Federal Policies to Turbocharge America's Biomanufacturing Renaissance

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ITIF

AURP BioHealth Caucus
America's Bio and Pharma Manufacturing Renaissance

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2019 Global Go To Think Tank Index Report

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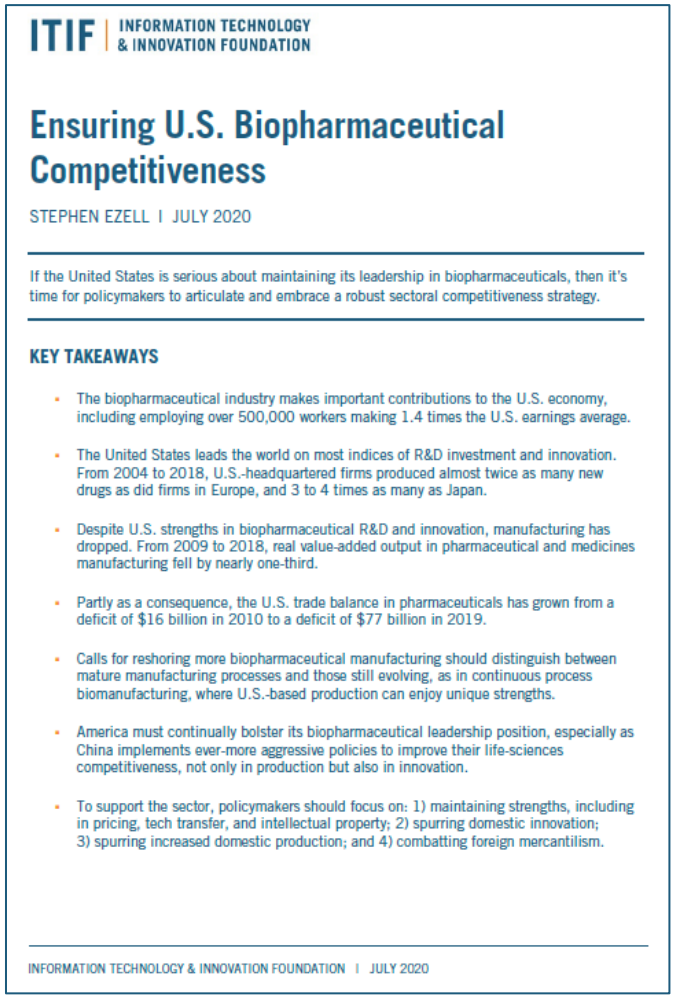
Today's Presentation

1 Assessing U.S. Biopharmaceutical Competitiveness

2 Stimulating U.S. Biomanufacturing Competitiveness



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Ensuring U.S. Biopharmaceutical Competitiveness

STEPHEN EZELL | JULY 2020

If the United States is serious about maintaining its leadership in biopharmaceuticals, then it's time for policymakers to articulate and embrace a robust sectoral competitiveness strategy.

KEY TAKEAWAYS

- The biopharmaceutical industry makes important contributions to the U.S. economy, including employing over 500,000 workers making 1.4 times the U.S. earnings average.
- The United States leads the world on most indices of R&D investment and innovation. From 2004 to 2018, U.S.-headquartered firms produced almost twice as many new drugs as did firms in Europe, and 3 to 4 times as many as Japan.
- Despite U.S. strengths in biopharmaceutical R&D and innovation, manufacturing has dropped. From 2009 to 2018, real value-added output in pharmaceutical and medicines manufacturing fell by nearly one-third.
- Partly as a consequence, the U.S. trade balance in pharmaceuticals has grown from a deficit of $16 billion in 2010 to a deficit of $77 billion in 2019.
- Calls for reshoring more biopharmaceutical manufacturing should distinguish between mature manufacturing processes and those still evolving, as in continuous process biomanufacturing, where U.S.-based production can enjoy unique strengths.
- America must continually bolster its biopharmaceutical leadership position, especially as China implements ever-more aggressive policies to improve their life-sciences competitiveness, not only in production but also in innovation.
- To support the sector, policymakers should focus on: 1) maintaining strengths, including in pricing, tech transfer, and intellectual property; 2) spurring domestic innovation; 3) spurring increased domestic production; and 4) combatting foreign mercantilism.

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https://itif.org/publications/2020/07/16/ensuring-us-biopharmaceutical-competitiveness

United States Leads the World In New Drug Innovation

New Chemical or Biological Entities: By Number and By Share GDP ($ Trillions)

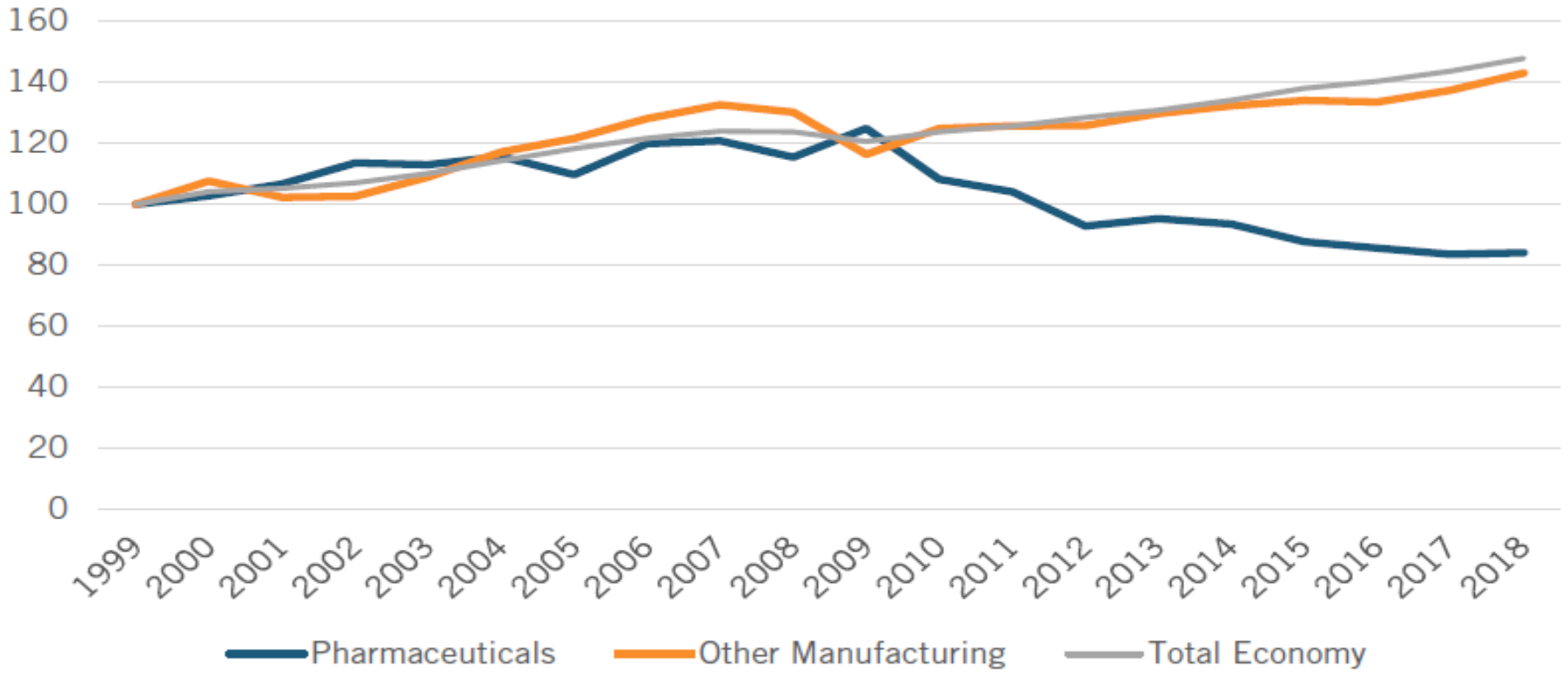
Region	1999–2003	2004–2008	2009–2013	2014–2018	Total: 2009–2018
Europe	62	47	66	67	133
U.S.	73	67	64	125	189
Japan	28	16	26	34	50
Other	8	14	23	41	64

Region	1999–2003	2004–2008	2009–2013	2014–2018	Total: 2009–2018
Europe	1.53	0.70	0.88	0.91	0.90
U.S.	1.38	0.98	0.82	1.32	1.10
Japan	1.25	0.68	0.91	1.42	0.95
Other	0.14	0.13	0.13	0.20	0.17

Source: ITIF, "Ensuring U.S. Biopharmaceutical Competitiveness" EFPIA, "The Pharmaceutical Industry in Figures, Key Data 2019"

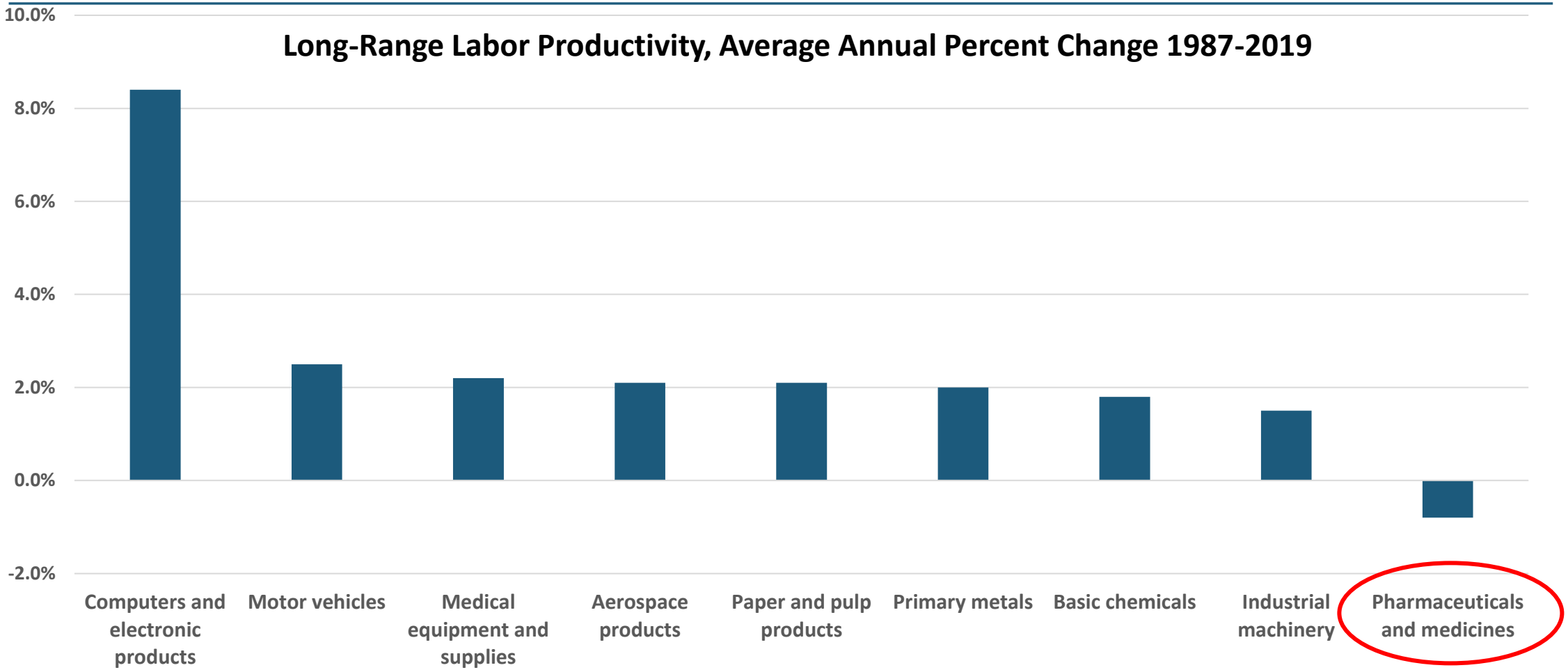
Yet U.S. Biopharmaceuticals Manufacturing Has Faltered

Change in Real Value Added for Pharmaceutical and Medicines Manufacturing (1999= 100)



Source: ITIF, "Ensuring U.S. Biopharmaceutical Competitiveness"

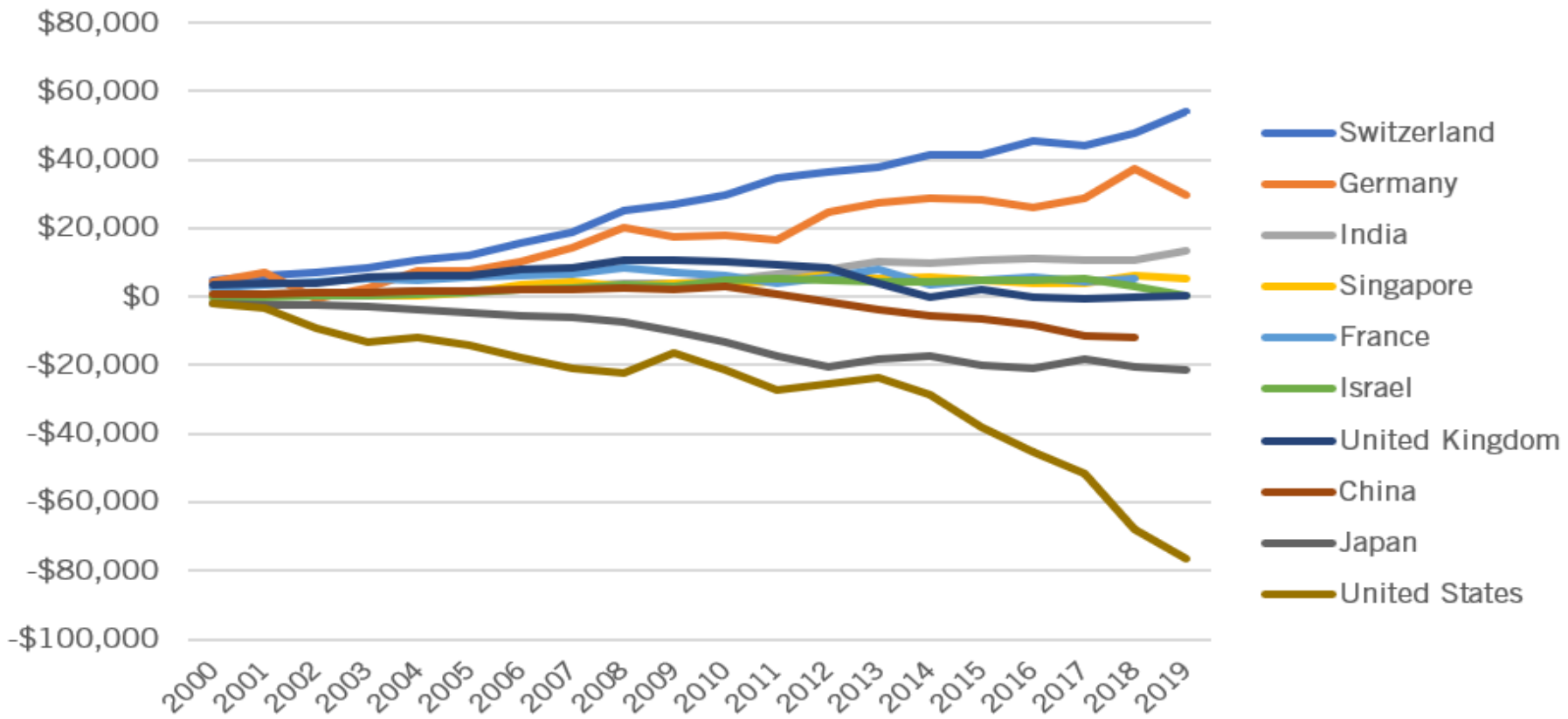
As Has Long-run Labor Productivity in Pharmaceuticals



Source: U.S. Bureau of Labor Statistics, "Productivity and Costs by Industry: Manufacturing and Mining Industries"

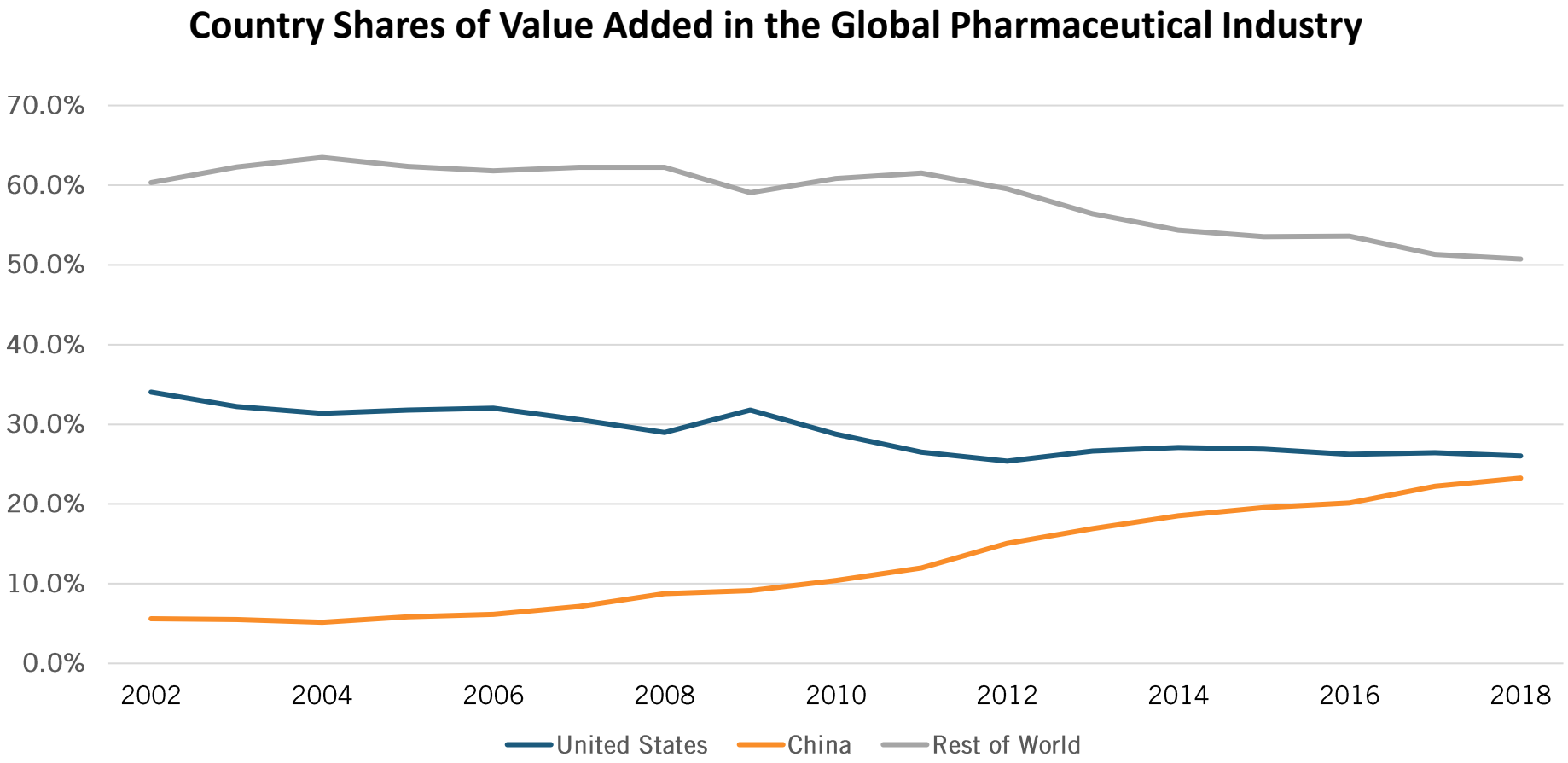
Collectively Leading to Declining U.S. Terms of Trade…

Trade Balance in Pharmaceutical Products and Preparations, 2000–2019 ($ millions)



Source: ITIF, "Ensuring U.S. Biopharmaceutical Competitiveness"

And Loss of Global Value-added in Pharmaceuticals



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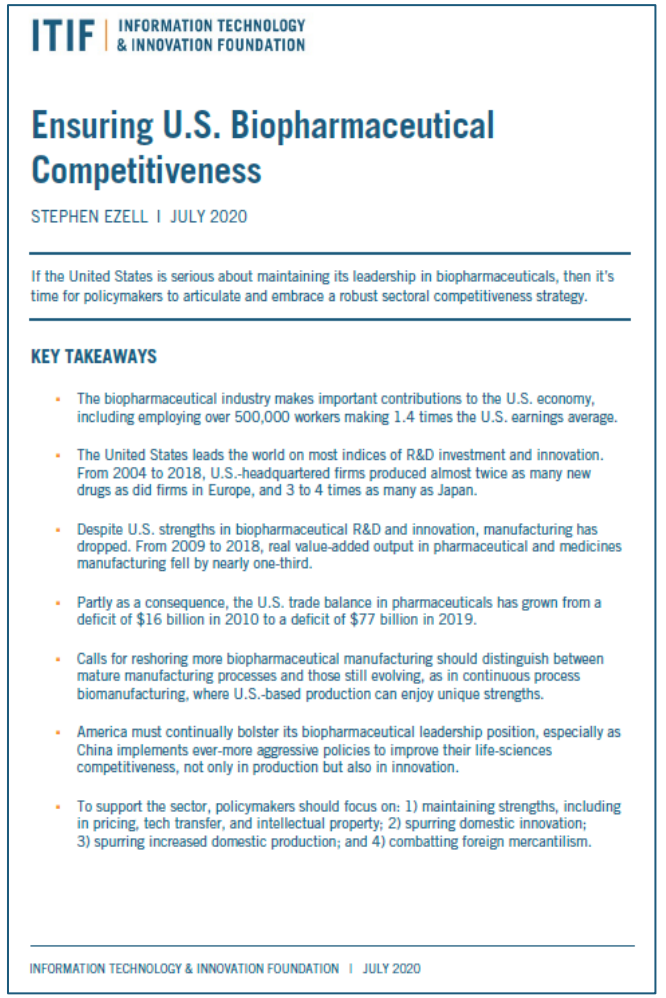

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Ensuring U.S. Biopharmaceutical Competitiveness

STEPHEN EZELL I JULY 2020

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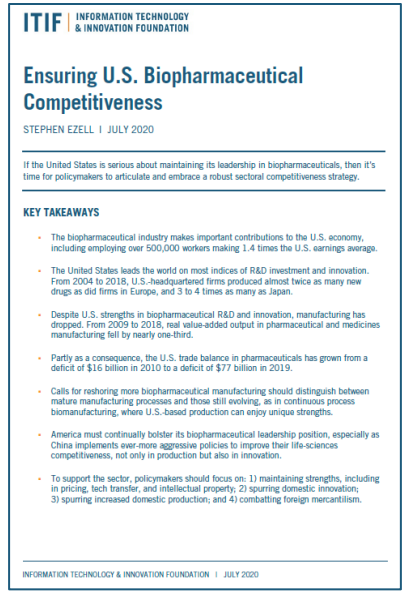
Ensuring U.S. Biopharmaceutical Competitiveness

1. Maintain Existing U.S. Strengths
   - Continuing to Lead World in Public/Private Biopharmaceutical R&D Investment
   - Enabling Innovators to Earn Profits that Can Be Reinvested in Biomedical Innovation
2. Expand/Adopt Policies to Spur Greater Domestic Innovation
3. Support Policies to Spur Increased Domestic Production
4. Aggressively Contest Foreign Biopharmaceutical Mercantilism



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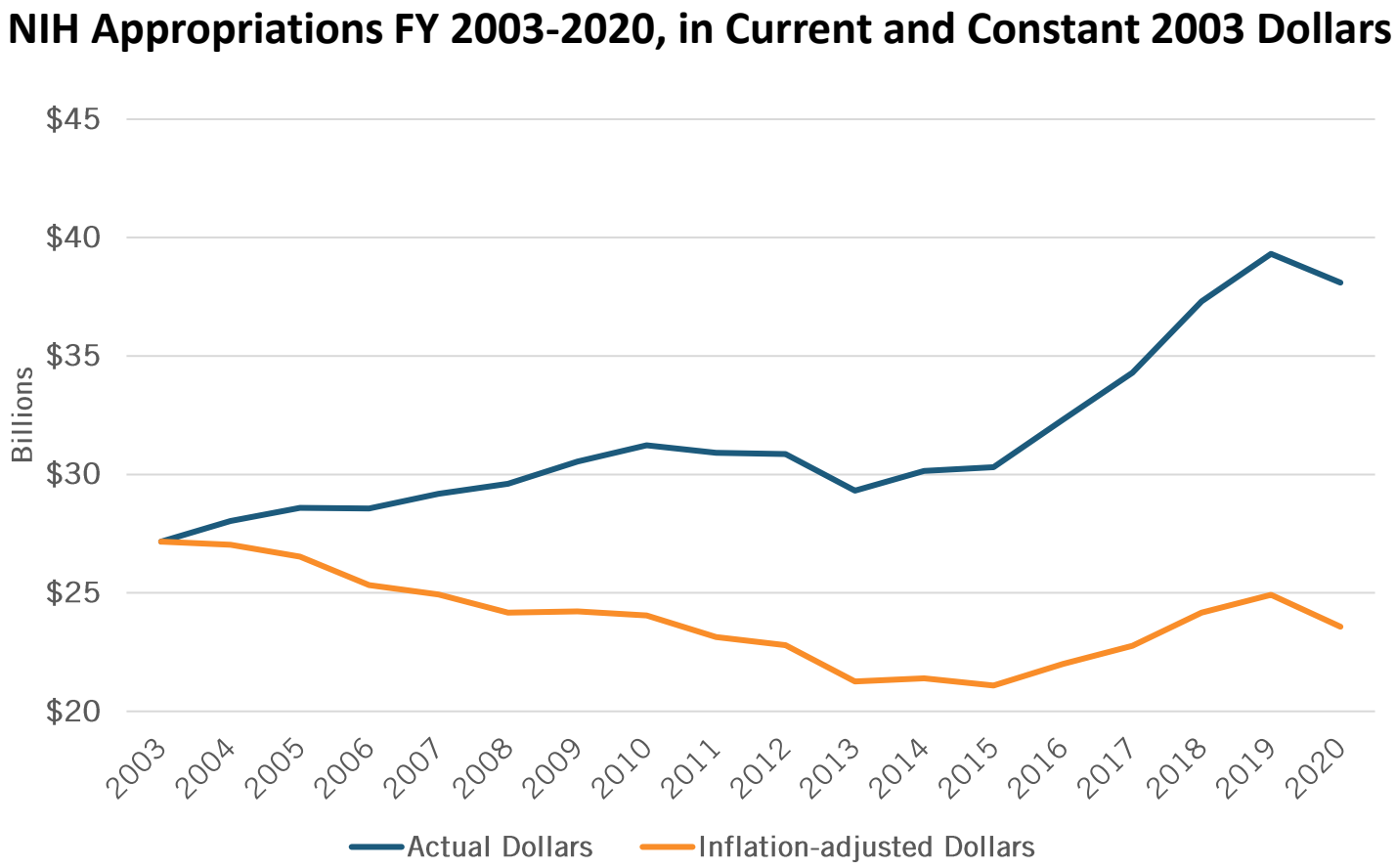
Federal Funding for Life-sciences R&D Faltering

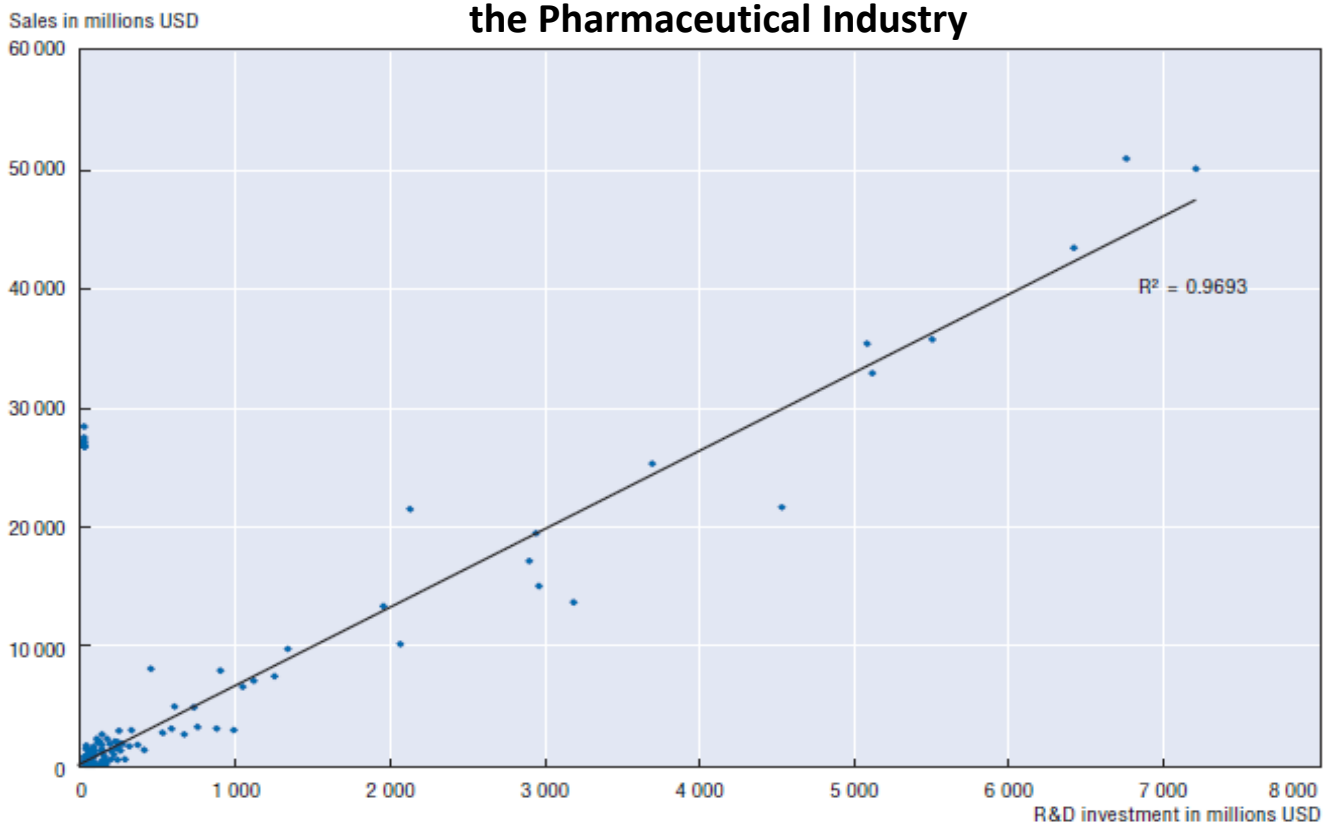


Source: Kavya Sekar, "National Institutes of Health (NIH) Funding: FY1995-FY2021," Congressional Research Service, May 12, 2020.

Drug Price Controls Could Undermine R&D and Innovation

- OECD: "There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures."
- Every $2.5 billion of additional revenue leads to a new drug approval.
- CBO: Price controls would reduce the number of new drugs 3-5% over the next decade.

Relationship Between Sales and R&D Expenditures in the Pharmaceutical Industry

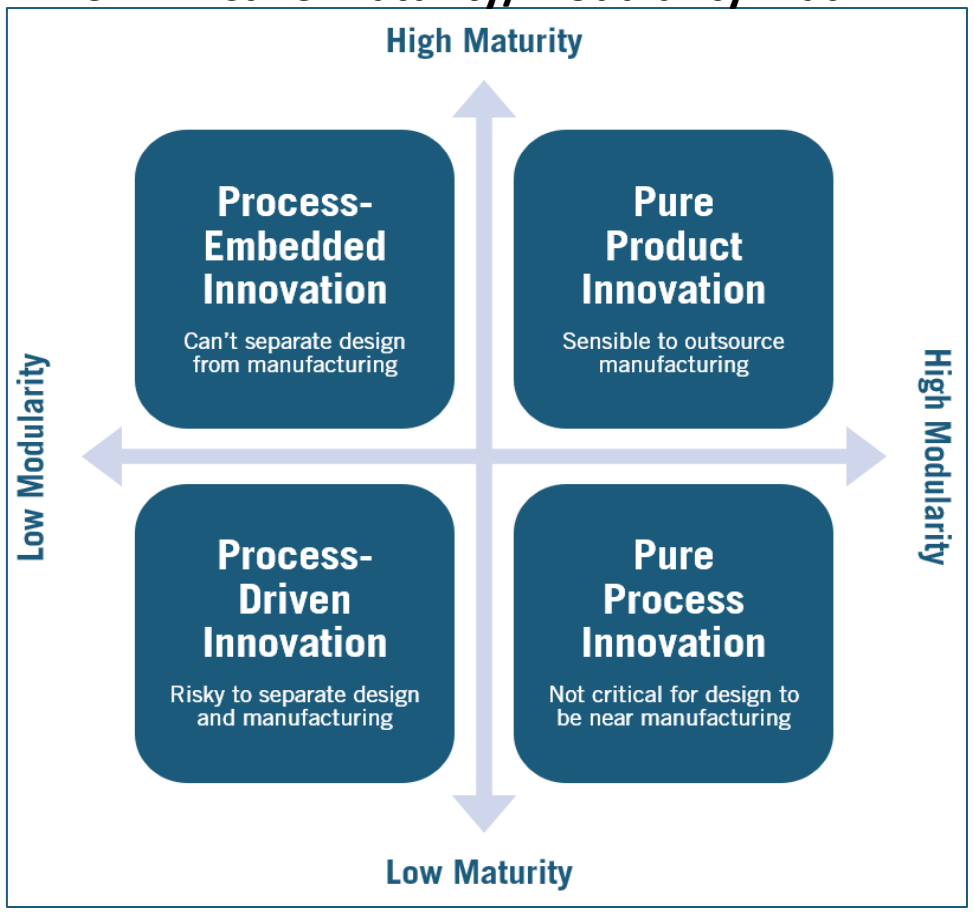


Sources: OECD, "Pharmaceutical Pricing Policies in a Global Market"; Dubois, "Market size and pharmaceutical innovation";
CBO: "Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare"

Spurring Greater Levels of Domestic Biopharmaceuticals Production

- Maturity: The extent to which technologies used to make a product are mature vs. evolving.
- Modularity: The extent to which information about product design is separable from manufacturing.
- APIs characterized as "pure product innovation"; biopharmaceuticals as "process-driven."
- Suggests that to extent policy can stimulate greater biologic innovation; manufacturing in U.S.

Shih-Pisano Maturity/Modularity Matrix



Source: Gary P. Pisano and Willy C. Shih, *Harvard Business Review*, "Does America Really Need Manufacturing?"

Dramatically Advance Biopharmaceuticals Process Manufacturing

- Modern biomanufacturing techniques could eliminate as much as $50 billion in annual production costs.*
- New bio-based manufacturing process can enable the biosynthesis of APIs through novel bio-brewing-based processes.
- U.S. should commit to disrupt dominant batch-flow manufacturing processes to make APIs with continuous-flow manufacturing processes.
  - Could significantly increase resilience of supply chain for small-molecule generic drugs.
  - DARPA funding a flexible, miniaturized mfg. platform for producing multiple APIs from shelf-stable precursors.**

Sources: *W. Nicholson Price II, *Boston College Law Review*, "Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing,"
** Willy C. Shih, *Harvard Business Review*, "Global Supply Chains in a Post-Pandemic World" September 2020

Invest in R&D for Biopharmaceutical Process Innovation

- ✓ Sustain federal funding for NIIMBL/other Manufacturing USA Institutes.
- ✓ Introduce a new Institute supporting continuous process biomanufacturing.
- ✓ Fund NSF to expand university-industry research centers (I/UCRCs) working on biopharmaceutical production technologies.
- ✓ Increase funding for NSF Engineering Division, especially the Chemical Process Systems Cluster and Engineering Biology and Health Cluster.
- ✓ Develop an SRC equivalent for biopharmaceuticals; match industry funds to develop biotech roadmaps.

Expand Incentives/Tax Credits to Stimulate Innovation/Production

- ✓ Expand R&D tax credit generosity (U.S. ranks 34th OECD).
- ✓ Introduce a collaborative R&D tax credit.
- ✓ Establish an investment tax credit for new U.S. manufacturing facilities.
- ✓ Provide federal match to state incentives for biomedical production facilities.
- ✓ Preserve first-year expensing provision for capital expenditures.
- ✓ Restore the biopharmaceutical production tax credit for Puerto Rico.

Source: ITIF, John Lester and Jacek Warda, "Enhanced Tax Incentives for R&D Would Make Americans Richer"

Invest in Biomedical Manufacturing Talent

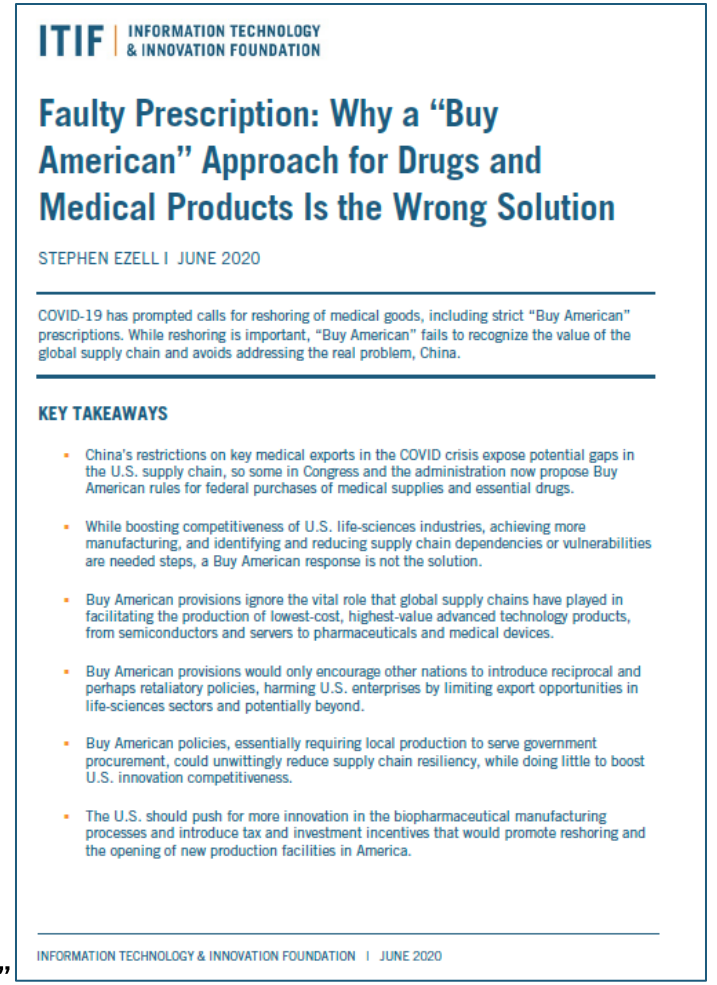
- ✓ Expand the Manufacturing Engineering Education Grant program.
- ✓ Increase funding for NSF's Advanced Technical Education program.
- ✓ Congress should direct DoD to develop a competition for biomedical manufacturing programs.

Additional Policy Recommendations

- ✓ Articulate a clear national biopharmaceutical competitiveness strategy.
- ✓ Initiate comprehensive pharmaceuticals/medical goods supply chain review.
- ✓ Recognize regulatory reforms may be needed as many FDA regulations developed according to traditional batch manufacturing approaches.

Why a Buy America Approach Isn't the Preferred Solution

1. Increases costs and ignores supply chain benefits.
2. Could unintentionally reduce supply chain resiliency.
3. Would only encourage and legitimize reciprocal behaviors.
4. Undermines the rules-based global trading system.
5. Fails to boost U.S. innovation and competitiveness.



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Faulty Prescription: Why a "Buy American" Approach for Drugs and Medical Products Is the Wrong Solution

STEPHEN EZELL I JUNE 2020

COVID-19 has prompted calls for reshoring of medical goods, including strict "Buy American" prescriptions. While reshoring is important, "Buy American" fails to recognize the value of the global supply chain and avoids addressing the real problem, China.

KEY TAKEAWAYS

- China's restrictions on key medical exports in the COVID crisis expose potential gaps in the U.S. supply chain, so some in Congress and the administration now propose Buy American rules for federal purchases of medical supplies and essential drugs.
- While boosting competitiveness of U.S. life-sciences industries, achieving more manufacturing, and identifying and reducing supply chain dependencies or vulnerabilities are needed steps, a Buy American response is not the solution.
- Buy American provisions ignore the vital role that global supply chains have played in facilitating the production of lowest-cost, highest-value advanced technology products, from semiconductors and servers to pharmaceuticals and medical devices.
- Buy American provisions would only encourage other nations to introduce reciprocal and perhaps retaliatory policies, harming U.S. enterprises by limiting export opportunities in life-sciences sectors and potentially beyond.
- Buy American policies, essentially requiring local production to serve government procurement, could unwittingly reduce supply chain resiliency, while doing little to boost U.S. innovation competitiveness.
- The U.S. should push for more innovation in the biopharmaceutical manufacturing processes and introduce tax and investment incentives that would promote reshoring and the opening of new production facilities in America.

INFORMATION TECHNOLOGY & INNOVATION FOUNDATION I JUNE 2020

Source: ITIF, "Faulty Prescription: Why a "Buy America" Approach for Drugs and Medical Products is the Wrong Solution"

Thank You!

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