



# Emerging Commercialization Strategies for Addressing the Needs of Ultra-Orphan Patients

**Accelerate Product Launch and Profitability by Building Regulatory Requirements into Distribution**

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***Conference Presentation***



# Advocacy Involvement

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# Advocacy Involvement

- Patient Advocacy should be considered in all phases of drug development, sales & marketing, and distribution
- There is a way to work with consumer groups that
  - Benefits patients
  - Benefits industry
  - Strengthens service and brand
    - Can expedite development and licensure (registries, protocol review, health policy)
    - Build brand trust and access to customer base
    - Community involvement addresses access and safety

# Advocacy Involvement

- Relationship of industry to consumer group
  - Corporate citizens - charitable contributions
  - Program support/sales & marketing
  - R&D
    - Physician relationships
    - Clinical trial recruitment/registries
    - Protocol review
    - Health policy
  - Defining “customer” relationships
    - Direct distribution

# Advocacy Involvement

- Define “customer” relationships
  - Legal issues
  - Regulatory framework
  - Appearance of conflict of interest/lack of independence
    - Lack of trust - both parties
    - Different missions
    - Voluntary organizations face challenge
- Next evolution - venture philanthropy

# Advocacy Involvement

- Consumer groups are effective partners
  - Alpha-1 experience
    - WHO
    - ATS-ERS professional societies
    - Organization of research community
    - Research registry
    - Research infrastructure
    - Fast track licensure
    - Public policy
    - Direct distribution
    - Comprehensive health management

# Advocacy Involvement

- Guidelines for industry and consumer groups
  - Be ethical
  - Understand mutual benefits and challenges
  - Keep boundaries clear
  - Manage expectations
    - Memorandums and agreements
    - Mutually agreed up on outcome measures/performance goals

## Summary

- Advocacy and industry are natural partners
- Involving advocacy groups builds customer loyalty and trust
- Direct distribution protects consumer interests
  - Comprehensive HM optimizes care
  - Increased therapeutic compliance
  - Safety
  - Customer retention