Product Development and Reimbursement

Vicki Farrar, JD
Greg Jones, PhD
Nic Anderson, MA MBA
Idea!

Product to disinfect & protect BOTH IV connectors
Drawer of Disposable Medical Devices in a Hospital Room
Customer Feedback

Reality

Perceived Waste
The DualCap System™

- Use when disconnecting IV tubing from catheter
- Use when setting up new IV tubing
- Use when only one connector needs capping

- Pouches color-coded for contents
- Completely sterile
Market Research - New Delivery

Early Design

Final Design – IV Pole Strips™
Litigation

• Green cap company sues all competitors for infringement (So. Cal.)

• We sue green cap company for infringement of our dark blue cap technology and unfair competition (Utah)

Catheter Connections has a Robust Patent Portfolio
Critical Asset, Constantly Revised & Monitored
iVeena

Relevant Research, Transformational Therapy

Product Development and Reimbursement

3rd Annual Translational Medicine Symposium
February 19, 2013

Greg Jones
Interim CEO, iVeena
iVeena’s Clinical Mission

To make Highly Effective Ophthalmic Therapies combining Proven, Clinically Effective Drugs with Innovative Drug Delivery Technology

iVeena
Relevant Research, Transformational Therapy
Initial Patient Population Target

Cataract/Macular Degeneration

- 3 million surgeries per year in the U.S.
- 200 million cataract patients worldwide
- Very large cross section with AMD

iVeena

*Relevant Research, Transformational Therapy*
Adjustments

AMD

- [x] Unmet Medical Need
- [x] Return would support costs
- [x] IP - Position in the Eye
- [x] Feasibility in Animal
- [x] FDA Feedback (pre-IND meeting)

iVeena

Relevant Research, Transformational Therapy
Adjustments - Market/Drug

Inflammation and Glaucoma

- ✔ Unmet Medical Need
- ✔ Return would support costs
- ✔ IP - Position in the Eye
- ✔ Feasibility in Animal
- ✔ FDA Feedback (informal discussion)
- ✔ CMC consultant
- *FDA consultant

iVeena

Relevant Research, Transformational Therapy
Adjustments - Redesign

Inflammation and Glaucoma

- Unmet Medical Need
- Return would support costs
- IP - Position in the Eye (FTO opinion)
- Feasibility in Animal
- FDA Feedback (informal discussion)
- CMC consultant
- FDA consultant
- Is financing available

iVeena

Relevant Research, Transformational Therapy
Adjustments - Market/Drug

Inflammation

☑ Unmet Medical Need
☑ Return would support costs
☑ IP - Position in the Eye (FTO opinion)
☑ Feasibility in Animal
☑ FDA Feedback (informal discussion)
☑ CMC consultant
☑ FDA consultant
☑ Is financing available

iVeena

Relevant Research, Transformational Therapy
iVeena

Relevant Research, Transformational Therapy

3rd Annual Translational Medicine Symposium
February 19, 2013
Payment or Reimbursement

1. Technology created by scientist and VC
2. Sales representative sales to physician/hospital
3. Doctor treats patient with new technology
4. Doctor spent someone else's money
5. Doctor asks to be reimbursed from patient’s insurance company
Principal-Agent Problem

- Physician buys...but doesn’t pay
- Insurance company has limited funds
Evidence Based Medicine: Blue Print for a Successful Product Launch

1. Technology must have FDA approval
2. Evidence must show clinical efficacy
3. Technology must improve net health outcomes
4. Must be as beneficial as established alternatives
   - This is all or nothing
   - Notice, there’s no mention of money
Watch-outs!

• Get funding specifically for clinical trials
  – RCT, Blinded, Placebo, Sham, Prospective, Multi-centered...

• Collect peer-reviewed data from day one

• Publish, publish, publish

• Logic and intuition are poor substitutes for science