Factual Errors about ClinicalTrials.gov and Other Federal Mandates in Special Report by Shuster

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To the Editor:

The Special Report by Jonathan J. Shuster¹ contains numerous factual errors. For example, the section on ClinicalTrials.gov is based on a false premise: “a new requirement under consideration is that trials opened after March 1, 2012 (exact data as yet unknown), will have to provide [to ClinicalTrials.gov] patient level deidentified information...” As the author

was told, as early as October 2011, there has never been such a requirement under consideration. I want to assure your readers that ClinicalTrials.gov has no plans to collect participant level data; our system is designed for summary data only.

Reference

1. Shuster JJ. US government mandates for clinical and translational research. *Clin. Transl. Sci.* 2012; 217.

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REPLY

Reply: Letter to the Editor

Jonathan J. Shuster, Ph.D.

Dr. Zarin¹ questioned the plausibility of future patient-specific data element requirements, as raised in Shuster.² While Dr. Zarin did send me an e-mail that ClinicalTrials.gov had no plans for this to happen, I am not unique about this concern. In a well attended Webinar by Huron Consultants in February 2011 and posted on CTSpedia, a Website used by Clinical and Translational Science Awardees (see http://www.ctspedia.org/wiki/pub/CTSpedia/DiscussionForum002/ClinicalTrialsgov_2-11.pdf), Slide 15 suggested to many that this may happen. With a strong constituency for transparency, all it would take is a simple directive from congress. I believe ClinicalTrials.gov has no plans to require patient level data, since her e-mail and article, Zarin et al³ say this explicitly. However, Zarin et al.³ also point out that the lack of actual protocols and raw data make independent scientific review of database entries impossible. In actuality, I favor such requirements as long as they have government funding and data

use agreement requirements. Open access to trial data could serve as a gold mine for attorneys, who might try to second guess whether their client, who was harmed on the inferior treatment arm, was not adequately protected by the trial monitors.

Acknowledgement

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References

1. Zarin DA. Letter to the Editor. *Clin. Transl. Sci.* 2012; 217.
2. Shuster JJ. US government mandates for clinical and translational research. *Clin. Transl. Sci.* 2012; 217.
3. Zarin DA, Ide NC, Tse T, Harlan WR, West JC and Lindberg DAB. Issues in the registration of clinical trials. *JAMA* 2007; 297(19):2112–2120.

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