

Committee on Energy and Commerce
Rep. Henry A. Waxman, Ranking Member

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**Reps. Waxman, Markey, DeGette Call on FDA and NIH to Address
Failures in Reporting of Clinical Drug Trial Results**

WASHINGTON, DC – Today Rep. Henry A. Waxman, Rep. Edward J. Markey, and Rep. Diana DeGette wrote to NIH Director Francis Collins and FDA Commissioner Margaret Hamburg expressing concern over a recent report documenting the underreporting of results of clinical drug trials. The report, published in the British Medical Journal, found that researchers and pharmaceutical companies routinely fail to publish clinical trial data from drugs in a timely fashion, in apparent violation of the Food and Drug Administration Amendments Act of 2007. This study raises concerns about whether NIH and FDA are appropriately implementing and enforcing the law.

In the letter the members state, “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.”

NIH is responsible for maintaining the public database of drug trial results, while FDA is responsible for enforcing the statutory drug trial reporting requirements.