2019 Translational Medicine Symposium: Medical Device Innovation

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"I'll be happy to give you innovative thinking. What are the guidelines?"
Product Development & Approval

- **US: Class I, II, III devices**
  - All devices must conform with FDA general controls, but many require “special controls”, i.e. more non-clinical and/or clinical testing prior to marketing (510k premarket clearance)
  - Class III requires Premarket Approval (PMA)
  - FDA publishes guidance documents for many types of devices and approval pathways

- **EU: CE Mark – notified bodies –** focus primarily on safety and manufacturing rigor (e.g. ISO certifications)
Why start with boring regulatory slide?

• Bringing a product to market requires a multidisciplinary team of good managers, engineers, clinicians, regulatory/quality experts, manufacturing gurus, patent lawyers, etc.

• It also requires $$$
  • Average 510(k) / Class II product can cost $10-30 million to approval
  • Class III / PMA > $50 million is more typical

• And it requires time
  • Class II often 2-5 years
  • Class III can be longer
It gets Worse before it gets Better ...
(or, all you wanted to hear about reimbursement)

• The FDA, time and money are not the only hurdles to be overcome.

• Who will pay for the new device?
  • Coding
  • Reimbursement
  • Technology Assessment / Coverage

• This process can take years, depending on novelty of device/procedure.
“Uh-oh, your coverage doesn’t seem to include illness.”
Now that we’ve seen the Bad and the Ugly, Here’s the Good ...

• There are many large unmet medical needs.

• Currently the US medical device market is $180 Billion and growing at >5% annually.

• Larger medtech companies have an insatiable need for growth fueled by new products and markets.

• Successful devices addressing a large market can command good acquisition prices upon product approval or sales.
Return on Capital is Key to Success

• **Goal:** Develop and commercialize your novel product for substantially less capital than could be obtained in an acquisition.

• Most VC investors will assume that successful start-up medical device companies could be eventually acquired for $50-150 million. Of course there are outliers …

• Speed and capital efficiency are critical. That means choosing the best idea and assembling the right team/talent around the table early.
Sources of Early Capital to Build Team and Product

• SBIR and other grants

• Friends, Family, Fellow clinicians who see the value

• Other angel/individual investors

• Occasionally strong industry relationships can lead to capital as well.
“Never, ever, think outside the box.”
Thank you!