CAROLYN B. MALONEY
CHAIRWOMAN

ONE HUNDRED SIXTEENTH CONGRESS

JIM JORDAN, OHIO
RANKING MINORITY MEMBER

Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND REFORM
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6143
MAJORITY (202) 225–5051
MINORITY (202) 225–5074
http://oversight.house.gov

May 4, 2020

Ms. Lisa Conte
Founder and Chief Executive Officer
Jaguar Health Inc.
201 Mission Street, Suite 2375
San Francisco, CA, 94105

Dear Ms. Conte:

We write to urge you to reverse your recent decision to increase the price of Mytesi, a medication used to treat gastrointestinal side effects caused by antiretroviral medications. We are concerned that the nearly three-fold price increase your company imposed earlier this month may prevent Americans from accessing Mytesi if it is approved for use during the current coronavirus outbreak.

Numerous antiretroviral drugs—including more than 15 drugs currently approved to treat HIV and AIDS—are being evaluated as potential treatments for patients suffering from coronavirus.[1] If these treatments prove effective, medications like Mytesi that are used to treat the side effects of these drugs also may be needed to treat coronavirus patients. While Mytesi is not currently approved to treat the symptoms of coronavirus or the side effects caused by coronavirus treatments, some coronavirus patients are experiencing gastrointestinal symptoms similar to those experienced by patients who take Mytesi in connection with HIV or AIDS.[2]

On March 21, 2020, Jaguar Health submitted an application to the Food and Drug Administration for an Emergency Use Authorization (EUA) for Mytesi for the symptomatic relief of diarrhea and other gastrointestinal symptoms in patients with coronavirus and those who have diarrhea associated with certain antiviral treatments.[3] While this application was denied on April 7, 2020, Jaguar Health reportedly is in discussions with the National Institute of Allergy and Infectious Diseases about the effectiveness of Mytesi for coronavirus patients.[4]

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[1] Centers for Disease Control and Prevention, *What to Know About HIV and COVID-19* (accessed Apr. 30, 2020) (online at www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/hiv.html).

[2] Centers for Disease Control and Prevention, *Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19)* (accessed Apr. 30, 2020) (online at www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html).

[3] Jaguar Health, *Form 8-K* (Mar. 21, 2020) (online at www.sec.gov/Archives/edgar/data/1585608/000110465920037082/tm2013455d1_8k.htm).

[4] *Drugmaker Tripled the Price of a Pill as it Pursued Coronavirus Use*, Axios (Apr. 23, 2020) (online at www.axios.com/pharma-jaguar-health-mytesi-drug-price-coronavirus-8ea874b1-9e75-47cf-ba47-475ef7d58e3b.html).

Two days after the EUA was denied, Jaguar Health raised the price of Mytesi from $688.52 per bottle to $2,206.52 per bottle, more than tripling the price.[5] The timing of Jaguar's price increase raises questions about whether this decision was connected with the company's expectation that it eventually could market Mytesi to treat coronavirus patients.

On April 2, 2020, Chairwoman Maloney wrote to the Pharmaceutical Research and Manufacturers of America (PhRMA) urging its member companies to commit to setting affordable prices for any medications that are or may be used to prevent or treat coronavirus. As she wrote in that letter, "no drug company should be allowed to profiteer, especially during this public health emergency."[6]

For these reasons, the Committee urges Jaguar Health to reverse this drastic price increase to ensure everyone who may need Mytesi is able to access it.

In addition, the Committee requests, by May 18, 2020, all communications, including e-mail communications between or among all executives, employees, investors, board members or other agents of Jaguar Health regarding the decision to increase the list price of Mytesi effective on or around April 9, 2020.

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 the Subcommittee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,

Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform

Jackie Speier
Member of Congress

Enclosures

cc: The Honorable Jim Jordan, Ranking Member

[5] *Id.*

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

Responding to 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 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, 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.

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 on Oversight and Reform, 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. When documents are produced to the Committee on Financial Services, production sets shall be delivered to the Majority Staff in Room 2129 of the Rayburn House Office Building and the Minority Staff in Room 4340 of the O'Neill House Office Building. When documents are produced to the Permanent Select Committee on Intelligence, production sets shall be delivered to Majority and Minority Staff in Room HVC-304 of the Capital Visitor Center.

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.