Congress of the United States
Washington, DC 20515

June 2, 2020

The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

During the ongoing coronavirus crisis, Americans are counting on the Department of Health and Human Services to responsibly partner with the private sector to develop effective and affordable vaccines and therapeutics. To that end, we write to request information on coronavirus research contracts that the Department has entered into with the private sector so that the American people can learn how these taxpayer dollars are being spent.

The Select Subcommittee on the Coronavirus Crisis is charged with ensuring that the government's response to the coronavirus pandemic is effective, efficient, equitable, and transparent, and the Committee on Oversight and Reform has been conducting a wide-ranging investigation into the pricing practices of pharmaceutical companies. Together, we are seeking to determine whether these contracts include provisions to ensure affordability and prevent profiteering, and we seek documents and information about the Department's funding of coronavirus research.

Transparency About Research Contracts with the Private Sector

The Coronavirus Aid, Relief, and Economic Security (CARES) Act provided $3.5 billion to the Department's Biomedical Advanced Research and Development Authority (BARDA) for the "manufacturing, production and purchase, at the discretion of the Secretary, of vaccines, therapeutics, diagnostics, and active pharmaceutical ingredients." The CARES Act also provided $706 million to the National Institute of Allergy and Infectious Disease, including $156 million in research funding.[1] BARDA has entered into over a dozen agreements with private companies to research and manufacture coronavirus vaccines and therapeutics, including:

- a $1.2 billion contract with AstraZeneca,
- $628 million in additional funding to Emergent BioSolutions,
- $608 million in contracts with Johnson & Johnson,
- a $430 million contract with Moderna Therapeutics,
- $98 million in contracts with Regeneron Pharmaceuticals,
- a $30 million contract with Sanofi, and
- a $25 million contract with Genentech.[2]

[1] Coronavirus Aid, Relief and Economic Security Act, P.L. 116-136.

[2] Biomedical Advanced Research and Development Authority, Department of Health and Human Services,

The Department has shared limited information about its coronavirus research expenditures with Congress and the American people. Federal procurement websites, such as USASpending.gov, list the amounts and brief descriptions of the contracts. BARDA's website lists a subset of its contracts with the private sector but does not disclose the terms of those contracts, such as requirements to make drugs affordable for U.S. patients or the allocation of any intellectual property rights between the government and private companies.[3]

Affordability of Approved Vaccines and Therapies

In order to protect the health of our entire society, all Americans must be able to access approved vaccines and therapies easily, quickly, and affordably. It endangers all of us if companies are allowed to charge exorbitant prices that cause families to hesitate or even decline to obtain vaccines or treatments.

Presumably for these same reasons, President Trump recently said that he is "looking at" making the coronavirus vaccine free.[4] We are hopeful that this will result in action and look forward to the Department sharing its plans for distributing or otherwise ensuring free access to the vaccine for all Americans.

When Congress passed the CARES Act, we empowered you to "take such measures authorized under current law to ensure vaccines, therapeutics, and diagnostics developed from funds provided in this Act will be affordable in the commercial market."[5]

The American taxpayers are investing a massive amount of money into these efforts to identify, develop, and disseminate vaccines and treatments. They expect to earn a fair return on their investments, and the federal government has an obligation to use all tools at its disposal to ensure access for consumers. Federal health care programs that may shoulder the costs of developed vaccines or therapeutics must also be protected from price gouging.

A few companies, such as Johnson & Johnson, have publicly committed to bringing an affordable vaccine to market on a not-for-profit basis.[6] It is important for other companies that are also relying on taxpayer funds to make a similar commitment.

BARDA's COVID-19 Medical Countermeasures Portfolio (online at www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx); Department of Health and Human Services, *HHS Adds $628 Million to Contract with Emergent BioSolutions to Secure CDMO Manufacturing Capacity for Operation Warp Speed* (June 1, 2020) (online at www.hhs.gov/about/news/2020/06/01/hhs-adds-628-million-contract-emergent-biosolutions-secure-manufacturing-capacity-operation-warp-speed.html).

[3] *Id.*

[4] *Trump "Looking At" Making Coronavirus Vaccine Free*, The Independent (May 15, 2020) (online at www.independent.co.uk/news/world/americas/us-politics/trump-coronavirus-vaccine-free-covid-19-latest-updates-a9517856.html).

[5] Coronavirus Aid, Relief and Economic Security Act, P.L. 116-136.

[6] Johnson & Johnson, *Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use* (Mar. 30, 2020) (online at www.jnj.com/johnson-johnson-announces-a-lead-vaccine-candidate-for-covid-19-landmark-new-partnership-with-u-s-department-of-health-human-

On April 2, 2020, the Oversight Committee wrote to the Pharmaceutical Research Manufacturers of America (PhRMA) to make clear that "no drug company should be allowed to profiteer, especially during this public health emergency." The letter asked PhRMA's member companies to "commit to setting affordable list prices for any medications, including vaccines, that may be used to prevent or treat coronavirus."[7]

In response, PhRMA declined to provide any assurance that its members would set affordable prices for approved coronavirus vaccines or therapeutics, citing antitrust concerns.[8]

The Committee also offered PhRMA's member companies the opportunity to respond individually. But the Committee received a response from only one company, Sanofi, which committed to price any vaccine or treatments "in a fair and reasonable manner" and to "provide a launch price rationale."[9] No other company provided a separate response.

Requests for Information and Documents

For these reasons, we request that you produce the following documents and information by June 16, 2020. We also request a staff briefing on these topics by June 19, 2020.

1. All contracts and other agreements between the Department and any private entities for research into or manufacturing of vaccines, diagnostics, and therapeutics for coronavirus, including, but not limited to:

    a. The companies included in BARDA's COVID-19 Medical Countermeasure Portfolio; and

    b. Companies selected through the ASPR Next program; and

2. All evaluations, rankings, Independent Government Cost Estimates, or other analyses of proposals for the contracts identified in response to Request 1, including but not limited to analyses by:

    a. BARDA's Technical Evaluation Panel; and

    b. The Medical Countermeasures Task Force; and

services-and-commitment-to-supply-one-billion-vaccines-worldwide-for-emergency-pandemic-use).

[7] Letter from Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, to Stephen J. Ubl, President and Chief Executive Officer, Pharmaceutical Research and Manufacturers of America (Apr. 2, 2020) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2020-04-02.CBM%20to%20PhRMA%20re%20Coronavirus%20Crisis.pdf).

[8] Letter from Stephen J. Ubl, President and Chief Executive Officer, Pharmaceutical Research and Manufacturers of America, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Apr. 9, 2020) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/PhRMA.040920.Response%20to%20CBM%20re%20COVID%20Treatments%20and%20Vaccines.pdf).

[9] Letter from Adam Gluck, Senior Vice President, Sanofi U.S., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Apr. 17, 2020).

3. A detailed description of how the Department will ensure that any approved coronavirus vaccine or therapeutic is affordably priced in public and private markets.

The Select Subcommittee on the Coronavirus Crisis, which was modeled after the Truman Committee during World War II, was established by the House of Representatives on April 23, 2020, pursuant to House Resolution 935, "to conduct a full and complete investigation" of the "efficiency, effectiveness, equity, and transparency of the use of taxpayer funds and relief programs to address the coronavirus crisis," the nation's "preparedness for and response to the coronavirus crisis," and "any other issues related to the coronavirus crisis."

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X.

An attachment to this letter provides additional instructions for responding to these requests. If you have any questions about this request, please contact our staff at (202) 225-5051.

Sincerely,

James E. Clyburn
Chairman
Select Subcommittee on the
Coronavirus Crisis

Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform

Enclosure

cc: The Honorable Steve Scalise, Ranking Member
Select Subcommittee on the Coronavirus Crisis

The Honorable Jim Jordan, Ranking Member
Committee on Oversight and Reform

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term “including” shall be construed broadly to mean “including, but not limited to.”

5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.

7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term “individual” means all natural persons and all persons or entities acting on their behalf.