Entrepreneurship in the Medical Device Industry

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

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- Understands how potential customers like hospitals and insurance companies do business – e.g. reimbursement methods.
- Builds an *A–Team* from day one.
- Can be *scientific, optimistic, and realistic.*

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.
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?

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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.

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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.