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To be updated as necessary

DEFENSE PRODUCTION ACT / COVID-19 TRADE CHECKLIST

This short checklist provides links to relevant documents related to DPA and COVID-19 and trade in medical devices, with short descriptions. All links are current as of April 9. Corrections are welcomed.

Background on DPA and COVID-19 response

DPA of 1950: PDF (as amended to Sept, 2009); US Code version with hyperlinks (50 USC Chapter 55). Note: DPA now consists of Titles I, III and VII. All other titles have been repealed.

FEMA: DPA Program; Federal Priorities and Allocations System (FPAS) regulations and Q&A.

Congressional Research Service report on DPA (history, authorities, policy considerations – 30 pp updated March 2, 2020) and short Insight on DPA and COVID-19 (4 pp updated March 18, 2020)

FEMA webpage on Coronavirus Response

HHS webpage on COVID-related news including DPA contract awards

FDA webpage of COVID-19 related guidance documents

CBP COVID-19 webpage: updates and announcements

Actions in 2020

March 11: Presidential Memorandum on Making General Use Respirators Available, 85 FR 15049

March 13: Presidential Proclamation 9994 on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, 85 FR 15337: declares national emergency under National Emergencies Act §§201, 301 and Stafford Act.

March 18: **EO 13909, Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID-19** (85 FR 16227): determines medical resources needed to respond to spread of COVIN-19 meet DPA §101(b); delegates Presidential authority under DPA §101 to HHS

March 23: **EO 13910, Preventing Hoarding of Health and Medical Resources To Respond to the Spread of COVID-19** (85 FR 17001): Delegates Presidential anti-hoarding authority under DPA §102, and related authorities, to HHS in consultation with FEMA.

March 23: CBP (for FDA) issues instructions to the import community on import clearance of PPE and COVID-19 related devices; updated on March 26 and April 5.

March 24: AdvaMed letter to FEMA Administrator urges Federal leadership in allocating ventilators; urges Administration to designate a lead agency (FEMA) to oversee allocation decisions with active input of clinical experts and other stakeholders

March 24: Justice Department and Federal Trade Commission announce expedited antitrust procedure and Guidance for Coronavirus Public Health Efforts; issue Joint Antitrust Statement Regarding COVID-19 setting out instructions for business to use this review procedure. (DOJ business review letters website)

March 25: HHS Notice of Designation of Scarce Materials of Threatened Materials Subject to COVID-19 Hoarding Prevention Measures (85 FR 17592): designates 15 materials pursuant to DPA §102 (4 types of

respirators incl. N95 and other; portable ventilators; drugs with API chloroquine hydrate or hydroxychloroquine HCl; sterilization services for medical devices and sterilizers; disinfecting devices; medical gowns or apparel; PPE coveralls e.g. Tyvek suits; PPE face masks; PPE face shields; PPE gloves; ventilators, ventilator tubing connectors and accessories

March 27: **EO 13911** **Delegating Additional Authority Under the Defense Production Act with respect to Health and Medical Resources to Respond to the Spread of COVID-19** (85 FR 18403): (a) delegates Presidential authority under DPA §§301-303 to HHS and DHS, waives certain requirements in DPA Title III; (b) delegates Presidential authority under DPA §708 to HHS and DHS, subject to consultation with DOJ and FTC and prior approval by DOJ in consultation with FTC; delegates Presidential authority under DPA §107 to HHS and DHS; further delegates Presidential authority under DPA §§102, 102 to DHS and authorizes DHS to determine (in consultation with other agencies) nationwide priorities and allocation of resources, including controlling distribution of COVID-19-related materials and services in US.

March 27: Memorandum on Order Under the Defense Production Act Regarding General Motors Company (White House website): orders HHS to use DPA authority to require GM to accept, perform, and prioritize contracts or orders for number of ventilators that HHS determines appropriate.

March 28: FDA Letter to stakeholders reissues earlier EUAs to authorize emergency use, and importation, of certain non-NIOSH-approved disposable respirators; guidance revised April 2.

April 2: Presidential Memorandum on Order Under the Defense Production Act Regarding the Purchase of Ventilators (White House website) Directs FEMA in consultation with HHS to use DPA authority to facilitate supply of materials to the appropriate subsidiary or affiliate of the following entities for production of ventilators: GE; Hill-Rom; Medtronic; ResMed; Royal Philip; Vyaire.

April 2: Presidential Memorandum on Order Under the Defense Production Act Regarding 3M Company (White House website): Directs FEMA to use authority available under DPA to acquire, from any appropriate subsidiary or affiliate of 3M Company, the number of N-95 respirators that FEMA determines to be appropriate.

April 2: DOJ and HHS announce confiscation of hoarded PPE under DPA §102 and redistribution to NY, NYC and NJ Departments of Health; owner of hoarded equipment was paid "pre-COVID-19 fair market value".

April 3: Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (White House website): Directs HHS and FEMA to use authority available under DPA §101 to allocate to domestic use, as appropriate, five listed PPE materials designated by HHS on March 27 under DPA §102: N95 respirators and certain other respirators; PPE surgical masks; PPE gloves.

April 3: Statement from the President Regarding the Defense Production Act (White House website): states that April 3 order is to prevent hoarding, price gouging, and profiteering by preventing "harmful export of critically needed PPE" and that nothing in the order will interfere with ability of PPE manufacturers to export when consistent with US policy and in US national interest.

April 4: Justice Department issues business review letter to medical supplies distributors supporting Project Airbridge under expedited procedure for COVID-19 pandemic response: Letter to McKesson, Owens & Minor, Cardinal Health, Medline, Henry Schein. (DOJ Press release with related letters)

April 8: FEMA issues temporary final rule, Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Defense Use (to be published April 10): Effective immediately, expires 120 days after date of publication. Applies to 5 PPE materials listed in April 3 memorandum; CBP to detain all exports of these materials for FEMA determination on potential allocation to domestic use; exception for exports by or on behalf of certain US manufacturers of medical equipment.

April 8: FEMA-CBP Joint Statement on DPA for PPE: announces CBP will detain shipments of this PPE while FEMA determines whether to return the PPE for use within the United States; to purchase the PPE on behalf of the United States; or, allow it to be exported.