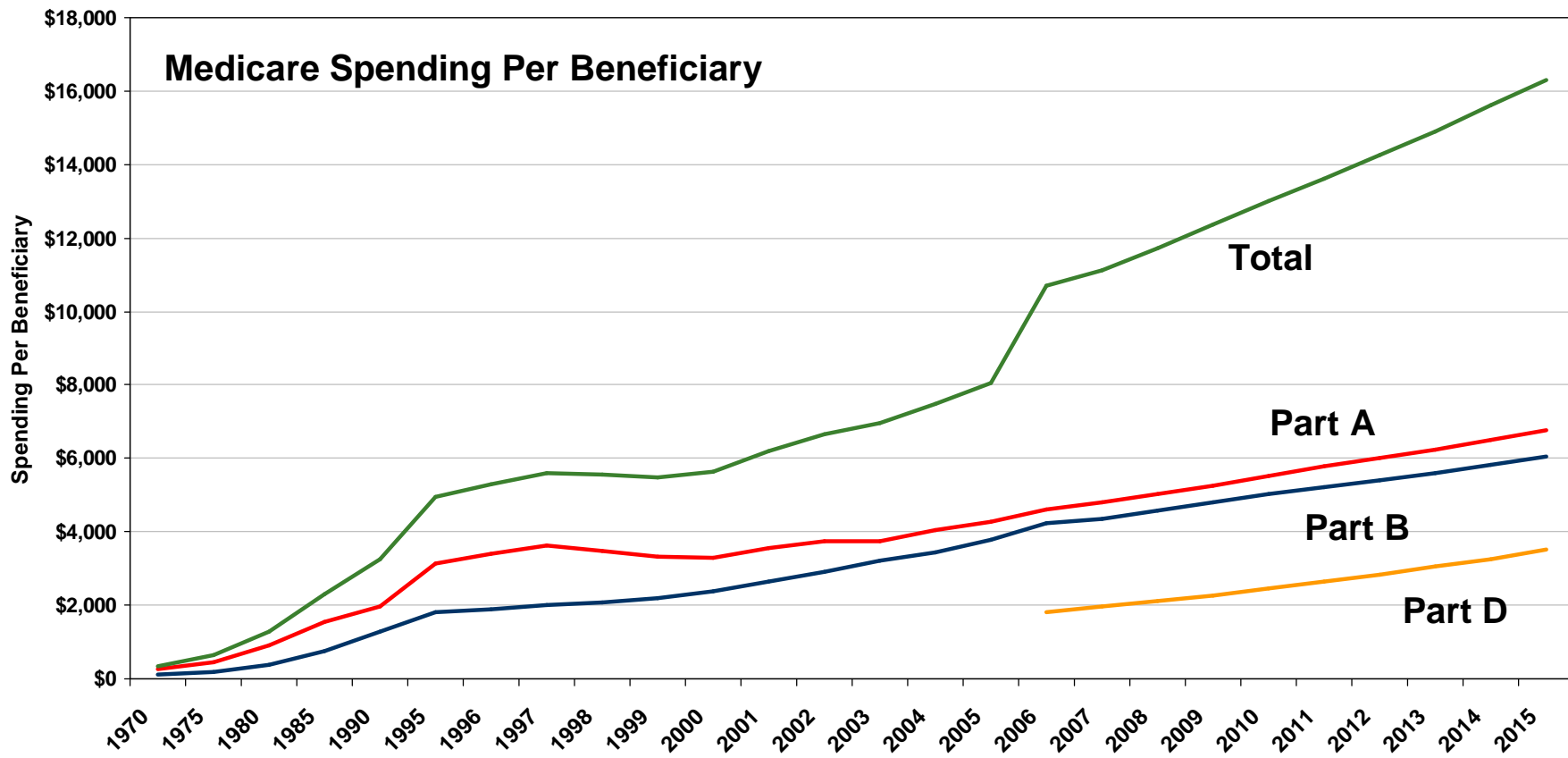


Improving Evidence for Decisions

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Unsustainable Trajectory

“So long as healthcare costs continue to grow faster than the economy as a whole, as seems likely, federal spending on health and retirement programs would rise at a rate that risks placing the budget on an unsustainable trajectory.” *Alan Greenspan (11/4/05)*



Technology and Spending

- BCBSA report: 18%
- Project Hope: 25-33%
- David Cutler: 50%
- Vic Fuchs: 81% of economists identify technology as primary cost driver in health care

Estimated Drug Costs for 2 months of Treatment for Colon Cancer

Regimen	Drug Costs (US\$)
Regimens containing 5-FU	
■ Mayo Clinic	63
■ Roswell Park	304
Regimens containing irinotecan or oxaliplatin	
■ IFL	9,539
■ FOLFIRI	9,381
■ FOLFOX	11,889
Regimens containing bevacizumab or cetuximab	
■ FOLFIRI with bevacizumab	21,399
■ FOLFOX with bevacizumab	21,033
■ Irinotecan with cetuximab	30,790
■ FOLFIRI with cetuximab	
<hr/>	
	30,675

Source: Schrag. The Price of Progress—Chemotherapy for Colorectal Cancer. NEJM. 2004.

Frequently Unanswered Questions

- Outcomes for patient and provider types excluded from trials
- Adverse events in real world
- Off-label uses or
- Combinations and sequences of approved uses
- Comparative effectiveness
- Risks and benefits in subgroups
- Outcomes not measured in trials

Why the gaps?

- NIH: discovery and proof of concept
 - Industry: FDA and market focus
 - AHRQ: modest budget, broad portfolio
 - DERP / BCBSA / Cochrane: review only
-
- Decision makers have no significant role in what evidence is created

CMS Coverage with Evidence Development

- Links CMS coverage with requirement for prospective data collection
- Applied to technologies that are unproven, promising, high demand
- Off-label use of drugs approved for colorectal cancer
- United Healthcare has adopted a similar approach to off-label use

Center for Medical Technology Policy (CMTP)

- Private non-profit in San Francisco
 - funded by CHCF, BSCF
- Neutral forum for decision makers, stakeholders to develop better evidence
- Activities:
 - Identify priorities of decision makers
 - Develop faster, cheaper methods
 - Select and design pilot projects

Take-home messages

- Better evidence is key to preserving innovation in face of spending trends
- Current clinical research enterprise is not producing all needed evidence
- Therefore need to expand capacity for “decision-based evidence making”

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