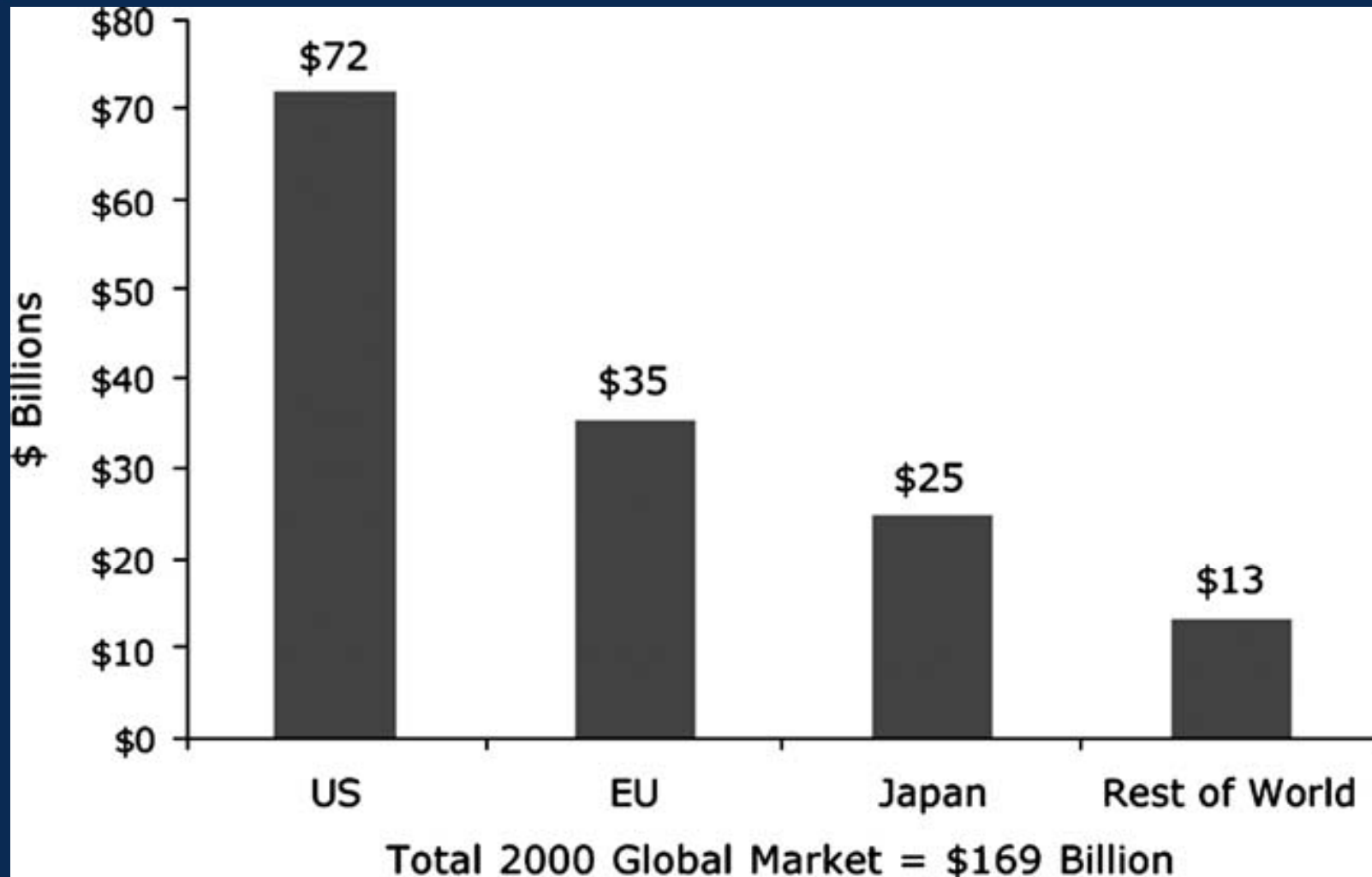


Medical Device Development

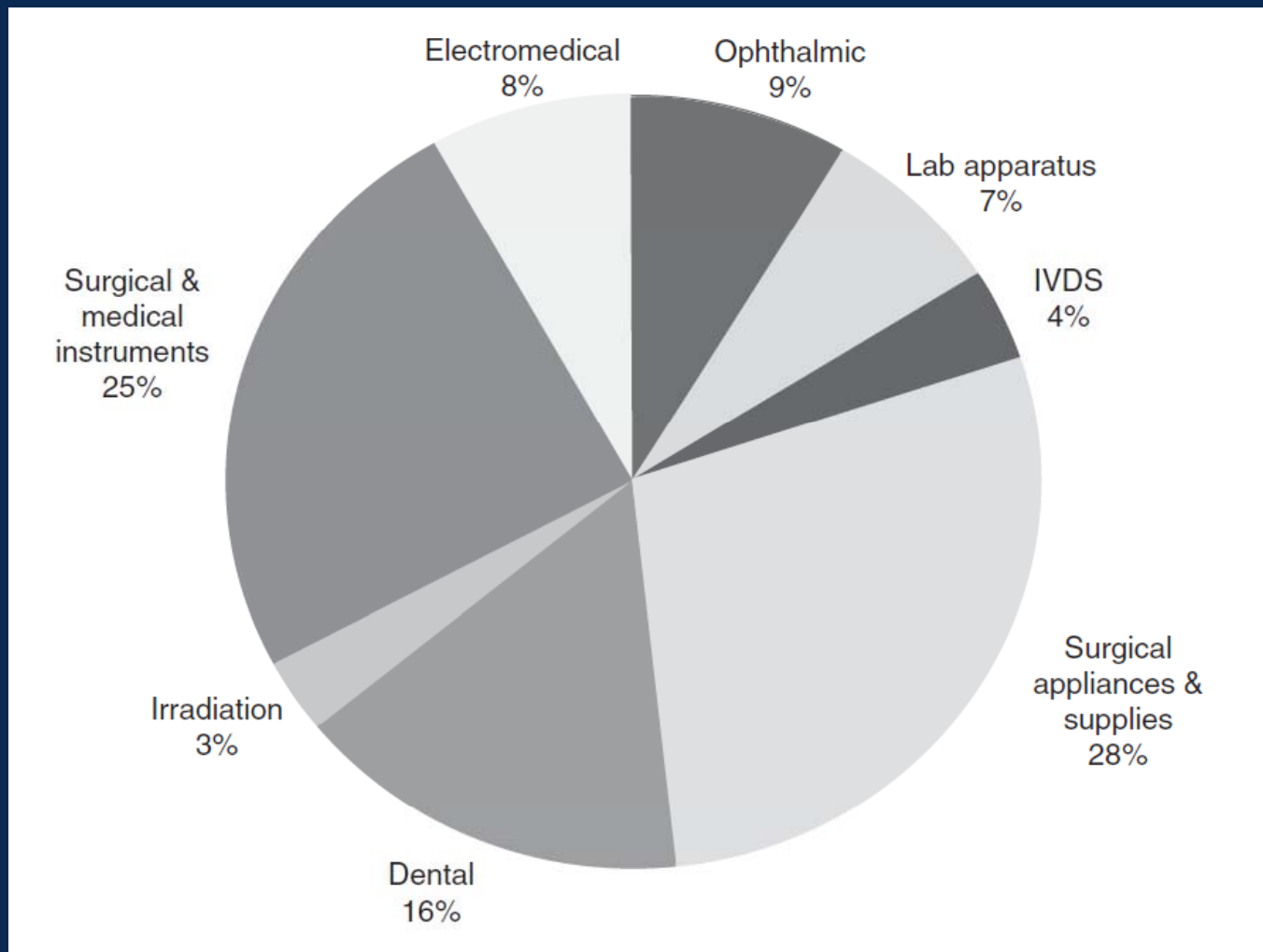
Dorin Panescu, Ph.D.

NewCardio, Inc. Santa Clara, CA, USA

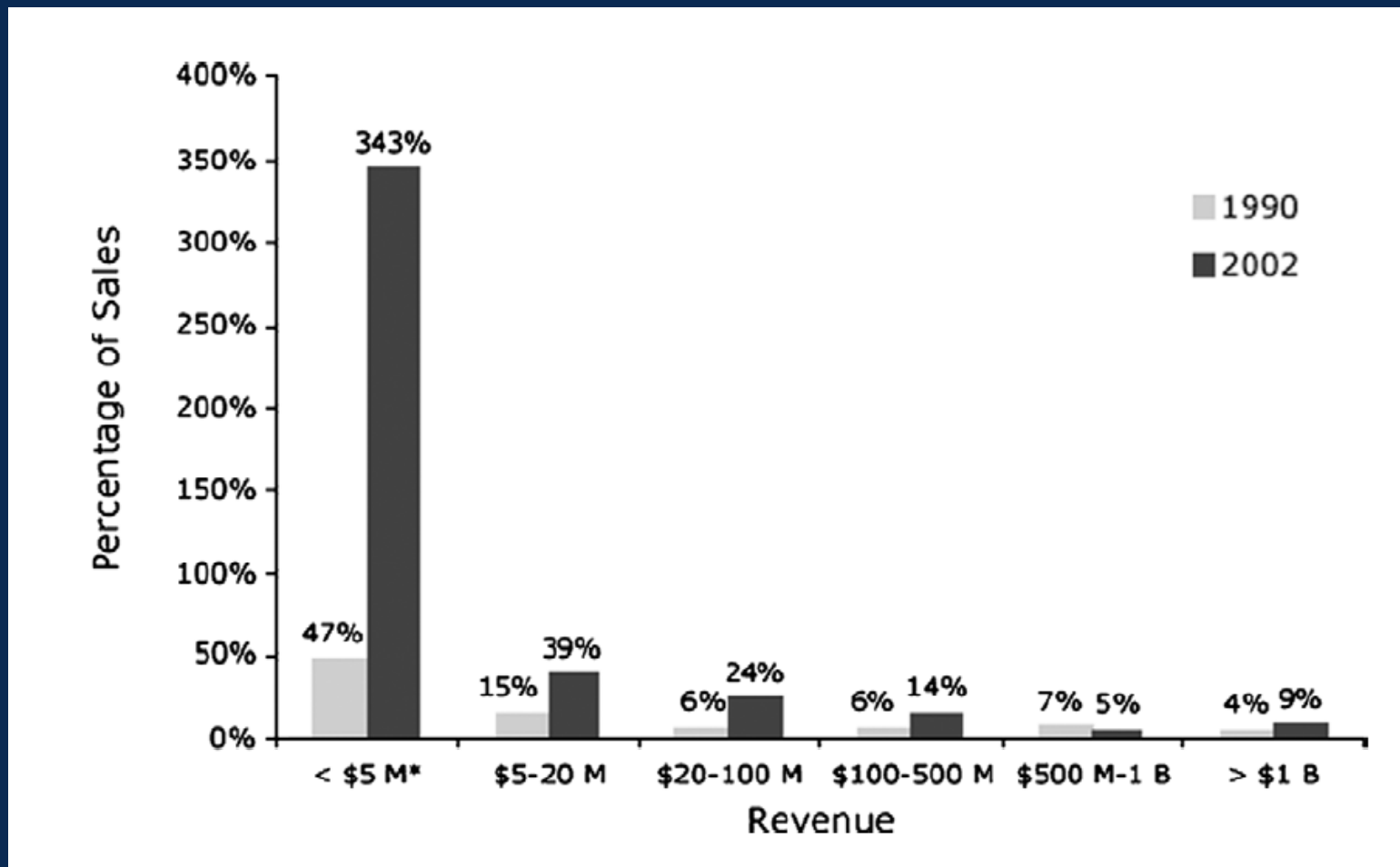
Medical Device Industry Overview – US largest market



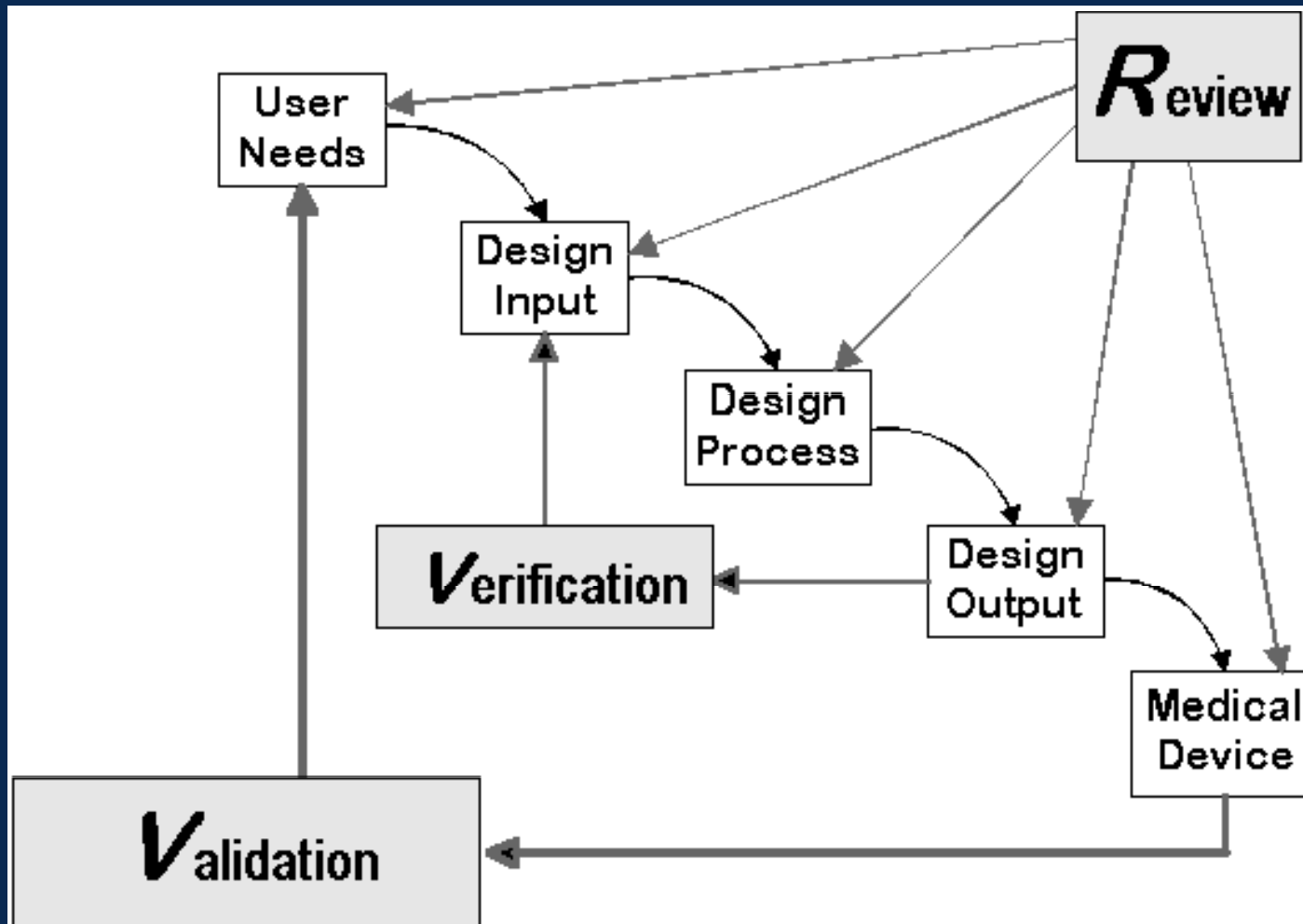
Medical Device Industry Overview – Surgical supplies and instruments largest segment



Medical Device Industry Overview – Small companies are most numerous



Medical Device Industry Development – Process Flow



Medical Device Industry Development – Funding Phase

- Idea:
 - Unmet need: Earl Bakken (Medtronic) – temporary pacing in children with AV block after surgical repair of ventricular septal defect
- Market potential, likely revenue stream
- IP landscape (Own vs Prior art)
- Regulatory roadmap (510k or PMA?)
- Are clinical studies required? Reimbursement?
- Schedules
- Budgets
- If start-up, valuation model

Medical Device Industry Development – Concept Phase

- Specifications:
 - Marketing
 - Product
- Risk analysis
- Update:
 - IP – start filing patents
 - Regulatory roadmap
 - Clinical/reimbursement
 - Schedules
 - Budgets

Medical Device Industry Development – Development Phase

- Lower-level Specifications:
 - Hardware
 - Software
 - Mechanical
- Traceability matrix
- Actual design/development
 - Engineering prototypes built
- Specification freeze
- Design freeze
- Verification and validation test protocols approved
- Update documents from previous phases

Medical Device Industry Development – V&V Phase

- Verification – testing against specifications
 - Hardware, Software, Mechanical
- Validation – test per intended use
- Schedules should allow for V&V iterations – rarely does a product pass V&V from first attempt
- Incremental V&V
- Regulatory submissions:
 - Market approval or for approval to start clinical trials?
- Preparation for Production Phase:
 - Release documentation to production level revisions
 - Production fixture desing/validation
- Regulatory approval (FDA, CE, MHLW - Japan)

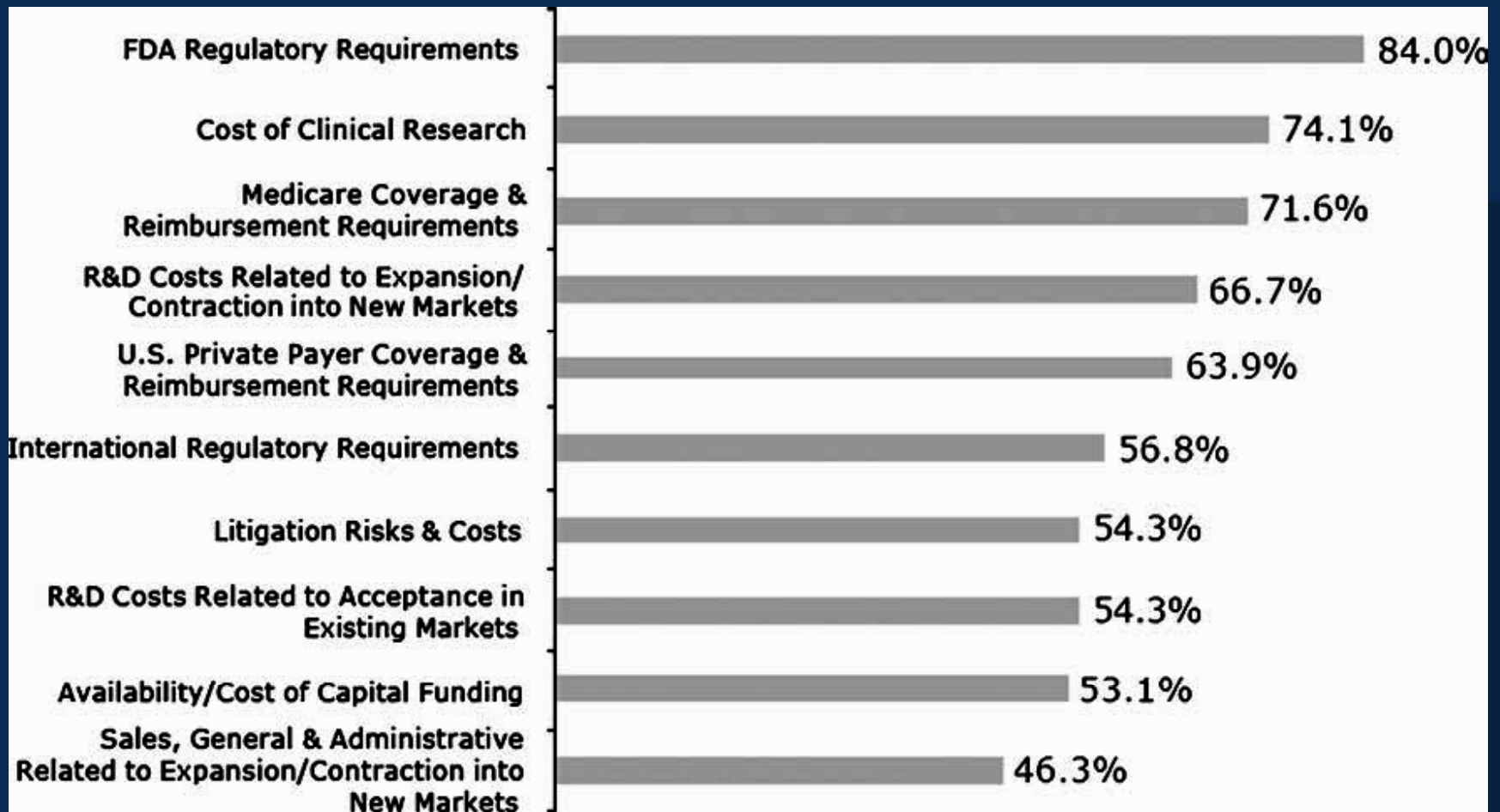
Medical Device Industry Development – Production Phase

- Manufacturing process
 - Recent emphasis by FDA on process validation
- Manufacturing quality goals:
 - Yields, rework, build time
- Continuing Improvement
- Inventory levels (trend towards just-on-time)

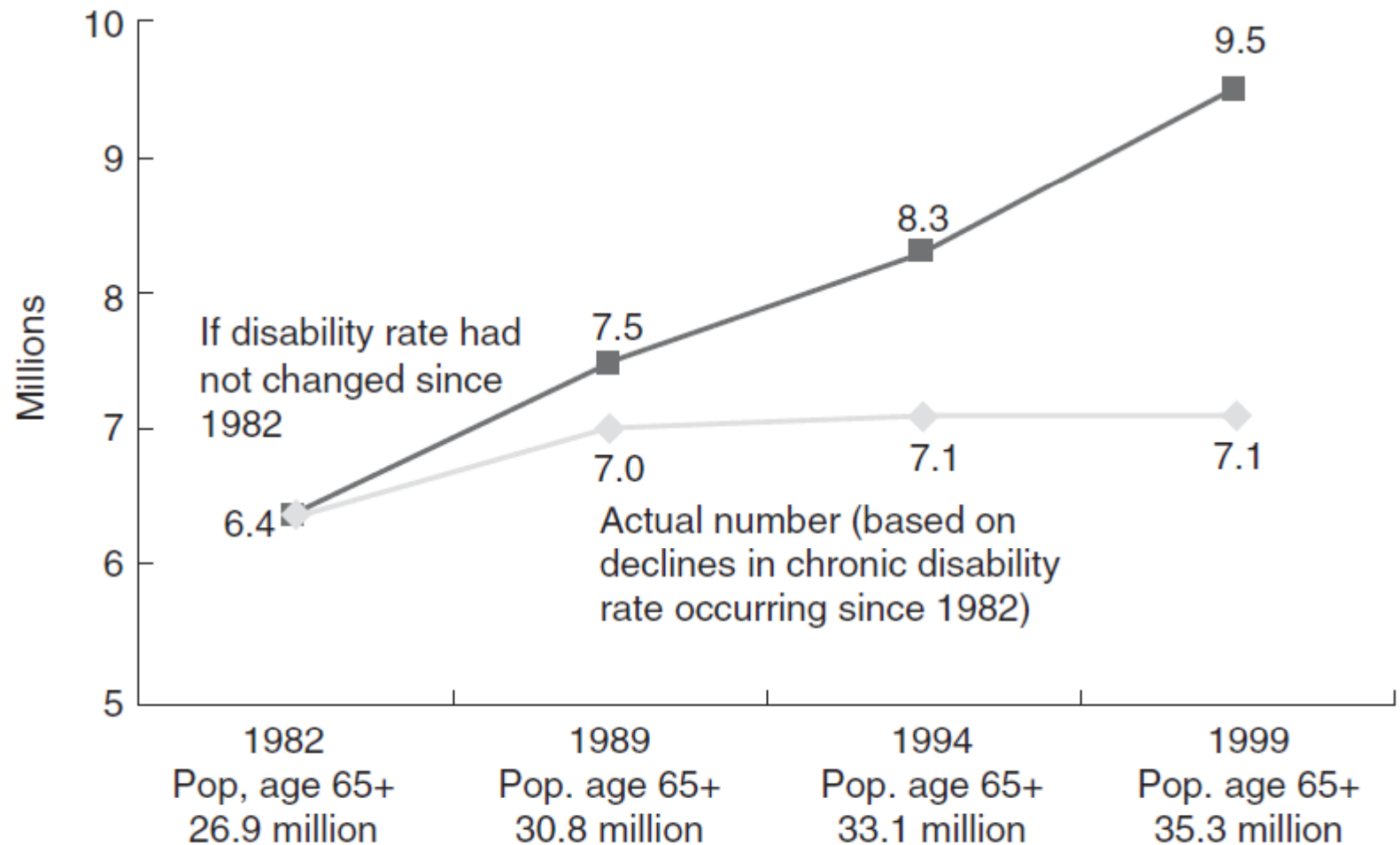
Medical Device Industry Development – Market Release Phase

- Labeling
 - User's manual
- Marketing materials:
 - Training
 - Promotion
- Regulatory approvals in other territories
- Corrective actions
- Post-market surveillance

Medical Device Industry Development – Top Ten Concerns



Medical Device Industry Overview – Patient benefits: reduction in chronic disease rates



Medical Device Industry Overview – Patient benefits: reduction in heart disease rates

Year	Deaths per 100,000 resident population
1950	586.8
1960	559.0
1970	492.7
1980	412.1
1990	321.8
1995	293.4
2000	257.6
2001	247.8