Different Perspectives From Industry and the FDA Regarding the Importance of Innovation, Engineering and Financial Rewards that Influence Innovation

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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.

Perception at a High Level

Summary from a day of discussion at the Greenberg Stent Summit regarding wants and needs from different perspectives

		Priority #1 (Got to have it)	Priority #2 (Would be nice)	Not a Priority (Apathetic)
Engineering/Testing	FDA	X		
	Industry	X		
Sustaining a Marketed Product	FDA	X		
	Industry	X		
Innovation	FDA	X (per goals)	X (perceived reality)	
	Industry	X (to survive)	X (2nd priority to sustaining)	
Financial Rewards that Influence Innovation	FDA			X
	Industry	X		

Engineering/Testing

- FDA sometimes wants more testing than industry believes is necessary when it comes to sustaining a marketed product or innovating (i.e., introducing new or improving currently marketed devices)

Sustaining a Marketed Product vs Innovation

Industry

- There are extensive/expensive FDA expectations around testing for some vascular devices
  - To support upkeep on currently marketed products, for example:
    - Post-approval studies with extended follow-up durations
    - Resource to address FDA data expectations around supplier changes, manufacturing improvements,…
  - To support the introduction of new or modified devices, for example:
    - EFS principles are not being applied (e.g., just-in-time testing) for devices early in development
    - Extensive repeat testing is expected for device modifications
- Industry has no choice but to put sustaining marketed products above innovation
- Currently R&D funds are being diverted to meeting requirements around sustaining marketed products

FDA

- FDA (unknowingly) is putting certainty around the safety and effectiveness of (some types of) marketed devices above innovation

Financial Considerations

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., randomized clinical studies) greatly influences the willingness to invest

Industry

- To stay competitive, industry must innovate; staying competitive is difficult in the presence of economic, global supply chain, and regulatory constraints
- Industry wants to bring the best devices to the patients; however, in a reasonable time, at a reasonable cost, with an acceptable margin
- Innovation is not possible if R&D funds are directed toward sustaining marketed products

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

Thank you