UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES

April 21, 2022

The Hon. Robert M. Califf, MD, MACC
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Dear Commissioner Califf,

On behalf of Universities Allied for Essential Medicines (UAEM), we welcome your appointment as U.S. Food and Drug Administration (FDA) Commissioner and leadership of one of our country's most critical agencies. We are particularly heartened to see your record of consistently and publicly calling for timely registration and results information reporting by clinical trial sponsors as required under law. Now, as you lead the FDA, which plays a critical role in enforcing this mandate, we hope that the agency will attend with real urgency to the significant but so far underserved issue of clinical trial registration and results reporting. As public trust in science[1] and the FDA[2] undergo concerning declines, it is more important than ever that the agency embrace transparency and take steps to improve patient, provider, and public access to scientific information. The COVID-19 pandemic has highlighted the need to ensure public confidence in the safety of new drugs and vaccines, honor the contribution of patients who bear the risks of clinical trials, and increase the efficiency of scientific innovation. Improving clinical trial transparency is an essential step toward those goals.

As you know, clinical trial sponsors—including universities, pharmaceutical corporations and medical device companies, and other organizations—are required to report results information from many interventional clinical trials under the FDA Amendments Act of 2007 (FDAAA), [3]

[1] Brian Kennedy et al., *Americans' Trust in Scientists, Other Groups Declines*, Pew Research Center (Feb. 15, 2022), https://www.pewresearch.org/science/2022/02/15/americans-trust-in-scientists-other-groups-declines/.
[2] Robert Wood Johnson Found. & Harvard T. Chan Sch. of Pub. Health, *The Public's Perspective on the United States Public Health System* (2021), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2021/05/RWJF-Harvard-Report_FINAL-051321.pdf.
[3] Food and Drug Admin., *Food and Drug Administration Amendments Act (FDAAA) 2007*, FDA.Gov (Mar. 29, 2018), https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-amendments-act-fdaaa-2007.

which was passed in response to industry malpractice and strategic veiling of poor results. FDAAA mandates that clinical trial sponsors input all eligible trial results information into the ClinicalTrials.gov database, including null and negative results. Should trial sponsors not comply with this law, the FDA can take enforcement action including issuance of fines of more than $10,000 for every late day. Although violations of the law have been so frequent and so flagrant that they could have generated over $30 billion in fines to date,[4] the FDA has historically neglected its duty to enforce FDAAA. The NIH, which shares enforcement authority with the FDA, has stated that they have no obligation to enforce the law unless the FDA takes action first. After significant pressure from the public, including our group of student advocates,[5] the FDA has taken limited enforcement action only in the past year, sending, to date, four Notices of Noncompliance to trial sponsors.[6]

By way of background, UAEM is a global student-led advocacy organization with its origins dating back to the height of the HIV/AIDS movement in 2001. We work to ensure a more equitable biomedical research system and access to its fruits, particularly those innovations which originate on university campuses. We believe universities and publicly funded research institutions will be part of the solution to the access to medicines crisis by promoting medical innovation in the public interest and ensuring that all people regardless of income have access to medicines and other health-related technologies. In 2019, we published our first report on clinical trial transparency at universities, which found that only 13 of the top forty academic medical research institutions in the United States were compliant with the law.[7] Our advocacy led to a 23% decrease in unreported results by target institutions by the time of our second report in 2021.[8]

However, this case-by-case improvement through student advocacy at research institutions has not been sufficient. Despite modest improvement, we found only 17 universities to be in full compliance with the law in 2021, and others have reported examples of noncompliance in clinical trial results reporting at academic institutions beyond our sample. Over three-fifths of thousands of clinical trial results from trial sponsors at universities, public research institutions,

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[4] FDAAA Trials Tracker, https://fdaaa.trialstracker.net/.

[5] Engelberg Ctr. on Innovation L. & Pol'y, *Food and Drug Administration Takes First-Ever Enforcement Action To Ensure Clinical Trial Transparency, Following NYU Technology Law & Policy Clinic's Work with Universities Allied for Essential Medicines (UAEM)*, New York University School of Law (June 30, 2021), https://www.law.nyu.edu/centers/engelberg/news/2021-06-30-uaem-fda-trial.

[6] https://www.fda.gov/science-research/fdas-role-clinicaltrialsgov-information/clinicaltrialsgov-notices-noncompliance-and-civil-money-penalty-actions

[7] Univ. Allied for Essential Meds. & TranspariMed, *Clinical trial transparency at U.S. universities: compliance with U.S. law and global best practices*, AltReRoute (Mar. 25, 2019), https://altreroute.com/clinicaltrials/assets/download/UniversityTransparencyReport2019.pdf.

[8] Univ. Allied for Essential Meds., *Clinical trial transparency at U.S. universities: a new report measuring legal compliance with clinical trial reporting obligations in 2021*, https://altreroute.com/clinicaltrials/assets/download/Clinical_Trials_Transparency_Report_UAEM_v5.pdf.

and the private sector remain noncompliant with results reporting requirements.[9] It is the FDA's responsibility to use its statutory authority to ensure improved compliance with the law, and with it, increased accountability and public trust in science. The FDA should therefore establish an actionable prioritization framework for enforcement of FDAAA, and demonstrate an intent to begin more rigorous enforcement.

In May of last year, we highlighted the need for an incoming FDA Commissioner who would commit to enforcing clinical trial registration and results reporting, in order to protect patients and improve societal trust in science.[10] We are encouraged to see that you have publicly recognized the importance of "transparent, interchangeable information" and the need for patient and public access to data on outcomes.[11] In addition, we strongly agree with your prior statement that reporting of clinical trial results is "fundamentally an ethical issue."[12] In 2016, President Biden also highlighted the need for stronger enforcement of clinical trial results reporting requirements at research institutions.[13] We hope that together, these statements are signs that the current leadership of the FDA will prioritize clinical trial results reporting and make significant progress on this front. We would appreciate the opportunity to meet with you to see if there may be ways for UAEM and the FDA to work collaboratively toward enabling greater compliance in registering and reporting clinical trials. We would be able to offer our understanding of the challenges universities face and the strategies they can use to improve reporting, as you address this critical issue. We look forward to hearing from you.

Sincerely,

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[9] Nicholas J. DeVito & Ben Goldacre, *Evaluation of Compliance With Legal Requirements Under the FDA Amendments Act of 2007 for Timely Registration of Clinical Trials, Data Verification, Delayed Reporting, and Trial Document Submission*, 181 JAMA Intern. Med. 1128 (2021).

[10] Joe Rabinovitsj, Celine Rohr & Reshma Ramachandran, *COVID-19 lesson: New FDA chief, when chosen, must crack down on clinical trial transparency*, Baltimore Sun (May 13, 2021), https://www.baltimoresun.com/opinion/op-ed/bs-ed-op-0514-fda-importance-20210513-x6cuesxc2ze5rogpkywledqlem-story.html.

[11] Derrick Gingery, *Califf Outlines Clinical Trial Reform Message, Which Could Travel With Him To Commissioner's Office*, Informa Pharma Intelligence (Nov. 22, 2021), https://pink.pharmaintelligence.informa.com/PS145289/Califf-Outlines-Clinical-Trial-Reform-Message-Which-Could-Travel-With-Him-To-Commissioners-Office.

[12] Sara Reardon, *U.S. toughens rules for clinical-trial transparency*, Nature (Sept. 16, 2016), https://www.nature.com/articles/nature.2016.20616.

[13] David Nather & Charles Piller, *Biden threatens funding cuts for researchers who fail to report clinical trial results*, STAT News (June 29, 2016), https://www.statnews.com/2016/06/29/biden-clinical-trials-cancer/.

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