The Impact of the 2012 Elections on MedTech Policy

JC Scott
AdvaMed Government Affairs

December 7, 2012
2012 Election… FINALLY OVER!!!

- Status Quo Election

- Pre-election
  - White House: Democrat
  - House: Republican (241 – 193)
  - Senate: Democrat (53-47)

- Post-election
  - White House: Democrat
  - House: Republican (234 – 200)
  - Senate: Democrat (55-45)
Outlook for Lame Duck

- Sequester cuts
- Bush tax cuts
- Business tax “extenders”
- Debt ceiling
- Unemployment benefits
- Payroll tax cuts
- SGR
$600 Billion Fiscal Cliff

- Bush Tax Cuts -- $250 Billion
- Obama (Payroll) Tax Cut -- $120 billion
- Doc Fix -- $25 billion
- Sequestration -- $110 billion
- Tax Extenders -- $90 billion
- Unemployment Insurance -- $40 billion
Three Potential Outcomes

• Thelma and Louise

• Kick the can down the road
  – Extend Bush Tax Cuts
  – Repeal/Delay Sequestration
  – Likely rating agency credit downgrade

• Bridge to Somewhere
  – Down payment
  – Commitment for tax reform, entitlement reform and deficit reduction in 2013

• X-factor: SGR
MedTech Related Risks

Potential Payfors

- Imaging
- Clinical Lab Fee Schedule
- Medicaid DME
- Lab Co-pay
Device Tax

• Status:
  • House voted on June 7 to pass Rep. Paulsen’s device tax repeal bill by a vote of 270 – 146, with 37 Democrats supporting.
  • No indications Senate will act this year on full device tax repeal.

• Goals:
  • Continue public messaging on repeal.
  • Work with key Members to address device tax in year-end package.
  • If repeal unsuccessful this year, bridge efforts into 2013 tax reform debate.
Year-end Congressional and Administration action to address federal spending will effect FDA’s appropriated budget and user fees:

– Continuing resolution (CR)
– Automatic cuts under sequestration
FDA and the CR

- Congress passed a continuing resolution (CR) to fund the federal government through March 2013 at FY12 spending levels.
  - FDA appropriated budget remains level.

- CR authorized FDA to spend user fee funds at FY12 levels, so FDA does not have access to the full amount of fees as authorized / collected under MDUFA III:
  - FY12 authorized user fee spending level: $58 million
  - FY13 projected user fee spending level: $97 million
  - Gap of approximately $20 million for 6 months

- FDA has some unobligated balances to lessen the impact.
Automatic “sequester” cuts scheduled to take place on January 1, 2013.

Administration’s analysis of how to implement these cuts: apply cuts to both FDA’s appropriated budget and user fees:

– Total cut of 8.2 percent to FDA’s overall budget: approximately $319 million for FY13.
– FDA able to collect full user fees, but expenditures allowed under the program reduced.
Outlook for FDA Funding

• Activity: AdvaMed working with FDA and other industry associations to encourage Congress to correct the CR and to remove FDA user fees from the sequester.

• Likely outcome:
  – CR:
    • FDA working to minimize impact using available balances.
    • Final resolution tied to timing of potential appropriations omnibus legislation. Stand-alone fix unlikely due to politics with appropriators.
  – Sequestration:
    • Fate tied to outcome of fiscal cliff negotiations.
    • No appetite for single-issue fixes.
The New Congress

Looking Ahead to 2013
Committee leadership - Senate

- HELP Committee:
  - Chairman: Tom Harkin (D-IA) (2014)
  - Ranking Member (NEW): Lamar Alexander (R-TN) (2014)
  - At least 1 new member

- Finance Committee
  - Chairman: Max Baucus (D-MT) (2014)
  - Ranking Member: Orrin Hatch (R-UT) (2018)
  - 4 new members

- Special Committee on Aging
  - Chairman: TBD (possibilities include Bob Casey (D-PA))
  - Ranking Member: TBD (current RM is Bob Corker (R-TN))
Committee leadership - House

• Energy & Commerce
  – Chairman: Fred Upton (R-MI)
  – Ranking Member: Henry Waxman (D-CA)
  – 10 new members out of 54

• Ways & Means
  – Chairman: Dave Camp (R-MI)
  – Ranking Member: Sandy Levin (D-MI)
  – New leaders of Health Subcommittee to replace Herger (R-CA) and Stark (D-CA)
  – 6 new members out of 37
Issue Outlook

• FDA:
  – FDASIA Implementation Oversight
  – Funding
  – ADUFA: potential riders

• Deficit reduction:
  – Entitlement Reform
  – Tax Reform
Achieve All Your 2013 Goals.

In One Place.
At One Time.