

Key Highlights for Manufacturing in the CARES ACT

- Directs the National Academies to study the manufacturing supply chain of drugs and medical devices and provide Congress with recommendations to strengthen the U.S. manufacturing supply chain
- \$50 million is provided for the Hollings Manufacturing Extension Partnership (MEP's) to help smalland medium-sized manufacturers recover by finding value within the supply chain and expanding markets. For every one dollar of federal investment, MEP generates \$27.20 in new sales growth for manufacturers.
- The bill also includes an additional \$10 million for the National Institute for Innovation in Manufacturing Biopharmaceuticals to support the development and manufacture of new medical countermeasures and biomedical supplies to combat the coronavirus.
- The bill provides \$1.5 billion for economic adjustment assistance to help revitalize local communities after the pandemic. EDA assistance can be used to help rebuild impacted industries such as tourism or manufacturing supply chains, capitalize local funds to provide low-interest loans to businesses of all sizes, and support other locally-identified priorities for economic recovery. Based on the impact of prior funding packages, EDA disaster assistance will leverage an additional \$20 billion in local and private investment and support more than 100,000 American jobs.
- \$1 billion for the Defense Production Act This funding allows the Department of Defense to invest in manufacturing capabilities that are key to increasing the production rate of personal protective equipment and medical equipment to meet the demand of healthcare workers all across the nation.
- More than \$27 billion for the Biomedical Advanced Research and Development Authority (BARDA)
 to support research and development of vaccines, therapeutics, and diagnostics to prevent or
 treat the effects of coronavirus, including:
- At least \$3.5 billion to advance construction, manufacturing, and purchase of vaccines and therapeutics to the American people. This is in addition to the major investments provided for these activities in the first supplemental.
- Funding for innovations in manufacturing platforms to support a U.S.-sourced supply chain of vaccines, therapeutics, and small molecule active pharmaceutical ingredients;
- Funding to support U.S.-based next generation manufacturing facilities

Manufacturing Personal Protective Equipment (PPE):

To help ensure medical devices, including PPE are safe and effective, the FDA has established <u>Quality Systems Regulations and Good Manufacturing Practices</u>. Manufacturers are expected to use these regulations and practices to maintain consistent product quality and to guide performance testing to make sure that their products conform to recognized consensus standards. For PPE, these standards may include for fluid resistance, leak protection, filtering capacity, or resistance to tears and snags. When these regulations and practices are followed, they provide reasonable assurance that the device is safe and effective. They can be found on the FDA Website.

- Any business with supplies to sell/contribute to New York's response can contact the Governor's team at COVID19supplies@esd.ny.gov.
- For up to date information, please see https://esd.ny.gov/.
- If you want to donate medical supplies or equipment to the federal response, please go
 to www.fema.gov and use the online medical supplies and equipment form at
 www.fema.gov/coronavirus/covid-19-donations
- If you want to sell medical supplies or equipment to the federal government, please email specifics to covidsupplies@fema.dhs.gov.
- The FDA established a special email inbox, <u>COVID19FDAIMPORTINQUIRIES@fda.hhs.gov</u>, for industry representatives to quickly communicate with the agency and address questions or concerns.