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Mr. Hetzel reported owning publically traded shares of Cardiovascular Systems Inc., a cardiovascular instrument development business for commercializing innovative solutions for treating peripheral and coronary vascular disease. The total value current value is < \$5,000.

Professor DeMets reported that he is a consultant to the National Institutes of Health, the Food and Drug Administration and the pharmaceutical and medical device industry on the design, monitoring and analysis of clinical trials. He receives compensation for serving on several industry sponsored data and safety monitoring committees including Astra Zeneca, Sanoti, Boehringer Ingelheim, Teva & Abbvie . He holds no stock in any pharmaceutical or

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All authors had access to the data and a role in writing the manuscript.

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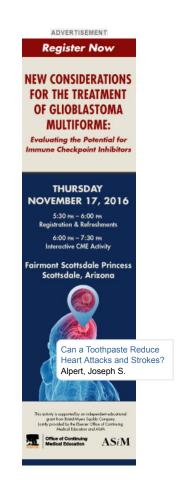
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