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Impact of US Healthcare Reform

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April 4, 2011

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Patient Protection and Affordable Care Act

Signed into law March 23, 2010

Goals of Act:

- Provide health insurance coverage for all Americans
- Provide regulatory framework for health insurance
- Establish minimum standards of coverage and increase quality of care
- Reduce insurance costs for individuals, businesses, government

Controversial Legislation:

- 2500 pages; passed in partisan vote using a parliamentary tactic
- While billed as health care reform, it is actually tax legislation
  - Bill provides funding for no new doctors, however funds additional ~12,000 IRS agents

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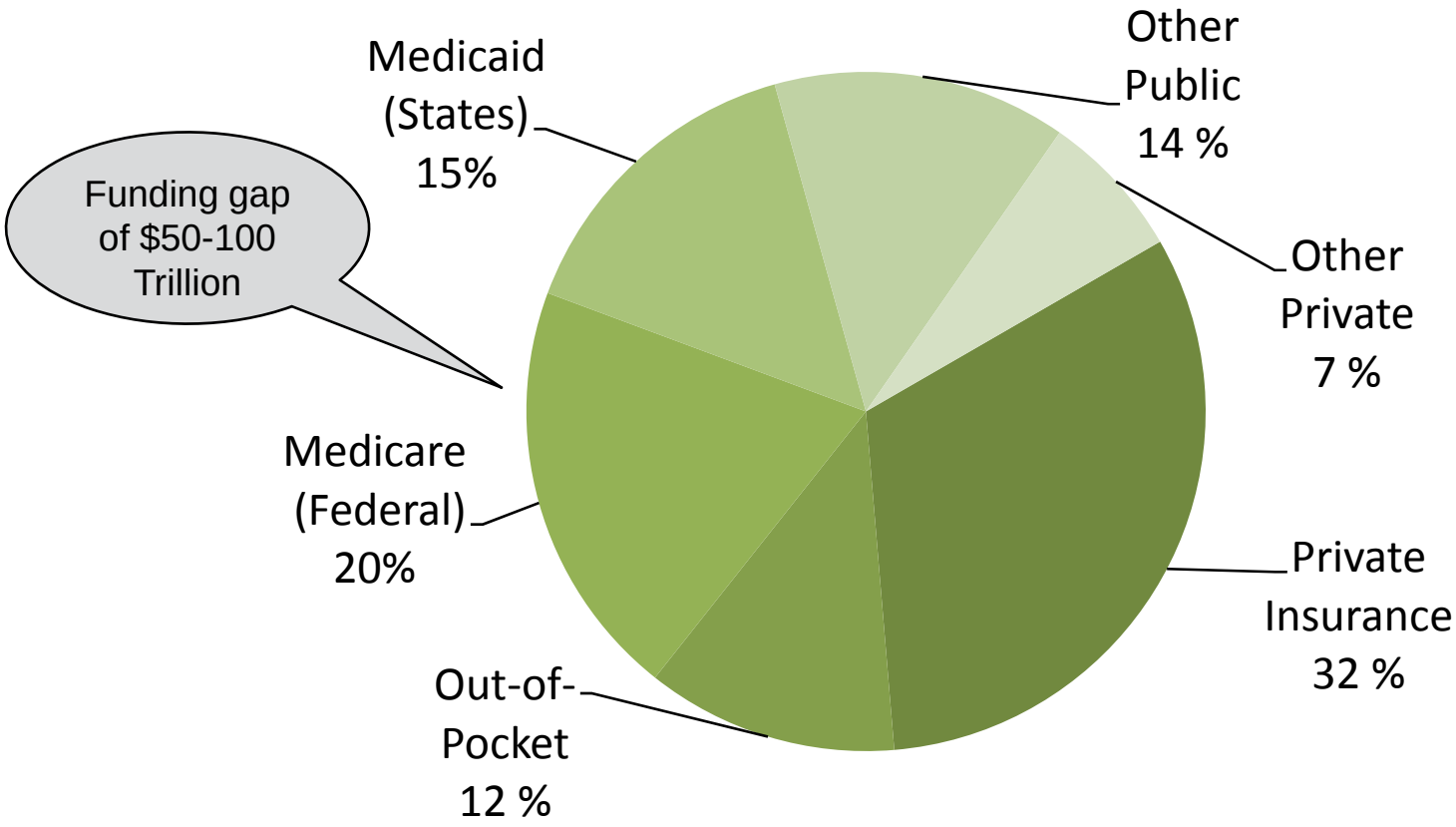
Taxes

Imposes $569 Billion in new or increased taxes in 10 years

- High-end Insurance Plans
- Payroll
- Investment Income – 3.8% of capital gains, interest and dividends
- Prescription Drugs – branded only - $2.5B (2011) to $4.2B (2018)
  - Proportionally assigned to manufacturers based on revenue formula
- **Medical Devices – 2.3% starting in 2013 - Can be waived by HHS for retail goods**
  - Estimated to cost each family of four $1000/yr in higher premiums
- Health Insurers – similar to prescription drugs
- Tanning Salons – 5%

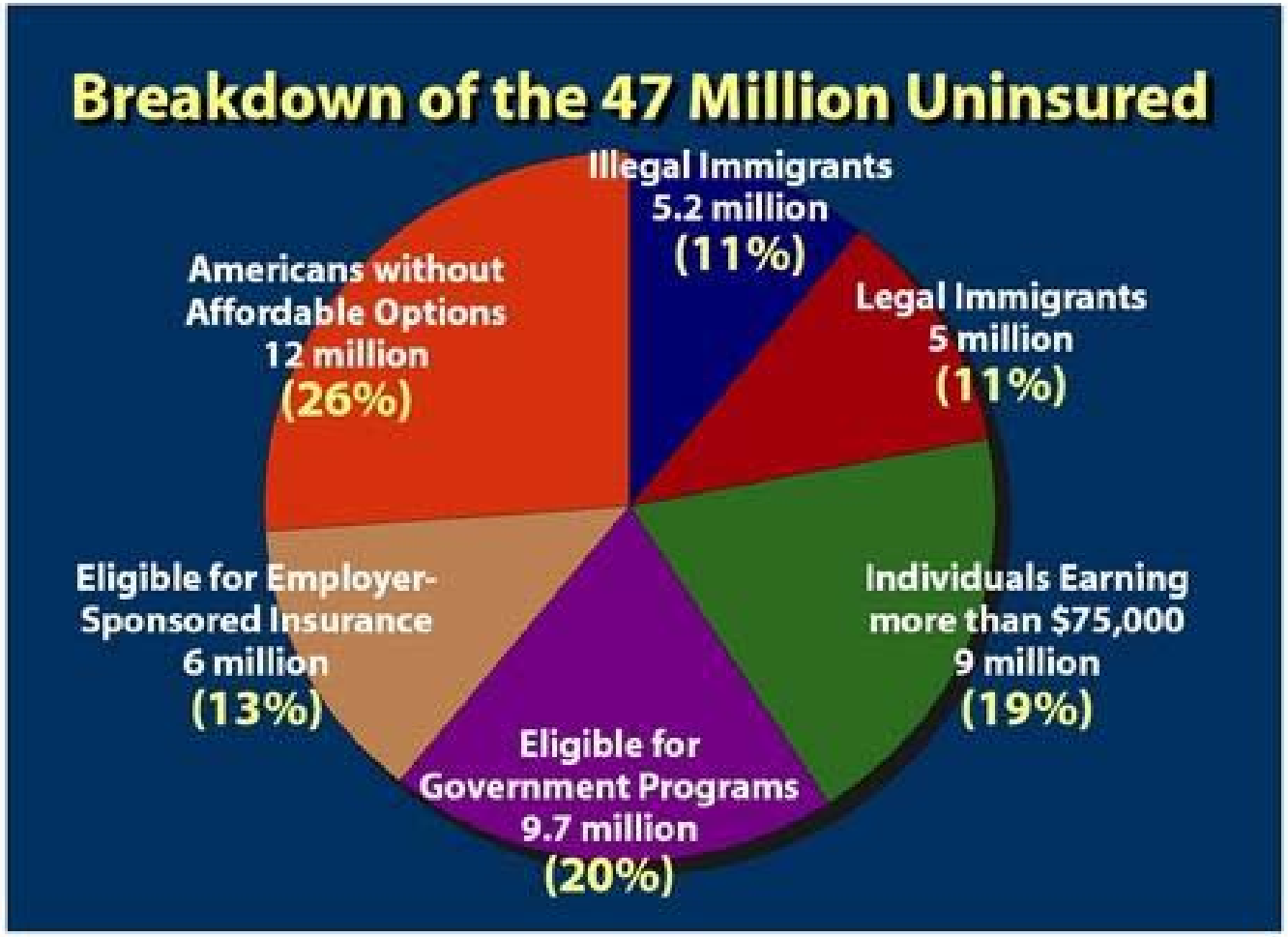
Estimated to cost family with $348,000 income an additional $52,000 per year in new taxes

Current Healthcare Situation



Centers for Medicare & Medicaid Services. Office of the Actuary, National Health Statistics Group

Goal: Provide Health Insurance for All Americans



Slide courtesy of the Galen Institute

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Patient Protection and Affordable Care Act

Goal: Provide health insurance coverage for all Americans

- 32M more people covered by insurance by 2019
  - 16 million through Medicaid expansion
  - 16 million through subsidized private insurance
  - Most gains will not come until after 2014

Reality:

- 23 million remain uninsured in 2019[1]
- Majority of states unable to pay for Medicaid expansion

Impact on Medtech Industry:

- Potential to significantly increase size of market

1. CBO estimate, 2011.

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Patient Protection and Affordable Care Act

Goal: Provide regulatory framework for health insurance

- Institutes strict federal regulation of health insurance
- Imposes mandates on individuals and employers
  - Fine of $95 or 1% of annual income (2014) for failure to buy insurance increases to $695 (or 2.5% of income, whichever is greater) in 2019
  - Business fines of $2000/employee for employees not covered by government sanctioned insurance

Reality:

- Creates 111 new bureaucracies each of which will be tasked with establishing regulations
- Significant uncertainty amongst businesses and individuals regarding costs and requirements

Impact on Medtech Industry:

- Period of transition – makes business planning difficult
- All business required to submit 1099 form to every vendor with whom they do more than $600 worth of business (2012) – likely to be repealed

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Patient Protection and Affordable Care Act

Goal: Establish minimum standards of coverage and increase quality of care

- Allow “children” up to age 26 on parent’s policies
- New coverage for some with high health risks
- Rules requiring coverage for those with prior health problems
- Help for some individuals over 65 with high drug costs
- Experimental programs to modernize care delivery in Medicare
- Health insurance portable and affordable (new subsidies for some)

Reality:

- Many provisions are popular, but individual mandate is widely unpopular

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Impact on Medtech Industry

Implementation of Comparative Effectiveness Research

- Mandates creation of Patient-Centered Outcomes Research Institute - Sets priorities for and publicizes research
- Will likely curtail investment in “me too” products
  - Medical improvements are often incremental
- Could lead to difficult purchasing decisions
  - Use of product that is 2X more effective but 3X more expensive?
- Will be used to make reimbursement decisions
- Potential to increase reimbursement and use for those products that score highly compared to other products

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Patient Protection and Affordable Care Act

Goal: Reduce insurance costs for individuals, businesses, government

- Widely implement less expensive preventive care
- Achieve benefits from economies of scale
- Drive down costs through greater purchasing power
- Eliminate waste and fraud

Reality:

- CMS lead actuary confirms Act will INCREASE health care costs

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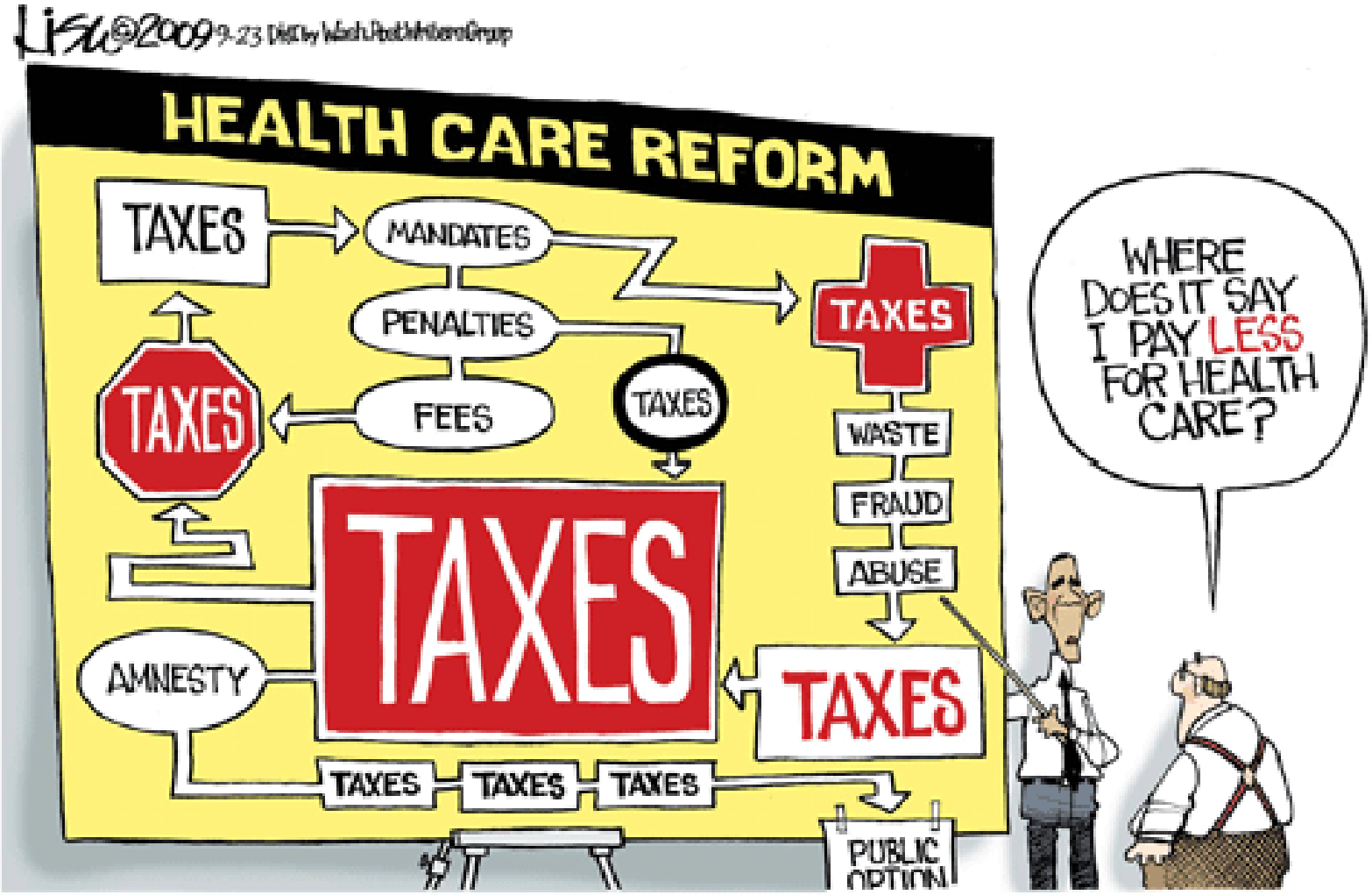
CMS Confirms Act Increases Costs

CMS Analyst Richard Foster report:

- Millions will lose their current coverage
- $120 billion in fines for companies and individuals
- Government spending will increase $311B to $1.56 Trillion/yr through 2021
- Many on Medicare will have trouble getting care
- CBO: Act will raise some family premiums by $2,100 in 2016 above what they would have been without the reform law

Primary Cost Drivers:

- Increased dependent age requirement
- 100% preventative care requirement
- Unlimited lifetime maximum (mostly impacting pooling and stop-loss)
- Removal of annual limits (minor impact)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HEALTH CARE REFORM
TAXES
MANDATES
PENALTIES
FEES
TAXES
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TAXES
TAXES
WASTE
FRAUD
ABUSE
TAXES
AMNESTY
TAXES
TAXES
TAXES
TAXES
PUBLIC OPTION
WHERE DOES IT SAY I PAY LESS FOR HEALTH CARE?

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Impact on Medtech Industry

Productivity Pricing Adjustments

- Applied to reimbursements to hospitals, skilled nursing facilities, etc
- Utilization Assumptions to be implemented – reduces “over-utilization” of high-cost equipment such as imaging

Independent Payment Advisory Board

- Will have the power to recommend changes to procedures that Medicare will cover and the criteria to determine when services will be covered
- Prohibited from making recommendations that increase revenue (taxes), or change benefits, eligibility, or cost sharing
  - Leaves only reduction in provider (doctor/hospital) payments
    - Hospitals exempt until 2020 – leaves doctor payments

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After the 2010 Election

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Major political battles being wages

Judicial

Legislative

Executive

States

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Judicial Actions – Court Challenges

Court challenges:

- 28 states have sued to rescind the law
- Two minor state lawsuits (MI, VA) have upheld law
- Two federal judges have declared the Act unconstitutional
- Broadest ruling: Federal judge (FL) ruled individual mandate violates U.S. Constitution:
  - Individual mandate is central to the workings of the health-overhaul law
  - No severability clause
  - Therefore whole law is unconstitutional
  - Injunction served against Administration

Judicial Actions – Court Challenges

Next Steps:

- Appeals court ruling likely in 2011
  - Commerce Clause Argument is Focus
  - 10th Amendment – State's Rights is secondary argument
- Likely decided by U.S. Supreme Court in 2012-2013 session

Legislative Actions

Midterm election impact:

- House: Republican Majority
  - Need simple majority to pass legislation
- Senate: Democrat Control
  - Need 60 votes to end filibuster

Unlikely to overturn law:

- Act difficult to overturn because of provisions enacted in 2010
  - Act includes $105 B/year in spending for implementation
- Repeal bill passed House in January (245-189), failed in Senate
- President Obama likely to veto any overhaul bill

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Legislative Actions

Likely Republican response:

- Appropriations Bills will be most significant impact to Act, however
  - Unlikely to use appropriations if it results in government shutdown government as in 1994 (debt ceiling)
- Restrict agencies from working on health care reform legislation
- Compromise on certain provisions of health care reform

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Executive Actions

Administration's Response:

- Issue numerous "Interim Final Regulations"
  - This avoids legal requirement for a public comment period
- Issue Interpretive Guidance for Regulations
  - Further codifies implementation
- "Run out the clock"

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Interim Final Regulations

Issued Interim Final Regulations:

- Early Retiree Reinsurance – May 5
- Web Portal – May 10
- Dependent age 26 – May 13
- Grandfathered plans – June 17
- Patient Bill of Rights – June 22
- Preexisting conditions – June 28
- Preventative cost sharing – July 14
- Consumer health plan appeals – July 23
- Preexisting conditions – July 30
- Amended Grandfathered rules – November 15
- Medical Loss Ratios – December 1
- Accountable Care Organizations – March 31 (429 pages of regulations)

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Response of the States

Health Care Freedom Acts:

- Seven states have passed laws prohibiting mandatory health insurance
- Similar legislation has been introduced in nearly all remaining states

Implementation of PPAC Act:

- State governments slow to cooperate with federal efforts to implement

Legal challenges

- 28 states (plus individuals, business groups and others) have filed court challenges

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States Rights Pathway

Legal Paths:

- Congress has no power to enact such a plan
  - Likely to fail due to Commerce Clause
- Plan unlawfully conscripts state governments into carrying out and paying for federal mandates
  - Potential for success – probability low
- Individual mandate amounts to an unlawful capitation or direct tax
  - Highest probability for success
  - Unprecedented expansion of Commerce Clause
  - Not apportioned among states in accordance with their population

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States Rights Pathway (10th Amendment)

Nullification:

- Legal theory original argued by Thomas Jefferson and James Madison:
  - when the national government acts beyond the scope of the Constitution, the states *"have the right, and are in duty bound, to interpose, for arresting the progress of the evil, and for maintaining, within their respective limits, the authorities, rights and liberties, appertaining to them."*
- 12 states have bills pending to nullify the Act – 1 has passed legislation (MT)
- All but one state bill includes a provision for criminal penalties for federal and state agents who would try to enforce the Act within the state
- Precedent:
  - California, and other states, have *de facto* if not *de jure* nullified Federal drug enforcement laws by enacting their own statutes
  - Supreme Court has never upheld nullification

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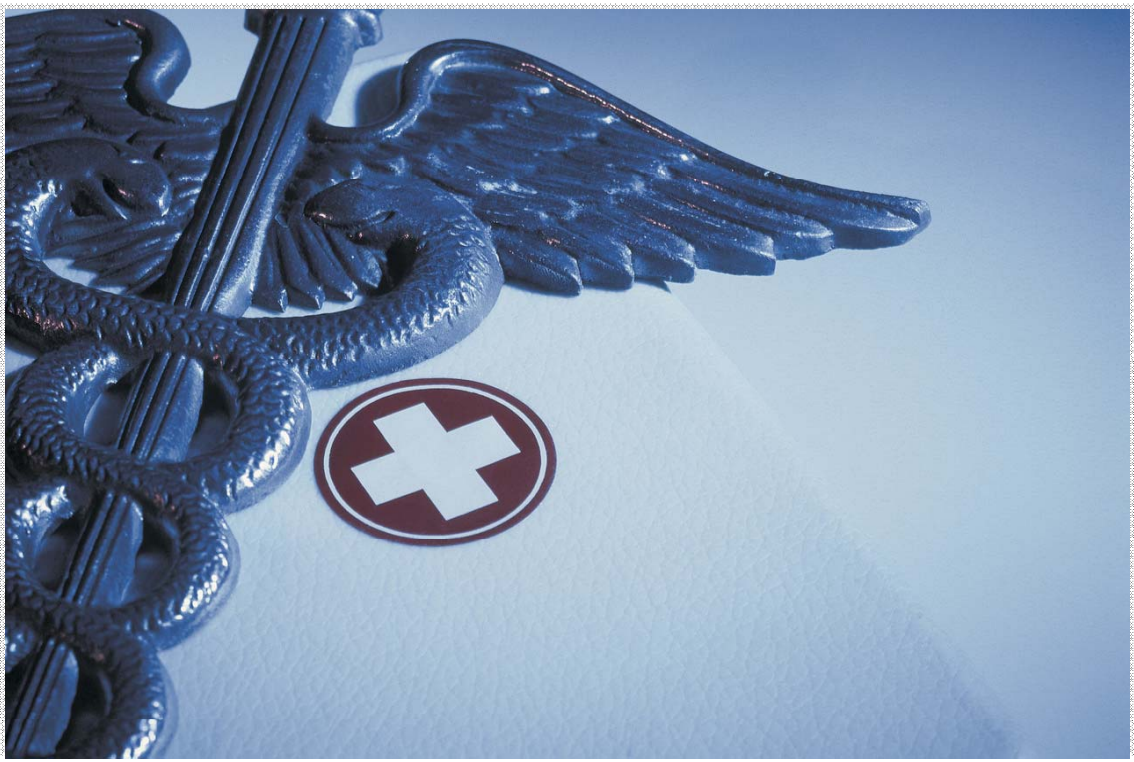
Conclusions



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Public Opinion

Americans Want Reform:

- There is broad agreement the U.S. needs health reform to reduce costs, increase quality, and expand coverage to everyone
- Most rate their own coverage as good/excellent
- But they want stability, coverage for others

But Not This Reform:

- The new health law does not have broad public support
- 100,000 calls/hr to Congress before vote, the great majority opposing passage
- Strong majorities fear lower quality, higher costs, and difficulty accessing care
- 63% want the Act totally repealed
- Only12% think the bill should go into effect in its current form
- 71% believe taxes will increase under “ObamaCare”

Slide courtesy of the Galen Institute

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The Act fails to deliver on promises

Health costs and health spending will increase

Only 92% covered – not universal coverage

Few changes to modernize care delivery, reduce "defensive medicine," or change incentives to spend more for more procedures

Successful ventures are restricted and innovations defunded in the new law

Slide courtesy of the Galen Institute

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The Act had/has many unintended consequences

Congressional members voted themselves out of health insurance – now have separate, better plan

One-third of companies are considering dropping health benefits to avoid heavy penalties and costs

Over 1000 waivers have been granted to companies, unions and even states

Fines, taxes, and kickbacks will dry up funds for research, especially for drugs and medical devices

41 states have filed legal challenges against Act, rebelling against federal control

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Overall Impact on Medtech Industry

Negative Impacts:

- Period of uncertainty as new regulations are written
- Will need to navigate additional bureaucracies
- Medical device excise tax could reduce profitability

Positive Impacts:

- Substantially increases size of market – additional 32M individuals
- Comparative Effectiveness requirement could lead to enhanced reimbursement and utilization of products
- Vigorous opposition will likely re-craft law in more business friendly ways

Thank you for your attention.

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