

U.S. Department of Homeland Security Centers of Excellence Summit

University research and workforce development for a safe and secure Homeland

Homeland Security Challenge



framework developed by our research group at Texas A&M University.



UIIFILM Diosynth," July 23, 2020; Platoff, "Texas Biotech Facility," July 27, 2020; Keown, "Federal Government Taps," July 28, 2020; BioSpace, "Vaxart Announces," March 18, 2020; Grand River Aseptic Manufacturing, "GRAM ust 4, 2020; GlavoSmithKline, "GSK Announces Intention," May 28, 2020; GRAM Website, "Large Scale Filling" (accessed November 15, 2020); Martin, "Inside the Operation Warp Speed Effort," November 8, 2020; Feliopol."

findings for this mitigating action.

COVID-19 Vaccination Supply Chains

Student(s): Enrique Zarate-Losoya, Juan Pablo Alvarado, Guillermo Duran, Alexi Allen, Audrey Guzman, Cesar Torres, Araceli Lopez-Acosta.

Gutierrez, Minerva Rojas

Outcomes / Results

Research Mentor(s): Zenon Medina-Cetina, PhD, Greg Pompelli, PhD, Matt Cochran, DVM, Maria J. Perez-Patron, PhD, Miriam Olivares, GISP, Oscar Sanchez-Siordia, PhD, Victor

Pfizer

Pfizer's U.S. vaccine production is mostly vertically integrated its supply chain is combining mRNA production with lipids which occurs during the first half of the manufacturing process

- Pfizer is producing DNA for the U.S. Market with plants located in Kalamazoo, Michigan, St. Louis, Missouri and Andover, Massachusetts
- Critical infrastructures updates during February 2021 caused a ~40% drop in weekly supply for that month but has since recovered

This research is supported by the DHS Countering Weapons of Mass Destruction Office (CWMD), and the DHS Science and Technology Directorate (S&T) Office of University Programs (OUP). This material is based upon work funded by the U.S. Department of Homeland Security under Cooperative Agreement No. 18STCBT00001. **Disclaimer:** The views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies, either expressed or implied, of the U.S Department of Homeland Security.

and investigations, committee on energy and commerce [Congressional Hearing]. 587, 522. https://doi.org/https://doi.org/10.1038/d41586-020-03334- w Boutron, I., Chaimani, A., Meerpohl, J. J., Hróbjartsson, A., Devane, D., Rada, G., Tovey, D., Grasselli, G., & Ravaud, P. (2020). The COVID-NMA project: Building an https://docs.house.gov/meetings/IF/IF0 2/20210223/111226/HHRG-117-IF02-Wstate- Neubert, J. (2021). Exploring the supply chain of the pfizer/BioNTech and mod- erna evidence ecosystem for the COVID-19 pandemic. American College of Physicians. NettlesR-20210223.PDF COVID-19 vaccines. https://blog.jonasneubert.com/2021/01/10/explo ring-the-supply-Brody, B. (2020). 4 high-tech tools johnson & johnson is using to get products to you Inc., P. (2018). American pharmaceutical innovationand job creation [Company Yearly chain-of-the-pfizer-biontech-and-moderna-covid-19-vaccines/ last accessed on *during the pandemic*. https://www.jnj.com/innovation/johnson-johnson- supply-chain- Review]. https://www.pfizer.com/sites/default/files/investors/fin ancial reports/2017/assets/media/Pfizer-infographic-US-Organization, W. H. (2021). International clinical trials registry platform (IC- TRP). In technology-during-coronavirus Canese, K., & Weis, S. (2013). PubMed: The bibliographic database. In *The NCBI* ManufacturingSites.pdf World Health Organization. Online. https://www.who.int/clinical-trials-registryhandbook [internet]. 2nd edition. National Center for Biotechnology Information (US). Johnson, J. &. (2021). Johnson & johnson COVID-19 vaccine authorized by u.s. FDA for platform/ Carl Zimmer, S.-L., Jonathan Corum. (2021). Coronavirus vaccine tracker. In *The New* emergency use - first single-shot vaccine in fight against global pandemic. Quentin, B. M. C. (2020). Europe is paying less than U.S. For many coronavirus York Times. Online. https://www.nytimes.com/interactive/2020/s https://www.jnj.com/johnson-johnson-covid-19-vaccine- authorized-by-u-s-fda-forvaccines. The Washington Post. https://www.washingtonpost.com/world/eu- coronaviruscience/coronavirus-vaccine-tracker.html emergency-usefirst-single-shot-vaccine-in-fight-14 vaccines-cheaper-than-united-states/2020/12/18/06677e34-4139-11eb-b58b-Carolyn, T. W. P. Inc., Y. Johnson. (2020). A vial, a vaccine and hopes for slowing a 1623f6267960 story.html against-global-pandemic. Kelly, K. (2020). Critical to vaccines, cold storage is wall street's shiny new thing. *The* R&D Blue Print, W. (2021). Draft landscape and tracker of COVID-19 candidate pandemic — how a shot comes to be. https://www.washingtonpost.com/health/2020/11/17/coronavirus-vaccine-manufacturing/New York Times. vaccines. World Health Organization. https://www.who.int/publications/m/item/draft-Lewis, T. (2020). Pfizer-BioNTech COVID vaccine is first to win u.s. authoriza- tion. landscape-of-covid-19-candidate-vaccines last accessed on 02/20/2021 Cohen, J. (2020). As COVID-19 vaccines emerge, a global waiting game begins. Science. Scientific American. https://www.scientificamerican.com/article/pfizer- biontech-covid-Ries, J. (2020). How much will it cost to get a COVID-19 vaccine? Healthline. https://doi.org/10.1126/science.abg1793 vaccine-is-first-to-win-u-s-authorization https://www.healthline.com/health-news/how-much-will-it-cost-to-get-a- covid-19-Dooling, K. (2020). The advisory committee on immunization practices' updated interim LinkedIn. (2021). LinkedIn company profile, premium insights. https: Romero, C., J. (2020). ACIP presentation slides: December 19 and 20, 2020 meeting recommendation for allocation of COVID-19 vaccine—united states, december 2020. //www.linkedin.com/company/pfizer/insights/ last accessed on 02/22/2021 MMWR. Morbidity and Mortality Weekly Report, 69. Lowe, D. (2021). Myths of vaccine manufacturing. https://blogs.sciencemag CDC Advisory Committee on Immunization Practices (ACIP). Dooling, K., McClung, N., Chamberland, M., Marin, M., Wallace, M., Bell, B. P., Lee, org/pipeline/archives/2021/02/02/myths-of-vaccine-manufacturing last accessed on https://www.cdc.gov/vaccines/acip/meetings/slides-2020-12-19-20.html Services. U. S. D. of H. &. H. (2021). Biden administration announces historic G. M., Talbot, H. K., Romero, J. R., & Oliver, S. E. (2020). The advisory committee on 02/18/2021 immunization practices' interim recommendation for allocating initial supplies of Medicine, U. S. N. L. of. (2021). Clinical Trials.gov, a database of privately and publicly manufacturing collaboration between merck and johnson & johnson to expand COVID-19 vaccine—united states, 2020. Morbidity and Mortality Weekly Report, 69(49), funded clinical studies conducted around the world. In U.S. National Library of Medicine production of COVID-19 vaccines. U.S. National Library of Medicine. https://www.clinicaltrials.gov/ Slaoui, M., & Hepburn, M. (2020). Developing safe and effective covid vaccines operation warp speed's strategy and approach. New England Journal of Medicine. (GRAM), G. R. A. M. (2021). *Development and manufacturing facilities*. https:// Moderna. (2021). Moderna provides u.s. COVID-19 vaccine supply update. https://investors.modernatx.com/news-releases/news-release-details/modern a-provides- 383(18), 1701–1703. https://doi.org/10.1056/NEJMp2027405 //www.grandriverasepticmfg.com/facilities/butterworth/ House, U. S. (2021). Statement of Dr. Richard nettles, m.d. Vice president of u.s. Medical us-covid-19-vaccine-supply-update-0. last accessed on 02/16/2021



A Department of Homeland Security Center of Excellence





Conclusions

Moderna

Expected to deliver a total of **300 million** Expected to deliver a total of **200 million** doses to the U.S. Government:

The most critical manufacturing step of 100 million by the end of March 2021, 100 million by the end of May 2021, 100 million by end of July 2021

- of its supply chain is the combining mRNA production with lipids which occurs during the first half of its supply chain
- Moderna and Lonza are producing DNA for the U.S. Market with plants located in Norwood, Massachusetts and Portsmouth, New Hampshire

Subcontracting: Lonza Corden Pharma **Catelent Pharma**

J&J Janssen

doses to the U.S. Government: 20m by the end of March 2021, 80m by the end of June 2021, 100m by the end of **December 2021**

- The most critical manufacturing step
 JJ's manufacturing cycle is the longest raging from 60 to 80 days
 - The most critical manufacturing step of its supply chain is the cell culture growth which occurs at the beginning of the manufacturing process
 - Emergent Bio Solutions and Merck **Pharmaceutical** are producing DNA for the U.S. Market with plants located in Baltimore, MD and Philadelphia, PA Subcontracting:
 - Emergent Bio Solutions
 - Merck Pharmaceutical
 - Grand River Aseptic
 - Manufacturing (GRAM) Catalent, Inc
 - PCI Pharma Services

Sources of information and evidence were identified to ingest into the Data-Lake The Risk Model was validated qualitatively based on this research problem Ongoing work focusing on applying more quantitative analyses, and methodologies based on public and premium data sources related to one specific binational supply chain to provide real-time reporting and forecasting

Acknowledgements

References

affairs, janssen infectious diseases and vaccines before the subcommittee on oversight Nature. (2020). The COVID vaccine challenges that lie ahead [Magazine Article]. Nature.