GARY C. PETERS, MICHIGAN, CHARMAN

THOMAS R. CARPER, DELAWARE MAGGIE HASSAN, NEW HAMPSHIRE KYRSTEN SINEMA, ARIZONA, JACKY ROSEN, NEWADA ALEX PADILLA, CALIFORNIA JON OSSOFF, GEORGIA

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DAVID M. WEINBERG, STAFF DIRECTOR PAMELA THIESSEN, MINORITY STAFF DIRECTO LAURA W. KLERIDE, CHIEF GLERK

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

December 14, 2021

Dr. Eric Rubin Editor-in-Chief New England Journal of Medicine 860 Winter Street Waltham, MA 02451

Dear Dr. Rubin:

I write to request information regarding the publication and subsequent retraction of a study published in the *New England Journal of Medicine* ("*NEJM*") titled, "Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19" ("the study" or "the paper").¹ This study, which first appeared in *NEJM* on May 1, 2020, reportedly found that, "taking certain blood pressure drugs, including angiotensin-converting enzyme (ACE) inhibitors, didn't appear to increase the risk of death among COVID-19 patients, as some researchers had suggested."²

On June 2, 2020, you issued an "expression of concern" regarding the study based on "substantive concerns [that had] been raised about the quality of the information in [the study's] database." The company that had provided the database in question was the Surgisphere Corporation ("Surgisphere"), a Chicago-based company, whose owner and founder, Dr. Sapan Desai, coauthored the study.⁴

On June 4, 2020, the authors of the study, including Dr. Desai, published a statement retracting their paper.⁵ Shortly after the retraction, you reportedly stated, "[w]e shouldn't have

¹ Mandeep Mehra, et al., *RETRACTED: Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19*, New England Journal of Medicine, May 1, 2020, https://www.nejm.org/doi/full/10.1056/NEJMoa2007621.

² Charles Piller and Kelly Servick, *Two elite medical journals retract coronavirus papers over data integrity questions*, Science, June 4, 2020, https://www.science.org/content/article/two-elite-medical-journals-retract-coronavirus-papers-over-data-integrity-questions.

³ Eric Rubin, Expression of Concern: Mehra MR et al. Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19, New England Journal of Medicine, June 2, 2020, https://www.nejm.org/doi/full/10.1056/NEJMe2020822.

⁴ Mandeep Mehra, et al., *RETRACTED: Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19*, New England Journal of Medicine, May 21, 2020, https://www.nejm.org/doi/full/10.1056/NEJMoa2007621. A study published in *The Lancet* also used a dataset supplied by Surgisphere and was retracted. Mandeep Mehra, et al., *RETRACTED: Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis*, The Lancet, May 22, 2020,

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31180-6/fulltext.

⁵ Mandeep Mehra, et al., *Retraction: Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19*, New England Journal of Medicine, June 4, 2020, https://www.nejm.org/doi/full/10.1056/nejmc2021225.

Dr. Eric Rubin December 14, 2021 Page 2

published this."⁶ Although this questionable study was ultimately retracted, it is concerning and shameful that, in the midst of a pandemic, *NEJM* published a paper on COVID-19 based on problematic data. In order to better understand *NEJM*'s actions regarding this study, I request the following:

- 1. The preservation of all records⁷ referring or relating to the study titled, "Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19."
- 2. All documents and communications between and among employees or representatives of *NEJM* and U.S. government employees referring or relating to the study.
- 3. All documents and communications between and among *NEJM* employees or representatives who reviewed this study, including any comments, ratings, findings and recommendations of the peer reviewers.
- 4. All documents and communications between and among employees or representatives of *NEJM* and individuals or organizations encouraging *NEJM* to publish the study.
- 5. All documents and communications between and among employees or representatives of *NEJM* and the study's authors, or their representatives.
- 6. All documents and communications between and among employees or representatives of *NEJM* and employees or representatives of Surgisphere.

Please provide this information as soon as possible but no later than January 4, 2022. Thank you for your attention to this matter.

Sincerely,

Ron Johnson Ranking Member

Permanent Subcommittee on Investigations

⁶ Roni Caryn Rabin, *The Pandemic Claims New Victims: Prestigious Medical Journals*, NY Times, June 14, 2020, https://www.nytimes.com/2020/06/14/health/virus-journals.html.

⁷ "Records" include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (emails, email attachments, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether or not they resulted in final documents).

⁸ Mandeep Mehra, et al., *RETRACTED: Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19*, New England Journal of Medicine, May 1, 2020, https://www.nejm.org/doi/full/10.1056/NEJMoa2007621.

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ROE FORTMAN, OHIO BON JUNISON, MISCONSIN HAND PAUL, KENTUCKY IAMES LANKFORD, DELAHOMA MET BOMNEY, UTAH RICK SCOTT, ELEMBA JOSHHAM, EV MISSOLIBI

DAVID M. WEINBERG, STAFF DIRECTOR. PAMELA THIESSEN, MINORITY STAFF DIRECTOR LAGRA W. KILBRIDE, CHIEF CLERK

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

December 14, 2021

Dr. Richard Horton Editor-in-Chief The Lancet 230 Park Avenue New York, NY 10169

Dear Dr. Horton:

I write to request information regarding the publication and subsequent retraction of a study published in *The Lancet* titled, "Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis" ("the study" or "the paper"). This study, which first appeared in *The Lancet* on May 22, 2020, reportedly found that, "treating people who have [COVID-19] with chloroquine and hydroxychloroquine did not help and might have increased the risk of abnormal heart rhythms and death."

According to reports, following the study's publication, scientists and clinicians raised concerns about the veracity of the data used in the study.³ Specifically, experts questioned, "the astonishing number of patients involved and details about their demographics and prescribed dosing[.]"

The Surgisphere Corporation ("Surgisphere"), a Chicago-based company, supplied the dataset that served as the basis for the study.⁵ Surgisphere's owner and founder, Dr. Sapan Desai, was one of the authors of the study.

¹ Mandeep Mehra, et al., *RETRACTED: Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis*, The Lancet, May 22, 2020, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31180-6/fulltext.

² Roni Caryn Rabin, *Scientists Question Validity of Major Hydroxychloroquine Study*, NY Times, May 29, 2020, https://www.nytimes.com/2020/05/29/health/coronavirus-hydroxychloroquine.html.

⁴ Kelly Servick and Martin Enserink, *A mysterious company's coronavirus papers in top medical journals may be unraveling*, Science, June 2, 2020, https://www.science.org/content/article/mysterious-company-s-coronavirus-papers-top-medical-journals-may-be-unraveling.

⁵ Mandeep Mehra, et al., *RETRACTED: Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis*, The Lancet, May 22, 2020, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31180-6/fulltext. A study published in the *New England Journal of Medicine* also used a dataset supplied by Surgisphere and was retracted. Mandeep Mehra, et al., *RETRACTED: Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19*, New England Journal of Medicine, May 1, 2020, https://www.nejm.org/doi/full/10.1056/NEJMoa2007621.

On June 3, 2020, *The Lancet* issued an "expression of concern" regarding the study after "serious scientific questions" were brought to the editors' attention.⁶ On June 5, 2020, the authors of the study, not including Dr. Desai, published a statement retracting their paper.⁷ Shortly after the retraction, you reportedly called the study a "fabrication" and "a monumental fraud."

Although this fraudulent study was ultimately retracted, it is concerning and shameful that, in the midst of a pandemic, *The Lancet* published such a misleading paper on a potential early treatment for COVID-19. In order to better understand *The Lancet*'s actions regarding this study, I request the following:

- 1. The preservation of all records⁹ referring or relating to the study titled, "Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis."¹⁰
- 2. All documents and communications between and among employees or representatives of *The Lancet* and U.S. government employees referring or relating to the study.
- 3. All documents and communications between and among *The Lancet* employees or representatives who reviewed this study, including any comments, ratings, findings and recommendations of the peer reviewers.
- 4. All documents and communications between and among employees or representatives of *The Lancet* and individuals or organizations encouraging *The Lancet* to publish the study.
- 5. All documents and communications between and among employees or representatives of *The Lancet* and the study's authors, or their representatives.
- 6. All documents and communications between and among employees or representatives of *The Lancet* and employees or representatives of Surgisphere.

⁶ The Lancet Editors, *Expression of concern: Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis*, The Lancet, June 3, 2020, https://www.thelancet.com/journals/lanpub/article/PIIS0140-6736(20)31290-3/fulltext.

⁷ Mandeep Mehra, et al., *Retraction—Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis*, The Lancet, June 5, 2020, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31324-6/fulltext.

⁸ Roni Caryn Rabin, *The Pandemic Claims New Victims: Prestigious Medical Journals*, NY Times, June 14, 2020, https://www.nytimes.com/2020/06/14/health/virus-journals.html.

⁹ "Records" include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (emails, email attachments, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether or not they resulted in final documents).

¹⁰ Mandeep Mehra, et al., *RETRACTED: Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis*, The Lancet, May 22, 2020, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31180-6/fulltext.

Dr. Richard Horton December 14, 2021 Page 3

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Sincerely,

Ron Johnson

Ranking Member

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