



Playing Fiddle While the World Burns: The \$16 Billion Dollars the Biden Administration *Hasn't* Used to End the Pandemic

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Summary

Production capacity for COVID-19 vaccines remains woefully insufficient to meet global vaccine demand, precluding vaccine access to many countries around the world until 2023 or later. U.S. government funding of manufacturing capacity in 2020 was essential to ensuring the United States was able to rapidly secure enough doses for its population – and could similarly be used to build vaccine manufacturing capacity that could rapidly meet global demand for COVID-19 vaccines. The purpose of this short memorandum is to estimate the amount of money that the Biden Administration has spent on increasing vaccine production capacity since its inauguration, as well as the level of resources allocated by Congress for this purpose, but which have not yet been spent. The memo concludes with a set of recommendations that this administration can begin immediately implementing

First, an analysis of publicly available metadata for all federal government spending events between January 21, 2021 and June 21, 2021 was conducted that identified 45 spending events associated with COVID-19 Disaster Emergency Funding Codes (DEFCs) and relevant North American Industrial Classification System (NAICS) codes for vaccine production and related industrial activity. To date, only \$145 million in spending by the Biden Administration for activities possibly related to increasing vaccine manufacturing capacity was identified representing a dramatic decrease from the multi-billion-dollar investments made by the Trump Administration for manufacturing capacity. *Second*, analysis was conducted on all spending associated with the American Rescue Plan Act (ARPA), which appropriates \$16.05 billion for manufacturing or procurement of vaccines, drugs, diagnostics, and personal protective equipment, to determine how much of the appropriated money has been spent. This analysis found that only \$12.043 million (0.09%) of the \$16.05 billion in ARPA appropriated for manufacturing has been spent so far on vaccine-related manufacturing activities. Even assuming appropriations for the recently announced small molecule COVID-19 therapeutic program and Pfizer mRNA vaccine donation derived funds exclusively from the relevant sections of ARPA, at least \$10.05 billion would be available for manufacturing scale up. This analysis assumes that those funds have not been spent on other statutorily authorized activities.

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The Biden's Administration apparent failure to continue adequate investment in scaling vaccine manufacturing capacity is inexplicable given the current crisis in global vaccine access. Unspent Congressional appropriations appear more than sufficient to build mRNA vaccine production capacity in 6 months that would be sufficient to vaccinate the entire world in a single year (16 billion dose per year capacity).

Introduction

The failure to scale production of highly effective COVID-19 vaccines for global access has resulted in continued mass death and widespread transmission of SARS-CoV-2. More people have died from COVID-19 since the phase 3 results of the Pfizer/BioNTech mRNA vaccine were announced in November than in the entire pandemic before. The current state of the pandemic is almost impossible to contemplate, as of August, 25 2024, the number of daily deaths were estimated at more than 29,000 a day – more than one death every 3 seconds. Similarly, the rate of viral transmission is stunning, more than 7.5 million new infections are estimated to occur each day – more than 85 new transmissions *per second*.¹

This represents not only a profound humanitarian disaster, but also a clear and present danger to the national security of the United States. With many countries unlikely to have widespread access to vaccines until 2023, continued transmission of SARS-CoV-2 increases the risk of variants evolving that undermine the ability of even our most potent vaccines to maintain population level epidemic control. Indeed, preliminary information regarding the B.1.617.2 or “Delta” variant shows that it is dramatically more transmissible than other variants of the virus², and may reduce the ability of existing vaccines to prevent COVID-19 disease.^{3 4}

Despite this emergency, the Biden Administration has yet to develop a comprehensive plan to ensure global vaccination. The actions announced to date; donations of approx. 500 million doses (enough to cover 250 million people – less than a *thirtieth* of the global population) by

¹ University of Washington, Institute of Health Metrics and Evaluation (IHME). COVID-19 Projections. URL: <https://covid19.healthdata.org/global?view=cumulative-deaths&tab=trend> (Accessed on 25 Aug 2021)

² See e.g. Campbell Finlay, et al. Increased transmissibility and global spread of SARS-CoV-2 variants of concern as at June 2021. *Euro Surveill.* 2021;26(24):pii=2100509. <https://doi.org/10.2807/1560-7917.ES.2021.26.24.2100509>

³ See e.g. Hoffman M et al. SARS-CoV-2 variant B.1.617 is resistant to Bamlanivimab and evades antibodies induced by infection and vaccination. *bioRxiv* 2021.05.04.442663; doi: <https://doi.org/10.1101/2021.05.04.442663>

⁴ Israeli Ministry of Health. הודעת משרד הבריאות*: הסבר מועילות החיסון נגד נגיף הקורונה בישראל (Ministry of Health announcement: * Explanation of the usefulness of the vaccine against the corona virus in Israel *) URL: <https://www.gov.il/he/departments/news/06072021-04>

mid-2022 of Pfizer\BioNTech's mRNA vaccine⁵ and efforts to scale Johnson and Johnson's vaccine by facilitating a manufacturing agreement with Merck & Company⁶, remain woefully insufficient to meet this problem.

The global vaccine supply is likely to further deteriorate if we need to manufacture new versions of existing vaccines that may be resistant to new viral variants or if individuals who had been previously vaccinated with two doses require additional dosing ("boosting"). This poses an additional challenge to the global COVID-19 vaccine supply. The nearly or entirely cell-free production process of mRNA vaccines are uniquely well suited to rapidly – estimated to take less than 100 days -- transitioning commercial scale production from an older version of a vaccine to a new version targeting a new viral variant. This is unique to mRNA vaccines – COVID-19 vaccines relying on other platforms (i.e., adenovirus vectored vaccines, protein subunit vaccines & inactivated vaccines) which are highly dependent on eukaryotic cell culture processes for drug substance production, take much longer to transition industrial capacity to a new version of a vaccine. This may selectively increase demand on mRNA vaccine production, while manufacturing capacity for other vaccine platforms are taken offline to transition to a new variant targeting version of the vaccine.

This memo lays out the need for expanded global mRNA manufacturing capacity and describes the existing authority and resources that the Biden Administration already has to ensure global vaccine access in the next 12 months. It also demonstrates that the Biden Administration has inexplicably failed to further adequately invest in vaccine manufacturing capacity.

The Continued Manufacturing Capacity Crisis for COVID-19 Vaccines

The surest way to dramatically reduce both deaths and viral transmission is to ensure an adequate supply of safe and highly effective COVID-19 vaccines globally and support programs that can administer those vaccines around the world. Unfortunately, limited manufacturing capacity is precluding global access to vaccines. Indeed, with the exception of the mRNA vaccines from Pfizer/BioNTech and NIH/Moderna, almost every manufacturer of COVID-19 vaccines has announced major production delays, making it nearly impossible to meet the already unacceptably modest goal of vaccinating 27% of people in low- and middle-income countries by the end of 2021.

⁵ The White House. "BRIEFING ROOM FACT SHEET: President Biden Announces Historic Vaccine Donation: Half a Billion Pfizer Vaccines to the World's Lowest-Income Nations". URL: <https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/10/fact-sheet-president-biden-announces-historic-vaccine-donation-half-a-billion-pfizer-vaccines-to-the-worlds-lowest-income-nations/> (10 June 2021)

⁶ See, e.g. Merck & Co. Merck to Help Produce Johnson & Johnson's COVID-19 Vaccine; BARDA to Provide Merck With Funding to Expand Merck's Manufacturing Capacity for COVID-19 Vaccines and Medicines. (2 March 2021). URL: <https://www.merck.com/news/merck-to-help-produce-johnson-barda-to-provide-merck-with-funding-to-expand-mercks-manufacturing-capacity-for-covid-19-vaccines-and-medicines/>

For example:

- Novavax, the manufacturer of a protein subunit vaccine, announced in May of 2021 that it had only manufactured 30 to 40 million doses *in total*, despite expecting to be manufacturing more than 80 million doses *a month*.⁷ Continued production failures at Novavax have resulted in the company continually delaying clinical trials and regulatory submissions.
- Johnson and Johnson, the manufacturer of a single dose adenovirus vectored vaccine, has only delivered slightly more than a *fifth* (20.23 million doses)⁸ of the 100 million doses it promised to supply to the U.S. market by the end of June 2021⁹. In the European Union, the company has delivered less than a *tenth* of the number of doses it was contracted to so far this quarter.¹⁰
- AstraZeneca, the manufacturer of a dual dose adenovirus vectored vaccine, has announced that it would deliver less than a *third* of the number of doses it had been contracted to the European Union (EU) this quarter, triggering two lawsuits from the EU against AstraZeneca¹¹.
- The Serum Institute of India (SII), a licensed manufacturer of both the AstraZeneca (under the name Covishield) and the Novavax vaccines (under the name Covovax), announced on 18 May 2021 that it will likely not be able to export any more doses outside of India until *the end of 2021*.¹²
- The Serum Institute of India's production of Covovax has been further delayed by export restrictions on raw materials implemented by the Biden Administration. Although it publicly claimed to have solved the issue, the Biden Administration sent supplies for *Covisheild* (SII licensed version of the AstraZeneca vaccine), whose production was not impacted by export restrictions, *not* Covovax (SII's licensed version of Novavax). This issue remains unresolved¹³.

⁷ See, e.g. Al Idrus, Amirah. Novavax delays COVID-19 vaccine regulatory submissions—again. URL: <https://www.fiercebiotech.com/biotech/novavax-delays-covid-19-vaccine-regulatory-submissions-again>

⁸ U.S. CDC. URL: COVID Data Tracker -- COVID-19 Vaccinations in the United States. Accessed on 19 May 2021. URL: <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

⁹ Johnson and Johnson, Inc. Johnson & Johnson Statement on U.S. COVID-19 Vaccine Manufacturing" (31 March 2021). URL: <https://www.jnj.com/johnson-johnson-statement-on-u-s-covid-19-vaccine-manufacturing>

¹⁰ See, e.g. [Johnson and Johnson cuts vaccine deliveries to EU by half this week - EU source \(breakingnews.ie\)](#)

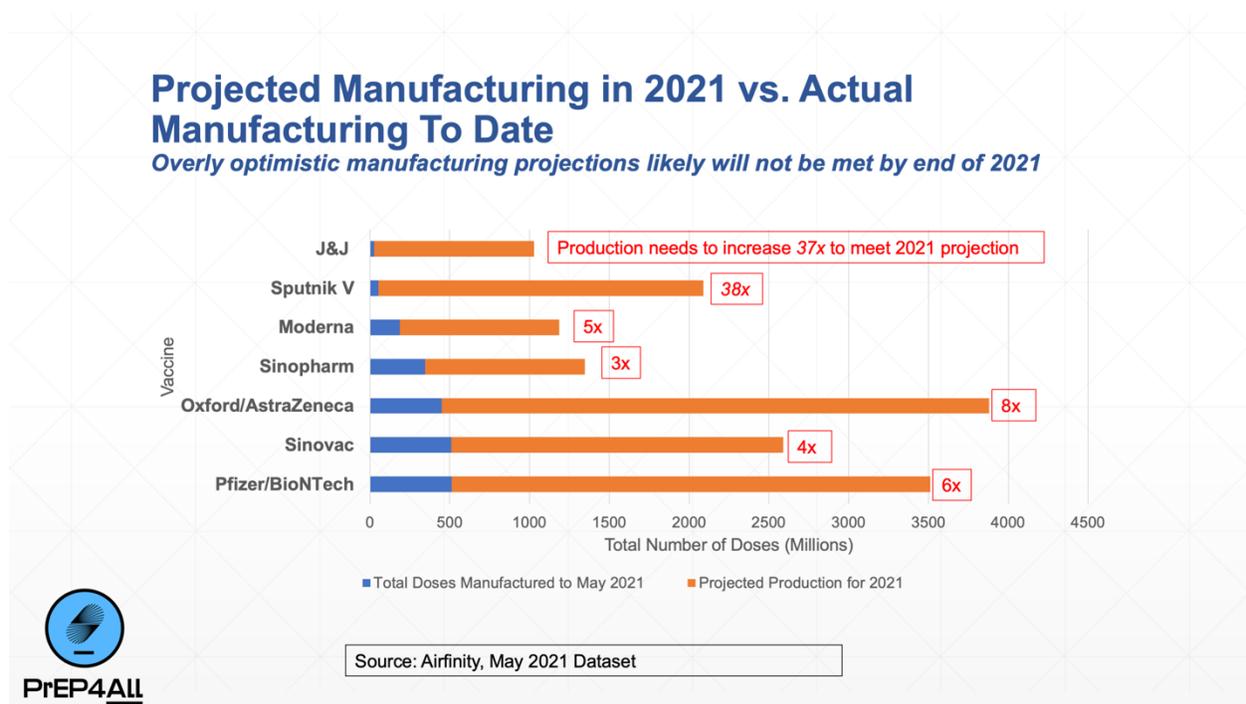
¹¹ See, e.g. [EU sues AstraZeneca over breach of COVID-19 vaccine supply contract | Reuters](#)

¹² See, e.g. [Indian Vaccine Manufacturer Signals it Won't Export Doses Before Year's End - The New York Times \(nytimes.com\)](#)

¹³ See, e.g. Raw materials are needed for Covovax, Serum tells US govt (livemint.com)

Although private vaccine manufacturers have repeatedly claimed that by the end of 2021, more than 12 billion doses will be available for distribution, this is unlikely to come to pass. Like 2020 – when less than 5% of projected vaccine doses were manufactured (837 million doses projected doses vs. 31 million doses produced)¹⁴ – it is likely that much of the projected doses for 2021 will not be produced.

Indeed, for the manufacturers of the seven primary COVID-19 vaccines used globally to meet their 2021 production targets, in the remaining six months of 2021, they would have to manufacture, *on average*, more than *six* times the total number of doses they have manufactured in total to date.



While mRNA vaccines have not faced the same production challenges as other vaccines, production capacity for mRNA vaccines is relatively low. Current mRNA vaccine production capacity in the world is limited to under 4 billion doses per year, with planned expansion to 2022 to 6 billion doses per year. Fortunately, rapid production scale up for mRNA vaccines is possible — with commencement of commercial operations starting within 6 months of construction start. However, bringing new mRNA capacity online rapidly is dependent on centralizing production in countries like the United States, the European Union, Japan & South

¹⁴ Airfinity Ltd. COVID-19 Vaccine Production. 8 March 2021. URL: https://www.ifpma.org/wp-content/uploads/2021/03/Airfinity_global_summit_master_final.pdf

Korea with mature biologics markets and experienced contract, development and manufacturing organizations (CDMOs) experienced in rapid production scale up.¹⁵

PrEP4All has prepared a comprehensive plan on scaling up mRNA vaccine production, which has estimated that the cost of building facilities that could produce enough mRNA vaccines to vaccinate the entire global population (approx. 8 billion people) in a single year would cost between US\$4 billion to US\$13 billion in capital expenditures.¹⁶ The fastest and most reliable way to manufacture enough vaccines for the world is to expand manufacturing capacity of mRNA vaccines, through U.S. Government investment.

Resources Available to the Biden Administration for Vaccine Manufacturing Scale Up

The American Rescue Plan Act of 2021 (ARPA) was passed by the U.S. Congress on 10 March 2021, and signed into law by President Biden the following day, becoming Public Law 117-2 . ARPA provides approximately US\$1.9 trillion in economic stimulus to numerous areas of the economy. Among other things, ARPA provides the Biden Administration US\$16.05 billion in funds to support the scale up of manufacturing of vaccines and other medical countermeasures for COVID-19.

Sections 2303 and 3101 of the ARPA designates US\$6.05 billion and US\$10 billion in funds, respectively, that explicitly are authorized for support for production of vaccines, including building new publicly owned or privately owned manufacturing capacity. Specifically, Section 2303 allocates \$6.05 billion, “...for necessary expenses with respect to research, development, **manufacturing, production** and the purchase **of vaccines**, therapeutics, or ancillary medical products...” for SARS-CoV-2 and COVID-19.

Section 3101(b)(1) meanwhile allocates \$10 billion for:

...purchase, production (**including the construction, repair, and retrofitting of government-owned or private facilities as necessary**), or distribution of medical supplies and equipment (including durable medical equipment) related to combating the COVID–19 pandemic...

Furthermore, in Section 3101(b)(1)(C), the bill specifically designates that these funds can be used for the production of:

¹⁵ Krellenstein J, Urrutia C. “Hit Hard, Hit Fast, Hit Globally.” PrEP4All. <https://www.prep4all.org/s/P4A-Hit-Hard-Hit-Fast-Hit-Globally-Report.pdf>

¹⁶ *Ibid.*

(C) drugs, devices, and **biological products** that are approved, cleared, licensed, or authorized for use in treating or preventing COVID–19 and symptoms related to COVID–19, and any materials, manufacturing machinery, additional manufacturing or fill-finish lines or facilities, technology, or equipment (including durable medical equipment) necessary to produce or use such drugs, biological products, or devices...

Both sections allocate funding that could be used not only for the manufacturing of drugs and vaccines at existing plants, but also any machinery, technology, or equipment (for example tangential flow filters and single use bioreactor bags) needed to produce drugs, including vaccines and new manufacturing facilities. As a result, the full \$16.05 billion could be used to build manufacturing facilities, both in the U.S. and elsewhere, to dramatically increase the supply of mRNA vaccines globally.

Analysis of the Biden Administration’s Investments to Current Day in Vaccine Production Capacity

A critical aspect of the success of the United States domestic vaccination program was large investments in production capacity in 2020. For example, A similar investment must be made in increasing production capacity to meet global demand. In order to determine whether the Biden Administration is investing in scaling vaccine manufacturing, we analyzed federal spending data through the USAspending.gov.¹⁷ All data for analysis was pulled on 31 July 2021.

Analysis Strategy

A four-step sequential process was employed to identify relevant spending events.

First, all contracts (including indefinite contract vehicles), grants, awards, direct payments, loans and other forms of spending were identified that were associated with a spending event or events on or after President Biden’s inauguration on 21 January 2021 to 24 June 2021. We identified 112,701,568 spending events during this time interval. We allowed approximately one month between the end of the spending period analyzed and pulling spending data.

Second, all spending activities specifically associated with all codified COVID-19 Disaster Emergency Fund Codes (DEFs)¹⁸ were included in the analysis and all others were excluded. Of the 112,701,568 spending events that have occurred since President Biden was inaugurated, 18,536,697 (16.5%) spending events were associated with a COVID-19 DEF or DEFs.

¹⁷ See, e.g. Congressional Research Service. Resources for Tracking Federal COVID-19 Spending. May 20, 2021. URL: [Resources for Tracking Federal COVID-19 Spending \(fas.org\)](https://fas.org/resources-for-tracking-federal-covid-19-spending)

¹⁸ See, e.g. USAspending.gov. “What COVID-19 spending does USAspending track?” URL: <https://www.usaspending.gov/disaster/covid-19/data-sources>

Specific DEFC codes included in this analysis are described in Appendix A.

Third, the North American Industry Classification System¹⁹ (NAICS) codes was utilized to identify spending events identified in the preceding steps of the analysis that are associated with vaccine drug substance and related feedstock component manufacturing activity, as well as manufacturing activities associated with the fabrication of production equipment.

NAICS codes included in this analysis step are described in Appendix B.

The analysis identified 45 spending events associated with these NAICS codes within the set of spending events identified in the preceding sections.

Fourth, a hand review by the author was conducted to determine whether the identified spending events were consistent with vaccine manufacturing scale up, which identified 9 spending events that were relevant to vaccine *production* scale up. For example, funded activities for vaccine clinical trials were excluded from this analysis. However, the analysis was conservative, including all *possible* spending events associated with this activity, even if no link between the spending event and COVID-19 vaccine drug substance manufacturing was known.

There are significant limitations to our analysis. It is possible that relevant spending events were not properly coded with either a correct DEFC or NAICS code, that a relevant spending event was not stored in the USAspending.gov database, or that we missed a relevant DEFC or NAICS code.

Award ID	Recipient	Description	Amount Spent (\$) During Biden Administration	Date
W911QY13C0010	Ology Bioservices, Inc.	Modification #P00068, is commissioning of the Advanced Development and Manufacturing Facility, which could be	\$1,859,179	17 Feb 2021

¹⁹ United States Office of Management and Budget. North American Industry Classification System, United States 2017. URL: https://www.census.gov/naics/reference_files_tools/2017_NAICS_Manual.pdf.

		used for vaccine manufacturing		
75A50121C00009	Merck Sharp and Dohme Corp.	Related to retrofitting of Merck facilities for production of Johnson and Johnson vaccine.	\$105,400,000	1 March 2021
75D30121C10558	Integrated DNA Technologies, Inc.	IDT is a well known manufacturer of e.g. DNA oligonucleotides which may be used for vaccine production, although other uses (e.g. diagnostics) may be possible, public data is insufficient to determine whether spending event is COVID-19 vaccine related	\$850,007	03/04/2021
75N93021P00313	GENSCRIPT USA INCORPORATED	Yes — synthesis of SARS-CoV2 variants genes, this could be used for other non-vaccine purposes, but may be used for vaccine development or manufacturing	\$727,163	02.05.2021
75N93021P00259	Beckton, Dickinson and Company	Yes — Reagents for vaccine studies	\$132,748	01.21.2021
75N93021P00282	Biolegend, Inc.	Yes — antibody supplies for COVID-19 work	\$98,517	01/29/2021
75N95021P00126	GOVERNMENT SCIENTIFIC SOURCE, INC.	Yes — supplies for single cell sequencing	\$65,778	03/12/2021
75A50120F33007	Emergent Manufacturing Operations Baltimore LLC	Yes — Vaccine Manufacturing Capacity at Baltimore CIADM	\$22,815,455 (mod 06)	03/23/2021

75A50121C00028	Meissner Filtration Products LLC	Related to filtration, bioreactor bag production, and fill and finish activities	\$13,392,790	04/01/2021
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Only \$145,341,637 million in spending by the Biden Administration for vaccine drug substance Production was identified. This represents a dramatic decline in compared to the investments made by the Trump Administration. For example, the Trump Administration spent more than \$483 million on just increasing Moderna’s production capacity – both by investing in Moderna’s facility in Norwood, Massachusetts and supporting the additional build out of capacity at the Lonza facility in Portsmouth, New Hampshire – that is more than double the Biden Administration *entire* spending on manufacturing scale up.²⁰

Conclusions

For all intents and purposes, the Biden Administration has stooped investing in mRNA vaccine production capacity. Ample resources passed by Congress and likely remain unused that could rapidly scale up production capacity. Given the deteriorating state of global vaccine supply, urgent efforts must be taken to dramatically increase capacity for production of vaccines on a scale commensurate with universal global access.

²⁰ See Spending event 75A50120C00034. Modification Number 00 (\$430,298,520 – executed on 3 April 2021), and P00001 (\$53,000,000 executed on 20 May 2020) for Moderna manufacturing and Lonza build out respectively.

Appendix A:

Table: Included COVID-19 DEFCs in Spending Analysis

<u>COVID-19 DEFC</u>	<u>Appropriation(s)</u>	<u>Funding Type</u>	<u>Public Law No(s).</u>
<i>L</i>	Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020	Emergency	Emergency Public Law 116-123
<i>M</i>	Families First Coronavirus Response Act	Emergency a	Emergency Public Law 116-127
<i>N</i>	Coronavirus Aid, Relief, and Economic Security Act or the CARES Act	Emergency	Emergency Public Law 116-136
<i>O</i>	Coronavirus Aid, Relief, and Economic Security Act or the CARES Act, Paycheck Protection Program and Health Care Enhancement Act, Consolidated Appropriations Act, 2021	Non-Emergency	Non-emergency Public Law 116-136, Non-emergency Public Law 116-139, Non-emergency Public Law 116-260
<i>P</i>	Paycheck Protection Program and Health Care Enhancement Act	Emergency	Emergency Public Law 116-139
<i>U</i>	Consolidated Appropriations Act, 2021	Emergency	Emergency Public Law 116-260

V	American Rescue Plan Act of 2021	Non-Emergency	Non-Emergency Public Law 117-2
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Appendix B: NAICS CODE Used In Analysis

<u>NAICS Code</u>	<u>NAICS Description</u>	<u>Example(s) of Possible Relevance to Vaccine Production</u>
325180	Other Basic Inorganic Chemical Manufacturing	Inorganic vaccine feedstock components or inorganic adjuvant synthesis (e.g. aluminum hydroxide)
325188	All Other Basic Inorganic Chemical Manufacturing	Inorganic vaccine feedstock components or inorganic adjuvant synthesis (e.g. aluminum hydroxide)
325199	All Other Basic Organic Chemical Manufacturing	Organic vaccine feedstock components or organic adjuvant synthesis
325411	Medicinal and Botanical Manufacturing	Active pharmaceutical ingredient (API) or excipient manufacturing
325412	Pharmaceutical Preparation Manufacturing	Manufacturing of saline diluent for injection
325414	Biological Product (except Diagnostic) Manufacturing	Vaccine Drug Substance Manufacturing, Fill and Finish
325988	All Other Miscellaneous Chemical Product and Preparation Manufacturing	Distilled Water Manufacturing
333249	Other Industrial Machinery Manufacturing	Chemical Processing Equipment Needed for Drug Substance Manufacturing
333298	(Deprecated) All Other Industrial Machinery Manufacturing	Chemical Processing Equipment Needed for Drug Substance Manufacturing
333914	Measuring, Dispensing, and Other Pumping Equipment Manufacturing	pumps for drug substance production processes
333913	(Deprecated) Measuring, Dispensing, and Other Pumping Equipment Manufacturing	pumps for drug substance production processes

333999	All Other Miscellaneous General Purpose Machinery Manufacturing	Centrifuges, industrial and laboratory-type, manufacturing
333911	(deprecated) Pump and Pumping Equipment Manufacturing	pumps for drug substance production processes
236210	Industrial Building Construction	Building or retrofitting new facilities for vaccine production
326111	Plastics Bag and Pouch Manufacturing	Fill and finish, also filtration supplies, single use bioreactor bags .