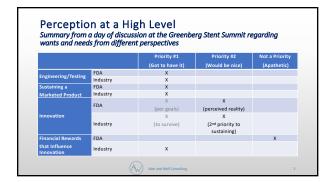


Disclosures

- I am a paid consultant to multiple medical device companies.
- My presentation will not include evidence or clinical recommendations and will not promote any technology.









FDA • FDA's mission is to protect and promote public health without consideration of the costs associated with meeting their requirements Investors • An investor's job is to generate returns on investment • Extensive testing requirements (e.g., rapdomized clinical studies) greatly influences the willingness to invest Investors • An investor's job is to generate returns on investment • Extensive testing requirements (e.g., rapdomized clinical studies) greatly influences the willingness to invest

What can we do to help?

- Understand the innovation landscape
- Clinicians can help both industry and FDA with prioritization (e.g., information needs, device improvements, unmet needs)
- Support industry in communicating with FDA
 It can mean the difference between acceptance and rejection of evaluation strategies
- Encourage surgical societies to engage with FDA
 Societies can provide support to FDA and industry in defining appropriate evaluation strategies and respectfully educating FDA regarding unmet needs



