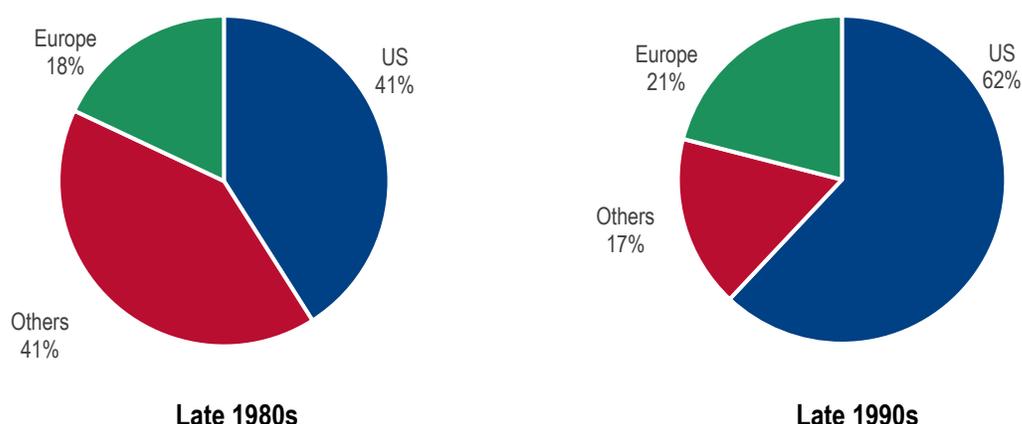
¹⁶ European Commission. 2006. “Economic reforms and competitiveness: key messages from the European Competitiveness Report 2006.” Staff Working Document accompanying the Communication from the Commission. Brussels, November 14.

¹⁷ Mitchell, Peter. 2007. “Price controls seen as key to Europe’s drug innovation lag.” Nature Reviews. April 6, 257-258.

- **Availability of new medicines:** Of new cancer medicines launched between 2011 and 2019, 96% are available in the U.S. compared to just 73% in Germany, 70% in the U.K., and 67% in France.¹⁸
- **Health outcomes:** In diseases where drugs have a significant impact on health outcomes, the U.S. does better. For example, the 5-year survival rate for all cancers is 42% higher for men and 15% higher for women in the U.S. than in Europe.¹⁹

Consequently, the shift in R&D, which is a crucial factor in innovative enterprises, created significant positive impacts on economic activities in the United States. Findings of empirical research show R&D investment has positive returns in all key economic measures in companies and industries with high R&D. IP-intensive companies and industries produce innovative products to sell at home and abroad. The rise in production induces companies to hire more workers and to pay higher wages which in turn boosts economic growth. Indeed, IP-intensive manufacturing industries create more jobs during economic upturns as well as economic downturns compared to other sectors. The biopharmaceutical industry in the U.S. expanded production and increased its workforce by 10% during the past two decades²⁰

Figure 2.
The share of U.S. top 50 innovative medicines increased by 50% from the 1980s to the 1990s²¹



Theoretical and empirical economic studies have examined the importance of public policy in fueling changes in biopharmaceutical R&D investment between Europe and the U.S. over the past few decades. Policies that impacted medicine pricing and patient access to new medicines were key contributing factors to this shift.

¹⁸ PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data on new active substances first launched in any country between January 1, 2011 and December 31, 2019. May 2020.

¹⁹ Allemanni C, Weir HK, et al. Global surveillance of cancer survival 1995–2009: analysis of individual data for 25,676,887 patients from 279 population-based registries in 67 countries (CONCORD-2). *Lancet*. March 2015. Available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(14\)62038-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)62038-9/fulltext)

²⁰ Pham, Nam. 2010. “The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs, Wages, and Exports.” ndp | analytics; Pham, Nam D. 2017. “IP-Intensive Manufacturing Industries: Driving U.S. Economic Growth.” ndp | analytics.

²¹ Günter Verheugen, Vice-President of the European Commission for Enterprise and Industry. 2005. “Biotechnology’s contribution to an innovative and competitive Europe.” Lyon. April 14.

Medicine Pricing. While the operations of the biopharmaceutical industry are governed by a myriad of policy, regulatory, educational and scientific considerations, all of which impact location decisions by industry executives, the focus of this paper is on the consequences of tinkering with the signaling mechanism of prices. Pricing and access policies are perhaps the areas of greatest divergence between Europe and the U.S. over the past several decades. Of all the tools at policy makers' disposal, pricing is probably the most immediate lever to manipulate, particularly in the relatively short timeframes governed by the legislative calendar – as seen in the current medicine pricing debate in the U.S. However, pricing can also be a blunt tool with broad unintended consequences. Indeed, research has shown that these policies can have considerable impact on incentives for innovation. For example, Dubois et al. found that “when governments engage in price regulation and reduce prices for pharmaceutical treatments, the short-run effect may be small because the innovation expenditure is already sunk. However, such regulations will affect firms' incentives to invest in discovering new treatments.”²²

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In fact, price control policies are shown to be one of the crucial factors affecting the shift of biopharmaceutical R&D investment from Europe to the U.S. in the late-1990s and early-2000s.²³ Since the 1980s, European governments imposed a wide range of policies to control drug prices, including price freezes, fixed pricing, profit controls, and reference pricing.²⁴ For example, Germany's Health Reform Act of 1989 instituted a reference pricing system for medicines, phased in stages over several years, which established reimbursement levels for drugs based on a basket of other nations' reimbursement levels, and not necessarily local market usage. France over a period of years instituted a variety of taxes, ad-hoc price cuts, spending caps and other policies that undercut incentives to conduct R&D and innovate medicines in that country. In 1999, the U.K.'s National Institute for Health and Clinical Excellence (NICE) was founded to appraise the value of drugs but has acted as a gatekeeper for the newest innovative medicines. NICE, and similar organizations across Europe, often use controversial, flawed standards to set prices, reimbursement rates or coverage policies for medicines and determine who has access to them. In particular, the use of the Quality Adjusted Life Year as a metric to determine the value of medicines has raised serious concerns related to its discriminatory effects on persons with chronic illnesses or disabilities. Medicare is prohibited from relying on

²² Dubois, Pierre, Olivier de Mouzon, Fiona Scott-Morton, and Paul Seabright. 2015. “Market size and pharmaceutical innovation.” *RAND Journal of Economics*. 46(4).

²³ Gambardella, Alfonso, Luigi Orsenigo, and Fabio Pammolli. 2000. “Global competitiveness in pharmaceuticals a European perspective.” Prepared for the Enterprise Directorate-General of the European Commission.

²⁴ International Trade Administration. 2004. “Pharmaceutical price controls in OECD countries: Implications for U.S. Consumers, pricing, research and development, and innovation.” U.S. Department of Commerce.

the types of standards NICE uses to determine coverage or reimbursement, in part because many stakeholders have expressed concern about the ethics of using such tools to ration health care.²⁵

“Investors tend to invest in places where there is less control over prices, and it is always better to do your clinical trials in countries where you plan to market.”

The net effect of these policies in Europe was to reduce the incentive to undertake R&D investments in areas of high scientific and regulatory uncertainty,²⁶ along with wider economic consequences. A study by the U.S. Department of Commerce measured the impact of price control policies on R&D expenditures in 11 OECD countries, finding that they reduced R&D investment by between \$5.3 billion and \$8 billion per year, representing 16.6% to 17.1% of R&D investment in 2003.²⁷ Studies have also shown that countries with price control systems have fewer new and innovative medicines available for patients,²⁸ as well as many lost research jobs.²⁹ Golec and Vernon showed EU price controls were associated with real costs of about \$5 billion in foregone R&D investment, 1,680 fewer

research jobs, and 46 foregone new medicines.³⁰ In contrast, the U.S. government has continued to maintain a market-based pricing system that fosters innovation and provides companies with the potential to recoup and earn a financial return on their risky investments.³¹ Pricing systems, investment, and R&D operations are tied together, according to Ken Kaitin at the Tufts Center for the Study of Drug Development: “Investors tend to invest in places where there is less control over prices, and it is always better to do your clinical trials in countries where you plan to market.”³²

Patient Access Barriers. Price setting policies not only hurt R&D investment but can also negatively impact the availability of innovative medicines for patients. In many countries that set prices for medicines, patients have access to fewer medicines than patients in the U.S., and often at a delay. For example, nearly 90% of new medicines launched from 2011 to 2019 are available in the U.S., compared to just 63% in Germany,

²⁵ National Council on Disabilities. Quality Adjusted Life Years and the Devaluation of Life with Disability. Nov. 6, 2019. Available at: https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

²⁶ For example, Golec, Joseph and John Vernon. 2010. European pharmaceutical price regulation, firm profitability, and R&D spending.” National Bureau of Economic Research; Golec, Joseph, Shanataram Hedge, and John A. Vernon. 2010. “Pharmaceutical R&D spending and threats of price regulation.” Journal of Financial and Quantitative Analysis. 45(1).

²⁷ The 6 of the 11 countries studied by the Department of Commerce were European (France, Germany, Greece, Poland, Switzerland, and the United Kingdom), but study also included several other systems with price controls (Australia, Canada, Japan, Korea, and Mexico); International Trade Administration. 2004. “Pharmaceutical price controls in OECD countries: implications for U.S. consumers, pricing, research and development, and innovation.” U.S. Department of Commerce.

²⁸ International Trade Administration. 2004. “Pharmaceutical price controls in OECD countries: Implications for U.S. consumers, pricing, research and development, and innovation.” U.S. Department of Commerce.

²⁹ Dubois, Pierre, Olivier de Mouzon, Fiona Scott-Morton, and Paul Seabright. 2015. “Market size and pharmaceutical innovation.” RAND Journal of Economics. 46(4).

³⁰ Golec, Joseph and John Vernon. 2010. “European Pharmaceutical Price Regulation, Firm Profitability, and R&D Spending.” The National Bureau of Economic Research.

³¹ For example, Atkinson, Robert D. 2019. “China’s biopharmaceutical strategy: Challenge or complement to U.S. industry competitiveness.” Information Technology & Innovation Foundation. August; Dranove, David, Craig Garthwaite, and Manuel I. Hermosilla. 2014. “Pharmaceutical profits and the social value of innovation.” National Bureau of Economic Research.

³² Mitchell, Peter. 2007. “Price controls seen as key to Europe’s drug innovation lag.” Nature Reviews. April, 6, pp. 257.

59% in the U.K. and 50% in France.³³ Of new cancer medicines launched between 2011-and 2019, 96% are available in the U.S. compared to just 73% in Germany, 70% in the U.K., and 67% in France.³⁴

Germany provides an example in which access barriers appear to be the result of stringent price setting policies. Patient access to innovative medicines has significantly worsened since Germany began setting prices. Prior to implementing the Pharmaceutical Market Restructuring Act of 2011, (or AMNOG) which moved the German pharmaceutical market away from market-based pricing to government price setting, 95% of innovative medicines that received regulatory approval were launched in Germany, compared to 77% from 2011 to 2015, after AMNOG was implemented. 14% (31 of 221) of innovative medicines with prices set under AMNOG have been withdrawn from the market.³⁵

Strong Intellectual Property Protections. Robust IP protections are essential for R&D investment.³⁶ Strong IP protection policies in the U.S. encourage investors and innovators to conduct their R&D activities in the U.S. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, amended patent laws to extend protection for drugs to 20 years from filing.³⁷ These patent terms encouraged drug innovation that requires significant time and capital. Additionally, the Biologics Price Competition and Innovation Act passed in 2010 complemented the Hatch-Waxman Act by establishing a framework for the development and approval of biological medicines, providing 12 years of data protection for innovator biologics (as well as a pathway for biosimilars). The share of biopharmaceutical patents held by U.S. inventors rose from 50.8% during 1984-1993 to 59% during 2004-2013.³⁸ From 2015, when the first biosimilar was approved, through 2019, FDA approved 26 biosimilars and there is a rich pipeline of both biologics and biosimilars in development.

³³ PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data on new active substances first launched in any country between January 1, 2011 and December 31, 2019. May 2020.

³⁴ PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data on new active substances first launched in any country between January 1, 2011 and December 31, 2019. May 2020.

³⁵ BPI as reported by IQVIA. Pricing & Reimbursement Concise Guide Germany, 2017.

³⁶ Qi, Jingzong, Qingli Wang, Zhenhang Yu, Xin Chen, and Fengshan Wang. 2011. "Innovative drug R&D in China." *Nature Reviews*. May, 10, 333-334.

³⁷ DeVol, Ross C., Armen Bedroussian, and Benjamin Yeo. 2011. "The global biomedical industry: Preserving U.S. leadership." Milken Institute.

³⁸ European Commission. 2006. "Economic reforms and competitiveness: key messages from the European Competitiveness Report 2006." Staff Working Document accompanying the Communication from the Commission. Brussels, November 14.

National Science Foundation, National Science Board. *Science and Engineering Indicators 2018*. Chapter 8 Appendix Table 8-13: USPTO patents granted in pharmaceuticals, by region, country, or economy: 2000-2016.

<https://www.nsf.gov/statistics/2018/nsb20181/data/appendix>

Sound Science-Based Regulatory Environment. In addition to stronger IP protections, the U.S. government has enacted a number of laws and regulations to ensure that the Food and Drug Administration (FDA) has appropriate expertise and is sufficiently resourced to ensure that the review and approval process is more efficient, which has reduced the time to bring a new medicine to market. As just one example, in 1991 it took on average over 30.2 months for FDA to approve a new medicine. About a decade later, the time was cut almost in half; the average approval time for a new medicine was down to 16.9 months in 2003.³⁹ By this time, new medicines were being approved in the United States about one year ahead of Europe; “of the 71 drugs receiving marketing clearance both in the European Union and the US between 2000 and 2005, 73% (that is, 52 drugs) received approval first from the US FDA. On average, the FDA approval came one year ahead of clearance by the European Medicines Agency”.⁴⁰

“European cancer patients are deprived of potentially effective treatments which are available for use in other parts of the world.”

Importantly, improvements in the U.S. regulatory approval process gave Americans faster access to innovative therapies. For example, from 1995 to 2001, the U.S. review process for cancer medicines was, on average, 195 days faster than the European Medicines Agencies (273 days compared to 468 days, respectively).⁴¹ As stated by researcher Kathy Redmond: “European cancer patients are deprived of potentially effective treatments which are available for use in other parts of the world.”⁴²

U.S. policies encouraged innovation and allowed U.S. firms to increase R&D output. In the 1980s, U.S.-headquartered firms accounted for less than one-third of new chemical entities (NCEs) produced by major countries, while European-headquartered firms produced 55% of NCEs. The trend reversed in the early-2000s. From 2000 to 2010, U.S.-headquartered firms produced 57% of NCEs and European-headquartered firms produced 33%.⁴³

Growing Biopharmaceutical R&D Investment in Asia

In order for the U.S. to maintain its role as the global leader in biopharmaceutical R&D and benefit from the resulting economic contributions, U.S. policy makers should be cautioned not to replicate the policy errors of their European counterparts two or three decades ago, particularly in light of the fact that policy makers in some Asian nations are increasingly adopting public policies more supportive of innovation, as the U.S. did in the years prior to the shift in the locus of R&D from Europe to the U.S.

³⁹ DeVol, Ross C., Armen Bedroussian, and Benjamin Yeo. 2011. “The global biomedical industry: preserving U.S. leadership.” Milken Institute. September.

⁴⁰ Mitchell, Peter. 2007. “Price controls seen as key to Europe’s drug innovation lag.” Nature Reviews. April, 6, 257-258.

⁴¹ International Trade Administration. 2004. “Pharmaceutical price controls in OECD countries: Implications for U.S. consumers, pricing, research and development, and innovation.” U.S. Department of Commerce.

⁴² International Trade Administration. 2004. “Pharmaceutical price controls in OECD countries: Implications for U.S. consumers, pricing, research and development, and innovation.” U.S. Department of Commerce.

⁴³ DeVol, Ross C., Armen Bedroussian, and Benjamin Yeo. 2011. “The global biomedical Industry: preserving U.S. leadership.” Milken Institute. September.

Just as biopharmaceutical R&D investment growth in the U.S. accelerated in the 1990s and 2000s, a similar surge has occurred in Asia in the late 2000s. Although still substantially lower than the investment level in the U.S. and Europe, total biopharmaceutical R&D investment in some Asian countries has been growing faster in recent years, particularly in China, Korea, and Taiwan. Biopharmaceutical R&D investment in these Asian countries totaled just under \$50 billion during 2008-16, compared to \$467 billion in the U.S. and \$349 billion in Europe during the same period. However, biopharmaceutical R&D investment in these Asian countries grew at an average 19.3% per year, compared to 3.8% per year in the U.S. and 3.3% per year in Europe. (Table 1)

Table 1.

Biopharmaceutical R&D investment in some Asian countries grew at an average 19.3% per year during 2008-16⁴⁴

	Asia	U.S.	Europe
Total R&D Investment during 2008-16	\$49.6 billion	\$468.9 billion	\$349.1 billion
Annual Average R&D Investment during 2008-16	\$5.5 billion	\$52.1 billion	\$38.8 billion
Annual Growth Rate during 2008-16	19.3%	3.8%	3.3%

Figure 3 below compares cumulative biopharmaceutical R&D investment growth in the U.S. and Asia. In 2008, biopharmaceutical R&D investment was \$2.2 billion in China, Korea, and Taiwan, compared to \$48.1 billion in the United States. Biopharmaceutical R&D investment in these Asian countries increased by 310.6% from \$2.2 billion in 2008 to \$8.9 billion in 2016, compared to 34.3% in the U.S. during the same period.

Figure 3.

Biopharmaceutical R&D has grown 8x faster in some Asian countries than in the United States between 2008 and 2016⁴⁵



⁴⁴ OECD and EFPIA. Note: Because R&D data dating back to 1990 is incomplete for many European countries, we use EFPIA data to compare the development between the U.S. and Europe during 1990-2005. We use OECD data to compare the development between the U.S. and Asian countries during 2008-16.

⁴⁵ OECD.

Closing the Gap with the U.S. While the U.S. has not heretofore implemented price controls on medicines, a mounting number of legislative proposals at both the state and federal level suggest policymakers in the U.S are seriously considering hamstringing the U.S. R&D ecosystem.⁴⁶ While U.S. policymakers debate medicine price control policies that would significantly chill R&D investments, research jobs and the pace of innovation, certain Asian markets have been making efforts to develop their own innovative biopharmaceutical sectors and reducing traditionally high barriers to entry for global pharmaceutical companies to market and sell their products. According to research by the Milken Institute: “U.S. industry leadership, so carefully cultivated over the past 30 years, is eroding. Europe and Japan are working to close the gap, while China, India, and Singapore have made impressive strides. In addition to improving the quantity and quality of their scientific research, competing nations are developing mechanisms to support entrepreneurs and strengthen commercialization. They are also instituting regulatory reforms and a range of public policies to improve incentives for innovation. These efforts are part of larger economic development plans that increasingly focus on cultivating biomedical innovation for its economic contributions and high-wage jobs.”⁴⁷ The ITIF pointed out that “if the United States wants to maintain, much less grow, its biopharma industry, strict drug price controls will make that extremely difficult.”⁴⁸

“[N]ations are actively working to close the gap with the U.S. [by] focusing on increasing scientific capacity [...] They are also implementing regulatory reforms and public policies to improve incentives for innovation.”

Conclusion

Public policies strongly influence where biopharmaceutical innovation (and the advanced manufacturing that goes with it) occurs. Beyond the need for large amounts of capital, extensive timeframes to bring developments to fruition, robust IP protections, an educated pool of skilled workers, and a science-based regulatory system, biopharmaceutical innovation requires an adequate financial return to compensate for the high risks of failure inherent in bringing new therapies to market. It is only natural that drug makers conduct research, manufacture and market new products and hire workers in countries that have emplaced a policy framework that supports innovation.

During the 1980s and 1990s, U.S. and European policymakers pursued different paths in their respective medicines pricing and reimbursement policies. Whereas European governments implemented stringent policies to control prices, the U.S. focused on supporting a market-based pricing system through its payment and coverage policies, which fostered continued R&D investments to bring new medicines to patients. As a result, the preponderance of biopharmaceutical R&D investment, research jobs, and drug innovation shifted

⁴⁶ Atkinson, Robert D. 2019. “China’s biopharmaceutical strategy: Challenge or complement to U.S. industry competitiveness.” Information Technology & Innovation Foundation. August.

⁴⁷ DeVol, Ross C., Armen Bedroussian, and Benjamin Yeo. 2011. “The global biomedical industry: preserving U.S. leadership.” Milken Institute. September, pp. 7.

⁴⁸ Ezell, Stephen. 2020. “Ensuring U.S. Biopharmaceutical Competitiveness.” Information Technology & Innovation Foundation. <https://itif.org/publications/2020/07/16/ensuring-us-biopharmaceutical-competitiveness>

from Europe to the U.S. By the late 1990s, the U.S. surpassed Europe to become the global leader in biopharmaceutical innovation, as the sector expanded and created high paying jobs.

“Should U.S. policymakers decide it is in the U.S. national interest to have a globally leading life-sciences industry, they will need to respond appropriately, particularly ensuring U.S. policies, including drug-pricing policies, support industry investment in research and development (R&D) and innovation.”

History may not repeat itself, but will it follow the same pattern? While the U.S. still dominates in the research and development of new medicines, the ongoing policy debate around whether to adopt price controls in the U.S. is not dissimilar to the negative policies enacted in Europe prior to the early 2000s. Enacting stringent medicines pricing policies would have negative impacts on drug innovation and jobs in the U.S., at the same time that Asian policymakers have taken steps to grow their own innovative biopharmaceutical sectors. In addition, many Asian countries have built up a broad talent base as well as a large capital pool needed to support the R&D enterprise. As summarized by the ITIF, “Should U.S. policymakers decide it is in the U.S. national interest to have a globally leading life-sciences industry, they will need to respond appropriately, particularly ensuring U.S. policies, including drug pricing policies, support industry investment in research and development (R&D) and innovation.”⁴⁹ If the U.S. is to maintain its position as a global innovator and job creator, it must support public policies that encourage, not deter, innovation.

⁴⁹ Atkinson, Robert D. 2019. “China’s biopharmaceutical strategy: Challenge or complement to U.S. industry competitiveness.” Information Technology & Innovation Foundation. August. pp. 1.

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