April 04, 2020


Dear Ms. Schechter, Ms. Mayer & Messrs. Ettinger, Liberman, and Pace:

This letter responds to your request on behalf of McKesson Corporation, Owens & Minor, Inc., Cardinal Health, Inc., Medline Industries, Inc., and Henry Schein, Inc. (together the “Requesting Parties”) for the issuance of a business review letter under the Department of Justice’s (the “Department”) Business Review Procedure, 28 C.F.R. §50.6. Specifically, the Department understands that the Requesting Parties’ request is made under the expedited, temporary review procedure as detailed in the Joint Antitrust Statement Regarding COVID-19 (the “Joint Statement”) dated March 2020.1 As indicated

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in the Joint Statement, the Department’s statement of its current enforcement intentions as set out in this letter will be in effect for one year from the date of this letter. The Requesting Parties may subsequently request, using this expedited, temporary procedure, that the Department reiterate its current enforcement intentions, if further time is necessary to respond to the unprecedented COVID-19 pandemic and its aftermath.

You have requested a statement of the Department’s current antitrust enforcement intentions with respect to your efforts to expedite and increase manufacturing, sourcing, and distribution of personal-protective equipment ("PPE") — including masks, gowns, gloves, and other equipment intended to help protect first responders and other members of the medical community against Coronavirus-related infection, as well as medication to treat COVID-19 patients ("Proposed Conduct"). The Department understands that the Proposed Conduct relates to the Requesting Parties’ response to the unprecedented COVID-19 pandemic and its aftermath and is “focused on, and limited to, facilitating the government’s efforts to guide PPE and medications to the places they are needed most.”

The Department likewise understands that the Requesting Parties are responding cooperatively to requests from the U.S. Government, as part of a collaborative process with government personnel and consultants, in which the Department’s Antitrust Division is regularly involved. Based on the information and representations you provided, the direct and continuing observations of Antitrust Division personnel, and after an expedited review, the Department presently does not intend to challenge the Requesting Parties’ efforts to expedite and increase manufacturing, sourcing, and distribution of PPE and medications for the reasons explained below.

I. Background

The Requesting Parties are U.S. healthcare distributors of PPE and medications. PPE includes masks, gowns, gloves, and other equipment designed to protect against infection. Recognizing challenges presented by the pandemic to global PPE supply, U.S. Government agencies, including the Federal Emergency Management Agency ("FEMA") and the Department of Health and Human Services ("HHS"), have asked the Requesting Parties and other distributors to use their industry expertise and contacts to address PPE supply chain shortages, in addition to applying their expertise to evaluate potential laboratory and medication supply issues.

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3 Id. at 2.
4 The Department understands that some aspects of the proposed conduct already have been underway to facilitate the delivery of critical equipment into the United States. Although the Department typically does not review ongoing conduct, given the President’s declaration of a national emergency and the current exigencies, I have determined that in these circumstances it is appropriate to consider the request.
5 We understand medications to also include oxygen used for medical purposes.
The circumstances that led to this request are exceptionally pressing and unlikely to recur frequently. In December 2019, a new, highly infectious coronavirus reportedly emerged in Wuhan, China and began to spread rapidly around the world. On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency under section 319 of the Public Health Service Act. A few weeks later, the World Health Organization announced that the COVID-19 outbreak had become a global pandemic. On March 13, 2020, President Donald J. Trump declared a national emergency under sections 201 and 301 of the National Emergencies Act, and announced that the crisis is of sufficient severity and magnitude to warrant a nationwide emergency determination under section 501(b) of the Robert T. Stafford Disaster Relief and Emergencies Assistance Act. The President also encouraged all governors and tribal leaders to consider submitting requests for declaration of a “major disaster” under Section 401(b) of the Stafford Act. As of April 1, major disasters have been declared in more than 25 states and territories. By April 1, more than 200,000 Americans had been infected with the virus and more than 4,500 had died. The White House has projected that, even with unprecedented measures to contain the virus, it could eventually take between 100,000 and 240,000 American lives.

In light of these exigent circumstances, the Antitrust Division of the Department of Justice has recognized that the COVID-19 pandemic “will require unprecedented cooperation between federal, state, and local governments and among private businesses to protect Americans’ health and safety.” As we have acknowledged, such coordinated efforts, “limited in duration and necessary to assist patients, consumers, and communities affected by COVID-19 and its aftermath,” may be “a necessary response to exigent circumstances that provide Americans with products or services that might not be available otherwise.”

Addressing potential disruptions to global PPE supply is central to the U.S. Government’s effort to save American lives and livelihoods from the destructive effects of COVID-19. On March 18, 2020, President Donald J. Trump issued Executive Order 13909, “Prioritizing and Allocating Health and Medical Resources to Respond to the

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13 Joint Statement, supra note 1.
14 Id.
Spread of COVID–19,” which declared it “critical” that “all health and medical resources needed to respond to the spread of COVID-19 are properly distributed to the Nation’s healthcare system and others that need them most.”\textsuperscript{15} Consistent with that aim, the President invoked the Defense Production Act to prioritize the swift production of PPE and delegated authority under section 101 of the Act to the Secretary of Health and Human Services “to determine, in consultation with … the heads of other executive departments and agencies as appropriate, the proper nationwide priorities and allocation of all health and medical resources, including controlling the distribution of such materials (including applicable services) in the civilian market, for responding to the spread of COVID-19 within the United States.”\textsuperscript{16} On March 26, 2020, President Donald J. Trump issued another executive order stating that “it is the policy of the United States that health and medical resources needed to respond to the spread of COVID–19, such as personal protective equipment …are not hoarded” and delegating additional authority to HHS.\textsuperscript{17}

FEMA has broad authority to implement these policies.\textsuperscript{18} Under Section 502 of the Stafford Act, in any “emergency,” and under Section 402 of the Stafford Act, in any “major disaster,” the President may “coordinate all disaster relief assistance (including voluntary assistance) provided by federal agencies, private organizations, and State and local governments.”\textsuperscript{19} By executive order, this power has been delegated to the Administrator of FEMA.\textsuperscript{20} Accordingly, the Stafford Act authorizes the Administrator to enter into voluntary agreements with private companies to ensure the distribution of PPE to the areas of the country that need it most. The Homeland Security Act of 2002, moreover, directs that “[t]o the maximum extent practicable, the Secretary [of Homeland Security, who oversees FEMA,] shall use national private sector networks and infrastructure for emergency response to … major disasters”\textsuperscript{21} and that “in order to further the policy of the United States to avoid competing commercially with the private sector, the Secretary should rely on commercial sources to supply the goods and services needed by the Department.”\textsuperscript{22}

II. The Requesting Parties’ Efforts to Expedite and Increase Manufacturing, Sourcing, and Distribution of PPE and Medication

All facts set forth in this section regarding the Requesting Parties and the efforts to expedite and increase manufacturing, sourcing, and distribution of PPE are based on your representations to the Department and publicly available sources. Moreover, Antitrust Division attorneys participate regularly in meetings related to the effort, and the facts set forth here are consistent with their observations.

\textsuperscript{16} Id.
\textsuperscript{18} See 42 U.S.C. §§ 5170, 5192-93.
\textsuperscript{19} 42 U.S.C. §§ 5170a, 5192.
\textsuperscript{21} 6 U.S.C. § 321h
\textsuperscript{22} 6 U.S.C. § 321i.
The Requesting Parties propose to collaborate with and at the direction of FEMA, HHS, and other government entities, to expedite and increase manufacturing, sourcing, and distribution of PPE and COVID-19-treatment-related medication essential to protect Americans’ health and safety. Specifically, and subject to the commitments described below, the Requesting Parties propose to collaborate with and at the direction of the U.S. Government to:

a) Help FEMA, HHS, and foreign governments address bottlenecks with our existing foreign suppliers;
b) Help FEMA and HHS identify and qualify new sources of supply;
c) Help FEMA and HHS identify and monitor areas of increased demand for supplies and medications;
d) Help expedite distribution of supplies and medications to FEMA-designated COVID-19 hotspots;
e) Help FEMA and HHS understand competitive prices for these supplies and medications;
f) Help FEMA and HHS negotiate competitive prices, through bilateral communication with FEMA;
g) Provide FEMA and HHS with data necessary to do the above;
h) Provide FEMA and HHS with claims data and data otherwise requested by FEMA;
i) Other related activities to manufacture, source, and distribute medications and healthcare products as directed by FEMA, HHS, or additional government agencies.

The Requesting Parties’ primary collaborative activity in these areas occurs at the direction of, and in the presence of FEMA, HHS, other government entities, and their agents.

One initiative currently underway is referred to as Project Airbridge. Organized by the United States, Project Airbridge is a partnership between U.S. healthcare distributors, such as the Requesting Parties, and the federal government. Project Airbridge includes a series of flights organized by the U.S. Government to quickly bring large quantities of medical supplies to the country to help fight COVID-19. Attorneys from the Department’s Antitrust Division participate in regular communications with the federal agencies organizing Project Airbridge, and in many cases directly observe the associated collaborative activity.

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23 Request Letter, supra note 2, at 3. The Department understands, consistent with safeguard (c) on the following page, that sharing of competitively sensitive information is proposed to be bilateral with the government and its agents, not directly between the Requesting Parties.
25 Id. (“As you know, we formed a historic partnership with your companies to bring massive amounts of medical supplies from other countries to the United States. And you bring in big amounts.”)
26 Request Letter, supra note 2, at 2.
The Requesting Parties’ collaborations undertaken within this system, including in the context of Project Airbridge, are largely under the explicit direction, and in the presence of, the U.S. Government and its agents. “To be effective and responsive,” however, “the Requesting Parties also will need to engage in the Proposed Conduct when agency representatives are not participating in the call or email chain.” To the limited extent the Requesting Parties will need to engage in the Proposed Conduct when U.S. Government representatives are not participating, the Requesting Parties have committed to follow several safeguards:

a) Any collaboration between the Requesting Parties is specifically intended to further U.S. government policy and efforts;
b) The Requesting Parties are not using any collaboration to increase prices, reduce output, reduce quality, or otherwise engage in COVID-19 profiteering;
c) If FEMA, HHS, other government entities, or their consultants and designees request any competitively sensitive information from any of the Requesting Parties, McKesson, Cardinal, OMI, Medline, and Henry Schein each will make all reasonable efforts to share this information only with the requesting government agency, and not with any other Requesting Party or competitor;
d) The Requesting Parties’ collaborations are limited to the “time period necessary to assist FEMA and other government agencies in responding to COVID-19 shortages;”
e) Upon resolution of the COVID-19-related disruptions and the disbanding of the related U.S. Government response initiatives, the Requesting Parties will formally dissolve this competitor collaboration and immediately notify the Department, in writing;
f) The Requesting Parties will commit to work with the Department to determine appropriate sequestration of competitively sensitive material that was produced during the collaboration period.

The Requesting Parties have committed to follow these safeguards at all times.

In sum, according to the Requesting Parties, their collaborations will be focused on, and limited to, facilitating the U.S. Government’s efforts to respond to the unprecedented COVID-19 pandemic, including by guiding PPE and medications to the places where they are needed most. Additionally, the Requesting Parties’ collaborations form an essential part of, and are directed by, a system developed by FEMA and other federal agencies in furtherance of expediting delivery of needed medical supplies, in which the Department’s Antitrust Division is involved. Further, in all other respects, the Requesting Parties will continue to pursue their respective business strategies as before. Finally, the Requesting Parties’ collaborations are limited only to responding to the unprecedented COVID-19

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27 Id. at 3.
28 Id. at 4.
29 Id.
pandemic and its aftermath and will only last for as long as such efforts are necessary for the welfare of Americans.

III. **Legal Framework & Analysis**

   a. **Collaboration and Cooperation with Federal Agencies**

   Conduct by federal agencies is not subject to scrutiny under the antitrust laws.\(^\text{30}\) Courts have extended this immunity to conduct by private parties acting individually or together when (i) the collaboration is compelled by an agreement with a federal agency or a clearly defined federal government policy and (ii) a federal agency supervises the conduct.\(^\text{31}\) The Department will not challenge conduct that satisfies this standard in responding to the COVID-19 pandemic and its aftermath.

   Collaboration among competitors in aid of a federal agency, even if it does not satisfy the standard described above, may still offer unique benefits and therefore be consistent with the antitrust laws.\(^\text{32}\) For example, the collaboration might allow a federal agency to “respon[d] to exigent circumstances [and] provide Americans with products or services that might not be available otherwise” more immediately, efficiently, and effectivley than if firms worked on their own or even bilaterally with the agency.\(^\text{33}\) The Department’s assessment of efforts to address COVID-19 and its immediate aftermath will account for these unique procompetitive benefits as appropriate.

   The Requesting Parties have represented that they intend to undertake various activities “directed by FEMA, HHS, or additional government agencies.”\(^\text{34}\) For example, they intend to help “distribut[e] . . . supplies and medications to FEMA-designated COVID-19 hotspots” and, in some cases, among other each other based on terms set through agreements with FEMA.\(^\text{35}\) Based on the Requesting Parties’ representations, it is

\(^{30}\) See, e.g., *Sea-Land Serv., Inc. v. Alaska R. R.*, 659 F.2d 243 (D.C. Cir. 1981). Although the antitrust laws do not apply directly to the federal government, the Department stands ready to work with federal agencies to ensure their efforts promote competition. *See United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972) (“Antitrust laws . . . are the Magna Carta of free enterprise. They are as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms.”).

\(^{31}\) *See Byers v. Intuit, Inc.*, 600 F.3d 286, 295 (3d Cir. 2010); *Name.Space, Inc. v. Network Sols., Inc.*, 202 F.3d 573, 581–84 (2d Cir. 2000); *see also* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶252. (4th Ed. 2018) (“The relevant question is the degree to which the immune federal agency asserts ‘plenary control’ over the private party with whom it has a contract.”).

\(^{32}\) See, e.g., Letter from J. Mark Gidley, Acting Assistant Atty Gen., U.S. Dep’t of Justice, to Stuart M. Pape, Patton, Boggs & Blow (Jan. 14, 1993) (“Gidley Letter”), https://www.justice.gov/atr/response-association-official-analytical-chemists-request-business-review-letter (concluding that a working group, formed at the request of HHS to help the agency develop tests for smokeless tobacco, was “unlikely to be anticompetitive and [would instead] facilitate a new, standardized means of testing the content of smokeless tobacco not currently available”).

\(^{33}\) *Joint Statement, supra* note 1; *see also* Gidley Letter.

\(^{34}\) *Request Letter, supra* note 2, at 3.

\(^{35}\) *Id.*
the Department’s conclusion that this conduct fits within the two-part framework described above. First, the Requesting Parties would be acting pursuant to agreements with the federal government (FEMA). Second, FEMA and its agents will be actively directing and supervising their conduct, and any determinations of prices, wages, output, quality, bids, or allocations will only occur if at FEMA’s direction. Thus, the Department is satisfied that this and similar conduct—pursuant to an agreement with FEMA or another federal government agency, supervised by the agency, and in furtherance of the agency’s defined policy goals—should not raise any concerns under the antitrust laws. For a similar reason, the Department is satisfied that the Requesting Parties’ sharing information “requested by FEMA” through “bilateral communication with FEMA,” as opposed to communication with each other, should not raise antitrust concern.

The Requesting Parties have also represented that they intend to engage in conduct at the request of FEMA, HHS, other federal agencies, and their agents. For example, they seek to “[h]elp FEMA and HHS identify and qualify new sources of supply” for PPE and other medical supplies. This conduct, under the exigent circumstances presented by COVID-19, offers Americans several unique benefits. In particular, it may well increase the supply of and access to PPE in the United States at a time when supply shortages could threaten the health and safety of millions of Americans. The Requesting Parties’ collaboration with each other and FEMA is also limited in scope and duration to address the pandemic, which minimizes the risk of anticompetitive harm. Thus, the Department is satisfied that this and similar conduct—at the request of FEMA, directed by the agency, and in furtherance of the agency’s defined policy goals to address a national emergency—offers unique procompetitive benefits under the exigent circumstances presented by COVID-19 that outweigh any hypothetical anticompetitive harm.

b. The Competitor Collaborations Regarding the Proposed Conduct Likely Do Not Raise Competitive Issues

The Requesting Parties have represented that their work on this initiative is at the direction or under the supervision of FEMA. As time is of the essence given the current circumstances, however, it may not be possible for FEMA representatives to be included in all discussions regarding the distribution of PPE and medications. Therefore, activities that occur outside of FEMA’s presence are treated as encompassed within the scope of this business review letter to the extent that they are necessary to facilitate FEMA’s directions and subject to the safeguards committed to by the Requesting Parties.

Still, to the extent the parties collaborate outside of this framework, they have represented that their activity would be limited and not involve discussions of

37 See Joint Statement, supra note 1.
38 See supra Sections I & II.
competitively sensitive information. Under the joint FTC/DOJ Competitor Collaboration Guidelines,\(^39\) these activities would be evaluated under the rule of reason, as they do not implicate per se antitrust violations such as price fixing or market allocation. “The central question is whether the relevant agreement likely harms competition by increasing the ability or incentive profitably to raise price above or reduce output, quality, service, or innovation below what likely would prevail in the absence of the relevant agreement.”\(^40\) As the Requesting Parties note in their letter, these Guidelines recognize that “a competitor collaboration may enable participants to offer goods . . . that are . . . brought to market faster than would be possible absent the collaboration.”\(^41\) Additionally, “[a] collaboration may allow its participants to better use existing assets” than would be possible absent collaboration. Those conditions appear to be present here.

The Requesting Parties have represented that they are working together to expand existing capacity and bring goods to communities in need. The proposed conduct is limited in scope and duration, necessary to address COVID-19-related scarcity, and will not extend beyond what is required to facilitate the availability of needed supplies. Based on these representations and given the current circumstances, it appears as if the procompetitive aspects of any arrangement far outweigh any potential harm.

Consumers may benefit from collaborations such as this, as they may enable participants to bring life-saving goods faster to market than would be possible absent the collaboration. For example, flights bring overseas goods to the United States much more quickly than ships, and Project Airbridge will thereby facilitate increasing near-term supply in the United States during times of particular need. To the extent that the Proposed Conduct addresses PPE and other healthcare products shortages and improves and enhances the supply chain of these products in the midst of the nationwide pandemic, the procompetitive benefits of the Proposed Conduct are unusually strong. The Requesting Parties have represented that the Proposed Conduct “is necessary to allow participants to offer PPE, lab supplies, and medications more quickly than otherwise would be possible and to address scarcity.”\(^42\) These benefits have the potential to save lives and limit the tremendous damage physically and economically the pandemic is causing.

The nature of the Proposed Conduct, which is “necessary” and in “support [of] the mission of FEMA and other agencies to improve and enhance the supply chain for PPE and other healthcare products,” indicates that the likelihood of anticompetitive harm, if any, is low. Further limiting the likelihood of anticompetitive harm is the fact that the Requesting Parties “are not using the collaboration to increase prices, reduce output, reduce quality, or otherwise engage in COVID-19 profiteering.”\(^43\)

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\(^40\) Id. § 3.3

\(^41\) Id. § 2.

\(^42\) Request Letter, supra note 2, at 4.

\(^43\) Id.
Representations from the Requesting Parties regarding particular limitations on the Proposed Conduct also reduce the likelihood of any anticompetitive harm. The safeguards described above ensure that any collaboration not overseen by the U.S. Government will nonetheless be specifically intended to further U.S. Government policy and efforts; that those collaborations will not be used to increase prices or reduce output or quality; that exchanges of information will be made directly with the U.S. Government; that the collaboration will end promptly when the exigent circumstances it is intended to address have passed; and that any competitively sensitive information acquired by the Requesting Parties will be sequestered and not used going forward. While the Requesting Parties do not propose to engage in unlawful collaboration, these safeguards further lower the risk that their legitimate collaborations would lead to unlawful price fixing, bid rigging, market allocation, or otherwise anticompetitive acts.

If, however, the parties were engaging in prohibited conduct, such as unlawful price fixing or directly exchanging sensitive forward-looking competitive information, the Division would be concerned. Competitor collaborations may harm competition and consumers by increasing the ability or incentive profitably to raise price above or reduce output, quality, service, or innovation below what likely would prevail in the absence of any relevant agreement. We have not seen evidence that is the case here, nor do the unique facts and circumstances presented by the collaboration suggest such harm is likely.

c. Other Antitrust Doctrines May Apply and Support the Proposed Conduct

Other antitrust exemptions and immunities may apply to particular aspects of the Proposed Conduct beyond those discussed above. These exemptions and immunities include the Noerr-Pennington exemption and implied immunity.

Under the Noerr-Pennington doctrine, collaborators may jointly petition government entities to take particular actions, and even if such actions have anticompetitive efforts, courts have conferred “petitioning immunity” upon the collaborators’ efforts to induce the particular government actions. To the extent the Proposed Conduct describes efforts to influence FEMA’s, HHS’s, or another governmental agencies’ decisions regarding the U.S. Government’s policy of expediting health and medical resources in response to COVID-19, such conduct would likely be covered by Noerr-Pennington immunity. While some courts have recognized a commercial exception to Noerr-Pennington, “[a]ssuming that the government does in fact know about the ‘restraint’ at issue, Noerr immunity becomes increasingly appropriate as (a) the resulting government decision reflects a policy choice rather than capitulation to the economic pressure of the private firm; and (b) anticompetitive injury to others is caused by the government decision rather than by the private restraint seeking to compel that decision.”

44 See generally 2-13 Antitrust Law Developments 13C; Areeda and Hovenkamp, supra, § 201-212.
45 Areeda and Hovenkamp, supra, § 209.
Particular activities within the Proposed Conduct may also benefit from implied immunity under the antitrust laws. Courts may hold conduct immune from antitrust liability where application of the antitrust laws would “disrupt” or be “repugnant” to the regulatory scheme. The Proposed Conduct appears to meet at least several of the factors that the Supreme Court requires before finding conduct immune, such as FEMA’s and HHS’s regulatory authority and direction under that authority. If particular activities within the Proposed Conduct “would produce conflicting guidance, requirements, duties, privileges, or standards of conduct” and the possible conflict is within an area that the pandemic laws seek to regulate, then implied immunity may cover those activities.

IV. Conclusion

This letter is predicated on the accuracy of the information the Requesting Parties have provided. This letter expresses the Department’s current enforcement intention in the exercise of its prosecutorial discretion. It reflects the outcome of an expedited, temporary review procedure that is necessarily less thorough than ordinary business review procedures. This letter should not be interpreted as applying to any matter other than the Proposed Conduct as it relates strictly to, or arises directly out of, the COVID-19 pandemic.

This statement is made in accordance with the Department’s Business Review Procedure, 28 U.S.C. § 50.6, and subject to the limitations and reservations of rights therein. Pursuant to its terms, your business review request and this letter will be made publicly available immediately, and any supporting data you have submitted will be made publicly available within thirty days of the date of this letter, unless you request that part of the material be withheld in accordance with paragraph 10(c) of the Business Review Procedure.

Sincerely,

/s/

Makan Delrahim


47 See Credit Suisse, 551 U.S. at 275-76.