ENSURING A HEALTHY FUTURE:

The Impact and Importance of Pharmaceutical Manufacturing

FOREWORD

Pharmaceutical manufacturers are essential to America's health and well-being and to the success of our economy. They have helped lead our country through crisis, fight the pandemic and drive our recovery. The sector creates hundreds of thousands of jobs, and the work its quarter of a million employees perform is literally lifesaving, improving society in ways that are almost impossible to overstate.

The American public and policymakers too often overlook these accomplishments. Traditional economic analysis ignores the way this industry extends and enriches lives, and the public is not fully aware of pharmaceutical manufacturers' constant focus on innovation and improving the quality of life for everyone. Pharmaceutical manufacturers are always researching, discovering and developing new medicines and treatments, operating at the core of our modern health care system. Their products make it possible for medical professionals to introduce and manage innovative new therapies, and of course, these manufacturers helped create lifesaving COVID-19 vaccines. Moreover, the industry has high economic multipliers that drive production and job creation in other industries.

Pharmaceutical manufacturers have an outsized positive impact on the world. For example, while cancer remains one of the leading causes of death in the United States, the death rate decreased significantly from 1999 to 2019, falling 27%, largely due to an acceleration of successful treatments, early interventions and other innovations in cancer care.

Jay Timmons
President and CEO
National Association of Manufacturers

The United States has been able to lead in the global biopharmaceutical market because of favorable conditions and a strong business environment enabling unparalleled investment, research and manufacturing. The sector's advances in medical innovation require major upfront private-sector investments far beyond what any government alone can invest or contribute.

Today, pharmaceutical manufacturers are implementing cutting-edge advanced manufacturing technologies, which will accelerate the discovery, production and distribution of new therapies and cures, including for diseases once thought untreatable. Many companies within the industry have thousands of potential formulas that could prove to be lifesaving medicines. Although it takes time and financial investment to assess each of these, artificial intelligence is streamlining this important work, and continuous manufacturing in modern smart factories will make these lifesaving medicines more widely available.

Pharmaceutical manufacturers are pioneers in improving the human condition. Our nation will continue depending on this industry to protect and enrich lives and livelihoods, so we cannot take it for granted nor allow poor policy decisions to diminish our strength. But if we maintain that business environment, the best is yet to come.

EXECUTIVE SUMMARY

This report estimates the pharmaceutical manufacturing industry's direct impact on the broader economy by quantifying measures such as output and labor income. This report also provides a more comprehensive view of pharmaceutical manufacturing's economic contributions by evaluating the impact the sector has on other U.S. industries and ultimately on Americans themselves.

When the pharmaceutical manufacturing industry purchases services and goods from other sectors to use as inputs in the products they design and build, they produce economic activity in those sectors. The economic impacts created in these supply chains are called indirect effects. Likewise, employees in the pharmaceutical manufacturing sector and related supply chains spend their earnings in downstream sectors, which, in turn, produces a range of economic activities at the local and national levels. These economic contributions are called induced effects. The total economic contribution of the pharmaceutical and medicine manufacturing sector includes these direct, indirect and induced effects.

This report finds the following:

- A successful pharmaceutical ecosystem requires strong private-sector investment.
  - In 2019, American pharmaceutical companies invested more than $83 billion in research and development, topping off nearly $1 trillion in R&D investment over the past 20 years. A recent study from the National Science Foundation's National Center for Science and Engineering Statistics estimates that the pharmaceutical and medicine manufacturing sector alone accounts for roughly 17% of total R&D investment in the United States.
  - The pharmaceutical industry invests nearly 11.4% of its sales back into R&D. Indeed, the U.S. pharmaceutical industry invests on average roughly three times more in R&D as a percentage of sales than all other manufacturing industries.
- The pharmaceutical manufacturing industry pays high wages and benefits to American workers.
  - Annual average labor income per worker in the pharmaceutical manufacturing industry is more than $172,000. This figure is greater than some of the highest-paying industries in the country, including finance and insurance ($90,000), professional, scientific and technical services ($96,000) and management ($133,000), and roughly 2.7 times the U.S. workforce average income.
- The industry creates valuable STEM jobs.
  - While roughly 6.7% of the U.S. workforce has a STEM occupation, some 29.9% of all jobs in pharmaceutical and medicine manufacturing are STEM related. The pharmaceutical manufacturing sector employs more than four times the percentage of STEM workers employed in the overall workforce.
- Industry employees are highly productive.
  - Industry employees produce $1.3 million in output per employee. This is nearly seven times greater than the U.S. economy's average output per employee ($188,000).
- The industry fuels other sectors of the economy.
  - Pharmaceutical and medicine manufacturing directly employs an estimated 267,000 individuals in the United States and supports nearly 1.9 million more jobs in America.
  - One job in the industry helps support six other jobs in the overall workforce.
  - Pharmaceutical and medicine manufacturing generates nearly $339 billion in output. Further, $1.00 in pharmaceutical and medicine manufacturing output generates $1.09 in output elsewhere in the economy.
  - For every $1.00 earned by an employee within the industry, $2.42 is earned by others elsewhere in the economy.

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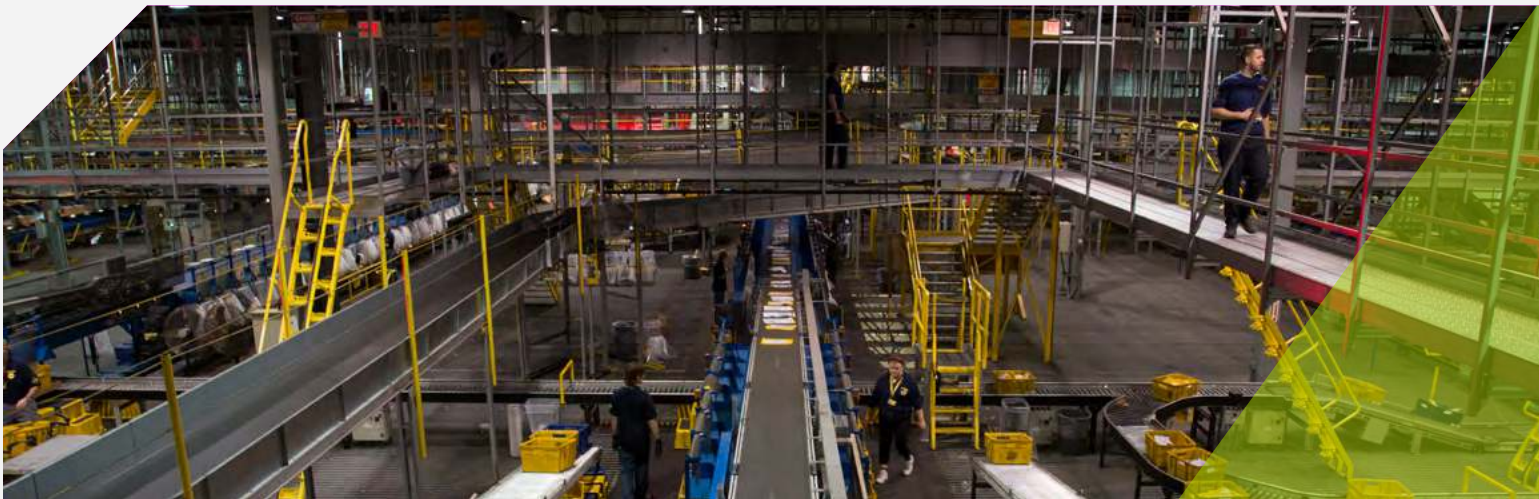

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WHY THE U.S. MUST CULTIVATE AND SUSTAIN THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is often seen narrowly through the lens of the products it produces. But those medicines and drugs bring with them substantial employment, vigorous economic activity and irreplaceable advanced manufacturing capabilities. For decades, Americans have benefited from life-improving drugs, while the entire economy has seen significant economic benefits.

The U.S. is a global leader in advanced pharmaceutical manufacturing because it enacted policies over the past 50 years that have incubated an environment in which innovation can thrive. Strong intellectual property protection, smart tax policy and market-oriented frameworks have fostered private capital investment that drives drug development while contributing to the U.S. economy on a massive scale.

The U.S. pharmaceutical industry is robust and dynamic; what we have in this country is one of a kind. But its future is not inevitable. Public policy's impact on capital will define the next 50 years. The wrong set of policy changes could erase decades of economic advancement.

For example, the Congressional Budget Office continues to analyze proposed drug pricing policy changes. The CBO found that the changes would adversely impact U.S. consumers through reduced R&D investment and the development of new drugs in the long run.

"CBO estimates that under the bill [H.R. 3, the Lower Drug Costs Now Act of 2019], approximately 8 fewer drugs would be introduced to the U.S. market over the 2020-2029 period, and about 30 fewer drugs over the subsequent decade… Those effects would occur because the potential global revenues for a new drug over its lifetime would decline as a result of enactment, and in some cases the prospect of lower revenues would make investments in research and development less attractive to pharmaceutical companies."

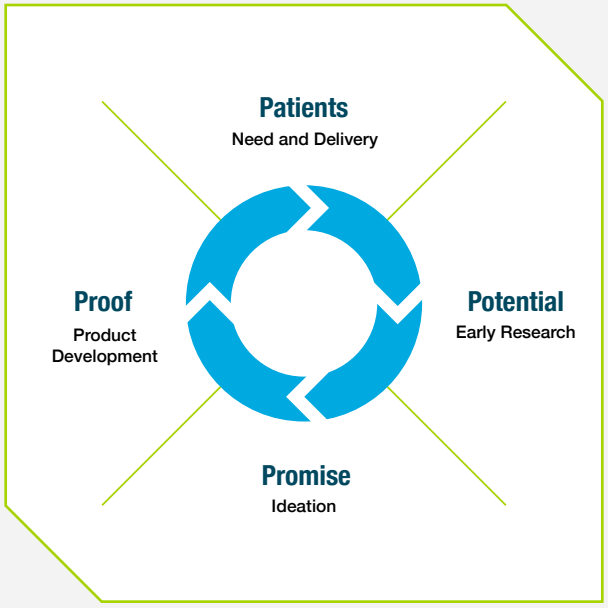
– Congressional Budget Office to Chairman Frank Pallone, December 10, 2019

The implication is that Americans do not only lose from reduced new drug introductions when anti-growth policies are employed. These policies also choke employment, economic activity and advanced manufacturing capabilities. Ultimately, these policies undermine the U.S. economy.

THE IMPORTANCE OF A PHARMACEUTICAL ECOSYSTEM

From identifying patient needs to educating both providers and the public about new medications, the pharmaceutical industry takes on the heavy lifting of escalating investment, risk and complexity within the collaboration among the private sector, public sector and academia that continues to keep the United States as the global leader in drug development.

- **Patients.** Patients represent the ultimate customer in the quest to extend and improve the quality of life. Patient needs inspire scientists across academic, government and industry domains to research new cures, treatments and vaccinations.
- **Potential.** Scientists and medical researchers from academic centers, pharmaceutical research companies and the National Institutes of Health explore novel approaches to improve knowledge of how diseases work and further molecule discovery.
- **Promise.** Public- and private-sector scientists further explore molecules that hold promise, developing new options for disease treatment.
- **Proof.** Pharmaceutical companies leverage investments in infrastructure, time and expertise to transform concepts into medications. If the U.S. Food and Drug Administration and other regulatory bodies approve medications after clinical trials conclude, pharmaceutical companies begin to manufacture the drug so that it can be distributed to patients. However, companies continue to invest in efforts such as safety monitoring and educating both the public and medical professionals on the drug's optimal use and potential side effects.



While public–private partnership is important in stewarding new drugs to market, pharmaceutical companies bear almost the entire cost of discovering new drugs, ushering them to approval and scaling them through manufacturing. In 2019, for example, the industry invested more than $83 billion in R&D, all of which was aimed at developing drugs.[1] In contrast, less than 9% of the NIH's fiscal 2019 budget of $39 billion was focused directly on research related to drug development.

The federal government, through the NIH, is an important funder of basic research in the biomedical sciences, but it is the biopharmaceutical industry that assumes the financial risk to advance basic science to safe and effective treatments. Roughly 90% of FDA-approved medicines are not associated with NIH-supported patents.[2] Moreover, even drugs associated with NIH-supported patents typically rely on other patents that were financed entirely through private R&D.[3]

A recent study traced NIH research grants from fiscal 2000 to determine how many of these grants eventually led to patented discoveries associated with approved medicines.[4] Of the 23,200 NIH grants awarded in 2000, patents supported by these grants were associated with 41 investigational medicines that reached clinical trials. Of these, 18 eventually became FDA-approved drugs. NIH funding totaled $670 million for these 18 approved medicines, while private-sector R&D spending totaled an estimated $44.2 billion. In other words, 98.5% of the total cost to make these medicines available to patients came from the private sector. It is abundantly clear that private investment from pharmaceutical companies drives new drug therapies. No country can maintain a healthy pharmaceutical ecosystem without a robust and financially strong private pharmaceutical sector.

1 Congressional Budget Office. (2021). Research and Development in the Pharmaceutical Industry. Government Printing Office.
2 Long, Genia. (2019). Federal government-interest patent disclosures for recent top-selling drugs. Journal of Medical Economics, 22(12), 1,261–1,267.
3 *Ibid*
4 VitalTransformation. (2021). Who Develops Medicines?: An Analysis of NIH Grants

A Conversation with Eli Lilly and Company Senior Vice President and President of Manufacturing Operations Edgardo Hernandez, Senior Vice President and Chief Financial Officer Anat Ashkenazi and Senior Vice President and President of Lilly Diabetes Michael Mason

What drives pharmaceutical manufacturing?

Innovation is what drives manufacturing. We look at global manufacturing through the lens of our patients. Patients want a reliable supply of high-quality medicines. That drives all of our initiatives and the context of how we operate. Our first priority will always be the safe and reliable supply of medicines.

There are many places you could manufacture. Why is the United States a valuable manufacturing environment?

The United States is a key customer, representing a significant percentage of our annual volume. It's an advantage to be able to manufacture in the market you are trying to serve. But that's not the only reason, or even the biggest reason. It comes down to two things. First, where do you have appropriate infrastructure? And second, where do you have the right regulatory and legal structure?

When it comes to infrastructure, you need access to stable utilities and good roads, but you also need access to talent. The availability of top universities with STEM programs is one of the key advantages of being in the United States. Access to a talented workforce makes the United States globally competitive. If a country wants to create a hub for manufacturing pharmaceutical products, it must develop a skilled workforce. That requires robust colleges and universities nearby, which requires years of investments. Here in the United States, pharma companies also help in that investment. For example, we make significant investments in Indianapolis, where we were established 145 years ago. The vast majority of our more than 8,000 manufacturing employees and most of the R&D employees are located in the United States.

Other countries are building regulatory, legal and financial infrastructures to provide incentives to local manufacturers to locate their facilities in their country. The 2017 tax reform in the United States enabled us to further invest in our country. This was one of the drivers for the decision to build a new pharmaceutical manufacturing facility in North Carolina. This nearly $500 million investment will employ hundreds of workers.

As we look into the future, other countries have put incentive systems in place where maybe the United States, with the 2017 tax reform, is closer to parity. But as we look at potential legislation being contemplated in the United States, this would take us back to where America is not going to be in a competitive position to garner additional manufacturing investment. Companies will likely take this into consideration when looking at additional manufacturing investments. Our largest manufacturing sites are in Indianapolis. We also have a site in New Jersey and are building one in North Carolina. We have made significant investment in the United States, and we're going to continue to do so to the extent we're able to, given that there is such a rich source of talent and robust infrastructure here.

> **"The nation's health care system is reliant on pharmaceutical innovation."**
> **– Michael Mason, senior vice president and president of Lilly Diabetes**

What benefits does local pharmaceutical manufacturing in the United States bring to education?

We collaborate closely with schools in the markets in which we operate. In North Carolina, for example, we will be making medicine in our new facility there in 2022. But already, we've partnered with local schools to help advance their curricula. There were local community colleges that already had STEM programs, and we were able to partner with them to help extend and advance their curricula. In Indianapolis, there is a STEM high school that supports through internships and other kinds of summer programs to help their students.

In the United States, we've seen pharmaceutical clusters develop. What are the benefits of these manufacturing clusters?

While we compete with other pharmaceutical companies when it comes to manufacturing, having other companies in the area really supports growth in that area. Having STEM education in the region, and local policymakers encouraging investment, stimulates interest to invest even further.

Can you talk about the importance of IP protection?

One of the most critical elements in our industry is IP protection. It is a pillar of our industry. If IP protection changes, our industry looks very different. It is something we rely on heavily. The lack of appropriate IP protection would have a significant impact on our ability to produce the products we do or invest billions of dollars in research and development. But it isn't just about drug discovery. Effective intellectual property includes protecting our clinical data as well as providing reliable patent and trade secret protection supporting our manufacturing processes. It isn't just the formulas needed to produce a given medicine. Having reliable IP protection, like we have in the United States, provides a unique competitive advantage and makes this country an important manufacturing hub.

Countries that respect IP protection are viewed differently than countries where that may be at risk. A country making a decision to not respect IP protection is a significant risk. The recent U.S. support of the TRIPS waiver is very concerning in this regard. In addition, countries that support compulsory licensing or forced technology transfer raise serious red flags. Countries need an IP regime—laws that protect IP and a judicial system that enables effective enforcement—to be attractive for manufacturing investment. Until recently, the United States was one of the best in terms of demonstrating IP protection, and we have a regulatory environment that is supportive of bringing and keeping innovation here.

Canada has a very rich talent base and good infrastructure. The pharmaceutical industry had quite a bit of R&D and manufacturing happening there, too. But over the past decade or so, the reliability of IP protection eroded; so did Canada's attractiveness to the pharmaceutical industry. Companies consider many factors before deciding in which markets to place R&D and manufacturing investments, including the environment for pharmaceutical innovation. As a result, the pharmaceutical industry has reduced their investments in Canada.

The United States is a favorable market, and it has led to pharmaceutical companies here being strong and globally competitive. The environment supports innovation today, but we shouldn't take that for granted, because you've seen other countries lose their lead.

When we think about drug pricing reform, we must ensure we balance affordability for patients who need our products, with stimulating the innovation that's driven major advancements in health care over the past decades.

R&D AND AMERICAN LEADERSHIP

For more than three decades, America's biopharmaceutical industry has been the world leader in the development of new medicines. Fueled by factors such as federal investment in life sciences research, strong IP protection, effective technology transfer policies, incentives to invest and drug pricing policies that encourage drug development, the United States is well positioned to continue its market share lead into the future.

The pharmaceutical industry's unparalleled investment in R&D has enabled it to create new, innovative treatments. The pharmaceutical industry is in the business of saving, extending and improving lives, and R&D has been crucial in accomplishing that mission. A recent study found that pharmaceuticals account for 35% of life expectancy increases.[5] And for some acute illnesses, pharmaceuticals are responsible for most improvements in mortality rates. For example, pharmaceuticals are responsible for 76% of mortality improvements for patients with HIV, 60% of mortality improvements for patients with breast cancer and 52% of mortality improvements for patients with heart disease.

In 2019, American pharmaceutical companies invested more than $83 billion in R&D, topping off nearly $1 trillion in R&D investment over the past 20 years. A recent study from the National Science Foundation's National Center for Science and Engineering Statistics estimates that the pharmaceutical and medicine manufacturing sector alone accounts for roughly 17% of total R&D investment in the United States.[6]

The fuel for R&D investment begins with sales, and the pharmaceutical industry allocates a substantial portion of its sales to future drug discovery. The NCSES estimates nonmanufacturing industries invest roughly 3.5% of their sales into R&D, while the broader manufacturing sector invests roughly 4.6% of its sales.[7] But the pharmaceutical industry invests nearly 11.4% of its sales back into R&D.[8] Indeed, the U.S. pharmaceutical industry invests on average roughly three times more in R&D as a percentage of sales than all other manufacturing industries. The pharmaceutical industry is one of the most R&D-intensive industries in the country. This is an industry that is betting on the future in a big way.

A decline in industry sales will undoubtedly shrink R&D investment. And this, in turn, means fewer innovative drug discoveries. In fact, researchers examining some of the most transformative drugs in health care over the past 25 years find that private-sector R&D was crucial.[9] Chakravarthy et al. find private-sector R&D accounted for 73% of major milestones in drug development phases and 81% in the manufacturing phase.[10]

The benefits of R&D are widely felt. This is especially true for the pharmaceutical industry. Policymakers often believe that private capital has much in common with public capital, but private capital is much less predictable than government funding. As other countries have adversely experienced, private capital moves when conditions change or become unfavorable for investment. And when private capital moves, it takes with it new product introductions and infrastructure that cultivate advanced manufacturing capabilities and capacity.

5 Buxbaum, J. D., Chernew, M. E., Fendrick, A. M., and Cutler, D. M. (2020). Contributions Of Public Health, Pharmaceuticals, And Other Medical Care To US Life Expectancy Changes, 1,990–2,015: Study examines the conditions most responsible for changing U.S. life expectancy and how public health, pharmaceuticals, other medical care and other factors may have contributed to the changes. Health Affairs, 39(9), 1,546–1,556.

6 Wolfe R.; National Center for Science and Engineering Statistics. (2020). U.S. Businesses Reported $441 Billion for R&D Performance in the United States During 2018, a 10.2% Increase from 2017. NSF 20–316. Alexandria, VA: National Science Foundation.

7 *Ibid*

8 *Ibid*

9 Chakravarthy, R., Cotter, K., DiMasi, J., Milne, C. P., and Wendel, N. (2016). Public- and Private-Sector Contributions to the Research and Development of the Most Transformational Drugs in the Past 25 Years: From Theory to Therapy. Therapeutic Innovation & Regulatory Science, 50(6), 759–768.

10 *Ibid*

Consider how R&D works in the industry. R&D investment drives discovery that is initially protected by patents, but eventually, those discoveries come off-patent. This feature enables generic drugs to be brought to market safely and efficiently without harming the incentives to innovate. In other words, the pipeline for generic drugs is investment in the primary pharmaceutical industry.

Policy that restricts R&D investment can have real consequences. Cutting off investment in the industry can risk the future development of low-priced drugs. Because the industry reinvests significantly in R&D, public policy interventions that cut or curtail revenue are sure ways of reducing future investments. Cuts to innovative medicine development could hinder the generic pipeline. The pharmaceutical industry is inexplicably tied to our future—and in ultimately lowering the cost of that future.

In addition, the spillover from R&D materializes in other ways. R&D investment is an important fuel for future economic growth. R&D helps drive total factor productivity by increasing output per employee. But firms and industries are not able to capture fully the totality of the benefits from their R&D spending. In other words, a company's R&D spending will benefit not only that individual company but also more broadly all firms in the economy. Economic estimates suggest a 1% increase in R&D stock produces a 0.06% to 0.61% increase in economic output.[11]

The private sector leads the way when it comes to developing medicines, treatments and vaccines. Maintaining strong private-sector incentives and policies that allow the market to work unencumbered supports research and manufacturing activity in the United States. A company can spend years as a research operation in its nascent stages before it can mature, manufacture and market products for American and global customers. Years of expensive research does not always materialize into a final product. But the infrastructure established to achieve the goals of FDA-approved medicines yields additional economic dividends along the way. In other words, pharmaceutical research, drug development and manufacturing are not year-to-year endeavors. It takes decades to build systems, operations and suppliers around this complex enterprise, and these investments increase the capability and capacity of the entire country.

11 Congressional Budget Office. (2005). R&D and Productivity Growth. Congress of the United States, Washington, D.C. https://www.cbo.gov/sites/default/files/109th-congress-2005-2006/reports/06-17-r-d.pdf.

A Conversation with Merck Senior Vice President of Global Biologics and Sterile Operations Karin Shanahan

What makes the United States an attractive market for pharmaceutical manufacturing?

It really comes down to IP protection. We have intellectual property protection rights in the United States that you don't necessarily have elsewhere. IP is extremely valuable in terms of getting 20 years' worth of exclusive rights to a pharmaceutical agent. Hopefully, in that period of time, you're able to develop and commercialize the product, especially given the significant investments required to commercialize a product, because the period of exclusivity begins on the patent on the pharmaceutical agent, not the commercialization of the resulting product. IP is one of the strongest reasons that the United States is such an attractive market, and it helps to maintain a pipeline of innovative medicines.

Some of the fundamental things we look for in manufacturing include educated people, a good infrastructure, good utility infrastructure, and good road infrastructure. And you've got that in the United States. The one thing that you're missing in America is cost advantage. Pharmaceutical manufacturing is under tremendous pricing pressures. But when you start to factor in the total cost of production, the United States can be an appealing place to manufacture. You don't necessarily save on labor costs by going to low labor cost markets, unless you've got a very labor-intensive process, which, for the most part, pharmaceutical manufacturing is not anymore. We are fairly automated, and therefore the salary discussion doesn't hold as much weight as it did 20 years ago. Your cost for utilities is generally lower in the United States. And more importantly, your utilities are much more stable in the United States. When your utility infrastructure is lacking, there are potentially interruptions to manufacturing, which can cause the loss of batches.

Manufacturing technologies are becoming much more sophisticated. We are now running plants that are highly automated, and we need to have access to technicians who can run that automated equipment. It requires more than someone who can just stand on a line and push a button. We need individuals who can actually interact with fairly sophisticated equipment. We want educated people, we want good infrastructure, and we want great technology we can employ. More importantly, we want all of these things in a location where we can protect the intellectual property.

What are some of the lessons learned from the COVID-19 pandemic?

The pandemic made clear to governments the tremendous benefit of having a pharmaceutical supply chain within your borders. During COVID, we experienced supply chain interruptions that, frankly, threatened not only the COVID vaccine production but also other pharmaceutical products. Antibiotics are a good example. They haven't been manufactured in the United States for some time due to the cost of production. For that reason, they've been outsourced to China and India, predominantly. There's now a recognition on the part of the U.S. government that we may want to bring some of that back. We are engaging in conversations now with the government to figure out what would be needed to make antibiotic production viable in the United States.

"When you think about the patent life, which is usually 20 years, you chew up 10 years of that in development. By the time you launch a product, you only have 10 years left on your patent. There are roughly $1 billion spent on every product a pharma company develops, not all of which are able to be commercialized. Trying to recover that cost is a very important goal. It takes roughly ten years to take a product through the clinical trial process and scale it up for commercial production. In the end, once a product is approved for commercial use, and before the generic competitors enter the market, there are roughly 10-years to supply patients the innovator medicines."

What forces would move pharmaceutical manufacturing out of the United States?

The cost to manufacturing is becoming increasingly more important. These costs are driven, in part, by the tax rate. Cost is also driven by capital and cost of labor, both of which can be very expensive in the United States. But that gets weighed against other factors, such as IP protection. It is a conversation that we have quite often in pharma. How do you balance the cost of goods with IP protection? There are some countries we are unlikely to build a factory because there are no assurances that our IP will be protected. With newer technology, IP protection is very important, whether the IP is for the compound or the manufacturing processes. There are some countries in the world where you have that protection and other countries where you don't. The United States can differentiate itself from other countries by providing strong protection.

When it comes to pharmaceuticals, we often talk about the importance of the compound, but how important is the actual manufacturing process?

The underlying manufacturing process can be very important. And there is a tremendous amount of IP that goes into manufacturing pharmaceutical products. For example, for antibody-drug conjugates — a biopharmaceutical designed to treat cancer — the manufacturing process is actually very important. Also, the manufacturing process is very important when you look at how you link pharmaceuticals to how the medicine will be administered. For example, if the medicine requires an autoinjector, we often want to develop very unique autoinjectors so that they marry up with the product in a very unique way. The manufacturing process can also be very important in biologics if it's a unique, new biologic compound.

It's really the new processes — the cutting-edge processes — that you want to try to protect for as long as possible and keep that advantage. The environment in the United States has ensured up to this point that the cutting-edge manufacturing processes are staying in the country and not going elsewhere.

Why do we need clear control over the manufacturing process?

There are unscrupulous producers in countries that don't necessarily follow the same GMPs — good manufacturing processes — that reputable pharmaceutical companies follow. These are the processes that ensure that everyone producing the product is trained to produce that product, that the ingredients that go into that product are the correct ingredients, and that the product at the end of the day tests against the standard that was approved by the FDA. This ensures the drug that you're putting into your body is actually the drug that the FDA said, "Yes, it's efficacious, and it's safe."

Why should we care where medicines are manufactured?

In a world where wars breakout, pandemics breakout, and natural disasters occur, having certain drugs manufactured in your own backyard ensures you can continue to get those drugs. Those medicines would be things like antibiotics. They would include certain maintenance drugs like cardiovascular medicines. If the patients don't receive these medicines, they may die of disease or they may suffer health consequences due to their underlying conditions. Those are the drugs for which you want a more secure supply chain.

Talk about your workforce.

On the manufacturing side more and more, we require a high technical skill set. We are building a lot of relationships with university programs and with vocational school programs to help develop the workforce the industry needs moving forward. From high school onward, we are helping to train the next generation of manufacturing workers. Pharmaceutical manufacturing is becoming a very technical field. Think about semiconductors manufacturing and the kind of cleanroom environments that are required. Those are the manufacturing processes we are moving towards.

THE ECONOMIC CONTRIBUTIONS OF THE PHARMACEUTICAL INDUSTRY

This study begins by examining the direct contribution of the pharmaceutical and medicine manufacturing sector to the U.S. economy. From there, we go deeper and provide a more comprehensive view of the industry's contribution by including indirect and induced impacts. We start with an explanation of the methodology and key terms.

Methodology and Key Terms

This study begins by examining the direct contribution of the pharmaceutical and medicine manufacturing sector to the U.S. economy. From there, we go deeper and provide a more comprehensive view of the industry's contribution by including indirect and induced impacts. We start with an explanation of the methodology and key terms.

The calculated economic impacts presented in this study make use of input–output (IO) tools, also known as interindustry analysis. These tools can be used to estimate chains of effects that occur through the interrelationships between businesses, government and households. This analysis uses the 2019 IMPLAN database and model. All economic impacts are presented as inflation-adjusted 2019 dollars. All results are for calendar year 2019. Appendix C provides estimates of approximate impacts attributed to the pharmaceutical and medicine manufacturing industry in 2020. Three types of economic impacts are derived in this study:

1. **Direct Impacts**—Activity generated within the focus industry. In this case, pharmaceutical and medicine manufacturing activity drives the direct impact.
2. **Indirect Impacts**—Activity generated in other industries due to purchases (materials, energy and services) by the focus industry through the supply chain. For example, an automobile manufacturing firm might purchase tires, steel and electrical components to produce their final product.
3. **Induced Impacts**—Activity generated by purchases of households from income earned from direct and indirect production.

Using IMPLAN, we estimate the direct, indirect and induced impacts on the following:

1. **Employment**—People employed by an industry. Employment figures use the Bureau of Economic Analysis and the Bureau of Labor Statistics' full-time/part-time annual average for a given industry. The data cover both wage and salary employees and those who are self-employed.
2. **Labor Income**—Labor income,[12] a component of value added, is the sum of salary/wages and supplements. Supplements may take the form of employer contributions for employee pensions and insurance funds (such as health insurance) and employer contributions for government social insurance (social security). This concept also includes proprietor income.
3. **Value Added**—Value added may be considered the industry's contribution to GDP and represents the enhancement a manufacturer provides (e.g., assembly)

12 Clouse, C. (2021). Labor income. IMPLAN. https://support.implan.com/hc/en-us/articles/115009668468-Labor-Income.

to a product before offering it to the end consumer. Put another way, value added is the difference between the total revenue of an industry and the cost of intermediate inputs. Components of value added include employee labor compensation, taxes on production and imports and gross operating surplus (including profits).

4. **Output**—Output, in economic terms, refers to the total value of all goods and services an industry. This includes both intermediate demand (sales of intermediate inputs to other industries) and final demand.

IO analysis shows the interrelationships between industries. These interrelationships are illustrated through tables. The column of a table provides all the inputs of other industries used to produce that industry's product. The table columns identify the industries and final uses that the industry sells to, and in sum, these tables are used to calculate the indirect impacts of a given industry's production.

A *multiplier* can be viewed as the ratio of an impact or contribution over the original stimulus. For example, the multiplier of output would show the ratio of additional indirect and induced output generated, divided by the output of the focus industry. The larger a multiplier is for a given industry, the more efficient that industry is at distributing wealth throughout the entire economy.

Output measures include *double counting*. For example, the tire used to build a motor vehicle is counted both as the output of tires and the output of motor vehicles. This is important only if both are produced in the same study area. However, employment, labor income and value added are additive, not double counted. Many slices of value added contribute to the final value of a product or service.

Direct Impacts

Table 1 summarizes the direct economic impacts of pharmaceutical and medicine manufacturing and its subsectors. Total pharmaceutical and medicine manufacturing (NAICS 32541) activity contributes more than $154 billion in value added, accounting for 0.7% of U.S. GDP. The industry employs nearly 267,000 individuals. Pharmaceutical and medicine manufacturing employees earn $45.9 billion in labor income, which includes salaries, wages and other supplements. This equates to labor income of more than $172,000 per worker.

Table 1. Pharmaceutical and Medicine Manufacturing, Direct Impacts Summary
Units: Thousand Jobs and Billion $

NAICS Industry	Employment	Labor Income	Value Added	Output
325411 - Medicinal and botanical manufacturing	28.4	$4.4	$8.2	$18.7
325412 - Pharmaceutical preparation manufacturing	180.4	$32.6	$127.9	$284.6
325413 - In-vitro diagnostic substance manufacturing	24.7	$3.8	$6.2	$13.0
325414 - Biological product (except diagnostic) manufacturing	33.3	$5.1	$12.1	$22.6
32541 - Pharmaceutical and medicine manufacturing	266.8	$45.9	$154.4	$338.9

Figure 1. Components of Pharmaceutical and Medicine Manufacturing Employment
Units: Percentage

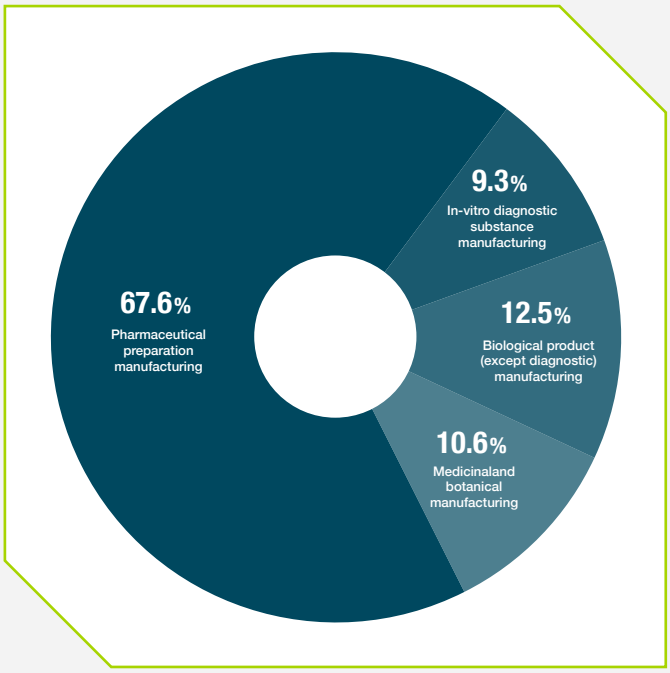


Figure 2 illustrates the industry's labor productivity. The aggregate pharmaceutical and medicine manufacturing industry generates almost $1.3 million in economic output per worker. This is nearly seven times greater than the U.S. economy's average output per worker ($188,000). Labor productivity was exceptionally high among workers in the pharmaceutical preparation manufacturing industry (NAICS 325412).

The pharmaceutical and medicine manufacturing industry generates almost $1.3 million in economic output per worker.

Figure 3 shows labor income per worker. Pharmaceutical and medicine manufacturing employees earn an average of more than $172,000 in labor income. This is roughly 2.7 times greater than the U.S. economy's average labor income ($64,500). It is also greater than many high-paying industries, including finance and insurance ($90,000), professional, scientific and technical services ($96,000) and management ($133,000).

Average labor income among pharmaceutical and medicine manufacturing workers is roughly 2.7 times the U.S. economy average.

Figure 2. Output per Worker
Units: Dollars

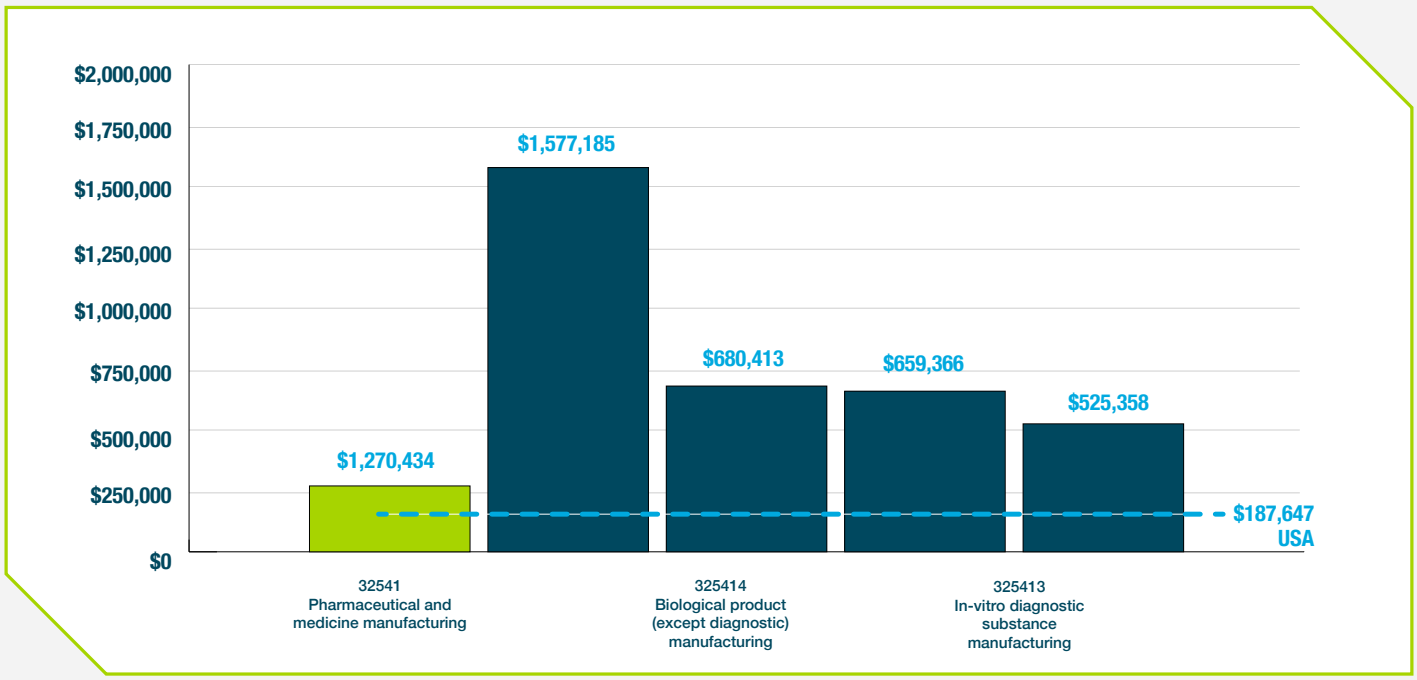
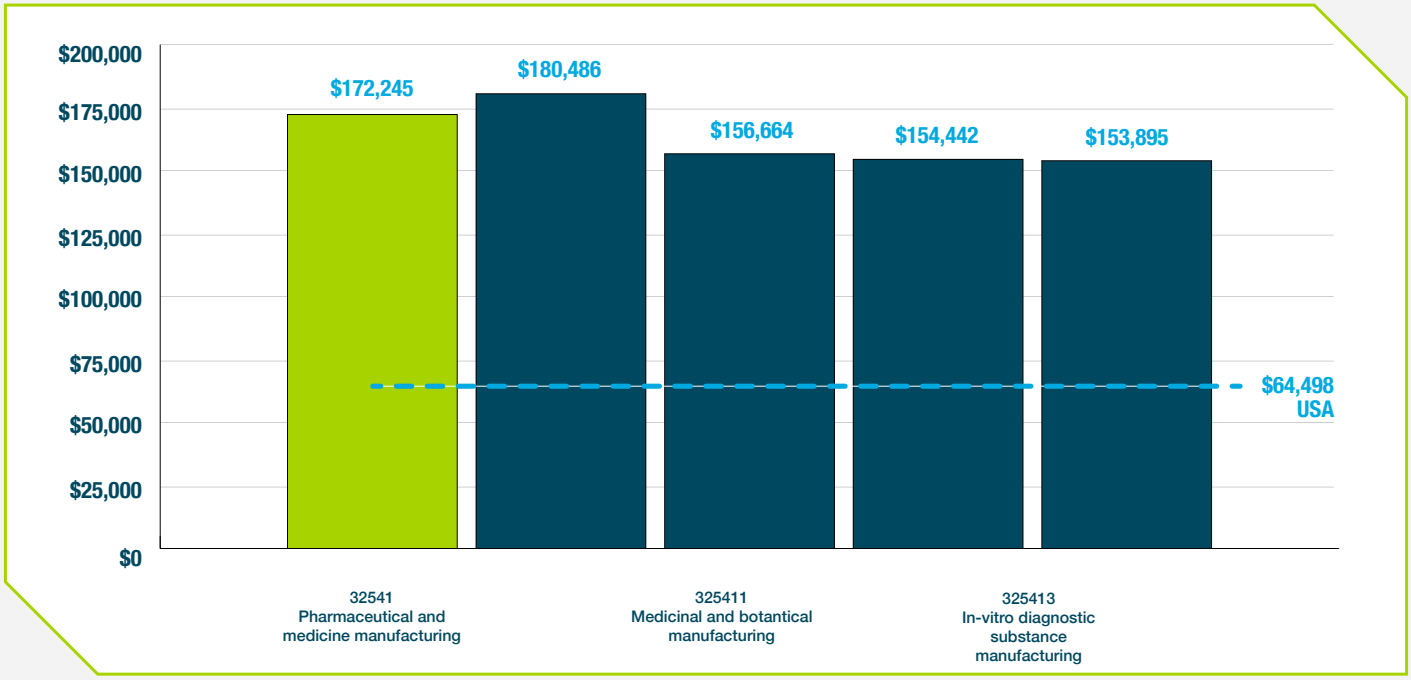


Figure 3. Labor Income per Worker
Units: Dollars



Indirect and Induced Impacts

The impact of the pharmaceutical and medicine manufacturing industry extends beyond the direct economic impacts described in the previous section. Output and jobs are also supported in supplier ("indirect") industries that provide components, materials, energy and various services to the industry. In addition, individuals employed by manufacturers and the associated supply chains earn income. A portion of these funds is used to purchase consumer goods and services, helping create jobs and support other industries. These impacts are known as induced effects.

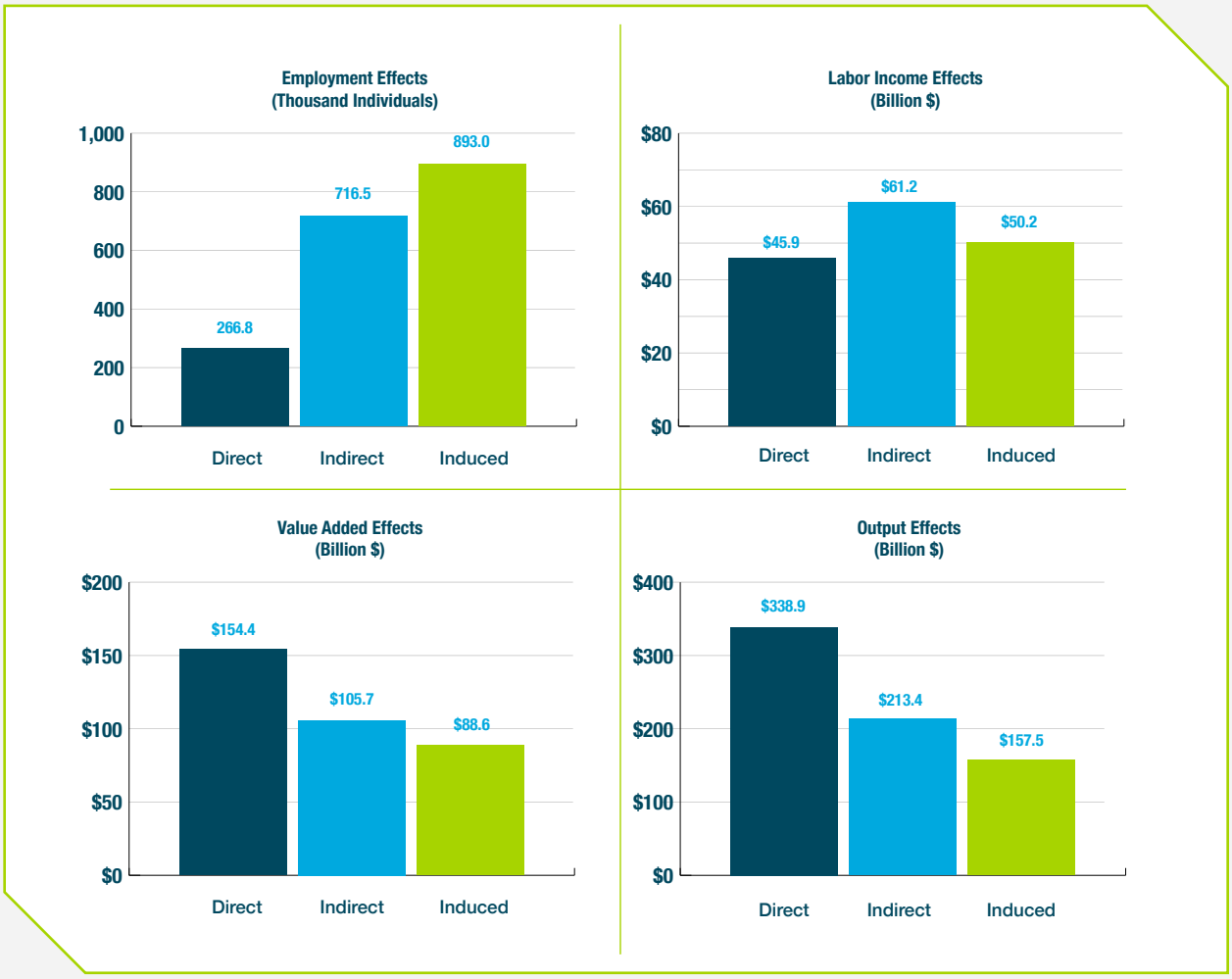
Pharmaceutical and medicine manufacturing directly employs nearly 267,000 people, generates more than $154 billion in value added and contributes nearly $339 billion in output. These numbers can be seen in the first row of Table 2. The direct activity helps generate indirect activity within the economy. These upstream suppliers, who provide inputs for manufacturers, employ more than 716,000 people and support more than $213 billion in economic output. Finally, a portion of the labor income earned by workers in the pharmaceutical and medicine manufacturing industry and their supply chains is spent on goods and services. This activity, seen in the third row of Table 2, supports an additional 893,000 workers and generates nearly $89 billion in value added. In total, pharmaceutical and medicine manufacturing activity contributes 1.9 million jobs, $157 billion in labor income, $349 billion in value added and $710 billion in economic output.

In total, pharmaceutical and medicine manufacturing activity helps contribute 1.9 million jobs and nearly $349 billion in value added.

Table 2. Pharmaceutical and Medicine Manufacturing (NAICS 32541) Total Impacts
Units Indicated

	Employment (1,000 Individuals)	Labor Income (Billion $)	Value Added (Billion $)	Output (Billion $)
Direct	266.8	45.9	154.4	338.9
Indirect	716.5	61.2	105.7	213.4
Induced	893.0	50.2	88.6	157.5
Total	**1,876.3**	**157.3**	**348.7**	**709.7**

Figure 4. Pharmaceutical and Medicine Manufacturing (NAICS 32541) Total Impacts
Units Indicated



Economic multipliers describe the ratio of the sum of indirect and induced impacts to direct impacts. Multipliers help us understand how well certain industries aid and positively influence other industries within the economy. The data shown in **Table 3** indicate that one pharmaceutical and medicine manufacturing job helps support six other jobs in the economy.[13] In addition, $1.00 of industry output generates $1.09 of output elsewhere in the economy.[14] The industry also helps drive income throughout the economy. For every $1.00 earned by an employee within the industry, a whopping $2.42 is earned by others elsewhere in the economy. Relative to their own income, workers within the pharmaceutical and medicine industry support economy-wide income better than almost any industry.

Table 3. Pharmaceutical and Medicine Manufacturing (NAICS 32541) Economic Multipliers
Units Indicated

	Employment	Labor Income	Value Added	Output
Economic Multiplier	6.03	2.42	1.26	1.09

As previously mentioned, the activity of pharmaceutical and medicine manufacturing companies stimulates business in industries upstream in the supply chain. This network of transactions helps support jobs and generates economic

13 Employment multiplier = (indirect employment + induced employment) / direct employment = (716.5 + 893.0) / 266.8 = 6.0
14 Output multiplier = (indirect output + induced output) / direct output = (213.4 + 157.5) / 338.9 = 1.09

output in a unique set of industries. **Table 4** describes *indirect* employment impacts by detailed industries. The largest affected industry is "management of companies and enterprises" (81,500 jobs). This industry helps support manufacturing firms by assisting in strategic or organizational planning. The second-largest industry, "wholesale – drugs and druggists' sundries" (54,000 jobs), supports the distribution of biological and medical products. Other top affected industries include "other real estate" (30,800 jobs), "employment services" (27,800 jobs) and "truck transportation" (25,400 jobs).

Table 5 showcases *indirect* output impacts by detailed industries. This list of industries is similar to the indirect employment in Table 4 but includes some unique sectors. Differences between Table 4 and Table 5 are due to varying labor productivity across industries. For example, industries that supply high-value (and relatively low labor intensity) feedstocks, such as "petrochemical manufacturing" ($8.6 billion) and "other basic organic chemical manufacturing" ($8.1 billion), are featured.

Table 4. Indirect Employment – Top 10 Industries
Units: 1,000 Individuals

Industry	Indirect Employment (1,000 Individuals)
Management of companies and enterprises	81.5
Wholesale - drugs and druggists' sundries	54.0
Other real estate	30.8
Employment services	27.8
Truck transportation	25.4
Advertising, public relations and related services	22.9
Couriers and messengers	18.4
Management consulting services	18.1
Warehousing and storage	16.9
Wholesale - other nondurable goods merchant wholesalers	16.6
All other Industries	404.1
Total Indirect Employment	**716.5**

Table 5. Indirect Output – Top 10 Industries
Units: Billion $

Industry	Indirect Output (Billion $)
Wholesale - drugs and druggists' sundries	40.8
Management of companies and enterprises	20.0
Petrochemical manufacturing	8.6
Other basic organic chemical manufacturing	8.1
Other real estate	6.2
Internet publishing and broadcasting and web search portals	6.1
Wholesale - other nondurable goods merchant wholesalers	5.3
Advertising, public relations and related services	4.2
Truck transportation	3.9
Petroleum refineries	3.6
All other Industries	106.6
Total Indirect Output	**213.4**

A Conversation with Nephron Pharmaceuticals CEO Lou Kennedy

What makes the United States unique?

The employment pool here is amazing. In South Carolina, where we are expanding our presence, we have three major research universities. In addition, we have a very healthy technical college school system. There is a technical college within 20 or 30 miles of any job site you could pick in this state.

We have 43 countries represented at Nephron. We have a workforce that is 53% female, and more than 35% of the Nephron workforce is African American. We know that a diverse population leads to the most productive workforce team. I believe because we have such strong university programs, we really brought much richer cultural heritage to the state, which allows us to hire a really diverse team for our workforce.

What does the factory of the future look like?

If we can use automation, and train folks to work on automation, rather than doing things with their hands, we can compete with the international market. Installing robotics and automation is not displacing the American worker. It increases the skill level of the American worker to enable them to team with robots. We're elevating the skill set of humans and teaching them about automation so we can compete with any country.

It is allowing us to innovate on the continuous manufacturing front so that you can go from API (active pharmaceutical ingredient) to finish dosage in one continuous process. So that's part of it. It's implementing automation, making the facilities that we have more flexible. The new wing we are building will have computers on wheels. We're eliminating that traditional brick-and-mortar look and moving to a more open flexible concept.

What will it take to keep the United States competitive?

I believe our schools are turning out the chemistry talent, microbiology talent and other talents that we need. If the government continues to support innovation in and around chemistry and Manufacturing 4.0, then we are setting ourselves up to be the same competitive America that we were at the turn of the century. The government can focus on encouraging that innovation here, and then we are setting ourselves up to be more competitive in manufacturing pharmaceuticals and devices here in America. COVID-19 encouraged all of us to look back here on our own home soil and do what's right for Americans and American patients. We can push our innovators to do greater things.

BUILDING AMERICA'S WORKFORCE OF THE FUTURE

Pharmaceutical manufacturing creates and depends on a highly skilled and productive workforce. Companies in the sector support nearly 267,000 well-paying jobs for American workers, with such employees averaging more than $172,000 in total labor income; this figure compares favorably with other sectors, such as retail ($37,000), construction ($66,000) and information ($134,000).

Strong Demand for Workers Now and in the Future

As the economy recovers from one of the worst recessions in history, pharmaceutical and medicine manufacturing is well positioned to help drive this recovery. An analysis of Burning Glass jobs data finds the pipeline for job openings in this sector is robust. More than 14% of manufacturing job openings through the first half of 2021 were for pharmaceutical and medicine manufacturing jobs. In fact, biopharmaceutical manufacturers posted more jobs than any other industrial sector through the first half of the year.

It is also worth noting that pharmaceutical and medicine manufacturing jobs are found across the distribution of education obtainment. The BLS estimates 46.5% of jobs in the industry are obtainable by individuals with a high school diploma or equivalent, and 4.2% of jobs require no formal educational credentials. The sector delivers both high-average labor income and opportunities for all education levels.

The pandemic created tremendous uncertainties that have both short- and long-term impacts. Long-term structural changes are just now coming to fruition. The extraordinary health crisis has likely changed the trajectory of job growth for the pharmaceutical and medicine manufacturing industry. The BLS recently estimated that employment in the industry will grow roughly 19% over the next decade—a sharp rise from the 5.4% growth projections prior to the onset of the pandemic.[15] While the Burning Glass data suggest industry job prospects are strong today, the future could be even brighter.

Creating Valuable STEM Jobs

STEM jobs are becoming even more important to a country's economic prosperity, especially as businesses become more technologically advanced and in a world where innovation plays such a crucial role in the nation's overall competitiveness. BLS estimates roughly 6.7% of the U.S. workforce has a STEM occupation,[16] but 29.9% of jobs in pharmaceutical and medicine manufacturing are STEM related.[17] In other words, nearly one in three jobs in the sector are STEM jobs. The pharmaceutical manufacturing sector employs more than four times the percentage of STEM workers who are employed in the overall economy. As such, these high-skilled and high-paid workers are crucial for the continued success of the sector.

These STEM workers help support the R&D-intensive nature of the industry. The NCSES estimates 22% of domestic pharmaceutical manufacturing jobs are related to R&D, far above other sectors of the economy.[18] For the rest of the economy, roughly 8% of jobs are focused on R&D. In other words, the share of R&D-focused jobs in the pharmaceutical manufacturing industry is nearly three times that of the rest of the economy.

15 U.S. Bureau of Labor Statistics. (2021). Employment projections in a pandemic environment. https://www.bls.gov/opub/mlr/2021/article/employment-projections-in-a-pandemic-environment.htm

16 U.S. Department of Labor. (2020). Occupational Employment and Wage Statistics.

17 *Ibid*

18 Wolfe R.; National Center for Science and Engineering Statistics. (2020). U.S. Businesses Reported $441 Billion for R&D Performance in the United States During 2018, a 10.2% Increase from 2017. NSF 20–316. Alexandria, VA: National Science Foundation. https://ncses.nsf.gov/pubs/nsf20316.

A Conversation with Andi Goddard, Global Head of Quality and Compliance, Pharmaceutical Technical Operations, Genentech and Roche

What drives pharmaceutical manufacturing?

Pharmaceutical manufacturing thrives in a diverse, collaborative and highly skilled environment facilitated by pioneering organizations, dedicated researchers and policies that encourage growth and investment. This carefully orchestrated ecosystem is essential to delivering our medicines safely, quickly and responsibly. It is important that this ecosystem evolves with science, and we tirelessly try to ensure this.

There are many places you could manufacture. Why is the U.S. a valuable manufacturing environment?

Genentech founded the biotech industry in 1976, establishing South San Francisco as the birthplace of biotechnology and a major biotech and life sciences hub. Over the past 45 years, we have significantly expanded our footprint across the United States, with considerable investments in R&D, manufacturing and distribution sites. Today, we have five manufacturing and distribution sites across the country, including one of the largest manufacturing facilities in the world in Vacaville, California, and our new state-of-the-art individualized therapies facility in Hillsboro, Oregon. With this footprint, Genentech is a net API exporter and a main source of biologic API production for Roche globally. And we continue to grow—over the past few years alone, we have invested $4 billion in infrastructure.

Our commitment to a strong U.S. manufacturing presence has been enabled by historically strong IP, regulatory and tax policies, as well as a robust pool of talent, including scientists, researchers and other highly skilled workers. As a result, the U.S. has become a hub for investment, innovation, growth and global leadership in the biopharmaceutical sector.

With careful attention to these and other factors, this environment offers a sustained competitive advantage for the U.S. However, several threats loom, including weakening IP protections, as well as several legislative proposals that, combined, would significantly increase taxes and make the U.S. less competitive with other economies for R&D and drug manufacturing. Thoughtful policymaking, particularly in an age of increasing manufacturing complexity and global competition, is critical to a flourishing industry.

Talk about the benefit local pharmaceutical manufacturing in the U.S. brings to education?

Genentech operates five manufacturing and distribution sites in the United States, which span three states: California, Oregon and Kentucky. We partner with local organizations to address critical issues relevant to the communities where Genentech is located. We support K-12 STEM programs where we have a site to support a more diverse and inclusive pipeline of talent in STEM.

Earlier this year, Genentech and the Genentech Foundation invested $3.2 million and partnered with the Stanford d.school to launch Reach for the Upside, an initiative to help Northern California public school districts and their community partners leverage the learnings of the COVID-19 era to reimagine education through human-centered design thinking.

"Our commitment to a strong U.S. manufacturing presence has been enabled by historically strong IP, regulatory and tax policies, as well as a robust pool of talent, including scientists, researchers and other highly skilled workers. As a result, the U.S. has become a hub for investment, innovation, growth and global leadership in the biopharmaceutical sector."

As an extension of the Genentech Foundation's commitment to building more equitable post-secondary educational pathways in STEM, we partner with local colleges and universities to provide direct financial assistance to low-income college students. Funds are also earmarked to ensure that at-risk students—especially incoming freshmen—have the additional resources they need to succeed against the backdrop of enhanced financial, emotional and academic challenges posed by the pandemic.

Genentech is reimagining how biotechnology is taught and designing a new open-access digital biotech curriculum with potential to reach 2 million high school students in California by 2026. We're committed to creating a science teacher incubator model to support, grow and retain more than 750 California teachers by 2026 through a Genentech biotech teacher training and credentialing program, teacher stipends and the development of professional learning communities. In 2015, we launched Futurelab, a STEM education initiative that now supports all 9,000 K-12 students in the South San Francisco Unified School

District with an investment that totals $32.5M and nearly 65,000 employee volunteer hours. This gets students excited to learn about science, improves their college readiness and inspires them to pursue careers in STEM fields. In 2019, we partnered with the San Diego STEM Ecosystem and other local organizations to start the San Diego STEM Role Model and Workforce Development Initiative to provide mentorship and career development for underrepresented students in STEM.

Can you talk about the importance of IP protection?

The existence of robust IP protections makes it possible for health care companies to identify, develop and deliver innovative solutions to some of the world's most prevalent and challenging health issues. The development of new medicines demands tremendous financial investment, many years of intensive effort and a willingness to accept significant risk. On average, only one to two of every 10,000 molecules complete the journey from lab bench to bedside. Biologics R&D can be even riskier than small molecule drug development. By providing time-limited but necessary protections, patents give innovators the degree of certainty they need to continue to invest in the future and turn science into breakthrough medicines that extend life, or even new medicines that simply improve the lives of patients. It is fair to say that, if there was no IP protection, there would be much less innovation and many fewer new medicines brought to market each year. Because the new medicines of today are the generics of tomorrow, absent strong patent protection, we will see even fewer new generics. Speaking of tomorrow, there are still many diseases that lack proper treatment, like Alzheimer's disease, many neurological disorders and countless untreated forms of cancer, and proper patent protection is essential to incentivize continued R&D for the development of new medicines to address those unmet needs of patients.

COMMUNITY IMPACT

Developing medications is not the only way that pharmaceutical companies improve the quality of human life. Pharmaceutical companies engage with both their local and global communities in a range of ways. But two areas of focus closely related to their industry are in 1) providing access to medications to low-income patients and 2) investing in STEM education programs to help nurture interest in science-related fields.

Expanding STEM Education Opportunities

Pharmaceutical companies have also invested heavily in education programs, especially when it comes to helping develop the next generation of scientists. In 2018, the Biogen Foundation made a $10 million investment in STEM education in the Boston area. Its initiative, dubbed STAR (science, teacher support, access, readiness), has emphasized racial equity.

One of its grantees, Breakthrough Greater Boston, serves more than 400 students; nearly 70% of its teaching fellows are teachers of color. Genentech has invested more than $20 million in an initiative called The Resilience Effect, aimed at advancing the health and well-being of Bay Area Children and families, with a goal of positively affecting the lives of 100,000 low-income children and families. Another grantee, uAspire, helped nearly 400 high school seniors with financial aid and financial planning. More than three-quarters of uAspire students in 2019 enrolled in college versus slightly more than half in similar schools nationwide. And four out of five of the 444 middle school students who participated in Citizens Schools' Expanded Learning Time program expressed interest in a STEM career.

In addition to sponsoring middle school, high school and college teams in the FIRST Robotics competition, Bristol Myers Squibb maintains Centers for Science Teaching and Learning at two universities in New Jersey and one in Connecticut. It also provides an annual grant to encourage recruitment of minority students for careers such as bioprocess engineering and biotechnology, and it works with Rutgers University 4H on a series of programs dubbed Tomorrow's Innovators.

Blossoming Public–Private Partnerships Are Expanding Local Life Science Programs

A number of life science programs are blossoming in regions with burgeoning biotech clusters. NCBioImpact is a first-of-its-kind collaboration between private companies and public institutions. The result is an internationally recognized training program that lets students at the University of North Carolina System and the North Carolina Community College System get hands-on experience with equipment and techniques employed by pharmaceutical manufacturers.

Another successful initiative is BioTrain, a partnership between government, nonprofits, biotech companies and Montgomery College, a community college based in Maryland. BioTrain provides short workshops designed to equip workers already in the industry with foundational skills to help them advance their life science careers. The workshops are free to individuals already working in the industry and are taught by industry experts who can provide actionable insights.

A final example is the Massachusetts Life Sciences Center. In 2008, Massachusetts made a $1 billion, 10-year commitment to strengthen the state's life sciences industries. The MLSC is a quasi-public agency of Massachusetts tasked with expanding employment opportunities in the commonwealth. Over the past decade, MLSC has co-invested with both public and private stakeholders to achieve a number of objectives designed to strengthen the local industry.

Canada: A Cautionary Tale

In 1969, the Canadian government altered the country's Patent Act to allow for compulsory licensing. "Under this system, a manufacturer of generic drugs could produce in Canada a drug newly patented in the United States or another country simply by notifying the patentee and paying a fixed four percent royalty fee."[19] While the policy helped to lower some drug prices in Canada, it also stymied economic output and, perhaps most importantly, domestic R&D investment in new medicines.

In 1983, the federal minister of consumer and corporate affairs called for a rebalancing of the 1969 policy to drive growth in the pharmaceutical industry. By 1987, Bill C-22 was passed, amending Canada's Patent Act and making significant changes to the country's compulsory licensing system. In subsequent years, further reforms were made as Canada modified the Patent Act and implemented the Agreement on Trade-Related Aspects of Intellectual Property Rights and the North American Free Trade Agreement provisions on IP.

In the years that followed, R&D investment increased notably. "Before the passage of Bill C-22, R&D spending in Canada as a percentage of sales was below five percent."[20] R&D spending from 1988 to 2002 increased from $165.7 million to $1.198 billion. By 2002, R&D investment as a percentage of sales increased to 9.9% after reaching a historic high of 11.7% in 1995.[21]

But these economic gains would be short-lived. In the 2000s, the Canadian government grew excessively aggressive on pricing. At the same time, the Canadian Federal Courts began invalidating entire patents based on "The Promise Doctrine." To meet the Patent Act's requirement that an invention be "useful," all uses "promised" in a patent's specification had to be demonstrated or soundly predicted by the filing date. If the patentee failed to do this, the entire patent could be invalidated.

The Supreme Court of Canada reversed The Promise Doctrine in a landmark decision in 2017, but the damage was done. After growing more than 600% between 1988 and 2002, R&D investment in Canada fell more than 25% over the ensuing 20 years. In 2019, total R&D expenditures were $893.2 million. Canada today is a large net importer of IP, and just 3.9% of total sales is allocated to R&D, the lowest level since data have been available.[22]

Canada continues to pursue policies that curtail domestic pharmaceutical investment. Most recently, Canada moved to lower drug prices and create further marketplace uncertainty. The country's Medicine Prices Review Board is a quasi-judicial agency that sets the maximum price pharmaceutical companies can change for drugs within Canada. Currently, the MPRB uses a list of comparison countries to set price thresholds, and forthcoming rule changes will adjust the reference countries to exclude some jurisdictions, including Switzerland and the U.S., which, in turn, will drive maximum allowable prices down in Canada. This change means some new innovative medicines will not be available at all in Canada.

Reimbursement times in Canada—how long it takes to get listed on a drug plan so that the product can be available to patients—are extremely slow compared to the U.S. and to many OECD nations. This erodes patent exclusivity periods for innovative companies operating in Canada and is also detrimental to Canadian patients, who have to wait longer for access to new treatments.[23]

Canada has created an unpredictable biopharmaceutical regulatory regime, and this uncertainty has led pharmaceutical companies to move capacity elsewhere. This was extremely clear when the COVID-19 pandemic began. It became evident that Canada lacked the domestic capacity and capability to produce mRNA COVID-19 vaccines. While Canada does have older technologies to produce vaccines for illnesses such as seasonal flus, the country had to import COVID-19 vaccines from facilities in Belgium and elsewhere.

Canada offers a cautionary tale for countries that think pharmaceutical capacity can grow or persist in the face of poor public policy. There are clear, long-term negative consequences when a nation does not place strategic value in critical parts of its manufacturing industry.

19 Christina Del Valle, Intellectual Property Provisions of the NAFTA, 4 No. 11 J.PROPRIETARY RTS. 8 (1992).
20 N. Lalitha. (2005). Review of the Pharmaceutical Industry of Canada. Economic and Political Weekly, 40(13), 1355-1362.
21 Patented Medicine Prices Review Board: Annual report 2019. PMPRB, Ottawa.
22 Schwanen, Daniel and Jacobs, Aaron, Patents, Copyright and Competition: Assessing the Impact of Trade Deals on Canada (March 30, 2017). C.D. Howe Institute Commentary 474.
23 http://innovativemedicines.ca/resources/pcpa-trends-update/#timeline

THE FUTURE OF PHARMA

For all that we have achieved, the road is long to a world without illness. Of about 7,000 rare diseases, only 5% have an available treatment. To meet the challenges of future drug discovery, pharmaceutical companies will need to invest in a range of transformative technologies. Indeed, a rich variety of emerging technologies have the potential to enhance the industry's progress in efficiently discovering new medications.

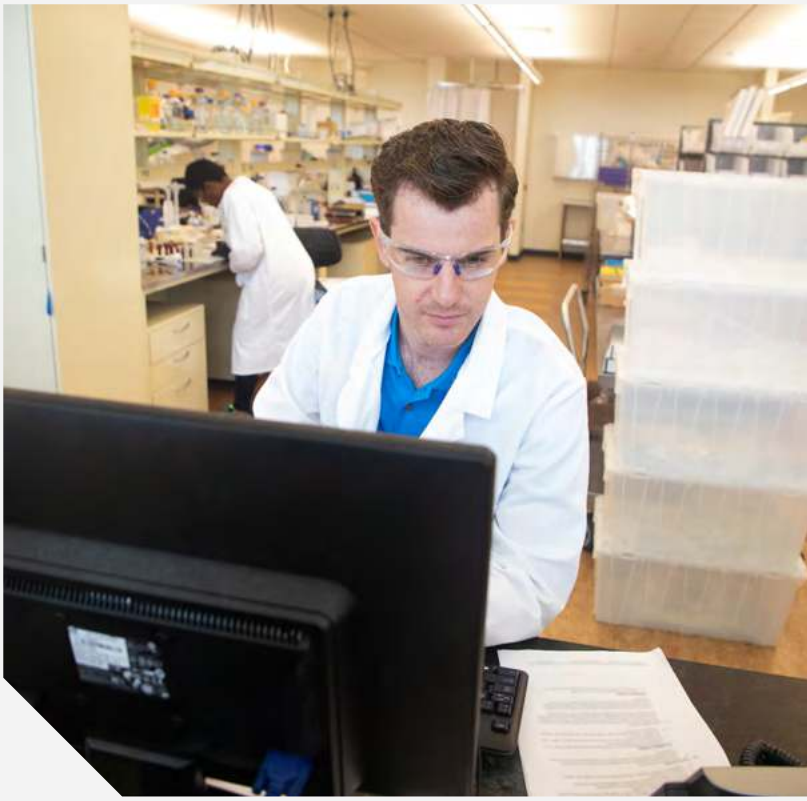
Primary among these is artificial intelligence. This technology's ability to analyze vast amounts of data efficiently is poised to become an invaluable component of the drug discovery process. It can be deployed early in the research process to pick molecular compounds more likely to prove effective, or later in the process to improve biomarker discovery and outlier identification and develop synthetic control arms that address the shortage of candidates for clinical trials by modeling patients in the control group based on a range of data. Longer term, the unique data processing needs of drug discovery make the problem a particularly suitable target for quantum computing.

Telemedicine can also be applied to the clinical trial phase to collect qualitative feedback from patients. And data from devices such as wearables identified with the Internet of Things have the potential to assist in efforts to collect real-world data and real-world evidence in response to how patients of clinical trial participants are reacting to medications over time.

Other opportunities include using software to share synthetic versions of confidential patient data to allow modeling, analysis and sharing without compromising patient privacy, as well as advancing personalized medicine by simulating the effects of drugs on individuals based on scientific literature, resulting in better predictions about effectiveness, safety and drug interactions. One startup is even working to create personalized cancer treatments based on identification of individuals' T-cell antigens. Blockchain technology also holds promise for protecting the transfer of patient and IP data with smart contracts helping to ensure secure and efficient sharing of sensitive information among industry stakeholders.

The pandemic forced many industries to explore remote collaboration in new ways. This was true for the pharmaceutical industry as well. In the future, extended reality promises to improve collaboration among remote research teams by enabling visualizations that provide a new degree of realism in areas in both research—envisioning molecular and protein variations— and manufacturing. Extended reality will be used to help train the next generation of employees, ensuring they are among the most competent workers in the world.

Another technology that can lend much to pharmaceutical advancement is additive manufacturing. 3D printing has been used to print human tissue or cells, which can be valuable in testing drug development. Additive manufacturing can also be applied to creating small batches of tablets for individualized medicines and clinical trials.



Continuous manufacturing is another major initiative that has the potential to transform how medicines are produced. Today, pharmaceutical manufacturing relies heavily on batch manufacturing, which involves manufacturing pharmaceuticals in multiple, sequential steps. At the end of each stage, production stops as the process moves to the next step. In some instances, these later stages might even be performed in other locations, requiring in-process pharmaceuticals to be moved to new locations. This can place weeks, or even months, between stages of production. In addition to the risk of material degradation and the length of

time it takes to produce medicines, it is difficult to scale production with batch processing. Continuous manufacturing reduces pharmaceutical manufacturing costs, shortens production times, improves quality and monitoring and creates an agile, flexible, scalable production environment. The FDA is one of the strongest proponents of continuous manufacturing.

These represent just some of the ways the pharmaceutical industry will step up its investments in the coming years and, in turn, keep the United States at the leading edge of health care innovation.

The pharmaceutical industry plays an essential role in the lives of American citizens and the U.S. economy. It produces goods that have the potential to enhance or even save the lives of consumers. In addition, these firms help support the United States' reputation as a leader in advanced manufacturing and are a valuable contributor to the nation's economy.

Pharmaceutical and medicine manufacturing generates nearly $339 billion in output and contributes 0.7% to U.S. GDP. Firms directly hire nearly 267,000 workers and provide almost $46 billion in labor income.

Industry employees are highly productive ($1.3 million output per worker) and well paid ($172,000 in labor income per worker).

The industry's contribution to the economy grows in significance when upstream supply chain (indirect) and income-related (induced) effects are considered. In total, pharmaceutical and medicine manufacturing firms help support nearly 1.9 million jobs and $710 billion in economic output. One job in the pharmaceutical industry helps support six other jobs in the nation's economy. In addition, $1.00 in pharmaceutical and medicine manufacturing output generates $1.09 in output elsewhere in the economy.

This all could be jeopardized by one wrong policy move. So, to avoid that risk and ensure a healthier future, policymakers would be well advised to double down on the policy and economic climate that has for decades fostered world-leading pharmaceutical innovation in the United States. If it chooses, the U.S. can continue to lead the world, discovering cures and saving lives.

APPENDIX A. DETAILED INDUSTRY DESCRIPTIONS

NAICS 32541 – Pharmaceutical and Medicine Manufacturing

- https://www.census.gov/naics/?input=32541&year=2017&details=32541
- "This industry comprises establishments primarily engaged in one or more of the following: 1) manufacturing biological and medicinal products; 2) processing (i.e., grading, grinding and milling) botanical drugs and herbs; 3) isolating active medicinal principals from botanical drugs and herbs; and 4) manufacturing pharmaceutical products intended for internal and external consumption in such forms as ampoules, tablets, capsules, vials, ointments, powders, solutions and suspensions."

NAICS 325411 – Medicinal and Botanical Manufacturing

- https://www.census.gov/naics/?input=32541&year=2017&details=325411
- "This U.S. industry comprises establishments primarily engaged in 1) manufacturing uncompounded medicinal chemicals and their derivatives (i.e., generally for use by pharmaceutical preparation manufacturers) and/or 2) grading, grinding and milling uncompounded botanicals."

NAICS 325412 – Pharmaceutical Preparation Manufacturing

- https://www.census.gov/naics/?input=32541&year=2017&details=325412
- "This U.S. industry comprises establishments primarily engaged in manufacturing in-vivo diagnostic substances and pharmaceutical preparations (except biological) intended for internal and external consumption in dose forms, such as ampoules, tablets, capsules, vials, ointments, powders, solutions and suspensions."

NAICS 325413 – In-Vitro Diagnostic Substance Manufacturing

- https://www.census.gov/naics/?input=32541&year=2017&details=325413
- "This U.S. industry comprises establishments primarily engaged in manufacturing in-vitro (i.e., not taken internally) diagnostic substances, such as chemical, biological or radioactive substances. The substances are used for diagnostic tests that are performed in test tubes, petri dishes, machines and other diagnostic test-type devices."

NAICS 325414 – Biological Product (Except Diagnostic) Manufacturing

- https://www.census.gov/naics/?input=32541&year=2017&details=325414
- "This U.S. industry comprises establishments primarily engaged in manufacturing vaccines, toxoids, blood fractions and culture media of plant or animal origin (except diagnostic)."

APPENDIX B. DETAILED ECONOMIC IMPACTS

This section provides detailed economic impacts for each of the four industry segments in the aggregate pharmaceutical and medicine manufacturing industry (NAICS 32541). These impacts sum to the figures presented in **Table 2**.

Table 6. Medicinal and Botanical Manufacturing (NAICS 325411) Total Impacts
Units Indicated

	Employment (1,000 Individuals)	Labor Income (Billion $)	Value Added (Billion $)	Output (Billion $)
Direct	28.4	4.4	8.2	18.7
Indirect	42.1	3.4	6.1	12.2
Induced	65.3	3.7	6.5	11.5
Total	**135.8**	**11.5**	**20.8**	**42.4**

Table 7. Pharmaceutical Preparation Manufacturing (NAICS 325412) Total Impacts
Units Indicated

	Employment (1,000 Individuals)	Labor Income (Billion $)	Value Added (Billion $)	Output (Billion $)
Direct	180.4	32.6	127.9	284.6
Indirect	621.0	53.3	91.2	185.3
Induced	715.4	40.2	71.0	126.1
Total	**1,516.9**	**126.0**	**290.1**	**596.0**

Table 8. In-Vitro Diagnostic Substance Manufacturing (NAICS 325413) Total Impacts
Units Indicated

	Employment (1,000 Individuals)	Labor Income (Billion $)	Value Added (Billion $)	Output (Billion $)
Direct	24.7	3.8	6.2	13.0
Indirect	26.2	2.2	3.9	7.7
Induced	50.0	2.8	5.0	8.8
Total	**100.8**	**8.8**	**15.1**	**29.5**

Table 9. Biological Product (Except Diagnostic) Manufacturing (NAICS 325414) Total Impacts
Units Indicated

	Employment (1,000 Individuals)	Labor Income (Billion $)	Value Added (Billion $)	Output (Billion $)
Direct	33.3	5.1	12.1	22.6
Indirect	27.2	2.3	4.4	8.2
Induced	62.4	3.5	6.2	11.0
Total	**122.8**	**11.0**	**22.7**	**41.8**

APPENDIX C. ESTIMATED IMPACTS THROUGH 2020

This section uses Census M3[24] (manufacturers' shipments, inventories and orders) data to provide a rough estimate of impacts attributed to the pharmaceutical and medicine manufacturing industry in 2020. **Table C-1** is a copy of **Table 2** from Section 3 and is printed here for comparison.

Table 10. Pharmaceutical and Medicine Manufacturing (NAICS 32541) Total Impacts, 2019
Units Indicated

	Employment (1,000 Individuals)	Labor Income (Billion $)	Value Added (Billion $)	Output (Billion $)
Direct	266.8	45.9	154.4	338.9
Indirect	716.5	61.2	105.7	213.4
Induced	893.0	50.2	88.6	157.5
Total	**1,876.3**	**157.3**	**348.7**	**709.7**

Table C-2 shows impacts that have been inflated using the growth rate of shipments of pharmaceutical and medicine manufacturing products between 2019 and 2020.[25] These impacts are not based on historical data. Instead, these rough estimates assume that all upstream supply chain and consumption patterns are identical between 2019 and 2020. In addition, it does not consider other important factors, such as productivity growth.

Table 11. Pharmaceutical and Medicine Manufacturing (NAICS 32541) Total Impacts, 2020 (Estimated)
Units Indicated

	Employment (1,000 Individuals)	Labor Income (Billion $)	Value Added (Billion $)	Output (Billion $)
Direct	293.7	50.6	170.0	373.2
Indirect	789.0	67.4	116.4	235.0
Induced	983.4	55.3	97.6	173.4
Total	**2,066.1**	**173.2**	**384.0**	**781.5**

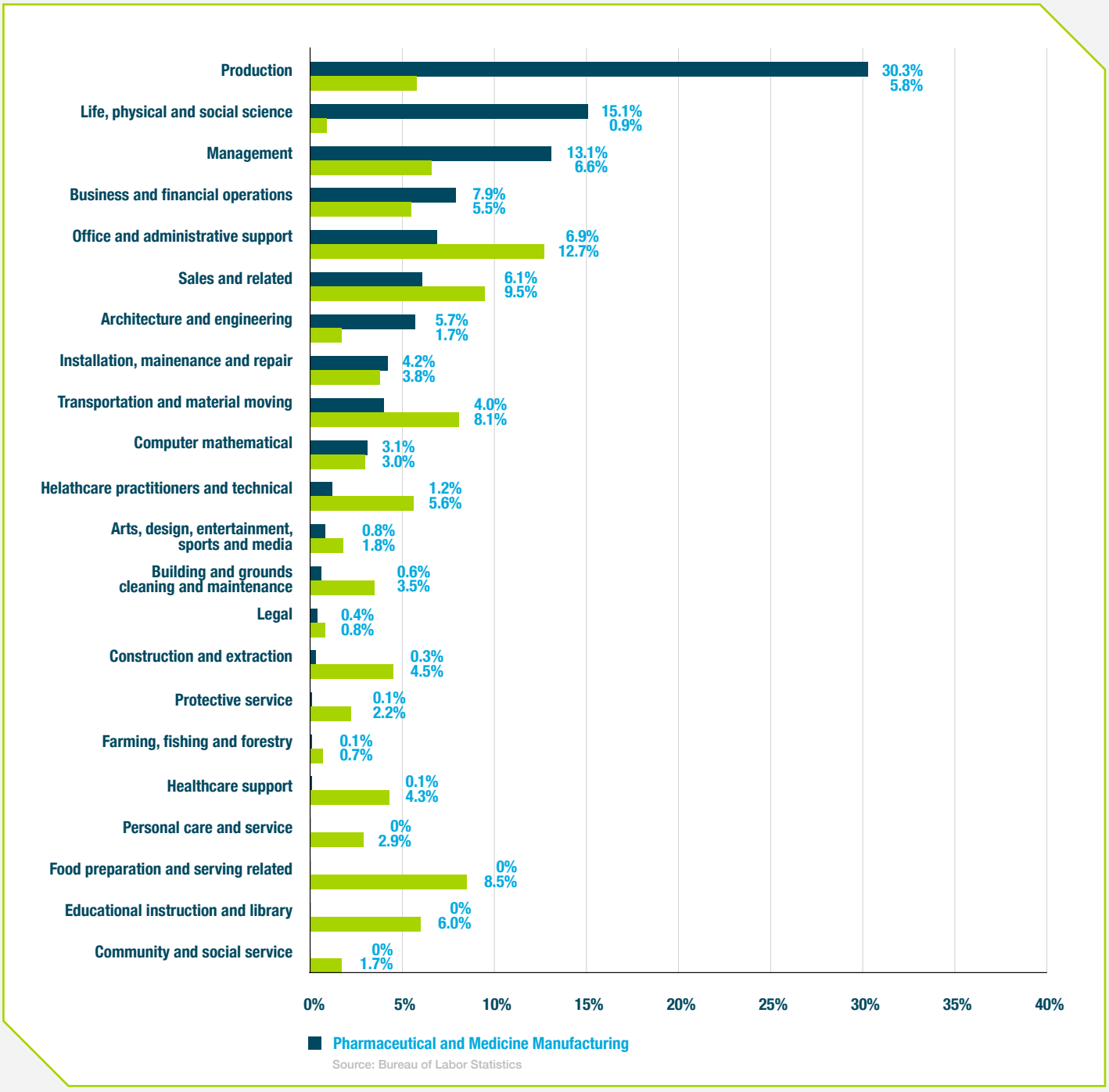
24 More information about the Census M3 dataset can be found at **https://www.census.gov/manufacturing/m3/index.html.**

25 U.S. Census Bureau. (2021). Business and Industry: Time Series/Trend Charts. **https://www.census.gov/econ/currentdata/dbsearch?program=M3&startYear=2010&endYear=2021&categories=25B&dataType=VS&geoLevel=US&adjusted=1&submit=GET+DATA&releaseScheduleId=**.

APPENDIX D. OCCUPATIONAL BREAKDOWN

Figure D-1 compares occupations for pharmaceutical and medicine manufacturing (NAICS 32541) versus overall U.S. employment in 2019. Pharmaceutical and medicine manufacturing is disproportionately overrepresented among the following occupation categories: production; life, physical and social science; management; business and financial operations; architectural and engineering; installation, maintenance and repair; and computer and mathematical.

Figure 5. Occupational Breakdown



Source: Bureau of Labor Statistics

About the National Association of Manufacturers

The National Association of Manufacturers is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. The NAM is the powerful voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

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