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IN THE UNITED STATES COURT OF FEDERAL CLAIMS
BID PROTEST

Redacted Version

AIRBOSS DEFENSE GROUP, LLC, Plaintiff, and STRINGKING LACROSSE LLC, Plaintiff-Intervenor v. THE UNITED STATES, Defendant, and NEW YORK EMBROIDERY STUDIO, INC., Defendant-Intervenor.	)	No. 24-365 (Judge Lettow) [redacted]

PLAINTIFF ADG'S SUPPLEMENTAL RESPONSE IN SUPPORT OF PLAINTIFF-INTERVENOR STRINGKING'S APPLICATION FOR TEMPORARY RESTRAINING ORDER AND MOTION FOR PRELIMINARY INJUNCTION

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I. INTRODUCTION

Pursuant to this Court's June 14, 2024 Order (ECF No. 58), Plaintiff, AirBoss Defense Group, LLC ("ADG"), files this Supplemental Response in Support of Plaintiff-Intervenor StringKing Lacrosse LLC's ("StringKing") Application for a Temporary Restraining Order and Motion for a Preliminary Injunction (ECF No. 54). As discussed below, StringKing is likely to succeed on the merits of its claim that Amendment 0009 to Request for Proposal No. 75A50322R00008 for Level 2 Isolation Gowns (the "RFP" or "Solicitation") is arbitrary and capricious, which claim mirrors the claim in Count III of ADG's Second Amended Complaint. *See Infra* § II.A; ECF No. 51 ¶¶ 86-104. StringKing is also likely to succeed on the merits of its claim that the deadline for receipt of proposals established by Amendment 0009—even as extended by Amendment 0011—is arbitrary and capricious. *See Infra* § II.B.

During this Court's hearing on June 14, 2024, the Court granted ADG leave to address in ADG's Supplemental Response additional defects in Amendment 0009, which were the subject of offeror questions that the Government did not answer until Amendment 0011. As discussed below, ADG is likely to succeed in demonstrating that the three-month date-of-manufacture requirement established by Amendment 0009 and confirmed in Amendment 0011 is inconsistent with customary commercial practice. *See Infra* § II.C. ADG is also likely to succeed in demonstrating that the Government is conducting a lowest-price, technically acceptable source selection, contrary to governing law and the terms of the RFP. *See Infra* § II.D.

Finally, each of the other factors for injunctive relief weigh in favor of StringKing and ADG. ADG will be irreparably harmed absent the relief requested because it will have no adequate remedy if it is required to invest substantial time and effort in developing a response to the current solicitation over the next two weeks, and if this Court subsequently determines that the current solicitation is unlawful. The Government, by contrast, will not be harmed by a short

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delay to this procurement to permit the Court to rule on these cases, particularly given that the Government is solely responsible for the many months of delays to this procurement to date.

II. ARGUMENT

As described in detail below, StringKing fully satisfies each of the four elements supporting the issuance of a temporary restraining order or preliminary injunction: (1) plaintiff's likelihood of success on the merits; (2) whether the plaintiff will suffer irreparable harm if the Court withholds injunctive relief; (3) whether the balance of hardships on all parties favors the grant of injunctive relief; and (4) whether it is in the public interest to grant injunctive relief. *Gen. Dynamics Mission Sys., Inc. v. United States*, 136 Fed. Cl. 355, 357-58 (2018) (citing *PGBA, LLC v. United States*, 389 F.3d 1219, 1228-29 (Fed. Cir. 2004)). Therefore, the Court should enter an order or injunction preventing HHS from accepting proposals and from proceeding with the Level 2 Isolation gown procurement while the Court reviews the important issues raised by this protest.

A. StringKing and ADG Are Likely To Succeed In Demonstrating that Amendment 0009 Improperly Removes Shelf-Life as a Consideration in this Procurement.

1. Amendment 0009 Effectively Eliminates Shelf-Life as a Consideration in this Procurement.

Prior to 2024, the RFP expressly stated that shelf-life would be considered in determining which proposed gown offered the best value to the Government: "The Government's overall best value determination will consider *the cost of the product as it relates to the shelf-life at time of delivery* and the best value determination will also consider *the time, effort, and cost to sustain product with lesser shelf-life*." AR 317 (emphasis added). To evaluate shelf-life, the RFP provided: "Offerors will be evaluated based on providing appropriate data and documentation,

[redacted]

such as accelerated aging and real-time testing reports and other validating documentation, to support their shelf-life claims." AR 330.

Amendment 0009 effectively removes shelf-life as a consideration in this procurement. Amendment 0009 states: "Isolation Gowns must have a shelf life of 3 years, and, at the time of delivery to the SNS, isolation gowns shall have no more than 3 months expended since the date of manufacture, as listed on the gown packaging labels." Ex. 1 at 16. Amendment 0009 further explains that a "shelf life longer than 3 years will not be evaluated higher or considered to be an additional strength." *Id.* at 53. Amendment 0011 further confirms that shelf-life will be evaluated only on a pass/fail basis to determine whether gowns have a three-year shelf-life, and that HHS assigns no value to gowns with a longer shelf-life. Ex. 2 at 6 (Q&A Nos. 18, 19, & 33). Finally, Amendment 0011 relieves offerors from providing any support or validation of their shelf-life claims beyond the offeror's certification of shelf-life. *Id.* at (Q&A No. 8).

HHS received proposals in response to the RFP proposing gowns with shelf-lives ranging from five years to 16.5 years.[1] The minimum shelf-life claim reflected in the administrative record is five years. *Id.* HHS's evaluation documents inconsistently state in September 2023 that a five-year shelf-life is the "industry norm," AR 1190, and then state in January 2024 that

[1] HHS received proposals from 21 offerors; however, the administrative record only includes the proposals of Essential Safety, NYES, StringKing, and ADG. AR 1682. The January 3, 2024 Amended Technical Evaluation Panel Report recites the shelf-lives claimed by the ten offerors who met the RFP's domestic end product requirements, each of which was a minimum of five years. *See* AR 1699 (Essential Safety—[redacted]); AR 1708 (NYES—[redacted]); AR 1720 (StringKing—[redacted]); AR 1734 (ADG—[redacted]); AR 1746-47 (Coulmed—[redacted]); AR 1760 (Gredale—[redacted]ars); AR 1775 (Health Supply US—[redacted]); AR 1790 (TomaHawk Safety—[redacted]); AR 1803 (Two One Two New York—[redacted]). Unifire proposed four gowns. AR 1806. Two of Unifire's gowns claimed a shelf-life of [redacted] years. AR 1812-13 & 1831. One gown proposed by Unifire did not include a shelf-life claim. AR 1824. The fourth was not evaluated for shelf-life because it did not meet the domestic end product requirement. AR 1833.

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the industry norm is "up to 10 years," AR 1693, 1711. The record provides no support for either conflicting assertion. Regardless, by establishing a minimum required shelf-life of three years, Amendment 0009 sets the bar far below what every offeror can meet and what HHS itself thought was the "norm" at any point in this procurement. Accordingly, by prohibiting any consideration of shelf-lives longer than three years, Amendment 0009 effectively removes shelf-life as a consideration from this procurement.

2. HHS's Elimination of Shelf-Life Violates Procurement Law, Ignores the Purpose of this Procurement, and Is Arbitrary and Capricious.

Amendment 0009's elimination of shelf-life as a consideration violates procurement law in two ways. *First*, removing shelf-life as a consideration fails to adequately consider "life-cycle cost" as required by FAR 7.105(a)(3)(i). The FAR defines life-cycle cost as "the total cost to the Government of acquiring, operating, supporting, and (if applicable) disposing of the items being acquired." FAR 7.101. As the RFP explains, the purpose of this procurement is to acquire gowns for the Strategic National Stockpile ("SNS"), which is a national repository of pharmaceuticals, vaccines, medical supplies, and medical equipment stored in strategic locations around the United States. AR 277; Ex. 1 at 10. HHS's own website for the SNS emphasizes the importance of shelf-life as a life-cycle cost to sustain the SNS:

> **Sustaining the Stockpile**
>
> Sustaining the Strategic National Stockpile (SNS) involves *managing the entire life cycle* of stockpile assets as well as acquiring, storing, and transporting supplies.
>
> SNS management includes:
>
> - *Overseeing the shelf life* of medicines to ensure the stock is rotated and kept within U.S. Food and Drug Administration (FDA) potency shelf-life limits
> - Conducting routine quality assurance on all products

[redacted]

- Performing annual inventory of all products

. . . .

See HHS, Administration for Strategic Preparedness & Response, "Sustaining the Stockpile," available at https://aspr.hhs.gov/SNS/Pages/Sustaining-the-Stockpile.aspx (last visited June 18, 2024) (emphasis added). Indeed, the statutory mandate for the Administration for Strategic Preparedness & Response is to plan for the "procurement, stockpiling, maintenance, *and potential replenishment of* all products in the Strategic National Stockpile." 42 U.S.C. § 300hh-10(b)(7) (emphasis added). And the Government Accountability Office has similarly recognized that, "[a]s these products [including gowns and other PPE] expire, they need to be replaced or rotated out of the inventory and replaced with new inventory." Gov't Account. Office, Public Health Preparedness, HHS Should Address Strategic National Stockpile Requirements and Inventory Risk at 41, Report No. GAO-23-106210 (Oct. 2022), *available at* https://www.gao.gov/assets/gao-23-106210.pdf.

It was therefore only natural that the original RFP and all amendments through Amendment 0007 provided that HHS would specifically evaluate shelf-life in determining best value, including both "the cost of the product as it relates to the shelf-life at time of delivery," and the "the time, effort, and cost to sustain product with lesser shelf-life." AR 317. These considerations go to the very heart of the SNS's mission. Gowns with a shorter shelf-life necessarily have a higher life-cycle cost because they are more likely to expire and need to be replaced prior to being needed. In fact, HHS's Acquisition Plan for this procurement states that HHS learned this the hard way during the COVID-19 pandemic:

> In response to the pandemic, an initial requirement for the SNS to procure and sustain a quantity of 265 million gowns, 50% surgical and 50% isolation, was established as part of the SNS 2.0 initiative in April of 2020. In April 2020, HHS/SNS engaged DLA to procure, on HHS' behalf. The

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> SNS was unable to accept more than 20% of the DLA contracted quantity due to various shelf-life, quality, performance, and other issues.

AR 102.[2]

Despite recognizing that shelf-life is inextricably linked to life-cycle cost, and despite factoring shelf-life into the best value analysis in the original RFP and all amendments through Amendment 0007, HHS has now eliminated shelf-life as a consideration altogether. In response to offeror question no. 37 regarding Amendment 0009, HHS provided the following answer:

> Q. Does the Government believe there are life-cycle costs associated with the gowns being acquired? If so, what are those life cycle costs?
>
> A. Lifecycle costs for PPEs typically include procurement, pallet receiving and storage costs, and disposal costs.

Ex. 2 at 8. HHS's answer recognizes that gowns will expire and need to be disposed of, but inexplicably omits the cost of *replacing gowns that are disposed of because they have expired*. This omission flies squarely in the face of Congress's mandate that HHS plan for the "procurement, stockpiling, maintenance, *and potential replenishment of* all products in the Strategic National Stockpile." 42 U.S.C. § 300hh-10(b)(7) (emphasis added).

HHS's response to question no. 38 is even more telling:

> Q. Does the Government agree that there is an inherent cost to the Government associated with replacing gowns whose shelf-life has expired? If so, what does the Government expect that cost to be? If not, why does the Government believe there is no such cost?
>
> A. Refer to the response for Question 37

[2] HHS's Acquisition Plan incorrectly states that "[l]ife-cycle cost does not apply to this commercial medical supply acquisition." The acquisition planning requirements of FAR Subpart 7.1—including FAR 7.105(a)(3)(i)'s requirement that life-cycle costs be considered—applies to "all acquisitions," including acquisitions of commercial products and services. FAR 7.102(a).

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Id. HHS's refusal to respond directly to question no. 38 demonstrates that HHS has failed to consider known life-cycle costs, as required by FAR 7.105, that go to the heart of the SNS's mission.

Second, by effectively removing shelf-life as a consideration, the Government also will not meaningfully evaluate cost and price as required by 41 U.S.C. § 3306(c)(1)(B). Agencies may not use an evaluation method that produces a misleading result; instead, the method chosen must include some reasonable basis for evaluating or comparing the relative costs of proposals, so as to establish whether one offeror's proposal would be more or less costly than another's. *See, e.g., S.J. Thomas Co., Inc.*, B-283192, Oct. 20, 1999, 99-2 CPD ¶ 73 (sustaining protest where agency considered offeror's proposed mark-up rates, without taking into account potential differences in offerors' labor rates, number of hours, mix of labor categories, and material costs); *R&G Food Service, Inc.*, B-296435.4 et al., Sept. 15, 2005, 2005 CPD ¶ 194 at 3. Amendment 0009 violates this mandate by ignoring altogether the higher costs associated with gowns with a shorter shelf-life, relying instead on the misleading, and illusory unit price of lower-quality gowns. Under Amendment 0009, the Government considers a gown with three years of shelf-life to have no greater value than a gown with six or nine years of shelf-life, despite the obvious increased cost to the Government of having to replenish gowns in the SNS that expire, which cost will necessarily be higher than gowns with a shorter shelf life.

Finally, the elimination of shelf-life as a consideration is simply arbitrary. Amendment 0007 slightly revised Section C.4 of the RFP, Shelf-Life, but Amendment 0007 did not eliminate the RFP's statement that shelf-life would be considered part of the best value analysis. *Compare* AR 317 (Amd. 0007 revision to Section C.4) and AR 330 (Amd. 0007 revision to Section M), *with* AR 317 (Amendment 0005 version of Section M). HHS's responses to offeror questions at

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the time stated that the revisions in Amendment 0007 were "based on the Agency's assessment of its needs." AR 334 (Q&A Nos. 29-30). Accordingly, as of November 18, 2022, the date Amendment 0007 was issued, HHS had affirmatively determined that its needs required an integrated assessment of shelf-life and price to determine best value.

The record contains no coherent explanation why HHS abandoned this determination. The record shows that HHS internally questioned the value of shelf-lives in excess of ten years in its September 2023 evaluation of StringKing's proposal, which offered gowns with a [redacted] shelf-life:

> USG should consider if it is appropriate, allowable, and beneficial to stockpile a gown for over 10 years, as the industry norm for personal protective equipment (PPE) shelf life is 5 years, and, longer dated shelf life could hinder the domestic manufacturing industry.

AR 1190; *accord* AR 1342 (September 2023 Award Decision Memo). In selecting NYES for award in September 2023, HHS recognized that the RFP required an integrated assessment of shelf-life and price, but stated, in conclusory fashion, that StringKing's longer shelf-life does not offer any value:

> The Contracting Officer considered the cost of the proposed products as it relates to the proposed shelf-life at time of delivery and determined that the industry norm for PPE shelf-life is 5 years and the extended shelf-life could hinder the domestic manufacturing industry. The Contracting Officer determine that any cost premium associated with the shelf-life does not offer the government any value.

AR 1344. This assertion makes no sense—clearly, there is a "cost premium" associated with having to replace gowns with shorter shelf-lives to maintain the SNS. HHS's Acquisition Plan for this procurement demonstrates that expired products hindered the Government's response to the COVID-19 pandemic. AR 102. Regardless, the record contains no effort on the part of HHS

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to quantify this "cost premium," let alone explain why it does not "offer the government any value."

Then, when HHS reevaluated proposals in late 2023, HHS recognized that "[t]he typical shelf life of PPE, including non-surgical isolation gowns, *is up to 10 years*." AR 1693, 1711 (emphasis added). HHS's January 2024 Technical Evaluation Panel Report stated that the "industry norm" is "less than 10 years," which backtracks from HHS's earlier suggestion that the industry norm is five years. *Compare* AR 1711, *with* AR 1344. Neither statement is supported by any evidence in the administrative record. Regardless, in January 2024, HHS revised its assessment of the benefits of shelf-life to state "there may not be benefits with stockpiling isolation gowns in the SNS for *longer than 10 years*." AR 1711(emphasis added). HHS now seemed to accept that there was a benefit to stockpiling gowns with shelf-lives up to ten years.

Then, inexplicably, Amendment 0008 removed shelf-life from the best value decision. AR 1917. Although the administrative record purports to be complete through Amendment 0008, the record contains no explanation for this change. To the contrary, the record indicates that HHS refused requests from offerors to explain this change. AR 1920-21 (Q&A Nos. 11-12).

In Amendment 0011, HHS provided the only explanation that exists in the record for ignoring shelf-life. Question No. 3 in Amendment 0011 asked, "What is the Agency's reasoning in procuring gowns with a 3-Year shelf-life which will likely expire prior to any future pandemics and/or emergencies?" Ex. 2 at 3-4. The Government's response misses the point entirely: "It is unknown if isolation gowns with any varying designated shelf life will expire prior to the next public health emergency since the timing of these cannot be predicted." *Id.* It is precisely *because* the timing of the next public health emergency *cannot* be predicted that shelf-life is an important consideration. If the Government does not consider the impact on shelf-life

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to the Government's requirement for a stockpile that will support an uncertain future public health emergency, the Government has "entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The fact that HHS's own Acquisition Plan recognized that this very problem hampered the Government's response to the COVID-19 pandemic, AR 102, and HHS's vacillation about what the "industry norm" is for shelf-life and whether the advantages of longer shelf-life diminish after five years or after ten years, only underscores the arbitrary and capricious nature of HHS's actions.

B. StringKing and ADG Are Likely To Succeed In Demonstrating that Amendment 0009's Proposal Deadline—as Further Extended in Amendment 0011—Is Arbitrary and Capricious.

FAR 5.203(b) requires contracting officers to "establish a solicitation response time that will afford potential offerors a reasonable opportunity to respond to each proposed contract action," and further requires agencies to "consider the circumstances of the individual acquisition, such as the complexity, commerciality, availability, and urgency, when establishing the solicitation response time." When the RFP was originally issued on June 27, 2022, it allowed offerors over a month before proposals were due on July 29, 2022. AR 124. That deadline was extended to November 17, 2022, through Amendment 0005, giving offerors nearly *five months* to submit their initial proposals. AR 271.

The record shows that HHS knew that offerors were using this time to develop the manufacturing capabilities, supply chains, and other infrastructure necessary to develop a *domestic* manufacturing capability for their proposed gowns. In fact, even before the original RFP was issued, HHS's Acquisition Plan acknowledged the efforts that potential offerors were making to prepare for the Solicitation:

[redacted]

> As a result of this RFI and on-going discussions with Industry, several manufacturers have been preparing over the past several months in anticipation of this solicitation and have expanded their domestic capabilities and entered into tentative agreements with domestic raw material providers in order to manufacture an end item in the United States with 100% raw materials/components. Those that indicated they have done such are Stringking, ADG, USA Medical Supply, NYES, and Gredale, however they also noted that domestic raw material availability was on a month-by-month basis.

AR 109. Offerors like ADG detailed in their proposals the considerable time and effort they spent building coalitions of businesses to form the supply chains and manufacturing capabilities necessary to *domestically* produce and deliver gowns at the scale required by the RFP. AR 343; *accord* AR 1140 (StringKing).

HHS's Acquisition Plan for this procurement explains that the RFP implements the Infrastructure Investment and Jobs Act (the "IIJA"), Pub. L. 117-58, 135 Stat. 429 (Nov. 15, 2021). Specifically, the RFP implements the "Make PPE in America" provisions in Subtitle C of the "Build America, Buy America" provisions in Title IX of the IIJA. 135 Stat. at 1312-16. Section 70952 if the IIJA recognizes that substantial investment in U.S. domestic manufacturing capabilities was necessary in order to expand those capabilities to meet the needs of the then-current and future pandemics. 135 Stat. at 1313. Congress found: "In order to foster a domestic PPE supply chain, United States industry needs a strong and consistent demand signal from the Federal Government providing the necessary certainty to expand production capacity investment in the United States." *Id.*

This procurement was always intended to be a core part of the "strong and consistent demand signal" that Congress wanted to send to industry to spur investment in manufacturing capabilities. AR 102 ("This effort, in conjunction with similar efforts for other PPE, is to protect the United States from experiencing a PPE shortage similar to what was experienced in the early

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stages of the COVID-19 response due to its dependence on foreign manufacturing and raw materials to supply these products amidst the breakdown of the global supply chain."); *id*. ("The need for these isolation gowns is not just driven by current shortage in the Stockpile, but by *a larger need to establish and maintain domestic sourcing* for this product; the Government's alternatives are limited." (emphasis added)). ADG and StringKing did exactly what Congress and HHS wanted and invested in expanding their domestic supply chains and manufacturing capabilities. AR 109.

ADG and StringKing built their expanded capabilities around their higher quality, longer shelf-life, but more expensive, gowns. By eliminating shelf-life from the evaluation, Amendment 0009 precludes HHS from concluding that ADG's and StringKing's higher quality and longer shelf-life is worth the price differential that exists between their gowns and NYES's. Yet Amendment 0009 only gave ADG seventeen days to identify cheaper alternatives, and to build a supply chain and manufacturing capability that would produce those cheaper alternatives at the scale required by the RFP. That deadline was impossible for multiple reasons, not the least of which was that Amendment 0009 included multiple defects that had to be clarified in Amendments 0010 and 0011. Amendment 0011, however, only provided an additional thirteen days to do what had previously taken months to do in 2022. Because no rational person can expect ADG and StringKing to accomplish such a feat, the proposal deadline in Amendment 0009, as extended by Amendment 0011, is arbitrary and capricious and violates FAR 5.203(b).

The Government's explanation for not providing additional time again misses the point entirely. The Government states that it "will not be extending proposal deadlines for offerors to design and develop new isolation gowns since that does not meet the requirement for commercial products or services as specified in the solicitation." Ex. 2 at 3. But even if offerors will not

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"design and develop" new gowns, offerors need time to validate that commercially available gowns meet the extensive requirements that the Government has established in the solicitation, including the numerous testing requirements, many of which are not standard commercial requirements for gowns. And, more importantly, offerors need time to develop the supply chain and manufacturing capabilities to produce gowns at the scale required by the RFP—*activities that the IIJA expressly promoted and which this procurement was intended to encourage.*

Again, the Government's position is hopelessly contradictory. Amendment 0009 requires that gowns have no more than three month's shelf-life expended since the gown's date of manufacture, which necessarily requires that gowns be manufactured on a rolling basis over the contract's period of performance. Ex. 2 at 8. Yet the Government's rationale for not extending the due date for proposals assumes that the Government is purchasing gowns off the shelf, and that no lead time is necessary to establish the necessary supply chain and production infrastructure to deliver according to the Government's own requirements. That assumption is directly at odds with the IIJA, which this procurement supposedly implements. AR 102. The IIJA and the Acquisition Plan for this procurement recognize that investment in supply chains and manufacturing capability is necessary in order to domestically produce gowns at the scale needed to confront the next pandemic. Pub. L. 117-58, 135 Stat. at 1313; AR 109. The Government's position on the reasonableness of the deadline for proposals—even as extended by Amendment 0011—"runs counter to the evidence before the agency" and is therefore arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

C. ADG Is Likely to Succeed In Demonstrating that Amendment 0009's Three-Month Date-of-Manufacture Requirement Violates FASA and Is Inconsistent with Customary Commercial Practice.

ADG is also likely to succeed in demonstrating that the revised RFP's arbitrary requirement that "isolation gowns shall have no more than 3 months expended since the date of

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manufacture" does not reflect customary commercial practice and is contrary to the Federal Acquisition Streamlining Act of 1994 ("FASA") and FAR Part 12. FASA, and its implementing regulations found at FAR Part 12, require the Federal government to purchase commercial items under commercial terms to the extent practicable. 41 U.S.C. § 3307(e)(2)(B); FAR 12.301(a); *CGI Fed., Inc. v. United States*, 779 F.3d 1346, 152 (Fed. Cir. 2015). Specifically, "FAR Part 12 implements FASA's mandate by requiring that 'contracts for the acquisition of commercial items shall, to the maximum extent practicable, include only those clauses' required by law or '[d]etermined to be consistent with customary commercial practice.'" *CGI Fed.*, 779 F.3d at 1352 (quoting FAR § 12.301(a)). It also precludes inclusion of "any additional terms or conditions in a solicitation or contract for commercial items in a manner that is inconsistent with customary commercial practice for the item being acquired unless a waiver is approved in accordance with agency procedures." FAR 12.302(c).

"FASA achieves its preference for commercial items in part through preliminary market research," and "[b]efore soliciting bids or proposals, agency officials must conduct market research concerning the availability of commercial items." *Palantir USG, Inc. v. United States*, 904 F.3d 980, 984 (Fed. Cir. 2018); FAR §12.101(a) (requiring that the head of the agency shall "conduct market research to determine whether commercial products, commercial services, or nondevelopmental items are available that could meet the agency's requirements"). "Next, agency officials must use that market research to determine whether commercial items can meet the agency's requirements, with or without modification of either the commercial items or the agency's requirements," pursuant to FASA. *Palantir*, 904 F.3d at 984. Ultimately, the market research assists the agency "[i]n evaluating whether a solicitation's terms are consistent with

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customary commercial practice." *See CW Gov't Travel, Inc. v. United States*, 99 Fed. Cl. 666, 676 (2011) (quoting *Smelkinson Sysco Food Servs.*, B-281631, Mar. 15, 1999).

Amendment 0009 states that gowns "shall have no more than 3 months expended since the date of manufacture," Ex. 1 at 16, and Amendment 0011 confirms that HHS will not accept any gown that is older than three months, even if it has more than 33 months of shelf-life remaining, Ex. 2 at 8 (Q&A No. 32). This requirement is not supported by the Government's Market Research Report, which details the market research HHS conducted before issuing the original Solicitation. *See* AR 11-18. Specifically, the Market Research Report states that SNS "held market research discussions with FDA in an effort to understand current industry capabilities and potential vendors of domestically manufactured isolation gowns" and that "ASPR reached out to the vendors FDA indicated as showing in their pre-market database as having domestic manufacturing for medical gowns . . . requesting capabilities and location of manufacturing to further understand current industry capabilities." *Id.* at 12.[3] The Report also states that SNS performed further research within GSAAdvantage, SAM.gov, previous contracts, and the VA National Acquisition Center, and that the ASPR Supply Chain Control Tower and Innovation and Industrial Expansion Branch also performed supply chain research and analysis. *Id.* Finally, the Report also states that in June 2021, the Contracting Officer issued a Request for Information for isolation and surgical gowns, which received 68 responses. *Id.* The Report states that these results were reviewed by the SNS Science team, which "developed a summary of the results in both written and Excel spreadsheet form." *Id.*

[3] The Market Research Report concedes that some of the information gathered from the FDA may be inaccurate, explaining that "FDA did provide a disclaimer and made SNS aware that the database used to identify the[] vendors is data directly input by vendors and may be inaccurate, did not indicate the type of gown (surgical or isolation), and did not indicate at which level of protection the manufactured gowns were being made." *Id.* at 14.

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Nothing in the Market Research Report indicates that commercial customers do not purchase gowns manufactured more than three months ago, regardless of how much shelf-life the gowns retain. The SNS Science Team's summaries are not included in the Administrative Record, nor is there any other documentation of the research that the Market Research Report claims HHS performed. Regardless, the record contains no indication whatsoever that HHS's market research indicated that commercial purchases of isolation gowns impose date-of-manufacturing requirements that are not dependent on a gown's shelf-life. As a result, the original RFP and all amendments through Amendment 0007 only required that gowns "have no more than 20% of total shelf-life expended upon delivery to the SNS." AR 326, 329. The RFP imposed a three-month date-of-manufacture requirement *only* for gowns that did not have an identified shelf-life. *Id*. The Government's actions in this procurement therefore demonstrate that customary commercial practice is to consider a gown's shelf-life in determining whether the gown should be rejected based on its date-of-manufacture.

Amendment 0009 arbitrarily prioritizes gowns with a short shelf-life, but a recent manufacture date, over gowns that may have been manufactured over three months ago, but that have a far longer shelf life. For example, under Amendment 0009, HHS would accept delivery of a gown with a three-year shelf-life that was manufactured three months prior to delivery and therefore had only thirty-three months of remaining shelf-life. By contrast, HHS would reject delivery of a gown with a ten-year shelf-life that was manufactured two years ago, even though that gown has eight years of remaining shelf-life. Ex. 2 at 8 (Q&A No. 32). The record does not provide a rational explanation for HHS's decision to allow the delivery of gowns with a shorter useful life, while precluding the delivery of gowns that could be used for a much greater period of time. No rational explanation exists.

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Finally, the Administrative Record does not contain any evidence that HHS obtained or even sought a waiver to include terms inconsistent with customary commercial practice as required by FAR 12.302(c). Accordingly, since the Market Research Report does not support the three-month date-of-manufacture requirement as a customary commercial practice, the Government was precluded from including such a term that is unless it obtained a waiver. *See* FAR 12.302(c). Amendment 0009 therefore violates FASA and its implementing regulations and must be rescinded.

D. ADG Is Likely to Succeed In Demonstrating that HHS Is Conducting a Lowest-Price, Technically Acceptable Source Selection, Contrary to Governing Law and the Terms of the Solicitation.

The solicitation purports to invite offerors to submit proposals that exceed the requirements of the solicitation, stating that the Government will perform a trade-off between price and non-price factors:

> This is a best value acquisition conducted in accordance with Federal Acquisition Regulation (FAR) 12.602; the Government intends to select the best overall offer, based upon an integrated assessment of Technical and Business Proposals. The Contract will be awarded to the offeror who is deemed responsible in accordance with the FAR, whose proposal conforms to the solicitation's requirements (to include all stated terms, conditions, representations, certifications, and all other information required by Section L of this solicitation); and is judged by an overall assessment of the evaluation factors and sub factors to be most advantageous to the Government. As part of making the assessment, an analysis to determine whether or not exceeding the minimum requirements at an associated price premium provides the best value to the Government will be performed if necessary.

AR 318; Ex. 1 at 54. Both Amendment 0005 and Amendment 0009 provide that HHS will review the technical capability of proposals and assign a rating of "outstanding," "acceptable," or "unacceptable." AR 314; Ex. 1 at 50.

The administrative record, however, indicates that HHS never considered, and does not intend to consider, whether any proposal is more than "acceptable." The only ratings assigned

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by HHS during the initial evaluation and the corrective action evaluation were "acceptable" and "unacceptable." AR 1162-1307 (initial technical evaluation); AR 1308-1345 (initial award decision); AR 1680-1834 (revised technical evaluation); AR 1835-1903 (revised competitive range determination). The technical evaluation reports, initial award decision, and revised competitive range determination do not contain a single reference to a proposal "exceed[ing] contractual requirements" in a manner that provides the Government with a "benefit." Although Amendment 0009 retains the same language as Amendment 0005 regarding a best-value tradeoff, the administrative record makes clear that the Government intends to make an award on a lowest-price, technically acceptable basis.

The use of a lowest-price, technically acceptable source selection process for the acquisition of personal protective equipment such as the gowns violates Section 880 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. 115-232, 41 U.S.C. 3701, and FAR 15.101-2(d). FAR 15.101-2 notes that LPTA procurements *shall only* be used when "[t]he agency would realize no, or minimal, value from a proposal that exceeds the minimum technical or performance requirements" *and* "[t]he contracting officer documents the contract file describing the circumstances that justify the use of the lowest price technically acceptable source selection process." FAR 15.101-2(c). Here the purpose of the procurement is to provide Level 2 Isolation Gowns to support the Strategic National Stockpile, whose mission it is to "provide the right materiel at the right time to secure the nation's health." Ex. 1 at 10. Nowhere has the Contracting Officer made the argument, nor could she reasonably do so, that proposals that exceed the requirements of the solicitation do not provide a better value to the government.

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Amendment 0009 is further unlawful because it does not advise offerors of the basis for award, as required by 41 U.S.C. § 3306(b)(1) and FAR 15.304(d). Amendment 0009 incorrectly states that HHS will consider the extent to which proposals exceed the requirements of the RFP in a manner beneficial to the Government, but HHS has no intention of doing so.

E. The Other Factors for Injunctive Relief Weigh in Favor of StringKing and ADG.

ADG will have no remedy if it is required to invest substantial time and effort in developing a response to the current solicitation over the next two weeks, and if this Court subsequently determines that the current solicitation is unlawful—particularly with respect to shelf life, the three-month date-of-manufacture requirement, and the RFP's incorrect statement that HHS will perform a best value tradeoff when it intends to award to the lowest-price, technically acceptable offeror. Essentially, ADG will have to try to replicate, in less than a month, the establishment of supply chains and manufacturing capabilities for a different gown that it previously took ADG over five months to develop for its proposed gowns. If this Court grants judgment in favor of ADG—which it is likely to do based on the points above—ADG's effort to respond to Amendment 0009 will have been wasted and ADG will have no remedy to recover the costs associated with that effort. This injury is textbook irreparable harm. *E.g., NetStar-1 Gov't Consulting, Inc. v. United States*, 101 Fed. Cl. 511, 530 (2011) ("When assessing irreparable harm, "[t]he relevant inquiry in weighing this factor is whether plaintiff has an adequate remedy in the absence of an injunction." (quoting *Magellan Corp. v. United States*, 27 Fed. Cl. 446, 447 (1993))).

The Government, by contrast, will not be harmed by a delay, particularly given that the Government has already delayed this procurement for nearly two years since the RFP was originally issued in June 2022, primarily based on errors that the Government voluntarily took

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corrective action to try to remedy. Indeed, after issuing Amendment 0008 on February 24, 2024, to the offerors then in the competitive range [redacted] the Government took *over three months* to issue Amendment 0009, which simply reaffirmed Amendment 0008's elimination of shelf-life as a consideration in the procurement. *Compare* AR 1917 (Amd. 0008), *with* Ex. 1 at 54 (Amd. 0009). Any suggestion by the Government that it will be harmed by a further extension of the due date for receipt of proposals so that this Court can hear this case on the merits ignores that the Government—not StringKing or ADG—is solely responsible for the delays to this procurement to date.

III. CONCLUSION

For the foregoing reasons, ADG submits that the Court should grant the relief requested by StringKing.

Dated: June 18, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 18, 2024, I caused a copy of the foregoing document to be electronically filed with the clerk using the Court's CM/ECF system. I further certify that I have served the foregoing document via Electronic Mail on the following:

United States Department of Justice
Commercial Litigation Branch
Civil Division, 8th Floor
1100 L Street NW
Washington, DC 20530
E-mail: nationalcourts.bidprotest@usdoj.gov

Dated: June 18, 2024

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