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October 9, 2020

Dr. Stephen Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Alex Azar
Secretary
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Mark T. Esper
Secretary
Department of Defense
1400 Defense Pentagon
Washington, DC 20301

Moncef Slaoui
Chief Advisor
Operation Warp Speed
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Dear Commissioner Hahn, Secretary Azar, Secretary Esper, and Mr. Slaoui,

I write concerning the critical need for transparency, independent review, and affordable pricing for Regeneron's COVID-19 antibody treatment—a treatment that has received over \$500 million dollars in American taxpayer investments. This week, President Trump announced that an emergency use authorization (EUA) is “all set” and likened the treatment to a cure, though no evidence has been provide that this represents a cure and little concerning its therapeutic benefit. Reportedly, he has spoken directly with Commissioner Hahn to urge immediate authorization for this treatment. It is imperative that political pressure not lead to premature authorization.

The President has previously advocated for authorization of treatments, one of which, hydroxychloroquine, has since been revoked due to its dangerous, even deadly, impact on some patients. EUAs and regulatory approvals must be based on scientific evidence and subject to

independent review. All clinical trial data should be made public prior to authorization and the safety and efficacy of the product must be of the utmost and sole concern.

To ensure an open and evidence-based decision-making process, and transparency on the manufacturing, distribution, patient prioritization, and pricing plans for Regeneron's antibody treatment, I respectfully request the following information and answers:

Emergency Use Authorization Process

- 1) Will you commit to publicly releasing all clinical trial data, safety and efficacy data, and any accompanying analysis at least one week prior to issuing an emergency use authorization or full regulatory approval for Regeneron's COVID-19 antibody treatment?
- 2) Please provide the safety and efficacy standards the FDA will require Regeneron to meet prior to issuing an EUA or full regulatory approval for its antibody treatment.
- 3) Please provide any commitments or plans the FDA will require of Regeneron prior to issuing an EUA or full regulatory approval, including commitments to completing clinical trials, plans for monitoring patients who receive the treatment, or any other condition the FDA may place on the authorization or approval.

Manufacturing, Distribution, and Prioritization

- 1) Please provide the unredacted manufacturing agreements the federal government, or its subcontractors, has entered into with Regeneron for its COVID-19 antibody treatment.
- 2) Please provide the unredacted distribution agreements the federal government, or its subcontractors, has entered into with any private company to distribute the Regeneron COVID-19 antibody treatment.
- 3) Please provide a detailed description of storage and transport requirements for the Regeneron antibody treatment, including necessary supplies, storage temperatures, and expiration dates for doses. Please also provide a list of supplies already secured and any additional supplies needed to support anticipated doses.
- 4) Please provide a detailed analysis on the current status of manufacturing capacity and any additional facilities that may be built, renovated, or retrofitted to manufacture the antibody treatment, as well as any companies that have received a license to manufacture the treatment.
- 5) Please provide the formula that will be used to allocate doses. This information should specify whether doses will be sent to states or directly to health care providers, and the formula to determine how many doses each entity shall receive. Please include the data and reasoning used to make these determinations.
- 6) Please provide any guidance states and/or health providers will receive regarding the prioritization of patients to receive the Regeneron antibody treatment, as well as the data and reasoning used to make this determination.

Research and Development Investments and Pricing and Procurement

- 1) Please the unredacted research and development funding agreements the federal government, or its subcontractors, has entered into with Regeneron for its COVID-19 antibody treatment.
- 2) Will you commit to establishing a formula for determining a reasonable price for the Regeneron antibody treatment? If yes, please include a detailed summary of the formula,

how the Secretary will enforce this reasonable price, and to what extent it accounts for taxpayer investments made in the research, development, and manufacturing and production of the drug. If no, please provide an explanation for not negotiating a reasonable price and an explanation for how the Secretary will protect taxpayer investments and equitable access with fair and reasonable pricing.

- 3) Will you commit to providing the Regeneron antibody treatment to all patients for free, including the cost of the dose, its administration, and any associated office visits? Will you ensure that uninsured and underinsured individuals receive the same access and free-of-charge treatment? Please provide a detailed explanation of how you will ensure insured, uninsured, and underinsured individuals receive free and equal access to this treatment.
- 4) Will you commit to providing the Regeneron antibody treatment free of charge to states and health care providers? If no, please provide an explanation for charging these entities as well as the estimated price per dose. Please also provide a detailed explanation of how you will ensure all patients, regardless of insurance status, still receive free access to the treatment even when their provider or state has been charged for it.

Taxpayers have spent over half a billion dollars financing the research, development, and manufacturing of Regeneron's antibody treatment. They have assumed all of the risk in this endeavor, and in return, taxpayers should receive a safe, effective, and affordable product.

Sincerely,

A handwritten signature in black ink, appearing to read "Lloyd Doggett". The signature is fluid and cursive, with a long horizontal stroke at the end.

Lloyd Doggett