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January 7, 2016

The Honorable Linda A. Halliday
Deputy Inspector General
Department of Veterans Affairs
Office of Inspector General (50)
810 Vermont Avenue, NW
Washington, DC 20420

Dear Deputy Inspector General Halliday:

Public Citizen, a consumer advocacy organization with more than 400,000 members and supporters nationwide, today sent the enclosed letter to the Department of Veterans Affairs' (VA's) Office of Research Oversight (ORO) calling for a prompt compliance oversight investigation of the following clinical trial, which was conducted, in part, at three VA health care facilities:

> A Clinical Trial Comparing Cangrelor to Clopidogrel Standard Therapy in Subjects Who Require Percutaneous Coronary Intervention (PCI) (CHAMPION PHOENIX)
> Sponsor: The Medicines Company
> ClinicalTrials.gov Identifier: NCT01156571

Our letter to ORO explains in detail that the CHAMPION PHOENIX trial, as conducted at VA health care facilities, was unethical and failed to satisfy the requirements of VA human subjects protection regulations at 38 C.F.R. Part 16. In particular, the CHAMPION PHOENIX research protocol failed to mandate appropriately timed, effective antiplatelet therapy in control group subjects undergoing percutaneous coronary intervention (PCI). As a result, appropriate antiplatelet therapy with clopidogrel was delayed in the vast majority of control group subjects enrolled at VA medical centers until *after* the subjects had undergone their PCI procedures. Such delays represented substandard antiplatelet therapy and unnecessarily exposed subjects to risk of serious complications related to coronary stent thrombosis during and immediately after their PCI procedures. Therefore, the design and conduct of the trial failed to ensure that risks to control group subjects were minimized, as required by VA human subjects protection regulations at 38 C.F.R. §16.111(a)(1).

A key issue that requires further investigation, but falls outside of the scope of ORO's jurisdiction, is whether the inappropriate delays in clopidogrel administration to control group subjects enrolled in the CHAMPION PHOENIX trial were limited to the conduct of this trial or also reflect more widespread inappropriate antiplatelet therapy in veterans undergoing PCI procedures at VA health care facilities as part of their clinical care during the time when the trial was conducted (i.e., September 30, 2010, to October 3, 2012) and after the trial ended.

Therefore, we urge that the VA's Office of Inspector General (OIG) promptly launch an investigation to answer this question.

We look forward to OIG's thorough and careful investigation of this matter. We would be happy to meet with you to answer questions and provide additional information.

Sincerely,

Michael A. Carome, M.D.
Director
Public Citizen Health Research Group

Sidney M. Wolfe, M.D.
Founder and Senior Adviser
Public Citizen Health Research Group

Enclosure

cc: The Honorable Dr. David J. Shulkin, Under Secretary for Health, VA
Dr. J. Thomas Puglisi, Chief Officer, Office of Research Oversight, VA
The Honorable Jeff Miller, Chairman, House Committee on Veterans' Affairs
The Honorable Corrine Brown, Ranking Member, House Committee on Veterans' Affairs
The Honorable Johnny Isakson, Chairman, Senate Committee on Veterans' Affairs
The Honorable Richard Blumenthal, Ranking Member, Senate Committee on Veterans' Affairs