

Drug Information and Communication in Health Care Reform Bill

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Disclosure

- Information Sharing session only
- Your choice on what to do with this information
- Information source: Advertising Coalition
- “Democracy is not a spectator sport”
- Your participate may make the difference



Elections Matter

- White House sets FDA/HHS policy agenda
- Congressional Oversight and Legislation
 - Democrats solidify control in House and Senate
 - Fewer moderates
- Obama honeymoon
 - Like FDR and LBJ's ?
 - or already over ?



Wall Street Crisis Matters

- Budget & trade deficits go from terrible to worse
- Decreases spending alternatives for healthcare.
- Expect:
 - Budget Neutral Initiatives, e.g., transparency, counter-detailing, marketing limits
 - Budget Enhancing Initiatives, e.g., reduce deductions for education and marketing costs
- Increased reliance on executive power
 - More room for FDA and HHS policy action
 - More room for enforcement by HHS & states
- Obama health leaders assert that healthcare costs part of financial crisis, thus part of financial rescue solution



Obama Positions Matter

- Focus on health cost savings & broad coverage
 - better technology
 - Improve primary & chronic care
 - decrease administrative overhead
 - Insurance savings (National Health Insurance Exchange)
- Promote generics & follow on biologics (FOB)
- Advocate direct negotiation of government prices for drugs ?
- Re-importation ? (Safety v. price controls)



Health Care Reform (HCR) Matters

- House and Senate drafts circulating
- Goal for bill on President's desk by August
- House needs no Republican votes
- Senate Question: 51 votes or 60 votes
- July deliberations key
- Two Major questions remain
 - Federal Insurance Plan v. Private plans
 - Who pays and how, including tax on employer health insurance?



Campaign Promises Matter

- No tax increase on persons earning less than \$250, 000
- No middle class tax increase
- Rejected McCain call to tax employer health benefits
 - Reconsidering, but exempts lower earners & plans from collective bargaining
 - Prominent D's offer support



Senate Finance Committee

- Chairman Baucus leads Senate efforts
 - Reforms considered moderate, possible
 - Follows Kennedy lead
- Ranking Member Grassley
 - Remains aggressive critic of industry
 - Picks up Baucus as “transparency” ally
 - May disfavor Ad Tax provision



House Leadership

- Congressman Henry Waxman (D, CA) leads Commerce Committee
 - Shifts Commerce Committee to left
 - Strident, effective critic of industry
- Congressman Charles Rangel (D, NY) leads Ways and Means Committee
 - Critic of DTC; estimate \$37 B savings



Communication Provisions in HCR

- Transparency (payments to prescribers)
 - may be the only topic of bipartisan agreement
- Payment provisions
 - Still mostly vague and undecided
 - PhRMA agrees to contribute \$80 Billion
 - Tax Deductibility calculated at \$37 Billion
 - Follow on Biologics
 - FTC provision on brand/generic settlements



Paying for HCR

- Obama & Baucus promise a “revenue neutral” bill, i.e., new revenue to cover new costs
- Medicare cost projections traditionally underestimated
- Cost and Revenue projections over ten years
- Most limited alternative = \$1 Trillion
 - may be closer to \$2 Trillion (Parente/Tomai HSI estimate nearly \$4 Trillion)



Contribution of drug, device and bio industries

- Biggest bites likely to come from doctors, hospitals and insurance
 - Willy Sutton reality
- PhRMA promises \$80 Billion
 - “Dollars for donuts”
 - Pre-emptive strike at Waxman “claw-backs”
 - Addresses serious voter concern; filling cost gap in Medicare Part D donut hole
 - May promote drug adherence



Tax deduction for marketing biopharmaceuticals and devices

- \$37 B in tax revenue requires \$100 B in expenditures over 10 years
 - Companies in approx. 35% tax bracket
- \$10 Billion per year
 - DTC “rack rate spend” = \$4.2 B; actually closer to \$3 Billion
 - Requires \$7 Billion in other expenditures, i.e., must include all marketing communications + some other marketing costs



Two Coalitions

Coalition for Healthcare Communication

(All MedCom)

and

Advertising (Tax) Coalition

(DTC only)



Advertising (Tax) Coalition

- Jim Davidson, leader
- AAAA, ANA, AAF (Advertising)
- NAB, NCTA, CBS, NBC, Time Warner, Disney (Media Organizations)
- NAA, MPA (Publishers)
- PhRMA (Research Drug Manufacturers)
- Grocery Manufacturers of America



Ad Coalition

Urges calls and Letters

- Senate Finance Committee and all Senators
 - Charles Schumer, NY
 - Robert Menendez, NJ
 - John Kerry, MA
- House Ways and Means Committee
 - Chairman Charles Rangel, NY
 - Richard Neal, MA
 - Bill Pascrell, NJ



Talking Points

- Support reform, not tax penalty for marketing
- Jobs, Jobs, Jobs
- Medical Communication supports patient care, medical innovation and lower costs
- Right medicine, right patient, right time
- First Amendment applies to medical communication
- Marketing communications (information) is a legitimate part of cost of doing business



Listen Carefully

- Report specific feedback
 - Intelligence critical to DC efforts
- Respond respectfully to counter-arguments
- Explain economic realities, esp., overstatement of \$37 B revenue estimate
- Request specific commitment to oppose
- Request follow up
- Close feed-back loop



More on Transparency Provision in HCR

- Grassley/Kohl circulating new Sunshine provisions
 - Part of Baucus HCR package
 - Includes a national website registry
 - Applies to all gifts and payments
- DeFazio/Stark version in HCR
 - \$5 Threshold for registration
 - Wish list of Prescription Project, NLARx
 - No preemption of state laws



“Conflicts of Interest”

- Only “pharma” conflicts targeted
 - Silence on conflicts by insurance, managed care, government, plaintiff’s, whistle blowers, etc.
 - Academic Medicine, Journal Editors & Prescription Project lead the charge
 - AMCs, Macy, AAMC, “ethics researchers”
- IOM report very important
- Macy Foundation & other reports will stimulate continued scrutiny



Transparency popular & important

- Intended to limit company-doctor interactions
- Revenue neutral
- Target for Class Action lawyers
- House version
 - strict liability reporting by companies
 - targets association payments, grants; threatens medical society memberships



IOM Report on Conflict of Interest

1. Endorses “Transparency” Legislation
2. Asserts that disclosure is only a significant 1st step, but more is needed
3. “Conflicted” doctors and researchers should have very limited roles in standards and review boards
4. Speaker Bureaus should end
5. “Two Year Consensus Process” for a new paradigm in certified CME



Kamp Crystal Ball

- Clouded at best, maybe shattered
- Some hope
 - Health reform part of economic crisis
 - PhRMA \$80 Billion promise
- Some despair
 - Financial times limit alternatives
 - Unrealistic expectations re: free healthcare, drugs
- Some certainty
 - Healthcare top priority of Boomers
 - Critics of healthcare communications energized



What must Happen

- **Value of Medical Communications Must Be Made Clear to Policy Makers**
 - Patient care, patient care, patient care
 - Must measure outcomes, circulate proof
 - Doctors and patients must join effort
- **Our organizations & businesses must gird for tough economic times and be prepared to respond quickly to change**
 - Must BE and be SEEN as part of the solution
- **Help lead the health leaders**



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