Entrepreneurship in the Medical Device Industry

Prof. Steven S. Saliterman
Department of Biomedical Engineering, University of Minnesota
http://saliterman.umn.edu/

Entrepreneurship

- "An entrepreneur is someone who organizes, manages, and assumes the risks of a business or enterprise."
  - An entrepreneur profits by marketing a new combination of resources (their "discovery") whose value is greater than the next-best alternative for those resources.
  - Opportunity cost is the loss of potential gain from the alternative.
  - Profit reflects the amount by which the resources have increased in value by the new endeavor.
  - Loss occurs if there is a reduced value. A learning experience!
  - Consider a novel polymer tubing presently marketed as a flexible fuel line. What if instead it was useful as a catheter for coronary artery procedures?

- The entrepreneur is an innovator who implements change in an economy by introducing new goods or new methods of production.
- Creative destruction – introduction of new products results in the obsolescence or failure of others.
- Funding follows ideas, not vice versa.
  - Infusions of venture capital funding do not necessarily foster entrepreneurship.
  - Promoting individual entrepreneurs is more important for economic development policy than is attracting venture capital at the initial stages.
  - While funding may increase chances of survival, it does not create new ideas.

**Traits of an Entrepreneur...**

- Has identified an opportunity.
- Can research and understand the possibilities within an opportunity.
- Knows that failing is always an option and that failure provides data that in turn leads to a better understanding of the problem and solution.
- Understands intricacies of research and commercialization or has a team that does.

**Physician as Entrepreneur...**

- Device manufacturers gain more from the patents of physician founded firms than from those of non-physician founded firms in their subsequent invention and innovation efforts.
- Investment in the physician founded firm leads to the use of more of its patents.

---


Prof. Steven S. Saliterman.
Physician–founded companies contribute a far greater amount of information to the devices for which incumbents ultimately seek approval.
- On average physician founded companies account for 11% of the information in a premarket application, compared with only 4% from non–physician founded companies.
- About 6.5% of the PMAs were >30% a result of information from physician patents, whereas 39% were >10% from physician–founded companies.

The Sunshine Act (section 6002 of the ACA 2010)
- Disclosure to CMS of physician payments from medical product manufacturers. Detriment to innovation?

Senior Design
- Senior design courses (or “capstone design”), provide clinical experiences, seminars, team effort and presentation of a medical device prototype.
- Seminar topics may include (alphabetically):
  - Business plan writing.
  - Commercialization
  - Customer validation.
  - Design controls and specifications.
  - Intellectual property.
  - Preclinical experiments.
  - Regulation.
  - Risk management.
  - Usability.

Setting Priorities...
- In senior design you will apply what you have learned toward the solution of a real-world problem.
- You should first learn how to design products that perform as required, and do not fail or injure patients. Technical skills come first!
- Develop a basic understanding of business concepts, such as cost, finance, and marketing, and a focus on the customer.
Realistic Expectations...

- 75–95% of venture-backed start-up firms in the United States fail.¹
  - Senior design does not teach entrepreneurship per se.
  - Consider alternative learning venues such as elective courses, workshops and student organizations.²
  - Developing skills is more important than being concerned about starting a new company.²
  - There is nothing wrong with being an “intrapreneur”—working for an established company.²
  - That said, if you so desire and are capable, being an entrepreneur has its rewards.

Summary

- Technical skills come first!
  - Design good products that do not injure patients.
- Understand basic business concepts before starting a new company.
  - Consider working for a company as an “intrapreneur.”
- Seek help and guidance.
- Be realistic about your goals, understand the risks, and consider alternative approaches to profiting from your expertise, ideas and discoveries.