

Entrepreneurship in the Medical Device Industry

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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.

- ▶ 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*.

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.*

- ▶ 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.

Goldberg, Jay. "Entrepreneurship in Capstone Design: Has the Pendulum Swung Too Far? [Senior Design]." *Pulse, IEEE* 5, no. 5 (2014): 58-62.

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.*

1. D. Gage. (2012, Sept. 20). The Venture Capital Secret: 3 out of 4 Startups Fail. Wall Street J. Online. [Online].
2. Goldberg, Jay. "Entrepreneurship in Capstone Design: Has the Pendulum Swung Too Far? [Senior Design]." *Pulse, IEEE* 5, no. 5 (2014): 58–62.

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.