

# “Top 10 Reasons” the Reimbursement Strategy is Essential!

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Early Strategy Integration is **CRITICAL** to any  
Product's Success



# #1: Some Things Won't Change Under Healthcare Reform

- Ultimately, at some point in a product's life cycle, it will be impacted by reimbursement
- Rising healthcare costs (direct and indirect) are cutting into hospital and physician profit centers and they are responding
- A well-designed reimbursement strategy, integrated early in the development phase with regulatory, clinical, and marketing strategies can impact the pendulum to swing to the positive
- Bottom line...if there is no reimbursement, it will not sell.



# #2: Reimbursement Must Start with the Initial Development of Product

- Product Design

- ▶ R&D must understand the need to show clinical value
- ▶ Diagnostic vs. therapeutic

- Setting of Care

- ▶ Different reimbursement based on site of care

- Provider type

- ▶ Surgical vs. Medical; Physician vs. Non-physician

- Clinical Indications

- ▶ Define subset of patients. Include target patients in clinical trials



# #3: All the Elements of Reimbursement Must Come Together

- Coverage
  - ▶ Is coverage in place? What kind of data will be required?
- Coding
  - ▶ Are there existing codes or is a new code(s) required?
- Payment
  - ▶ Is payment adequate to support your pricing?
- Understand reimbursement landscape for competitive products
- “Staying under the radar” is not a strategy



# #4: Understand how CMS Continues to Change

- CMS is “packaging” more and more services (meaning no additional payment)
  - ▶ Think about marketing terminology and descriptors for CPT codes
- Coverage dependent on clinical data specific to Medicare patients



# #5: More and More Clinical Evidence will be Required

- Clinical evidence will become even more important!
  - ▶ Increased expectation on level of evidence
  - ▶ CER will compare competitive products (not just placebo or standard treatment)
  - ▶ Clinical evidence is not only needed for coverage, but payment (“clinical improvement” is required)
- Remember that you can get payment for your clinical trial



# #6: Must have a Coverage Strategy

- No longer writing blanket coverage decisions
  - ▶ Requires data!
- Payers are looking at the subset of patients who have best outcomes
  - ▶ (i.e. Only Type 1 patients with diabetes or patients who have failed standard therapies)
- Consolidated decision making within Medicare
  - ▶ NCD vs. LCD, MACs result in fewer decision makers



# #7: Getting Codes is Becoming More Complex

- Specialty societies less inclined to support “using existing codes”
- CPT Panel is giving more and more Category III codes
  - ▶ Moving procedures from Category I to III
- Which is harder to get--HCPCS codes or FDA approval?



# #8: Must be able to Demonstrate “Value”

- Must understand your economic value proposition
- Economic value may differ by customer (payer, hospital, MD)
- Metrics are changing
  - ▶ No longer just “increase revenue or decrease costs”
  - ▶ Help achieve performance measures or avoid penalties (HACs or Never Occurring Events)



# #9: Reimbursement and Regulatory Must be Aligned

- 510(k) clearance may appear to be the quickest and most affordable way to enter market
- Substantially equivalent = substantially equivalent payment
  - ▶ May make it more difficult to get unique coding or coverage
- 510(k) submission may not provide the clinical outcome data required by payers



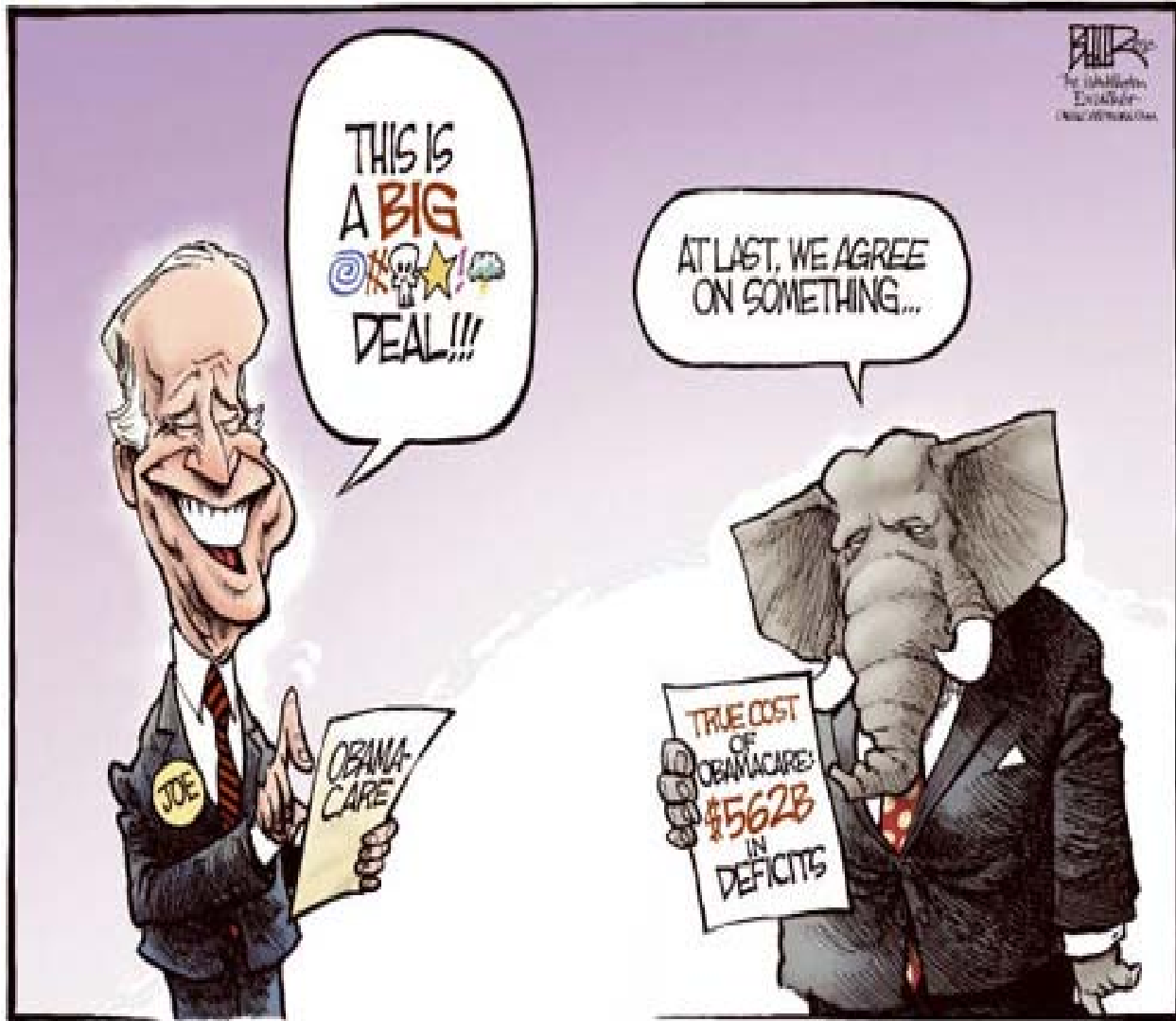
# #10: Is Healthcare Reform Good or Bad?

## Depends on Who You Ask!

### Expanded market share

- 32 million potential new customers
- Removal of lifetime caps
- Coverage for pre-existing conditions
- Expanded coverage for preventive services





# Moving Forward

- Healthcare Reform will continue to evolve...stay tuned!
- Opportunities for innovative products focusing on preventive services, showing reduction in hospital costs, emphasis on primary care
- Expect increased price pressure from hospitals and physicians
- Reimbursement must be factored into early product design and integrated with regulatory and market development
- Lack of reimbursement can limit market acceptance to innovative technologies despite clinical value



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QUESTIONS?

