Supplement to the preprint "Most clinical trials involving American children that violated FDAAA legal reporting requirements had not published outcomes in the scientific literature"

CORRESPONDENCE WITH THE U.S. FOOD AND DRUG ADMINISTRATION

- Email sent to FDA on 15 November 2022
- Reminder email sent on 08 December 2022
- No response received from FDA

Media enquiry: paediatric clinical trial FDAAA violations – RSVP by 22 November

To:
Chanapa.Tantibanchachai@fda.hhs.gov
Cc:
Michael.Felberbaum@fda.hhs.gov

Dear Chanapa Tantibanchachai,

We have identified 83 paediatric clinical trials involving American children that according to ClinicalTrials.gov records are in violation of reporting requirements set out by the FDA Amendments Act, Section 801.

Specifically, these trials are ACTs whose primary completion date lies more than 12 months in the past and that have not submitted summary results to ClinicalTrials.gov.

Attached a spreadsheet containing data on all 83 trials.

TranspariMED, a global campaign to improve medical research, is currently preparing a report on clinical trials involving American children that have not made their results public in violation of FDAAA. The report will highlight the harms to patients and waste of resources caused by companies and institutions that fail to make clinical trial results public, and will discuss the role of FDA enforcement in this context.

We will share the report with the media. We anticipate strong media interest. A list of previous media coverage generated by TranspariMED can be found here:
https://www.transparimed.org/about

Could you please provide an on the record statement answering the following questions for inclusion in the report:

(1) Have any of the 83 trials been incorrectly identified as violating FDAAA Section 801 reporting requirements? If yes, please flag the incorrectly identified trials.

(2) Has FDA taken any enforcement actions regarding any of the 83 trials, such as sending Pre-Letters of Notification? If yes, please provide individually for each applicable trial information on the type of enforcement action taken, its date, and its current status.

(3) How many Pre-Letters of Notification has FDA sent out to date in relation to FDAAA Section 801 reporting requirements (a) specifically for paediatric trials, and (b) for all trials?

(4) Going forward, what plans does FDA have to enforce FDAAA Section 801 reporting requirements (a) for paediatric trials and (b) for all trials?

(5) Going forward, what plans does FDA have to improve sponsors' compliance with FDAAA Section 801 reporting requirements?

Your response will be included verbatim in the report.

Please respond by COB Tuesday 22 November 2022.

Thank you for your time, I look forward to hearing from you,

Till Bruckner, PhD
TranspariMED
www.TranspariMED.org