**DEFENCE PRODUCTION ACT**

**March 27 Executive Order**

Brief Analysis

This very long message explains the surprise EO of late Friday. Things to notice:

* The President’s DPA powers are now all delegated to both HHS and DHS (probably DHS = FEMA, which has been working with Navarro on GM).
* So if anyone points to Trump and asks him about why there is no DPA action, that is now the responsibility of Azar, Chad Wolf/FEMA and Peter Navarro.
* Navarro doesn’t have the legal authority to sign off on anything; that is reserved to the Secretaries of HHS and DHS.
* DPA section 107 talks about building up reliable suppliers. That means Navarro will promote his Buy American agenda – which could head-off anything more.
* The part of all this that really matters is probably Title III, which has now been bankrolled with $1 *billion* by the CARES Act. Will this get spent without any waste-fraud, abuse or scandal?
	+ As I read DPA §302(d), if the aggregate loans made from the DPA Fund exceed $50 million, any new loan will be subject to a 30-day notice and layover period; the layover can only be waived if the President himself signs a determination that the loan is necessary to avert a shortfall that would severely impair national security. This determination cannot be delegated. So Trump’s name will be on the line for these loans.
* Yes there is a possibility of cooperative action under DPA Title VII, but Title VII is tied to too much red tape and DOJ/the FTC/the antitrust bar are unfamiliar with it. DOJ/the FTC issued a joint statement that invites companies to get expedited business review letters if they want to cooperate (for instance if two device companies want to pool distribution of their ventilators). Business review letters are something that DOJ/FTC/the antitrust bar know and understand. That route probably makes much more sense and will be much faster than constructing some elaborate agreement under Title VII. But ask your antitrust lawyer. I am not an antitrust specialist and I can’t advise about antitrust law.

Detailed Analysis

On March 27, President Trump signed another Executive Order invoking the Defense Production Act (DPA).

This Executive Order delegates Presidential authority to the Secretaries of HHS and DHS, under DPA Title III (on loans, loan guarantees and purchase commitments), Title VII (voluntary agreements by the private sector), and Section 107 (actions to maintain reliable sources of supply including restricting contracts to reliable and/or domestic sources, and stockpiling critical components). The Executive Order also delegates the allocation, prioritization and anti-hoarding authorities in DPA Title I to DHS in addition to HHS. DHS (FEMA) may allocate and prioritize health and medical resources to respond to COVID-19 in the US.

Friday’s Executive Order also designates the Assistant to the President for Trade and Manufacturing Policy (Peter Navarro) as National Defense Production Act Policy Coordinator.

The Executive Order indicates the administration’s plan that HHS and FEMA will handle the job of allocation/prioritization of health resources to fight the pandemic, and will manage procurement, loans and loan guarantees bankrolled  by $1 billion appropriated by the CARES Act. HHS and FEMA may also sponsor private sector voluntary agreements and plans of action, in consultation with DOJ/the FTC. Peter Navarro will have a major role as coordinator. Based on DPA §107, it is likely that the procurement, loans, loan guarantees and purchase commitments will be subject to Buy American requirements and/or localization requirements. Meanwhile, last week DOJ and the FTC issued a joint statement on private sector cooperation to fight coronavirus (see below).

(1)   DPA Title III: loans, loan guarantees, purchase commitments

Friday’s Executive Order formally delegates to the Secretary of HHS and the Secretary of Homeland Security the President’s authority under DPA Title III.

The CARES Act, enacted on Friday, also appropriated $1 billion for “Defense Production Act Purchases”. This should be credited to the DPA Fund, a Treasury Department trust fund established by Title III of the DPA ([50 USC §4534](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2F4534&data=02%7C01%7CRIves%40AdvaMed.org%7C22056068f78240eb635d08d7d3959929%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637210511791931763&sdata=N9IHf5P1ZN4IXsc3GsUApJ0vGljzvVyJKY5yVojKAnQ%3D&reserved=0)). The $1 billion will remain in the DPA Fund indefinitely, available to be spent on coronavirus response. It will not expire at the end of the fiscal year.

* DPA Title III gives the President authority to authorize provision of loan guarantees under DPA §301 ([50 USC 4531](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2F4531&data=02%7C01%7CRIves%40AdvaMed.org%7C22056068f78240eb635d08d7d3959929%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637210511791931763&sdata=hNCsAb7o8FTcJgo%2FUpje0luO848AzqyCIxe72No8Ypc%3D&reserved=0)), loans under DPA §302 ([50 USC 4532](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2F4532&data=02%7C01%7CRIves%40AdvaMed.org%7C22056068f78240eb635d08d7d3959929%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637210511791941762&sdata=LEgSN1IIdkTw%2FmZ0xKk7833uW4MvJI9TPNR3F95Dffg%3D&reserved=0)), and purchase commitments under DPA §303 ([50 USC 4533](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2F4533&data=02%7C01%7CRIves%40AdvaMed.org%7C22056068f78240eb635d08d7d3959929%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637210511791941762&sdata=TetSkDPNYtxzNEQyUc0jitcyUBBRSo8Bk55NczHwWSQ%3D&reserved=0)). Friday’s Executive Order delegates that authority, and related implementing authority in [50 USC §4554-4556 and 4560](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2Fchapter-55%2Fsubchapter-III&data=02%7C01%7CRIves%40AdvaMed.org%7C22056068f78240eb635d08d7d3959929%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637210511791951756&sdata=ZsONTsMOy7HaE%2Bl1ygpKQIS6vgNfAyM0JkhklOW7wNI%3D&reserved=0).  HHS and DHS may each use this authority, in consultation with DoD and other heads of executive departments and agencies, to respond to the spread of COVID-19. DHS is directed to consult with HHS.
* The Executive Order also executed various waivers to adapt to the current situation, in which the amounts to be spent on COVID-19 greatly exceed the program caps contemplated in the DPA.
	+ The Executive Order waives DPA §301(a)(2) (which requires a Presidential determination for each loan guarantee and imposes other conditions on the loan guarantee), 301(d)(1)(A) (which puts a $50 million ceiling on aggregate loan guarantee amounts), and 303(a)(1)-(a)(6) (which provide authorities and limitations for purchase commitments).
	+ DPA §302(d)(2) requires that if total DPA loan commitments would exceed $50 million, the President must make a determination, on a nondelegable basis, that a specific loan is necessary to avert an industrial resource or critical technology shortfall that would severely impair national defense capability. The Executive Order authorizes HHS and DHS to each submit such determinations to the President for signature.
	+ The CARES Act (H.R. 748) signed on Friday also waived DPA §301(a)(3)(A) and 302(c)(1) (requiring budget authority for loans or loan guarantees), 302(d)(1) (putting a $50 million ceiling on aggregate loan amounts) and 303(a(6)(B) (reporting and layover period if purchase commitments exceed a $50 million threshold).

(2)   DPA Title VII

DPA §708(c)(1) ([50 USC §4558](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2F4558&data=02%7C01%7CRIves%40AdvaMed.org%7C22056068f78240eb635d08d7d3959929%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637210511791961753&sdata=cTFzSCkhaCYo0t8VZHQx48f8KYNMiHBSLiSqLQv5%2BVs%3D&reserved=0)(c)(1)) authorizes the President to “consult with representatives of industry, business, financing, agriculture, labor, and other interests in order to provide for the making by such persons, with the approval of the President, of voluntary agreements and plans of action to help provide for the national defense.” The President must first determine that “conditions exists which may pose a direct threat to the national defense or its preparedness programs”.

Following the consultation process, the President may approve and implement the agreement or plan of action. DPA §708(j) provides a defense to civil or criminal actions under the antitrust laws (or similar state laws) for actions taken to develop or carry out any voluntary agreement or plan of action under §708. DPA §708(o) provides a similar defense to actions for breach of contract.

The DPA provisions on voluntary agreements have elaborate strings attached, including requirements for advance consultation with DOJ and the FTC, DOJ approval, and government presence (e.g. DOJ, FTC) at any meeting of the participants in the agreement. Existing FEMA regulations at [44 CFR Part 332](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fcfr%2Ftext%2F44%2Fpart-332&data=02%7C01%7CRIves%40AdvaMed.org%7C22056068f78240eb635d08d7d3959929%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637210511791961753&sdata=jpQk1iATK1hUxoK1ZQpSIdjaILiBWMZ%2FCINErrFi5dQ%3D&reserved=0) provide for a government official to “sponsor” a voluntary agreement.

Friday’s Executive Order delegates the President’s authority under §708(c)(1) to the Secretaries of HHS and DHS. It requires them to consult with DOJ and the FTC and obtain prior approval from the Attorney General. The consultation requirement may be waived.  However the non-waived requirements are significant, and consultation with antitrust counsel would be advisable for any economic actor considering such collaborative activity.

Antitrust flexibility and expedited business review letters:  On Tuesday March 24, the Justice Department Antitrust Division and the FTC issued a [joint statement](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.justice.gov%2Fatr%2Fjoint-antitrust-statement-regarding-covid-19&data=02%7C01%7CRIves%40AdvaMed.org%7C22056068f78240eb635d08d7d3959929%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637210511791971747&sdata=jU1GjxPixyMHEixx20jhWbnArTu8CISos%2F38LYaXQ0o%3D&reserved=0) (attached) on cooperation between governments and among businesses to fight COVID-19. The statement notes that health care facilities may need to work together in providing resources and services to assist patients, consumers, and communities affected by the pandemic and its aftermath; also that other businesses may need to temporarily combine production, distribution, or service networks to facilitate production and distribution of pandemic-related supplies. The statement notes that where the government enlists help from private businesses in addressing COVID-19, DOJ and the FTC stand ready to assist, such as by working with HHS to carry out the DPA.

DOJ and the FTC will provide expedited business review letters stating their enforcement intentions in relation to a written description of proposed activities.

The joint statement also discusses specific types of joint responses to COVID-19 that would be consistent with the antitrust laws. Please consult the joint statement for details.

(3)  DPA Section 107

DPA Section 107 authorizes the President to  provide appropriate incentives to develop, maintain, modernize, restore, and expand the productive capacities of domestic sources for critical components, critical technology items, materials, and industrial resources essential for the execution of US national security strategy. The President can use DPA Title III (loans, loan guarantees, purchase commitments ) or any other provision of law.

Section 107 also mandates that the President take “appropriate actions” to assure that critical components, critical technology items, essential materials, and industrial resources are available from “reliable sources”. “Appropriate actions” may include:

* Restricting contract solicitations to reliable sources, or to domestic sources;
* Stockpiling critical components; and
* Developing substitutes for a critical component or a critical technology item.

Friday’s Executive Order delegated the President’s authority under Section 107 to the Secretaries of HHS and DHS, with respect to responding to the spread of COVID within the US.

This specific delegation may indicate that the incentives provided under DPA Title III will be conditioned on Buy American requirements and/or localizing production in the United States.

(4)  More delegations

EO 13909 and 13910 delegated the President’s authority under DPA section 101 (allocation and prioritization) and 102 (anti-hoarding) to the Secretary of HHS. Friday’s EO also delegates these authorities to DHS, with respect to health and medical resources needed to respond to the spread of COVID-19 in the US.

Friday’s EO specifically states that DHS (in practice, probably FEMA) may determine proper nationwide priorities and allocation of health and medical resources, including by controlling distribution of materials (and applicable services) in the civilian market, for responding to the spread of COVID-19 within the US.

(5)  National Defense Production Act Policy Coordinator

Friday’s EO names the Assistant to the President for Trade and Manufacturing Policy (Peter Navarro) as National DPA Policy Coordinator.  In a [press briefing late Friday afternoon](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.whitehouse.gov%2Fbriefings-statements%2Fremarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-13%2F&data=02%7C01%7CRIves%40AdvaMed.org%7C22056068f78240eb635d08d7d3959929%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637210511791971747&sdata=5%2FeC3EVFmmGQwegDlsQJ3KdMQ%2BR%2BOb3xOBePN%2BbmeGc%3D&reserved=0), President Trump introduced Navarro as “a very trusted person from the White House” who will take on this very important position.

Navarro’s role is only as a coordinator, and is based only on this executive order, not the DPA. All delegations of DPA legal authority have been made to the Secretary of HHS and the Secretary of DHS.

About Anti-trust case

The ASME v. Hydrolevel case provides a powerful warning that not just member companies, but trade associations too can be sued for antitrust.

The story doesn’t match what’s going on now, but it is a caution.

The story: ASME maintains the Boiler & Pressure Vessel Code through committees of engineers. Company A got the BPV Committee to interpret the Code to show Company B’s products were unsafe. Company B went bankrupt and sued everyone involved. The company settled, ASME held out, and ultimately the Supreme Court found ASME was is civilly liable under the antitrust laws for the antitrust violations of its agents committed with apparent authority. ASME’s legal fees were more than $6 million in 1982 dollars.

Wikipedia: [https://en.wikipedia.org/wiki/American\_Society\_of\_Mechanical\_Engineers,\_Inc.\_v.\_Hydrolevel\_Corp.](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fen.wikipedia.org%2Fwiki%2FAmerican_Society_of_Mechanical_Engineers%2C_Inc._v._Hydrolevel_Corp.&data=02%7C01%7CRIves%40AdvaMed.org%7C69182a276d054efd529b08d7d32ed387%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637210070383103888&sdata=3LgSdbmn1ebVZKQTB%2BnJr3s7nWWWURqBkpkC8fLw5v0%3D&reserved=0)

Supreme Court: [https://supreme.justia.com/cases/federal/us/456/556/](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsupreme.justia.com%2Fcases%2Ffederal%2Fus%2F456%2F556%2F&data=02%7C01%7CRIves%40AdvaMed.org%7C69182a276d054efd529b08d7d32ed387%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637210070383103888&sdata=h2v3MfWiC8d7vqN%2B%2BQCTicsGljdE5jVhaRrBYSriZ8c%3D&reserved=0)

More of the story: [https://www.engineering.com/Library/ArticlesPage/tabid/85/ArticleID/68/categoryId/7/ASME-vs-Hydrolevel.aspx](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.engineering.com%2FLibrary%2FArticlesPage%2Ftabid%2F85%2FArticleID%2F68%2FcategoryId%2F7%2FASME-vs-Hydrolevel.aspx&data=02%7C01%7CRIves%40AdvaMed.org%7C69182a276d054efd529b08d7d32ed387%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637210070383113885&sdata=bAFfv3y26fNow206NIZ3xxyaT5ybVSiamcXhtrK89Ro%3D&reserved=0)

**Questions/Answers**

About invocation of the DPA

Since January, HHS has been announcing interest in contracting for development of COVID-19 diagnostic tests and therapies, to be done under contract with the HHS Biomedical Advanced Research and Development Agency (BARDA). On March 4, HHS also [announced](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hhs.gov%2Fabout%2Fnews%2F2020%2F03%2F04%2Fhhs-to-procure-n95-respirators-to-support-healthcare-workers-in-covid-19-outbreaks.html&data=02%7C01%7CRIves%40advamed.org%7C62e1e80416d44e0297fa08d7d20818e1%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637208804549640436&sdata=5XRp5o4FuZxJWtVXBr4Y8wDprYkhGC76L8CX%2B36Gs98%3D&reserved=0) a solicitation for procurement of 500 million N95 respirators for the Strategic National Stockpile. But these are not actions invoking (based on) the allocation provisions of DPA Title I, because compliance by the private sector is voluntary.

State governments, Congress and the public have increased pressure for stronger action by the administration to somehow get more PPE and respiratory equipment to the front lines. In response, Trump has signed two executive orders that delegate some of his DPA Title I authority to HHS.

The next step – applying or invoking the DPA – would be for HHS to issue “rated orders”. HHS already had this authority under the Health Resources Priorities and Allocations System regulations at [45 CFR Part 101](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fcfr%2Ftext%2F45%2Fpart-101&data=02%7C01%7CRIves%40advamed.org%7C62e1e80416d44e0297fa08d7d20818e1%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637208804549640436&sdata=VCIUcZefFP0n8ep6Mf5%2BRnn2JNMAeiQZ9OkdMWetqlo%3D&reserved=0) (attached).  If you have government contract staff who deal with defense contracting, or government contracts counsel with defense contract experience, they can advise you about how rated orders and prioritization work in practice.  Trump said that he doesn’t want to “invoke” the DPA – meaning that he does not want this administration to use DPA authority to engage in direct production, allocation or rationing of health resources.

Regarding purchase commitment authority. This is in DPA §303 ([50 USC 4533](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2F4533&data=02%7C01%7CRIves%40advamed.org%7C62e1e80416d44e0297fa08d7d20818e1%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637208804549640436&sdata=DChYOSHN%2FWPP8Wu4sKaOT76m4D9ctIzpqsSnesvTpKw%3D&reserved=0)). HHS has been delegated the authority to make such commitments. Any budgetary doubt is resolved by H.R. 748, which passed the Senate Wednesday and could be enacted Friday.

To recap:

So far, the Trump administration has:

1. Invoked/implemented the DPA Title I provisions on allocation and prioritization via E.O. 13909 of March 18 (attached). This executive order made a Presidential finding that the health and medical resources needed to respond to the spread of COVID-19, including PPE and ventilators, meet the requirements of DPA §101(b) (50 USC 4511(b)). It also delegated to the Secretary of HHS the authority to designate additional health products or services under DPA §101(b), and (c) delegated to HHS the command, allocation and prioritization powers of the President under DPA §101, and the President’s authority “to implement the Act in subchapter III of chapter 55 of title 50”. Subchapter III is [50 USC §4551-4568](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2Fchapter-55%2Fsubchapter-III&data=02%7C01%7CRIves%40advamed.org%7C62e1e80416d44e0297fa08d7d20818e1%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637208804549650398&sdata=NVWQFSmW4G5krpBS72%2FGAOT2AZRPoviA3%2Fl50iFuepE%3D&reserved=0).
2. Invoked/implemented the DPA anti-hoarding provisions, via E.O. 13910 of March 23. This E.O. makes policy findings and delegates to HHS the president’s authority under DPA §102 ([50 USC §1552)](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2F4512&data=02%7C01%7CRIves%40advamed.org%7C62e1e80416d44e0297fa08d7d20818e1%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637208804549650398&sdata=us%2BrIce7TVAewi8vYPztNaTkAYGs47m0IlZDoiFIYpE%3D&reserved=0), including the authority to designate materials as scarce and to prescribe conditions with respect to accumulating such materials. It also delegates to HHS Presidential implementation authority in subchapter III of chapter 55 of title 50, specifically, 50 USC 4554-4556 and 4560. HHS was directed to consult with FEMA.
	* On March 25, HHS issued a notice implementing E.O. 13910 (also attached). The notice designates specific materials as in short supply for coronavirus response: specific masks, respiration equipment, sterilization services for medical devices and certain sterilizers, disinfecting devices, PPE, and chloroquine and hydroxychloroquine. The notice did not impose limits on accumulation or stocks, or penalties for hoarding.

Question Concerning DPA Title III powers to promote expansion of supply:

On March 25, the Senate passed H.R. 748 including a $1 billion appropriation for “Defense Production Act Purchases”; H.R. 748 also waives some of the reporting provisions in the DPA (see the attached).

When H.R 748 has been enacted, the $1 billion should be credited to the Defense Production Act Fund, a Treasury Department trust fund established by Title III of the DPA ([50 USC §4534](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2F4534&data=02%7C01%7CRIves%40advamed.org%7C62e1e80416d44e0297fa08d7d20818e1%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637208804549660362&sdata=TjF93vpiVOZbbYBgrhttGXVghkpraKSoHwj7tmo%2Fmz8%3D&reserved=0)). The $1 billion will remain in the DPA Fund indefinitely, available to be spent on coronavirus response. It will not expire at the end of the fiscal year.

Title III of the DPA gives the President authority to authorize provision of loan guarantees under DPA §301 ([50 USC 4531](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2F4531&data=02%7C01%7CRIves%40advamed.org%7C62e1e80416d44e0297fa08d7d20818e1%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637208804549660362&sdata=AhfLPJ20MGSHy4bmGmAuRrPsnQEWMjj5ehCCVrjqnkc%3D&reserved=0)), loans under DPA §302 ([50 USC 4532](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2F4532&data=02%7C01%7CRIves%40advamed.org%7C62e1e80416d44e0297fa08d7d20818e1%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637208804549670306&sdata=Pye6JFwncYLjvSj6t1yC69uDNZjw09fBDa55ei79DqU%3D&reserved=0)), and purchase commitments under DPA §303 ([50 USC 4533](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2F4533&data=02%7C01%7CRIves%40advamed.org%7C62e1e80416d44e0297fa08d7d20818e1%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637208804549670306&sdata=dbxZcLoNuoAWCU19bhkql1y5RXpQPuxL4lQb%2FCPwzUw%3D&reserved=0))

E.O. 13603 of March 16, 2012 (attached) delegated these authorities to (inter alia) the Secretary of HHS (see section 801(h) and 201 of E.O. 13603). Section 305 of E.O. 13603 (and DPA Title III) requires that there be budget authority provided by an appropriations act before the agency head can use these authorities -- but H.R. 748 has taken care of that.

Question about voluntary agreements under DPA Title VII ([50 USC 4558](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fuscode%2Ftext%2F50%2F4558&data=02%7C01%7CRIves%40advamed.org%7C62e1e80416d44e0297fa08d7d20818e1%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637208804549670306&sdata=VtRkBhVp1cRNC1LHGqk43bMzvLJ6L%2FBiM4gVmxxnO1o%3D&reserved=0)).

Section 401 of EO 13603 explicitly delegated to HHS (among others) the President’s authority under 50 USC §4558, so that HHS has all the powers of the President to convene private industry to make voluntary agreements and plans of action.  But the DPA provisions on voluntary agreements have strings attached: elaborate requirements for advance consultation with DOJ and the FTC, DOJ approval, and government presence (e.g. DOJ, FTC) at any meeting of the participants in the agreement. There are FEMA regulations ([44 CFR Part 332](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.law.cornell.edu%2Fcfr%2Ftext%2F44%2Fpart-332&data=02%7C01%7CRIves%40advamed.org%7C62e1e80416d44e0297fa08d7d20818e1%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637208804549680260&sdata=Xx3kvlY05XiOFRJSNYJ9MSz45XoGmaKgzi6XP3GaHuE%3D&reserved=0)) which provide for a government official to “sponsor” a voluntary agreement – perhaps HHS. HHS would carry out the consultation, notice and transparency requirements in these regulations and in 50 USC §4558. The payoff would be a limited antitrust immunity.

The procedural requirements attached to these voluntary agreements look to be time- and resource-consuming. It is not clear that the benefit of these agreements would be worth the time and trouble they would take, particularly considering the time pressure of the coronavirus pandemic. The participants would also need to be very careful to stay within the scope of their authorization from DOJ, because collaboration outside that scope could be targeted by later lawsuits by the government or private parties. If you are interested in pursuing this possibility, you may wish to consult with your antitrust counsel about how to structure your participation to minimize the ongoing risk generated by participating in an agreement like this.

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