Legal Backgrounder

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FEDERAL LAW PROVIDES PROCESS FOR JOINT DEVELOPMENT OF BIO-TERROR VACCINES

by

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The government's current homeland security efforts require various agencies, including the Department of Defense, to purchase a number of vaccines, countermeasures, and other drugs to address multiple bio-terror threats. There are a limited number of companies capable of supplying such products to meet the government's growing needs. No single company has the resources necessary to respond effectively to multiple solicitations for such products. Moreover, the government market for these products is rather limited and uncertain.[1] These limitations and uncertainties inhibit research, development and production of products needed for national defense, products whose production would normally be spurred through competitive market forces.

To address these challenges, the government should use its express authority under the Defense Production Act (DPA) of 1950, as amended, 50 U.S.C. App. § 2361 *et seq.*, to convene a meeting of all relevant companies competing for government contracts requesting the development and production of certain vaccines and countermeasures for national defense purposes. Under such authority, the government may provide immunity from potential antitrust liability to a company that participates in a process the objective of which is to address issues of common concern to industry and the government. The government may, in exercising this authority, require competitors to act in collaboration or share information that otherwise could not be shared due to antitrust laws and regulations.

Summary. The DPA provides the government with the authority to permit companies to enter into certain agreements that could include potential competitors and would have the effect of altering competitive behavior for the development of vaccines — activities which would otherwise violate antitrust

[1] *See Anthrax Makers Call Finances Shaky,* N.Y. TIMES, Aug. 5, 2002 (Noting the failure of the Department of Defense to commit to future budgets that will include funding for anthrax vaccine).

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laws. Under the DPA, the government may convene a meeting with all or some of the nation's vaccine and countermeasure manufacturers to discuss the government's vaccine procurement requirements. If the DPA's statutory prescriptions are satisfied, the government's valid exercise of its DPA authority would provide complete protection against the operation of certain antitrust laws for the private-entity participants in this process.

Competitors Can Meet and Enter into Voluntary Agreements and Plans of Action under the Defense Production Act. The government has the authority to convene meetings and execute agreements creating what could be described as a "managed market" that fall under the DPA's exemption from the antitrust laws. Under this authority, parties could meet to discuss a proposed division of the total market for vaccines, countermeasures, and other drugs necessary to support homeland security, including possibly allocating drug research development and production contracts among potential competitors to avoid inefficient procedures associated with full and open competition in this context. The conduct of such meetings undoubtedly would require the sharing of information that could otherwise not be shared due to the operation of antitrust laws and regulations.

The DPA, and specifically 50 U.S.C. App. § 2158, expressly enable the creation of agreements among potential competitors, with the participation of the U.S. government, the purpose of which is to manage the development and production of defense-related goods and services and which agreements, but for this provision, might violate certain antitrust laws. Thus, the DPA will provide immunity[2] from any public or private antitrust action brought against a company that participates in such a meeting, provided that all of the technical elements outlined in the DPA have been met.

The active participation of the federal government is an essential element to the operation of this exemption from the antitrust laws and regulations. The government's participation is described in considerable detail in the DPA itself. When conditions exist that directly threaten the national defense or its preparedness programs, the DPA authorizes the President to give antitrust immunity to rival contractors for the purposes of forming agreements to develop preparedness programs and to expand production capacity and supply beyond levels needed to meet essential civilian demand. William E. Kovacic, *Antitrust Analysis of Joint Ventures and Teaming Arrangements Involving Government Contractors*, 58 ANTITRUST L.J. 1059 (1989). Immunity against any civil or criminal action brought under federal antitrust laws or any similar law of any state may be conferred on any person that:

- Takes any action in the course of developing a voluntary agreement initiated by the President or a plan of action adopted under such agreement; or
- Takes any action to carry out an approved voluntary agreement or plan of action initiated by the President; and
- Complies with the requirements of the DPA; and
- Acts in accordance with the terms of voluntary agreement or plan of action.

[2]While the statute itself refers to an "immunity" that is being conferred, we do not believe that the exemption amounts, literally, to an "immunity." Our reason for differing on the effect of the law is that a company would not be "immune" from an action brought by a private party or government, but rather could prevail in an antitrust action brought against it by showing that it had complied with a government supervised voluntary agreement or plan of action. *See* 50 U.S.C. App. § 2158(j).

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50 U.S.C. App. § 2158(j)(1).[3]

"Antitrust laws" for purposes of the DPA, have "the meaning given to such term in subsection (a) of the first section of the Clayton Act, except that such term includes Section 5 of the Federal Trade Commission Act to the extent that such section 5 applies to unfair methods of competition." 50 U.S.C. App. § 2158(b). That definition includes (by referencing the Clayton Act) the Sherman Act, 15 U.S.C. § 1, *et seq.*, which contains the antitrust prohibitions potentially applicable to discussions and other joint actions among competitors. The person seeking the immunity has the burden of persuasion to establish that each of the elements for receiving immunity under the DPA have been met. 50 U.S.C. App. § 2158(j)(3).

While immunity is not available if "the action was taken for the purpose of violating the antitrust laws," this provision does not present a problem for the government to achieve the overall objectives of the DPA. This language was inserted during reauthorization of the DPA in 1991 as a "face-saving" measure for those legislators hesitant to reenact the antitrust immunity provisions of the DPA for fear of eviscerating existing antitrust law. Assuming that a company acts in accordance with provisions of the DPA, and follows the government's directions in that regard, by definition, they are not acting for the "purpose" of violating antitrust laws.

The Federal Maritime Administration used the DPA for these purposes as recently as 1996. Under that voluntary agreement, the Department of Transportation convened a meeting with eligible U.S.-flag vessel operators to enter into a "Voluntary Intermodal Sealift Agreement" (VISA) to address the total sealift needs of the United States in the event of a national emergency. Specifically, the action was undertaken with the intention that "the participants that are party to a VISA will provide capacity to support a significant portion of surge and sustainment requirements in the deployment of U.S. military forces." 60 Fed. Reg. 54144 (Oct. 19, 1995). While the DPA was used to allocate market-share on at least fifty occasions during the Korean War,[4] the VISA program is the most recent example of the government's use of the DPA for these purposes. The VISA program remains in effect today.

Procedures for Establishing Voluntary Agreements under the Defense Production Act. As a prerequisite to establishing a voluntary agreement under the DPA, the President (or his approved designee) must find that "conditions exist which may pose a direct threat to the national defense or its preparedness programs." 50 U.S.C. App. § 2158(c)(1). By Executive Order 12919, dated June 3, 1994, the President has delegated this authority to the heads of each federal department or agency. E.O. 12919, Part V, Sec. 501. Once appointed, the President's designee (defined as the "sponsor" by the governing regulations) must consult with the Attorney General and the FTC not less than ten days before attending a meeting discussing any proposal to develop a voluntary agreement. In addition, the sponsor must have received prior approval from the Attorney General to have such a meeting. 50 U.S.C. App. § 2158(c)(2).

Upon a finding that the prerequisites for initiating a meeting to discuss a voluntary agreement under the DPA have been met, "the President [or the approved sponsor] may consult with representatives of industry, business, financing, agriculture, labor, and other interests…[to facilitate the creation of]…voluntary agreements and plans of action to help provide for the defense of the United States through the development of preparedness programs and the expansion of productive capacity and supply beyond levels needed to meet essential civilian demand in the United States." 50 U.S.C. App. § 2158(c)(1).

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[3] If a voluntary agreement or plan of action is accompanied by contracts with the United States that call for the conduct of the necessary research, development, and production, additional statutes exist which would protect against antitrust laws. *See* 10 U.S.C. § 2304(c) and 41 U.S.C. § 303(c).

[4] *See generally*, Harold L. Schilz, *Voluntary Industry Agreements and Their Exemptions from the Antitrust Laws*, 40 VA. L. REV. 1 (1954).

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Voluntary agreements may only be developed with the direct involvement of the Attorney General, the Chairman of the FTC, and the Director of FEMA, or their designees. The sponsor of the agreement must serve as the chairman of any meeting discussing proposed voluntary agreements. In addition, all interested persons must be invited to attend any meeting discussing the proposed agreement, unless the chairman finds the subject of the meeting is protected under the Freedom of Information Act (FOIA). Finally, a full and verbatim transcript must be prepared for any meeting discussing the proposed agreement. This transcript must be provided to the Attorney General, the FTC, and Congress, and be made available for public inspection and copying, subject to FOIA. 50 U.S.C. App. § 2158(d); 44 CFR 332.2.

Voluntary agreements are executed through a "plan of action," which may include the conduct of research and development contracts. Such a plan may also include contracts for the production of goods and services or other actions as agreed to by the parties to the voluntary agreement and the government.[5]

Voluntary agreements, and any plans of action contemplated by such agreements, become effective when the sponsor certifies, in writing, that the agreement or plan is necessary and the sponsor submits the agreement or plan to Congress. In addition, the Attorney General (with consultation from the FTC Chairman and the FEMA Director) must find, in writing, that the purpose of the action "may not reasonably be achieved through a voluntary agreement or plan of action having less anticompetitive effects or without any voluntary agreement or plan of action and publishes such finding in the Federal Register." 50 U.S.C. App. § 2158(f)(1); 44 CFR 332.1(b)(2); E.O. 10480, §§ 101 & 501(a).

Voluntary agreements and plans of action contemplated by such agreements expire two years from the effective date and may be extended upon certification or finding by the sponsor and the FEMA Director that such extension is appropriate. 50 U.S.C. App. § 2158(f)(2). The Attorney General may terminate or modify a voluntary agreement, in writing, after consultation with the FTC Chairman. The sponsor of the agreement, with the concurrence of the FEMA Director, may terminate or modify a voluntary agreement, in writing, after consultation with the Attorney General and the FTC Chairman. Any person who is a party to a voluntary agreement may terminate his participation in the agreement upon written notice to the sponsor. No antitrust immunity shall apply to any act or omission occurring after the termination of the voluntary agreement or any act or omission that is beyond the scope of the agreement. 44 CFR 332.5.

Conclusion. The federal government should exercise its explicit authority under the DPA to convene a meeting with industry to call for the development and production of certain vaccines and countermeasures for national defense purposes. However, if the government fails to act, and if the technical elements of the DPA have been satisfied, industry leaders should meet to discuss petitioning the government to permit competitors to enter voluntary agreements that could have the effect of dividing the markets or developing common contract terms for the vaccines to be developed. Such voluntary agreements may include a plan of action to be issued by the sponsoring agency that permits, among other things, division of market share and/or assignment of certain contracts among participants to the agreements. To ensure compliance with the DPA and prevent potentially serious antitrust liability, counsel knowledgeable of antitrust and DPA requirements should be involved in all aspects of this process.

[5]The term "plan of action," as defined by the DPA, means "any of 1 or more documented methods adopted by participants in an existing voluntary agreement to implement that agreement." 50 U.S.C. App. § 2158(b)(2). A plan of action is issued by the government with the express agreement and cooperation of all of the parties to the voluntary agreement.

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