# In the United States Court of Federal Claims

No. 18-927C
(Originally filed: September 25, 2018)
(Re-filed: October 3, 2018)[1]

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ELECTRA-MED CORPORATION, *et al.*,

*Plaintiffs*,

v.

THE UNITED STATES,

*Defendant*,

and

AMERICAN MEDICAL DEPOT, *et al.*,

*Intervenors*.

Bid protest; Cardinal change; Contract modification; MSPV-NG; Sole source; Competition in Contracting Act; Rule of two; *Kingdomware*; SDVOSB; Injunctive Relief; Balance of the harms; Public interest.

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*David M. Kerr*, Trial Attorney, United States Department of Justice, Civil Division, Commercial Litigation Branch, Washington, DC, with whom were *Chad A. Readler*, Acting Assistant Attorney General, *Robert E. Kirschman, Jr.*, Director, *Claudia Burke*, Assistant Director, for defendant. *Steven Devine*, *Sarah M. McWilliams*, and *Patrick Turner*, U.S. Department of Veterans Affairs, Office of General Counsel, of counsel.

*Aron C. Beezley*, Washington, DC, for Kreisers, LLC, intervenor.

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[1] This opinion was originally issued under seal to afford the parties an opportunity to propose redaction of protected information. The parties have agreed that no redactions are necessary. The opinion thus appears in full.

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OPINION

*Bruggink*, Judge.

This is a protest of a decision by the Department of Veterans Affairs ("VA") to modify four existing contracts for the distribution of medical and surgical supplies. The contracts were modified to expand the scope of work to include supply as well as distribution. The plaintiffs are suppliers of medical and surgical items and allege that the change will result in loss of opportunity to compete to sell their products to the VA. We denied a motion for a preliminary injunction on July 13, 2018. The case is now presented on fully-briefed cross-motions for judgment on the administrative record. Oral argument was held on September 13, 2018. As announced at the conclusion of oral argument, because the balance of the harms favors the government, we cannot grant an injunction.

BACKGROUND

I. Factual History

The VA awarded contract No. VA119-16-D-002 to Kreisers, Inc. ("Kreisers"), No. VA119-16-D-0004 to American Medical Depot ("AMD"), No. VA119-16-D-0005 to Cardinal Health 200, Inc., and No. VA119-16-D-0006 to Medline Industries, Inc. ("Medline") on February 24, 2016. The VA refers to these companies as the "Prime Vendors" or "PVs" of its Medical-Surgical-Prime Vendor-Next Generation program ("MSPV-NG" or "MSPV" generally). Each contract covers a geographical area and requires the PVs to stock, store, and distribute the medical supplies that are available on the "Master List" against which VA hospitals can place orders. The agency also refers to this as the "formulary." An item on the list comes from a specific supplier and is available for a set price. The VA local centers place orders

with the PVs, which then ship those items to the hospitals and bill the VA for them. The dispute in this case concerns who should populate the Master List with particular items, suppliers, and prices. It is worth noting up front that plaintiffs do not contend that they are able to do the precise work sought by the modifications–populating the Master List. Rather, they are able to furnish some of the end-product supplies which will appear on the Master List.

The MSPV program has been in existence for over a decade. It is intended to further standardize and expedite the buying process by "narrowing the range of items purchased to meet a given need in order to improve buying power, simplify supply chain management, and provide clinical consistency." AR 1972. The goal of the VA was to establish a "national strategic sourcing solution that combines a Government-provided capability for ordering a wide range of medical and surgical supplies via a master listing with electronic cataloging (e-catalog) and ordering capability." *Id.* VA medical centers around the country have used the legacy MSPV program to order frequently-used medical and surgical supplies. In 2016, the Government Accountability Office ("GAO") issued a report about the program. It stated that the former version of the MSPV was not fully realizing its purpose of "standardizing items used across [the VA's] medical centers" nor had it achieved cost savings that ought to follow from the buying power generated by a standardized ordering process. AR 408.[2] The VA hoped to improve outcomes with the new MSPV.

The VA actually began the process to replace the legacy MSPV in 2015 when it issued a solicitation seeking prime vendors for four regional indefinite delivery/indefinite quantity ("IDIQ") distribution contracts to handle warehousing, distribution, and delivery of the items that the VA hoped would eventually populate the Master List. The idea was that the VA would tell the PVs what items to stock, who to buy them from, and what price to pay. The PVs would then enter contracts with those VA-identified suppliers for the price determined by the VA. The VA medical centers could then place orders for those items with the PVs. The contracts provided for a distribution fee to be added on top of the price of the orders to reimburse the PVs for their role.

[2] The AR contains a 2017 GAO report regarding the MSPV-NG program which includes statements from and references to an earlier 2016 report concerning the legacy program.

The VA originally intended to populate the Master List with items and prices by either using typical competitive government contract vehicles to select suppliers and prices or by using an "acquisition-like" process to identify and price items. "Price contracts and agreements for medical/surgical supplies include: Federal Supply Schedules (FSS), VA National Contracts, Blanket Purchase Agreements (BPAs), Basic Ordering Agreements (BOAs) with Ability One Nonprofit Agreements, VISN and facility contracts/agreements." AR 23. If the VA did not have a contract vehicle or other pricing agreement in place, it went through what it described as an "acquisition-like" process whereby a solicitation for an item or group of items would be issued by the VA through a normal competition, resulting in tentative winners being selected for each product solicited. A BPA would then be entered into with those suppliers, but no orders would be placed. Instead, that supplier and price would be entered onto the Master List; the PVs would then enter into separate contracts with the suppliers to buy those items at the VA-agreed upon price. AR 1974. Alternatively, the VA would identify a supplier of an item it desired and enter into a sole-source agreement with that supplier for that item, thereby placing the item on Master List. The population of the Master List was to be an ongoing process, but the hope was to quickly populate it with many thousands of items.

In June 2015, VA issued its first solicitations for 6000 items to be placed on the Master List. It received responses, however, to only 30% of the solicitations. Suppliers reported that the VA's process of issuing solicitations for small batches of items was contrary to industry practice, which was to solicit for larger batches of related items. Responding to requests for smaller batches of items was too time and resource intensive. By April 2016, the VA had agreements in place for only 200 items. This delayed the rollout of the MSPV-NG until late 2016. In order to speed up the process of identifying suppliers for the Master List, the VA largely abandoned the competitive process and repeatedly used non-competitive alternatives, such as limited source BPAs with FSS vendors and other similar means. AR 422.

The MSPV-NG did launch in October 2016 with only approximate 1600 items identified by the VA.[3] AR 1982. A November 2017 GAO report

[3] The record contains different figures for how many items were actually available on the Master List at launch. The J&A reports that 1600 items were (continued...)

states that medical centers were faced with a drastic change in the Master List as compared to the old MSPV program. The list was narrowed from hundreds of thousands of items to a tiny fraction of that at rollout. Substantial effort had to be undertaken by medical centers to match up supplies previously purchased off the formulary with the new slimmer list, and this effort was not uniformly undertaken across all of the VA hospital network. *See* AR 423-27. As of May 2017 utilization across the nation was approximately 24%. *Id.* at 428. The GAO report states that, instead of using the MSPV formulary, medical centers resorted to charge cards or local contracts. *Id.* This resulted in far less utilization of the MSPV-NG than the VA intended and, as GOA reported, undercut the purpose of the MSPV program. "Greater Utilization of the MSPV-NG is essential to VA achieving the cost avoidance goal of $150 million for its supply chain transformation effort." *Id.* at 429.

By March 2018, the Master List contained only 7800 out of the 80,000 that the VA anticipated as necessary to support its national healthcare network. This failure was untenable in the view of the VA, thus it sought rapidly to enlarge the number of items on the Master List by outsourcing to the PVs the selection for items to be included on the formulary. In order to do so, it modified the four PV contracts, allowing the PVs "to assist the Government in sourcing thousands of new items quickly. This will be accomplished by allowing the PVs to leverage their existing commercial networks in order to propose sources and prices for items identified by the MSPV Program Office." AR 1974 (Class Justification and Approval). VA retained the ultimate authority to place items on the Master List, but it no longer bothered to go through the acquisition-like process of identifying sources and setting prices through competing BPAs and the like (or other legal non-competitive alternatives).

In order to cover its change to the PV contracts from distribution only to also include supply, the VA issued a Class Justification and Approval ("J&A") as required by 41 U.S.C. § 3304(e)(1)(A) (2012), which dictates that an agency using non-competitive procedures "justif[y] the use of those procedures in writing and certif[y] the accuracy and completeness of the

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[3](...continued)
on the list in October 2016, while the GAO report states that 6000 were available at launch, although it states that the formulary was launched in December 2016.

justification." Subsection (e)(2) then lists the requirements of such a written justification, which includes, among other things: (A) a description of the agency's needs; [and] (B) an identification of the statutory exception from the requirement to use competitive procedures and a demonstration, based on the proposed contractor's qualifications or the nature of the procurement, of the reasons for using that exception." *Id.* § 3304(e)(2)(A)-(B). The exception identified by the VA was that the "services needed by the executive agency are available from only one responsible source and no other type of property or services will satisfy the needs of the executive agency." *Id.* § 3304(a)(1); *see* AR 1976 (citing subsection (a)(1) as the statutory authority for the sole-source modification).

The J&A at issue here states that the VA "proposes to justify and obtain approval for the execution of contract modifications to modify the process of creating the Master Item Lists for VA's [MSPV-NG] . . . contracts." AR 1972. It further states that the aim of the MSPV program was to "achieve timely delivery [of medical supplies] in response to the heavy volume of orders in support of the [VA's] urgent operational medical/surgical supply needs. The [PV] model is required because VA lacks sufficient internal capability to warehouse, coordinate deliveries, and consolidate supply stores." *Id.* The J&A goes on to state that, once the Master List is sufficiently populated, "substantial savings in VA's costs to purchase those supplies is anticipated." *Id.* The reality, however, is that "the MSPV-NG has fallen considerably short of the intended outcomes. In order to address patient concerns resulting from VA's current supply chain inefficiencies, the scope of the proposed modifications includes changing the regional MSPV-NG contracts from 'distribution' contracts to 'distribution and supply' contracts . . . ." *Id.* The change would enable the PVs to "meet the diverse needs of the VA's facilities and the Veterans which they support" by increasing the number of "healthcare supplies available to VHA facilities nationwide in order to enhance the quality of care provided to Veterans." *Id.* at 1972-73.

The J&A goes on to state that approximately 80,000 items need to be on the Master List to fully support the healthcare network but that the acquisition-like strategy that the VA had been using produced only 7800 entries on the list. This deficiency caused "VA's healthcare facilities [to] utiliz[e] a variety of non-p[referred contract methods to procure necessary items not available on the [Master List]." *Id.* at 1973. One such method was the use of purchase cards. The J&A states that this practice "jeopardizes the MSPV-NG program's ability to adequately monitor and review supplies being

purchased and used for direct patient care." *Id.* This is particularly problematic for "patient health and/or safety" because, without the standardized ordering process, VA lacks the ability to ensure that supplies are compliant with safety regulations and lacks the ability to otherwise "monitor[] and conduct[] appropriate safety and defective-item recalls." *Id.* at 1974. Additionally, the J&A explains that the acquisition-like process of populating the list "exposes the Master List generation process to all of the delays inherent in the acquisition process including multiple protests, spotty vendor response, and several rounds of canceled competitive solicitations." *Id.*

Thus, the J&A explained, the contract modifications sought to "streamline the MSPV-NG process in order to rapidly expand the quantity and types of items contained" on the Master List, "allowing the MSPV to continue maturing as a viable enterprise which is ultimately expected to yield substantial efficiencies." *Id.* The new process—allowing the PVs to populate the list—was anticipated to quickly place thousands of items on the Master List by "allowing the PVs to leverage their existing commercial network in order to propose sources and prices for items identified by the MSPV Program Office."[4] *Id.* The J&A detailed that, although the VA continued to control the trigger on whether an item proposed by a PV was added to the list, if the item and prices met muster, "the approved items would be added to the Government master list" without further VA involvement or further competition. *Id.*

The period of performance for this sole-source J&A would be 24 months, the remaining life of the PV contracts. The contracting officer ("CO") also stated that the modification was expected to add no cost to the MSPV program because the PVs were given no additional monetary incentive beyond the distribution fee added to orders to which they were already entitled.[5]

The J&A's rationale for the lack of competition for this new work—only one responsible source—was that the PVs had the "existing infrastructure, ordering capability, and required resident knowledge which makes them uniquely qualified and the only sources currently capable of both enhanced

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[4] The J&A also noted that the acquisition-like process would continue to be used by the VA for certain high volume items "with potential for significant strategic sourcing efficiencies." *Id.* at 1975.

[5] PVs were not entitled to their distribution fee if they were also the supplier of an item chosen to be on the list.

sourcing and distributing required medical commodities throughout the entire VA healthcare network." *Id.* at 1976. The VA stated that any alternative arrangement "would cause unacceptable delays in fulfilling the VA's requirements and would directly impact the health, safety, quality and timeliness of care to Veterans." *Id.* Further, to "solicit, evaluate and fully implement new competitive contracts rather than fulfill this requirement via the proposed modification" was anticipated by the VA to take "a minimum of 16 months" while use of the PVs to fill the formulary was expected to take only three months. *Id.* The rationale section went on to state that "no other vendors other than the current PVs" could "quickly add the volume of required items." *Id.* at 1977. The J&A stated that the PVs were positioned to immediately add this sourcing function to their distribution contract requirements because "they already have established commercial contracts with suppliers and have existing relationships with many of the suppliers where products need to be added." *Id.* No effort was made to explain why four prime vendors were the equivalent of a sole-source or why the contracts could not be competed nationally between the vendors.

The VA further stated that this would result in a "significant increase [to] the safety and efficiency of patient care because VHA's Ordering Officers will be able to procure necessary supplies while simultaneously monitoring the full supply chain for any critical issues" such as safety recalls or non-compliant or grey-market items. *Id.* The VA anticipated a $32 million dollar savings over the 24 months by having a fully formed Master List available for nationwide ordering (not counting any administrative savings). *Id.* at 1978. The J&A added that continuing without this modification would have resulted in "continued disruption of VA's healthcare supply chain," higher cost for supplies, more man-hours necessary for ordering activity, and all of the increased risk to healthcare outlined above. *Id.* "A well-coordinated supply chain is necessary to ensure VA's healthcare facilities are fully supported and Veterans are cared for timely. There are no reasonable, short-term alternatives that would adequately address these critical circumstances." *Id.* at 1979. The J&A also stated that the MSPV Program Office "considered the impact to competition that would result" from the modification but explained that this was an "extraordinary situation" due to the "critical nature of the items that will be accessible" for use in providing care "to millions of Veterans, and the need to quickly expand the number of supplies available from the PVs . . . justif[ies] the unusual measure proposed." *Id.*

The next section of the J&A detailed the VA's earlier attempts to use

competitive measures to select suppliers for the formulary. It describes this process as a "substantial previous and ongoing effort[] . . . to maximize and obtain competition for the required supplies" *Id.* at 1980. The J&A briefly described work that began in 2005 with the previous MSPV program. That effort resulted in seven PV distributor contracts that supported not just the VA but also various other federal agencies with healthcare supply needs. Two five-year contracts with these seven PVs made up the duration of the legacy MSPV program. *See id.* Those contracts expired in 2015, which, because of the delays outlined above, caused VA to execute "a set of bridge contracts" to extend the legacy contracts into April 2016. This was followed by another set of contract extensions that extended the existing program until April 19, 2017. *See id.* at 1981. The next several pages of the J&A contain detailed information regarding the failed efforts of the VA during this time frame to solicit suppliers for the initial 7000 items for the new Master List. This historical compendium concludes with the statement that "new packages [of solicitations for items] are currently being developed for a projected release of quarter one 2018," but "due to protests and current low response rates, multiple acquisition efforts for medical supplies resulted in little to no return on investment; hence the current need to amend the [MSPV-NG distribution contracts] to enable them to function as supply and distribution contracts." *Id.* at 1982.

The J&A also contains sections dealing with veteran and disabled veteran preferences for contracts, which promised that the PVs would follow their own subcontracting plans and that the agency would negotiate new plans with the PVs to ensure that these goals were met. *See id.* at 1982-83. Cost was determined by the VA to be fair and reasonable because the items to be sourced and supplied by the PVs "are widely available commercial items for which fair and reasonable pricing can be easily established." *Id.* at 1983. Lastly, a catch-all section for any other facts supporting the justification recapitulated the VA's position that its efforts to update the MSPV program have been unsuccessful. "To avoid potential catastrophic disruption to VA's healthcare supply chain, the only feasibly alternative to quickly supply current and urgent healthcare supply chain needs across the VA network is to use a more agile process to satisfy requirements." *Id.* The section provided some statistics regarding the problem faced by the VA if it cannot adequately track product recalls and cited a study to the effect that there is a "major threat to patient safety" from the use of "grey market" medical supply items. *Id.* at 1984. The J&A was signed and dated by the CO on March 20, 2018, and signed several days later by more senior VA personnel on March 23, 2018.

The contract modifications were executed by the four PVs and the CO in April and May of 2018. The Statement of Work ("SOW") was amended to include the following language:

> Additionally, the MSPV shall propose for VA approval, and inclusion on the master listing, sources of supply and product prices for additional items as requested by VA via a Program Office Item List; and shall provide, maintain and distribute all such additional items approved for inclusion on the master listing.

*E.g.*, AR 380 (modification for Kreisers). The price clause of the PV contracts was modified to eliminate language stating that the agency would set the prices paid for items through "separate, price contracts and agreements" with vendors and replaced it with the statement that the price "reflects the amount agreed to by the [PV] and the VA, added to the contract via contract modification and reflected in the MSPV electronic catalog." *E.g.*, *id.* at 381. Similarly, the SOW for "Product Price" was changed to reflect that, instead of the government setting the catalog price "established by authorized contracts/agreements," now "the catalog price of the product shall be the amount agreed to by the [PV] and the VA." *E.g.*, *id.* The appendix of definitions was amended to revise the definition of the PVs to eliminate any reference to the PVs maintaining inventory of supplies that the VA contracted for with other government contract vehicles. *See, e.g.*, *id.*

II. Procedural History

On June 27, 2018, plaintiffs filed their complaint here, which challenges the J&A as insufficient legally to justify the sole-sourcing of thousands of medical and surgical supply items, many of which the four plaintiffs assert that they could provide. The complaint alleges that plaintiffs will lose the opportunity to compete to sell these items to the VA. Plaintiffs also moved for a preliminary injunction. That motion was briefed, and oral argument was held on July 12, 2018. We denied the request on the record and confirmed that denial by order on July 13.[6] The process as outlined in the J&A

[6] We denied the motion for preliminary relief on the basis that plaintiffs' harms in the short-term were not likely to be realized and based on the government's (continued...)

and contract modifications then began, and some 30,000 items were added to the Master List in July.

Three of the PVs, AMD, Medline, and Kreisers, filed motions to intervene, which were unopposed and granted by the court. Intervenors have participated in each briefing phase of the case, independently responding to plaintiffs' motions and separately moving for judgment.

The parties have now filed cross-motions for judgment on the administrative record. After reviewing some of the briefing, the court convened a status conference with the parties on August 30, 2018, to seek clarification regarding factual representations made by the parties in their briefing and regarding statements in the J&A. During that conference, government counsel deferred to the CO, Dr. Jamie Friedel, to answer many of the court's questions, which largely concerned the process for populating the Master List, both pre and post-modification. Dr. Friedel's answers were very helpful in understanding the "acquisition-like" process described in the J&A. She provided additional context by explaining that, prior to the modifications, the process for populating the list was largely (90%) by sole-source procurement justified by the issuance of J&As for the items added to the list in that manner. *See* Tr. 12-13 (Aug. 30, 2018). All of those J&As were published, which meant that they could be challenged through a bid protest.

Post-modification, as explained by Dr. Friedel, the selection of suppliers would be handed over to the PVs, although the VA retained the final word on selection. *See id.* at 22. The vendors become "subcontractor[s] to the prime vendor. So they're telling us this is the supplier for this item at this price. The prime vendors are doing all the negotiating with the suppliers. That's the net change." *Id.* At the conclusion of that conference we also ordered the record supplemented with a presentation made by the VA to industry that was referenced in the AR.

Oral argument was held on September 13, 2018, at the conclusion of which we announced that plaintiffs' protest would be denied because, although plaintiffs have carried their burden on proving the J&A deficient, the court was

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[6](...continued)
arguments on the merits that no real change to the ordering process was being made by the contract modifications. *See* Tr. 127-28 (July 12, 2018).

unwilling to enter an injunction due to the balance of the harms and the public's interest in the VA's uninterrupted provision of healthcare to veterans. This opinion more fully explains our reasoning.

## DISCUSSION

We are fully sympathetic with plaintiffs' challenge to this "procurement." The VA appears to have thrown up its hands in its decade long effort to develop an efficient system for the procurement of high volume items by its many field hospitals using competitive or quasi-competitive methods. It frankly concedes now that using competition is too time consuming, too fraught with challenges, and too subject to inefficiencies triggered by the myriad set-asides required by Congress. Having failed abjectly in prior efforts, what it proposes here is tantamount to a wholesale outsourcing of a large portion of its management of procurement to a few private companies. And yet, we are sympathetic. And as we explain below, we are unwilling to question the agency's assessment that anything less dramatic will jeopardize patient care.

Plaintiffs challenge the decision to modify the contracts and hand the task of identifying suppliers to the PVs for five reasons: lack of competition, failure to consider VA's statutorily mandated preferences for service disabled veteran-owned small businesses, improper bundling of distribution with supply requirements, inherent conflict of interest due to the PVs also being suppliers of some items, and an illegal outsourcing of inherently governmental functions. Plaintiffs ask the court to enjoin the contract modifications and require the VA to continue under its prior system of soliciting suppliers through BPA solicitations and other competition-substitutes.

Defendant responded by moving to dismiss, arguing that plaintiffs lack standing because the modifications were within the scope of the original contracts, meaning that the change is not a protestable event. Defendant also moved to dismiss for lack of standing on the basis that the plaintiffs are not distributors of medical supplies and thus are not eligible for the work being added to the PV contracts. Lastly, on the merits, the government cross-moved for judgment, arguing that the J&A reasonably justifies the change, that any harm to plaintiffs is merely hypothetical, that the VA will be significantly harmed by any further delay in populating the list, and that the public interest favors timely provision of healthcare to veterans as enabled by this modification. Intervenors join in these arguments by filing their own cross-

motions and, in one case, an independent motion to dismiss.

I. Standing

Jurisdiction is proper in this court for any challenge to agency action in connection to a procurement or proposed procurement brought by an interested party. *See* 28 U.S.C. § 1491(b) (2012). The interested party requirement incorporates into our jurisdictional grant the need for the protestor to have a real stake in the outcome of the procurement. The Federal Circuit has explained interested party standing as a demonstration by a plaintiff that it is "an actual or prospective bidder" and that the plaintiff has "a direct economic interest" in the procurement or proposed procurement. *Orion Tech., Inc. v. United States*, 704 F.3d 1344, 1348 (Fed. Cir. 2013). The direct economic interest prong of the test is met, at least in the post-award context, if a protestor can show that it would have a substantial chance of receiving the contract award but for the alleged error. *See Digitalis Educ. Sols., Inc. v. United States*, 664 F.3d 1380, 1384 (Fed. Cir. 2012) (affirming dismissal for lack of standing when the protestor could not show that it would have been able to submit a bid had the agency not sole-sourced the procurement). The question is thus, in the context of a contract modification supported by a sole-source J&A for work admittedly not performed by these protestors, what is required to show an economic interest in the outcome.

Defendant points to the result in *Digitalis* as the guiding principle because, like the protestor there, plaintiffs here cannot show that they would have bid on the work added by the modification. Plaintiffs thus cannot show that they have a substantial chance of award but for the alleged errors.

Plaintiffs respond that they are protesting, not the loss of opportunity to supplant the PVs as the provider of supplier identification services, but the loss of the chance to compete to be those suppliers, which is inherent in this change because the acquisition-like process, which the agency has admitted was open to competition or other protestable sole-sourcing, is jettisoned by the modifications. Plaintiffs cite to the *RAMCOR* decision, in which the Federal Circuit found jurisdiction in this court to review an agency's decision to override the Competition in Contracting Act's mandatory stay of a performance/award when a protest is lodged at GAO. The court in *RAMCOR* stated that section 1491's jurisdictional grant "does not require an objection to the actual contract procurement, but only to the 'violation of a statute or regulation in connection with a procurement or proposed procurement.'"

*RAMCOR Servs. Group, Inc. v. United States*, 185 F.3d 1286, 1289 (Fed. Cir. 1999) (quoting 28 U.S.C. § 1491(b)). Plaintiffs also cite to the *Distributed Solutions* and *McAfee* decisions as situations similar to the one presented by this protest where the plaintiffs were not challenging agency action as direct bidders for the work being acquired by the agency but instead as losers of the opportunity to compete for other subsidiary work. In both of those cases, jurisdiction was found. *Distributed Solutions, Inc. v. United States*, 539 F.3d 1340, 1345-46 (Fed. Cir. 2008) (finding jurisdiction where the protestor lost the opportunity to compete to provide software to the agency when the agency modified a current contract to give that contractor the responsibility to select the software vendor); *McAfee, Inc. v. United States*, 111 Fed. Cl. 696, 707-708 (2013) (finding jurisdiction to protest the decision of the Air Force to move from multiple providers of network security to a sole provider without the need to show that the contract modification to effect the change was out-of-scope).

We agree with plaintiffs. The net effect of the modifications is the loss of the opportunity by these plaintiffs to sell their products directly to the government. Under the modified PV contract scheme, they are at the mercy of the PVs to select them as suppliers and have none of the statutory and regulatory rights afforded by law to bidders for government contracts. It is no answer, as the intervenors suggest, that plaintiffs do not offer most of the items potentially headed for the formulary. Their relative individual loss might be substantial even if there were only a small amount of overlap. They have thus shown a non-trivial competitive injury because of the clear potential to deprive them of sales to the government. Standing is established.

II. The Merits

Jurisdiction established, we turn to plaintiffs' arguments that the modifications are illegal as an end-run around the Competition in Contracting Act's ("CICA") competition mandate and the VA's obligation to consider veteran-owned small businesses for award of contracts. We need not consider plaintiffs' other arguments because these first two, or just the first, are sufficient to establish the insufficiency of the J&A.[7]

[7]The agency argues that the addition of "supply" to the distribution contracts was not a cardinal change and hence not protestable. We assume this argument was added for levity.

A. The Contracts' Modifications Are an End-Run Around CICA

CICA requires that, except as otherwise provided by law, agencies procuring goods or services must use "full and open competition through the use of competitive procedures in accordance with the requirements of this division and the Federal Acquisition Regulation." 41 U.S.C. § 3301(a)(1) (2012). CICA itself provides a number of exceptions to the full and open competition requirement in section 3304. As detailed above, the VA availed itself of subsection (a), which allows an agency to select a single source and buy from that source when the agency determines that the goods or services needed "are available from only one responsible source and no other type of property or services will satisfy the needs of the executive agency." *Id.* § 3304(a)(1). The agency found that only the four PVs were in a position to quickly identify sources and prices for the items the VA wanted on the Master List.[8] It justified the sole-source award of the modifications for that reason. The inquiry does not end there, however.

Neither we nor the plaintiffs question the government's conclusion that the PVs are well, and perhaps critically, positioned to rapidly populate the VA's national formulary for medical supplies. The contract modifications may indeed be justified as sole-source changes in scope, but CICA applies to the purchase of all goods and services unless otherwise exempted by law. Plaintiffs' point is that their loss is at the supplier level, the level of the sales of the individual items to the government. Neither the government nor the intervenors answer this question other than to suggest that this problem pre-existed the change and thus this challenge comes too late.

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[8] We note the inherent contradiction behind the idea that four sole-source modifications are needed to do identical work that supposedly only "one responsible source" could provide. At oral argument, defendant suggested that the court need only look to the geographic divide between the four contractors to assuage our concerns. That answer only begs the question. The J&A makes no attempt to explain whether these contractors are physically able only to provide sources for formulary items within their regions; we note that the Master List is not regional, it is national in scope. Nevertheless, this is not the reason that brings us to our ultimate conclusion, and we note that plaintiffs did not raise this problem (understandably, as plaintiffs are not concerned with the actual distribution work that the PVs undertake).

Defendant points to the fact that both pre and post-modification the actual sale of supply items to the government was and is between the PVs and the VA. Although competition or competition substitutes were used prior to the modification, avers defendant, it was always and still is the PVs selling to the VA. Plaintiffs are thus too late, urges the government and intervenors.

We agree with plaintiffs, however, that this fact is not dispositive because a new non-trivial competitive harm results from the modifications, which is the loss of competition. Prior to the modifications, VA solicited and entered into purchase agreements with vendors or justified sole-source arrangements (as the case most frequently was). Competition was had and the right to protest attached even when the vendor was a sole-source selection. The subsequent purchase at those prices from those vendors by the PVs and then resale to VA does not change the fact that the government competed or otherwise lawfully avoided competition for each item placed and then purchased off the Master List. The intermediary step provided by the PVs makes no difference.

After the modification, the VA has foresworn competition as unwieldy and impractical. By outsourcing the selection of suppliers to the PVs entirely, the government has avoided the multitude of legal and regulatory requirements appurtenant to a federal procurement.[9] The change is obvious. Plaintiffs are not in the same situation today as they were when the MSPV-NG contracts were competed and originally awarded. Thus neither waiver nor laches applies. CICA has been violated unless the J&A provides legal cover for the lack of competition. As we explain next, it does not.

B. The J&A Does Not Justify the Lack of Competition at the Supply Level

As plaintiffs rightly point out, the J&A is silent as to the availability of suppliers for the many thousands of items that have been and still will be placed on the Master List. 30,000 new items have been placed on the

[9] It is also no answer to suggest, as defendant does, that the VA still holds a veto power over the selection of sources, as it did before the modifications. The fact that the agency might reject a PV's selection of a vendor suggests nothing with regard to whether the ultimate selection of a vendor for that item will be lawful. The J&A is clear; avoiding competition is the aim.

formulary since this protest was filed. The record does not indicate whether any items have been ordered from those 30,000, but regardless, when they are, those sales will not have been competed. The law requires a justification and approval for that purchase without competition. It is no answer to hide behind the PVs' role in adding to the list of items in the formulary. That aspect of the modification is inseparable from the associated work of picking vendors. By eliminating the price and vendor competitions or competition substitutes, the VA has no-doubt bought itself significant expediency. But it has not bought itself legal cover.

The J&A is silent as to the purchase of any particular item on the now much-expanded list. Neither the government nor the intervenors have provided a lawful reason why CICA is satisfied by this arrangement. Section 3304(a) allows agencies to forego full competition when they conclude and explain that only one source can provide what they are purchasing, but that is a far different circumstance than that provided by this case. We understand the attraction; expediency is undoubtedly key when it comes to purchasing medical supplies, but Congress has made no such particular exception to the competition mandate. We are thus left to conclude that the law has been violated.

C. The Modifications Ignore the VA's Rule of Two Requirement

Plaintiffs' second merit-based challenge regards the VA's unique requirement that it must consider whether a service-disabled veteran-owned small business ("SDVOSB") or, failing that, veteran-owned small business ("VOSB") could provide the goods it wishes to procure. If two or more such entities could provide the items, the VA is required by law to attempt to buy from those sources by running a competition limited to only those concerns. This is the "rule of two." 38 U.S.C. § 8127(d) (2012); *Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1976-77 (2016). The four plaintiffs are SDVOSB companies and argue that, not only does the new PV-provided sourcing violate CICA's competition requirements, but it also robs them of their entitlement to a competition limited to only them and other similarly situated VOSBs.

The Supreme Court has left no doubt that the Veterans Benefits, Health Care, and Information Technology Act of 2006, codified at sections 8127 and 8128 of title 38, requires that the "rule of two" be applied to every purchase possible made by the VA with limited exceptions. *Kingdomware*, 136 S. Ct.

at 1977. Plaintiffs allege that they stand ready to provide many of the goods needed by the government here, and there are more than two of them. According to *Kingdomware*, VA must consider awarding to them. The PVs, on the other hand, as private businesses, are not under such constraints and thus plaintiffs are harmed. We agree.

The government again provides no legal cover for this arrangement. Defendant and intervenors instead suggest that the PVs will be bound by their small-business participation plans, which will protect the rights of VOSBs, and thus the court should be unconcerned. We are not so sanguine. There is no legal requirement that the PVs consider whether two VOSBs can provide an item that they source for the Master List nor is there any requirement that they limit their consideration to such businesses. Further, plaintiffs would not have any right to challenge the selection of non-VOSBs by the PVs should they ignore this requirement. The government might attempt to hold the intervenors' feet to the fire in this regard, as a contract administration issue, but plaintiffs have lost valuable procurement rights in the process. The PVs are private purchasers untethered to the FAR, VA regulations, and procurement statutes.

The bevy of protests filed in this court and at GAO since the Supreme Court's decision in *Kingdomware* are evidence enough that these requirements are strict and difficult to follow in the mean and no doubt doubly so when the law requires that they be applied without fail or exception. And yet the law remains. Only Congress has the kill switch. Plaintiffs are correct that 38 U.S.C. § 8127 is violated by the VA's outsourcing of its selection of supply vendors.

III. An Injunction Is Not Warranted

Because plaintiffs have shown a violation of procurement law, we must consider whether an injunction is appropriate. The four factors we must consider are 1) whether plaintiffs have succeeded on the merits, as they must to receive permanent injunctive relief; 2) whether plaintiffs will suffer irreparable harm absent the injunction; 3) whether the balance of the hardships to the respective parties favors an injunction; and 4) whether it is in the public interest to grant the requested relief. *PGBA, LLC v. United States*, 389 F.3d 1219, 1229 (Fed. Cir. 2004). Success on the merits is established, but an injunction is not merited.

A. Irreparable Harm to Plaintiffs

Plaintiffs allege two types of harm from the VA's actions, the first, discussed in detail above, is the loss of opportunity to compete to sell supplies to the government. This is a pecuniary harm. Although this is sufficient to establish standing, we note that this harm is at least somewhat speculative given the possibility these plaintiffs could ultimately be selected by the PVs to supply the VA. Further, this harm is only temporary. This modification to the MSPV is slated to be replaced again in about eighteen months.

The second type of harm alleged by plaintiffs is damage to their relationships with their manufacturing partners. As explained in their brief, "by funneling sales of the MSPV items to other distributors, rather than Plaintiffs, the changes to the program will significantly lessen the value of the manufacturers' relationships with Plaintiffs as distributors." Pls.' Mot. for J. on the AR 42. Damage to manufacturer relationships is also speculative. Plaintiffs do not identify specific manufacturers of any items with whom their relationships will be jeopardized. Further, if they are selected by a PV to supply items to the government, this harm will be ameliorated. Additionally, this problem might have arisen even absent the change. There is no guarantee that these suppliers would have won their bids to supply any items to the VA. This harm is too attenuated from the challenged agency action to weigh in plaintiffs' favor.

We find harm to plaintiffs in the loss of the opportunity to compete. There is no remedy at law absent an injunction; the harm is thus irreparable. But we note that it does not weigh as heavily in plaintiffs' favor as they allege because it is temporary and somewhat speculative.

B. Balance of the Harms

Defendant argues that the harm to the VA overwhelms any risk to plaintiffs. Defendant avers that enjoining the VA from continuing to populate the Master List through the efforts of the PVs will disrupt the VA's supply chain for medical and surgical supplies. This disruption has two facets. The first is the loss of potential savings realized through the enhanced buying power offered by centralizing and standardizing the purchase of frequently used medical supplies across the VA's network. The second is the inability to properly monitor and review the purchase of these supplies absent this standardization. Without a centralized supply chain in place, the VA loses the

ability to adequately monitor the quality and regulatory compliance of the supplies purchased through other contractual means. Without this oversight, the VA may miss product recalls and the sale and use of grey-market items at various hospitals. This in turn has potential to affect clinical outcomes and patient health, the real end goal of any medical system. Thus, in defendant's view, even assuming plaintiffs' harms, the VA's potential harm is far too great to risk enjoining the MSPV program.

As rebuttal, plaintiffs argue that the previous system for populating the formulary works, at least to an extent, so the harm to the government is not irreparable. Plaintiffs also offer that, even assuming *arguendo* the harms proffered by the government, the MSPV contract modifications will not solve the longer term problems outlined by the GAO report and the J&A. Plaintiffs urge that the VA should consider leadership and organizational changes and oversight efforts better tailored for the long-term success of the MSPV program.

We agree with defendant, however. The history of the MPSV-NG and the J&A speak for themselves. The new formulary is failing absent the ability to rapidly populate the Master List. The VA selected the four PVs as particularly well-situated to take that task off the government's hands and with it, relieve the VA from the web of public procurement preferences and requirements which have ensnared this program from inception. Plaintiffs' own complaint makes the case. We have no basis to question the representations made in the J&A about the potential effect on the provision of healthcare that comes from the inability to properly manage the VA's supply chain for medical and surgical supplies. Likewise we have no reason to doubt the method chosen to remedy these compelling problems. It is only rational that a standardized ordering process is of little benefit to hospitals if it does not offer a fulsome selection of supplies needed by hospitals. It also follows that having a well-populated centralized catalog of supplies that have been properly vetted for safety and effectiveness is necessary to achieve the supply chain management benefits mentioned above. Those benefits have positive effects on the provision of healthcare to veterans. We thus find that the harm to the VA outweighs that to plaintiffs.

C. Public Interest

We begin with the obvious: the public does have an interest in the law being followed as it applies to public procurement. We have long recognized

this as sufficient to support an injunction absent some other countervailing public interest. This case presents one of the few in which we find another interest to outweigh it. We agree with defendant that the provision of high quality healthcare to veterans is a weighty public interest. As we explained above, we find it rational that healthcare is negatively affected when the supply chain for medical supplies is disrupted, and we find it rational that the VA's chosen method to fix that supply chain will do so, at least temporarily, which is all the modifications purport to be. The benefits from a well-managed supply chain can only inure to veterans if that supply chain is fully utilized and can provide the wide variety of items that VA health centers need to provide quality healthcare. The public interest therefore does not favor an injunction.

## CONCLUSION

In this case, the VA is hamstrung by the myriad requirements and preferences layered onto the process of federal purchasing, and especially the preferences unique to the VA. The complaint here is exhibit A. Plaintiffs are correct that Congress has granted to them and bidders generally a variety of rights when it comes to selling things to the VA. It is for Congress and the voters to weigh the merits of the benefits and burdens imposed by such a labyrinth of legal and regulatory hoops and hurdles. This case presents a circumstance in which the VA could not timely clear the hurdles. The result is danger to veterans' healthcare and increased cost to the government. The agency found a detour around the obstacles and tried to legally justify it. It could not do so, but the court is in no position to restore the status quo ante by enjoining a process aimed at protecting and improving the management of the VA's supply chain for medical and surgical supplies. The equities do not favor the plaintiffs: the harm to the plaintiffs is somewhat speculative, while the harm to the agency is real and potentially grave. The public interest favors avoiding those harms. The protest must therefore be denied. Accordingly, the following is ordered:

1. Plaintiffs' motion for judgment on the administrative record is denied.

2. Defendant's and intervenor's motions to dismiss are denied.

3. Defendant's and intervenors' motions for judgment on the administrative record are granted.

4. The Clerk of Court is directed to enter judgment for defendant. No costs.

s/Eric G. Bruggink
Eric G. Bruggink
Senior Judge