Health Care Reform and Its Impact on the Medical Device Industry
Agenda

• Current Status of Health Care System Reforms Initiatives
  - Key Topics (access, cost, quality)
  - Status Report
  - Key Issue Summary
  - Cost Offset Ideas

• Implications for Medical Device Industry
  - Medical Device Tax
  - Comparative Effectiveness
  - Device Registry

• Key Takeaways
  - Need for better evidence/value demonstration
Health Reform Must Address Each of These Issues
Stakeholder Positions Have Changed Since Reform Attempts of the Early 1990s

<table>
<thead>
<tr>
<th>AGAINST</th>
<th>FOR</th>
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|         | American Medical Association  
          | Physicians dedicated to the health of America |
|         | AHIP  |
|         | NFIB  |
|         | PhRMA  
          | New Medicines. New Hope.® |
Debate/Votes Expected by Mid-October

- Filibuster ability means 60 votes are needed to stop debate and push legislation forward
- Currently efforts are led by Senate Finance Committee Chair Sen. Baucus who has been working with bi-partisan “gang of 6”
- Finance and HELP Committee versions need to be merged

Senate

- Health committee’s chaired by long-standing (liberal) members Waxman, Rangel, etc.
- Speaker has tight control of the process
- Conservative Democrats (Blue Dogs) playing key role in negotiations
  - Focused on cost containment

House

- Obama may be drafting his own bill
- House bill under-going unusual “second” round of revisions

Baucus bill under-going revisions

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## Health Reform Key Components

<table>
<thead>
<tr>
<th>Item</th>
<th>Issue</th>
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| Public option                 | • Key element of reform for Democrats  
|                               | • Opposed by Republicans, Health insurance industry                                                                                  |
| Health insurance pooling      | • Opposed by Democrats favoring public option  
|                               | • In Senate called co-ops, in House it’s the Exchange                                                                               |
| Individual mandate            | • Supported by health insurance plans  
|                               | • Formerly opposed by Obama but now he supports                                                                                     |
| Employers coverage mandate    | • Of great concern to business (especially smaller)  
|                               | • Current Baucus bill does not include strong mandate but beginning in 2013 employers with >50 employers will have to pay government for employees with co-op insurance |
| Physician payment reform & medical liability caps | • Key elements desired by physicians groups                                                                                     |
| Expansion of Medicaid and SCHIP, Health care quality measures, Value-based purchasing/pay-for-performance, minimum standard benefit design |
# Health Reform Key Revenue Sources

<table>
<thead>
<tr>
<th>Item</th>
<th>Issue</th>
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<tbody>
<tr>
<td>Tax on Insurers</td>
<td>• The fee would raise $6 billion a year</td>
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<td>Tax on Pharmaceuticals</td>
<td>• Pharma has $80 billion drug rebate deal in place</td>
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<td>• Not every Democrat is on board with preserving the deal</td>
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<td>Hospital Cost-Cutting</td>
<td>• AHA has $155 cost cutting deal in place</td>
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<td>Clinical Laboratory Tax</td>
<td>• Recent revision to Baucus bill allow labs to avoid tax by agreeing to freeze on fee update</td>
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<tr>
<td>Medicare Advantage Cuts</td>
<td>• Favorite target of Democrats who favor traditional Medicare</td>
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<td></td>
<td>• Opposed by health plans</td>
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<tr>
<td>Tax on High Cost health plans</td>
<td>• Attack on “Cadillac” plans</td>
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<tr>
<td>Annual Provider Payment Updates</td>
<td>• Incorporating productivity adjustments and outlier payment reductions</td>
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<td>Tax on the “Wealthy”</td>
<td>• House Democrats offered but it has been resisted</td>
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Medical Device Tax

- Baucus Bill contains $40 billion tax on medical devices over 10 years
- Amounts to $4 billion per year which is near 10% of industry’s annual profits
  - Significantly more than the 4% proposed fee on pharmaceutical companies
- Tax will be assessed to companies based on market share
- Amount is well above the $2.5 billion in venture funding for medical devices over the last 4 quarters or $1 billion raised in IPOs in 2007
- Strong suggestion it will harm innovation
Medical Device Tax (continued)

• In response to criticisms Baucus adjusted initial proposal to:
  - Apply only to companies with $5 million in annual domestic sales
  - Exempt Class I devices and products that are less than $100 per unit

• Focus on sales suggests un-profitable companies will face tax

• A blunt instrument that penalizes successful valuable technologies along with less beneficial ones

• Some suggestions that current negotiations between industry and Hill staff are nearer to $2 billion
Comparative Effectiveness Research (CER)

- $1.1 Billion was set aside for CER in the recent stimulus bill
- Health reform efforts create Patient-Centered Outcomes Research or Center for Comparative Effectiveness Research Institute
- Key points of debate:
  - Clinically focused or should it consider costs?
  - Should information be used to inform Medicare coverage and/or reduce spending?
  - Will it be tied to HHS/AHRQ or independent?
- IOM has generated priority list which is focused on biggest cost areas
- In Baucus bill, CER secures $150 million in funding per year

### Potential Duties of Institute

| Establish national research priorities and agenda | Providing a peer review process |
| Carry out research project agenda | Dissemination of research findings |
| Determine feasibility of in-house research | Adoption of priorities, standards, processes, and protocols |
| Appointing advisory panels | Coordination of research and resources |
| Establishing a methodology committee | Annual reports |
| Data collection from Federal, State and private entities | |
Device Registry

- House Democrats bill creates a national device registry
- Established by HHS and linked to FDA
- Includes all Class II and Class III devices that are implantable, life-supporting, or life-sustaining
- Links Medicare claims, patient survey, and private-sector insurance claims data to facilitate analysis of post market safety and outcomes
- Industry notes that this:
  - Could be redundant with FDA activities
  - May include devices with no safety concerns (e.g., sutures, staples, prosthetic eyes)
  - Add costs to health care system
Key Takeaways

• Less political headwind from special interest groups than in previous years but a lot of work remains
  - Bringing together liberal and conservative Democrats

• Medical device tax will impose burden on industry
  - Burden more focused on larger companies however

• Emphasis on quality and cost containment will mean that medical device companies will need to be able to produce more clinical utility evidence
  - Rather than simply meeting FDA’s safety and effectiveness

• Opportunities will exist for truly innovative technologies to differentiate themselves
  - Funding data may come from CER Institute
Thank You