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Congress of the United States

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Majority (202) 225–2927
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February 14, 2012

The Honorable Francis S. Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Collins:

We are writing to express our concern over a recent report documenting the underreporting of results of clinical drug trials. The most recent issue of the British Medical Journal contains a study by researchers from the University of Nottingham that finds that researchers and pharmaceutical companies routinely fail to publish data from clinical drug trials in a timely fashion. This study raises concerns whether NIH is adequately implementing the law requiring such reporting. We are also concerned that these publication delays may allow ineffective or dangerous drugs to remain on the market, resulting in significant harm to patients and waste in the health care system.

Section 801 of the Food and Drug Administration Amendments Act of 2007 requires publication of a results summary on clinicaltrials.gov for all "applicable drug trial(s)" initiated or ongoing as of September 2007 within 12 months of their completion.[1] An "applicable drug trial" under this section is a clinical investigation, other than a phase I clinical investigation, of a drug subject to section 351 or section 505 of the Federal Food, Drug, and Cosmetic Act .[2] NIH is responsible for maintaining the public database of drug trial results on clinicaltrails.gov, and FDA is responsible for enforcing the statutory requirements.[3]

The research published in the British Medical Journal found that of the 738 trials in 2009 for which reporting was mandatory under the FDAAA, only 22% were published within the

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[1] 42 U.S.C. 282(j)
[2] 42 U.S.C. 282(j)(I)(A)(iii)
[3] 42 U.S.C. 282(j)

required time period.[4] The parties responsible for the 575 clinical trials that did not publish results appear to be in direct violation of the FDAAA and subject to penalties of $10,000 per day.[5] We are unaware of any enforcement action related to these apparent violations.

Section 801 was enacted in response to similar reporting failures that contributed to dangerous or ineffective drugs remaining on the market far longer than they should have. For example, results of clinical trials for Vioxx and Avandia—which revealed that the drugs posed significant safety risks—were not made public until long after their completion, resulting in these drugs being prescribed to far more patients than likely otherwise would have occurred.[6] The new study suggests this underreporting is continuing today.

To help us understand this issue, we request that you provide answers to the following questions:

1) Do the findings of the new study outlined above correspond with NIH's internal data on compliance with the reporting requirements of Section 801 of the FDAAA? Please summarize NIH's internal compliance data.

2) Does NIH have adequate resources and authority to implement these reporting requirements?

3) Does NIH believe additional statutory changes are necessary to address the issues of underreporting of clinical trial data and non-compliance with the reporting requirements in Section 801 of the FDAAA?

Timely and accurate reporting of clinical drug trial results is critically important to reveal and reduce the risks from drugs already on the market and to allow physicians and patients to make informed health care decisions. We hope we can work together to make sure the reporting system is working as the law intends.

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[4] Andrew Prayle, Matthew Hurley, Alan Smyth, *Compliance with Mandatory Reporting of Clinical Trial Results on ClinicalTrials.gov: Cross Sectional Study*, British Medical Journal (Jan. 3, 2012)

[5] 21 U.S.C. 333(f)

[6] Henry A. Waxman, *The Lessons of Vioxx — Drug Safety and Sales*, New England Journal of Medicine (June 23, 2005) and
Drug Research Routinely Suppressed, Study Authors Find, McClatchy-Tribune News Service (Jan. 4, 2012)

Please contact Matthew Siegler or Rachel Sher with the Committee staff at 202-225-3641 with any questions about this request.

Sincerely,

Henry A. Waxman
Ranking Member

Edward J. Markey
Ranking Member
Natural Resources Committee

Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations