

How Big Companies Innovate New Products

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Disclosure

- Employed by W.L. Gore and Associates
- Not a M.D., but Ph.D. (Biomedical Engineering)

Overview: Innovation at Big Companies

- What are the considerations of big companies regarding innovation?
 - Big companies typically look at the market first, then identify/develop the technological solution
 - Ideas to innovate come from various places
 - The **customer** is most important and their needs must be satisfied...

Innovation at a “Big Company”

Innovation:

- The commercialization of *something* (ie medical device) into the market

Company:

- Some entity with purpose of generating revenue, typically desiring to be profitable

How does a company generate revenue?

- Sell *something* to a CUSTOMER

Who is the “customer”?



www.forixcommerce.com

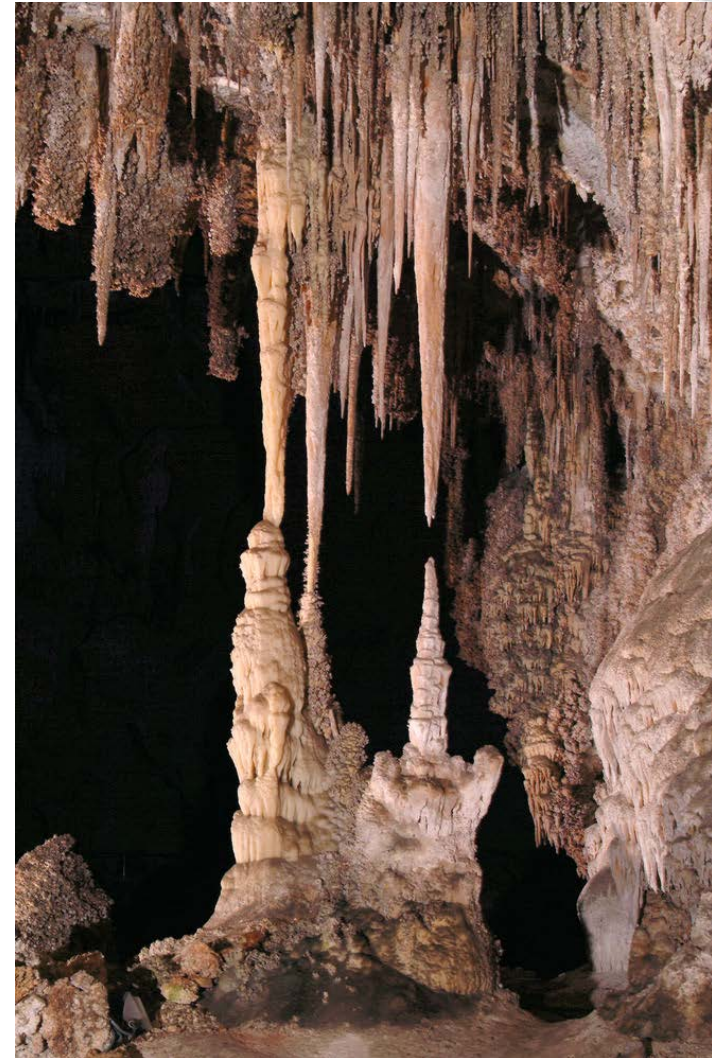
The goal of *innovation* is to develop and commercialize something valuable into the market

1. Stalactite: Top to bottom

Develop the TECHNOLOGY
→ to meet CLINICAL NEED

2. Stalagmite: Bottom to top

Assess the CLINICAL NEED
→ to meet TECHNOLOGY



Where do ideas come from?

INSIDE the Company

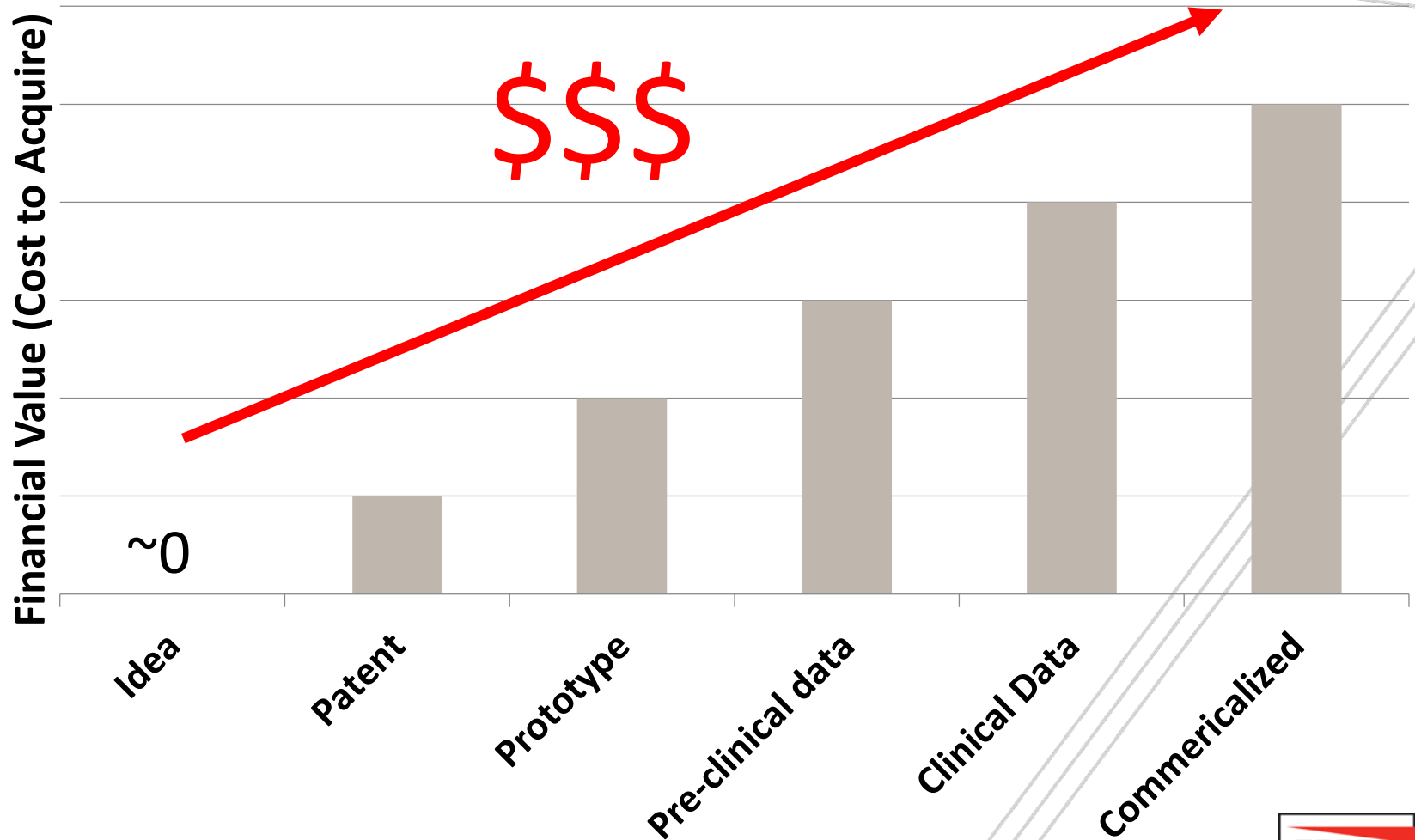
- Company engineers and business/finance folks
 - Manufacturing improvements (increase profitability)
 - Exploitation of core technologies
 - Incremental improvements on existing products line-extensions

OUTSIDE the Company

- Physicians, Academia, Start-ups
 - Challenge of ownership of the idea



Idea value during innovation cycle



Defining the customer and determining their needs: 4 P's (+1)

1. **P**atient (beneficiary)
2. **P**hysician (user)
3. **P**ayer (reimbursement)
4. **P**rovider (purchaser, literal “customer”)
5. **P**olicy Maker (*government*)

All the needs of the 4+1 P's must be satisfied, at least to some extent, for a medical device to be successful in market place

P1: Needs of the **PATIENT** as a customer

- What does the ESRD patient want?
 - To be cured, “get their life back”
 - Limited / no re-interventions
- Device must have benefit to the patient
 - The device shows positive difference from existing technology and/or treatment options
 - If the device doesn’t help the patient, is it worth bringing to market?
- Obviously the most important “customer”
 - But the patient does not directly give money to the company...



www.cdc.gov

P2: Needs of the **PHYSICIAN** as a customer

- The physician, as an end-user, must be wanting and able to “use” the device
 - But do they give money directly to company?
 - Sometimes... (Physician owned practices)
- They want to see the product’s value
 - How is it made and how does it work?
 - How does it get used? (Usability)
 - What is the clinical performance data?
 - How is it better, faster, cheaper than what they currently do or currently use?
- What does the physician want?
 - Something that can be used to best treat the patient
 - A device to treat the condition the best way possible



<http://www.haivision.com/>

P3: Needs of the **PAYER** as a customer



- Payer: Entities other than the patient that finance or reimburse the cost of health services.
- If the payer is not going to offer **adequate reimbursement** for the procedure and purchase of a device, then most likely the device will not be purchased.
- What does the payer want?
 - To provide the best, most durable solution and have reduce overall treatment costs

P4: PROVIDER as a customer

- The provider can be an individual hospital or a group of hospitals
 - Purchasers and New Product Committees typically decide what products are on the shelves of hospitals
- The provider is usually the entity actually paying a company for a device: **Literal customer**
- What does the Provider value?
 - Lowest cost, best performance
 - Reducing part numbers in inventory
 - Health economic data
 - Limited patient re-admissions
 - Low sepsis rates



5th P: *Policy Maker* as a customer

Government entities who have impact and influence on medical device development and commercialization.

- Their needs need to be satisfied, therefore making them a form of “customer”.
- **Food and Drug Administration (FDA)**
 - Approve or clear the release of a product to market based on demonstration of safety and efficacy (510k, PMA)
- **Center for Medicaid and Medicare Services (Payer)**
 - Approve reimbursement for use of product
- **United States Patent and Trademark Office (USPTO)**
 - Without an issued patent to protect an idea, others can copy your idea and take-away your business

How do big companies successfully innovate to satisfy all needs of the customers and make money?

- **Patient:** Design a device with demonstrable clinical benefit
- **Physician:** Make device usable and convince with data that device is better than alternatives
- **Provider:** Generate cost saving data and/or health economic argument
- **Payer:** Ensure reimbursement exists for device
- **Policy Maker:** Satisfy regulatory approval requirements, patent protection

Vascular Access: The 4P's

Effort made to gauge the value of idea to each of the 4 P's prior to development effort (Scope the Market)

- **ESRD Patient**

- Don't want to be on dialysis, they "want their life back"
- Durable access, no complications, limited re-interventions, maintain dialysis schedule

- **Physician**

- Typically desiring to provide best care for patient, more durable dialysis access, value added technology that's usable

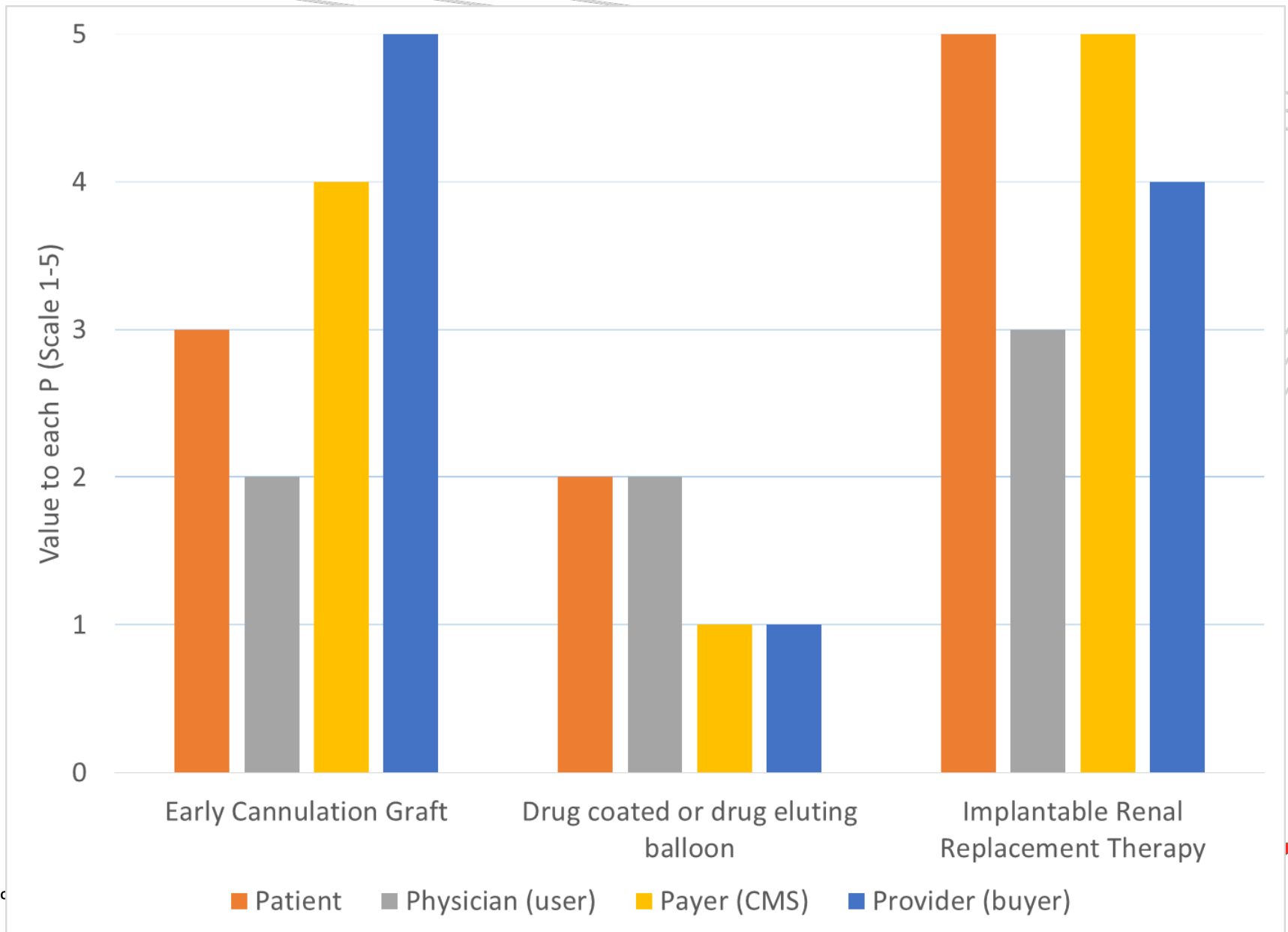
- **Payer**

- More durable access, alternate therapies, lower sepsis rates

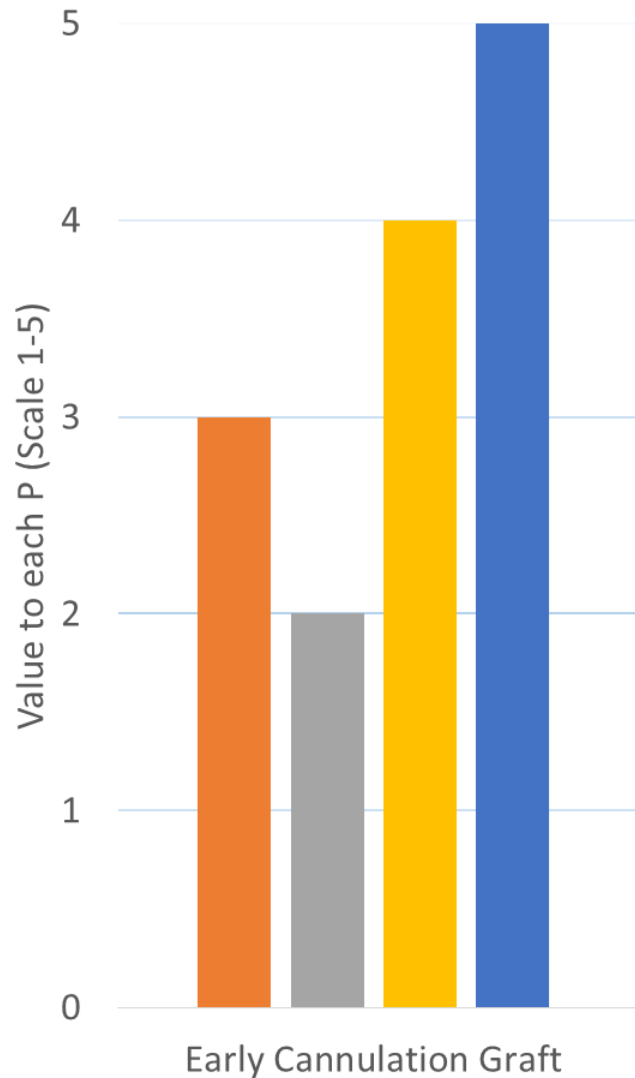
- **Provider**

- Durable access, limit readmissions, lower sepsis rates

Examples: Arbitrary value to the 4 P's



Examples: Early Cannulation Graft



Technology is Real
Customer Value is Real

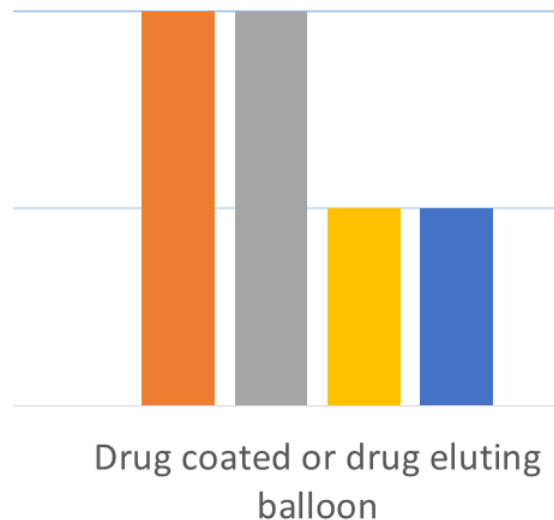
- Patient: Prefer functioning graft over CVC
- Physician: User may not prefer handling characteristics
- Payer: Values the potential to lower CVC usage and associated sepsis
- Provider: Desires lower sepsis rates

Examples: Drug Eluting/Coated Balloons

5 Real Technology / Uncertain Customer Value

- Patient: May improve access durability
- Physician: May improve outcomes, "no leave behind"
- Payer: No increase in reimbursement over POBA
- Provider: May not like increased cost

Value to each P (Scale 1-5)

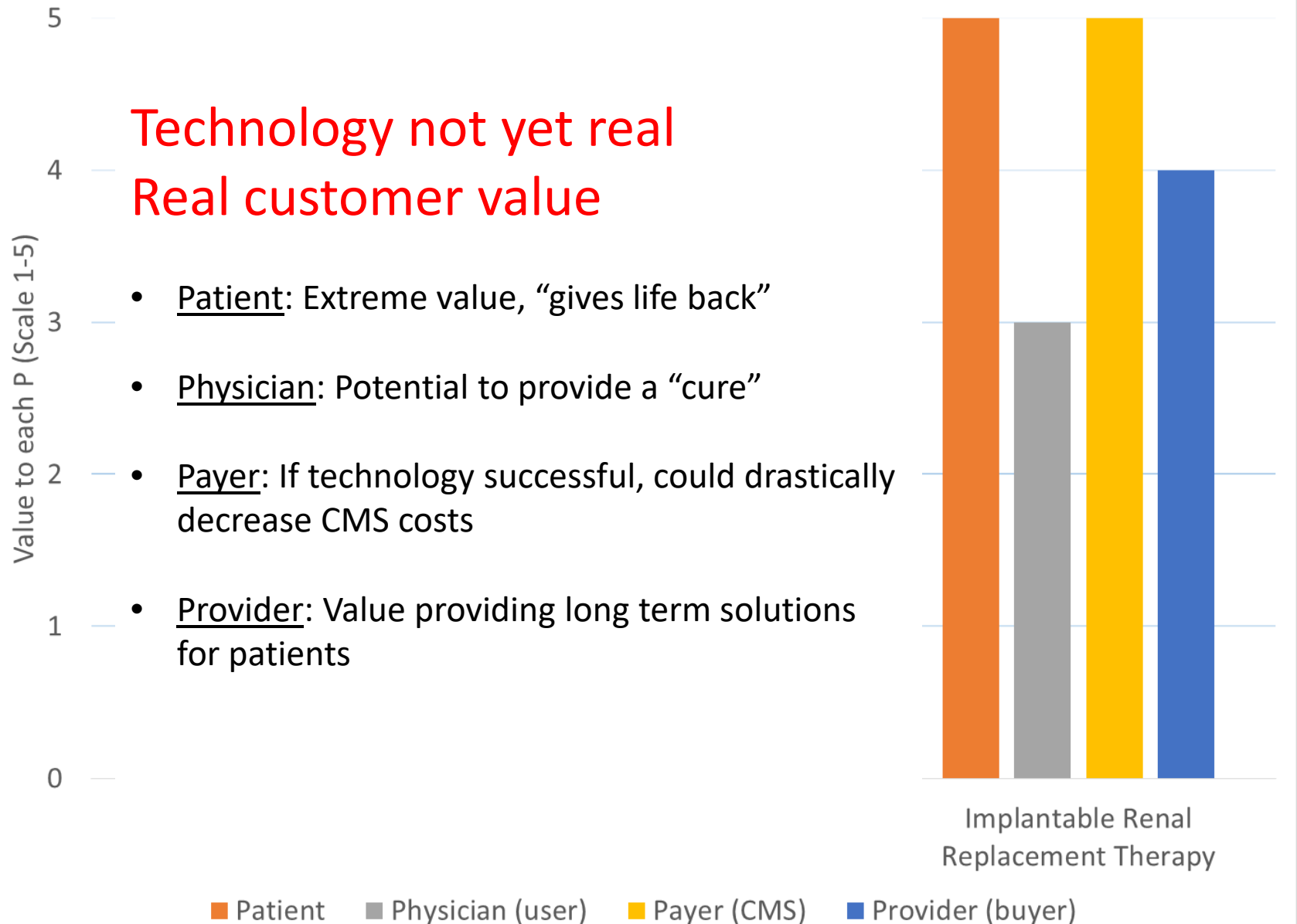


■ Patient ■ Physician (user) ■ Payer (CMS) ■ Provider (buyer)

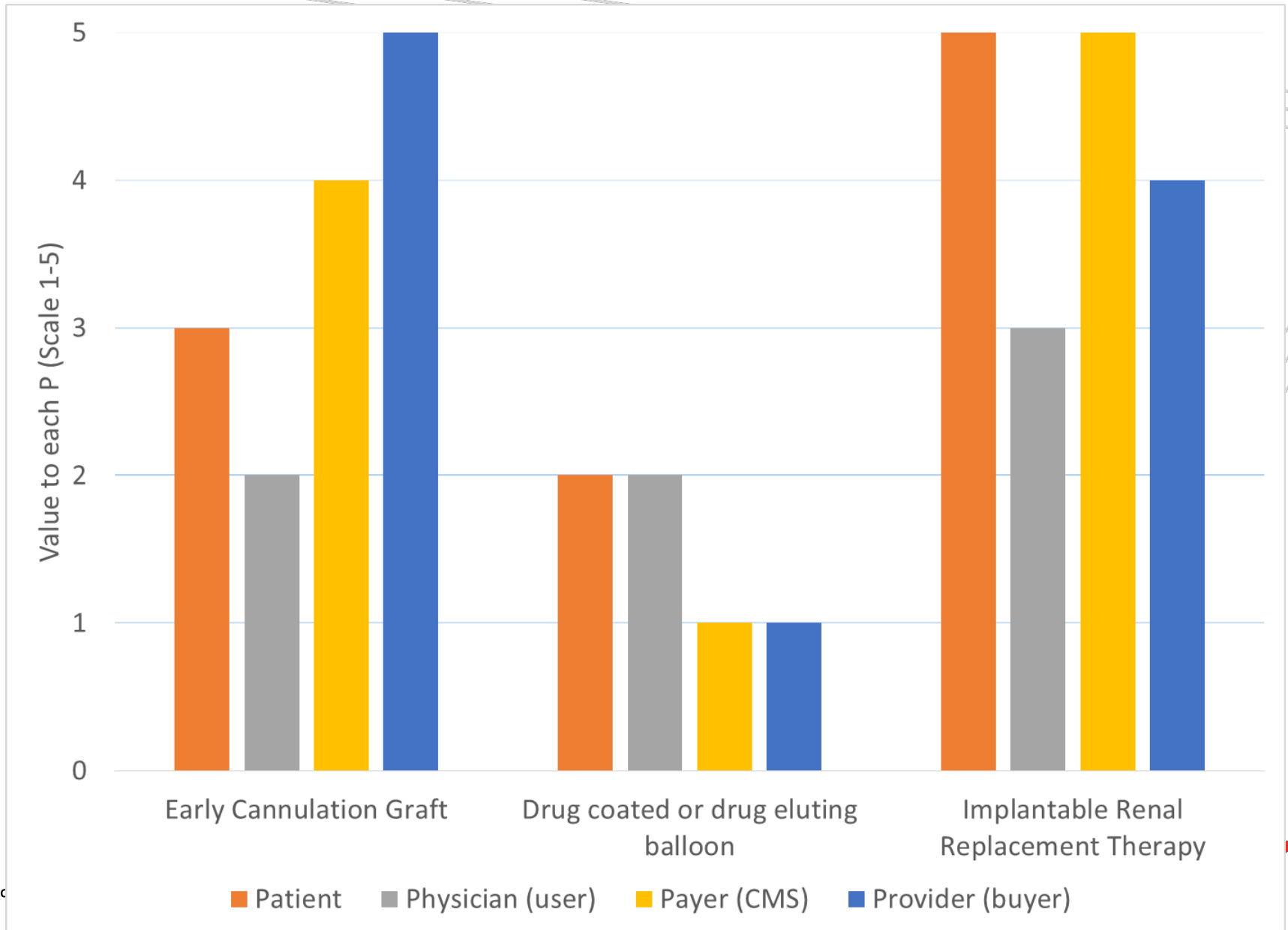
Examples: Implantable RRT

Technology not yet real Real customer value

- Patient: Extreme value, “gives life back”
- Physician: Potential to provide a “cure”
- Payer: If technology successful, could drastically decrease CMS costs
- Provider: Value providing long term solutions for patients



Examples: Such data can help prioritize efforts



Summary

- Most big companies are “big” because they have experience with successful medical device innovation
- Assessment of the market value of an idea is as important as the technology development
- Innovating a successful medical device requires understanding of the value of the device to each of the 4 P's