U.S. DEPARTMENT OF JUSTICE
Antitrust Division

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July 23, 2020

By Electronic Mail

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RE: Eli Lilly and Company, AbCellera Biologics, Amgen, AstraZeneca, Genentech, and GSK Expedited Business Review Request Pursuant to COVID-19 Expedited Procedure

Dear Mr. Barnett:

This letter responds to your request, on behalf of Eli Lilly and Company, AbCellera Biologics, Amgen, AstraZeneca, Genentech, and GSK ("the Requesting Parties"), for the issuance of a business review letter under the Department of Justice's 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 dated March 2020 ("Joint Statement").[1] You have requested a statement of the Department's current antitrust enforcement intentions with respect to the Requesting Parties' efforts to exchange limited information about the manufacture of monoclonal antibodies that may be developed to treat COVID-19 ("Proposed Conduct").[2] Based on the representations

[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 [hereinafter Joint Statement].

[2] Letter from Thomas O. Barnett, Covington, James Ford, GSK, Jonathan Graham, Amgen, Anat Hakim, Eli Lilly, Sean Johnston, Genentech, Jeff Pott, AstraZeneca, and Tryn Stimart, AbCellera Biologics, to Makan Delrahim, Ass't Att'y Gen., Antitrust Div., U.S. Dep't of Justice (July 15, 2020) [hereinafter Request Letter] at 1. The Department understands that some aspects of the proposed conduct already have been underway to begin to facilitate scale up for the manufacture of monoclonal antibodies that may treat COVID-19 patients. Although the Department typically does not review ongoing conduct, given the President's declaration of a national emergency and the current exigencies, we have determined that, in these circumstances, it is appropriate to consider the request.

you provided and after an expedited review, the Department presently does not intend to challenge the Proposed Conduct, as it is described in this letter.

Pursuant to 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 Parties may subsequently ask the Department to reiterate its current enforcement intentions using this expedited, temporary procedure if more time is necessary or additional collaboration is needed to make these critical treatments available to patients during this unprecedented COVID-19 pandemic.

I. Background

This request arises in the context of a pandemic caused by a novel coronavirus that threatens the health, safety, and security of millions of Americans. President Donald J. Trump recognized as much by declaring a national emergency on March 13, 2020.[3] Major disasters were declared in all 50 states, the District of Columbia, and several territories. Moreover, as the Division previously recognized, "[m]easures to mitigate the spread of COVID-19 . . . have taken a dramatic toll on the United States economy."[4] Although states have gradually begun reopening with different health and safety measures, the pandemic continues to pose significant risks for Americans across the country.

Diagnostics, treatments, and vaccines are critical for mitigating the effects of this pandemic. Through an initiative called Operation Warp Speed, the federal government is working to accelerate and support the development, manufacture, and distribution of these therapeutic tools.[5] Treatments and vaccines incorporating monoclonal antibodies (or "mAbs")—copies of naturally occurring proteins that can directly target viruses and other pathogens—are a particularly promising option being pursued by Operation Warp Speed and the pharmaceutical industry generally.[6]

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[3] Proclamation No. 9994, 85 Fed. Reg. 15,337 (Mar. 13, 2020); *see also* 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.

[4] Letter from the Honorable Makan Delrahim, Assistant Attorney General for Antitrust, U.S. Dep't of Justice to Martin M. Toto, National Pork Producers Council (May 15, 2020) at 2 (quoting Exec. Order No. 13,1917, 85 Fed. Reg. 26, 313 (April 28, 2020)) (internal quotations omitted).

[5] 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.

[6] Hearings on Operation Warp Speed: Researching, Manufacturing, & Distributing a Safe & Effective Coronavirus Vaccine Before the Subcomm. on Labor, Health and Human Serv's., Educ., and Related Agencies, 116th Cong. at 6 (July 2, 2020) (statement of Hon. Francis S. Collins, Dir. of the Nat'l Insts. of Health); Dr. Anthony Fauci, Dir. of the Nat'l Inst. of Allergy and Infectious Diseases, Remarks at Stanford Medical School (July 14, 2020), http://med.stanford.edu/news/all-news/2020/07/anthony-fauci-in-conversation-with-lloyd-minor.html; *see also* Dep't of Health and Human Serv's, *HHS, DOD Collaborate with Regeneron on Large-Scale Manufacturing*

Producing mAbs involves several steps.[7] First, a cell line that produces the desired antibody has to be identified and cultivated. This cell line is then grown into larger and larger containers and, ultimately, into steel bioreactors (ranging from 5,000L to 20,000L in size). In these bioreactors, the cells consume nutrients, multiply, and produce antibodies. Eventually, this mixture is harvested from the bioreactor and purified to remove other cells, impurities, or contaminants. The remaining antibodies are then formulated into an injectable drug.[8] Once injected, the antibodies can help a patient's immune system identify and destroy a specific virus, *e.g.*, the novel coronavirus.

There are a limited number of facilities in the world that can carry out this process at industrial scale.[9] Moreover, calibrating existing facilities to produce a particular monoclonal antibody can take several months.[10] Companies therefore "typically wait until a drug or vaccine is in the advanced stages of testing, and looks like it will succeed," before beginning this effort.[11] The Requesting Parties have indicated that undertaking the development and calibration in parallel may accelerate and ultimately expand the production of mAb therapeutics once they prove effective against COVID-19.

II. The Requesting Parties' Proposed Information Exchange

The Requesting Parties are pharmaceutical companies engaged in the research, development, and manufacture of biologic products, including mAbs, which target a wide array of diseases, including asthma, cardiovascular, neurological, oncological, and rheumatic

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Demonstration Project of COVID-19 Investigational Therapeutic Treatment, (July 7, 2020), https://www.hhs.gov/about/news/2020/07/07/hhs-dod-collaborate-regeneron-large-scale-manufacturing-demonstration-project-covid-19-investigational-therapeutic-treatment.html.

[7] The process described here is provided only as a summary of how the process typically takes place. In many cases, the process varies by manufacturer, cell line, and other factors. *See also* Isha Sharma, et al, *COVID-19 Manufacturing for Monoclonal Antibodies*, Duke Univ. Margolis Center for Health Policy (June 2020), https://healthpolicy.duke.edu/sites/default/files/2020-06/Issue%20Brief%20-%20COVID-19%20Manufacturing%20of%20Monoclonal%20Antibodies_0.pdf [hereinafter Duke Study] (providing an overview of the manufacturing process).

[8] The amount of antibodies included in a particular dose varies depending on a variety of factors. Early evidence suggests, however, that monoclonal antibody treatments for COVID-19 may require a significant amount of antibodies to be effective. This would further strain production capacity.

[9] *See, e.g.*, Duke Study at 3; Carolyn Y. Johnson, *Operation Warp Speed is pushing for covid-19 therapeutics by early fall*, Washington Post (July 13, 2020), https://www.washingtonpost.com/health/2020/07/13/operation-warp-speed-is-pushing-covid-19-therapeutics-by-early-fall/ [hereinafter Johnson, OWS (July 13, 2020)].

[10] Request Letter at 2.

[11] *Id.*

conditions. Some of the Requesting Parties compete with each other to provide biologics for the same condition, such as asthma, cervical cancer, and leukemia.[12]

The Requesting Parties are currently independently developing monoclonal antibody agents that may be used to treat COVID-19 and planning for mass production of safe and effective mAb therapeutics.[13] The extraordinary circumstances of the COVID-19 pandemic have necessitated that the Requesting Parties ramp-up their production capacity much earlier in the research and development process.[14] The Requesting Parties point out that one recent article noted, "[i]n a pandemic, [manufacturers] can't wait to start making [their] investment in the manufacturing until [they're] sure [they] have a product. . . . To be ready to make large volumes of the products, companies must begin preparing their plants now. They need to secure supply chains for key ingredients[,] install new equipment, and find contract manufacturers who can help."[15]

Additionally, the demand for whichever mAb treatments ultimately prove effective will likely dwarf the capacity available to any one manufacturer. One recent report estimated that in 2019 "approximately 53 million standard units (*i.e.*, doses) of mAbs were sold . . . in the United States, many of which treat severe illnesses that address otherwise unmet medical needs."[16] The report then estimates that the "lower bound for . . . the true demand" for a COVID-19 mAb treatment is over 25 million doses, in other words, nearly half of all mAb treatments administered annually in the nation.[17] Even if a pharmaceutical company chose to devote all of its capacity to COVID-19 mAB treatments, this lower bound estimate of demand is still more than any one manufacturer could produce.

Given the need for expedited production of any approved COVID-19 mAb treatments and capacity constraints facing the industry, the Requesting Parties propose to exchange information regarding "manufacturing facilities, raw materials, and supplies that could be used to produce COVID-19 mAb treatments, specifically global capacity that has been reserved internally or through third parties for the potential production of COVID-19 mAb treatments."[18]

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[12] All facts set forth in this letter regarding the Requesting Parties, background, and the Proposed Conduct are based on the Requesting Parties' representations to the Department, our limited investigation, and publicly available sources.

[13] Eli Lilly and AbCellera are collaborating on the development of an effective monoclonal antibody to treat COVID-19 that is beyond the scope of this review. *See AbCellera and Lilly to Co-develop Antibody Therapies for the Treatment of COVID-19* (Mar. 12, 2020), https://investor.lilly.com/news-releases/news-release-details/abcellera-and-lilly-co-develop-antibody-therapies-treatment.

[14] Request Letter at 2-3.

[15] Request Letter at 2 (quoting Peter Loftus & Joseph Walker, *Drugmakers Scale Up for Virus Treatments*, Wall St. J. (Apr. 24, 2020)) (internal quotations omitted).

[16] Duke Study at 1.

[17] *Id.* at 2.

[18] Request Letter at 3.

The Requesting Parties intend, by exchanging such information, to "identify ways to expand production of any approved treatments beyond the level that each could achieve on its own."[19] Exchanging this information before regulatory approval of the COVID-19 mAbs would allow the Requesting Parties to "reduce the lead time" necessary to prepare their facilities for production of these treatments.[20] In short, exchanging this information is intended to bring more COVID-19 mAb treatments to the market and in a shorter timeframe.

Specifically, the Requesting Parties foresee that they may need to exchange the following relevant categories of information to accomplish this objective:

- Technical details regarding a company's relevant manufacturing facilities, including total potential capacity [that it would consider making available for COVID-19 mAbs[21]], technical specifications (such as the type of bioreactors), time period(s) during which the facilities would be available, and whether the facility is owned by the company or by a third party.

- Technical information regarding a company's manufacturing processes/platforms and/or the manufacturing processes/platforms of their contract manufacturers or their other manufacturing partners.

- Information regarding the source and amount of available raw materials and supplies that are necessary for the manufacture of COVID-19 mAb treatments. For purposes of clarity, the Parties would not exchange any information regarding prices or commercial terms of any arrangements for raw materials and supplies.[22]

In sum, the Requesting Parties propose to share information to expedite and increase the production of COVID-19 mAb treatments. The information to be exchanged is largely technical and will not encompass competitively sensitive information about production costs or treatment prices. The Requesting Parties have also committed to several safeguards, described below, including limiting the scope and duration of the Proposed Conduct to meet the demand for COVID-19 mAbs required to respond to the unprecedented COVID-19 pandemic and its aftermath.[23]

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[19] *Id.*

[20] *Id.* at 4.

[21] As explained below, based on the Requesting Parties' representations and Request Letter, we understand that they are proposing to share only the "total potential capacity" that each company would consider making available for the production of COVID-19 mAbs.

[22] Request Letter at 4.

[23] *Id.* at 4–5.

III. Legal Analysis

A. Benefits and Harms of Competitive Collaborations and Information Exchanges

The Department has long recognized that "[a] competitor collaboration may enable firms to offer goods or services that are cheaper, more valuable to consumers, or brought to market faster than would otherwise be possible."[24] Collaborations involving information sharing can be procompetitive and necessary to generating efficiencies.[25] For example, the DOJ-FTC Collaboration Guidelines explain that participants in a collaboration may combine "know-how . . . to enable the collaboration to produce a good more efficiently or to produce a good no one participant could alone produce."[26] At the same time, information exchanges among competitors may allow competitors to collude or to tacitly coordinate on price or output in a manner that harms competition.[27] "Collusion may involve the relevant market in which the collaboration operates," here in the manufacturing of COVID-19 mAbs, "or another market in which the participants in the collaboration are actual or potential competitors," *i.e.*, in the development and sale of mAbs for other conditions.[28] The Department concludes that the Proposed Conduct is unlikely to result in collusion or harm competition in either market, and that it is likely to generate significant efficiencies.[29]

B. The Proposed Information Exchange

The Requesting Parties represent that knowledge about manufacturing facilities, production capacity, and raw materials will help them scale up manufacturing capability so they

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[24] U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for Collaborations Among Competitors* § 3.36 (2000) [hereinafter DOJ-FTC Collaboration Guidelines], https://www.justice.gov/atr/page/file/1098461/download.

[25] *See United States v. U.S. Gypsum Co.*, 438 U.S. 422, 441 n.16 (1978) (recognizing information exchanges may create efficiencies); *Maple Flooring Mfrs' Ass'n v. United States*, 268 U.S. 563, 582–83 (1925) ("Competition does not become less free merely because the conduct of commercial operations becomes more intelligent through the free distribution of knowledge of all the essential factors entering into the commercial transaction."); DOJ-FTC Collaboration Guidelines § 3.31(b) ("[T]he sharing of information among competitors may be procompetitive and is often reasonably necessary to achieve the procompetitive benefits of certain collaborations.").

[26] DOJ-FTC Collaboration Guidelines § 3.31(a).

[27] *Id.* § 2.2; Phillip Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, Areeda § 2111c (updated 2020); *see also* Letter from Christine Varney, Ass't Att'y Gen., Antitrust Div., U.S. Dep't Justice, to Mit Spears, Ropes & Gray (2010), https://www.justice.gov/atr/response-pacific-business-group-healths-request-business-review-letter ("The central inquiry in analyzing a data sharing arrangement is whether it is likely to facilitate express or tacit collusion resulting in increased prices or reduced quantity or quality, or otherwise reduce competition among the recipients of the data.")

[28] DOJ-FTC Collaboration Guidelines § 2.2.

[29] In light of the considerable efficiencies involved, the Department reviews this information exchange under the rule of reason. *See id.* §§ 1.2, 3.3.

can "move quickly" when safe and effective COVID-19 mAbs are approved.[30] The Department finds that exchanging this information in this context is unlikely to harm competition because the likely result is that the information exchange will expand output of these critical treatments. Furthermore, we conclude that the information exchange is unlikely to result in collusion in the markets for COVID-19 mAb treatments, or for mAb treatments for other conditions, such as cancer or rheumatoid arthritis, in which the parties may compete. In addition, the Requesting Parties have agreed to certain safeguards that will mitigate concerns regarding the potential for anticompetitive effects. Finally, the Proposed Conduct is unlikely to lessen incentives to invest or develop critical COVID-19 mAbs.

Significant here is the nature and purpose of the proposed information exchange, which "is relevant to whether it may cause anticompetitive harm."[31] To be sure, the Proposed Conduct has a procompetitive objective. The purpose of the information exchange is to "expedite production of greater quantities of COVID-19 mAb treatments" once they are deemed safe and effective.[32] Moreover, the Department understands that the Requesting Parties would face significant obstacles absent the collaboration because there are a limited number of manufacturing facilities that produce mAbs at a scale large enough to respond to the pandemic, and establishing new ones that are appropriately calibrated takes considerable time.[33] Given the immediate need for effective therapeutics, and the likely demand,[34] the Proposed Conduct, which is seeking to use production capacity efficiently and enable the rapid, large-scale production of mAbs, could offer Americans considerable benefits and "provide [them] with products or services that might not be available otherwise."[35]

Furthermore, the proposed information exchange appears unlikely to harm competition either in the markets for COVID-19 mAb treatments or for mAb treatments for conditions other than COVID-19.

With respect to COVID-19 mAbs, most of the information that the Requesting Parties propose to exchange is highly technical concerning the details regarding a company's relevant manufacturing facilities, including the type of bioreactors it could use to produce COVID-19 mAbs (or that are used by the company's contract manufacturers for this purpose), the technical specifications for producing a particular COVID-19 antibody injectable, a company's processes and platforms, and the source and amount of available raw materials needed.[36] As discussed

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[30] *See* Request Letter at 3, 5.

[31] DOJ-FTC Collaboration Guidelines § 3.31.

[32] *See* Request Letter at 5.

[33] *See, e.g.*, Duke Study at 3; Johnson, OWS (July 13, 2020).

[34] Doses needed to treat COVID-19 effectively could be very high, and prophylactic use would only increase demand. *See* Request Letter at 3.

[35] *See* Joint Statement.

[36] *See* Request Letter at 5.

above, the manufacturing process for producing mAbs is complex. Each category of information appears to be reasonably tailored to facilitate the Requesting Parties' procompetitive efforts to prepare for the large-scale production of the most safe and effective COVID-19 mAbs. Moreover, the sharing of this information is unlikely to result in collusion. For example, in accordance with the safeguards the Requesting Parties propose to implement, they will not exchange competitively sensitive information about prices or commercial terms of any arrangements for raw materials or supplies.[37] They also are not proposing to exchange information about their research and development plans, sales or marketing strategies, treatment prices, or capacity or output for the other biologics that they sell.[38]

Although sharing information about production capacity can raise antitrust concerns because it could lead to collusion that would reduce output,[39] the Proposed Conduct is likely to have the opposite effect. The Requesting Parties here propose to share information about capacity so that they can enable firms with successful therapeutics to increase output and markets served, not for the anticompetitive purpose of decreasing output and raising prices.[40] Indeed, the Requesting Parties have been working with the U.S. Department of Health and Human Services on how best to address the anticipated demand for effective COVID-19 mAbs. That demand is expected to be significant and there is likely to be considerable pressure to produce these therapeutics at rapid pace. We understand that large doses may be needed to make a meaningful difference in health outcomes. Thus, sharing information about available capacity reserved by each Requesting Party for the production of COVID-19 mAbs will have the procompetitive purpose of identifying facilities that can produce needed treatments and reduce the lead time for preparing that facility, potentially enabling the Requesting Parties to meet the anticipated demand.[41] The Requesting Parties have also agreed to share information about capacity dedicated to COVID-19 only as long as necessary to address the pandemic.[42]

Moreover, based on the information provided, the sharing of production capacity is unlikely to harm competition in markets for mAb therapeutics that are used to treat diseases other than COVID-19. Antitrust concerns can arise if a collaboration requires dedication of

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[37] *See id.* *See also infra* Part III.C. discussing Proposed Safeguards.

[38] We understand that the Requesting Parties may need to determine for quality control purposes whether a facility is producing any products that could contaminate the mAbs. Discussing such information necessary to ensure quality would not raise antitrust concerns.

[39] *See* Areeda & Hovenkamp § 2111c.

[40] *See also* Letter from William J. Baer, Ass't Att'y Gen., Antitrust Div., U.S. Dep't Justice, to Steven A. Bowers, Fish & Richardson P.C. (Oct. 2, 2014), https://www.justice.gov/atr/response-cyberpoint-international-br-request-business-review-letter (considering the business purpose of the proposed agreement and nature of the information shared, which was technical and "unlikely to facilitate tacit or explicit price or other competitive coordination among competitors").

[41] *See* Request Letter at 3–4.

[42] *See infra* Part III.C. discussing Proposed Safeguards.

specialized resources that reduces participants' ability to compete elsewhere. "[I]f participants in a production collaboration must contribute most of their productive capacity to the collaboration, the collaboration may impair the ability of its participants to remain effective independent competitors regardless of the terms of the agreement."[43] This antitrust concern is mitigated here both because the Requesting Parties do not intend to commit their entire capacity to COVID-19 mAbs and because the Requesting Parties have committed to exchange information not on their total production capacity or output, but on the portion of their production capacity that each firm independently decides that it can make available to produce COVID-19 treatments, in light of capacity constraints from the production of each firm's non-COVID-19 medically critical mAbs.[44] The Department would be concerned, however, if the collaboration jointly agreed to shift capacity away from non-COVID-19 mAb treatments in order to reduce output or raise prices for these treatments, or if the shifting of capacity away from non-COVID-19 treatments resulted in a market allocation among the Requesting Parties that compete to provide similar treatments for the same disease. We have no reason to believe the Requesting Parties intend to engage in this anticompetitive conduct.[45]

Finally, the Requesting Parties have represented that they will exchange and use information for the strictly limited purpose of facilitating the production of COVID-19 treatments. Because the Requesting Parties have represented that they are not exchanging information about total production capacity or output for all of their mAb treatments, which is specific to the type of monoclonal antibody produced, collusion is less likely after the pandemic ends.

C. The Proposed Safeguards

As mentioned above, the Requesting Parties have also proposed a number of safeguards to further reduce antitrust concerns.[46] "In general, it is less likely that the collaboration will facilitate collusion on competitively sensitive variables if appropriate safeguards governing information sharing are in place."[47] Here, these safeguards include:

- **Limiting the Scope of the Information Exchange.** The scope of the Proposed Conduct is limited to only facilitating the rapid production of safe and effective COVID-19 mAbs. Moreover, the parties are only sharing total potential capacity that they have independently determined that they will dedicate or would be willing to make available for the production of COVID-

[43] DOJ-FTC Collaboration Guidelines, § 3.34(b) n. 44.

[44] Request Letter at 4. *See also infra* Part III.C discussing Proposed Safeguards.

[45] *See* DOJ-FTC Collaboration Guidelines § 3.31 ("The Agencies . . . consider evidence of the subjective intent of the participants to the extent that it sheds light on competitive effects.").

[46] *See* Request Letter at 4.

[47] DOJ-FTC Collaboration Guidelines § 3.34(e).

19 mAbs, taking into account the capacity need for the production of other critical treatments.[48]

- **Limiting the Duration of the Collaboration**. The exchange of information is limited in duration to "extend only as long as necessary to address the COVID-19 crisis,"[49] which lessens the chance of collusion and makes it more likely the Requesting Parties will "compete against each other and their collaboration."[50]

- **Independent Decision Making.** The Requesting Parties represent that the information exchange will not limit independent decision making of the individual participants. For example, the Requesting Parties will not make joint decisions on whether to deal with certain customers or the terms for selling finished COVID-19 mAbs. The exchange also will not involve collaboration on whether any participant will develop or invest in additional capacity.[51]

- **No exchange of competitively sensitive information concerning input prices or commercial terms**. The Requesting Parties represent that they will not share competitively sensitive information "relating to costs of inputs, costs of production, or prices of the treatments" which could lead to collusion.[52]

In addition, we understand that the Requesting Parties will not use the information exchanged other than to facilitate the production of COVID-19 mAbs, and they represent that any collaboration or information exchange beyond the Proposed Conduct would be outside the scope of the business review letter.[53] The Department finds these safeguards sufficiently address the antitrust concerns raised by the information exchange.

D. Innovation Concerns

Finally, the Department finds the Proposed Conduct is unlikely to lessen incentives to continue to innovate or invest in COVID-19 mAbs. Innovation related to this treatment is

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[48] *See* Request Letter at 3–4.

[49] *See id.* at 5.

[50] DOJ-FTC Collaboration Guidelines § 3.34(f).

[51] Request Letter at 5.

[52] *Cf.* DOJ-FTC Collaboration Guidelines § 3.31(a) ("[P]roduction collaborations may involve agreements on the level of output or the use of key assets, or on the price at which the product will be marketed by the collaboration, or on other competitively significant variables, such as quality, service, or promotional strategies, that can result in anticompetitive harm.")

[53] *See* Request Letter at 5.

critical to improving Americans' health and safety during the COVID-19 pandemic.[54] The Department finds this collaboration may help to encourage innovation and investment in R&D because market participants may have found an efficient solution for developing their treatments and planning for the scale up of production in parallel. Indeed, the collaboration may be necessary to expand capacity in order to manufacture sufficient doses of COVID-19 mAbs.[55] This is the type of collaboration that the antitrust laws should encourage.[56] Moreover, the Proposed Conduct does not include a collaboration on R&D, and thus, all Requesting Parties have the incentive to compete and continue to develop their own safe and effective treatment for COVID-19 at the lowest cost.

IV. Conclusion

This letter is predicated on the accuracy of the information the Requesting Parties have provided and expresses the Department's current enforcement intention in the exercise of its prosecutorial discretion in the context of the antitrust laws. The letter also reflects the outcome of an expedited, temporary review procedure that is necessarily less thorough than ordinary business review procedures and 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 letter 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

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[54] *See* Johnson, OWS (July 13, 2020).

[55] *See* Joint Statement ("These sorts of joint 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.")

[56] *See also* Areeda & Hovenkamp § 2111b1 ("[A]ntitrust develops rational rules for sorting out those kinds of information exchanges that are socially valuable on balance from those posing significant anticompetitive threats").