Implications on Drug Labeling

Norman Stockbridge
Division of Cardiovascular and Renal Products, FDA/CDER
Strong priors

• Radial artery bleeding will be easier to manage
• Opportunity to have a fatal retroperitoneal-equivalent bleed is low

This probably suffices to overcome usual reservations regarding reliance upon a non-randomized registry to support assessment of comparative safety
Labeling likely

- Adverse Reactions section?
- Probably not cite specific TREATT results
- Agents with approved use based on studies with fPCI
- Cited bleeding results can be expected to be less with rPCI
Other (labeling?) considerations

- TREATT no help in concluding rPCI outcome as good as fPCI

- If the dose of antiplatelet agent that you use with fPCI is not already providing maximal inhibition, ought not the dose with rPCI be increased?