

ONLINE FIRST

Expression of Concern: Kiel et al. Efficacy of a hip protector to prevent hip fracture in nursing home residents: the HIP PRO randomized controlled trial. *JAMA*. 2007;298(4):413-422.

Howard Bauchner, MD

Phil B. Fontanarosa, MD, MBA

WE HEREBY ISSUE AN EXPRESSION OF CONCERN regarding the conduct of the research reported in the article entitled "Efficacy of a Hip Protector to Prevent Hip Fracture in Nursing Home Residents: The HIP PRO Randomized Controlled Trial," published in the July 25, 2007, issue of *JAMA*.¹ This study has been the subject of an investigation conducted by the Office for Human Research Protections (OHRP) in the Department of Health and Human Services regarding 45 CFR part 46, federal regulations that govern the ethical conduct of research.

After review of the reports from OHRP dated June 23, 2011,² February 17, 2012,³ and July 5, 2012,⁴ and evaluation of additional information requested by *JAMA* and provided to us by the participating institutions (Hebrew SeniorLife [an affiliate of Harvard Medical School], Washington University School of Medicine, and the University of Maryland School of Medicine), we concur with the OHRP determination that the failure to notify research participants about potential risks they may have experienced by participating in the study represents serious concerns regarding their protection as research participants in this study. Therefore, we are issuing this Expression of Concern regarding the ethical conduct of this study. When the study was first published in 2007, the authors acknowledged¹ and an editorial in *JAMA*⁵ anticipated that having only 1 hip protector could have altered the gait of participants and the propensity to fall to the protected side. However, at that time, the authors were not forthcoming with providing information *JAMA* requested that would have been informative in understanding this risk.^{2(p9)}

As a corrective action, OHRP required the investigators to notify the study participants or their legally authorized

representatives of its findings in writing.³ To inform our readers and other researchers about the seriousness and consequences of these matters, we requested that the institutions consent to our posting of a template of these notices as Supplemental material on the *JAMA* website (available at <http://www.jama.com>) and encouraged them to consider a similar posting on their institutional websites.

Based on information reported to *JAMA* by Hebrew SeniorLife, Washington University School of Medicine, and the University of Maryland School of Medicine in response to our requests, there was no evidence provided that raised concerns about the scientific integrity of the data and the veracity of the study conclusions; therefore, we are taking no further action at this time. If additional information should become available about the ethical conduct of this study, about harms to patients that occurred by virtue of failure of notification of possible risk, or about the scientific integrity of the research, we will evaluate that information carefully and determine whether additional notifications will be necessary.

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Online-Only Material: The supplement containing the 3 institutional notices is available at www.jama.com.

REFERENCES

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5. Kannus P, Parkkari J. Hip protectors for preventing hip fracture. *JAMA*. 2007;298(4):454-455.

Author Affiliations: Dr Bauchner is Editor in Chief and Dr Fontanarosa is Executive Deputy Editor, *JAMA*.