Making Health Policy: How the Money Matters

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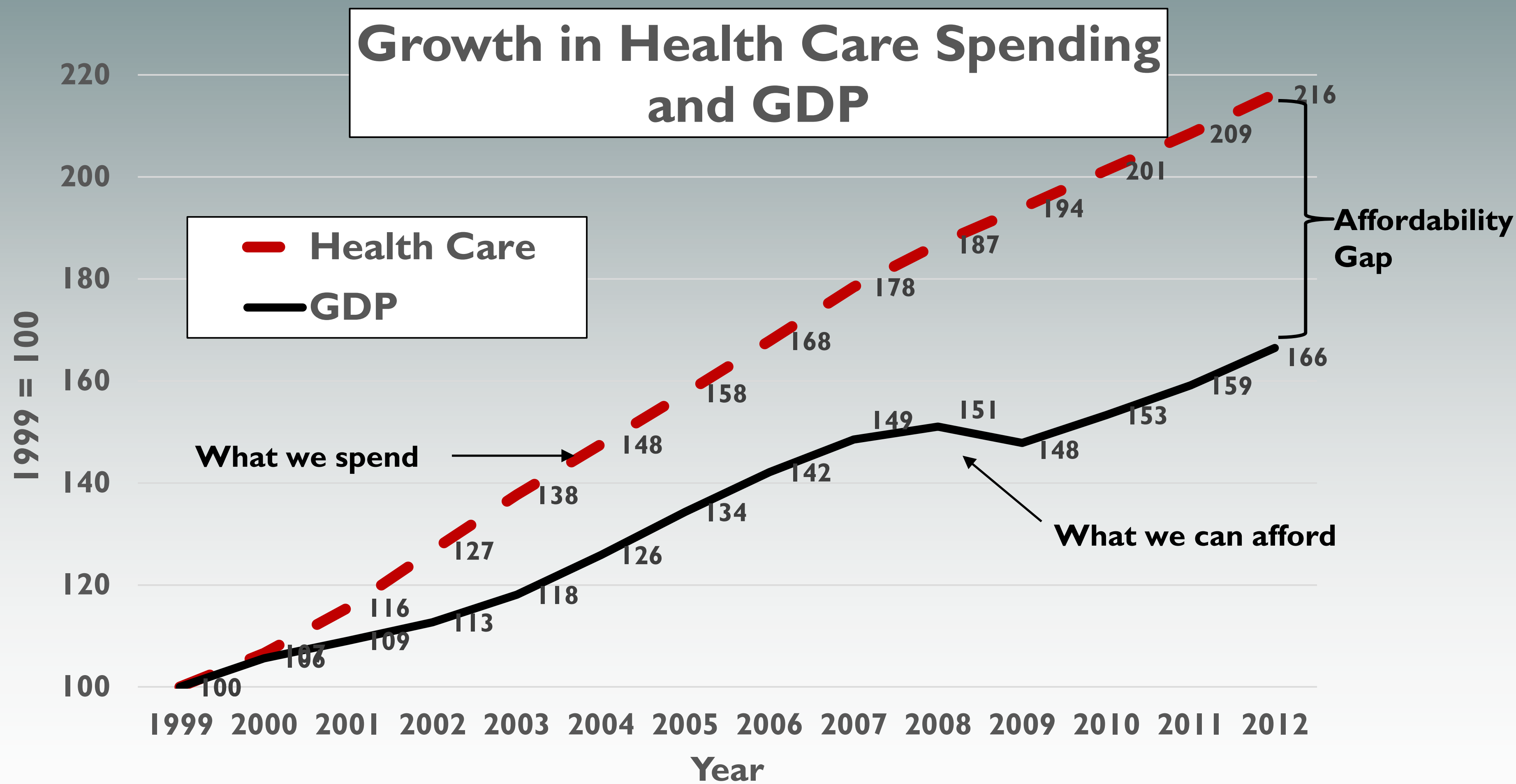
The Ever Increasing Impact of Economic Factors on Health Care Policy

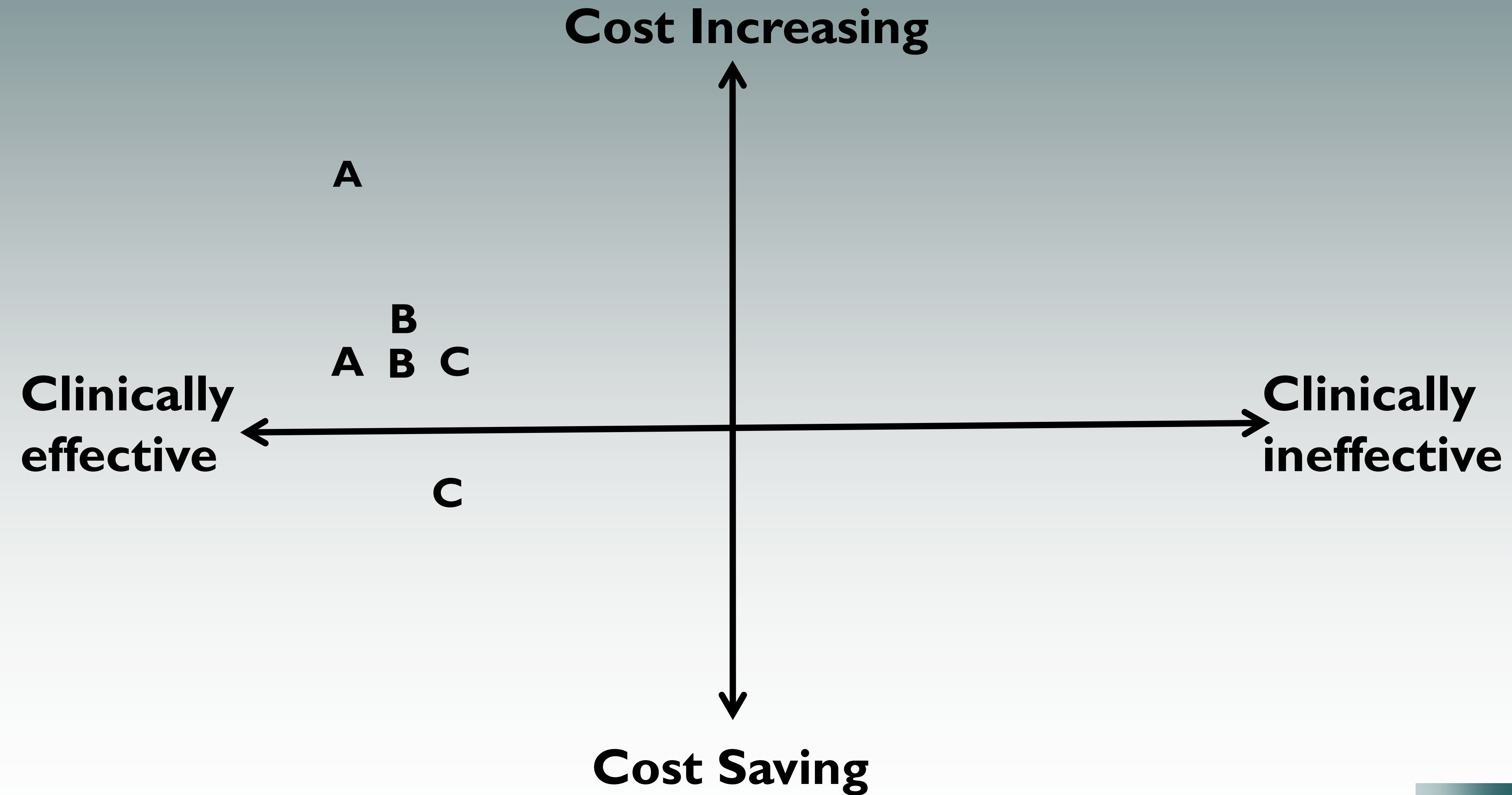
- As both public and private budgets grow tighter not all new technologies are affordable.
- Breakthrough clinical advances with the potential to reduce health care spending are easier to justify to both public and private payers than those that increase health care spending.

Why Has Economics Become More Important?



http://www.cms.gov/ NHE Projections 2013-2023 – Tables.

Interactions Between Medicine and Economics



How do Policymakers Legislative & Executive Use Health Economics

- Few policymakers have health economics backgrounds. They rely on third parties who they trust.
- Trust has two forms:
  - Trust that the third party knows what their talking about.
  - Trust that the third party have no unrevealed political or policy agenda.

Trusted Third Parties Within the Legislative Branch

- Congressional Budget Office (CBO),
  - Cost estimates – federal budget, and unfunded mandates for states, local government and the private sector.

- Congressional Research Service (CRS),
  - Background briefings,
  - Policy proposal development,
  - Analysis and comparison of alternative proposals.

Trusted Third Parties Within the Legislative Branch (continued)

- Government Accountability Office (GAO),
  - Policy analysis,
  - Evaluations and audits.

- MedPAC - Medicare Payment Advisory Commission & MACPAC - Medicaid and CHIP Payment and Access Commission.
  - Offset to Administration's technical upper hand,
  - Expert panel, plus representative body.

Trusted Third Parties Within the Executive Branch

- CMS Office of the Actuary –
  - Official modeler of Medicare's future financial viability, e.g., Trustees' Reports.
  - Deep expertise on Medicare claims.
- OMB –
  - Strong policy gatekeeper, not the analytic power it once was.
- ASPE –
  - Secretary's own policy analysis team. Provides second opinion to balance CMS. Incubator for new policy efforts.

Trusted Third Parties Within the Executive Branch (continued)

- The NIH/FDA/CDC Scientific Expert Panels. For example:
  - US Preventive Services Task Force –
    - Guide for insurers on what preventive benefits to cover.
    - ACA expanded there power significantly. preventive services with a Task Force grade of A or B must be covered without cost-sharing under new health insurance plans or policies.
  - Advisory Committee on Immunization Practices –
    - Recommendations inform Medicare coverage, school enrollment requirements, etc.

Two Major Methodologies for Estimating the Cost of Health Policy Changes

1. Budget estimates
   a) Based on Economic and Actuarial techniques
   b) Claims focused

2. Cost effectiveness analysis (CEA)
   a) Based on Epidemiological techniques
   b) Clinical trial focused

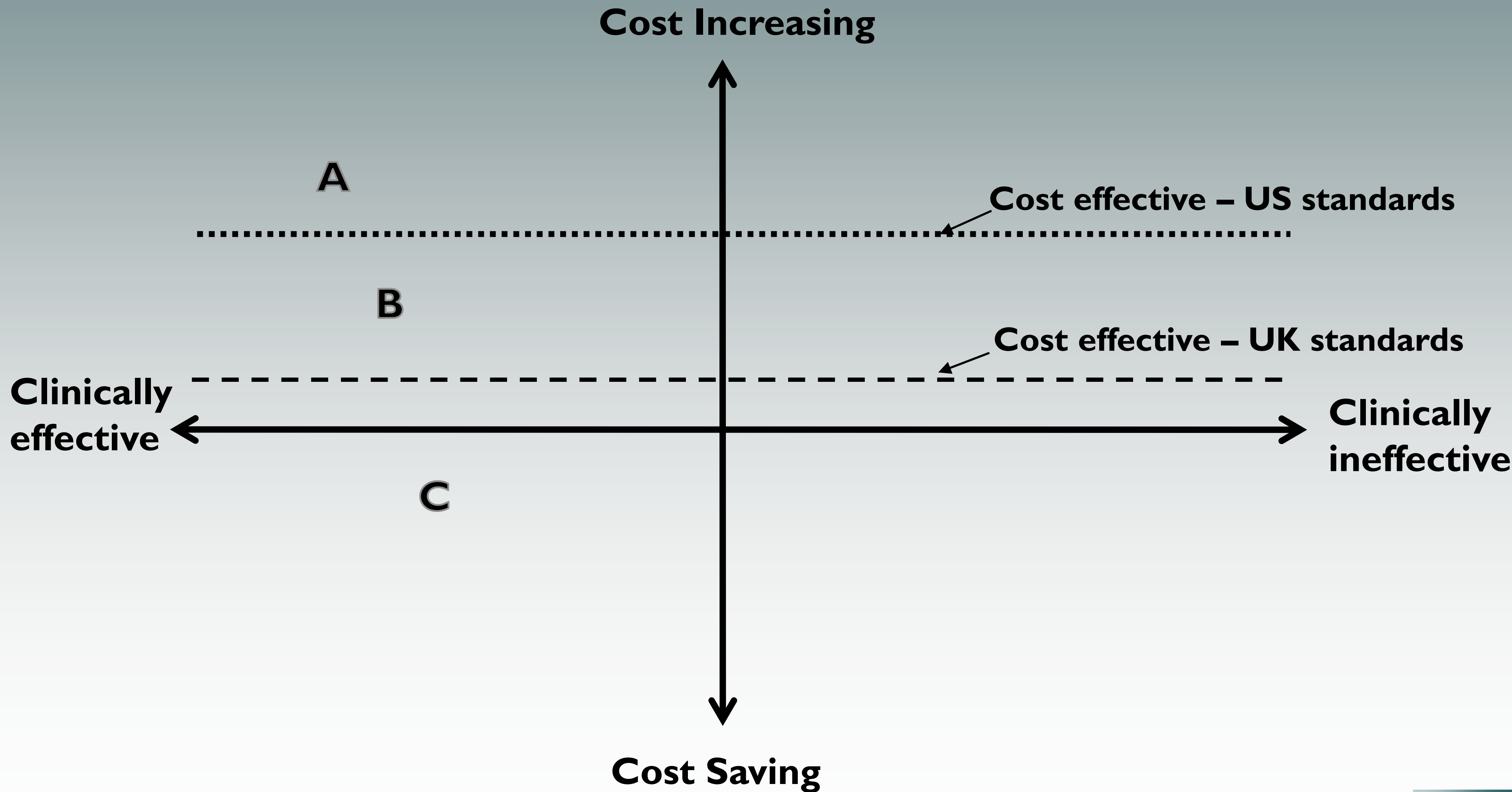
Budget Estimates:

- Commonly used for federal and state programs, e.g., Medicare, and Medicaid, by organizations like the Congressional Budget Office (CBO) and the Medicare actuaries.
- Projects a spending stream under current practice (baseline) and a proposed alternative.
  - Quality-of-life is not considered and probably won't be given significant sensitivity around possible government involvement in end-of-life decisions.
- For legislation, 10-year estimates based on congressional budget rules. For the Medicare Trust Fund, 75-year estimates.

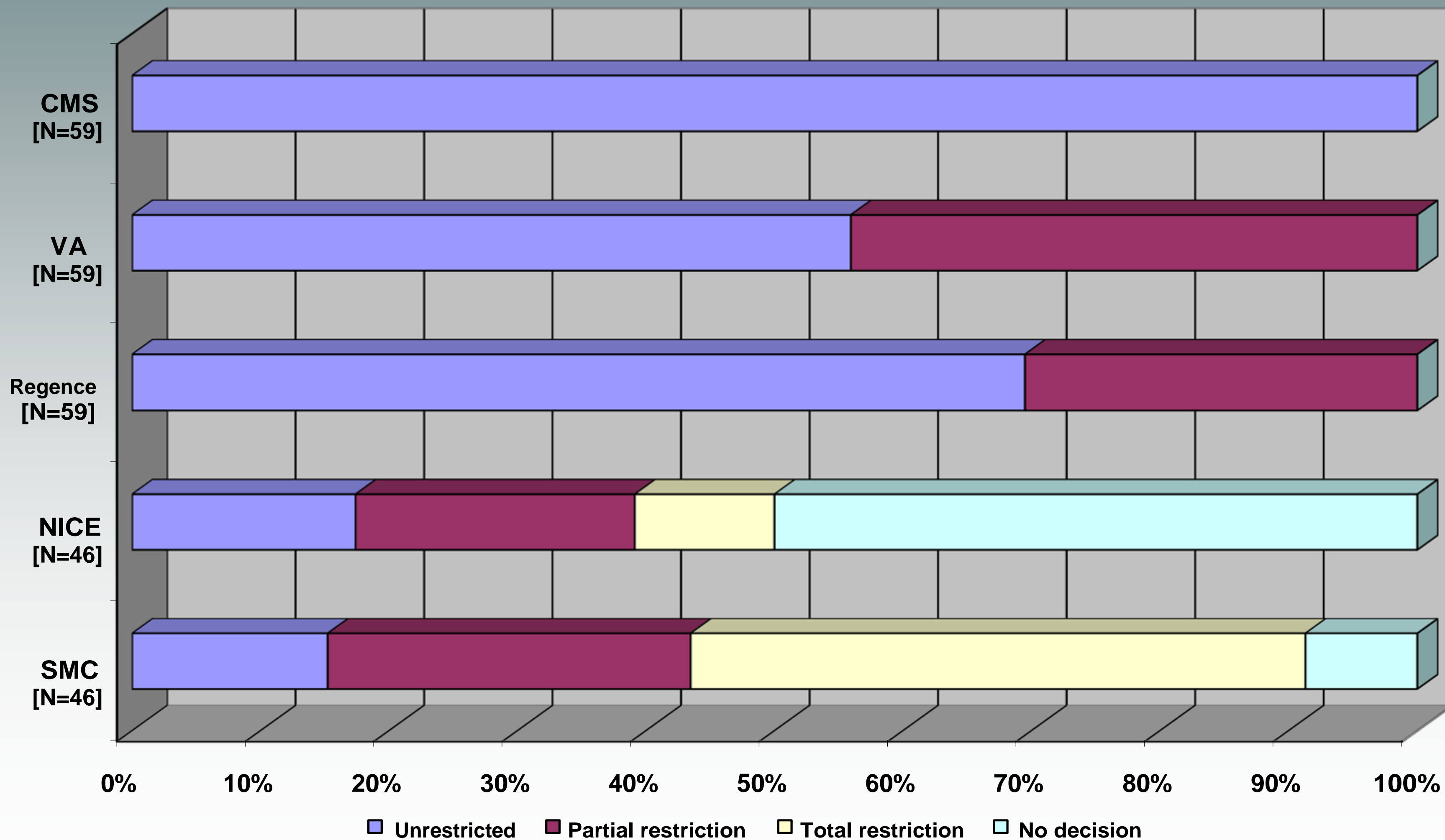
Cost effectiveness analysis (CEA):

- Balances – Improvements in both Clinical Outcomes and Patient Quality-of-Life Against Cost.
- Projects the natural history of the disease under current practice compared the intervention.
- The intervention does not have to be less expensive, but cannot cost more than a commonly used spending threshold, e.g., $100,000 per quality adjusted life year (QALY) in the US; £20,000 ($30,600) in the UK (NICE).
- This is used in policy applications like coverage decisions, especially in Europe and more and more commonly by private payers in the US.

Interactions Between Medicine and Economics



Coverage Restrictions for Eligible Anti-Cancer Drugs, FDA Approved 2004-2008



Political Controversy Regarding Use of CEA for Federal Policymaking

- Two criticisms:
  - Not always a fair game. The more expensive the drug or device, the more evidence that's asked for. Maybe just reasonable science, but it feels like "moving the goal posts" to industry.
  - Use of time trade-off measures of quality-of-life raises serious concerns from religious leaders about government involvement in end of life decisions better left to the patient and their family.

Political Controversy Regarding Use of CEA for Federal Policymaking (continued)

- CEA is effectively blocked from many public programs:
  - "The Patient-Centered Outcomes Research Institute established under section 1181(b)(1) shall not develop or employ a dollars per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended." – ACA SEC. 1182.
  - Two exceptions – USPSTF and Advisory Committee on Immunization Practices. Review of the latest peer-reviewed scientific literature will almost always include CEA.

Policy and Methodological Implications?

- Two competing methodologies – one clinical trial focused, the other claims focused.
  - Clinical trial focus (CEA) allows linking of clinical outcomes to spending. Allows projection of future spending based on expected changes in disease progression, but non-representative sample and often relies on pre-market prices.
  - Claims focus (budget estimates) allows capturing of negotiated discounts, cost sharing effects on utilization and other post-trial market effects. Closer to a representative sample, but can only make ad hoc adjustment for clinical changes.

- Cost will only grow as a consideration in the adoption of new technologies.
- Accurately measuring cost will become a more important priority.
- Any methodology will need to be analytically rigorous, as well as generally accepted as fair by patients, manufacturers and payers.
- A hybrid approach incorporating the best of both current methods may be the next generation methodology.

Shawn Bishop

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Congress Functions Via Committees

Senate

- 20 committees
  - Finance
  - HELP
  - Budget
  - Judiciary
  - Appropriations
  - Commerce
- 68 subcommittees
- 4 joint committees
  - Joint Committee on Taxation

House

- 21 committees
  - Ways and Means
  - Energy and Commerce
  - Budget
  - Judiciary
  - Appropriations
  - Rules
- 94 subcommittees
- 4 joint committees
- 1 select committee
  - On Benghazi

*As of 113th Congress 2013-2014

Congressional Functions and Activities

Functions of Congress

Authorize Programs

Authorize Spending

--Appropriations

--Entitlements

Raise Revenues

Declare War

Senate also presides over:

-Presidential Nominations

-Impeachments

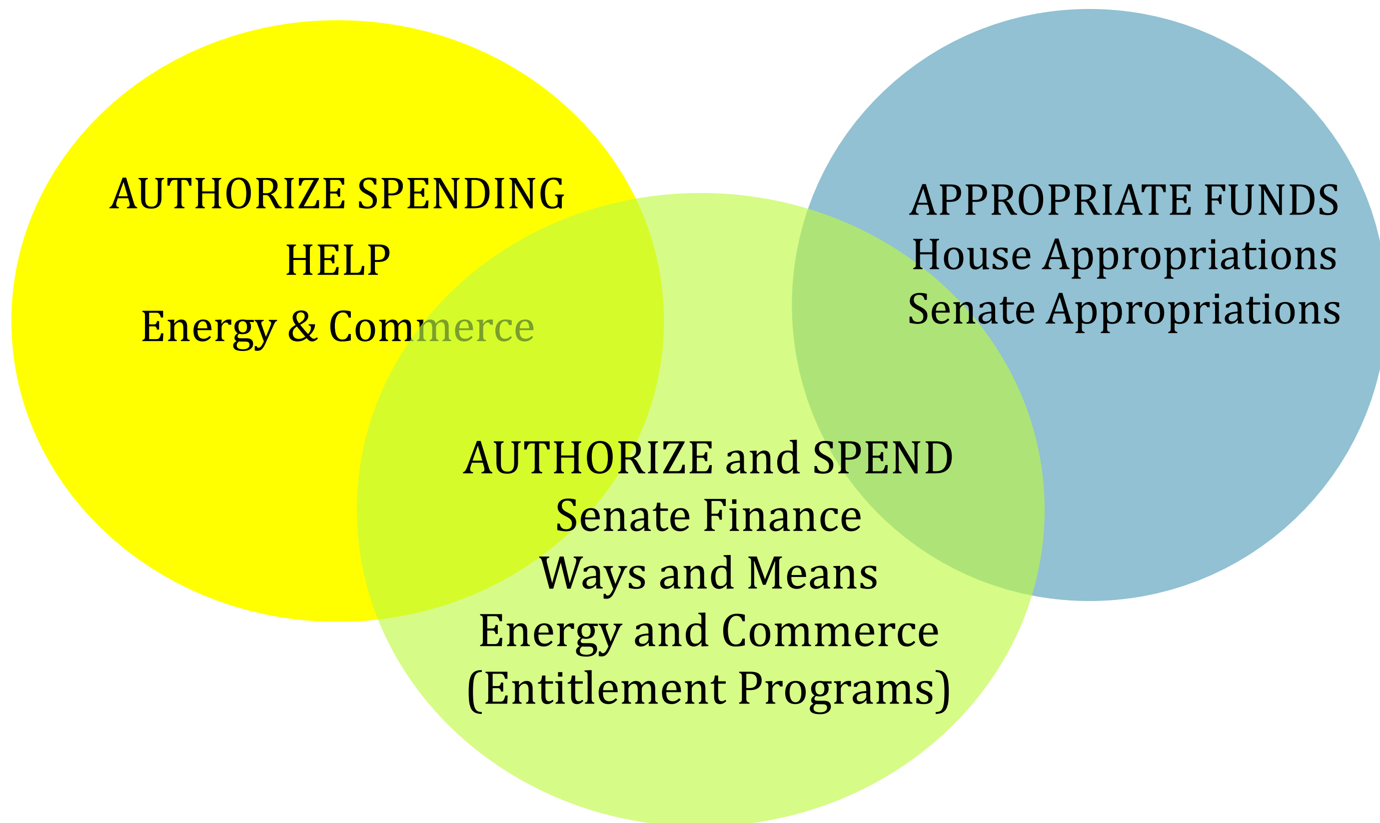
-Presidential Vetoes

-Treaties

Committee, Member and Staff Activities

- Draft and negotiate legislation
- Monitor on-going government operations (oversight)
- Identify issues for legislative review
- **Evaluate effects of legislative proposals**
  - **Budgetary, economic, political, industry, community, district, and policy impacts**
- **Gather information**
  - Hold hearings
  - Meet with stakeholders and constituents
  - **Consult Congressional support agencies**
    - **CBO, MedPAC, CRS, GAO**
- Write reports
- Give speeches, write articles
- **Set self-governing rules**
- Vote

Some Committees Have Dual Functions



Committees Have Legislative Jurisdiction

Senate Finance	House Ways and Means	Senate HELP	House Energy/Commerce
Revenue Debt Health Programs of Social Security Act Social Security Prog Trade Agreements Tariffs, Customs	Revenue Debt National Social Security Programs Trade, Tariffs, Customs	Health • Public Health • Programs (not of Soc. Sec Act) Education Labor Pensions Cabinet-level Depts. • Authority (not appropriations)	Telecomm Consumer protect Food/Drug Safety Health • Public Health Protection • Research Enviro quality Energy policy Interstate/Foreign Commerce Cabinet-level Depts. • Authority (not appropriations)

Sources: http://www.finance.senate.gov/about/jurisdiction/; http://waysandmeans.house.gov/about/jurisdiction.htm; http://www.help.senate.gov/issues/; http://democrats.energycommerce.house.gov/index.php?q=page/committee-jurisdiction

Congress Often Requires Offsets of Budgetary Costs of Proposed Law

Congress has required itself to offset the cost of proposed legislation through statutes and self-governing rules

- Congressional Budget and Impoundment Act of 1974
  - Created the Congressional Budget Office and rules for tracking federal budgetary costs and spending and consideration of annual budget documents from Congress and President.
- Pay-go statute included in the Budget Enforcement Act of 1990
  - Required all increases in direct spending or revenue (tax) decreases to be offset by other spending decreases or revenue increases.
  - Expired in 2002
- House and Senate have adopted internal rules for tracking and offsetting the budgetary cost of legislation (pay-go rules)
- President Obama signed Statutory Pay-As-You-Go Act of 2010

Congress enforces pay-go rules through the Budget Committees

Example: Legislating Entitlement to Medicare Hospital Insurance

"Sec. 1812. **[**42 U.S.C. 1395d**]** (a) The **benefits** provided to an individual by the insurance program under this part shall consist of **entitlement to have payment** made on his behalf or, in the case of payments referred to in section 1814(d)(2) to him (subject to the provisions of this part) for—

(1) inpatient hospital services or inpatient critical access hospital services for up to **150 days** during any spell of illness…;

(1) (A) post-hospital extended care services for up to **100 days** during any spell of illness…"

Example: Legislating Medicare Payment for Graduate Medical Education

The Social Security Act includes the following language as a component of Medicare's hospital payment formula to reimburse teaching hospitals for costs of training doctors in the U.S.:

"1886(d)(5)(B)(ii) For purposes of clause (i)(II), the indirect teaching adjustment factor is equal to **c –0A (((1+r) to the nth power) – 1),**
where "r" is the ratio of the hospital's full–time equivalent interns and residents to beds and "n" equals .405. Subject to clause (ix), for discharges occurring—
(I) on or after October 1, 1988, and before October 1, 1997, "c" is equal to 1.89;
(II) during fiscal year 1998, "c" is equal to 1.72;
(III) during fiscal year 1999, "c" is equal to 1.6;
(IV) during fiscal year 2000, "c" is equal to 1.47;
(V) during fiscal year 2001, "c" is equal to 1.54; and
(VI) during fiscal year 2002, "c" is equal to 1.6;
(VII) on or after October 1, 2002, and before April 1, 2004, "c" is equal to 1.35;
(VIII) on or after April 1, 2004, and before October 1, 2004, "c" is equal to 1.47;
(IX) during fiscal year 2005, "c" is equal to 1.42;
(X) during fiscal year 2006, "c" is equal to 1.37;
(XI) during fiscal year 2007, "c" is equal to 1.32; and
(XII) on or after October 1, 2007, "c" is equal to 1.35."

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Budget dynamics in Congress

- Resources are scarce
- Members on both sides of the aisle are extremely reluctant to propose or support new spending
- Any new spending or proposed increase must have a compelling justification
- Offices will usually ask for an offset
  - Recognize the pitfalls!

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March of Dimes Commemorative Coin Act

- Authorized the U.S. Mint to strike a commemorative coin for our 75th anniversary
- Portion of proceeds to benefit MOD
- Bill required this coin to be *budget-neutral*; no proceeds to MOD until sales had covered the Mint's costs
- As a result, the bill had zero cost

PREEMIE Reauthorization Act

- Bill renewed a range of federal programs focusing and coordinating prematurity prevention, education & research
- Bipartisan, bicameral, no formal opposition
- Authorized slight increases in funding
- Initial CBO score was $42M over 5 years

For the activities described …, the bill would authorize the appropriation of about $10 million a year for each of fiscal years 2014 through 2018. CBO estimates that implementing the bill would cost $4 million in 2014 and $42 million over the 2014-2018 period, assuming the appropriation of the authorized amounts.

- During process, funding was reduced below current authorization levels to currently appropriated levels
- A bitter pill but a necessary sacrifice to secure passage

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Newborn Screening Saves Lives Reauthorization Act

- Renewed key federal programs that support state-based efforts to screen every newborn for conditions that threaten their life or health
- Bipartisan, bicameral, no formal opposition
- Bill *reduced* authorization levels
- Authorized slight increases in funding for 3 accounts for $9M
- CBO estimate:

CBO estimates that implementing H.R. 1281 would cost $80 million over the 2015-2019 period, assuming appropriation of the necessary amounts. H.R. 1281 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

- Still didn't get increases ultimately, but was necessary to secure passage

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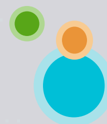
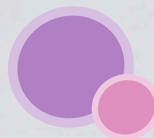
Thank you!





Thank You

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