



Marketing Considerations: “Approval, now what?”

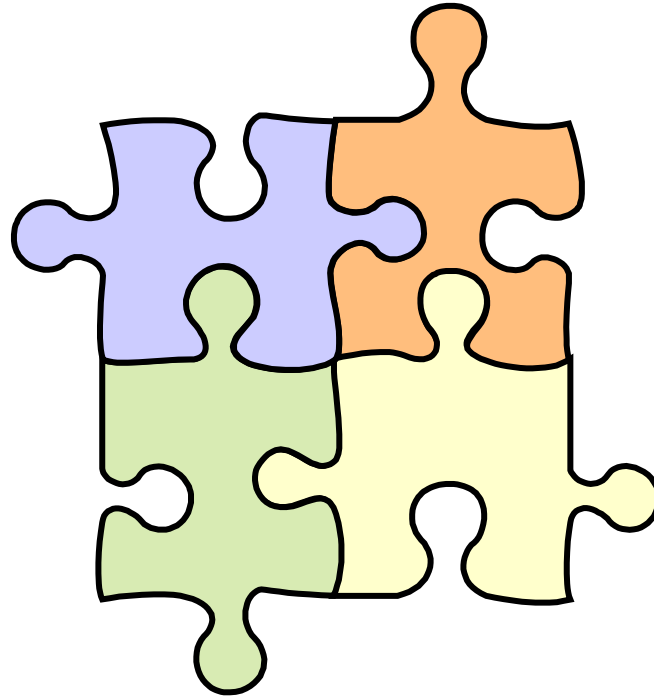
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GETTING STARTED

FDA



- FDA clearance does not mean you have achieved market access

GETTING STARTED

FDA



- Problem: You reach the top of the mountain and then realize you are just getting started..

A WALK IN THE PARK



DEER IN THE HEADLIGHTS



Reimbursement

DEER IN THE HEADLIGHTS



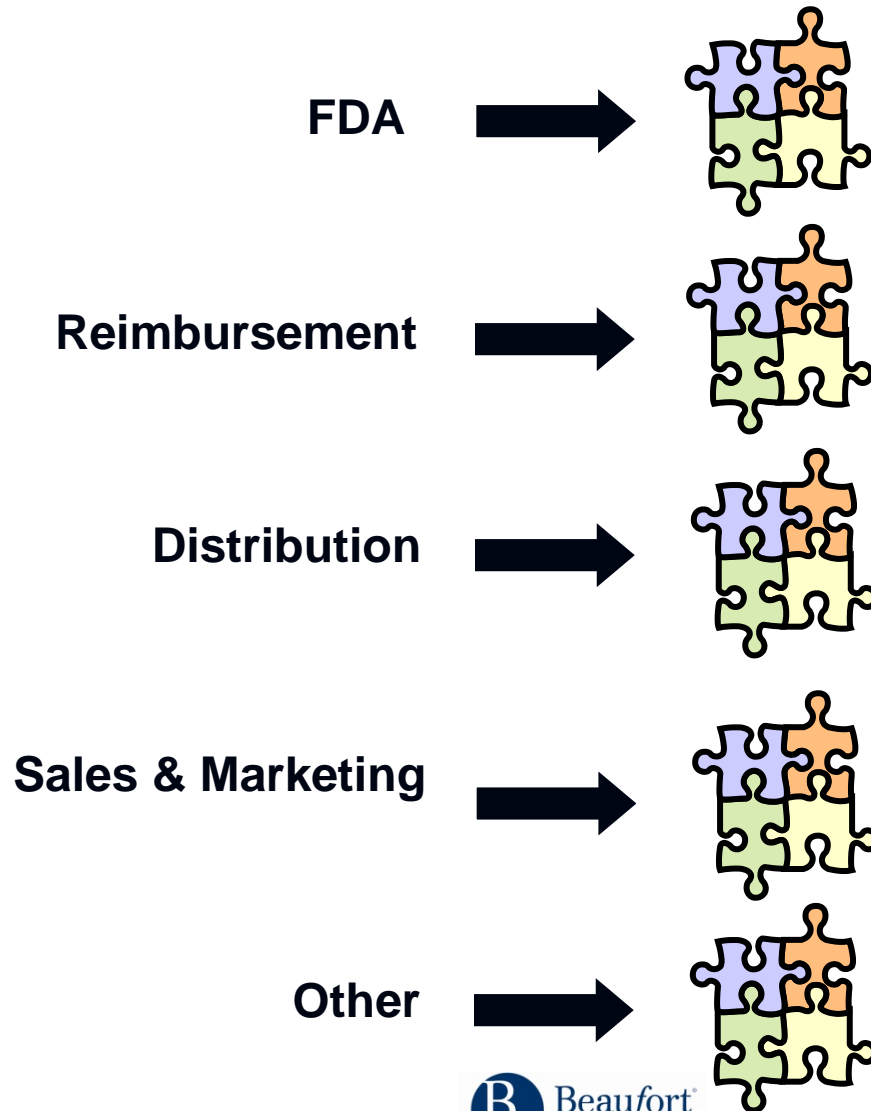
Distribution

DEER IN THE HEADLIGHTS



Sales & Marketing

ACCESSING THE US MARKET



REIMBURSEMENT

- CMS = Centers for Medicare and Medicaid Services
 - The Agency of the US Federal Government that determines if and how much insurers will pay for your product
- Why is this so important?
 - Will it be coded? [Is there a market?]
 - How will it be coded? [Are there profit margins to be made?]
- Reimbursement is a complicated field and you should seek appropriate guidance.

DISTRIBUTION

- How will you get your product to the consumer?
- The US Market is quite large:
 - 6505 Hospitals
 - 221,000 outlets including hospitals, pharmacies, clinics, and nursing homes
 - 829,763 Physicians and Surgeons
 - Land area of 9,827,000 square km in the continental US
 - Group Purchasing Organizations (P&T)

www.census.gov and www.stathealthfacts.org

DISTRIBUTION

- The US medical equipment and supplies distribution industry includes about 7,000 companies with combined annual revenue of about \$130 billion.
- Major companies include Henry Schein, Owens & Minor, Patterson Companies, and PSS World Medical.
- The industry is concentrated: the top 50 companies account for about 70 percent of revenue.

DISTRIBUTION

- Increasing consolidation in hospitals as well
 - 72% of all hospital purchases are made through Group Purchasing Organizations (GPOs)
 - 97% of hospitals are members of at least one GPO
 - More than 600 GPOs exist; about 30 of these are true-GPOs that negotiate sizeable contracts for their members
 - Independent purchasing decisions are disappearing with the increase in GPOs and Integrated Health Networks (IHNs)

DISTRIBUTION

- Consolidation makes it increasingly difficult for anyone outside of the largest companies to access the market.
- How do you get a seat at the table?



SALES & MARKETING

- Develop a traditional marketing plan?
 - What is the market size assuming you can get clearance and reimbursement for your product?
 - Product / Price / Placement / Promotion / People – pick your model
- Sales Strategy – how will you sell your product?
 - Build a sales force from scratch
 - Out-license the product entirely
 - Partner with an existing company's sales force
 - Jobbers
 - Wholesalers (small business units exist within these groups)
 - Internet

OTHER HURDLES

- Quality Systems:
 - Baseline (Gap) Assessment
 - Review of Product requirements, Review of Existing Systems and Documentation
 - Recommendations to close gaps or improve existing systems
 - Implementation Support
 - Development of Action Plans to improve or implement Quality Systems
 - Guidance on or authoring of Quality System Documentation (Quality Manuals, Policies, Procedures, Work Instructions, Device Master Files)
 - Training
 - Auditing
 - Corrective and Preventative Action
 - Root causes analysis
 - Risk Management
 - Effectiveness Monitoring
- cGMP ≠ ISO
- Cautionary Tales: Genzyme, Medtronic, Chiron, J&J

SUMMARY

- In most instances, your primary hurdles are process not other products.
- It's not enough to solve one puzzle, you need to address all issues before accessing the market.
- Build your team to address all of the hurdles
 - Outsourcing versus insourcing – specific to your circumstances

- Be prepared!
- Don't wait!
- Get going!





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