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To Whom It May Concern:

It is common knowledge among foot and ankle surgeons that the Augment pivotal trial is being discussed at the FDA in May and I would like to provide support regarding the research design and study implementation. As the Editor of Foot and Ankle International, the journal of the American Orthopedic Foot and Ankle Society, and an experienced researcher, I have been exposed to the Augment PDGF safety and pivotal trials. After rigorous peer review, we have accepted the initial safety study on Augment for publication. I am very familiar with the pivotal trial which mirrors the study design of the safety study and believe it to be of the highest level of science, a Level 1 prospective randomized trial with excellent outcome measures and the largest trial to date in foot and ankle with 37 centers involved in this initiative. The study includes validated pertinent outcome measures, safety assessments and radiographic criteria to assess fusion rates with Augment vs Autologous bone graft (a non-inferiority study). The radiographic assessment of fusion with the use of CT is clinically more appropriate than plain radiographs themselves, and our reviewers particularly supported the use of this technology to assess fusion rates. It is this level of science that we strive to obtain to assess efficacy and inform our readers and patients on treatment options for clinically important problems.

Sincerely,

David B. Thordarson, M.D.  
Editor-in-Chief, Foot and Ankle International  
Professor, Dept. of Orthopedics  
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