TAG

Treatment Action Group

Comment on The Food and Drug Administration (FDA) Notice: Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Draft Guidance for Food and Drug Administration Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to the Food and Drug Administration

Treatment Action Group (TAG) fully supports the https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM607698.pdf proposed guidance regarding civil money penalties relating to the clinicaltrials.gov data bank.

Treatment Action Group (TAG) is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and hepatitis C virus. TAG works to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end HIV, TB, and HCV.

The clinicaltrials.gov registry is a vital resource for individuals seeking information on research protocols and for organizations like TAG that track the overall portfolio of clinical trials for specific conditions.

TAG has direct experience of the apparent nefarious entering of false information about proposed clinical trials into clinicaltrials.gov.

In a case encountered four years ago, a company that appeared to be little more than a shell had acquired the rights to an experimental candidate for HIV infection that had failed in several large studies, after the original manufacturer went out of business. This company sought to create a narrative that the candidate was undergoing further development, and created clinicaltrials.gov listings for trials that were not, in fact, going to occur.

At the time, representatives of clinicaltrials.gov stated they had no recourse to address the problem. In addition to misleading potential participants, the trials were cited in at least one published scientific review of current and planned research for the population that was stated to be the target for enrollment in the entries.

TAG encourages the administrators of clinicaltrials.gov to consider streamlining the process by which users can flag potentially problematic entries. Currently it takes

multiple steps to reach a form to report to the help desk, and it would be more useful to have a direct link from the trial listing page.

The addition of results to clinicaltrials.gov entries has been inconsistent in our experience, and TAG also supports enforcement to ensure more complete reporting. As such, we reiterate our unequivocal support for proposed guidance regarding civil money penalties relating to the clinicaltrials.gov data bank.

Suggested Additional Guidance

While not directly within the scope of civil money penalties, we take this opportunity to encourage the FDA to explore additional requirements to report to clinicaltrials.gov the cost of clinical trials. Spiraling drug costs are often justified by pharmaceutical companies as necessary to compensate for research and development (R&D); however, publicly available data on actual R&D costs are non-existent, and claims cannot be verified. Clinicaltrials.gov has been an invaluable resource for transparency in clinical trials; extending this transparency to R&D costs would be extremely beneficial. Having these data reported to clinicaltrials.gov, a natural choice for housing R&D data, would facilitate and streamline reporting additional information, minimizing burden on sponsors, and allowing the public to access all relevant clinical trials data in one place. We look forward to the possibility of supporting FDA and other stakeholders in developing an approach to requiring R&D cost data on clinicaltrials.gov.