July XX, 2015

Joe V. Selby, MD, MPH Executive Director Patient-Centered Outcomes Research Institute 1828 L Street, NW Suite 900 Washington, DC 20036

Dear Dr. Selby,

The undersigned members of the AFib Optimal Treatment Task Force write to express our sincere appreciation for holding the Patient-Centered Outcomes Research Institute's (PCORI) June 9th stakeholder workshop on the use of new oral anticoagulants (NOAC). We are aware that stakeholder workshops examining other important diseases were held on the same day. We also understand that PCORI may not have the ability to provide resources to support every project resulting from these discussion, but we urge you prioritize funding for all of the research questions identified during the NOAC workshop because they will help improve health outcomes for older adults with atrial fibrillation (AFib).

As you know, AFib is the most common form of cardiac arrhythmia, affecting about 5% of patients age 65 or older, and 10% of patients age 80 or older. Those afflicted with AFib are at an increased risk of stroke and AFib-related strokes are deadlier than non-AFib-related stroke, with roughly twice the mortality rate. Additionally, the condition is associated with an approximate doubling of the risk of all-cause mortality and is a contributory cause of death for around 99,000 Americans each year. To reduce stroke risk, patients with AFib are often treated with anticoagulant or antiplatelet therapy, both of which increase the risk of bleeding— from minor bleeding to fatal hemorrhage. While oral anticoagulation is highly effective at reducing stroke risk, elderly patients are often under-anticoagulated owing in part to under-appreciation of the stroke risk associated with AFib, the tendency of some health care professionals to prioritize bleeding risk over stroke prophylaxis, concern over falls and bleeding risk, and limited competency with NOACs.

On October 16, 2014 we convened a <u>symposium</u> with representatives from federal agencies, patient advocacy groups, and medical professional societies to discuss those factors leading to undertreatment of older AFib patients and to identify gaps in current clinical practice, education, research, and policy. Symposium participants concluded that an integrated, national effort is needed to promote adoption of best practices, develop alternate reimbursement models, expand patient and caregiver education on stroke risk and treatment, leverage existing initiatives, and address gaps in research on stroke and bleeding in AFib. We feel that the research priorities emerging from the PCORI workshop will close important information gaps on appropriate treatment with NOACs and improving patient adherence to these medications.

AFib has proven to be a major economic burden for the United States. At least \$6.65 billion in health care costs are attributable to the condition each year. The \$6.65 billion a year estimate for

direct health care costs from AFib may in fact be extremely low. One study estimates that Medicare pays \$15.7 billion per year to treat newly diagnosed AF patients. Based on demographic factors, the American Heart Association estimates the annual healthcare expenditures related to stroke can be expected to increase to \$140 billion by 2030.

Due to the prevalence of AFib among aging Americans and the cost of the disease, we believe it is critical to devote further resources to tackling the condition. Such research is critical for improving anticoagulation rates and reducing the burden of AF. Thank you for considering our views. If you should have any questions, please contact Ryne Carney at rcarney@agingresearch.org or (202) 293-2856.

Sincerely,

Alliance for Aging Research