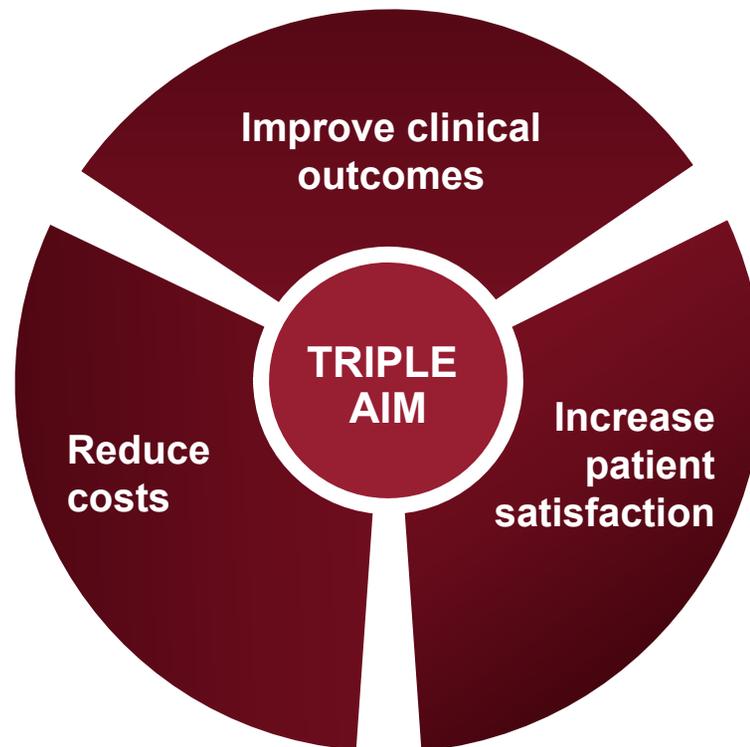


# MAJOR INDUSTRY: SUCCESS METRICS FOR DEVELOPMENT IN PEDIATRIC SPINE

Andrea Light  
Group Product Director  
DePuy Synthes Spine\*



# WHAT IS SUCCESS FOR ANY PROJECT?

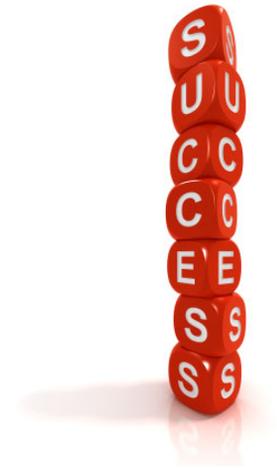


# WHAT IS SUCCESS FOR ANY PROJECT?

- Key Stakeholders: “The 5 P’s”

## What are the Barriers to Entry with Each of These?

- **Patient**
  - Is there a true clinical need?
  - Can we develop a solution to address the need?
- **Physician**
  - What are the needs of the physician and how can our solution address those?
- **Provider**
  - What are the requirements of hospital administration?
- **Policy Maker**
  - Regulatory requirements
- **Payer**
  - Will this product be reimbursed by major payers?



# WHAT IS SUCCESS FOR ANY PROJECT?



# WHAT IS SUCCESS FOR ANY PROJECT?



*Revenue*  
*Pull through Sales*  
*Complete Product Offering*

*People Resources*  
*Development Time*  
*Manufacturing Cost*  
*Cannibalization*  
*Study costs*

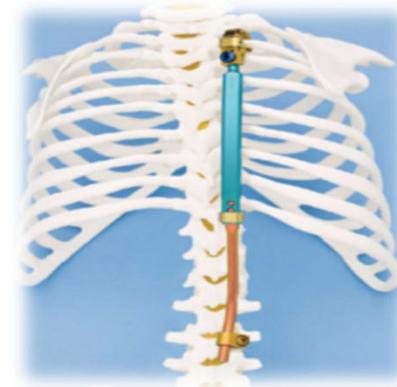


# NOVEL & INNOVATIVE TECHNOLOGIES

Bulletin of the Hospital for Joint Diseases 2013;71(1):49-53 49

## Fusionless Surgery for Scoliosis

Stuart H. Hershman, M.D., Justin J. Park, M.D., and Baron S. Lonner, M.D.



\*



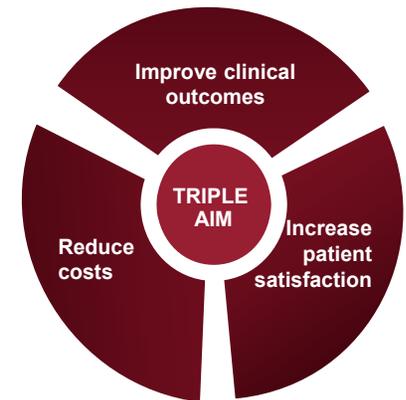
## Next Generation of Growth-Sparing Techniques

*Preliminary Clinical Results of a Magnetically Controlled Growing Rod in 14 Patients With Early-Onset Scoliosis*

Behrooz A. Akbarnia, MD,\*† Kenneth Cheung, MD,‡ Hilali Noordeen, FRCS, (Orth),§  
 Hazem Elsebaie, MD, FRCS,¶ Muharrem Yazici, MD,|| Zaher Dannawi, FRCS(Orth),§ and Nima Kabirian, MD\*

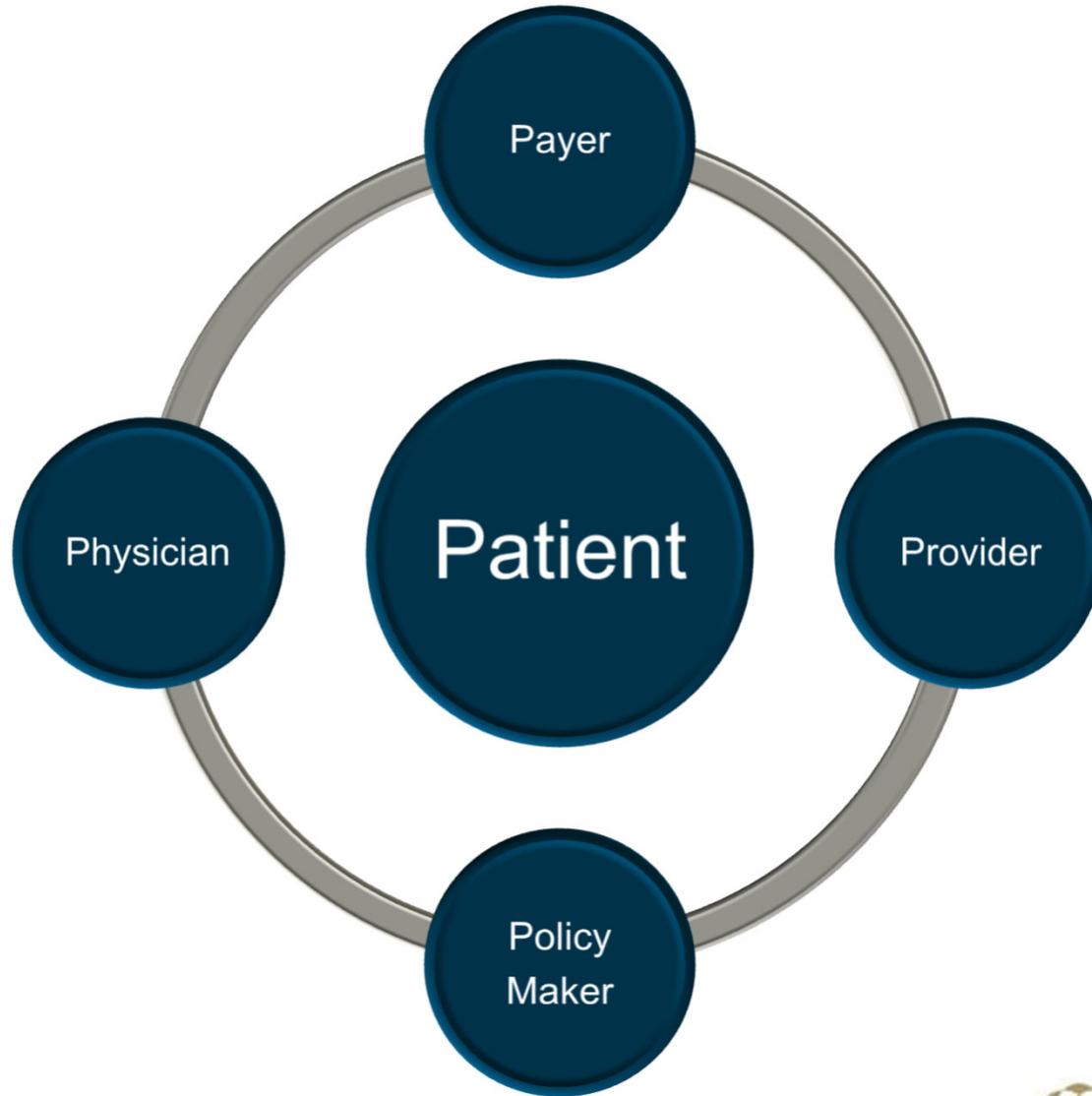


# IS THIS ACHIEVABLE IN PEDIATRICS?



- **Improve Clinical Outcomes**
  - A different norm exists with sick children
- **Increase Patient Satisfaction**
  - Morbidity and complication rates are significantly higher
- **Reduce Costs**
  - Often these are some of the most expensive cases, with significant hospital stay and care required.

# IS THIS ACHIEVABLE IN PEDIATRICS?



# PATIENT

## Clinical need is high in pediatric patient population



- Disease state can often be life threatening or at best, associated with reduced quality of life
- Relatively few implant options to choose from
- Current systems are often designed for adults
- The size of the patient population, however, is relatively small in number

## Ability to address clinical need is moderate



- Significantly higher complication rates
- Spine deformity is often linked to other etiologies



# PHYSICIAN & PROVIDER

## Physician: Positive Surgeon Environment

- Surgeons are dedicated to advancing musculoskeletal & spinal care for children
- Supportive & collaborative society relationships



## Provider: Mixed Environment

- Also dedicated to the care of pediatric patients
- Significant focus on profitability resulting in price erosion, contracting, etc. for industry

U.S. Hospitals are in the Leading  
Edge of an Economic Storm

# POLICY MAKER



## Positive Evolving Regulatory Environment

- FDA is encouraging innovation for Pediatric pathologies
- Previously required FDA pathways
  - Humanitarian Device Exemption (HDE) – i.e. VEPTR® Vertical Expandable Prosthetic Titanium Rib
  - Class III PMA / IDE requiring long term clinical study – i.e. future growth modulation innovation
- Recent alternative FDA pathways
  - 510k with clinical data – biomechanically equivalent to predicate device
  - Accelerated PMA / IDE pathway



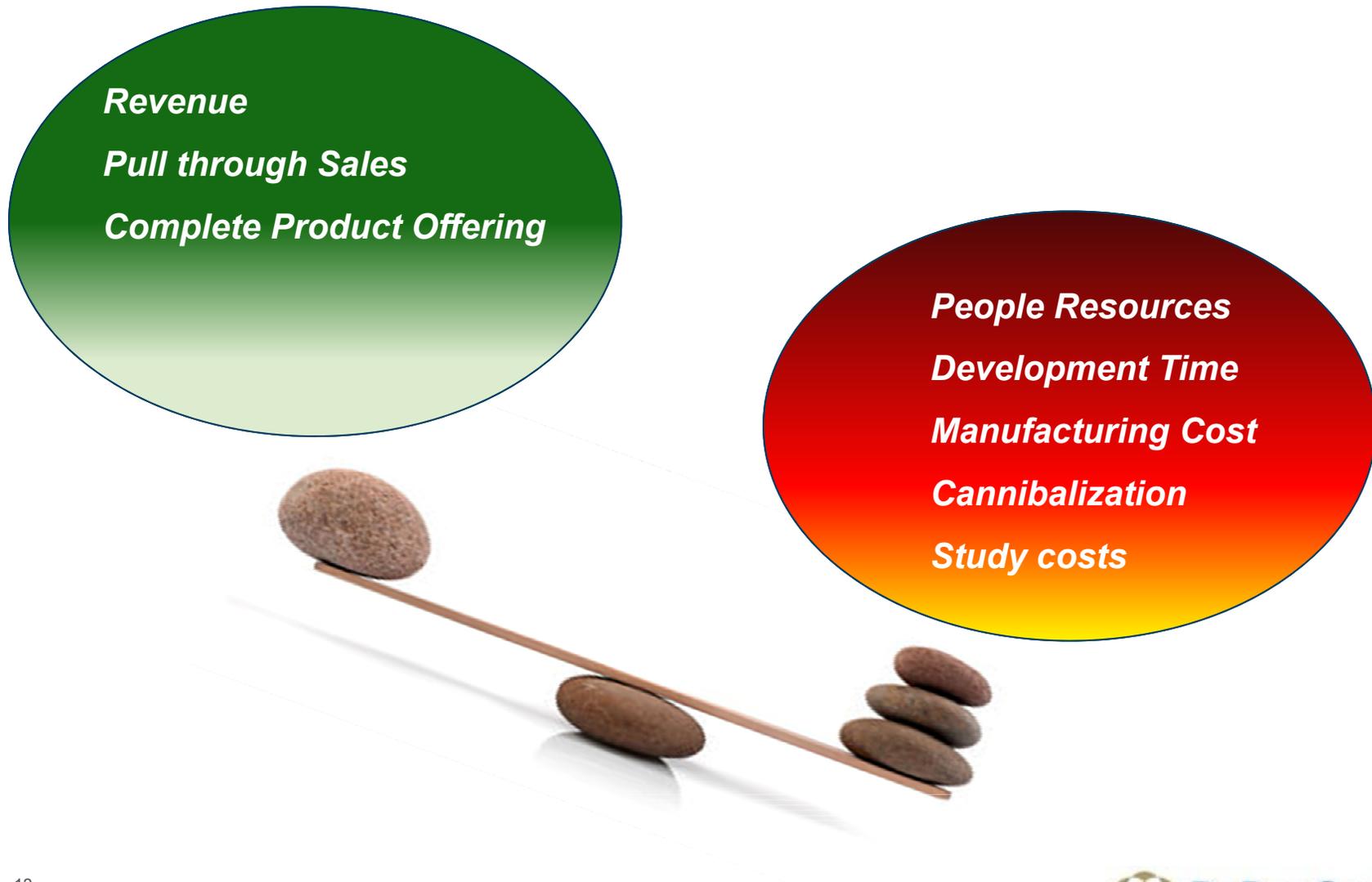
# PAYER

## Mixed Reimbursement Environment

- Traditional technologies & procedures gain positive reimbursement
  - Traditional rods & screws
  - Fusion
- New, novel technologies receive significant scrutiny
  - Novel flexible materials
  - Growth modulation
- Payers burden of proof is high
  - Clinical superiority
  - Economic superiority
- With the pediatric population, this burden of proof may be unachievable



# RETURN ON INVESTMENT IN PEDIATRICS



# SO WHY DO WE DO IT?

- Inherent Ethical Obligation
- Must provide a complete portfolio to remain competitive
- Opportunity for differentiation
- The Patient



# SUMMARY

- Success metrics for pediatric spine development are consistent with non-pediatric development initiatives
- Our ability to score highly in the metrics is arguably more difficult to achieve
  - Regulatory challenges
  - Complex patient pathology
  - High burden of proof
  - Challenging economic pressures
- The clinical need of the pediatric patient and desire to serve all our customers outweighs the challenges.

# THANK YOU



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