

**Congress of the United States**  
**Washington, DC 20515**

August 24, 2020

Dr. Stephen M. Hahn  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Hahn,

As the United States continues to grapple with the ongoing COVID-19 pandemic, we urge you to be vigilant and watchful of individuals peddling “cures” directly to high-level government officials, including Donald Trump. We are alarmed by recent reports that Mr. Trump and individuals close to him have publicly endorsed another unproven treatment, oleander plant extract, as a cure for COVID-19 infection.

This is a dangerous pattern that cannot be ignored by your agency. As the nation saw with hydroxychloroquine, Trump and individuals close to him repeatedly claimed publicly that the malaria drug is an effective treatment for COVID-19, even though there is no scientific data to back up these assertions. Trump then pressured the Food and Drug Administration (FDA) to speed up its review of hydroxychloroquine and issue an emergency use authorization (EUA), which the agency later had to revoke due to overwhelming evidence that the drug does more harm than good for COVID-19 patients. Now, after purportedly being lobbied by Secretary of Housing and Urban Development Ben Carson and Mike Lindell, a close Trump confidant and the CEO and founder of MyPillow, a Minnesota company best-known for its ubiquitous late night cable television infomercials, Trump is pushing FDA to either approve oleandrin as a drug or allow it to be marketed as a dietary supplement.<sup>1</sup> Lindell also has a financial stake in the company developing the oleandrin drug, Phoenix Biotechnology, Inc.<sup>2</sup>

Oleandrin, which has never been tested in animals or humans, is derived from *Nerium oleander* and is toxic and potentially fatal. In fact, the European Food Safety Authority lists *Nerium oleander* in its compendium of botanicals that have been reported to contain toxic, addictive, psychotropic, or other substances of concern.<sup>3</sup> The FDA has never approved any form of *Nerium oleander* to treat any condition. In 2000, the FDA sent a Warning Letter to Ozelle Pharmaceuticals, the manufacturer of Anvirzel, an oleander extract manufactured to treat non-small cell lung cancer, for promoting the drug and making claims regarding efficacy and safety based on inconclusive data prior to the drug’s approval.<sup>4</sup> PBI-05204, the oleander extract drug manufactured by Phoenix Biotechnology, Inc. that is being promoted by Trump, has shown promise in treating patients with advanced solid tumors, but it has not been studied for the treatment of any coronaviruses.<sup>5</sup>

In May 2020, the United States Army Medical Research Institute of Infectious Disease (USAMRIID) performed preliminary tests on oleandrin on SARS-CoV-2 and data was inconclusive. Because of this result, USAMRIID decided not to move forward with researching oleandrin because it was not as promising as other therapeutics to treat COVID-19.<sup>6</sup> In July 2020, a test tube study conducted at the University of Texas Medical Branch in Galveston indicated that oleandrin could inhibit SARS-CoV-2 in monkey kidney cells.<sup>7</sup> While this is promising data, oleandrin must demonstrate safety and efficacy through an adequate and well-controlled trial for COVID-19 patients before it can be promoted as a treatment. Additionally, one of the authors of the study is also the Chairman of the Board of Phoenix Biotechnology, Inc., which reinforces the need for scientific rigor to prevent conflicts of interest and achieve legitimate treatments.<sup>8</sup>

We do not write to dispute that oleandrin may be a viable option for treatment of COVID-19. But at this time evidence of this possibility does not exist and so the FDA must not rush to approve or grant an EUA for oleandrin because of political pressure emanating from Donald Trump, his associates, or other officials in his government. Statements from non-scientists promoting a therapy with no evidence, combined with the FDA's silence, may cause many Americans to believe that these experimental drugs are a cure-all. Worse, unfounded assertions may inspire some to abandon social distancing and other proven preventative measures critical to controlling this virus.

Please answer the following questions:

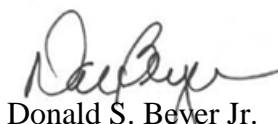
- 1) Has any FDA official received undue political pressure from administration staff to approve, grant an EUA, or allow oleandrin to be marketed as a dietary supplement? Has any FDA official received undue political pressured from individuals outside of the government to approve, grant an EUA, or allow oleandrin to be marketed as a dietary supplement?
- 2) Has FDA received any human clinical trial data from Phoenix Biotechnology, Inc? If so, does this data indicate that oleandrin is safe and effective for the treatment of COVID-19, as stated by a Phoenix Biotechnology, Inc, board member?
- 3) Is there any data from an adequate and well-controlled clinical trial that indicates that oleandrin is a candidate for treatment of COVID-19?
- 4) Is oleandrin available to the public in any form over-the-counter (OTC)? Does the FDA consider oleandrin to be generally recognized as safe (GRAS) and effective for any therapeutic indication?

We understand the FDA is under immense pressure to quickly evaluate therapies for COVID-19, but it remains more important than ever that the FDA remain true to its standard processes and be guided by the science and the data. We look forward to your response.

Sincerely,



Bill Pascrell, Jr.  
Member of Congress



Donald S. Beyer Jr.  
Member of Congress



Katie Porter  
Member of Congress

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- <sup>1</sup> Swan, J. (2020). Trump eyes new unproven virus "cure" promoted by ben carson and the CEO of MyPillow. Retrieved from <https://www.axios.com/trump-covid-oleandrin-9896f570-6cd8-4919-af3a-65ebad113d41.html>
- <sup>2</sup> Phoenix Biotechnology, Inc. - Board of Directors. (2020). Retrieved from [http://www.phoenixbiotechnology.com/board\\_of\\_directors.php](http://www.phoenixbiotechnology.com/board_of_directors.php)
- <sup>3</sup> European Food Safety Commission. (2009). EFSA compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern. Retrieved from <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2009.281>
- <sup>4</sup> U.S. Food and Drug Administration. (2000). *Anvirzel warning letter*. Retrieved from <http://wayback.archive-it.org/7993/20170112070809/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM165406.pdf>
- <sup>5</sup> Yang, P., Menter, D. G., Cartwright, C., Chan, D., Dixon, S., Suraokar, M., . . . Newman, R. A. (2009). Oleandrin-mediated inhibition of human tumor cell proliferation: Importance of na,K-ATPase alpha subunits as drug targets. *Molecular Cancer Therapeutics*, 8(8), 2319-2328. doi:10.1158/1535-7163.MCT-08-1085
- <sup>6</sup> Solender, A. (2020). U.S. army halted tests on oleandrin, A drug touted to trump as covid-19 cure by MyPillow CEO lindell. Retrieved from <https://www.forbes.com/sites/andrewsolender/2020/08/19/us-army-halted-tests-on-oleandrin-a-drug-touted-to-trump-as-covid-19-cure-by-mypillow-ceo-lindell/>
- <sup>7</sup> Plante, K. S., Plante, J. A., Fernandez, D., Mirchandani, D., Bopp, N., Aguilar, P. V., . . . Weaver, S. C. (2020). Prophylactic and therapeutic inhibition of in vitro SARS-CoV-2 replication by oleandrin. *bioRxiv: The Preprint Server for Biology*, doi:10.1101/2020.07.15.203489
- <sup>8</sup> Phoenix Biotechnology, Inc. - Board of Directors. (2020). Retrieved from [http://www.phoenixbiotechnology.com/board\\_of\\_directors.php](http://www.phoenixbiotechnology.com/board_of_directors.php)