

Congress of the United States

Washington, DC 20515

July 12, 2021

Mr. Michel Vounatsos
Chief Executive Officer
Biogen Inc.
225 Binney Street
Cambridge, MA 02142

Dear Mr. Vounatsos:

The Committee on Oversight and Reform and the Committee on Energy and Commerce are investigating the approval process for Biogen's new Alzheimer's drug, Aduhelm (aducanumab), as well as Biogen's pricing and business strategies for the drug. Millions of Americans suffering from Alzheimer's disease are in need of innovative treatments. While we share in the hope for new advancements to treat this debilitating disease, it is critical that these treatments be safe, effective, and affordable. We are concerned by reports of an atypical approval process for Aduhelm amid significant questions about the drug's clinical benefit, and the steep \$56,000 annual price tag, which will have serious implications for seniors, federal health care programs, and future Alzheimer's research.

On June 7, 2021, Biogen was granted accelerated approval by the Food and Drug Administration (FDA) for Aduhelm.¹ FDA's use of its accelerated approval pathway for Aduhelm was surprising to many, including members of FDA's Peripheral and Central Nervous Systems (PCNS) Drugs Advisory Committee (the "Advisory Committee").² None of the 11 empaneled members of the Advisory Committee recommended approval, and the question of whether to grant accelerated approval was never raised for discussion at the Advisory Committee meeting.³ Additionally, the accelerated approval was granted despite internal concerns raised by experts in FDA's Office of Biostatistics about the "inconsistency" of the drug's supporting clinical data.⁴

¹ Food and Drug Administration, *Press Release: FDA Grants Accelerated Approval for Alzheimer's Drug*, (June 7, 2021) (online at www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug).

² *The FDA's Approval of Aduhelm: Potential Implications Across a Wide Range of Health Policy Issues and Stakeholders*, Health Affairs Blog (June 10, 2021) (online at www.healthaffairs.org/doi/10.1377/hblog20210609.921363/full/); *Three F.D.A. Advisers Resign Over Agency's Approval of Alzheimer's Drug*, New York Times (June 10, 2021) (online at www.nytimes.com/2021/06/10/health/aduhelm-fda-resign-alzheimers.html).

³ All 11 members of the Advisory Committee declined to recommend approval, with ten "no" votes and one vote of "uncertain." Food and Drug Administration, *Final Summary Minutes of the Peripheral and Central Nervous System Drugs Advisory Committee Meeting* (Nov. 6, 2020) (online at www.fda.gov/media/145690/download); *Three F.D.A. Advisers Resign Over Agency's Approval of Alzheimer's Drug*, New York Times (June 10, 2021) (online at www.nytimes.com/2021/06/10/health/aduhelm-fda-resign-alzheimers.html).

⁴ Center for Drug Evaluation Research, Food and Drug Administration, *Application Number*:

Aduhelm was approved based on data that demonstrated the drug reduced the buildup of amyloid beta plaque in the brain.⁵ Some research has suggested that accumulation of amyloid beta plaque causes Alzheimer's disease.⁶ In September 2015, Biogen initiated two Phase 3 clinical trials designed to test this theory and the safety and efficacy of Aduhelm for individuals with early Alzheimer's disease.⁷ Both trials were cancelled in March 2019, following an independent data-monitoring committee report indicating the drug was unlikely to benefit people with Alzheimer's disease and that further clinical study would be futile.⁸

Recent reporting indicates that in the months following its halted clinical studies, Biogen undertook a secret campaign, termed Project Onyx, to persuade FDA to approve Aduhelm. Contrary to FDA guidance on communication between companies and the agency during drug development, in May 2019 a company official reportedly arranged for an "off-the-books" meeting to explore potential avenues for approval with FDA's Director of the Office of Neuroscience. That meeting was reportedly followed by a formal meeting between Biogen and FDA in June 2019. According to one press report, in a memo prepared by FDA after that meeting, FDA wrote that development of Aduhelm "should be continued" and that "[a] further possibility that the sponsor may give consideration to, depending on what further analyses demonstrate, is to seek accelerated approval of Aduhelm based on its effect on reducing brain amyloid."⁹

Following the June 2019 meeting, Biogen and FDA reportedly convened a "working group" of Biogen executives and FDA officials, which "met or communicated almost daily" in June, July, and August 2019.¹⁰ Biogen, in discussion with FDA, conducted a post hoc analysis of data from the cancelled clinical trials, and the company announced in October 2019 that "after consulting with the U.S. Food and Drug Administration," it would seek approval of Aduhelm on

761178Orig1s000, *Statistical Review(s)* (July 7, 2020) (online at www.accessdata.fda.gov/drugsatfda_docs/nda/2021/761178Orig1s000StatR_Redacted.pdf).

⁵ Food and Drug Administration, *Press Release: FDA Grants Accelerated Approval for Alzheimer's Drug*, (June 7, 2021) (online at www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug).

⁶ Food and Drug Administration and Biogen, *Combined FDA and Applicant Briefing Document for the November 6, 2020 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee Meeting Regarding NDA/BLA #761178, Aducanumab* (Nov. 6, 2020) (online at www.fda.gov/media/143502/download).

⁷ Biogen Inc., *Press Release: Biogen Enrolls First Patient in Global Phase 3 Study of Investigational Treatment Aducanumab (BIIB037) for Early Alzheimer's Disease* (Sept. 8, 2015) (online at <https://investors.biogen.com/news-releases/news-release-details/biogen-enrolls-first-patient-global-phase-3-study>).

⁸ Food and Drug Administration and Biogen, *Combined FDA and Applicant Briefing Document for the November 6, 2020 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee Meeting Regarding NDA/BLA #761178, Aducanumab* (Nov. 6, 2020) (online at www.fda.gov/media/143502/download).

⁹ *Inside 'Project Onyx': How Biogen Used an FDA Back Channel to Win Approval of Its Polarizing Alzheimer's Drug*, STAT (June 29, 2021) (online at www.statnews.com/2021/06/29/biogen-fda-alzheimers-drug-approval-aduhelm-project-onyx/).

¹⁰ *Id.*; Food and Drug Administration and Biogen, *Combined FDA and Applicant Briefing Document for the November 6, 2020 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee Meeting Regarding NDA/BLA #761178, Aducanumab* (Nov. 6, 2020) (online at www.fda.gov/media/143502/download).

the basis of these findings.¹¹ Biogen submitted its Biologics License Application (BLA) for approval of Aduhelm in July 2020 and requested priority review.¹²

The Advisory Committee meeting on Aduhelm's application was held on November 6, 2020, and the primary document presented was jointly authored by Biogen and FDA.¹³ Despite the Advisory Committee's unanimous vote that there was not reasonable evidence of Aduhelm's effectiveness to treat Alzheimer's disease, on June 7, 2021, FDA announced it would grant accelerated approval for the drug.¹⁴ Following FDA's announcement, three Advisory Committee members resigned in protest, with one member calling it "probably the worst drug approval decision in recent U.S. history," and another saying he did not "wish to be part of a sham process."¹⁵

As scientific and medical experts expressed alarm at FDA's decision, Biogen celebrated what it called a "historic moment."¹⁶ The company announced a list price of \$56,000 per year for the drug. In addition to the price of the drug itself, additional associated expenses will include the costs of necessary brain imaging and other diagnostic services that will be required for patients in conjunction with the treatment.¹⁷ While the company has claimed this price is

¹¹ Biogen Inc., *Press Release: Biogen Plans Regulatory Filing for Aducanumab in Alzheimer's Disease Based on New Analysis of Larger Dataset from Phase 3 Studies* (Oct. 22, 2019) (online at <https://investors.biogen.com/news-releases/news-release-details/biogen-plans-regulatory-filing-aducanumab-alzheimers-disease>); Food and Drug Administration and Biogen, *Combined FDA and Applicant Briefing Document for the November 6, 2020 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee Meeting Regarding NDA/BLA #761178, Aducanumab* (Nov. 6, 2020) (online at www.fda.gov/media/143502/download).

¹² Biogen Inc., *Press Release: Biogen Completes Submission of Biologics License Application to FDA for Aducanumab as a Treatment for Alzheimer's Disease* (July 8, 2020) (online at investors.biogen.com/news-releases/news-release-details/biogen-completes-submission-biologics-license-application-fda).

¹³ Food and Drug Administration and Biogen, *Combined FDA and Applicant Briefing Document for the November 6, 2020 Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee Meeting Regarding NDA/BLA #761178, Aducanumab* (Nov. 6, 2020) (online at www.fda.gov/media/143502/download).

¹⁴ Food and Drug Administration, *Press Release: FDA Grants Accelerated Approval for Alzheimer's Drug* (June 7, 2021) (online at www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug); Food and Drug Administration, *Final Summary Minutes of the Peripheral and Central Nervous System Drugs Advisory Committee Meeting* (Nov. 6, 2020) (online at www.fda.gov/media/145690/download).

¹⁵ Letter from Dr. Aaron Kesselheim, Brigham and Women's Hospital/Harvard Medical School, to Acting Commissioner Janet Woodcock, M.D., Food and Drug Administration (June 10, 2021) (online at <https://pbs.twimg.com/media/E3jKN4GWYAUGj9U.png>); *Three Experts Have Resigned from an FDA Committee Over Alzheimer's Drug Approval*, National Public Radio (June 11, 2021) (online at www.npr.org/2021/06/11/1005567149/3-experts-have-resigned-from-an-fda-committee-over-alzheimers-drug-approval); *Two Members of an FDA Advisory Committee Quit After Approval of Controversial Alzheimer's Drug*, Washington Post (June 9, 2021) (online at www.washingtonpost.com/health/2021/06/09/alzheimers-drug-controversy/).

¹⁶ Biogen Inc., *Press Release: FDA Grants Accelerated Approval for Aduhelm as the First and Only Alzheimer's Disease Treatment to Address a Defining Pathology of the Disease* (June 7, 2021) (online at <https://investors.biogen.com/news-releases/news-release-details/fda-grants-accelerated-approval-aduhelmtm-first-and-only>).

¹⁷ *F.D.A. Approves Alzheimer's Drug Despite Fierce Debate Over Whether It Works*, New York Times (June 7, 2021) (online at www.nytimes.com/2021/06/07/health/aduhelm-fda-alzheimers-drug.html).

“fair” and “substantiated by the value it is expected to bring,” an independent analysis determined that a fair price for Aduhelm would be a small fraction of Biogen’s price—between \$3,000 and \$8,400 per year.¹⁸ Biogen’s price is also far higher than many investors reportedly expected.¹⁹

Aduhelm’s approval and price will have significant implications for seniors and their families, health care providers, federal health care programs, and taxpayers. Although clinical trials were only conducted on early-stage Alzheimer’s patients and those with mild cognitive impairment, of which roughly 1.5 million patients are afflicted in the United States, the FDA-approved label for Aduhelm indicates the drug can be more widely marketed “for the treatment of Alzheimer’s disease”—a patient population of more than 6 million people.²⁰

On July 8, 2021, Biogen announced that FDA had approved updated prescribing information for Aduhelm that now states that treatment “should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.” The amended label further states that there is no safety or effectiveness data for treating earlier or later stages of the disease, but does not change the broad indication “for the treatment of Alzheimer’s disease.”²¹ According to conservative estimates, Biogen’s annual list price of \$56,000 could result in annual expenditures in excess of \$57 billion per year for the Medicare Part B program if one million beneficiaries receive Aduhelm. In 2019, Medicare Part B and its beneficiaries spent a total of \$37 billion on all drugs covered by the program.²²

¹⁸ *Biogen CEO Says \$56,000 Annually for Alzheimer’s Drug Is ‘Fair,’ Promises Not to Hike Price for at Least 4 Years*, CNBC (June 7, 2021) (online at www.cnn.com/2021/06/07/biogen-ceo-says-56000-annually-for-alzheimers-drug-is-fair-promises-not-to-hike-price-for-at-least-4-years.html); *FDA’s Hasty Approval of Alzheimer’s Drug Is Bad News for Everyone*, Los Angeles Times (June 10, 2021) (online at www.latimes.com/business/story/2021-06-10/fda-alzheimers-drug-aduhelm); Institute for Clinical and Economic Review, *Aducanumab for Alzheimer’s Disease: Effectiveness and Value, Evidence Report* (June 30, 2021) (online at https://icer.org/wp-content/uploads/2020/10/ICER_ALZ_Revised_Evidence_Report_06302021.pdf).

¹⁹ *Biogen’s \$56K Alzheimer’s Drug Is Rounding Up Bipartisan Drug Pricing Critics in Congress*, Fierce Pharma (June 25, 2021) (online at www.fiercepharma.com/pharma/concerned-about-medicare-biogen-s-56k-alzheimer-s-drug-gaining-bipartisan-critics-washington); *Biogen Faces Tough Questions Over \$56,000-a-Year Price of Newly Approved Alzheimer’s Drug*, CNBC (June 8, 2021) (online at www.cnn.com/2021/06/08/biogen-faces-tough-questions-over-56k-a-year-price-of-newly-approved-alzheimers-drug.html).

²⁰ *F.D.A. Approves Alzheimer’s Drug Despite Fierce Debate Over Whether It Works*, New York Times (June 7, 2021) (online at www.nytimes.com/2021/06/07/health/aduhelm/fda-alzheimers-drug.html); *New Drug Could Cost the Government as Much as It Spends on NASA*, New York Times (June 22, 2021) (online at www.nytimes.com/2021/06/22/upshot/alzheimers-aduhelm-medicare-cost.html); Food and Drug Administration, *Aduhelm Label* (online at www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s0001bl.pdf).

²¹ Biogen Inc., *Press Release: FDA Approves Updated Aduhelm Prescribing Information to Emphasize Population Studied in Clinical Trials* (July 8, 2021) (online at <https://investors.biogen.com/news-releases/news-release-details/fda-approves-updated-aduhelmtm-prescribing-information-emphasize>).

²² *FDA’s Approval of Biogen’s New Alzheimer’s Drug Has Huge Cost Implications for Medicare and Beneficiaries*, Kaiser Family Foundation (June 10, 2021) (online at www.kff.org/medicare/issue-brief/fdas-approval-of-biogens-new-alzheimers-drug-has-huge-cost-implications-for-medicare-and-beneficiaries/).

To assist the Committees with this investigation, please provide the following documents and information by July 26, 2021. Except as otherwise noted, documents and information should be produced for the period from January 2018 to present:

1. All internal and external documents and communications relating to assessments of the safety, efficacy, or clinical benefit of aducanumab, including, but not limited to:
 - a. materials prepared for or provided to officers, directors, or senior executives;
 - b. documents relating to the use of amyloid beta plaque reduction as a surrogate endpoint for the treatment of Alzheimer's disease, including whether such plaque reduction predicts efficacy in treating cognitive decline;
 - c. assessments of clinical trials, including assessments related to Biogen's decision in 2019 to cancel aducanumab's Phase 3 clinical trials or any independent assessments (including by a Data Safety Monitoring Board or similar body) of the safety, efficacy, or benefits of aducanumab, or futility of the trials; and
 - d. analyses or projections related to the potential financial impact to the company resulting from the outcomes of any clinical trials of aducanumab;
2. All internal and external documents and communications relating to the regulatory review process and approval of aducanumab, including, but not limited to:
 - a. materials prepared for or provided to officers, directors, or senior executives;
 - b. documents relating to Biogen's decision to seek FDA approval of aducanumab; Project Onyx; the evaluation of different FDA review pathways; or the progress, timing, or expected results of FDA's review and approval determination;
 - c. the contents of Aduhelm's label, including the indication of Aduhelm for "the treatment of Alzheimer's disease" rather than for a patient population consistent with the clinical trial populations, and updates to that label and indication;
 - d. preparations for the November 6, 2020, Advisory Committee meeting;

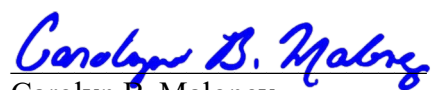
- e. any questions, critiques, or concerns raised by Advisory Committee members, FDA employees, or medical and other experts, and any responses to related questions, critiques, or concerns;
 - f. financial analyses or projections related to the regulatory review process; and
 - g. communications among FDA personnel and representatives of Biogen related to aducanumab;
3. The dates, times, locations, attendees, and any notes or minutes taken of all calls and informal and formal meetings or discussions among FDA officials or personnel and representatives of Biogen related to aducanumab, and all related communications;
4. The following information, broken down by each year since aducanumab entered Biogen's development pipeline, as well as a description of the sources and methodology used to calculate this information:
- a. the amounts spent on pre-clinical testing, and Phase 1, Phase 2, and Phase 3 trials for the drug; and
 - b. the total amount of research and development tax credits claimed annually by the company, including any disaggregated amounts specifically attributable to aducanumab;
5. All internal and external documents and communications relating to Biogen's pricing, manufacturing costs, commercialization, or potential marketing strategies for aducanumab, including:
- a. materials prepared for or provided to officers, directors, or senior executives;
 - b. the determination of aducanumab's list price, projected price increases, and the authorization process by which the price may be increased;
 - c. projections, estimates, or analyses of Biogen's likely return on investment, profitability, or sales for the drug, including materials prepared for executives, directors, investor presentations, and earnings calls;
 - d. projections, estimates, or analyses of the patient populations that may be prescribed aducanumab; their health insurance coverage status, including the likelihood of their participation in federal health care programs; and the affordability or accessibility of this medication;

- e. the development of patient assistance programs, discounts, coupons, or rebates, as well as education or outreach to patient organizations; and
 - f. sales materials or campaigns, and discussions or plans for direct-to-consumer advertising, third-party consumer outreach, and provider advertising, education, or outreach;
6. A list of each business unit, component, or division within Biogen involved in the commercialization or pricing of aducanumab and organizational charts for those entities;
 7. A list of all third-party entities that provided services to Biogen related to its regulatory or pricing strategies for aducanumab;
 8. All internal and external documents and communications related to Biogen's plans to conduct Phase 4 confirmatory trials of aducanumab, including information on the estimated timeline including, but not limited to, the date(s) of initial participant enrollment, full enrollment, initial results, and conclusion, as well as any enrollment plans and efforts to recruit diverse trial participants to reflect the populations affected by the disease; and
 9. All internal and external documents and communications related to Biogen's decision to seek approval of Biogen's other Alzheimer's drug Lecanemab, including the decision to obtain a breakthrough therapy designation for the drug, as well as any discussions relating to Biogen's potential pricing, marketing, or sales strategies for this drug.

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. Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce has the authority to investigate issues under its jurisdiction, including matters relating to health care.

An attachment to this letter provides additional instructions for responding to the Committees' request. If you have any questions regarding this request, please contact Oversight Committee staff at (202) 225-5051 or Energy and Commerce Committee staff at (202) 225-2927. Thank you for your prompt attention to this matter.

Sincerely,



Carolyn B. Maloney
Chairwoman
Committee on Oversight
and Reform



Frank Pallone Jr.
Chairman
Committee on Energy
and Commerce

Mr. Michel Vounatsos

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Enclosure

cc: The Honorable James Comer, Ranking Member
Committee on Oversight and Reform

The Honorable Cathy McMorris Rogers, Ranking Member
Committee on Energy and Commerce

Responding to Committees' 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 Committees.
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, including alternate spellings or transliterations of any names, the request shall be read also to include that alternative identification.
4. The Committees' 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 Committees 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 Committees 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 Committees' 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.
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 Committees.

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 terms “relating to” and “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 “involving”, with respect to any given subject, means sending, receiving, or being copied (CC or BCC), or being the subject matter on any documents or communications described in the request.
9. 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.
10. The term “individual” means all natural persons and all persons or entities acting on their behalf.