U.S. DEPARTMENT OF JUSTICE
Antitrust Division

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January 12, 2021

Ms. Sara Y. Razi, Esq.
Simpson Thacher & Bartlett LLP
900 G Street, NW
Washington, D.C. 20001

Re: Request for COVID-19-Related Business Review Letter

Dear Ms. Razi:

This letter responds to your request on behalf of Baxalta US Inc., Emergent BioSolutions Inc., Grifols Therapeutics LLC, and CSL Plasma Inc., and each of those companies' respective subsidiaries and affiliates (altogether, the "Requesting Parties" and each independently, a "Party") 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 your 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 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 subsequently may 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 assist the Biomedical Advanced Research and Development Authority ("BARDA") in the development of a Quality Assurance Addendum that provides technical parameters for blood banks. These parameters would allow COVID-19 convalescent plasma collected by blood banks for direct transfusion under Operation Warp Speed to be repurposed for use in the manufacture of each Requesting Party's hyperimmune globulin ("HIg") therapies targeting COVID-19 (the

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1 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.

"Proposed Conduct").[2] Based on the information and representations you provided, and after an expedited review, the Department, for the reasons explained below, presently does not intend to challenge the Requesting Parties' efforts to develop a Quality Assurance Addendum that provides technical parameters to ease and accelerate the development and manufacture of HIg therapies.

I. The Requesting Parties' Efforts to Develop HIg Therapies Using COVID-19 Convalescent Plasma

a. Background

This request arises in the context of the national health crisis caused by the novel coronavirus known as SARS-CoV-2, which threatens the health, safety, and security of millions of Americans. In response to the ongoing COVID-19 pandemic, the National Institutes of Health ("NIH") is sponsoring clinical trials to develop HIg therapies for COVID-19.[3] The Requesting Parties are participating in NIH's clinical trials to develop their respective HIg therapies by using plasma collected from individuals who have contracted and recovered from COVID-19, also known as "COVID-19 convalescent plasma."[4]

In addition to participating in these NIH trials, the Requesting Parties generally are "competitors in the commercial areas of plasma collection and development of plasma-derived therapies."[5] Given that convalescent plasma cannot be developed artificially,[6] the Requesting Parties have two main sources of plasma: source plasma and recovered plasma. Source plasma is plasma collected through plasmapheresis, a process that takes only plasma from a human donor and returns the other cellular components to the donor.[7] Recovered plasma is produced by separating blood into its cellular components, typically collected from blood donation centers. It then undergoes testing to confirm that the plasma meets U.S. Food and Drug Administration's ("FDA") rules and regulations,[8] and each party determines whether it is suitable for their respective needs. The Requesting Parties then,

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2 Letter from Sara Y. Razi, Esq., to the Hon. Makan Delrahim, Ass't Att'y Gen., Antitrust Division, U.S. Dep't of Justice (Jan. 5, 2021) [hereinafter "Request Letter"].

3 *Id.* at 1 n.2.

4 *Id.* The specific clinical trial in which the Requesting Parties are contributing is the Phase III clinical trial called the Inpatient Treatment with Anti-Coronavirus Immunoglobulin, also known as INSIGHT 013. *See* Press Release, National Institutes of Health, "NIH Clinical Trial Testing Hyperimmune Intravenous Immunoglobulin Plus Remdesivir to Treat COVID-19 Begins," (Oct. 8, 2020), *https://www.nih.gov/news-events/news-releases/nih-clinical-trial-testing-hyperimmune-intravenous-immunoglobulin-plus-remdesivir-treat-covid-19-begins.*

5 Request Letter at 2.

6 *Id.*

7 *See* 21 C.F.R. § 640.60.

8 The FDA promulgates rules, regulations, and licenses regarding the development, manufacture, and usage of HIg therapies, including COVID-19 convalescent plasma, and licensure of blood banks. *See generally* 21 C.F.R. § 640.

in competition with one another, develop and manufacture plasma-based therapies using proteins that remain in the plasma through fractionation.

As part of Operation Warp Speed, the federal government is working to accelerate and to support the development, manufacture, and distribution of treatments that target COVID-19.[9] Specifically, the federal government is supporting the collection of COVID-19 convalescent plasma through BARDA's supply contracts with America's Blood Centers, the American Red Cross, and potentially other COVID-19 convalescent plasma collection blood banks (collectively, the "Blood Banks").[10] The primary intent under these contracts currently is to use the COVID-19 convalescent plasma for direct transfusion. The federal government also is supporting the development of HIg products and "has engaged the Requesting Parties to ensure that the collected COVID-19 convalescent plasma, and specifically excess stores of convalescent plasma collected by the Blood Banks under contract with BARDA but not needed or appropriate for direct transfusion, can be repurposed for use in the Parties' HIg therapies for COVID-19."[11]

To facilitate a seamless redirection and repurposing of COVID-19 convalescent plasma, BARDA seeks to develop a "single set of Quality Assurance parameters to be implemented by the Blood Banks, as an addendum to BARDA's existing convalescent plasma supply agreements with the Blood Banks" (the "Quality Assurance Addendum").[12] The purpose of the Quality Assurance Addendum is to ensure that "COVID-19 convalescent plasma collected by the Blood Banks under contract with BARDA would meet the requirements of each participating Party as a manufacturer of HIg therapies targeting COVID-19, as well as all requirements for the manufacture of HIg therapies targeting COVID-19 as set by FDA."[13] BARDA therefore plans to develop the Quality Assurance Addendum in coordination with the Requesting Parties.[14]

b. The Requesting Parties' Proposed Conduct

The Requesting Parties seek to assist BARDA in the development of the Quality Assurance Addendum according to the following procedures. BARDA first would develop a draft Quality Assurance Addendum and share it with the Requesting Parties. After reviewing the draft, "[e]ach Requesting Party would comment on the template individually and provide its comments only to BARDA and not to any other Requesting Party."[15] BARDA then would convene at least one meeting collectively with the Requesting Parties

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9 Dep't of Health and Human Serv's, *Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'*, (May 15, 2020), https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html.

10 Request Letter at 1–2. BARDA is part of the U.S. Department of Health and Human Services.

11 *Id.* at 2-3.

12 *Id.* at 3.

13 *Id.*

14 *Id.*

15 *Id.*

"to discuss and finalize the parameters of the proposed Quality Assurance Addendum."[16] Once the draft Quality Assurance Addendum is finalized, BARDA then would confirm with the Blood Banks and the FDA that the Addendum is agreeable, and BARDA may invite the Requesting Parties to join these future conversations as well.[17] Direct communications between the Requesting Parties will occur only in the presence of an official from BARDA. BARDA will seek to limit the frequency of direct joint discussions as much as possible. Any live discussions involving the Requesting Parties will be held only on an "as-needed basis" with counsel present.[18]

The Proposed Conduct also is clear about practices the Requesting Parties do *not* seek the Division's prior review of at this time:

- "there will be no disclosure or discussion by the Requesting Parties of information regarding pricing, volumes of source plasma collected, volumes of their respective HIg products expected to be produced, or any other data that would traditionally be considered competitively sensitive,"

- "none of the Requesting Parties would discuss or disclose commercial information related to their individual ordinary course supply contracts with blood centers," and

- the Requesting Parties do not anticipate that they will engage in discussions with BARDA regarding the allocation or distribution among them of COVID-19 convalescent plasma.[19]

To the extent the Requesting Parties later engage in this or other conduct excluded from the Request Letter, this letter takes no position on that conduct.

The Requesting Parties also have entered into a Confidential Disclosure Agreement, which "outlin[es] the narrow scope of technical information that the Requesting Parties would provide to BARDA and potentially also discuss jointly in discussions that would include BARDA, the Requesting Parties, the Blood Banks, and/or FDA."[20] The categories of information to be discussed and shared would be "technical in nature and focused on the quality requirements for the Blood Banks' collection processes

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16 *Id.*

17 *Id.*

18 *Id.*

19 *Id.* at 3 n.4, 5.

20 *Id.* at 4. The Requesting Parties submitted the Confidential Disclosure Agreement to the Department and incorporated it by reference into the Business Review Letter Request. The Requesting Parties submitted a timely request pursuant to 28 CFR § 50.6(c) for the Confidential Disclosure Agreement to remain confidential. After reviewing the Requesting Parties' request, the Department found good cause for non-disclosure.

under BARDA's existing supply contracts."[21] The parameters include sampling, testing, labeling, titering, anticoagulants, and storage specifications.[22]

The Confidential Disclosure Agreement also contains several provisions limiting the use and dissemination of information acquired by the Requesting Parties. The Requesting Parties agreed that any information to be shared shall be used by each Party solely for the development of the Quality Assurance parameters and submission for required regulatory approvals.[23] Disclosure of information is limited to a "need-to-know" basis within each company.[24] Upon termination of the Confidential Disclosure Agreement, the Parties shall cease to use any shared information from another party.[25] Finally, no Party will acquire the intellectual property or know-how of another Party under the Confidential Disclosure Agreement.[26]

II. Legal Framework & Analysis

a. The Competitor Collaboration Regarding the Proposed Conduct Should Be Analyzed Under the Rule of Reason

Under the joint FTC/DOJ Competitor Collaboration Guidelines (the "Guidelines"),[27] the Proposed Conduct would be evaluated under the rule of reason. *Per se* treatment is appropriate only for "[a]greements of a type that always or almost always tends to raise price or to reduce output."[28] These types of agreements include "agreements among competitors to fix prices or output, rig bids, or share or divide markets by allocating customers, suppliers, territories, or lines of commerce."[29] The Proposed Conduct does not involve such an agreement but rather is focused on information sharing to assist the federal government in expanding output of HIg therapies. Thus, the *per se* rule does not apply, and the Proposed Conduct is subject to the rule of reason.

In analyzing conduct using the rule of reason, "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."[30] As the Requesting Parties

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21 *Id.*

22 *Id.*

23 Confidential Attachment 1 to Request Letter at 2 [hereinafter "Confidential Disclosure Agreement"].

24 *Id.* at 3.

25 *Id.* at 3-4.

26 *Id.*

27 Fed. Trade Comm'n & U.S. Dep't of Justice, Antitrust Guidelines for Collaborations Among Competitors (2000), https://www.justice.gov/atr/page/file/1098461/download [hereinafter "Competitor Collaborations Guidelines"].

28 *Id.* § 3.2.

29 *Id.*

30 *Id.* § 3.3.

note in their Request Letter, the Guidelines recognize that "a competitor collaboration may enable participants to offer goods or services that are . . . brought to market faster than would be possible absent the collaboration."[31] Additionally, "[t]he Agencies recognize that the sharing of information among competitors may be procompetitive and is often reasonably necessary to achieve the procompetitive benefits of certain collaborations."[32]

b. The Proposed Conduct Appears to Lack Significant Risk of Anticompetitive Effects

The Proposed Conduct includes several features that minimize the potential for anticompetitive harm arising from the collaboration. Most importantly, the information that may be shared by the Requesting Parties is technical in nature and does not involve "price, output, costs, or strategic planning" which are more likely to raise competitive concerns.[33] Although sharing even only technical information may sometimes lead to anticompetitive effects, such as by facilitating collusion on the upper bounds of quality or the production limitations faced by competitors, such circumstances do not appear to be present here. Indeed, the vast majority of the quality assurance parameters to be discussed are driven by FDA regulations and not specific to each Requesting Party. The Parties will retain commercial control over each of their HIg therapies and will continue to compete independently in offering any approved therapies to the public.[34] Moreover, this collaboration is led by a government agency, BARDA. BARDA will be responsible for reconciling and consolidating the initial sets of comments, submitted unilaterally by the Requesting Parties, on the draft Quality Assurance Addendum.[35] This approach has the benefit of anonymizing specific changes proposed by a given Requesting Party and does not require the Requesting Parties to disclose their specific requirements. Instead, each Requesting Party only needs to review the draft Addendum and comment to BARDA to the extent it fails to meet their requirements. In addition, to the extent joint discussions of the quality assurance parameters are required, an official from BARDA will be present for any direct communications between the Requesting Parties, and any live discussions only will take place as-needed and with counsel present.[36] This should serve to limit the number of direct communications between the Requesting Parties and ensure that the scope of those communications remain within the confines of the technical requirements. Finally, BARDA, not the Requesting Parties, will "serve as the central authority and decision-maker in presenting the final Quality Assurance Addendum to the Blood Banks and FDA for their respective approvals," ensuring the collaboration ultimately serves to further BARDA's purposes.[37] Accordingly, the conduct poses little risk of anticompetitive harm.

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31 *Id.* § 2.1.
32 *Id.* § 3.31(b).
33 *Id.*
34 *See* Request Letter at 2.
35 *See id.* at 3.
36 *Id.*
37 *Id.* at 5.

Further, the Confidential Disclosure Agreement signed by the Requesting Parties provides additional safeguards that minimize the potential for anticompetitive harm arising from their collaboration. For example, the Confidential Disclosure Agreement limits the scope and duration of the collaboration to the finalization of the Quality Assurance Addendum.[38] In terms of scope, only technical specifications will be discussed, and only for the purpose of ensuring the Blood Banks collect COVID-19 convalescent plasma that the Requesting Parties can use to develop and produce HIg therapies.[39] In terms of duration, because the Quality Assurance Addendum will be added to BARDA's existing contracts with the Blood Banks, the results of the Requesting Parties' collaboration will terminate when those contracts terminate.[40] The Confidential Disclosure Agreement also provides for usage and disclosure limitations by the parties for information that they receive.[41] The Requesting Parties participation in future discussions with BARDA and the Blood Banks and/or FDA, already subject to the discretion of BARDA, is limited further by the Confidential Disclosure Agreement, which outlines the information the Requesting Parties may discuss jointly at such meetings as being limited to a "narrow scope of technical information."[42]

c. *The Proposed Conduct Also Appears to Have Several Procompetitive Justifications*

As the Department has stated previously, collaboration among competitors in aid of a federal agency may offer unique benefits and therefore be consistent with the antitrust laws, even if that collaboration may not satisfy the standards for federal instrumentality immunity.[43] 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 effectively than if firms worked

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38 *See* Confidential Disclosure Agreement.

39 *See id.*

40 Request Letter at 5.

41 *See* Confidential Disclosure Agreement.

42 Request Letter at 4.

43 Letter from the Hon. Makan Delrahim, Ass't Att'y Gen., Antitrust Division, 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). *See also*, Letter from J. Mark Gidley, Acting Ass't Att'y Gen., Antitrust Division, 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"). *See also 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); 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.").

on their own or even bilaterally with the agency.[44] The Department reiterates that its assessment of efforts to address COVID-19 and its immediate aftermath accounts for these unique procompetitive benefits as appropriate.

Based on the Requesting Parties' representations, the Department understands that the Proposed Conduct is just such a collaboration because it appears likely to be output and efficiency-enhancing. Specifically, the Proposed Conduct will ensure that the COVID-19 convalescent plasma collected by the Blood Banks under their contracts with BARDA will be more efficiently and quickly re-purposed for use in manufacturing HIg therapies.[45] Further, the Proposed Conduct may facilitate the ongoing NIH clinical trials for HIg therapies, which may show that COVID-19 convalescent plasma is more efficaciously deployed in HIg therapies rather than through direct transfusion. In that case, the Proposed Conduct would provide BARDA with important information to help direct the COVID-19 convalescent plasma collected by the Blood Banks wherever it can be used most efficaciously. By coordinating with all of the Requesting Parties in the development of the Quality Assurance Addendum, BARDA ensures that any COVID-19 convalescent plasma that it wants to re-purpose can be used by each of the Requesting Parties, thereby increasing BARDA's flexibility when it decides to re-purpose COVID-19 convalescent plasma.

Ultimately, the Proposed Conduct will help BARDA develop the Quality Assurance Addendum which will "ensure that COVID-19 convalescent plasma collected by the Blood Banks under contract with BARDA would meet the requirements of each participating Party as a manufacturer of HIg therapies targeting COVID-19."[46] To the extent those therapies are safe and effective, the Proposed Conduct could therefore improve the health and safety of Americans. Based on the representations of the Requesting Parties, including the safeguards discussed above, and given the current circumstances, the Department is satisfied that this conduct offers unique procompetitive benefits under the exigent circumstances presented by COVID-19 that outweigh any potential for anticompetitive harm.

d. Some of the Proposed Conduct May Implicate **Noerr-Pennington**

In certain circumstances, "courts have conferred 'petitioning immunity'" on collaborators' efforts to jointly petition the government to take a particular action under the *Noerr-Pennington* doctrine.[47] "The scope of this protection depends . . . on the source, context, and nature of the anticompetitive restraint at issue."[48] To the extent the Requesting Parties seek to influence BARDA's policy decisions, some aspects of the Proposed

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44 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; *see also* Gidley Letter.

45 Request Letter at 3.

46 *Id.*

47 Letter from the Hon. Makan Delrahim, Ass't Att'y Gen., Antitrust Division, U.S. Dep't of Justice to John G. Chou, AmerisourceBergen at 11–12 (Apr. 20, 2020), https://www.justice.gov/atr/page/file/1269911/download.

48 *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988).

Conduct may implicate *Noerr-Pennington*.[49] It is unnecessary to resolve this question, however, because the Proposed Conduct clearly is procompetitive for the reasons described above.

III. 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 necessarily is 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 C.F.R. § 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,

Makan Delrahim

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49 *But see In re Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 789 (7th Cir. 1999) ("[T]he doctrine does not authorize anticompetitive *action* in advance of government's adopting the industry's anticompetitive proposal." (emphasis in original)); *Sandy River Nursing Care v. Aetna Cas.*, 985 F.2d 1138, 1142 (1st Cir. 1993) ("[P]rivate actors who . . . violate the Sherman Act . . . may be held responsible for direct marketplace injury caused . . . even if [the defendants'] ultimate goal is to obtain favorable state action.").