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INSIGHT

Supply Chain Considerations for COVID-19 Vaccine Manufacturing

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The development of a vaccine for the Coronavirus Disease 2019 (COVID-19) pandemic has been of concern to Congress, as vaccination can be one of the most effective methods of preventing disease spread. On November 18, 2020, Pfizer/BioNTech announced that an interim analysis found its newly developed vaccine to be "95% effective against COVID-19" and has since filed for an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration. On November 16, 2020, Moderna announced that its vaccine, tentatively evaluated as 94.5% effective, will also be submitted for an EUA. According to media reports, "Moderna said it would have 20 million doses ready by the end of 2020; Pfizer said it would have about 50 million by then." Providing COVID-19 vaccines—complex, specially manufactured and distributed products—involves significant supply chain considerations. Needed supplies may be limited in quantity and face global competition. This Insight provides an overview of selected supplies required to manufacture vaccines and ancillary vaccination materials that may pose supply chain challenges and describes the federal government's role in this process. It does not cover particular contracts issued, or supplies potentially required for transportation, distribution, and administration of eventual vaccines.

Federal Role in COVID-19 Vaccine Manufacturing

Through Operation Warp Speed (OWS), a public-private partnership engaged in deploying countermeasures against COVID-19, the federal government has entered into contractual agreements with medical supply and pharmaceutical companies to procure necessary supplies for countermeasure manufacturing. OWS has also invested in manufacturers' production capabilities, partly by financing new factory construction. While investigational vaccines are still undergoing late-stage clinical trials, production of vaccination supplies has begun. Any shortages may hamper vaccine distribution efforts and delay the vaccination campaign timeline. Materials of concern include those used to contain the vaccine, inject it into the body, increase the body's immune response, and ensure vaccine safety. Vaccine manufacturers stated in a congressional hearing, "we believe we have a path to be able to have all the necessary materials for a vaccine program, should we be successful." Yet, throughout the pandemic, transparent, up-to-date reporting on the medical supply chain to federal agencies has, in general, been an issue, particularly for drug ingredients or supplies required for manufacturing.

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Medical-Grade Glass Vials

Medical-grade glass vials store vaccine doses during transport and are tempered to protect the vaccine from temperature fluctuations. They are also specifically engineered not to interact with the vaccine itself, thus protecting the formula from degradation or inactivation. Given that multiple doses of vaccine per person may be required to ensure immunity, hundreds of millions of vials may be required to meet global demand. The federal government has entered into contracts to procure or produce medical-grade glass vials, but potential shortages of vials may delay the vaccination campaign. The federal government has also entered into contracts for glass vial alternatives, such as plastic vials or prefilled syringes. Plastic vials have a thin glass coating on the inside of the vial to protect vaccine purity in transport. Prefilled syringes are filled with vaccine and transported to administration sites where they can be used.

Needles and Syringes

Needles and syringes are used to physically inject the vaccine into the body, where the formula can then elicit an immune response to confer disease immunity to the recipient. As these are single-use supplies, used needles cannot be repurposed and must be appropriately disposed of. Just as with glass vials, OWS has entered into public-private contracts with domestic suppliers for needle and syringe production.

Vaccine Potency and Adjuvant

Adjuvant is a vaccine ingredient that interacts with immune mechanisms to increase the speed and magnitude of the body's response to an antigen (a substance that initiates an immune response and the production of antibodies). The use of adjuvant reduces the amount of antigen required per dose of vaccine, allowing the same amount of antigen to go toward creating more doses. There are many different formulations of adjuvants, each optimized for a particular class of vaccine. The MF59 adjuvant used for influenza vaccine, for example, contains the oil squalene, which is sourced best from shark livers. While there are alternative sources of squalene, production capabilities of these alternatives may not be sufficient to meet demand. Plant sources, for example, yield far less squalene than shark liver, and synthetic versions have yet to be evaluated for safety and efficacy. Squalene's sourcing from scarce animal products may raise environmental concerns as well, given the scale of vaccine production required to meet global demands. Neither Pfizer/BioNTech nor Moderna are using this type of adjuvant in their vaccines, but other COVID-19 vaccines supported by OWS plan to use squalene adjuvants; potential supply shortages may thus affect vaccination timelines.

Vaccine Quality Control Testing

Limulus Amoebocyte Lysate (LAL), an enzyme found in the blood of horseshoe crabs, is used to evaluate vaccine safety by detecting whether a sample has bacterial contamination. Similar to concerns about squalene harvesting from sharks, ramping up LAL harvest from animal sources raises potential environmental implications. While there is one approved synthetic variety of LAL, production capabilities may need to be evaluated.

Considerations for Congress

A lack of needed supplies may hinder efforts to manufacture and distribute vaccines, as some cannot be manufactured without ingredients like LAL, and vaccines, in general, cannot be distributed without items such as needles and syringes. It may be important, therefore, to ensure continuity of supplies by addressing potential shortages early. Congress may benefit from regular, publicly available updates on whether supply companies are meeting their production deadlines. This includes deadlines for contracts currently in place and for factory improvements to increase production capacity. Congress may also

consider whether additional contracts may be required to fully meet demand for these supplies. Lastly, Congress may consider evaluating whether there is adequate monitoring of supply chain integrity, as any interruptions in manufacturing may hamper the vaccination campaign. These efforts may help ensure timely rollout of the vaccine(s) following licensure or authorization by the Food and Drug Administration.

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