

#### U.S. DEPARTMENT OF JUSTICE

Antitrust Division

#### MAKAN DELRAHIM

Assistant Attorney General

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April 20, 2020

John G. Chou Executive Vice President Chief Legal Officer and Secretary AmerisourceBergen Corporation 227 Washington Street Conshohocken, PA 19428

Re: AmerisourceBergen Corporation Business Review Request Pursuant to

**COVID-19 Expedited Procedure** 

Dear Mr. Chou:

This letter responds to your request on behalf of AmerisourceBergen Corporation ("AmerisourceBergen") 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 AmerisourceBergen's 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. As indicated 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. AmerisourceBergen 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 identify global supply opportunities, ensure product quality, and facilitate product distribution to the most imperiled communities of medications and other healthcare supplies to treat COVID-19 patients ("Proposed Conduct").<sup>2</sup> The Department understands that the Proposed Conduct relates to

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<sup>&</sup>lt;sup>1</sup> Dep't of Justice & Fed. Trade Comm., Joint Antitrust Statement Regarding COVID-19 (Mar. 2020), https://www.justice.gov/atr/joint-antitrust-statement-regarding-covid-19 [hereinafter Joint Statement].

<sup>&</sup>lt;sup>2</sup> Letter from John G. Chou, AmerisourceBergen Corporation, to the Honorable Makan Delrahim, Assistant Attorney General for Antitrust, U.S. Dep't of Justice (April 14, 2020) [hereinafter Request Letter] at 2.

AmerisourceBergen's response to the unprecedented COVID-19 pandemic and its aftermath and is "focused on facilitating the government's efforts to guide medications and other healthcare supplies to the places where they are needed most." The Department likewise understands that AmerisourceBergen is 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.<sup>4</sup> The Department also understands that the Proposed Conduct significantly overlaps with the conduct described in the request letter from McKesson Corp., Cardinal Health Inc., Henry Schein, Inc., Medline Industries, Inc., and Owens & Minor, Inc. (collectively "PPE Distributors") and the Department's subsequent Business Review Letter to the PPE Distributors dated April 4, 2020.<sup>5</sup> 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 AmerisourceBergen's efforts to identify global supply opportunities, ensure product quality, and facilitate product distribution of medications and other healthcare supplies for the reasons explained below.

### I. Background

AmerisourceBergen is a U.S. distributor of medications and other healthcare products. Recognizing challenges presented by the COVID-19 pandemic to the global supply of certain medical products, U.S. Government agencies, including the Federal Emergency Management Agency ("FEMA"), the Defense Logistics Agency, and the Department of Health and Human Services ("HHS"), have asked AmerisourceBergen and other distributors to use their industry expertise and contacts to address supply chain shortages and direct medical supplies to the areas in greatest need.

This request arises from exigent circumstances created by the rapid spread of the dangerous and highly infectious COVID-19 virus.<sup>6</sup> On March 13, 2020, President Donald J. Trump declared a national emergency under the National Emergencies Act<sup>7</sup> and issued a nationwide emergency determination under the Robert T. Stafford Disaster Relief and

<sup>&</sup>lt;sup>3</sup> *Id*.

<sup>&</sup>lt;sup>4</sup> 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.

<sup>&</sup>lt;sup>5</sup> Letter from the Honorable Makan Delrahim, Assistant Attorney General for Antitrust, U.S. Dep't of Justice to Lori A. Schechter, McKesson Corp., Jessica L. Mayer, Cardinal Health, Inc., Michael S. Ettinger, Henry Schein, Inc., Alex Liberman, Medline Indus., Inc., & Nicholas J. Pace, Owens & Minor, Inc. (Apr. 4, 2020), *available* https://www.justice.gov/atr/page/file/1266511/download [hereinafter, "PPE Distributor BRL"].

<sup>&</sup>lt;sup>6</sup> See also further discussion of the exigent circumstances regarding the response to the COVID-19 virus in the PPE Distributors BRL.

<sup>&</sup>lt;sup>7</sup> Proclamation No. 9994, 85 Fed. Reg. 15,337 (Mar. 13, 2020).

Emergencies Assistance Act.<sup>8</sup> The President also encouraged all governors and tribal leaders to consider submitting requests for declaration of a "major disaster" under the Stafford Act. As of April 16, major disasters have been declared in all 50 states.<sup>9</sup> By that date, more than 670,000 Americans had been infected with the virus and more than 33,000 had died.<sup>10</sup> In light of this national emergency, the Federal Trade Commission and the Antitrust Division of the Department of Justice have recognized that coordinated efforts among government agencies and private businesses, "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."<sup>11</sup>

Addressing potential disruptions to the global medical 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 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." Consistent with that aim, the President invoked the Defense Production Act and delegated authority under the Act to the Secretary of HHS "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." 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 ... are not hoarded" and delegating additional authority to HHS.14

An important component of the effort to ensure an adequate supply of medical resources is the Strategic National Stockpile (the "Stockpile"). Authorized by the Public Health Service Act,<sup>15</sup> the role of the Stockpile is to supplement state and local supplies

<sup>&</sup>lt;sup>8</sup> Letter from President Trump to Chad Wolf, Acting Sec'y, Dep't of Homeland Sec., Steven Mnuchin, Sec'y, Dep't of Treasury, Alex Azar II, Sec'y, Dep't of Health and Human Servs., and Pete Gaynor, Admin'r, Fed. Emergency Mgmt. Agency (Mar. 13, 2020), https://www.whitehouse.gov/wp-content/uploads/2020/03/LetterFromThePresident.pdf.

<sup>&</sup>lt;sup>9</sup> Fed. Emergency Mgmt. Agency, Disasters, https://www.fema.gov/disasters (last visited Apr. 16, 2020).
<sup>10</sup> Johns Hopkins University, Coronavirus COVID-19 Global Cases by the Center for Systems Science and Engineering, https://coronavirus.jhu.edu/map html (last visited Apr. 16, 2020).

<sup>&</sup>lt;sup>12</sup> Exec. Order No.13,909, 85 Fed. Reg. 16,227 (Mar. 18, 2020).

<sup>13</sup> Id.

<sup>&</sup>lt;sup>14</sup> Exec. Order No. 13,910, 85 Fed. Reg. 17,001 (Mar. 23, 2020).

<sup>&</sup>lt;sup>15</sup> 42 U.S.C. § 247d-6b.

during public health emergencies and distribute stockpiled products, such as pharmaceuticals, medical devices, and test kits, where they are needed most. <sup>16</sup> In carrying out that mission, the Stockpile coordinates information sharing with state and local governments to formulate an efficient response and works with public and private sector partners to support optimal distribution of medical countermeasures. <sup>17</sup> AmerisourceBergen intends to work with FEMA, HHS, and other federal agencies to distribute medications and other health care products from the Stockpile to COVID-19 hotspots.

FEMA has broad authority to implement these policies. <sup>18</sup> Under the Stafford Act, in any "emergency" or "major disaster," the President may "coordinate all disaster relief assistance (including voluntary assistance) provided by federal agencies, private organizations, and State and local governments." <sup>19</sup> By executive order, this power has been delegated to the Administrator of FEMA. <sup>20</sup> Accordingly, the Stafford Act authorizes the Administrator to enter into voluntary agreements with private companies to ensure the distribution of medical resources 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" <sup>21</sup> 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."

## II. AmerisourceBergen's Efforts to Identify Global Supply Opportunities, Ensure Product Quality, and Facilitate Product Distribution of Medications and Other Healthcare Supplies

All facts set forth in this section regarding AmerisourceBergen's efforts to identify global supply opportunities, ensure product quality, and facilitate product distribution of medications and other healthcare supplies to treat COVID-19 patients are based on your

<sup>16</sup> https://www.phe.gov/about/sns/Pages/default.aspx

<sup>&</sup>lt;sup>17</sup> https://www.phe.gov/about/sns/Pages/about.aspx; see also 42 U.S.C. § 247d-6b(a)(3)(E) (providing that the Secretary of HHS "shall . . . devise plans for effective and timely supply-chain management of the stockpile, in consultation with the Director of the Centers for Disease Control and Prevention, the Assistant Secretary for Preparedness and Response, the Secretary of Transportation, the Secretary of Homeland Security, the Secretary of Veterans Affairs, and the heads of other appropriate Federal agencies; State, local, Tribal, and territorial agencies; and the public and private health care infrastructure, as applicable"); § 247d-6b(a)(3)(F) (providing that the Secretary of HHS "shall . . . deploy the stockpile as required by the Secretary of Homeland Security to respond to an actual or potential emergency").

<sup>&</sup>lt;sup>18</sup> See 42 U.S.C. §§ 5170, 5192-93.

<sup>&</sup>lt;sup>19</sup> 42 U.S.C. §§ 5170a, 5192.

<sup>&</sup>lt;sup>20</sup> Exec. Order No. 12,148, 44 Fed. Reg. 43,239 (July 4, 1979), Exec. Order No. 12,673, 54 Fed. Reg. 12,571 (Mar. 23, 1989).

<sup>&</sup>lt;sup>21</sup> 6 U.S.C. § 321h

<sup>&</sup>lt;sup>22</sup> 6 U.S.C. § 321i.

representations to the Department and publicly available sources. Moreover, just as with the PPE Distributors, Antitrust Division attorneys participate regularly in meetings related to these efforts, and the facts set forth here are consistent with their observations.

AmerisourceBergen's proposed collaboration with and at the direction of FEMA. HHS, and other government entities to identify global supply opportunities, ensure product quality, and facilitate product distribution of medications and other healthcare supplies to treat COVID-19 patients will take place under much of the same framework as that which applied to the PPE Distributors. AmerisourceBergen's Proposed Conduct includes collaborations involving the PPE Distributors under this framework.<sup>23</sup> Because of this, there is substantial overlap between AmerisourceBergen's Proposed Conduct and conduct addressed in the Department's Business Review Letter to the PPE Distributors.<sup>24</sup> In particular, AmerisourceBergen proposes 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, and potential shortages of, medications and other healthcare supplies;
- d) Help expedite distribution of medications and other healthcare supplies, including medications from the Strategic National Stockpile, to FEMA-designated COVID-19 hotspots;
- e) Provide FEMA and HHS with data necessary to do the above;
- f) Provide FEMA and HHS with claims data and data otherwise requested by FEMA;
- g) Engage in related activities to source and distribute medications and other healthcare supplies as directed by FEMA, HHS, or additional government agencies.<sup>25</sup>

Just as the same framework dictates specific proposed collaborations, so too does it require AmerisourceBergen to commit to the same safeguards as the PPE Distributors.<sup>26</sup> AmerisourceBergen has committed to follow the following safeguards at all times,

<sup>&</sup>lt;sup>23</sup> See PPE Distributors BRL.

<sup>&</sup>lt;sup>25</sup> Request Letter, *supra* note 2, at 3–4. 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, and competitively sensitive information will not be shared between competitors. Further, in contrast to the conduct proposed by the PPE Distributors, AmerisourceBergen will not help FEMA and HHS with any price-specific terms. Compare PPE Distributors BRL at 3. <sup>26</sup> Compare PPE Distributors BRL at 6.

including during those limited times when AmerisourceBergen will need to engage in the Proposed Conduct when U.S. Government representatives are not participating:<sup>27</sup>

- a) Any collaboration between AmerisourceBergen and other distributors is specifically intended to further U.S. government policy and efforts;
- b) AmerisourceBergen is 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 AmerisourceBergen, AmerisourceBergen will
  - make all reasonable efforts to share this information only with the requesting government agency, and not with any other distributor or competitor;
- d) AmerisourceBergen's collaborations are limited to the time period necessary to assist FEMA, HHS, 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, AmerisourceBergen and other distributors will formally dissolve their competitor collaboration and immediately notify the Department, in writing;
- f) AmerisourceBergen will commit to work with the Department to determine appropriate sequestration of competitively sensitive material that was produced during the collaboration period.<sup>28</sup>

AmerisourceBergen implements its commitments to the specific collaborative activities and safeguards listed above within initiatives organized and directed by FEMA, HHS, other government entities, and their agents.

One initiative is the distribution of hydroxychloroquine from the Stockpile to health care providers in areas of greatest need.<sup>29</sup> In this distribution initiative, AmerisourceBergen and other distributors act as the U.S. Government's distribution agents. The U.S. Government will instruct AmerisourceBergen on the amount of hydroxychloroquine it will receive and where the hydroxychloroquine is to be sent. The U.S. Government does not inform AmerisourceBergen of its instructions to other distributors. The hydroxychloroquine is donated, meaning the U.S. Government does not charge AmerisourceBergen or other distributors for it. Further, AmerisourceBergen does not

<sup>&</sup>lt;sup>27</sup> AmerisourceBergen's communications that do not have direct participation of U.S. Government representatives are carried out with the intention and sole purpose of maximizing the effectiveness of the response to the national health emergency created by the COVID-19 pandemic. For example, alignment on data fields (but not the content of those fields), as well as the interpretation of things such as the FDA's Emergency Use Authorization ("EUA"), ensures consistency, and consistency increases effectiveness.

<sup>28</sup> Request Letter, *supra* note 2, at 4.

<sup>&</sup>lt;sup>29</sup> The Department understands that other, additional medicines could eventually be added to this distribution initiative.

charge the U.S. Government for its distribution services, nor does AmerisourceBergen charge the health care providers for the medicines that they receive. Recognizing the extreme urgency of getting medicines to areas of greatest need, AmerisourceBergen, along with other distributors, are serving as the U.S. Government's distributors while concurrently seeking to memorialize their role in a written agreement.

AmerisourceBergen is also complying with FEMA's data gathering and data analytics initiatives. The purpose of the data gathering initiative is to enable FEMA to identify the medications critical to combating the unprecedented COVID-19 pandemic and prevent or limit any shortages of such medications. FEMA issued RFIs to AmerisourceBergen, as well as other distributors and manufacturers, to solicit this information. AmerisourceBergen responded directly to FEMA for both RFIs. AmerisourceBergen expects that its detailed responses will only be shared with FEMA and its agents and that any discussion of RFI responses would be high-level and take place in for ain which FEMA is both present and participating. FEMA's data analytics initiative relies on the foundation provided by its data gathering initiative. Its aim is to build a supply chain control tower tool that will provide FEMA with a full picture of the pharmaceutical supply chain, from manufacturing to deployment. Given the complexities and opacity of pharmaceutical supply chains, distributors such as AmerisourceBergen provide the insight and expertise essential for the successful functioning of such a tool. Under the current exigent circumstances, AmerisourceBergen is complying with FEMA's requests while negotiating a data sharing agreement to protect the confidentiality of its data in parallel. In that spirit, it is expected that the detailed output of the supply chain control tower tool will only be accessed and used by FEMA, and that only high-level insights, such as the identification of areas of need, will be shared with AmerisourceBergen and other distributors.

In conclusion, AmerisourceBergen represents that its efforts to expedite and increase distribution of medications and healthcare supplies are designed to combat and alleviate the national health emergency caused by the COVID-19 pandemic. Under the direction, guidance, supervision, and instruction of FEMA, HHS, other government entities, and their agents, AmerisourceBergen is working with both federal and private partners to ensure that needed medications and healthcare supplies move quickly and efficiently to areas of greatest need during the COVID-19 crisis. As with the PPE Distributors, in all other respects, AmerisourceBergen will continue to pursue its independent business strategies as before. Consistent with this independent business strategy, AmerisourceBergen's collaboration is limited only to Coronavirus-related efforts 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

Courts have extended this immunity to conduct by private parties when their conduct is (i) "compelled by an agreement with a federal agency or a clearly defined federal government policy" and (ii) "supervise[d]" by a federal agency. The Department has also indicated that it will not challenge conduct aimed at addressing COVID-19 and its aftermath if it satisfies this standard. For example, the Department recently concluded that conduct by the PPE Distributors — "pursuant to an agreement with [FEMA], supervised by the agency, and in furtherance of the agency's defined policy goals" — satisfied this standard and therefore did not raise any antitrust concerns. 32

AmerisourceBergen intends to distribute certain medications from the Stockpile "[a]t the direction of FEMA, HHS, and other government agencies . . . to FEMA-designated COVID-19 hotspots."<sup>33</sup> This conduct fits within the two-part framework described above. First, while AmerisourceBergen does not have a formal contract with FEMA or HHS yet,<sup>34</sup> it will be acting at their direction in the context of a clearly defined federal program, *i.e.*, distributing products from the Strategic National Stockpile during a national emergency.<sup>35</sup> Second, FEMA, HHS, and its agents "will be actively directing and supervising Amerisource's conduct."<sup>36</sup> For example, based on AmerisourceBergen's representations, FEMA would decide where and how many products AmerisourceBergen can distribute — AmerisourceBergen is simply an instrumentality transporting products owned by the U.S. Government to locations designated by the U.S. Government on terms dictated by the U.S. Government. The Department is satisfied that this and similar conduct should not raise any concerns under the antitrust laws.

AmerisourceBergen also intends to work with other firms in providing FEMA and HHS with data, as "requested by FEMA," to help the agencies "identify and qualify new sources of supply," "address bottlenecks with . . . existing foreign suppliers," and "identify

<sup>&</sup>lt;sup>30</sup> Sea-Land Serv., Inc. v. Alaska R. R., 659 F.2d 243 (D.C. Cir. 1981); see also PPE Distributors BRL at 7 n.30 (noting, however, that "the Department stands ready to work with federal agencies to ensure their efforts promote competition").

<sup>&</sup>lt;sup>31</sup> PPE Distributors BRL at 7.

<sup>&</sup>lt;sup>32</sup> *Id.* at 8.

<sup>&</sup>lt;sup>33</sup> *Id* at 3.

<sup>&</sup>lt;sup>34</sup> AmerisourceBergen has indicated that it is seeking to enter such an agreement.

<sup>&</sup>lt;sup>35</sup> See, e.g., 42 U.S.C. § 247d–6b(a)(3)(E), (F), (G) (directing HHS to "devise plans for effective and timely supply-chain management of the stockpile, in consultation with . . . the public and private health care infrastructure"); 42 U.S.C. § 300hh-10(b)(5), (c)(3) (empowering HHS to "work[] with other relevant Federal, State, local, Tribal, and territorial public health officials and private sector entities . . . including by establishing methods to exchange critical information and deliver products consumed or used to preserve, protect, or sustain life, health, or safety, and sharing of specialized expertise"); cf. Fuchs v. Rural Elec. Convenience Co-op. Inc., 858 F.2d 1210, 1215 (7th Cir. 1988) ("The [government] may, and often must, also turn to private actors to effect its policies. While the [government] itself is immune from any actions or agreements which would violate the antitrust laws, its purposes would be thwarted if the instrumentalities chosen to implement its policies could be held liable.").

<sup>&</sup>lt;sup>36</sup> Request Letter at 5; see also PPE Distributors BRL at 8.

and monitor areas of increased demand for, and potential shortages of, medications and other healthcare supplies."<sup>37</sup> To the extent this conduct does not fit within the framework discussed above, it "may still offer unique benefits and therefore be consistent with the antitrust laws."<sup>38</sup> Among other things, helping the U.S. Government secure and distribute medical supplies can "provide Americans with products or services that might not be available otherwise more immediately, efficiently, and effectively than if firms worked on their own or even bilaterally with [an] agency."<sup>39</sup> Moreover, any risk of anticompetitive harm is low given the involvement of FEMA and HHS and in light of various safeguards to which AmerisourceBergen has committed. 40 The Department is therefore 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."41 The Department also recently explained that sharing information "requested by [a federal agency] through bilateral communications [with that agency]" does not raise antitrust concerns.42 Thus, where helping FEMA and HHS source supplies, address bottlenecks, or monitor shortages involves AmerisourceBergen bilaterally sharing data with FEMA or HHS this conduct is unlikely to raise concerns under the antitrust laws.

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

Although AmerisourceBergen has represented that the Proposed Conduct will be "[a]t the direction of FEMA, HHS, and other government agencies," it acknowledges that discussions outside of FEMA's presence may be necessary given "the fast-moving nature of the COVID-19 crisis." The scope of this business review letter will therefore encompass activities necessary to carry out directions from FEMA, HHS, or another U.S. Government agency, even if they occur outside the presence of those agencies, so long as the discussions abide by the safeguards discussed below.

According to AmerisourceBergen, these discussions will not include competitively sensitive information.<sup>44</sup> AmerisourceBergen has also "commit[ted] to follow several safeguards," including limiting what information is exchanged and how long it will be

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<sup>&</sup>lt;sup>37</sup> Request Letter at 3–4.

<sup>&</sup>lt;sup>38</sup> PPE Distributors BRL at 7–8.

<sup>&</sup>lt;sup>39</sup> *Id.* at 7 (internal quotation marks omitted); Request Letter at 5 ("AmerisourceBergen's collaboration . . . is necessary to allow us to offer medications and other healthcare supplies more quickly than otherwise would be possible and to address scarcity.").

<sup>&</sup>lt;sup>40</sup> See Section III(c).

<sup>&</sup>lt;sup>41</sup> PPE Distributors BRL at 9.

<sup>&</sup>lt;sup>42</sup> *Id.* at 8 (internal quotation marks omitted).

<sup>&</sup>lt;sup>43</sup> Request Letter at 4.

<sup>&</sup>lt;sup>44</sup> *Id*.

exchanged or kept, to minimize the risk that its conduct might harm competition. <sup>45</sup> Thus, under the Antitrust Guidelines for Collaborations Among Competitors issued jointly by the Federal Trade Commission and the Department, AmerisourceBergen's Proposed Conduct does not involve appear to involve a per se violation of the antitrust laws such as price fixing or market allocation. <sup>46</sup> Instead, the Proposed Conduct would likely be evaluated based on the rule of reason. <sup>47</sup> In applying that framework, "[t]he 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."

The Department recently applied this same framework in evaluating the proposed collaborations by the PPE Distributors responding to the COVID-19 pandemic under the direction of FEMA. In doing so, the Department noted that their conduct made it possible for the distributors "to bring life-saving goods faster to market than would be possible absent the collaboration." The Department also concluded that the conduct there offered "unusually strong" procompetitive benefits, including strengthening supply chains in ways that could "save lives and limit the tremendous damage" caused by the COVID-19 pandemic. In balancing these benefits against the risk of harm to competition, the Department concluded that the risk of harm was low because the distributors committed to several safeguards against using the collaboration "to increase prices, reduce output, reduce quality, or otherwise engage in COVID-19 profiteering." <sup>50</sup>

AmerisourceBergen represents that its Proposed Conduct offers similar procompetitive benefits. For example, distributing medications or other medical supplies from the Stockpile will help increase short-term supply at a time when these products are needed most. Similarly, AmerisourceBergen's data sharing will help FEMA and other government agencies identify and combat potential pharmaceutical shortages. The Proposed Conduct will therefore "allow [AmerisourceBergen] to offer medications and other healthcare supplies more quickly than otherwise would be possible." In the context of a nationwide pandemic, these benefits are "unusually strong." <sup>52</sup>

<sup>&</sup>lt;sup>45</sup> *Id*.

<sup>&</sup>lt;sup>46</sup> To the extent it does, "any determinations of prices, wages, output, quality, bids, or allocations will only occur if at FEMA's direction." PPE Distributors BRL at 8; *see also* Section III(c).

<sup>&</sup>lt;sup>47</sup> PPE Distributors BRL at 8–9 (applying rule of reason treatment to similar conduct).

<sup>&</sup>lt;sup>48</sup> Fed. Trade Comm'n and U.S. Dep't Of Justice, Antitrust Guidelines for Collaborations Among Competitors at § 3.3 (2000), https://www.justice.gov/atr/page/file/1098461/download ("Competitor Guidelines").

<sup>&</sup>lt;sup>49</sup> PPE Distributors BRL at 9.

<sup>&</sup>lt;sup>50</sup> Id.

<sup>&</sup>lt;sup>51</sup> Request Letter at 5; *see also* Competitor Guidelines at § 2.1 (recognizing that "competitor collaborations may enable participants to offer goods or services that are cheaper, more valuable to consumers, or brought to market faster than would be possible absent the collaboration").

<sup>&</sup>lt;sup>52</sup> PPE Distributors BRL at 9.

AmerisourceBergen has also committed to safeguards that minimize any potential harms to competition that might flow from its collaboration. For example, any competitor-collaboration AmerisourceBergen pursues within the context of the Proposed Conduct will be "specifically intended to further U.S. government policy and efforts." AmerisourceBergen will also not use this collaboration "to increase prices, reduce output, reduce quality, or otherwise engage in COVID-19 profiteering." And it will limit the information it shares with or seeks from competitors and then "sequestrat[e] . . . competitively sensitive material that was produced during the collaboration period" once the collaboration is over. As the Department said previously, "[t]hese safeguards further lower the risk that their legitimate collaborations would lead to unlawful price fixing, bid rigging, market allocation, or otherwise anticompetitive acts." The same is true here.

Based on these representations and given the current circumstances, the procompetitive benefits of the Proposed Conduct appear to far outweigh any potential harm. Even so, the Department would be concerned if AmerisourceBergen used this collaboration to engage in prohibited conduct "such as unlawful price fixing or directly exchanging sensitive forward-looking competitive information." The Department has not seen any evidence, however, that this is likely to occur. Indeed, given the unique facts and circumstances here, such harm seems unlikely.

# 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, similar to those the Department previously found may apply to the PPE Distributors conduct. 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. <sup>58</sup> To the extent the Proposed Conduct describes AmerisourceBergen's 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

<sup>&</sup>lt;sup>53</sup> Request Letter at 4.

<sup>&</sup>lt;sup>54</sup> *Id*.

<sup>&</sup>lt;sup>55</sup> *Id*.

<sup>&</sup>lt;sup>56</sup> PPE Distributors BRL at 10.

<sup>&</sup>lt;sup>57</sup> Id.

<sup>&</sup>lt;sup>58</sup> See generally 2-13 Antitrust Law Developments 13C and Areeda and Hovenkamp, supra, § 201-212.

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."<sup>59</sup>

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. AmerisourceBergen's 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 AmerisourceBergen has 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

<sup>&</sup>lt;sup>59</sup> Areeda and Hovenkamp, *supra*, § 209.

<sup>&</sup>lt;sup>60</sup> See Credit Suisse Sec. (USA) LLC v. Billing, 551 U.S. 264 (2007); Gordon v. New York Stock Exch., 422 U.S. 659 (1975); see generally 2-13 Antitrust Law Developments 13D; Areeda & Hovenkamp, supra, § 243

<sup>&</sup>lt;sup>61</sup> See Credit Suisse, 551 U.S. at 275–76.