Memo

To: **Domestic Manufacturers of Personal Protective Equipment (PPE) and Critical Medical Equipment**
Fr: **SMI Defense Manufacturing Team**
Dt: **March 19, 2020**

Re: **Implications and Opportunities Related to President Trump's Invoking of the Defense Production Act for COVID-19 Pandemic-- SMI DPA Title III Experience**

On March 18, 2020, in response to the COVID-19 pandemic, the President invoked the authorities of the Defense Production Act (DPA) of 1950 to increase the supply of personal protective equipment (PPE) and critical medical equipment, such as N95 respirator masks and ventilators. The DPA declares that Congress finds "the security of the United States is dependent on the ability of the domestic industrial base to supply materials and services for the national defense and to prepare for and respond to military conflicts, natural or man-caused disasters, or acts of terrorism within the United States." With public health experts warning that the coronavirus could be the deadliest infectious disease the world has faced in over 100 years, it is clear that this is a national security matter.

Title III of the DPA authority authorizes the President to provide direct capital investment to private companies to address manufacturing capacity issues for critical national security materials. DPA Title III is a powerful tool that can quickly ramp up the domestic industrial base for PPE and critical medical equipment for both COVID-19 and future public health emergencies.

Defense Production Act (DPA) Background

The DPA was created at the beginning of the Cold War to provide the President of the United States with the ability to incentivize, and in some cases mandate, private industry to provide the United States government with items it deems essential to national defense. Originally it had seven provisions and provided the government with several invasive authorities, including the ability to fix wages and prices. Most of the provisions were not reauthorized and were eventually repealed. The three active provisions are: 1) Title I - "Priorities and Allocations" 2) Title III - "Expansion of Productive Capacity and Supply," and 3) Title VII - "General Provisions," which contains the Committee on Foreign Investment in the United States.

Although DPA is typically viewed as a set of authorities that is only accessible to the Department of Defense (DoD), several civilian federal agencies have the ability to deploy them in order to meet their missions. In Congress the DPA is under the jurisdiction of the House Committee on Financial Services and Senate Committee on Banking, Housing, and Urban Affairs – not the Armed Services Committees.

Justification for DPA and COVID-19

The COVID-19 virus threatens the health and well-being of all Americans and could adversely impact national security. Although academic institutions and industry throughout the world are collaborating to develop therapeutics and vaccines to decrease mortality and prevent infection, immediate focus will be

directed towards PPE to protect healthcare workers and minimize the spread of the virus as well as the medical equipment necessary to mitigate the symptoms on the most severely infected. Unfortunately, there is presently insufficient domestic manufacturing capacity for PPE, ventilators and other necessary items. Medical facilities are anticipating shortages for this critical equipment. This issue will only become of even greater concern as the number of cases increases.

Initial Focus on Title I of the DPA

Much of the initial press coverage and public discussion around President Trump's invocation of DPA has been focused on Title I Authorities which ensures that industry prioritizes government orders over commercial orders and that critical resources are allocated for use in products needed to combat COVID-19. Indeed, the executive order granted authority to Health and Human Services (HHS) Secretary Alex Azar to determine "proper nationwide priorities."

DPA Title III Authority

Receiving far less attention in the press and in public statements by federal officials has been the Title III authority of the DPA. Title III of the DPA is intended to "create, maintain, expedite, expand, protect, or restore production and deliveries or services essential to the national defense." This specific authority provides the President with the ability to provide grants, loans, loan guarantees, purchases, and purchase commitments to the DoD. While a combination of these tools can be used to address the shortage of manufacturing capacity for PPE and critical medical equipment, in recent years the DPA Title III program has typically awarded multimillion dollar grants with matching fund requirements to companies to scale up or build factories to produce items or materials that the President has determined are critical for national security. Generally, DPA Title III investments are $10 million or greater and require a matching investment from the awardee.

Historically the lead time for a DPA Title III award has taken more than a year due to the requirement of a justification, Presidential Determination (PD), to be signed by the President for each investment. A PD certifies that the all statutory requirements for Title III have been met. In the case of a national emergency, however, the PD requirement is waived. Since President Trump has declared a national emergency, Federal agencies have the ability to enter into public-private partnerships immediately.

The HHS Secretary can move quickly, i.e. within weeks, to enter into agreements to expand productive capacity through the purchase of equipment and facilities, by becoming the buyer of last resort through purchase guarantees, or by using one of the loan authorities to incentivize industry to meet demand for PPE products. To expedite this effort, prospective domestic industry partners must quickly assemble their capital requirements to rise to meet the demand to combat COVID-19.

While there may be some investments the government can make now to immediately affect the outcome and impact of the COVID-19 pandemic, the positive effects of DPA Title III awards will be felt for years to come. Companies that expand productive capacity with government assistance will be prepared to meet future surge requirements. In addition, the production equipment can provide companies with a competitive advantage in the commercial marketplace when demand returns to normal.

Should HHS remain in charge for PPE productive capacity, it will be the first time in several years that a civilian agency has executed a DPA Title III investment. Pre-positioning for such an award will require

demonstrating knowledge of the capital requirements to enable increased manufacturing capacity, the ability to demonstrate leadership to execute such a large-scale effort within the least amount of time possible, and commitment to serving US government needs for years to come. Congressional direction will also play a role, but emphasis must be placed on establishing relationships with federal agency officials in the short-term.

DPA Title III investment has the ability to establish the capacity needed to address this pandemic and fulfill demand for future surge requirements. Industry should work closely with US government decision makers to ensure the right investments are made into the right capabilities so that future threats can be mitigated before they pose unnecessary risk to public health.

SMI and DPA Title III

Navigating the DPA during this time of national emergency will be difficult for both the industry partners that will be expanding production capacity and government leaders responsible for utilizing it. The DoD has been executing DPA Title III projects consistently since at least the 1980s, however, the civilian agencies do not have that experience. SMI has unparalleled in-house expertise with DPA to help your company establish a public-private partnership. In fact, SMI has supported about 50% of all DPA Title III awardees over the last 5 years. This DPA expertise is complemented by SMI's Life Sciences team, which has the technical expertise and a strong network of decision makers within HHS. SMI will not only connect companies to Congress but our team can help educate and support Members of Congress and their staff as they advocate on a company's behalf. Our ability to pre-position and assist your company with contracting can help your company take advantage of this unprecedented opportunity and answer the government's call for more PPE and critical medical equipment.

SMI Defense Manufacturing Team

Glen Mandigo, President & CEO
Mr. Mandigo combines over twenty years of lobbying and federal marketing experience with a background in advanced materials development and aerospace engineering. Mr. Mandigo has successfully created federal program opportunities for clients since 1995 for high technology programs in areas such as composite materials, power electronics, and energy storage. He has built relationships in the leading federal agencies engaged in science and technology. Mr. Mandigo also has experience working congressional initiatives across all the federal appropriations bills associated with science and technology and economic development. Mr. Mandigo has a Bachelor's degree in Aerospace Engineering from the University of Arizona.

Bill McCann, Chief Operating Officer
Mr. McCann combines political, policy and strategy experience to help clients navigate the federal market and successfully secure funding and policy goals. With over ten years of experience on Capitol Hill, Mr. McCann served as Chief of Staff to a senior member of the House Armed Services Committee. Both on and off the Hill, Mr. McCann works with companies and universities to plan and execute comprehensive strategies to secure federal R&D funding for innovative technologies as well as major procurement programs. Mr. McCann is on the Board of Directors of the Government Relations Association. Mr. McCann holds a Bachelor of Arts in American Government from Georgetown University and a Masters of Business Administration from the Ross School of Business at the University of Michigan with an emphasis in Corporate Strategy.

Ken Wetzel, Senior Vice President
Prior to joining SMI, Mr. Wetzel was responsible for identifying technology investment targets and creating partnerships with government and industry for the Department of Defense Manufacturing & Industrial Base Policy Office's Defense Production Act Title III program. Mr. Wetzel also advised the Department of Defense's Director of Manufacturing on supply chain issues and was a member of the team that established the pilot Manufacturing Innovation Institute. Mr. Wetzel began his career as an Army civilian project engineer at Picatinny Arsenal. Mr. Wetzel holds a Bachelor's degree in Chemical Engineering from Villanova University and an MEng. in Chemical Engineering from the Stevens Institute of Technology.

Mark Gillman, Senior Vice President
Mr. Gillman worked on Capitol Hill for nearly 12 years, including six years managing national security issues. Prior to joining SMI in 2002, he was the Legislative Director and Military Legislative Assistant for two Members of Congress from Texas who served on the House Armed Services Committee. Mr. Gillman's expertise includes defense research and development, health care research, education policy and funding, government infrastructure policy, and manufacturing and defense industrial base issues. Mr. Gillman holds a Bachelor's degree in Economics from Southern Methodist University.

Dennis Padilla, Federal Contracting Specialist
Mr. Padilla has over 30 years of experience in Government contracting. He is the former Director of Contracts and Grants for the Office of Naval Research (ONR), where he focused on business processes for basic research, manufacturing technology, weapon systems prototypes and commercial-military dual-use applications. His contracting activities centered on transitioning new technologies from industry, academia and government into fielded fleet-ready systems. Prior to his work at ONR, he served as the Deputy Director of Contracts for the Navy's Strategic Systems Programs Office and as Chair of the Defense Acquisition Research & Development Committee. Mr. Padilla has also served a Contracts Negotiator to NASA's Ames Research Center. Mr. Padilla holds a Bachelor's in Business Administration from San Jose State University and a Master's Degree in National Resource Strategy from the Industrial College of the Armed Forces.

Travis Taylor, Associate, Life Sciences Team
Prior to joining SMI, Dr. Taylor served as a Policy Officer at the National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases (NIAID) where he was an expert on foreign Select Agents and Dual Use Research Concerns. He also participated in the formulation, development and coordination of extramural research policy. Dr. Taylor also served as Scientific Review Officer at NIAID during which time he reviewed proposals and managed peer review panels. He has also held a number of senior scientist positions supporting federal agencies including the DoD, DARPA, National Cancer Institute, USAID's Emerging Pandemic Threats Program, the Department of Homeland Security, and the World Bank. He is a former AAAS Science and Technology Fellow during which time he served as a Science Advisor for the Defense Threat Reduction Agency. Dr. Taylor holds a BA in Biology from the University of Southern Indiana and a PhD in Virology from Harvard University.

David Visi, Associate, Life Sciences Team
Prior to joining SMI, Dr. Visi served as an AAAS Science and Technology Policy Fellow at the Department of Defense (DoD) Office of the Deputy Assistant Secretary of Threat Reduction and Arms Control (TRAC). Within TRAC, Dr. Visi provided oversight and program governance on the Defense

Threat Reduction Agency Biological Threat Reduction Program (BTRP), which focused on enhancing partner states' biosecurity, biosafety, and biosurveillance capacity. He had previously worked on The Pew Charitable Trusts' Antibiotic Resistance Project on research and policies to advance antibacterial discovery and development, including an analysis of the global development pipeline of antibiotics and nontraditional approaches, BARDA reauthorization, and domestic and global antibiotic regulatory structure. Dr. Visi also served as a policy advisor on health and agriculture for Congresswoman Louise M. Slaughter. Dr. Visi has a PhD in molecular biology and biochemistry from the University of North Texas.

SMI supports companies, universities, and trade associations to advocate for Federal policies that enable technology commercialization and growth. Our team is comprised of technical and policy experts, lobbyists, and former executive branch decision-makers who work to capture non-dilutive federal funds and to change policies in support of client interests.