



Unmet Medical Product Needs - Trends & Opportunities

Medical Development Group

www.meddevgroup.com

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EIGHT IMPORTANT UNMET MEDICAL NEEDS

- 1. Reducing Medical Errors**
- 2. Inadequate Information Technology**
- 3. Emerging Demands from Consumers**
- 4. Advancements in Minimally Invasive Surgery**
- 5. Focus on the Continuum of Care**
- 6. Products for the Decentralization of Care**
- 7. Faster & Cheaper Product Development**
- 8. Increasing International Demand for Products**

not a comprehensive list, not in order of priority



MAJOR UNDERLYING TRENDS IN HEALTHCARE

- **↑ POPULATION COVERED → ↑ COST PRESSURES**
- **↓ MARGINS & ↑ VOLUMES FOR SUPPLIERS AS POPULATION COVERED ↑**
- **↑ ROLE OF REGULATORS, GATEKEEPERS AND PAYORS WHILE PROVIDING THEM ↓ RESOURCES**
- **↑ AGING POPULATION & ↑ FOCUS ON CHRONIC CARE**
- **↑ TRANSPARENCY OF QUALITY & EFFICIENCY MEASURES**
- **↑ % OF COST PAID BY CONSUMER & ↑ TRANSPARENCY → INCREASING ROLE OF CONSUMER**



MAJOR TRENDS IN HEALTHCARE (CONTINUED)

- **↑ COST PRESSURES →**
 - **↑ USE OF OUTPATIENT FACILITIES**
 - **↑ INVESTMENT IN INFORMATION TECHNOLOGIES**
 - **↑ INVESTMENT IN MINIMALLY INVASIVE PROCEDURES**
 - **↑ FOCUS ON WELLNESS, PREVENTION & IDENTIFICATION OF AT RISK POPULATION**
 - **↑ REQUIREMENT TO SHOW COST BENEFIT IN THE REGULATORY PROCESS**



UNMET NEED: REDUCING MEDICAL ERRORS

COUNCIL ON SURGICAL &
PERIOPERATIVE SAFETY



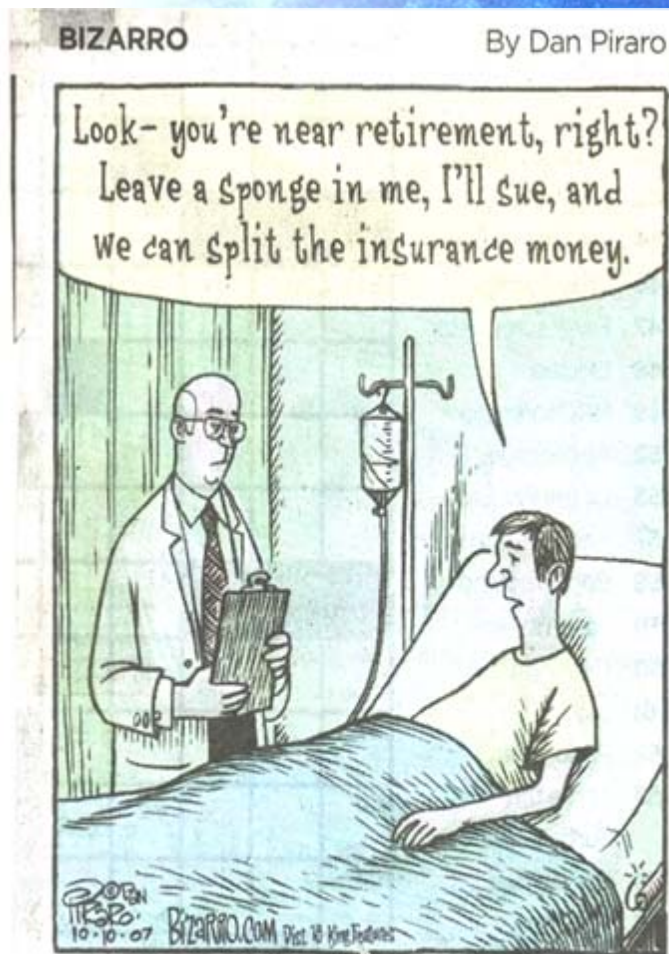
Anesthesia Patient Safety
Foundation

The Patient Safety Group



UNMET NEED: REDUCING MEDICAL ERRORS

- Health care quality is being addressed with new vigor
- Finally, as of October 1, 2008, Foreign Retained Objects (FRO) left in a patient from surgery is not reimbursed!





QUALITY REPORTING & REIMBURSEMENT CHANGES

Three significant changes from payors:

- **Non-reimbursement of Hospital Associated Conditions (HACs)**
 - Change to MS-DRGs (Medical Severity) from CMS-DRGs
 - Reimbursement tied to severity of illness at admission
- **Pay-for-Quality for Hospitals and Physicians**
- **Reporting/Benchmarking/Accrediting**



CMS PAY-FOR-PERFORMANCE FOR PHYSICIANS & HOSPITALS

- **Physician Quality Reporting Program**

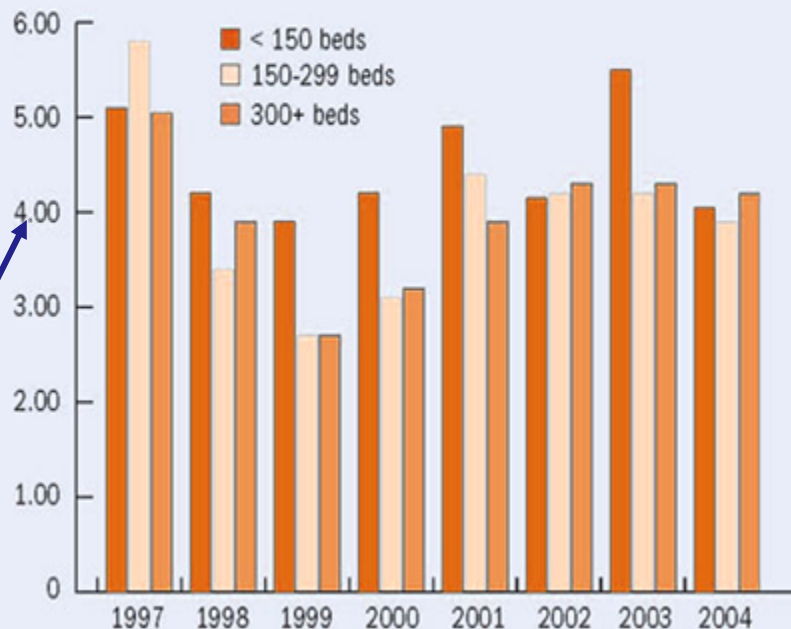
- 74 measures
- Adjustment up to +1.5%

- **Hospital Quality Reporting Program**

- 43 measures
- 4.6% swing from -1.3% to +3.3%!

Hospital margins about 4%!

Average hospital operating margins by bed size, 1997-2004





INVESTMENT OPPORTUNITIES RELATED TO REDUCING MEDICAL ERRORS -- USE THIS LIST!!

Non-Reimbursement of 11 Hospital Associated Conditions (HACs)

- 1. Hospital associated infections (HAIs)**
 - 2. Catheter-associated UTIs**
 - 3. Catheter-associated blood stream infections**
 - 4. Surgical infections**
- 5. Air embolism**
- 6. Blood incompatibility**
- 7. Pressure ulcers (Stage III and IV)**
- 8. Injuries from patient falls & trauma**
- 9. Poor blood sugar control**
- 10. Vein thrombosis or pulmonary embolism post knee or hip replacement procedures**
- 11. Retained foreign objects after surgery**



INVESTMENT OPPORTUNITIES RELATED TO REDUCING MEDICAL ERRORS (CONT.)

- Prevention of non-reimbursable conditions (the 11 HAC's)
- Improve care for the publicly reported measures
- Examples of above
 - Remote patient monitoring
 - Drugs, devices & diagnostics to detect & reduce infections
 - Smart medical objects (tagging of surgical items & fluids)
- Information Technology
 - tools to track/measure quality
 - automate complex reimbursement
- Consumer-centered medicine – *finally meaningful information available*



UNMET NEED: INADEQUATE INFORMATION TECHNOLOGY

HEALTH CARE I.T. TO MAKE BIG COMEBACK

CONTRARIAN PREDICTION MADE FOR 1,000th TIME AT DEVICE SOCIETY

1970's or 2008?!



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WALTHAM, MASSACHUSETTS USA

TO: MEDICAL DEVELOPMENT GROUP

FROM: YET ANOTHER WRONG INDUSTRY ANALYST

MEDICAL DEVELOPMENT GROUP,

HEALTH CARE INFORMATION TECHNOLOGY WILL BE THE BIGGEST GROWTH INDUSTRY OF THE 1920'S AND 1930'S STOP

PUT ALL YOUR MONEY INTO "GENERAL INFO TECH" STOP

TICKER SYMBOL "GETIT" STOP

GUARANTEED 100000% RETURN STOP



UNMET NEED: INADEQUATE INFORMATION TECHNOLOGY– TRENDS

- **Trends**
 - **Significant IT under-spending in health care sector**
 - **Increased demand for real world practice data and cost/benefit data**
 - **Increasing reimbursement complexity**
 - **Untapped efficiencies in administration & management**
 - **Need for increasing clinical automation to reduce costs & increase quality**



UNMET NEED: INADEQUATE INFORMATION TECHNOLOGY—OPPORTUNITIES

- **Decision making tools**

- **eMedicine** -- reduced cost, more coverage and faster response
- **Smart devices** Identification of “at risk” patients through modeling
- Monitoring of more and complex patient and clinical data
 - » Specialist assistants
 - » Remote patient monitoring
 - » Measurement of quality
- **Data Mining**
 - » Registries
 - » Public health data



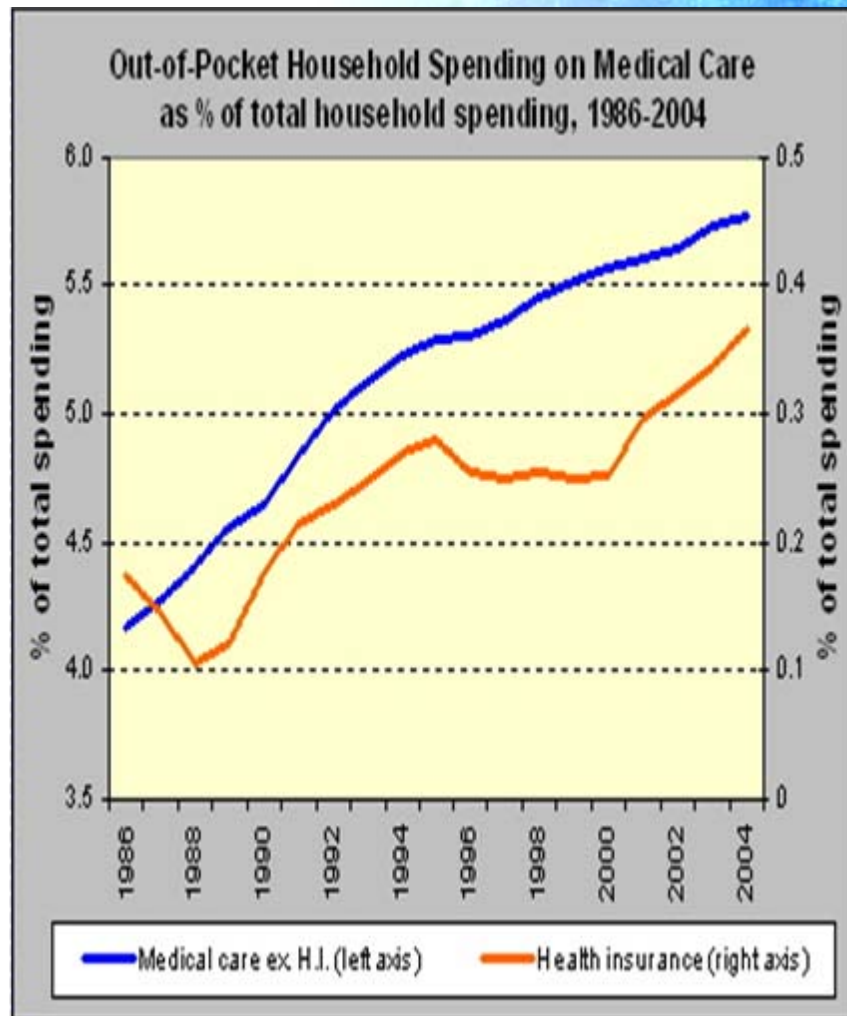


UNMET NEED: EMERGING DEMANDS FROM CONSUMERS

CONSUMERISM IN HEALTH CARE TO MAKE BIG COMEBACK

CONTRARIAN PREDICTION MADE FOR 1,000th TIME AT DEVICE SOCIETY

Consumer Reports





UNMET NEED: EMERGING DEMANDS FROM CONSUMERS

- Trends

- Overused term except in health care: **TRANSPARENCY!**
- Increased % of healthcare costs paid by consumers
 - » ~ 26% & increasing
 - » Increased drug tiering very visible to patients
 - » Increased % of household income spent on healthcare

- Opportunities

- As consumers pay more, they will want more data
- Informed decision-making reduces costs

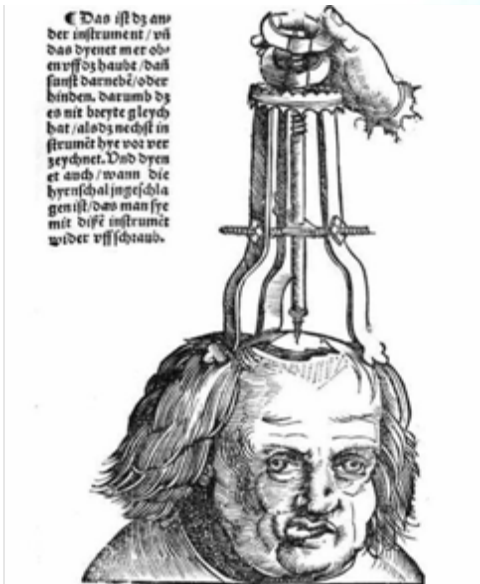


UNMET NEED: ADVANCEMENTS IN MINIMALLY INVASIVE SURGERY



We've come a long way, baby!

Although, not such a bad skull incision!





UNMET NEED: ADVANCEMENTS IN MINIMALLY INVASIVE SURGERY

- **Trends**
 - **Cost reductions from reducing recovery**
 - **Advances in enabling technologies**
 - » **Imaging**
 - » **Specialized tools and instruments**
- **Opportunities**
 - **NOTES (natural orifice transluminal endoscopic surgery)**
 - **Image guided surgery & more tools customized for various specialties and procedures**
 - **Increased shift towards Ambulatory Surgical Centers**

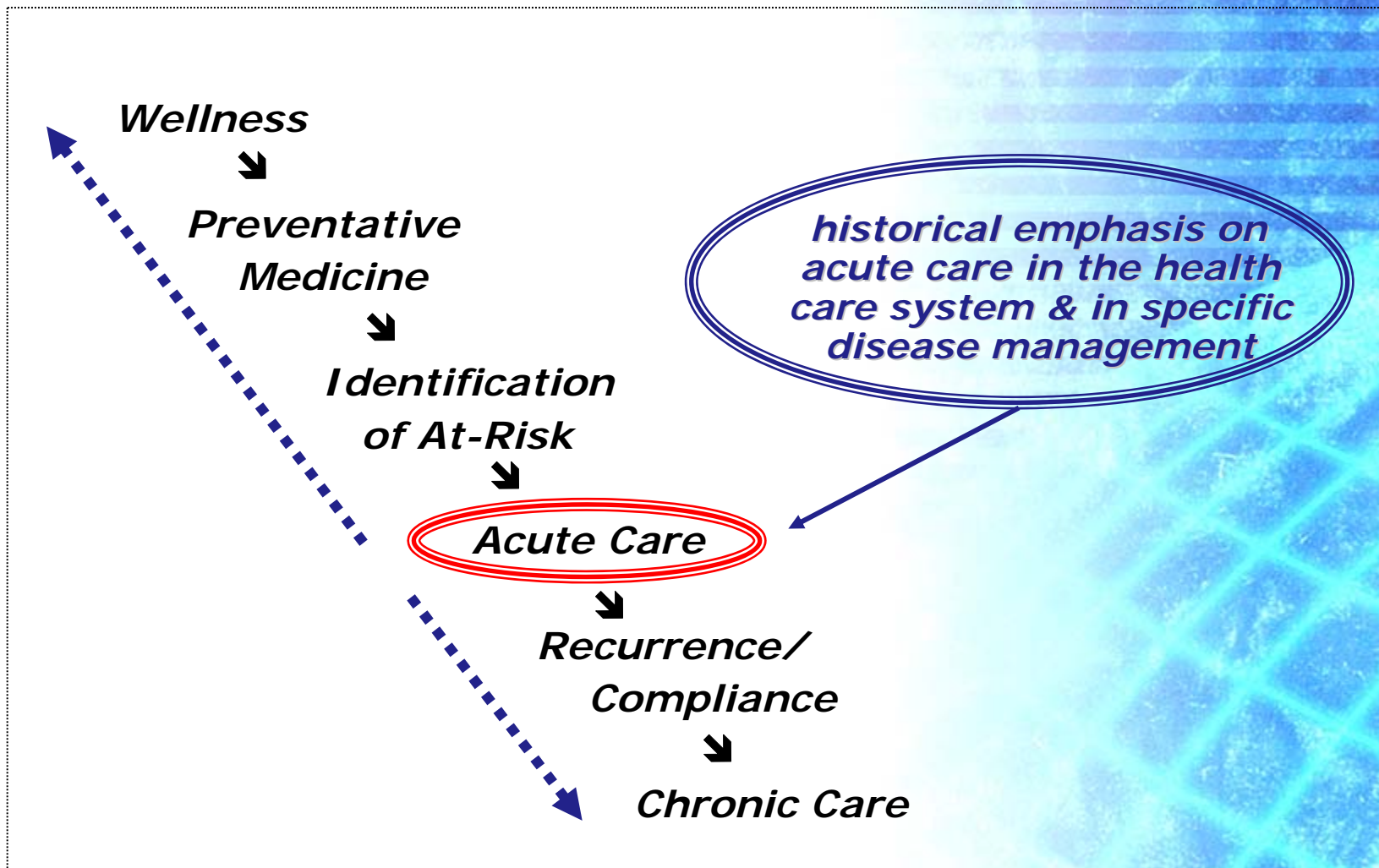


UNMET NEED: FOCUS ON CONTINUUM OF CARE – FROM HEALTH THROUGH DEATH





UNMET NEED: FOCUS ON CONTINUUM OF CARE – FROM HEALTH THROUGH DEATH





TRANSITION TO CONTINUUM OF CARE - TRENDS

Acute Care => **Recurrence/ Compliance** => **Chronic Care**



- **Continuum Trend: From Acute => Chronic**
 - Health system has focused on the most visible diseases
 - Health system is changing focus from acute to chronic
 - » Morbidity & mortality leading causes are now chronic diseases
 - » Aging population and increased coverage → chronic diseases



TRANSITION TO CONTINUUM OF CARE – TRENDS (continued)

Wellness => Preventative => Identification => Acute
Medicine of At-Risk Care



- **Continuum Trend: From Acute => Wellness**
 - Increased consumer knowledge & self-care → increasing demand for wellness and preventative medicine
 - Increased influence of CMS
 - » Cost savings from earlier stages of the continuum
 - » Average time of relationship highest in CMS



TRANSITION TO CONTINUUM OF CARE – OPPORTUNITIES

Wellness => Preventative => Identification => Acute => Recurrence/ => Chronic Care
Medicine of At-Risk Care Compliance



- **Dearth of pharma, device & diagnostic products for chronic diseases**
 - Increased remote patient monitoring and eVisits
 - Shortage of direct care personnel => efficiency solutions
 - Growth of chronic care facilities
- **Wellness & preventative medicine will be demanded by consumers**
 - Point-of-Consumer diagnostics
 - Meeting consumer demand for data
- **Improved and faster diagnostics to reduce cost by**
 - Identification of those "at risk"
 - Prevention of recurrence



UNMET NEED: PRODUCTS FOR THE DECENTRALIZATION OF HEALTH CARE

• Trends

- Minimally invasive surgery
- Trend from acute => chronic illnesses
- Improved Point-of-Patient monitoring
- Focus on shifting ER visits to primary care
- Long term care will bankrupt Medicare unless we reduce institutional care

• Opportunities

- Closing or repurposing of hospitals
 - » Ambulatory Surgical Centers
 - » Repurposing of hospitals to assisted living
- Products to support home care and community centers





UNMET NEED: CHEAPER PRODUCT DEVELOPMENT & MANUFACTURING

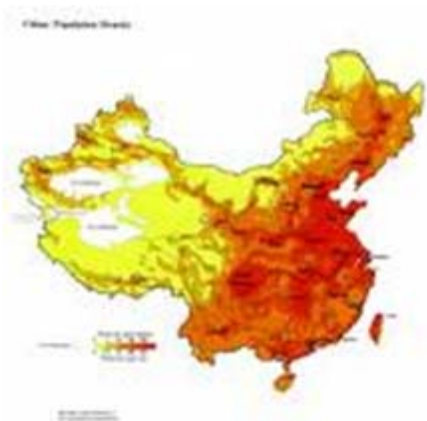
- Trends
 - Decreasing margins in the industry
 - Increasing coverage => greater volumes
- Opportunities
 - Development
 - » Better animal models and cell lines
 - » Predictive methodologies
 - » Repurposing & new drug delivery
 - Manufacturing efficiencies



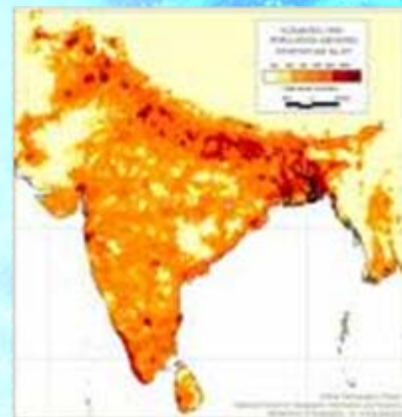


UNMET NEED: INTERNATIONAL EXPANSION

- Trends:
 - Higher growth rates abroad
 - » Rising middle class in countries such as China & India
 - » Government increasing worker, health welfare benefits
 - Reverse brain drain
- Opportunity: *LOCATION, LOCATION, LOCATION*



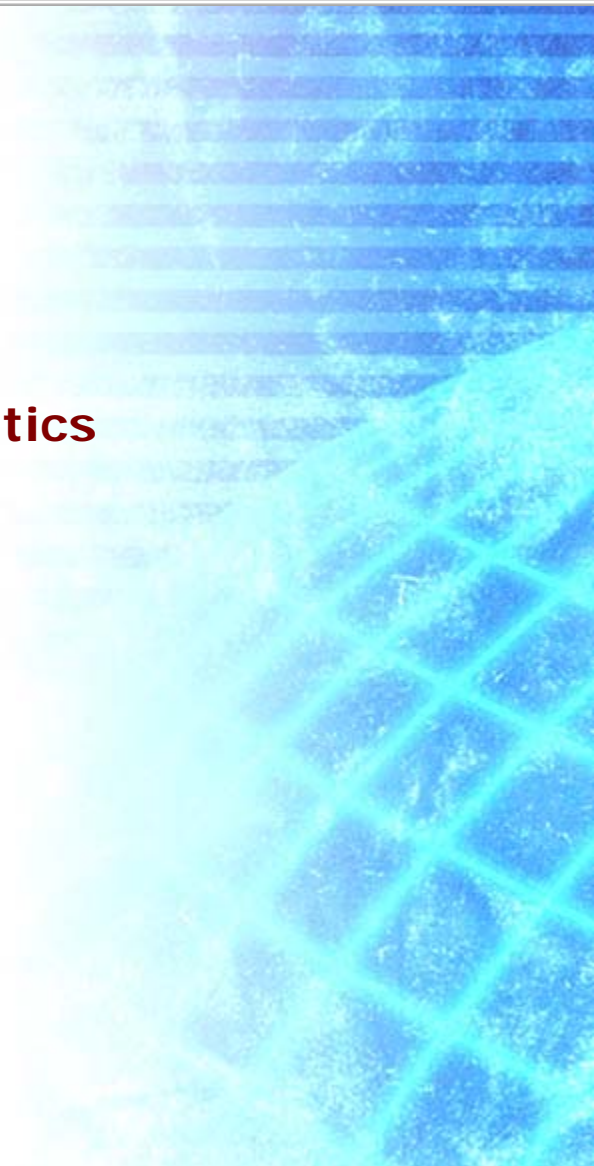
China has 1.3 billion people, give or take the population of the U.S!





Many Other Unmet Needs

- **Mental Health**
- **Workforce training**
- **Pediatric products**
- **Improved primary screening diagnostics**
- **Many diseases and conditions**
 - **COPD**
 - **Stress urinary incontinence**
 - **Rotator cuff tears**
 - **Obesity**





Barriers to Solving Unmet Needs

SOME AXIOMS OF GOOD BUSINESS

SOLVING UNMET NEEDS ≠ GOOD BUSINESS

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*SOLVING BARRIERS = GOOD BUSINESS OPPORTUNITIES*

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TIMING, TIMING, TIMING

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*DON'T ANSWER A QUESTIONS WHEN NO ONE WANTS OR NEEDS THE ANSWER*



# ***SOLVING UNMET NEEDS ≠ GOOD BUSINESS***

- **Policy and regulation**
  - Gatekeepers slowing product development, approval & uptake
  - Understaffed @ FDA, IRBs, health systems, CMS
  - View of technology as the cause/problem not the solution to increasing costs
- **Limitations on changing the practice of medicine**
  - Decreasing available time for new product training & information
  - Academic Center adoption has long lead times but is critical
  - Reduction in consultative sales force due to tightening margins
- **Financial decisions may slow clinical or long term savings**
  - Need for fast payback
  - Difficulty in dealing with this year's financial burdens
- **Uncertainty in the sector slows investment in creating new technology & in buying new technology**
- **TIMING, TIMING, TIMING**



***SOLVING UNMET NEEDS ≠ GOOD BUSINESS***

***TIMING, TIMING, TIMING***

# An Optimist Viewpoint on U.S. Healthcare

Technology is not the problem, it is part of the solution.

As Winston Churchill said, "You can count on the Americans to do the right thing, after they've tried everything else."



*Ignore the cigar!*



*With more and better products and a better health care system, I hope for an old age like this fellow...*





# **THANK YOU!**

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