

# Health Care Reform: What It Means For Pharma

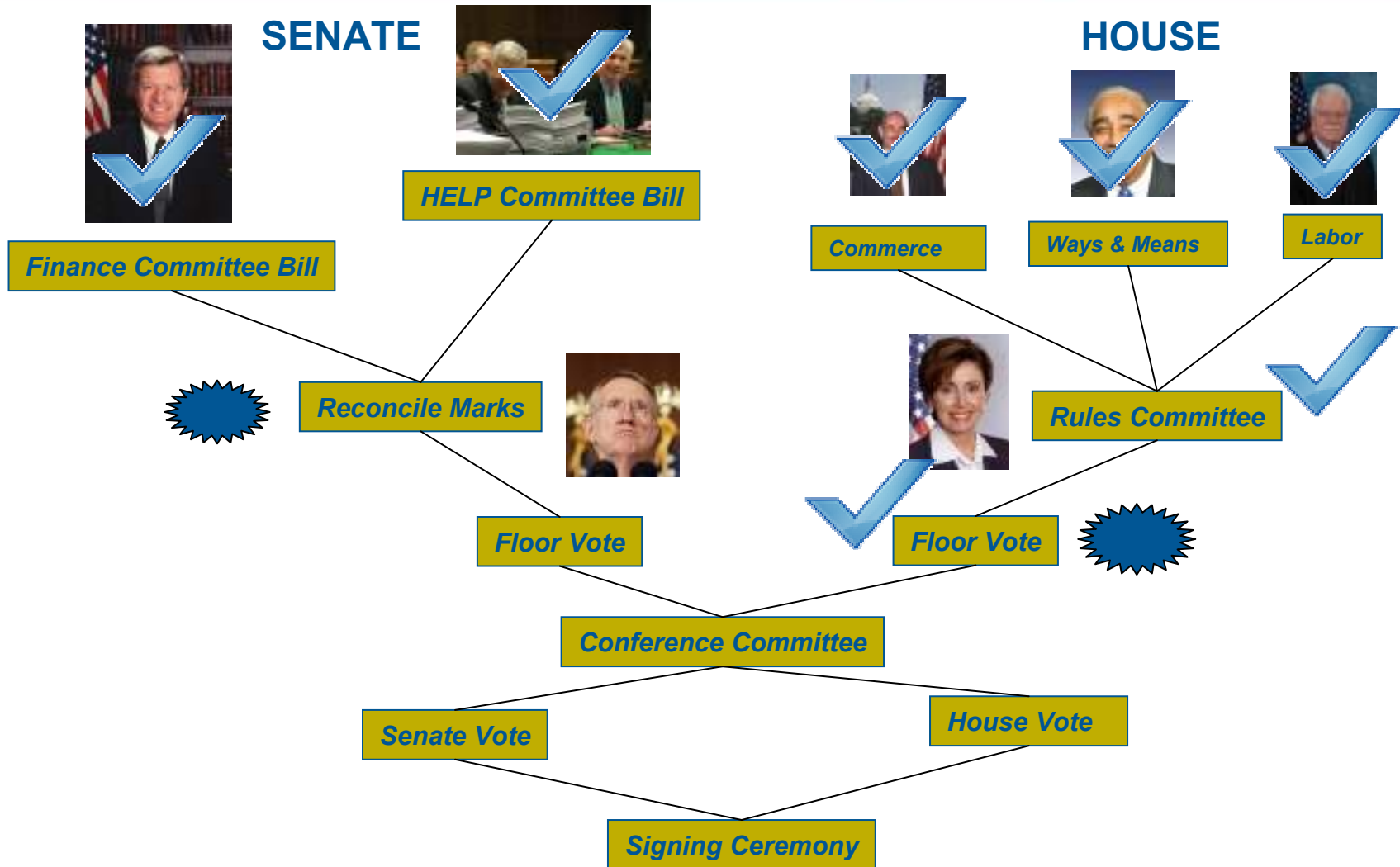
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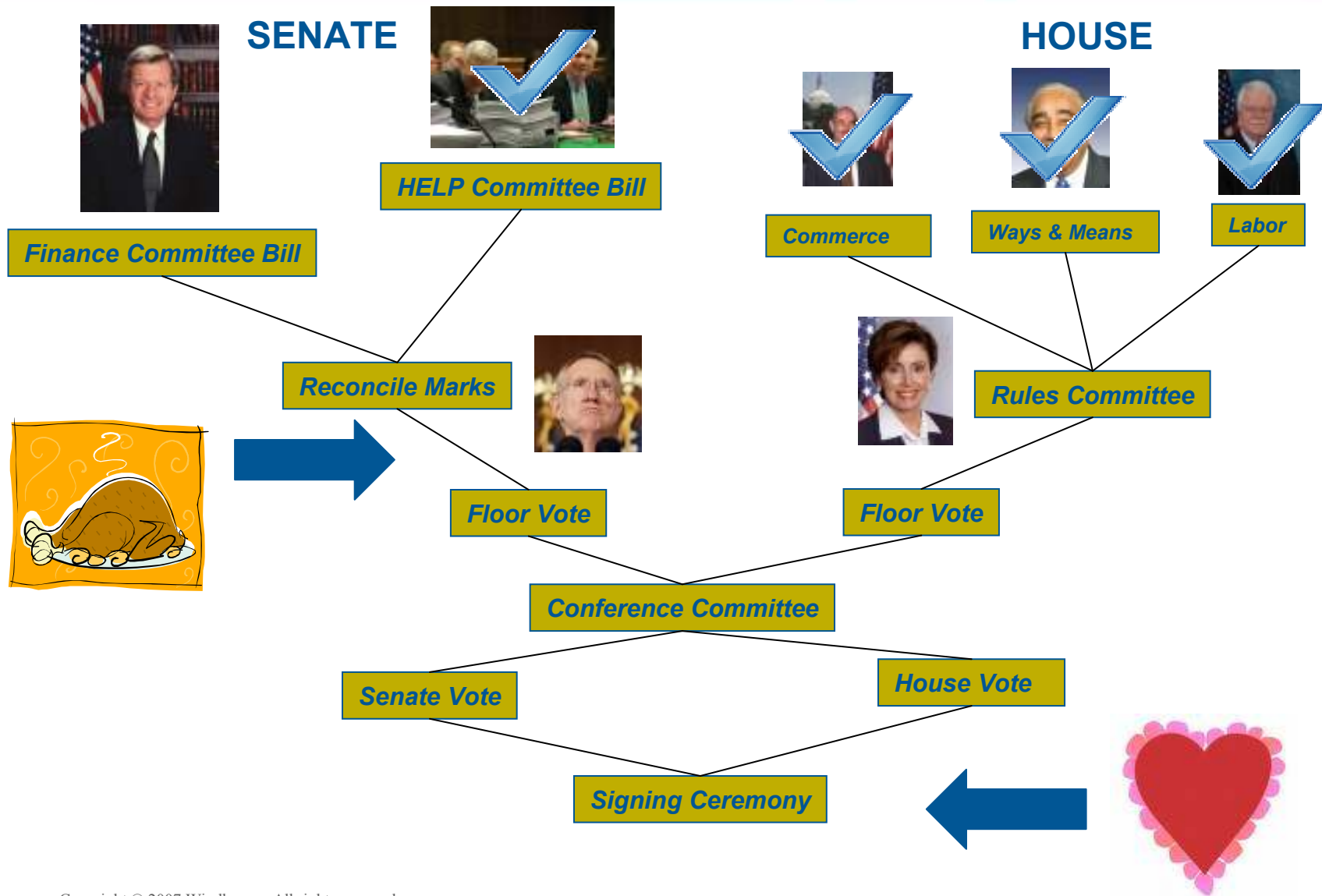
**Elsevier Business Intelligence**

**November 11, 2009**

# Complex Legislative Map



# The Weeks (Months) Ahead



# A Rose By Any Other Name...

## **House Bill: (HR3962)**

Affordable Health Care for America Act

## **Senate HELP Bill (S1679)**

Affordable Health Choices Act

## **Senate Finance Bill (S1796)**

America's Health Future Act

**Market Expansion,  
Insurance Control &  
Biologics IP Act of 2010**

# HCR 2009: The Second Act

The **RPM**  
Report

For Pharma, health care reform began six years ago .



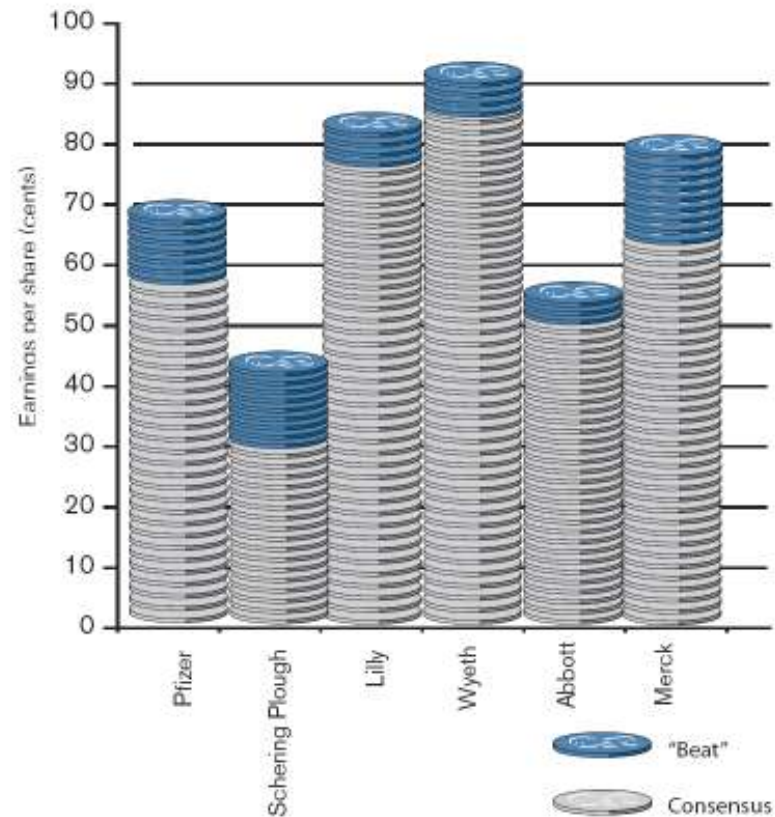
*Dec. 8, 2003*

***The Medicare Modernization Act***

# First Act Paid Off

- **Expanded Insurance Expands Volume**
  - Approximately 16 million beneficiaries add quality coverage
  - Elderly and Disabled Are Best Pharma Customers
- **Prices Squeezed Vs. Cash Price**
  - But NOT Vs. Medicaid Price
- **Best Possible Bill For Pharma—But Not Perfect**
  - Donut Hole – an immediate and growing concern

*The Part D “Boom”*



## Second Act Looks Better



### *New Customers: Emerging Market*

25 million newly insured in 2013

By 2019, uninsured will drop to 18 million from 50 million now

Uninsured will drop to 6% of total population

-



### *Rebates & Other Offsets*

\$80 billion over 10 years

➤ **\$352 per new insured life pays for the \$80 billion**

=

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# New Paying Patients

CBO estimates of where the non-elderly will get insurance under House Affordable Health Care Bill

	2010	2013	2016	2019
<b>Medicaid &amp; CHIP</b> (watch MCO plans)	40	46	49	50
<b>Employer</b>	150	170	169	159
<b>Nongroup</b>	27	23	23	24
<b>Exchanges</b>	--	9	20	30 <sup>a</sup>
<b>Uninsured</b>	50	26	18	18 <sup>b</sup>

a: Six million in public plan; b: Six million of uninsured are unauthorized immigrants

# Forget 2012; Watch 2013

- Medicaid to cover nonelderly with income below **150 percent** of the FPL
  - Very generous coverage
    - The real “public option”
- Federal government to provide 91 percent of the costs of newly eligible Medicaid enrollees
  - A big jump from current levels -- about 57 percent.
    - Access to a deeper pocket.
- Feds will spend **\$425 billion** net over 10 years for Medicaid/CHIP
- States will chip in about \$34 billion above current expenditures over the 2010–2019 period

2013

Medicaid



## ■ AIDS Treatments

- **Drug therapy starts earlier:** Allows states to extend Medicaid benefits to thousands of low-income people living with HIV who are presently ineligible because their HIV has not progressed enough.
- **Drug therapy continues longer:** Improves coordination between Medicare and the AIDS Drug Assistance Programs (ADAPs) to ensure more people can access ADAP and consistently adhere to their treatment regimens.
- **Access to insurance:** “Currently, fewer than one in five (17%) people living with HIV has private insurance, due to most insurers' denial of coverage to people living with HIV. The House bill would end the exclusion of people with ‘preexisting conditions.’”

Source Gay Men's Health Crisis

## Key Objective for Vaccine Industry Create Adult Vaccine Market



- Health reform jump starts that goal
  - \$33 billion over ten years on public health, prevention and wellness
  - \$1.4 billion directly “to expand access to vaccines”
  - But, more importantly, vaccines will become part of the required baseline benefits for many forms of private insurance
    - Vaccines are part of “essential services”
    - No co-payments permitted for preventive services:
      - *ACIP-recommended vaccines are a defined preventive service*
      - *Vaccines will be covered at no cost to insured members*
      - *Vaccine marketers will fight about price with insurers, with public health community on vaccine companies’ side*

## Two Key Provisions

### 1. Prescription drugs are covered as an “essential benefit” in the minimum package for acceptable insurance plans.

Solidly ensconced as component number five on the list of covered items: hospitals, outpatient clinics, doctors, equipment for hospitals and home use, prescription drugs.

### 2. Co-pay standards for essential benefits are defined

- Sets limits for co-pays for services including drugs
  - Initially, the annual limit would be \$5,000 for an individual and \$10,000 for a family;
  - Amounts would be indexed for inflation using the CPI
- HHS is required to favor co-payment formulas over co-insurance when determining out-of-pocket expenses levels for basic, enhanced and premium plans.

**Delivering on PhRMA’s Goal to Equalize Co-pay Levels for Medicines and “other healthcare services”**

- Predictable Copays
- No Cost-Sharing On Preventative Services (Inc. Vaccines)
- End of Lifetime/Annual Caps
- Elimination of Pre-Existing Condition Exclusions (and Rescissions)

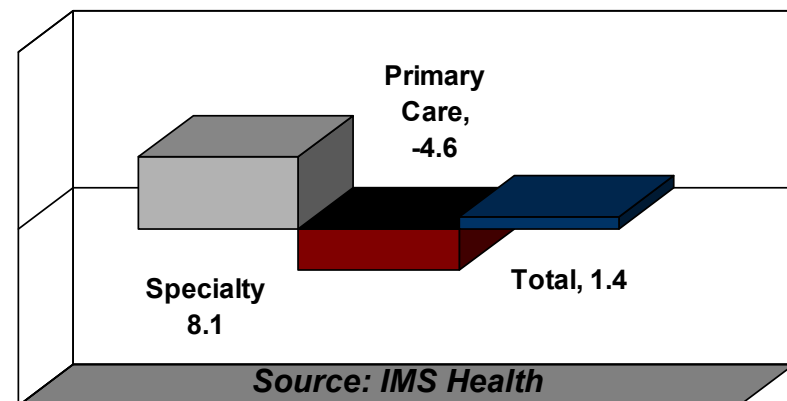


*Boon For  
High Cost  
"Specialty" Products*

## “Specialty” Drugs

- Copay Reforms Address Key Issue
- FOBs Eliminates IP Uncertainty
- Special Protections for Orphan Products
  - Exempt From Excise Tax
  - Exempt From New Formulation Rebates
  - Special Consideration In Comparative Effectiveness Research

*Rx Spending Growth, By Segment*



**Pharma Already  
Going There**

# Riding Health Reform



**Pharma's Dog in This Race is FOBs**

- From pharma's perspective, health reform is a great delivery vehicle for a top IP priority.
  - Protection for biologics will create a solid proprietary market for the biopharma industry for decades – in an area where IP protection is more problematic than traditional drugs
  - Creates a market of many individual brands – think the ARB or statin markets from @2000.

## Competing in a Fishbowl

### House Bill:

- ✓ Follow-on developers would have to supply to the current marketer (reference product sponsor) a copy of the application and information
  - ✓ About the biosimilar product
  - ✓ Method of manufacture
  - ✓ Materials used in manufacture
- ✓ Then third parties – with a relevant patent -- can also ask for the information

### Senate Bill:

- ✓ Limits access to specific attorneys and third-party representatives

## Questions?

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