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January 28, 2020

The Honorable Stephen M. Hahn, MD
Commissioner of Food and Drugs
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr. Hahn:

I write today to inform you that the Food and Drug Administration (FDA) is this month's recipient of my Golden Fleece Award. The Golden Fleece Award, instituted by Sen. William Proxmire, highlights wasteful government spending by our nation's federal agencies.

A recent study published in *The Lancet* found that, of the trials conducted during an 18-month period that were required to be reported to clinicaltrials.gov, only 41% reported within the required one-year deadline and more than 35% did not report results at all.¹ Additionally, although the FDA has the authority to fine trial sponsors \$10,000 per day that a trial sponsor does not report results after the one-year deadline, the study found no evidence that the FDA has exercised this enforcement mechanism, which could have resulted in over \$4 billion in fines as of September 2019.

The findings of this study are concerning principally because of the public health implications of trial sponsors not reporting results. The absence of publicly released trial results can contribute to research waste, non-publication bias, and a distorted evidence base for clinical practice. The failure of the FDA to use the enforcement mechanisms available to it seems to be a failure to fulfill its mission to protect the public health. Additionally, when our nation is over \$20 trillion in debt, it is essential that our federal agencies act as good stewards of taxpayers' dollars.

I urge you to rectify this practice, and should you require any additional authority from Congress to address these concerns, notify us as soon as possible. Thank you for your consideration, and I look forward to working with you to address this important issue.

Sincerely,

French Hill
Member of Congress

¹ DeVito, N., Bacon, S. and Goldacre, B. (2020). Compliance with legal requirement to report clinical trial results on [ClinicalTrials.gov](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)33220-9/fulltext): a cohort study. *The Lancet*. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(19\)33220-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)33220-9/fulltext) [last visited January 28, 2020].