Justification Review Document
FAR 6.302-1 Other than Full and Open Competition
Limited/Sole Source for COVID-19

Program/Equipment: Joint Program Executive Office – Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), the Assistant Secretary for Preparedness and Response (ASPR), Biomedical and Advanced Research and Development Authority (BARDA), Manufacture and Distribution of Vaccines in Response to the Coronavirus Disease 2019 (COVID-19) Pandemic.

Authority: Title 10 United States Code (U.S.C.) 3204(a)(1) as implemented by Federal Acquisition Regulation (FAR) 6.302-1 – Limited/Sole Source.

Amount: $18,000,000,000

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Reviews

I have reviewed this justification and find it adequate to support other than full and open competition.

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Class
Justification and Approval
FAR 6.302-1 Other than Full and Open Competition
Limited/Sole Source for COVID-19

1. Contracting Activity: Army Contracting Command – Joint COVID-19 Response Division (ACC-JCRD). 6472 INTEGRITY COURT, BUILDING 4401, ABERDEEN PROVING GROUND, MD 21005-3013

2. Description of Action: This is a request for approval to immediately award two new and separate contracts to Moderna US, Inc. and Pfizer, Inc. to manufacture, store, and deliver up to 300M doses each of Messenger Ribonucleic (mRNA) COVID-19 vaccines. The United States Government (USG) requires up to, approximately 600 million (600M) doses of United States (US) Food and Drug Administration (FDA) authorized or approved mRNA COVID-19 vaccines to support fall 2022 domestic adult and pediatric vaccination efforts, with a rapid turnaround time in response to the mutations of the original SARS-CoV-2 virus since the development of primary vaccine formulations. As of 04 February 2022, the SARS-CoV-2 virus, which causes COVID-19, has mutated into eleven different monitored variants, wherein Delta (B.1.617.2) and Omicron (B.1.1.529) have been categorized as Variants of Concern (VOC) according to the World Health Organization (WHO) and US Centers for Disease Control and Prevention (CDC). Scientists expect that more variants with unknown consequences are highly likely to emerge.

This action is specific to the requirement for mRNA vaccines given their (a) clinical superiority, (b) technical maturity, and (c) agility for modification of the vaccine to protect against variant strains. At this time, other vaccine types and vaccine manufacturers do not meet the USG's requirement. The Department of Defense (DoD) intends to pursue the following contract actions under this class J&A, exact quantities to be determined based on manufacturers' ability to produce in the needed quantities on the needed schedule and via negotiations:

A. New procurement contract with Moderna US, Inc., Global Headquarters, 200 Technology Square Cambridge, MA 02139, to manufacture, store, and distribute up to, approximately, 300,000,000 (300M) doses of an mRNA COVID-19 vaccine ("SPIKEVAX"[1]), consisting of a base period of up to 90M doses and option periods of up to 210M, with a 20-month Period of Performance (PoP) from the date of award. Depending on the characteristics of the circulating strain and regulatory requirements issued by U.S. Public Health Authorities[2], this vaccine may encode the prototype strain of SARS-CoV-2, a variant strain, or be multi-valent. The number of doses could be up to approximately 600M if no other mRNA

[1] Including the FDA-licensed formulation of SPIKEVAX or additional formulations that receive emergency use authorization (EUA) using the base SPIKEVAX mRNA vaccine as a platform or component of a formulation required by U.S. Public Health Authorities.
[2] "U.S. Public Health Authorities" means any combination of the CDC and U.S. Food and Drug Administration (FDA).

COVID-19 vaccine can meet the USG's needs.

B. New procurement contract with Pfizer Inc., 235 East 42nd Street, New York, NY 10017, to manufacture, store, and distribute up to, approximately, 300M doses of an mRNA COVID-19 vaccine ("COMIRNATY[3]"), consisting of a base period of up to 90M doses and option periods of up to 210M, with a 20-month PoP from the date of award. Depending on the characteristics of the circulating strain and regulatory requirements issued by US Public Health Authorities, this vaccine may encode the prototype strain of SARS-CoV-2, a variant strain, or be multi-valent. The number of doses could be up to approximately 600M if no other mRNA COVID-19 vaccine can meet the USG's needs.

Looking at the current landscape for COVID vaccines, only the mRNA COVID-19 vaccine manufacturers can support either primary series or boosters used to protect the adult and pediatric general US population (330 million) against current and future variant threats with specific changes needed based on Public Health Authorities' guidance. (b) (4)

[redacted]

The anticipated contract type for each mRNA vaccine acquisition action is Firm Fixed Price. The requirements and funding are from the US Department of Health and Human Services (HHS). These efforts are entered into by the DoD and ACC-JCRD on behalf of BARDA, in accordance with the Memorandum of Understanding between HHS and the DoD regarding DoD Acquisition Support, signed 20 May 2021. The DoD will be the contracting agency. At an estimated unit price of (b) (4) [redacted] per dose, the total estimated cost for this requirement is $18,000,000,000. This is an estimated total dollar value only, based on both the previous prices the Government has paid to purchase COVID-19 vaccines and an anticipated inflation rate to account for the private development of updated formulations. This estimated total dollar value is subject to current market conditions and contract negotiations. The USG set aside funds specifically to develop therapeutics, treatments, and vaccines against COVID-19. Those set aside funds, Public Health and Social Services Emergency Funds (five-year funds), are being used to support these efforts. $5B of funding is currently available for the base period

[3] Including the FDA-licensed formulation of COMIRNATY or additional formulations that receive emergency use authorization (EUA) using the base COMIRNATY mRNA vaccine as a platform or component of a formulation required by U.S. Public Health Authorities.

quantities.

3. Description of Supplies/Services: HHS and the DoD require the ability to procure mass quantities of FDA authorized or approved mRNA COVID-19 vaccines to support military locations and personnel throughout the Continental United States and outside of the Continental United States. In addition, the USG requires the ability to procure mass quantities of FDA authorized or approved mRNA COVID-19 vaccines for the US population. In total, the USG requires up to, approximately 600M doses of US FDA authorized or approved mRNA COVID-19 vaccines to support fall 2022 domestic adult and pediatric vaccination efforts to advance the US response to COVID-19, requirements and technology continue to be identified that are crucial to addressing the Public Health Emergency (PHE). Accordingly, the USG is acquiring only mRNA vaccines to meet this need given their (a) clinical superiority, (b) technical maturity, and (c) agility for modification of the vaccine to protect against variant strains.

Clinical Superiority of mRNA COVID-19 Vaccines. The mRNA COVID-19 vaccines are clinically superior to alternative vaccines, such as viral vector or adjuvanted protein subunit vaccines. Large clinical trials have shown unprecedented effectiveness for the two US licensed mRNA COVID-19 vaccines, both about 95 percent after the second dose, with less adverse events associated with their use.[4] The mRNA vaccine technology is the most promising application for COVID-19 and their utility will extend past the current public health emergency.[5] The US Food and Drug Administration has issued biologics license applications (BLA) under Section 351(a) of the Public Health Service Act (PHSA), acknowledging that the clinical benefits of the mRNA COVID-19 vaccines outweigh their risks for COVID-19.[6] No other vaccine platform has received a full BLA and, as such, cannot be considered as clinically preferential as the mRNA vaccine. The CDC has determined that the mRNA COVID-19 vaccines are "preferable" to alternative COVID-19 vaccines.[7] The mRNA vaccine technology is a "revolutionary innovation" and "played a unique role in controlling the COVID-19 pandemic."[8]

In December 2021, the omicron variant became the prevalent COVID-19 variant in the United States, burning rapidly across populations through the end of February 2022.

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[4] Welsh J. "Coronavirus Variants-Will New mRNA Vaccines Meet the Challenge?", *Engineering (Beijing)*. 2021;7(6):712-714. doi:10.1016/j.eng.2021.04.005, available at: (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8053359/.

[5] Fang, E., Liu, X., Li, M. *et al.* "Advances in COVID-19 mRNA vaccine development." *Sig Transduct Target Ther* **7,** 94 (2022). Available at: https://doi.org/10.1038/s41392-022-00950-y https://www.nature.com/articles/s41392-022-00950-y.

[6] *See* FDA BLA Approval Letter for Pfizer COVID-19 Vaccine, mRNA, "COMIRNATY" dated August 23, 2021 available at: https://www.fda.gov/media/151710/download. Pfizer was granted license number 2229 (see page 1). ModernaTX received BLA approval for their "COVID-19 Vaccine, mRNA", proprietary name "SPIKEVAX," on January 31, 2022 with license number 2256. *See* FDA BLA Approval Letter available at: at https://www.fda.gov/media/155815/download.

[7] The CDC has states that "Three COVID-19 vaccines are authorized or approved for use in the United States to prevent COVID-19. Pfizer-BioNTech or Moderna (COVID-19 mRNA vaccines) **are preferred**. You may get Johnson & Johnson's J&A COVID-19 vaccine in some situations." (emphasis added), available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html.

[8] See Fang, supra at note 5.

Despite the high transmissibility of the omicron variant, mRNA vaccines remained approximately 70% effective at preventing hospitalization in adults who were previously infected with COVID-19.[9] Current research indicates that the greatest levels of protection against omicron were achieved after adults received three mRNA vaccine doses.[10] Indeed, the data shows that adults who had received three doses of an mRNA vaccine had an 86% lower risk of COVID-19 hospitalization during the omicron surge period. Moreover, adults who had received three doses of an mRNA vaccine decreased their risk of death or invasive mechanical ventilation by 94% during the omicron period.[11]

In addition, the safety profile of the mRNA vaccines also makes these vaccines better than the Janssen[12] vaccine (viral vector). The actual post-market use data suggests that the overwhelming majority of vaccinations are with the Pfizer and Moderna mRNA vaccines. Recently published figures from the CDC database suggest that COVID-19 deaths among Janssen recipients may have peaked at more than double the rate of other vaccinated Americans during the Omicron variant wave.[13] For the week of January 8, COVID-associated deaths among Americans who were vaccinated with Janssen reached a rate of more than 5 out of every 100,000, according to the CDC's figures. That number is higher than the rate among recipients of the Pfizer or Moderna vaccines, which was around 2 deaths per 100,000 people. Traditional vaccines, like Janssen's adenovirus vaccine, can carry substantial risks due to decreased effectiveness over pre-existing immunity to adenoviruses and, given a second time, antibodies directed against the viral vector may limit utility. [14] Furthermore, FDA addressed the reduced safety profile of Janssen's vaccine with its recent update: "[a]fter conducting an updated analysis, evaluation and investigation of reported cases, the FDA has determined that the risk of thrombosis with thrombocytopenia syndrome (TTS), a syndrome of rare and potentially life-threatening blood clots in combination with low levels of blood platelets with onset of symptoms approximately one to two weeks following administration of the Janssen COVID-19 Vaccine, warrants limiting the authorized use of the vaccine."[15]

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[9] Effectiveness of COVID-19 mRNA Vaccination in Preventing COVID-19–Associated Hospitalization Among Adults with Previous SARS-CoV-2 Infection — United States, June 2021–February 2022, MMWR available at cdc.gov; *see also* Lauring A S, Tenforde M W, Chappell J D, Gaglani M, Ginde A A, McNeal T et al., "Clinical severity of, and effectiveness of mRNA vaccines against, covid-19 from omicron, delta, and alpha SARS-CoV-2 variants in the United States: prospective observational study", *BMJ* 2022; 376.

[10] See Lauring A S, supra at note 9.

[11] "Associated Invasive Mechanical Ventilation and Death — United States, March 2021–January 2022.", MMWR Morb Mortal Wkly Rep 2022;71:459–465. Available at: http://dx.doi.org/10.15585/mmwr.mm7112e1

[12] J&A Biotech Inc., is "a J&A Pharmaceutical Company of Johnson & Johnson" hereafter referred to as "J&J".

[13] *See* "Omicron Deaths of Johnson & Johnson were double the rate of other vaccinated Americans, new data show." CBS News, available at: https://www.cbsnews.com/news/covid-omicron-johnson-johnson-vaccine/.

[14] *See* Welsh J., *supra* at note 4.

[15] May 05, 2022, Coronavirus (COVID-19) Update: FDA limits Use of J&A COVID-19 Vaccine to Certain Individuals, available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-J&A-covid-19-vaccine-certain-individuals.

Technical Maturity of mRNA COVID-19 Vaccines. The mRNA vaccines have demonstrated technical maturity over the alternative COVID vaccine approaches. The mRNA COVID-19 vaccines have achieved an estimated Technical Readiness Level (TRL) level of "9" whereby the "[a]ctual system [is] proven through successful mission operations."[16] The FDA licensure of SPIKEVAX and COMIRNATY, represents an objective assessment by a science-based organization that the mRNA vaccines have achieved a high level of confidence in their safety and effectiveness through rigorous testing and evaluation that exceeds such evidence for any of other vaccines or vaccine candidates. The bar for demonstrating safety and efficacy to obtain a BLA is higher under Section 351(a) of the PHSA than mere authorization under an EUA under Section 564 of the FD&C Act, which employs a "totality of the circumstances" test.[17] FDA has acknowledged the important technical differences between BLA and EUA vaccines.[18] The BLA submission alone for the mRNA vaccines is required to include chemistry/manufacturing/controls information, pre-clinical data, clinical data, robust and well-defined product labeling and meet other legal requirements. The EUA standard does not require this level of technical maturity. While it is unclear what US Public Health authorities will require for the fall 2022 (e.g., prototype vaccine, booster, variant-specific booster, or a bi-valent booster), the technical maturity of the mRNA vaccines – having reached full BLA – will retain technical maturity over other vaccine candidates because the robust dossier is foundational to BLA approval. This advantage in technical maturity for the mRNA vaccines is evident regardless of whether a future, variant-specific formulation is submitted to FDA via a supplemental BLA (sBLA) or an EUA; the benefit of FDA's confidence in the mRNA BLA vaccines will be brought to bear on any subsequent regulatory filing.

The other vaccine platforms for COVID-19 are likely at an estimated TRL level of between "5" ("Component and/or breadboard validation in relevant environment" and "7" ("system prototype demonstration in an operational environment") and only then if the product has been studied in Phase 2 and 3 clinical trials under "adequate and well-controlled" conditions.[19] Compared with the traditional production methods for inactivated, subunit, or viral vector vaccines, mRNA vaccine technology avoids complicated and time-consuming production steps, while also reducing the risk of contamination from cell sources.[20] The mRNA vaccines demonstrate technical advantages over more traditional vaccine models.[21] Even where the mRNA vaccines

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[16] *See* Defense Acquisition Guidebook (2010), "Technology Readiness Levels" available at: https://api.army.mil/e2/c/downloads/404585.pdf

[17] See FDA Guidance for Industry, "Emergency Use Authorization for Vaccines to Prevent COVID-19," May 25, 2021, available at: https://www.fda.gov/media/142749/download. FDA

[18] "It is FDA's expectation that, following submission of an EUA request and issuance of an EUA, a sponsor **would continue to collect data** in any ongoing trials and would also work towards submission of a Biologics License Application (BLA) as soon as possible." See Section III. at p. 4, FDA Guidance for Industry, "Emergency Use Authorization for Vaccines to Prevent COVID-19," May 25, 2021, available at: https://www.fda.gov/media/142749/download. FDA

[19] *See* Defense Acquisition Guidebook (2010), "Technology Readiness Levels" available at: https://api.army.mil/e2/c/downloads/404585.pdf

[20] *See* Fang, E., *supra*, at note 5.

[21] Id.

need to be modified at the margins for variant-specific purposes, such development will still exceed the TRL levels of other vaccine platforms.

Agility of mRNA COVID-19 Vaccines for Variants. The mRNA vaccines provide a distinct advantage over inactivated, subunit, or viral vector vaccines to prevent and manage infectious diseases like COVID-19 because the mRNA vaccine "enable(s) adjustment of antigen design and even allows combining sequences from several variants to respond to new mutations in the virus genome."[22] Unlike traditional vaccine approaches, mRNA vaccines are agile because of their quick development cycle, no requirement for cell culture, and preferable immunogenicity outcomes.[23] "Unlike traditional whole virus vaccines, mRNA vaccines can be quickly and relatively easily adjusted to target new variants."[24] Reformulating an mRNA vaccine to address new variants can take a "matter of months—in contrast to the typical timetable of years."[25] "The advantage of mRNA-LNP vaccines lies in the modularity of the platform and the rapid manufacturing capabilities."[26]
The mRNA technology's "speed and flexibility may prove doubly valuable by helping to meet the challenge of a swiftly evolving virus." The mRNA vaccine approach offers the "possibility of quick industrialization of vaccine production" with adjustments in the mRNA vaccine strain sequence using in vitro synthesis technology that, including production, qualification, and release, "the product can be available on the market within 40 days."[27]

In light of the forgoing, only mRNA vaccines can meet the USG need for the fall 2022 vaccination campaign. The mRNA COVID-19 vaccines are clinically superior, technically more mature, and able to be modified for variant-specific needs as directed by US Public Health Authorities

4. Authority Cited: 10 U.S.C. Section 3204(a)(1), as implemented by FAR 6.302-1, "Only one or a limited number of responsible sources and no other supplies or services will satisfy agency requirements." When the supplies or services required by the agency are available from only one responsible source, or, for DoD, NASA, and the Coast Guard, from only one or a limited number of responsible sources, and no other type of supplies or services will satisfy agency requirements, full and open competition need not be provided for.

5. Reason for Authority Cited: FAR 6.302-1 allows for other than full and open competition based on supplies and services being only available from one or a limited number of responsible sources and no other type of supplies or services will satisfy

[22] Id.
[23] See the "flexibility" cited by Fang et al., *supra* at note 5.
[24] Welsh J. Coronavirus Variants-Will New mRNA Vaccines Meet the Challenge?. *Engineering (Beijing)*. 2021;7(6):712-714. doi:10.1016/j.eng.2021.04.005 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8053359/)
[25] Id.
[26] E. Kon, U. Elia, D. Peer, **Principles for designing an optimal mRNA lipid nanoparticle vaccine,** Curr. Opin. Biotechnol., 73 (2021), pp. 329-336, 10.1016/j.copbio.2021.09.016
[27] *See* Welsh J., *supra*, at note 4.

agency requirements. This action satisfies the requirements of FAR 6.302-1 because there is a limited number of responsible sources producing mRNA COVID-19 vaccines with FDA licensure and boosters with EUA authorization that, if contracted for now and in this manner, will be available in sufficient quantities to meet the demand to vaccinate the US population consistent with direction of US public health authorities, which could include prototype vaccine, variant strain, or multi-valent vaccine/booster approaches. As mentioned above, mRNA COVID-19 vaccines are, as compared to other vaccine candidates, a) clinically superior, (b) demonstrate greater technically maturity, and (c) demonstrate the agility for modification of the vaccine to protect against variant strains The CDC has determined that the mRNA vaccines are preferable to alternative vaccines.[28] FDA has granted BLA to only mRNA vaccines.[29] Pfizer and Moderna are the only two FDA authorized or approved manufacturers of mRNA vaccines, making these companies the only two responsible sources under FAR 6-302-1.

To date, three vaccines (Pfizer's COMRINATY, Moderna's SPIKEVAX, and Janssen's viral vector vaccine) have been granted Emergency Use Authorization (EUA) for initial doses. As stated above, only two (Pfizer and Moderna), have demonstrated the degree of safety and effectiveness to achieve FDA BLA to prevent COVID-19 in adults. Additionally, Pfizer and Moderna have received EUA from the FDA to be utilized as boosters, and Pfizer has received an EUA for adolescent and pediatric indications.

Because Pfizer-BioNTech and Moderna are the only two companies that have BLAs for adult use of their mRNA COVID-19 vaccines, their mRNA vaccines cover the broadest scope of authorized/approved use of any of the COVID-19 vaccines currently marketed in the US, their mRNA COVID-19 vaccines are preferred by the CDC and FDA when they are available and clinically appropriate, and the mRNA vaccine platform allows these manufacturers to alter their mRNA vaccines and ramp up their production to timely meet the USG's needs for a variant specific approach. In sum, Pfizer and Moderna are the only two responsible sources with the required mRNA vaccine to meet the demand for initial series, boosters or variant formulations as directed by US Public Health Authorities for this fall. No other vaccine type demonstrates the agility to be altered for variant-specific US public health needs like the mRNA vaccines. And there is also no other mRNA vaccine globally that is available to meet URG needs.[30] Securing additional mRNA vaccine from Pfizer-BioNTech and Moderna will ensure that the USG will be able to continue to provide protection against the current and new

[28] The CDC has states that "Three COVID-19 vaccines are authorized or approved for use in the United States to prevent COVID-19. Pfizer-BioNTech or Moderna (COVID-19 mRNA vaccines) **are preferred**. You may get Johnson & Johnson's J&A COVID-19 vaccine in some situations." (emphasis added). https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

[29] *See* FDA BLA Approval Letter for Pfizer COVID-19 Vaccine, mRNA, "COMIRNATY" dated August 23, 2021 available here: https://www.fda.gov/media/151710/download. Pfizer was granted license number 2229 (see page 1). ModernaTX received BLA approval for their "COVID-19 Vaccine, mRNA", proprietary name "SPIKEVAX," on January 31, 2022 with license number 2256. *See* FDA BLA Approval Letter at https://www.fda.gov/media/155815/download.

[30] See 17 May 2022 World Health Organization (WHO) landscape of mRNA vaccines in clinical trials around the word. Available at: https://www.who.int/teams/blueprint/covid-19/covid-19-vaccine-tracker-and-landscape,

variants of concern to the US population and military personnel around the world by obtaining mRNA vaccines have the maximum flexibility to comply with the guidance of US Public Health Authorities (prototype, booster, variant formulation).[31]

We are aware that both companies are already working to produce mRNA vaccines for the fall 2022 vaccination campaign. However, the international demand for these mRNA vaccines will be significant. It is strategically imperative that USG reserve doses of the mRNA vaccines from Moderna and Pfizer now. The anticipated need for the US fall campaign is delivery of (b) (4) doses the first week of September 2022, (b) (4) doses the second week of September 2022, with a minimum of (b) (4) doses per week thereafter. Currently, Pfizer has the capacity to manufacture (b) (4) doses per week to the US through the end of the calendar year, with Moderna indicating it can provide (b) (4) total doses to the US through the end of the calendar year. Given these constraints, contracts with both manufacturers are necessary to meet the required quantities and schedule. In light of the forgoing, Pfizer and Moderna are responsible sources to satisfy the USG's need for FDA authorized or approved mRNA vaccines. No other manufacturers can meet the mRNA vaccine requirement to protect against current and future COVID-19 variant threats by the fall of 2022.

While Janssen manufactures a third EUA vaccine, J&J's COVID-19 vaccine is a viral vector vaccine and has not yet received BLA from FDA for any indications. Additionally, on May 5th, 2022, the FDA limited the authorized use of J&J's EUA COVID-19 vaccine to individuals 18 years of age and older for whom the Pfizer-BioNTech and Moderna vaccines are not accessible or clinically appropriate. FDA has determined that the risk of thrombosis with thrombocytopenia syndrome (TTS), a syndrome of rare and potentially life-threatening blood clots in combination with low levels of blood platelets with onset of symptoms approximately one to two weeks following administration of the Janssen COVID-19 Vaccine, warrants limiting the authorized use of the vaccine "to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would

[31] It is currently unclear precisely what U.S. Public Health Authorities will direct as it relates to the fall 2022 vaccination campaign and whether or not this will consist of mRNA prototype vaccines, mRNA boosters, or mRNA variant-specific or bivalent formulations, or other approach to fall vaccination. FDA has scheduled a general meeting of its Vaccines and Related Biological Products Advisory Committee (VRBAC) for June 28, 022, to "discuss whether the SARS-CoV-2 strain composition of COVID-19 vaccines should be modified…". *See* FDA New Release, dates April 29, 2022, available here: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-announces-tentative-advisory-committee-meeting-schedule-regarding. Recent data have demonstrated that a third, or 'booster' dose increases protection against Omicron. In addition, recent international data suggest that a fourth dose might further increase protection of our most vulnerable populations against the Omicron variant. Currently, the exact timing of the third dose relative to the second dose for pediatrics is still being determined by US Public Health Authorities, and the need/timing for a fourth dose is uncertain. The USG currently does not have enough vaccine to cover a third dose for the pediatric population, or support a fall campaign for adults. However, the mRNA vaccines provided the broadest possible vaccine capability as compared to the rest of the vaccine field.

otherwise not receive a COVID-19 vaccine."[32] Given the relative benefits of mRNA vaccines as compared to the viral vector vaccine[33] and the limitations of the J&J vaccine itself, the Janssen viral vector vaccine cannot meet the USG requirement. This rationale applies with equal force to AstraZeneca's viral vector vaccine for which the company has made no regulatory filings to date and is not authorized for commercial use commerce in any way. No viral vector vaccine has shown the technical maturity of the mRNA vaccines.

Additionally, the USG has contracts with Novavax and Sanofi to deliver up to 100 million doses each of adjuvanted protein subunit vaccine if those company's vaccines receive an EUA or BLA. However, neither Novavax nor Sanofi currently have an EUA or BLA for any COVID-19 vaccine indication nor is it anticipated that they will have an EUA or BLA for their respective vaccines in time to have product available in sufficient quantities to meet the USG's demand for a vaccine capable to meet the demands of US Public Health Authorities (e.g., CDC and FDA) for fall 2022. Furthermore, the protein subunit vaccines are not as mature as the mRNA vaccines. The USG cannot include Novavax or Sanofi in this contracting action because they are not mRNA vaccines, and therefore not authorized to market their COVID-19 vaccine in the US at the time the USG needs to place orders to ensure sufficient supply of safe and effective vaccines by fall 2022. However, if at any time Novavax or Sanofi receives authorization for their protein subunit vaccines, their contracts with the USG will trigger the orders for (b) (4) doses of the authorized COVID-19 vaccine.

6. Efforts to Obtain Competition: The USG has not sought competition for this contract action due to the limited availability of responsible sources capable of producing authorized or approved mRNA vaccines with the level of clinical superiority, technical maturity or agility to deal with variants as compared to Pfizer and Moderna's mRNA vaccines.

Beginning with Operation Warp Speed and now under the HHS Coordination Operations and Response Element (H-CORE) program, there was an "all of government" approach to identifying vaccine candidates that could achieve FDA BLA. There are currently two companies – Pfizer and Moderna - that have full FDA approval for mRNA vaccines, which means these two products are clinically superior, technically more mature, and given the mRNA platform, more agile to adjust to the emerging public health need as articulated by US Public Health Authorities. HHS and DoD scientific and acquisition teams have explored the market to determine if any other vaccine manufacturer could produce an mRNA vaccine. There are no other known sources with this mRNA capability. Consistent with the forgoing discussion in Section 4, other COVID-19 vaccine candidates are either restricted in their utility (FDA restricted the use

[32] *See* FDA Press Release re: Limitation of J&J Vaccine at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-J&A-covid-19-vaccine-certain-individuals, viewed 17 May 2022

[33] CDC states that "In most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the J&J/J&A COVID-19 vaccine for primary and booster vaccination due to the risk of serious adverse events, " Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/J&A.html.

of Janssen's adenovirus vector vaccine) or do not yet even meet the lower bar of FDA EUA (Novavax and Sanofi). The May 19, 2022, Market Research report issued by BARDA and DoD substantiate these conclusions.[34]

In order to promote small business participation, commercial subcontracting plans will be required to be submitted with all proposals; however, due to the proprietary nature of the product, subcontracting opportunities may be limited.

7. Actions to Increase Competition: Based upon market research, there are currently two companies capable of developing and delivering safe and effective authorized or approved mRNA COVID-19 vaccines for the fall 2022 vaccination campaign. Furthermore, only the mRNA vaccines have the requisite clinical superiority, technical maturity and agility to address the variant-specific demands of US Public Health Authorities to support domestic needs in sufficient quantities to protect the US. The USG currently has a contract with Moderna, whose COVID-19 mRNA vaccine is FDA-approved in adults ages 18 years and older, and has previously purchased 500M doses of vaccine for domestic use. The USG also currently has a contract with Pfizer, whose COVID-19 mRNA vaccine is FDA-approved in adults and children 16 years and older, and is FDA-authorized for emergency use in children ages 5-15 years. The USG has already purchased 1.6 billion doses of Pfizer vaccines for domestic use and international donation to low-income countries.

The USG also currently has a contract with Janssen, which was used to acquire 100M doses of their viral vector vaccine; however, as discussed above, with the superiority of the mRNA vaccines COMRITY (Pfizer) and SPIKEVAX (Moderna) and recent FDA decision to limit the use of their vaccine to a subset of adults, the Janssen viral vector vaccine is not a viable solution to meet the current demand under this specific action.

The USG has existing contracts with Novavax and Sanofi; however, no adjuvanted protein subunit vaccine has been delivered since they lack any marketing authorization (either full BLA licensure or EUA) from the FDA for a primary vaccine series or booster. The USG will continue to monitor Novavax, Sanofi, and Janssen for new developments regarding their vaccines that could make them responsible sources for future acquisitions. In addition to the doses the USG has already purchased or agreed to purchase from each of the manufacturers of COVID-19 vaccines, the USG will monitor and consider all changes to the vaccine market so that additional sources of COVID-19 vaccines can be included in future vaccine requirements, thereby increasing competition.

8. Market Research: The DoD, in partnership with BARDA, has various methods by which to stay connected to industry and to leverage current research and development to meet mission needs. BARDA and JPEO-CBRND have conducted extensive and continuous market research into the commercial domestic marketplace for this requirement. The USG has, to date, invested in six vaccine candidates: Pfizer,

[34] Market Research Report, dated May 19, 2022, signed by (b) (6) , Director, Division of CBRN MCMs, HHS BARDA.

Moderna, Janssen, AstraZeneca, Novavax, and Sanofi. H-CORE, previously known as Operation Warp Speed and then the Countermeasures Acceleration Group, have also held multiple meetings with other companies who are developing additional COVID-19 vaccines. While several of these companies continue to work towards EUA, including several that produce recombinant protein vaccines, none have a definitive timeline for receipt of EUA or BLA, timing of product availability in sufficient quantities, demonstrated cGMP manufacturing for large-scale production capability based on historical performance, or a clear approach to rapidly switch to and produce new variant vaccines if required by US Public Health Authorities.

In addition to contacting Contracting Officers, Contract Specialists, and Project Officers in other Federal agencies and individuals from private industry, The USG conducted interchange meetings and pre-solicitation/vendor conferences with potential offerors early in the acquisition process on April 20th and 24th, May 20th and 25th, June 9-11, 14, 17, 22-23, 2021. The USG team also conducted in depth market research through Tech Watches, BARDA Industry Days, and interviews with individuals knowledgeable of industry trends and requirements, through in-depth market research of companies or product specific research. This in-depth market research was conducted from January 2020 to May 13, 2022, to determine the availability of capable sources to develop, produce and deliver a sufficient number of vaccine doses within the required time constraints. BARDA has held 660+ Tech Watches related to this technology since January 2020. A Request for Information (RFI no. 75A50122R00014) was also posted by BARDA onto sam.gov January 21 through February 2, 2022, seeking interested parties with demonstrated cGMP large-scale manufacturing capabilities for COVID-19 vaccine supply. The focus was on next generation COVID vaccines, and the USG received 18 responses, with several focused on mRNA and recombinant protein platforms. A team of vaccine researchers on advanced development efforts from the National Institutes of Health (NIH) and BARDA did a thorough assessment of responses, looking primarily at potential to be improved relative to current vaccines, manufacturing scale potential, and potential timeline for starting pivotal trials. The USG did not identify any candidates that would be able to file an EUA and obtain an EUA for primary series and booster vaccines prior to the fall. One important point to note, the FDA has made it clear that at this time, they are not willing to give an EUA for a booster vaccine unless the vaccine has a primary series indication.

To date, several primary vaccines have been developed and development status ranges from early-stage clinical development to active EUA and/or BLA granted by the FDA, & some with mature manufacturing capacity and supply chains in place. The table below lists companies, product, regulatory status, and currently active USG procurement contracts.

Company / Product	Regulatory Status	Type of Vaccine	Active USG Contract
Moderna Vaccine	FDA Full Approval, EUA granted for booster for ages 18 and up	mRNA	Awarded Contract No. W911QY-20-C-0100. Manufacture & delivery of 500M doses
Pfizer-BioNTech Vaccine	FDA Full Approval for 16 and up, EUA granted for booster in adults and primary series in ages 5-15	mRNA	Awarded Contract No. W15QKN-21-C-0012. Manufacture & delivery of 600M doses
Janssen Vaccine	EUA granted, FDA has limited the authorized use to ages 18 and above for specific populations	Viral Vector	Awarded Agreement No. W15QKN-16-9-0002. Manufacture & delivery of 100M doses
Sanofi Pasteur/GSK	EUA submitted	adjuvanted protein subunit vaccine	Awarded Agreement No. W15QKN-16-9-1002. Manufacture & delivery of 100M doses.
AstraZeneca AZD1222	No EUA or BLA (no active submittals)	Viral Vector	Awarded Agreement No. W15QKN-21-9-1003 – No doses to be provided under this Agreement.
Novavax NVX-CoV2373	EUA submitted	adjuvanted protein subunit vaccine	Awarded under Agreement W15QKN-16-9-1002. Manufacture & delivery of 100M doses.

9. Interested Sources: To date, no other companies have written to express an interest in this procurement.

10. Other Facts:

1. Procurement history.

i. Moderna
(1) Contract W911QY-20-C-0100; Delivery of 500 million doses of SARS-CoV-

2 Vaccine, awarded on 11 August 2020.
(2) Competitive Status: Sole-source.
(3) Authority Previously Cited: 10 U.S.C. 3204(a)(2) as implemented by FAR 6.302-2, Unusual and Compelling Urgency.
(4) Changed Circumstances: (b) (4) [redacted].
(5) Unusual Patterns: N/A
(6) Significant Changes: No significant changes. The need for vaccines to combat COVID-19 continues as variants continue to emerge increasing the spread and the impact of the disease.

ii. Pfizer
(1) Contract W15QKN-21-C-0012; Delivery of 600 million doses of SARS-CoV-2 Vaccine, awarded on 21 July 2020.
(2) Competitive Status: Sole-source
(3) Authority Previously Cited: 10 U.S.C. 3204(a)(2) as implemented by FAR 6.302-2, Unusual and Compelling Urgency.
(4) Changed Circumstances: As COVID-19 cases continue to rise, BioNTech and Pfizer have expressed their commitment to rapidly adapt, manufacture and distribute a newly designed mixed vaccine within approximately three months.
(5) Unusual Patterns: N/A
(6) Significant Changes: No significant changes. The need for vaccines to combat COVID-19 continues as variants continue to emerge increasing the spread and the impact if the disease

iii. Janssen (J&J)
(1) Contract W15QKN-16-9-002; Delivery of 100 million doses of the Ad26.COV2.S vaccine, awarded on 05 August 2020.
(2) Competitive Status: Competitive, in accordance with Medical CBRN Defense Consortium No. MCDC2011-004.
(3) Authority Previously Cited: Other Transaction for Prototype, pursuant to 10 U.S.C. § 2371b
(4) Changed Circumstances: As COVID-19 variants continue to propagate the need to provide additional vaccines capable of countering this evolving threat will be a necessity.
(5) Unusual Patterns: N/A
(6) Significant Changes: US Food and Drug Administration has limited the authorized use of the Janssen COVID-19 Vaccine to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.

2. Other facts. N/A

11. Technical Certification:

I certify that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Signature: (b) (6) Date:

Typed Name: (b) (6) Title: Deputy, ASPR

12. Requirements Certification:

I certify that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Signature: (b) (6)

Typed Name: (b) (6) Title: Antivirals & Antitoxins Branch Chief

13. Fair and Reasonable Cost Determination:

I hereby determine that the anticipated cost to the USG for this contract action will be fair and reasonable. The basis for this determination will be price analysis. In accordance with FAR 15.403-1(b)(3), certified cost or pricing data will not be required, as this is a commercial item.

Signature: (b) (6) Date: 24 May 2022

Typed Name: (b) (6) Title: Contracting Officer

14. Contracting Officer Certification: I certify that this justification is accurate and complete to the best of my knowledge and belief.

Signature: (b) (6) Date: 24 May 2022

Typed Name: (b) (6) Title: Contracting Officer

Control Number: JA-22-JCRD-391

Approval

Based on the foregoing class justification, I hereby approve the procurement of up to a total 600M doses of SARS-CoV-2 mRNA vaccines from Moderna and Pfizer as a countermeasure to COVID-19 on an Other than Full and Open Competition basis, pursuant to the authority of Title 10, United States Code, Section 3204(a)(1), as implemented by Federal Acquisition Regulation 6.302-1, "Only one or a limited number of responsible sources and no other supplies or services will satisfy agency requirements." The estimated amount of the contract actions is $18,000,000,000, with an up to 20-month performance period. The approval is subject to availability of funds, and provided that the services and property herein described have otherwise been authorized for acquisition.

6/3/22
Date

(b) (6)

Senior Procurement Executive