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

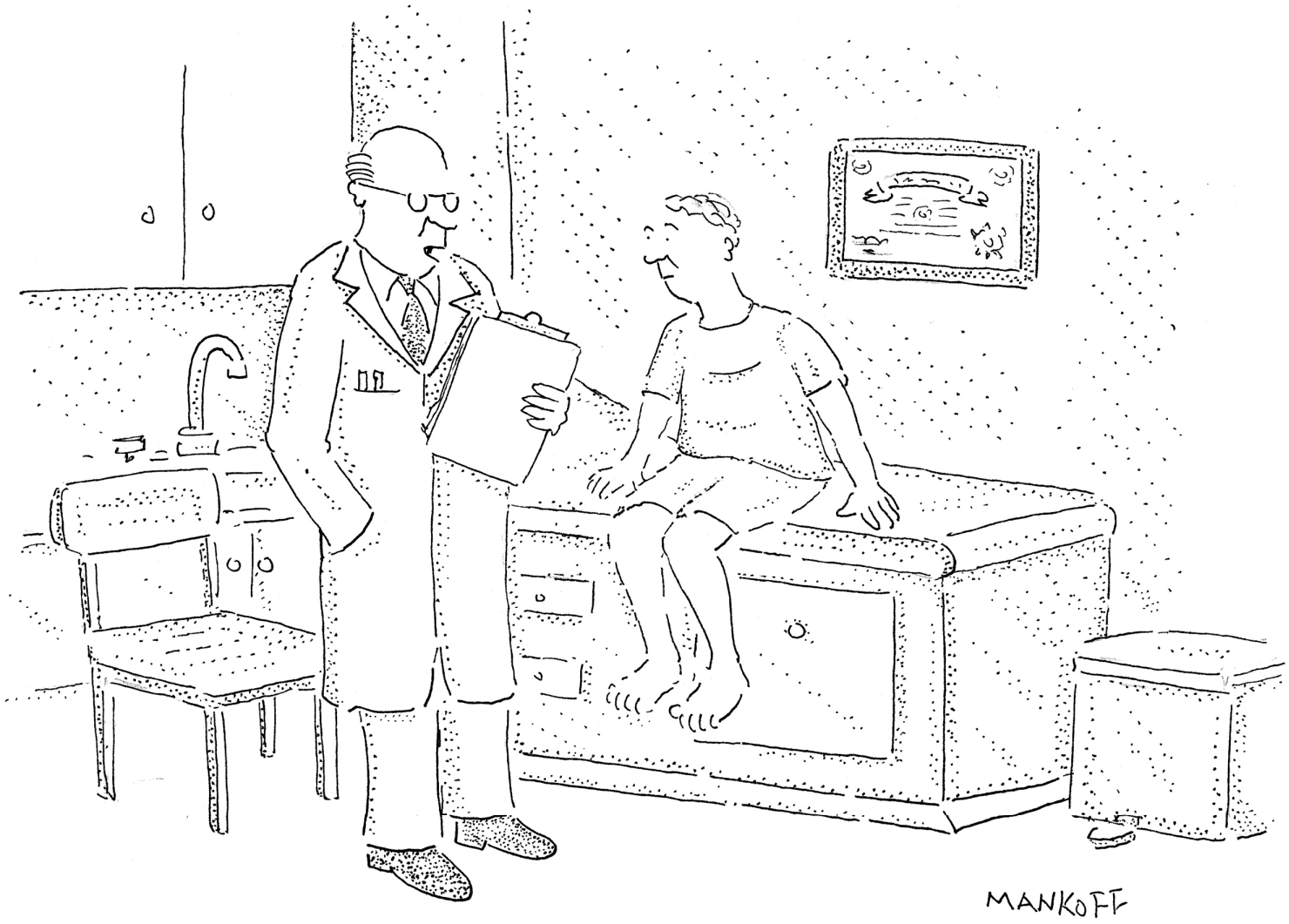
- And it requires **time**
  - Class II often 2-5 years
  - Class III can be longer

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 !