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November 23, 2021

The Honorable Dr. Francis Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

The Honorable Joni L. Rutter
Acting Director
National Center for Advancing Translational Sciences
6701 Democracy Boulevard
Bethesda, Maryland 20892

Dear Director Collins and Acting Director Rutter:

We write to you regarding the drug Fenofibrate and its promising results that studies have shown quickly reduce the effects faced by severe COVID-19 patients. We also write to thank you for your assistance in supporting continued research into Fenofibrate for COVID-19 patients.

Fenofibrate is an oral medication approved by the Food and Drug Administration (FDA) in 1993 to treat high cholesterol and triglycerides.¹

As we continue to spend billions of dollars on treatment for COVID-19, with a large number of individuals with vaccinations and antibodies, it still sadly appears over 1,100 deaths occur each week from this disease.² Fenofibrate can help lower the cost we spend on treatment given the generic version of Fenofibrate is available for \$9 a month.³

In July of 2020, a study conducted at Hebrew University in Israel and by Mount Sinai Medical Center in New York examined Fenofibrate and its effect on patient lung cells infected with COVID-19. Their preliminary research found Fenofibrate can block the ability of COVID-19 to reproduce and prevent it from damaging lung cells.⁴ This work was later validated in August of 2021 by an independent team from the University of Birmingham in the United Kingdom.⁵

¹ *Highlights of Prescribing Information*. (n.d.). Retrieved from Accessdata.FDA.Gov: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021656s029lbl.pdf

² *COVID Data Tracker Weekly Review*. (2021, November 8). Retrieved from CDC: <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>

³ *Tricor*. (2021, September 23). Retrieved from GoodRx: https://www.goodrx.com/tricor?dosage=145mg&form=tablet&label_override=fenofibrate&quantity=30&sort_type=popularity

⁴ JAFFE-HOFFMAN, M. (2020, July 15). *Hebrew U. scientist: Drug could eradicate COVID-19 from lungs in days*. Retrieved from The Jerusalem Post: <https://www.jpost.com/health-science/hebrew-u-scientist-drug-could-eradicate-covid-19-from-lungs-in-days-635028>

⁵ *Licensed drug could reduce SARS-CoV-2 infection by up to 70 per cent, reveals study* (2021, August 6). Retrieved from the University of Birmingham: <https://www.birmingham.ac.uk/news/latest/2021/08/covid-licensed-drug-reduce-infection.aspx>

In August of 2021, Hebrew University completed a study with Israel's Barzilai Medical Center with support from Abbott Laboratories, who owns Fenofibrate's branded version Tricor, and found astounding results. The study looked at 15 severe patients who had pneumonia and required oxygen support due to COVID-19. The patients, in addition to standard care, were given 145 mg per day of Fenofibrate for a total period of 10 days. The results showed that 14 of 15 patients no longer needed oxygen support after a week and inflammation markers were drastically reduced within two days.⁶ Since this study had a small sample size and was not blinded, it is important to support further research into Fenofibrate's effect on COVID-19 patients.

The researchers at Hebrew University of Jerusalem are actively working on a Phase III trial titled FENOC.⁷ After speaking with the lead investigator of the study, it is clear the addition of one clinical center with 20-30 patients in the United States would be enough to finalize the study.

Therefore, we ask for your support in helping this incredibly important study receive the patient access they need to complete this life saving research.

Furthermore, the National Institutes of Health (NIH) is currently supporting Phase II clinical research into Fenofibrate for its treatment in COVID-19 patients at University of Pennsylvania and with help from University of Arizona, Hospitales Civiles de Guadalajara in Mexico, and a number of hospitals in South America.⁸

The investigator leading the study stated that the study currently has enrolled about 270 participants, with the aim to enroll 700. Even with continued enrollment rates, enrollment is projected to be complete no sooner than March 2022, leading to a May 2022 completion date. This is in part due to the limited number of patients that individual centers can enroll in a given period of time.⁹

After asking about ways to shorten the time to its completion, the investigator mentioned that working with additional research centers would speed up enrollment, thus helping to reach the goal sooner. He also mentioned the burdensome amount of paperwork required to deal with allocating more resources.

Therefore, we also seek the NIH and the National Center for Advancing Translational Sciences to support study enrollment by facilitating a greater number of medical centers to work on this very important and promising clinical study as well as your assistance to reduce the burden caused by superfluous paperwork requirements.

Thank you in advance for your consideration and attention to this matter.

Sincerely,

⁶ JAFFE-HOFFMAN, M. (2021, August 23). *\$15 drug gets COVID patients off oxygen support in under week – study*. Retrieved from The Jerusalem Post: <https://www.jpost.com/health-science/15-treatment-gets-covid-patients-off-ventilators-in-under-a-week-study-677479>

⁷ *Fenofibrate for Patients With COVID-19 Requiring Hospitalization (FENOC)*.(n.d.). Retrieved from ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT04661930>

⁸ *Fenofibrate as a Metabolic Intervention for COVID-19*. (n.d.). Retrieved from ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT04517396>

⁹ Chirinos, J. (2021, September 24). Doctor. (R. G. Grothman, Interviewer)

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A handwritten signature in blue ink that reads "Glenn Grothman".

Glenn Grothman
Member of Congress

A handwritten signature in blue ink that reads "Doug LaMalfa".

Doug LaMalfa
Member of Congress

A handwritten signature in blue ink that reads "Clay Higgins".

Clay Higgins
Member of Congress

A handwritten signature in blue ink that reads "Claudia Tenney".

Claudia Tenney
Member of Congress

A handwritten signature in blue ink that reads "Andy Biggs".

Andy Biggs
Member of Congress

A handwritten signature in blue ink that reads "Tom Rice".

Tom Rice
Member of Congress

A handwritten signature in blue ink that reads "Mary E. Miller".

Mary Miller
Member of Congress