

How to Ensure That America's Life-Sciences Sector Remains Globally Competitive

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About ITIF

- World's leading science and technology policy think tank.
- Supports policies that promote innovation, productivity, economic growth, and higher living standards.
- Focuses on issues at the intersection of technology and public policy across several sectors:
 - IT and data
 - Telecommunications
 - Trade and globalization
 - Life sciences, agricultural biotech, and energy

Life-Sciences Sector a Key Driver of U.S. Economy

- Consists of pharmaceutical, research, and medical device industries.
- Employs over 1.2 million workers (Pharma alone supports another 3.5 indirectly).
- Much higher salaries than average.
- Highly skilled workers.
- Output of \$675 billion \approx 4% GDP.
- \$80 billion in domestic research in 2013.
- \$90 billion in exports in 2017.



How to Ensure That America's Life-Sciences Sector Remains Globally Competitive

BY JOE KENNEDY | MARCH 2018

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Since the postwar period, America's life-sciences sector has been a major contributor to U.S. economic competitiveness and, in the process, has created millions of high-wage jobs. But over the last two decades, other nations have challenged that position. This report looks at several indicators of the sector's contribution to the U.S. economy. It then examines the international competitiveness of the United States in the face of concerted challenges by other countries, paying particular attention to why life sciences seem to underperform in international trade. Finally, it suggests specific policies that Congress could enact to ensure U.S. life sciences remain competitive going forward.

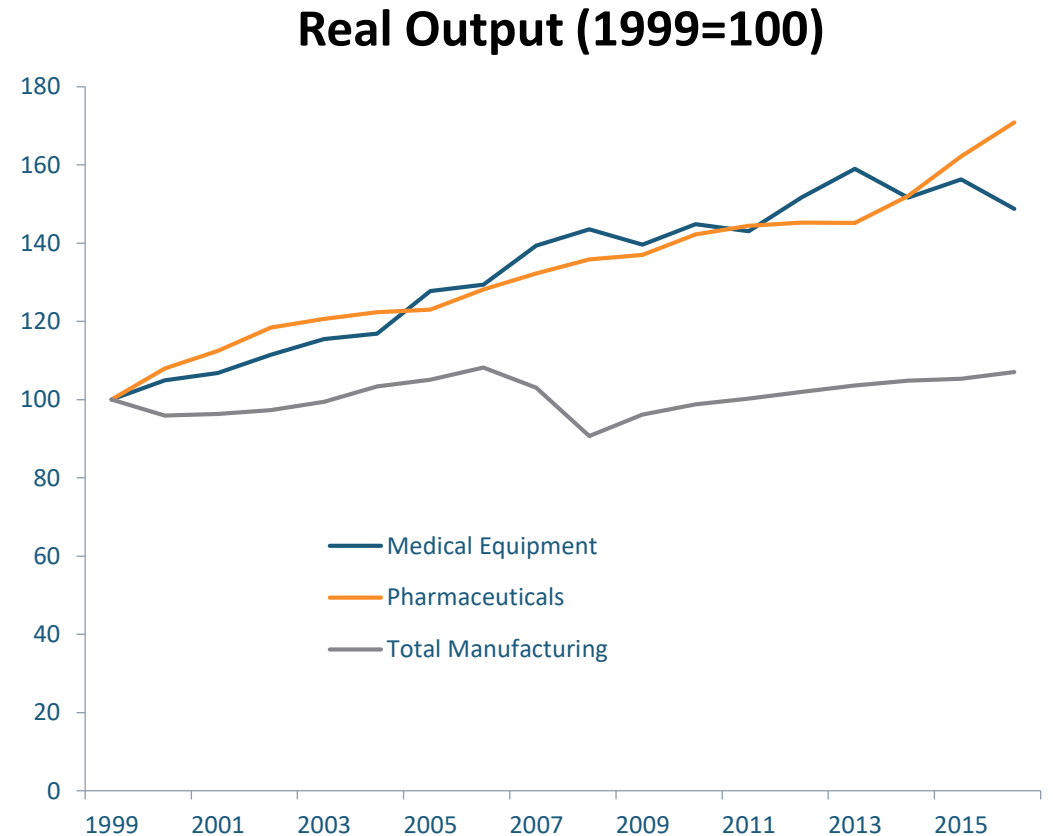
Life sciences—particularly the pharmaceuticals industry (defined here as the traditional pharmaceutical industry and the biotechnology industry)—is a key sector of the U.S. economy. It generates a large number of well-paying jobs, conducts an enormous amount of research and development (R&D), and is a key traded sector that supports U.S. global competitiveness. But the sector also requires a complex ecosystem that integrates research, investment, skilled labor, specific manufacturing skills, protection of intellectual property (IP), and approval of and payment for drugs and devices. During the last few decades, other nations have come to realize the importance of the sector to their economies and have therefore increasingly tried to win a larger share of global life-sciences activity. These efforts have been marginally successful, in part because U.S. policy has been less than fully adequate. The competitive threat is important because if the United States' advantage of having a strong ecosystem gets eroded beyond a certain point, it will be extremely difficult to regain. Should this come to pass, relative U.S. competitiveness, per-capita incomes, and good-paying jobs will decline. As such, U.S. policy makers will need to ensure that policies

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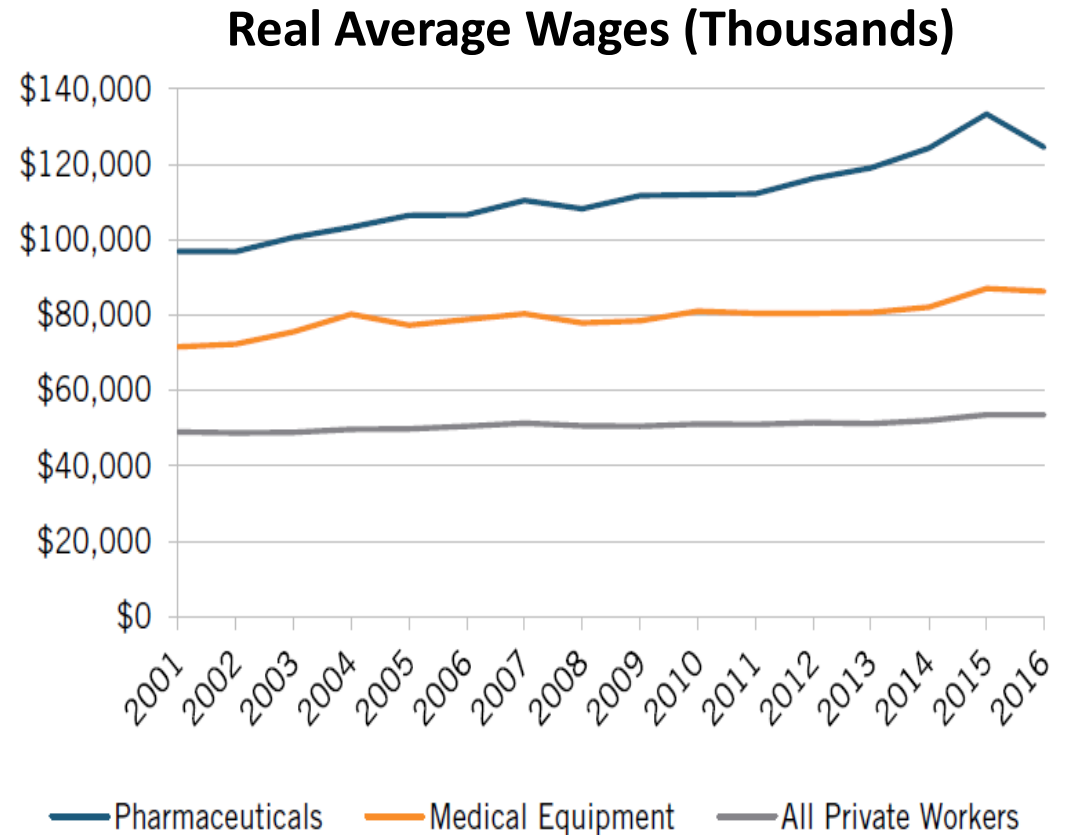
Strong Growth

- Pharmaceutical output up 70% in real terms since 1999.
- Medical equipment up 45%.
- Meanwhile U.S. Manufacturing has been stagnant.



High Wages

- Pharmaceutical wages up 70% in real terms since 2001.
- Avg. pharmaceutical wage = \$124,400.
- Biotech average wage = \$152,000.
- Medical equipment average wage = \$86,200.



Characteristics of a Classic Innovation Sector

1. Companies need to generate continuous innovation to survive.
2. Marginal costs are lower than average costs, so policies that base prices on marginal cost guarantee firms lack the ability to reinvest in new research.
3. Intellectual property is critical to recovering upfront costs.
4. Product development depends on the unfettered movement of knowledge, information, and data across borders.
5. Need access to global markets to lower costs.

Key Components of the Life-Science Ecosystem

- Close cooperation between research, clinical care, and product development.
- Specialized laboratory facilities.
- Capital willing to invest for the long-term with great uncertainty.
- Backing for small, start-up companies conducting promising research.
- Highly-skilled workforce of scientists, technicians, and engineers.
- Specialized manufacturing facilities.

U.S. Life-Sciences Sector Has Several Strengths

- Ownership of half of the top 25 companies in both pharmaceuticals and medical products.
- Largest source of research and development.
- World class research facilities with many of the best scientists.
- Largest and most experienced venture capital market.
- Strong patent protection.
- Relatively efficient testing and approval process.

U.S. Leads in New Drug Discoveries

- Strong growth since 2002.
- Dramatic change from the late 1970s when Europe led the U.S. 149 entities to 66.

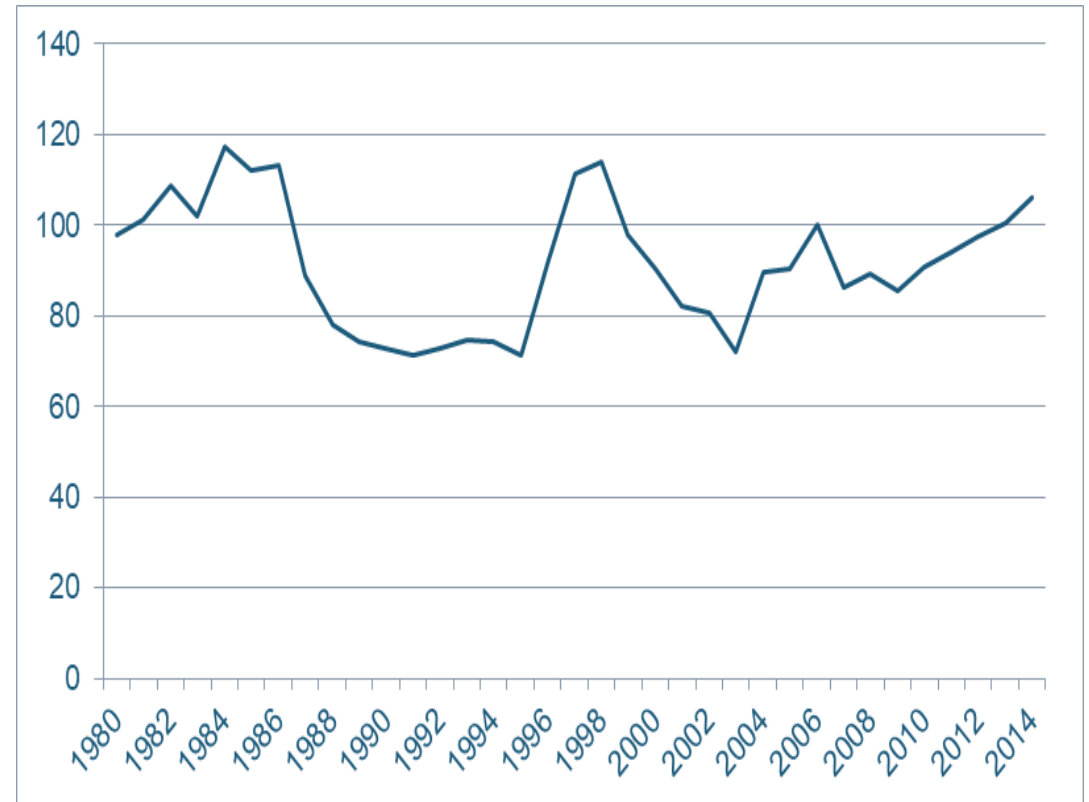
Number of New Chemical or Biological Entities

Region	1997-2001	2002-2006	2007-2011	2012-2016	Total
U.S.	84	67	65	88	304
Europe	79	46	52	75	252
Japan	29	21	20	32	102
Other	4	14	12	38	64

FDA is Approving More Drugs

- FDA has improved its performance in clearing new drugs for market.
- In 2017 FDA set a new record for novel drug approvals.

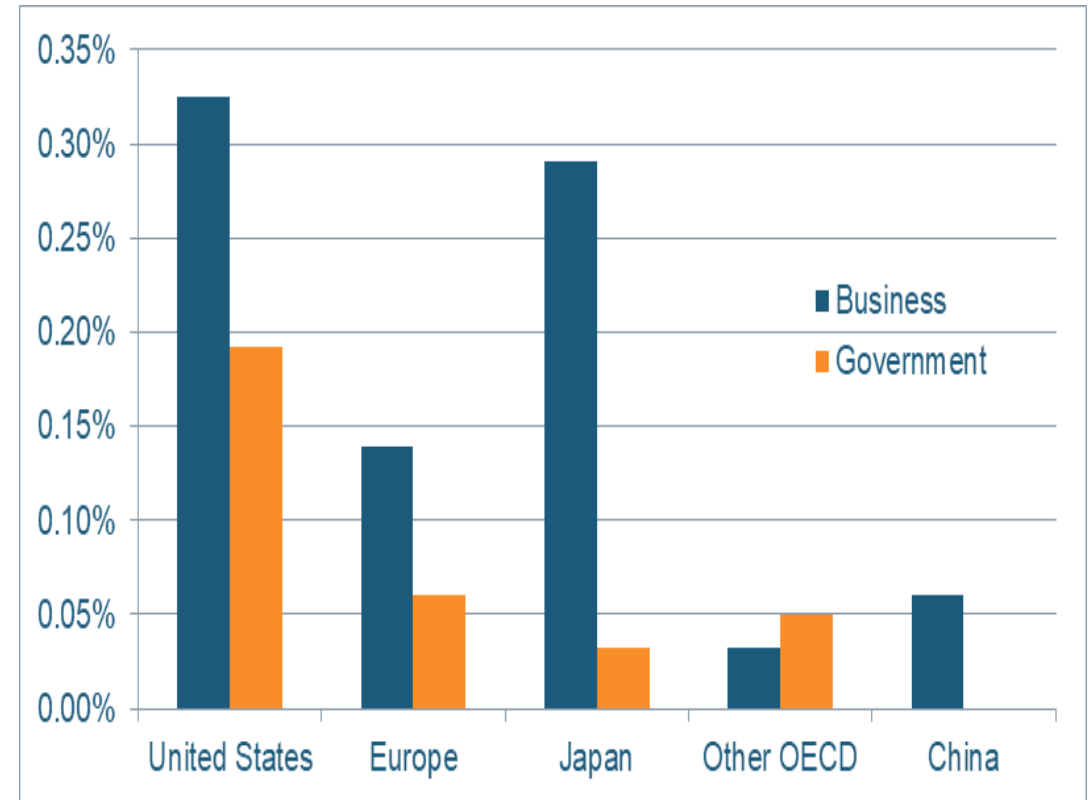
New Drug Approvals by FDA



U.S. Spends More on R&D

- U.S. spends significantly more on R&D.
- Most of this spending comes from the private sector.

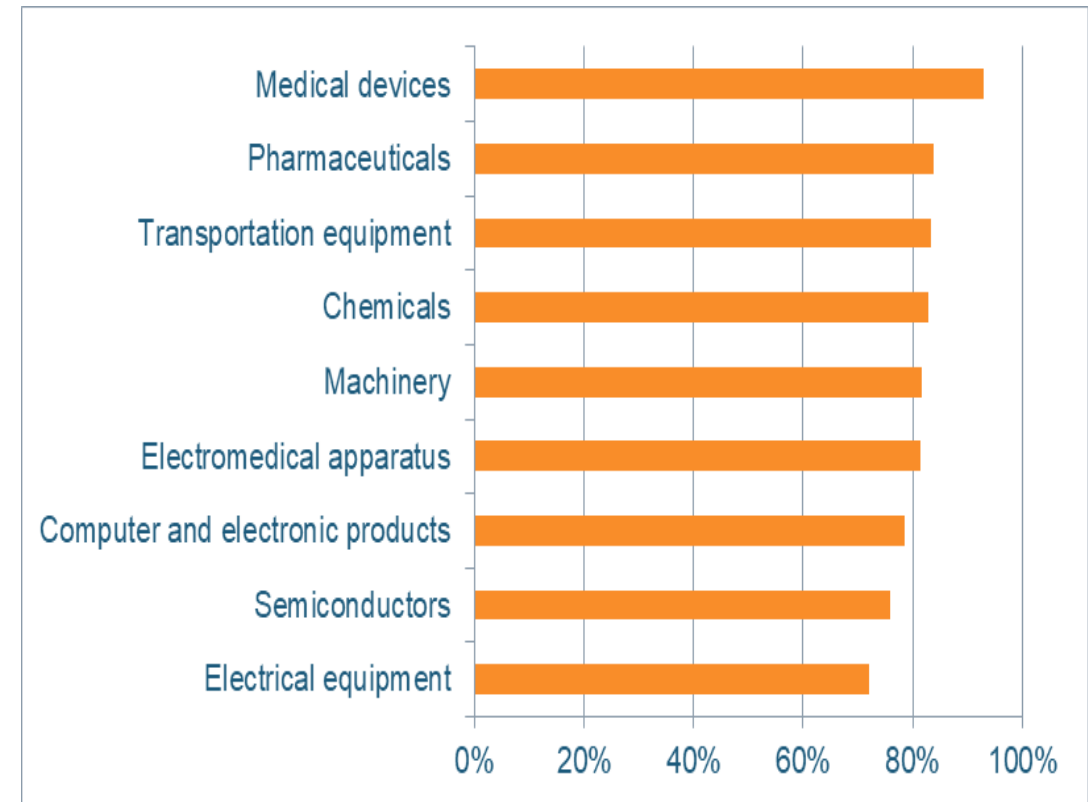
Business and Government Investment in Pharmaceutical R&D as % of GDP, 2017



High Portion of R&D is Spent in the U.S.

- Domestic pharmaceutical companies performed \$62.5 billion in domestic research in 2013.
- Other life-sciences companies spent \$27 billion.

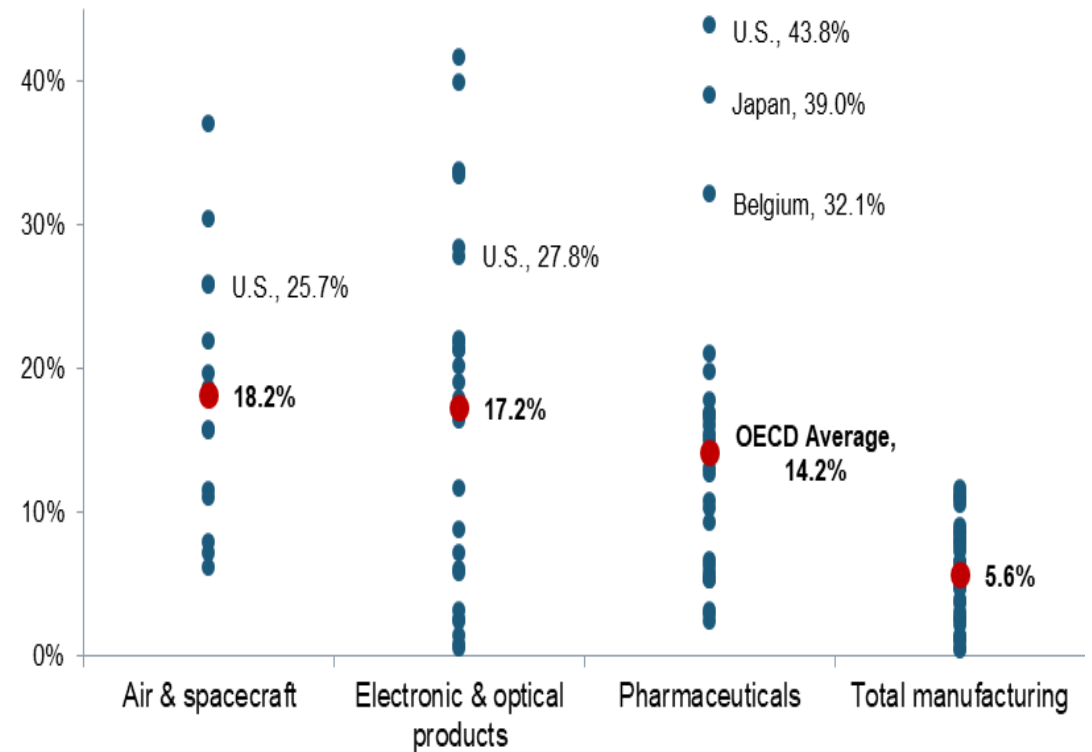
Domestic R&D as a Percent of Total R&D



U.S. Life-Sciences R&D is Driven by the Private Sector

- Domestic pharmaceutical companies spend 43.8% of their gross value added on R&D.
- Much higher than any other country.
- Much higher than any other industry.

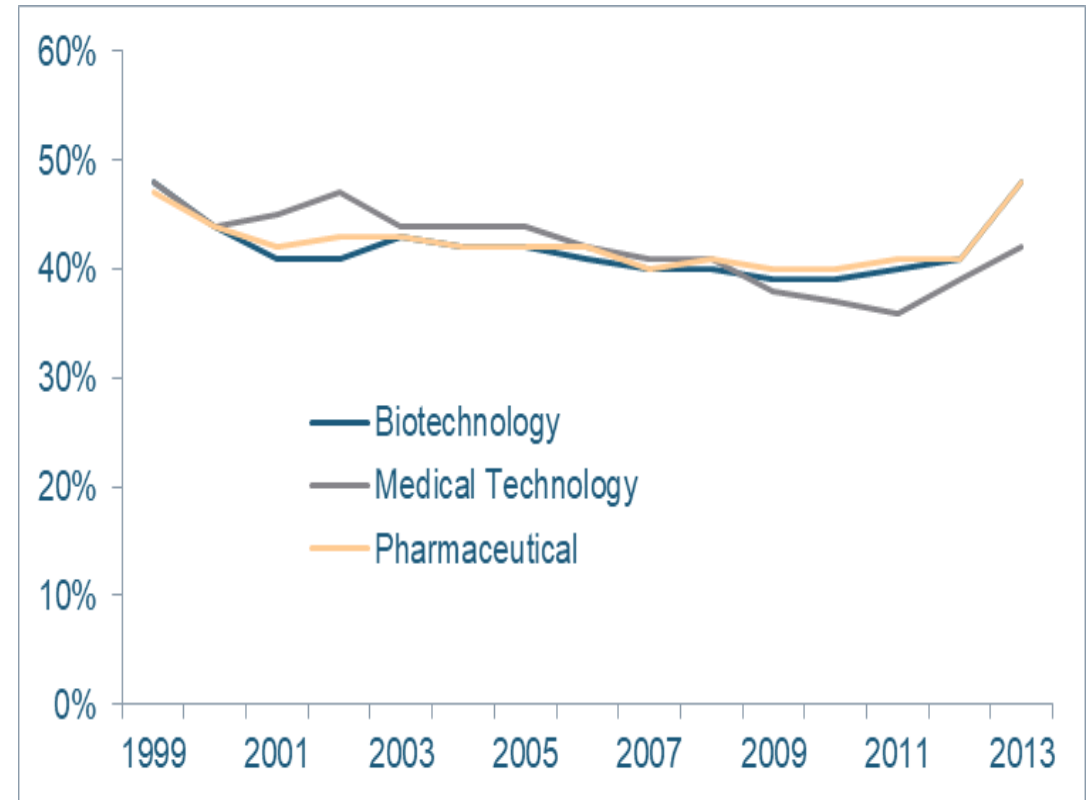
Business R&D as a Percent of Gross Value Added



U.S. Scientists Continue to Lead in Patents

- U.S. maintains share of important patents at 40-45 percent.
- In 2014, 13 states had more than 1,000 biopharmaceutical patents issued to their residents.
- Study of almost 3,300 FDA approved drugs over the last 25 years showed that U.S. researchers led with 61.7 percent of patents granted.

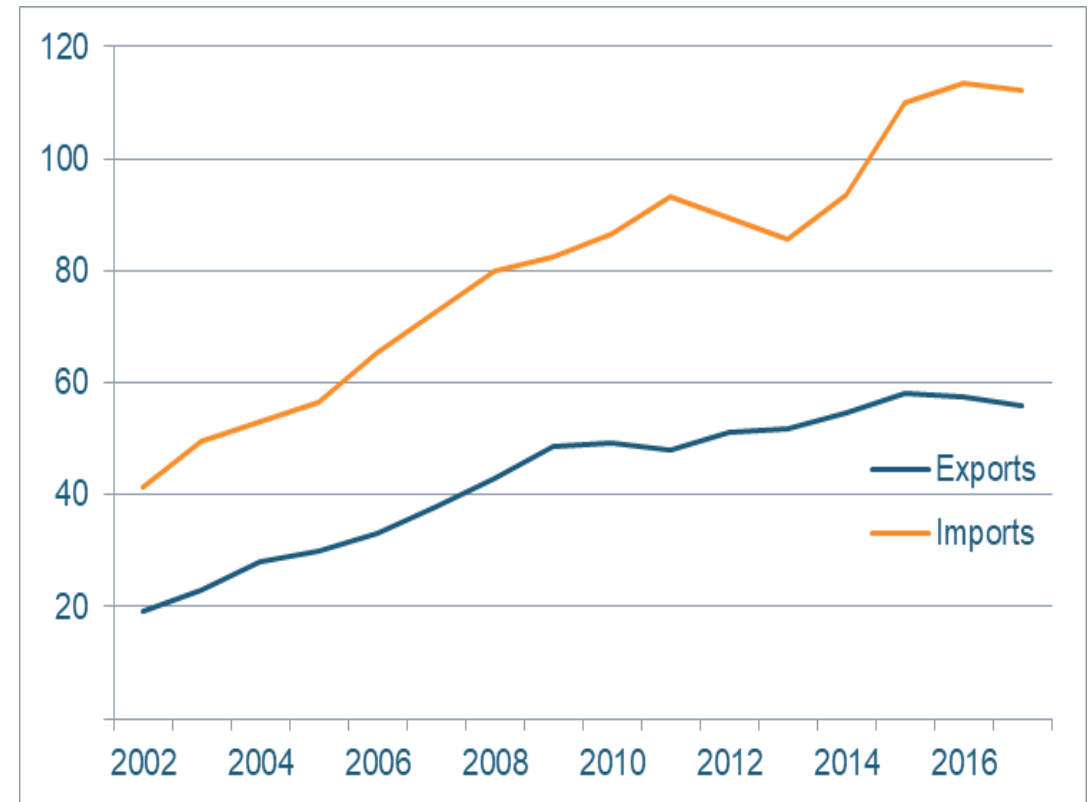
Percent of World Triadic Patents Issued to U.S. Filers



The U.S. Underperforms in Trade

- Pharmaceutical trade deficit is large and growing.
 - 2017 deficit = \$56.2 billion.
 - 101 percent of exports.
- Despite fact that exports have grown 191% over the last 15 years.

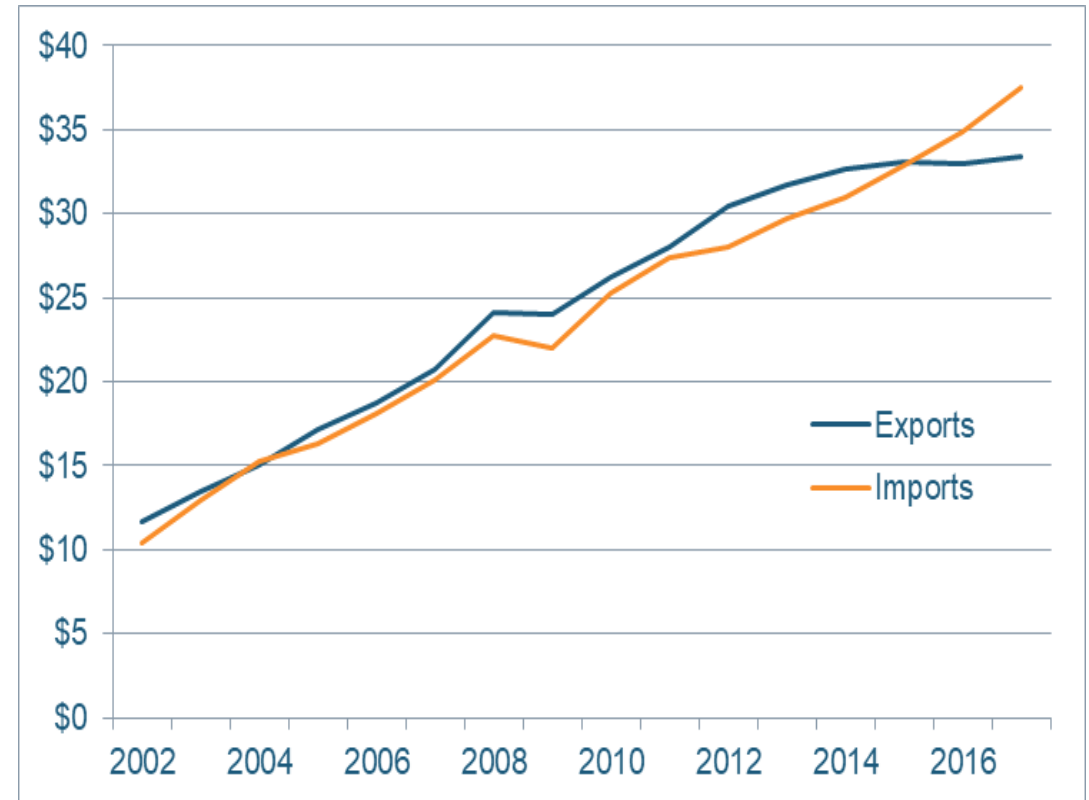
Trade in Pharmaceuticals and Medicines (\$ Billion)



The Trade Balance in Devices is Better

- Trade in medical products has been relatively balanced.
- Stagnation in exports over the last few years has led to a deficit of \$4.1 billion last year, 12% of exports.

Trade in Medical Equipment and Supplies (\$ Billion)



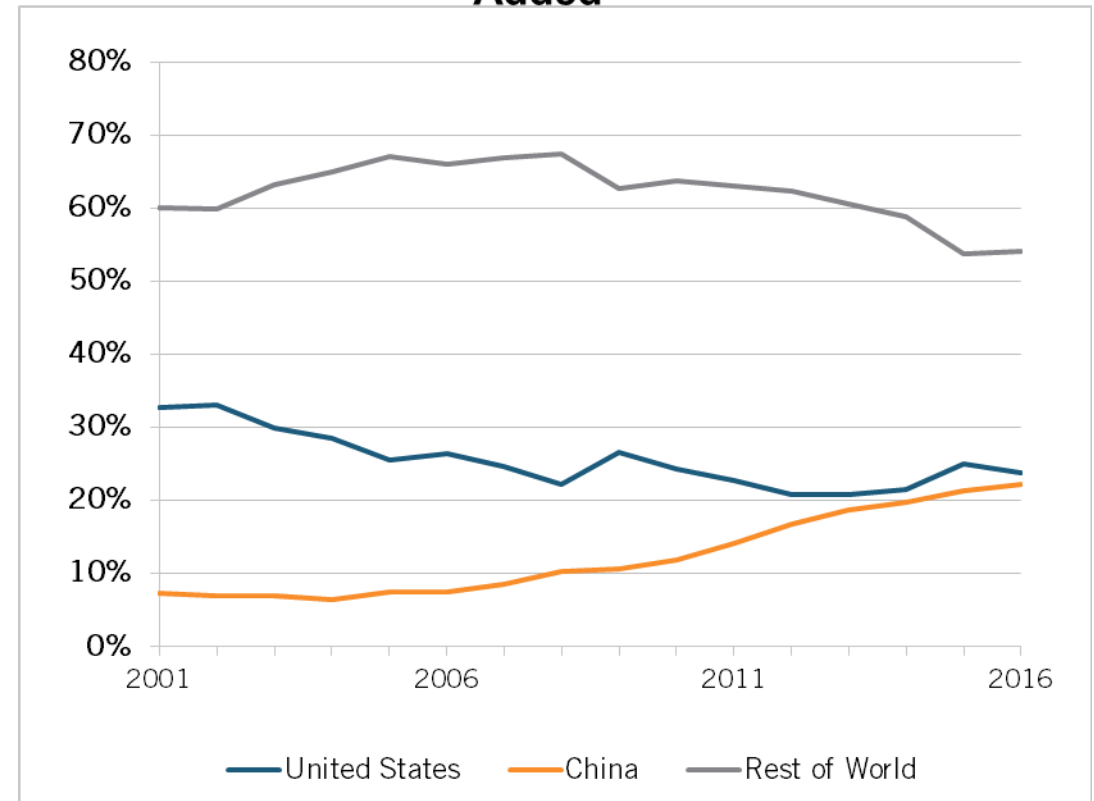
Possible Causes Harming Trade Balance

1. Market Factors
2. Profit Shifting
3. Foreign Price Repression

U.S. is Losing Global Market Share

- U.S. has lost market share since 2001.
- Although China has gained market share, most of the U.S. loss came before China's rise

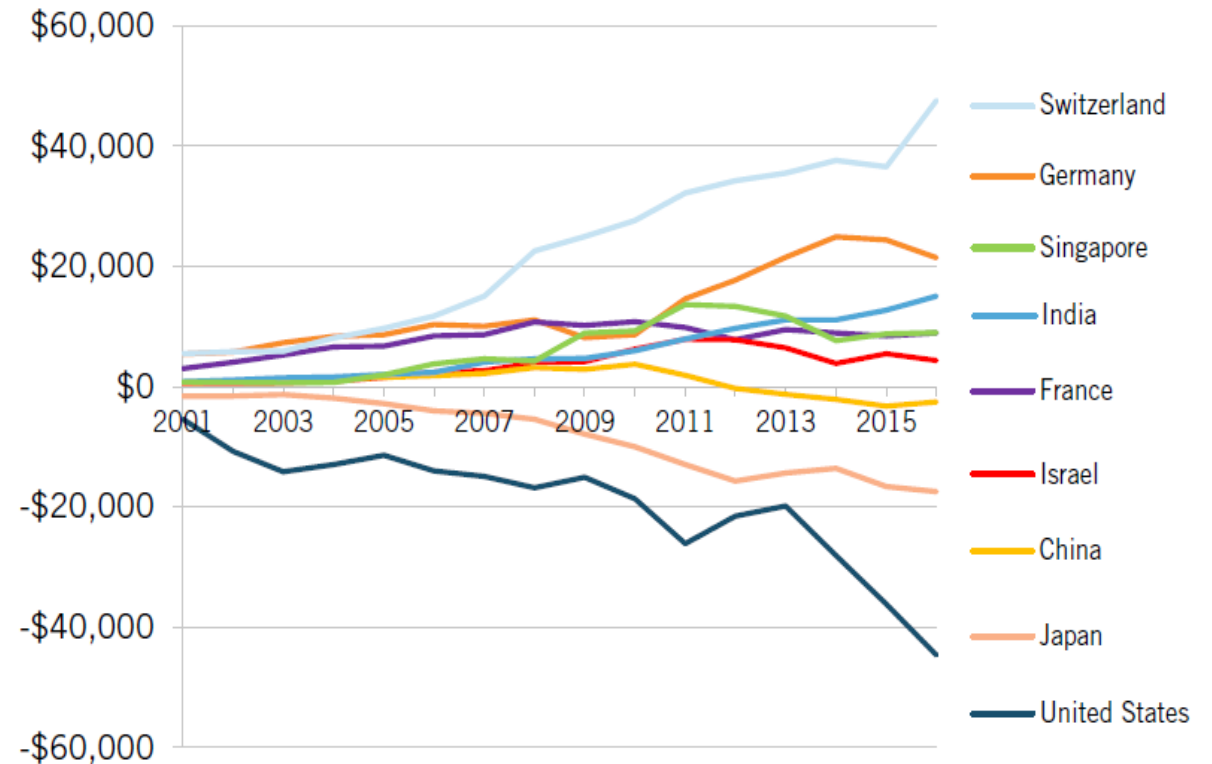
Share of Global Pharmaceutical Industry Value Added



Developed Countries are Gaining it

- U.S. and Japan are running growing trade deficits.
- China is running a slight deficit.
- The big winners have been Switzerland and Germany.

Trade Balance in Pharmaceutical Products, 2001-2016



Trade Deficit Has Increased in Pharmaceuticals

- Trade deficit grew by \$42.1 billion between 2001 and 2016.
- Four countries account for almost all of the growth.
- Three of these are developed countries that are home to global pharmaceutical companies.

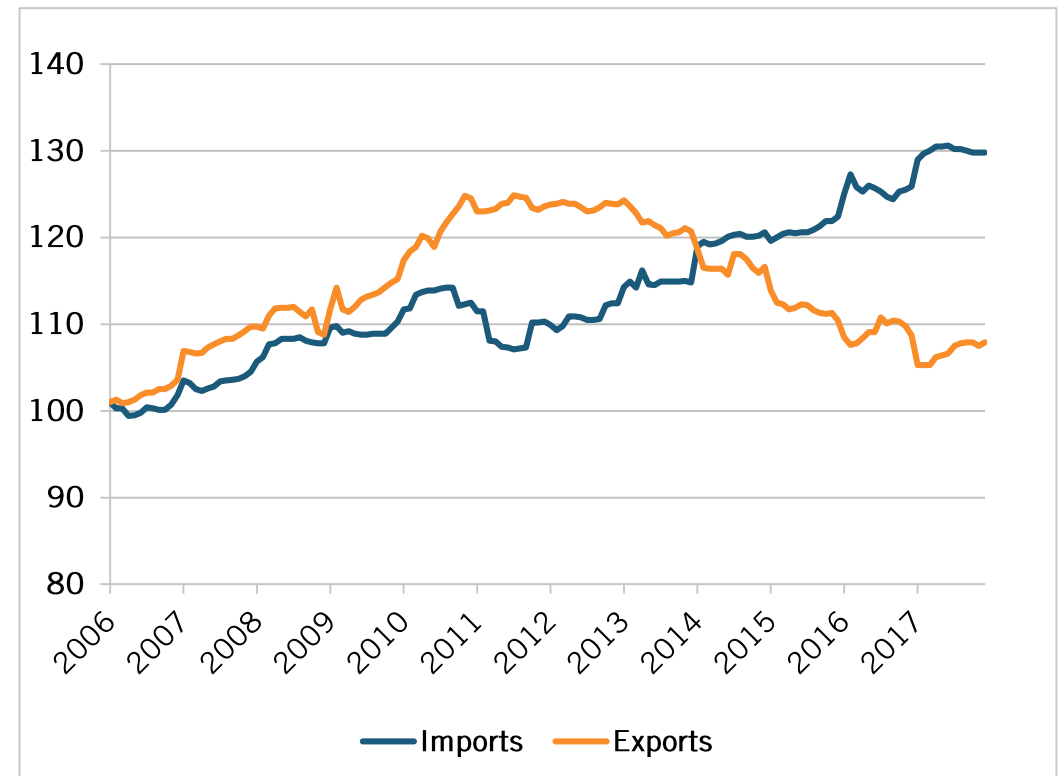
Trade Balance with U.S., 2001-2016

Country	2001	2006	2011	2016
Germany	-\$1.6	-\$4.8	-\$6.0	-\$10.6
India	-\$0.1	-\$0.4	-\$3.2	-\$7.2
Ireland	-\$1.7	-\$5.5	-\$13.6	-\$13.7
Switzerland	-\$0.6	-\$0.4	-\$4.3	-\$8.2
Rest of World	\$0.5	-\$6.2	\$-0.7	\$-5.9
United States	-\$3.5	-\$17.3	-\$27.8	-\$45.6

Foreign Government Price Suppression

- U.S. has a relatively free market for drugs and devices.
- Other countries suppress both demand and prices in their markets.
- Government purchasers often demand steep discounts.

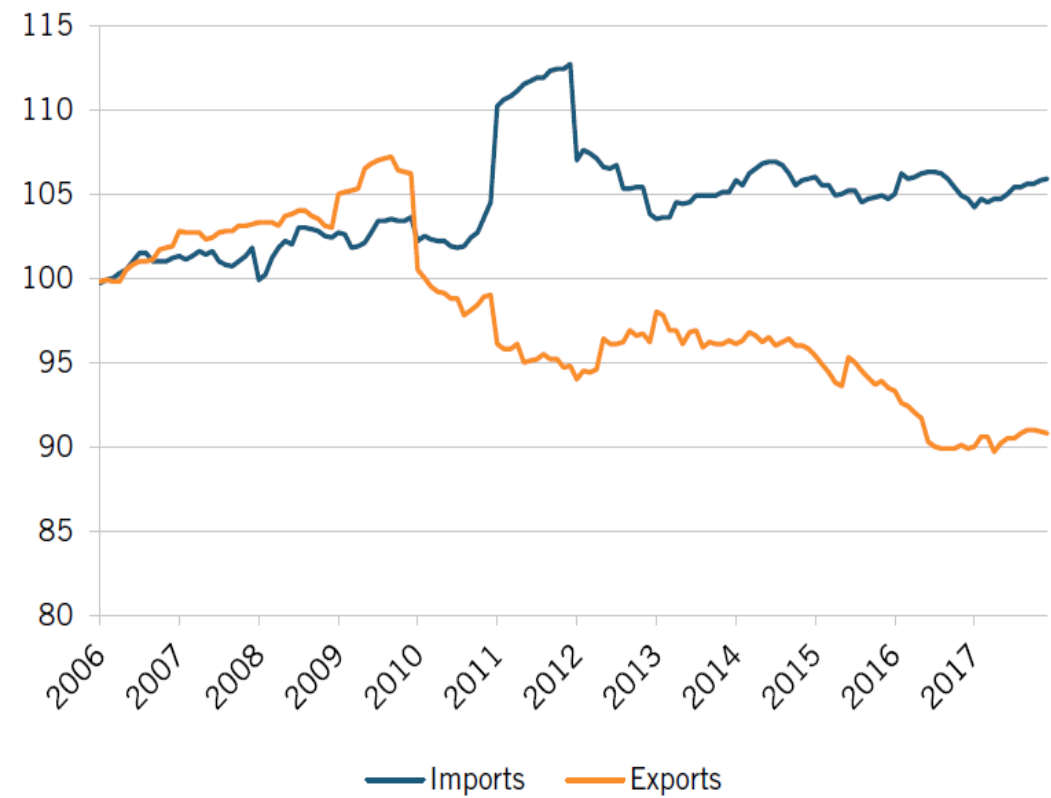
BEA Price Indexes for Pharmaceutical and Medicine Manufacturing (December 2005 = 100)



While Export Prices Have Fallen

- In both industries import and export prices started diverging after 2010.
- Import prices grew while export prices fell.
- Holding prices constant explains roughly 40% of the pharmaceutical deficit.

BEA Price Indexes for Medical Equipment and Supplies Manufacturing (December 2005 = 100)



Policies to Strengthen U.S. Life-Science Competitiveness

1. Expand Alternative Simplified R&D Tax Credit to 20 percent and implement an innovation box.
2. Continue to reverse the long-term decline in NIH funding.
3. Expand workforce training in STEM fields.
4. Pass health care reforms that restore long-term financial stability and provide adequate reimbursement for new therapies.
5. Address unfair trade practices by other countries, including IP theft, compulsory licenses, and the use of monopsony pricing by governments.

Thank You!

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