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December 23, 2015

VIA ELECTRONIC TRANSMISSION

Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health
1 Center Drive
BG 1, Room 126
Bethesda, MD 20814

Dear Director Collins:

Medical professionals rely on timely and complete reporting of data to see how effectively a drug or device performs and to understand the frequency of side effects in order to make informed treatment decisions. This need for timely and reliable information is part of what motivated me to co-sponsor legislation to require the findings of clinical trials performed by industry, academia, non-profits and federal agencies be posted on the National Institutes of Health (NIH) website.¹ These requirements are now part of the Public Health Service Act.²

A recent report in STAT indicates that the required reporting is significantly incomplete.³ The article reports on a study conducted by STAT that finds that while the reporting record of drug companies has been poor, compliance by medical schools, teaching hospitals and nonprofit groups has been worse. Apparently only two companies managed to comply with reporting requirements more than half the time. Academic institutions did not report or were late 90% of the time. Even NIH staff

¹ ClinicalTrials.gov

² Public Health Service Act (42 U.S.C. 282) (j) Expanded clinical trial registry data bank

³ Law ignored, patients at risk, STAT, December 13, 2015 by Charles Piller
<http://www.statnews.com/2015/12/13/clinical-trials-investigation/#dataviz>

scientists who are required to post trial results have either failed to report or have reported late three quarters of the time.⁴

The law requires that “[t]he responsible party for an applicable clinical trial ... shall submit to the Director of NIH for inclusion in the registry data bank the clinical trial information described ... 21 days after the first patient is enrolled in such clinical trial.”⁵

The law also establishes that the Director of NIH is to make public notices on the website when there are reporting violations.⁶ The violations requiring the posting of notices to the registry and results data bank include failure to submit required information as well as submitting false or misleading information. The notices are required to include what penalties if any have been imposed and whether the responsible party for the clinical trial has corrected the information in the registry and results data bank.

In order to better understand how the reporting of clinical trial information is being reported and posted to ClinicalTrials.gov, please examine and report on the following questions no later than January 12, 2016:

1. For the last two years that data are available (calendar, fiscal or whatever period of account used), how many clinical trials of all types should have had information reported to NIH? Please categorize the type of responsible party for these clinical trials (industry, hospitals, academic institutions, federal government etc.).
2. For the same two years as question 1, how many of the required clinical trial reports were received on time? How many have not been received at all? Of those that were received late please provide an average and/or mean time until the required materials were received.
3. For the same two years as question 1, what was the average time it took from receipt of clinical trial data for NIH to post the information in the registry data bank?
4. For the same two years as question 1, how timely and how often did NIH post the required notices that submissions were late or not received at all?
5. Over the last five years, what efforts, if any, has NIH made to see that violations of these reporting requirements resulted in penalties being

⁴ Id.

⁵ Public Health Service Act (42 U.S.C. 282) (j)(2)(C)(ii)

⁶ Public Health Service Act (42 U.S.C. 282) (j)(5)(E)

assessed for the responsible party? Have any penalties been assessed for violations of the clinical trial reporting requirements over the last five years?

6. Please describe the steps NIH has taken and will take to see that clinical trials conducted by its own scientists, as well as those conducting work under an NIH grant, will comply with these reporting requirements.

Please contact Paul Junge of my Committee staff at (202) 224-5225 if you have any questions concerning this request. Thank you.

Sincerely,



Charles E. Grassley
Chairman
Committee on the Judiciary