

The tax impacts affecting pharmaceutical, medical device and biotechnology companies



October 2009

Agenda

- I. Background & motivation for health reform
- II. Industry perspective
- III. Primary elements of reform packages
- IV. Tax implications
- V. Timing

Several forces are driving the push for healthcare reform

- I. Three goals: increase coverage, improve quality, lower costs
 - A. 46 million lack coverage*
 - B. International comparisons suggest U.S. outcomes are worse
 - C. Significant regional variation in costs; current cost trajectory is unsustainable, need to “bend the curve”
- II. Health insurance markets
 - A. Employers play a key role in health insurance
 - B. Individual market is small, subject to state mandates, and expensive
 - C. Government becoming an increasingly important player (Medicare, Medicaid, SCHIP)
- III. Past attempts at reform have failed

* Census Bureau, “Income, Poverty, and Health Insurance Coverage in the United States: 2008,” September 2009.

Positive implications for Pharma

- More insured means more demand for drugs
- Minimum benefit package and fewer underinsured will increase demand for drugs
- Emphasis on chronic disease management increases demand for drugs
- Increased adoption of EHR and IT in healthcare will help in accessing clinical data, patient recruiting, tracking outcomes, etc., and thus help speed up drug R&D
- Incentives and funding for personalized medicine research
- Less need for patient assistance programs

Negative implications for Pharma

- Higher rebates in Medicare Part D (“negotiated prices”), and more drugs could come under Medicaid-type rebates
- Comparative effectiveness studies and pay-for-performance could impact R&D and sales
 - * Companies with strong drug portfolios have funding such studies to differentiate their drugs
 - * ‘Me-too’ no longer be a viable strategy
- Increased competition from bio-equivalent drug manufacturers
- Increased importance of payers in drug decision-making, relative to the role of physicians, will impact drug sales model
- Proposals on ‘biosimilars’ have added uncertainty around patent protection and R&D investment for biologics
- Potential for increased price leakage, as coverage for uninsured adds another layer to the access tier
- OTC ineligibility for HSA/FSA

Polling question 1

Do you see tax reform or health reform as a higher priority issue in 2010?

- A. Tax
- B. Health
- C. Not sure

Focus of reform is improving coverage

- Common provisions in all 3 bills (House Tri-Committee, Senate HELP, Senate Finance Committee)
 - Individual mandates
 - Medicaid expansion and individual tax subsidies
 - Insurance exchange
 - Small business credits
 - Insurance market reform
- Differences
 - Employer mandates
 - SFC adopts “free rider” penalty
 - Public option
 - SFC creates CO-OPs
- Details are still unclear

Sources: Senate Finance Committee, “Chairman’s Mark, America’s Healthy Future Act of 2009,” as Amended and Released 2 October 2009; H.R. 3200, “America’s Affordable Health Choices Act of 2009,” 19 June 2009.

October 2009

Funding sources in house and senate bills

(FY 2010-19 total, \$billions)

	Tri-Committee *	Senate Finance **
Health-related sources		
Surtax on high-cost health plans	NA	\$201
Medicare and Medicaid cuts	219	404
Increase required rebates on pharmaceuticals	30	15
Fees on providers (pharma, device, insurers)	NA	121
Limit FSA contributions	NA	15
Individual / Employer Mandates	192	27
Eliminate deduction for Medicare Part D subsidy	NA	5
Other		
AGI surtax	543	NA
Delay worldwide interest allocation until 2020	26	NA
Corporate information reporting	NA	17
Codification of economic substance	4	NA
Tax treaty withholding limitation	8	NA

* Congressional Budget Office, Letter to Charles Rangel, 17 July 2009; Joint Committee on Taxation, “Estimated Effects of the Revenue Provisions of H.R. 3200, the “America’s Affordable Health Choices Act of 2009,” 14 July 2009.

** Congressional Budget Office, Letter to Max Baucus, 7 October 2009; Joint Committee on Taxation, “Estimated Revenue Effects of the Revenue Provisions Contained in Title VI of the “America’s Health Future Act of 2009,” As Amended through October 2, 2009, and Under Consideration by the Committee on Finance,” 8 October 2009; Congressional Budget Office, Budget Options Volume I: Health Care,” December 2008 (Options 74 & 75)

October 2009

PricewaterhouseCoopers

Slide 8

Identified funding sources could raise a range of revenues, depending on how they are designed

	10-year Revenue Potential
Health-related sources	
Tax exclusion for employer provided health insurance	\$160 billion to \$1.2 trillion
Medicare and Medicaid cuts	\$200 billion to \$600 billion
Increase required rebates on pharmaceuticals	\$15 billion to \$110 billion
Excise taxes on alcohol, tobacco, sugared drinks	\$100 to \$200 billion
Limit deduction for health spending over 7.5% of AGI	\$15 billion to \$180 billion
Repeal exclusion for HRA and FSA spending	\$15 billion to \$70 billion
Modify treatment of tax exempt hospitals	NA
Other	
AGI surtax	\$544 billion
Worldwide interest / Codification of economic substance / tax treaty withholding limitation	\$37 billion
Limit value of itemized deductions	\$270 billion

Sources: Joint Committee on Taxation, Letter to Senators Max Baucus and Charles Grassley, 2 June 2009; H.R. 3200, "America's Affordable Health Choices Act of 2009," 19 June 2009; Palmer, D., "Obama Eyes \$313 Billion More Cuts for Healthcare Reform," *Reuters*, 13 June 2009, Available at: <http://www.reuters.com/article/topNews/idUSTRE55A54E20090613>; CBO, "Budget Options Volume I: Health Care," December 2008 (Options 67, 74, 75, 106, 107, 108); Joint Committee on Taxation, "Estimated Revenue Effects of the Revenue Provisions Contained in Title VI of the "America's Health Future Act of 2009," As Amended through October 2, 2009, and Under Consideration by the Committee on Finance," 8 October 2009; Joint Committee on Taxation, "Estimated Effects of the Revenue Provisions of H.R. 3200, the "America's Affordable Health Choices Act of 2009," 14 July 2009; Hoffa, J., "Taxing Employer Health Benefits: The Poison Pill that would Kill Health Care Reform," *RollCall*, 29 June 2009, Available at: <http://www.rollcall.com/news/36374-1.html>.

Polling question 2

If additional funding is needed to fund health reform, do you think the government will turn to tax increases or spending reductions?

- A. Taxes
- B. Spending
- C. Not sure
- D. N/A

Proposed fee on branded drug manufacturers and importers

The new fee proposed by Senate Finance on branded drug manufacturers

- Fee imposed beginning in 2010 and would be nondeductible
- All manufacturers or importers of drugs or biologics offered for sale under prescription in the United States subject to fee
 - Both domestic and foreign manufacturers and importers included
- Fixed total collection of \$2.3 billion apportioned to covered entities based on market share in government sales in prior year
 - Single source and innovator multi-source drugs subject only
 - Only domestic sales included in sales
 - Sales under Medicare, Medicaid, Tricare, and Veterans Administration used to determine share of fee
 - Government collects sales data from agencies and notifies companies of obligation

Source; Senate Finance Committee, "Chairman's Mark, America's Healthy Future Act of 2009," As amended and released 2 October 2009.

October 2009

Proposed fee on branded drug manufacturers and importers (continued)

- Initial sales excluded from market share calculation. Covered sales include:
 - No sales under \$5 million
 - 10 percent of sales between \$5 million and \$125 million
 - 40 percent of sales between \$125 million and \$225 million
 - 75 percent of sales between \$225 million and \$400 million
 - 100 percent of sales over \$400 million

Source; Senate Finance Committee, "Chairman's Mark, America's Healthy Future Act of 2009," As amended and released 2 October 2009.

Polling question 3

Do you feel the international tax provisions will be enacted to fund a portion of this health care reform?

- A. Yes
- B. No
- C. Not sure
- D. N/A

Other provisions of interest to pharmaceutical/biologic companies

- Increased required Medicaid rebates for branded drugs
- Mandatory discounts in coverage gap under Part D
- Elimination of deduction for Part D Employer Subsidy
- Abbreviated path for follow-on biologics
- Waive copayments for generic “first fill” prescriptions under Part D
- Require Medicaid rebates for Dual Part D enrollees
- Other provisions
 - Excise tax on high-value plans (drugs likely target for cutting back plans?)
 - Comparative effectiveness research could increase or decrease demand for drugs?
 - Impact of cuts to Medicare Advantage program

Sources: Senate Finance Committee, “Chairman’s Mark, America’s Healthy Future Act of 2009,” As amended and released 2 October 2009.; Senate HELP Committee, “Affordable Health Choices Act of 2009,” 9 June 2009.

Proposed fee on medical device manufacturers and importers

The new fee proposed by Senate Finance on medical device manufacturers

- Fee imposed beginning in 2010 and would be nondeductible
- All manufacturers or importers of medical devices regulated by the FDA offered for sale under prescription in the United States subject to fee
 - Both domestic and foreign manufacturers and importers included
 - Class II devices with retail price under \$100 per unit and all Class I devices exempt from fee
- Fixed total collection of \$4 billion apportioned to covered entities based on market share in government sales in prior year, beginning in 2010
 - Companies must file annual report to Secretary of the Treasury, who will then calculate market shares and communicate obligation to companies

Source: Senate Finance Committee, "Chairman's Mark, America's Healthy Future Act of 2009," As amended and released 2 October 2009.

Proposed fee on medical device manufacturers and importers (continued)

- Initial sales excluded from market share calculation. Covered sales include:
 - No sales under \$5 million
 - 50 percent of sales between \$5 million and \$25 million
 - 100 percent of sales over \$25 million

Source: Senate Finance Committee, "Chairman's Mark, America's Healthy Future Act of 2009," As amended and released 2 October 2009.

Issues for device manufacturers

- Could Medicare and Medicaid provider cuts impact demand?
- Impact of changes to Medicare Advantage funding
- Response of manufacturers to the new fee
- Comparative effectiveness and potential impact on demand for products

Polling question 4

Have you calculated your liability under the new medical device fee or branded pharmaceutical fee?

- A. Yes
- B. No
- C. Not sure
- D. N/A

Fee on Health Insurance Premiums

- The largest of the three fees on health industry sectors is the \$6.7 billion annual fee on health insurance premiums.
- This fee is only on commercial insurance and does not apply to self-insured plans.
- In addition, the Senate Finance legislation, known as America's Healthy Future Act, includes a 40 percent excise tax on health insurance premiums in excess of \$8,000 for individuals and \$21,000 for families.
- The legislation provides for a higher threshold of \$9,850 for individuals and \$26,000 for families for those who work in professions designated as high-risk and for individuals older than 55

Source: Senate Finance Committee, "Chairman's Mark, America's Healthy Future Act of 2009," As amended and released 2 October 2009.

Budgetary impact of proposed industry fees has been revised upwards, but the impact on companies remains the same

- The revision is attributable to a technical issue dealing with certain assumptions about how the overall economy would respond to the fees
- Impact of fees on companies remain the same

	Original 10-Year Impact	Revised 10-Year Impact
Pharmaceutical Fee	17.2	22.2
Medical Device Fee	29.9	38.6
Health Insurer Fee	45.3	60.4
Total	92.4	121.2

Sources: Joint Committee on Taxation, “Estimated Revenue Effects of the Revenue Provisions Contained in the Chairman’s Mark of the “America’s Healthy Future Act of 2009,” 16 September 2009; Joint Committee on Taxation, “Estimated Revenue Effects of the Revenue Provisions Contained in the Chairman’s Mark, as Modified, of the “America’s Healthy Future Act of 2009,” 22 September 2009; Joint Committee on Taxation, “Estimated Revenue Effects of the Revenue Provisions Contained in the Chairman’s Mark of the “America’s Healthy Future Act of 2009, as Amended through October 2, 2009” 8 October 2009.

Proposals would improve coverage through new subsidies

- Both the House and Senate proposals would significantly increase insurance coverage
 - House bill would cover 97 percent of the population (excluding unauthorized immigrants)
 - Senate Finance bill would cover 94 percent of the population (excluding unauthorized immigrants)
- Original House bill estimated to raise new costs of \$1.042 trillion over the 2010-2019 budget period
 - Originally scored to increase deficit by \$239 billion
 - Revisions to bill in committees lowered cost to approximately \$900 billion
- Senate bill would increase spending by \$829 billion
 - Overall impact is to lower deficit by \$81 billion
 - Only provides for one year of Medicare physician payment fix

Sources: CBO, Letter to Representative Charles Rangel, 17 July 2009; CBO, Letter to Senator Max Baucus, 7 October 2009; Senate Finance Committee, "Chairman's Mark, America's Healthy Future Act of 2009," as Amended and Released 2 October 2009; Montgomery, L., "CBO Estimates House Health Bill at \$905 billion or Less," *Washington Post*, 16 October 2009, Available at: http://voices.washingtonpost.com/capitol-briefing/2009/10/house_health_bill_trimmed_by_3.html?hpid=topnews.

Health reform will impact all employers

- New options for health insurance could displace employers as the primary source of coverage
 - In the short run, employers could reap benefits of lower health insurance costs
 - In the longer term, these benefits would accrue to employees through other forms of compensation
- Increased regulation of the insurance market could raise administrative costs for employers that continue to provide insurance
- Medicare cuts could increase retiree medical costs covered by employers
- Healthcare reform will be expensive and Congress has to pay for it
 - Savings generated within the sector will be inadequate to fund reform
 - Congress may look to other sources of funding, including business tax increases

The long-term impacts of health reform will depend on its success in controlling cost growth

- Standard of living: decreasing the level of resources devoted to health care will provide increased incomes to households
- Budget deficits: government spending path for health care is not sustainable at current growth rates.
- Economic growth: improving the functioning of the healthcare system will improve the flexibility of the labor market
- Larger deficit problem: in the past Medicare and Medicaid have funded deficit reduction.
 - If those programs are used for health reform, will taxes be used for deficit reduction?

Negotiations with Industry Groups

Senator Baucus and Administration have come to agreement with certain industry groups on contributions toward health reform:

- Brand drug makers provide \$80 billion contribution:
 - 50% discount on sales in the Medicare Part D “coverage gap”
 - Increase minimum Medicaid rebate from 15.1% to 23.1% and population subject to rebate
 - Addition fee
- Hospitals agree to cut spending by \$155 billion through lower reimbursement rates
- Provisions in the House bill are contrary to the agreements
 - Additional rebates required for Medicare dual eligibles
 - Unclear what impact this will have on the political environment

Sources: Jensen, K., & Andersen, K., “HCA, Hospitals Agree to \$155 Billion Health-Care Deal (Update 3),” *Bloomberg.com*, 8 July 2009, Available at: <http://www.bloomberg.com/apps/news?pid=20601103&sid=acmk0SbcgSzQ>; Associated Press, “Drug Industry OKs \$80 Billion Medicare Deal,” *MSNBC.com*, 20 June 2009., Available at: http://www.msnbc.msn.com/id/31464689/ns/politics-white_house/.

October 2009

Polling question 5

Does your organization have a team with global involvement to monitor the impacts and implications of proposed health care reform?

- A. US only
- B. US and Global
- C. Nothing formal in place
- D. N/A

Timing

- Congress hopes to consider legislation on the House and Senate floor in coming weeks
- Conference would follow to hammer out differences between House and Senate versions
- President still expects to sign a bill by year-end.

Questions and answers

Contacts

Michael Swanick, Partner
(267) 330-6060
michael.f.swanick@us.pwc.com

Todd Evans, Director
(312) 298-3368
todd.d.evans@us.pwc.com

Jack Rodgers, Managing Director
(202) 414-1646
jack.rodgers@us.pwc.com

© 2009 PricewaterhouseCoopers LLP. All rights reserved. "PricewaterhouseCoopers" refers to PricewaterhouseCoopers LLP (a Delaware limited liability partnership) or, as the context requires, other member firms of PricewaterhouseCoopers International Ltd., each of which is a separate and independent legal entity. *connectedthinking is a trademark of PricewaterhouseCoopers LLP.

Solicitation.

This is for general information purposes only, and should not be used as a substitute for consultation with professional advisors.

PRICEWATERHOUSECOOPERS 