The Impact of Future Healthcare Reform on MedTech Communications
Perspectives From an Early-Stage Medical Device Company

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The Impact of Future Healthcare Reform

Things that are certain……..

• There will be change
• The change will be disruptive
  – Multiple interested parties
  – Conflicting agendas, perspectives, objectives & policies
• Disruptive change creates opportunities
  – Healthcare delivery & innovation
  – Regulatory (federal, state, OUS)
  – Reducing overall costs (resources, availability, access)
  – Funding (government, private, charitable, tax-impact)
  – Evolving business models (pharma, medtech, biotech, IT, etc.)
The 3 “R’s” of Healthcare…and the Implications

• Reform (inherent conflicts)
  – Reduce the rising cost of healthcare
  – Expanded coverage – uninsured/under-insured; pre-existing conditions
  – Relative roles & responsibilities – individuals / payers / government

• Reimbursement (no pay = no use)
  – Who pays – individuals / providers / payers / government
  – Addressing the incentives & competition that govern spending
  • Today – we pay for the delivery of services vs. paying for outcomes

• Regulation (conflicting interagency objectives / policies)
  – FDA – devices, technologies, drugs, biologics
  – CMS – Medicare / Medicaid, state governments & private payers,
  – DOJ & State AGs - enforcement
Building MedTech Businesses – Risks / Considerations

- **Products / Technologies**
  - Proof of concept – improvements/enhancements vs. unmet needs
  - Intellectual property and freedom-to-operate

- **Clinical / Regulatory Pathways**
  - FDA vs. OUS vs. Reimbursement

- **Reimbursement / Pricing**
  - Understanding payer priorities (CMS, private, self-pay)
  - U.S. - code + coverage = payment (how to achieve)

- **Financing / Capital Requirements**
  - Business models – rate of market adoption
    - Capital efficiency - achieving valuation step-ups
  - Investor liquidity events

- **Commercialization / Execution**
  - Consumers / patients; providers; payers
New Business Challenges – Conflicting Demands

- Dueling objectives of healthcare reform
  - Slowing the growth of healthcare expenditures
  - Expanding coverage to the uninsured / underinsured / pre-existing conditions
  - Demographics guarantee increasing healthcare demand

- Accelerating innovation vs. market adoption vs. costs

- Evolving healthcare delivery models & venues

- Growth in emerging markets > growth in traditional markets
  - Geographically
  - Pricing pressure in mature markets vs. getting reimbursement in new markets

- Clinical data requirements
  - Safety vs. efficacy vs. comparative effectiveness – different expectations
  - Who pays for expanded studies – time, resources, affected patients

- Who pays – fundamental philosophical differences
  - Consumer choice / market competition vs. government mandates
Communication Challenges
Conflicting Priorities Between Governmental Agencies

• Regulatory vs. Reimbursement
  – CMS vs. FDA vs. Private Payers vs. Professional Societies
  – Clinical data for FDA clearance ≠ clinical data for reimbursement

• Innovation vs. Ethics
  – Medical device development requires clinical collaboration (as compared to lab-based drug discovery)
  – Physician involvement requires transparency in clinical studies and product commercialization
  – Complete “bans” on physician/industry collaboration will hurt innovation / patient care improvements
Communication Challenges
Healthcare System Reform – Conflicting Demands

• New, emerging business models
  – Moving from chronic/sickness to preventive/wellness systems
  – Patients’ roles in the healthcare treatment/delivery decisions
  – Payment for treatment vs. delivery – future linkage between
    • Users (patients)
    • Providers (physicians, hospitals, caregivers)
    • Payers (government, insurance, managed care)

• Legal liability & implications
  – Ethics (mistakes vs. negligence vs. fraud)
  – Off label vs. improper use
  – Medical liability / tort reform – no guarantees in medicine
  – Conflicts of interest – differences in devices vs. drugs
Communication Challenges

Continued Medtech Innovation Requires Risk Capital

• Investment for product / technology development & growth
  – Angel & individual investors
  – Venture capital
  – Healthcare investment funds
  – Strategic / corporate investment & partnerships
  – Public equity markets & various forms of debt instruments
  – Investors hate & avoid uncertainty

• Government-sponsored research
  – R&D grants/gifts
  – NIH

• Disease advocacy / charitable organization sponsored R&D
  – e.g., American Cancer Society; American Heart Association
  – The Bill & Melinda Gates Foundation
Venture Capital – The Lifeblood of MedTech Start-Ups

Capital Raised 1980–2009

- Partnering
- Financing
Key Communication Considerations
New Products / Technologies / Services

- **Customers (patients)**
  - Addresses an unmet medical need
  - Improves outcomes (and costs)

- **Providers & payers**
  - Addresses an unmet / complex / costly problem
  - Impact on the care delivery model – clinically & economically
  - How market adoption will improve overall costs to the system
  - Incentivized delivery networks to reinforce adoption / disruption

- **Investors**
  - Transparency, predictability & certainty
  - Understandable, quantifiable risks & returns
Healthcare Reform Communications

Keys to success

• Knowledge – listening & understanding multiple agendas
• Communication & advocacy – multiple audiences; tailored, consistent messages
• Active participation – across complex, inter-related functions
• Anticipation – avoid “pot holes” & unintended consequences
• Flexible, adaptive & opportunistic
• Positive perspectives – results orientation