

Designing and Utilizing Clinical Trials To Inform Mental Health Policy Assessments

February 27, 2008
Washington, DC

ISCTM 2008 Annual Meeting, Session IV

Designing and Utilizing Clinical Trials To Inform Mental Health Policy Assessments

Speakers:

Phil Wang, Director Division of Services and Intervention research, NIMH

David Meltzer, University of Chicago; President Society for Medical

Dan Polsky, University of Pennsylvania; White House Council of Economic Advisors

Panelists:

Ron Manderscheid, Constella Group; Co-Chair IOM Report on Mental Health Quality

David Shern, CEO Mental Health America

Darrel Regier, Director of Research American Psychiatric Association

James McNulty, NAMI

Scott Gottlieb, American Enterprise Institute; former FDA Deputy Commissioner

Michael Schoenbaum, NIMH

Discussant: **Howard Goldman**, Univ of Maryland, MacArthur Network, *Psychiatric Services*

Co-Chairs: **Larry Alphs**, **Reuven Ferziger**; **Ron Manderscheid** (panel co-chair)

Guests...

ISCTM 2008 Annual Meeting, Session IV

Designing and Utilizing Clinical Trials To Inform Mental Health Policy Assessments

Distinguished Guests:

Charles Curie – immediate past Administrator of SAMHSA
John Calfee – American Enterprise Institute
William Emmet – Campaign for Mental Health Reform
Kana Enomoto – SAMHSA
Michael Freed – DOD Deployment Health Clinical Center
Robert Goldberg – Center for Medicine in the Public Interest
Eric Goplerud – GWU; President of ACMHA
Katherine Harris – RAND Health
Erin Holve – Academy Health
Michael Knable – Stanley Medical Research Institute
Noel Mazade – NASMHPD Research Institute
Roger Meyer – Best Practice; ACNP
Anne Michaels – National Foundation for Mental Health
Hazel Moran – Mental Health America
Sam Muszynski – APA
John Robinette – Constella
Stephen R. Smith – HRSA
Ken Thompson – Medical Director SAMHSA
Donald Weaver – Assistant Surgeon General
Joyce West – APIRE

DAN BLEVINS



Agenda

Speakers

Phil Wang: "Designing Clinical Effectiveness Research to Inform Mental Health Decision Making"

David Meltzer: "Value of Research Analysis on the Comparative Cost Effectiveness of Antipsychotic Drugs"

Dan Polsky: "National Comparative Effectiveness Policy: The case of antipsychotic drugs"

Panelists

Ron Manderscheid

James McNulty, NAMI

David Shern

Scott Gottlieb

Darrel Regier

Michael Schoenbaum, NIMH

Discussant

Howard Goldman

Press Release

September 19, 2005

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NIMH Study To Guide Treatment Choices for Schizophrenia

A large study funded by NIH's National Institute of Mental Health (NIMH) provides, for the first time, detailed information comparing the effectiveness and side effects of five medications — both new and older medications — that are currently used to treat people with schizophrenia. Overall, the medications were comparably effective but were associated with high rates of discontinuation due to intolerable side effects or failure to adequately control symptoms. One new medication, olanzapine, was slightly better than the other drugs but also was associated with significant weight-gain and metabolic changes. Surprisingly, the older, less expensive medication used in the study generally performed as well as the newer medications. The study, which included more than 1,400 people, supplies important new information that will help doctors and patients choose the most appropriate medication according to the patients' individual needs. The study results are published in the September 22 issue of the *New England Journal of Medicine*.

"The study has vital public health implications because it provides doctors and patients with much-needed information comparing medication treatment options," said NIMH Director Thomas R. Insel, M.D. "It is the largest, longest, and most comprehensive independent trial ever done to examine existing therapies for this disease."

Schizophrenia, which affects 3.2 million Americans, is a chronic, recurrent mental

Washington Post, Page 1, September 20, 2005

New Antipsychotic Drugs Criticized

Federal Study Finds No Benefit Over Older, Cheaper Drug

By Shankar Vedantam
Washington Post Staff Writer

Expensive new antipsychotic drugs that are among the most widely prescribed pills in medicine are no more effective and no safer than an older, cheaper drug that has been largely discontinued, according to the most comprehensive comparative study ever conducted.

The surprising result of a federally funded study released yesterday challenges widespread assumptions among psychiatrists about the best way to treat serious mental illness and underscores the extent to which physicians, patients and policymakers can be blindsided by self-interested research by drugmakers.

The study also paints a sobering picture of the state of treatment of schizophrenia, a disabling illness that afflicts about 3.2 million Americans with symptoms such as delusions, hallucinations and disordered thinking: Every drug, old and new, caused serious side effects, and the vast majority of patients stopped taking each of them.

"The study has vital public health implications," said Thomas Insel, director of the National Institute of Mental Health, which funded the study. "It is the largest, longest and most comprehensive, independent trial ever done to examine existing therapies for this disease."

Heavily marketed on the grounds they caused fewer side effects, the newer drugs, known as atypical antipsychotics, cornered about 90 percent of the market. All won Food and Drug Administration approval on the basis of short-term studies that showed they were better than sugar

Press Release

October 28, 2005

Director's Update:

NIMH Perspective on Antipsychotic Reimbursement: Using Results from CATIE

The recent publication of the phase I results from the National Institute of Mental Health (NIMH)-funded Clinical Antipsychotic Trials in Intervention Effectiveness (CATIE) has raised questions among advocates and clinicians alike about reimbursement policies for antipsychotic medications. Antipsychotics have now become the fourth largest group of medications prescribed in the United States, with a collective cost expected to surge past \$10 billion this year. As 80 percent of the prescriptions for antipsychotics are paid via the public sector, it is not surprising that the phase I CATIE results could be interpreted by some as an opportunity to save several billion dollars in public funds. **NIMH would like to raise a note of caution about how the CATIE results are used to inform reimbursement policy.**

In the September 22, 2005, *New England Journal of Medicine* (NEJM) report, the CATIE research team compared discontinuation rates with four atypical antipsychotics (olanzapine, quetiapine, risperidone, ziprasidone) and one older conventional antipsychotic (perphenazine). The new atypical medications, representing 90 percent of the current market, are approximately 10 times the cost of the older conventional antipsychotics. The results demonstrated few differences among the various medications. The older medication, perphenazine, was as well tolerated as the newer compounds and as effective as three of the four newer drugs. The fourth compound, olanzapine, was slightly better than all the others in terms of discontinuation and hospitalization rates but paradoxically was also associated with higher rates of weight gain and metabolic side

- CBO Report
 - IOM Report
 - President's New Freedom Commission

 - NASMHPD White Paper

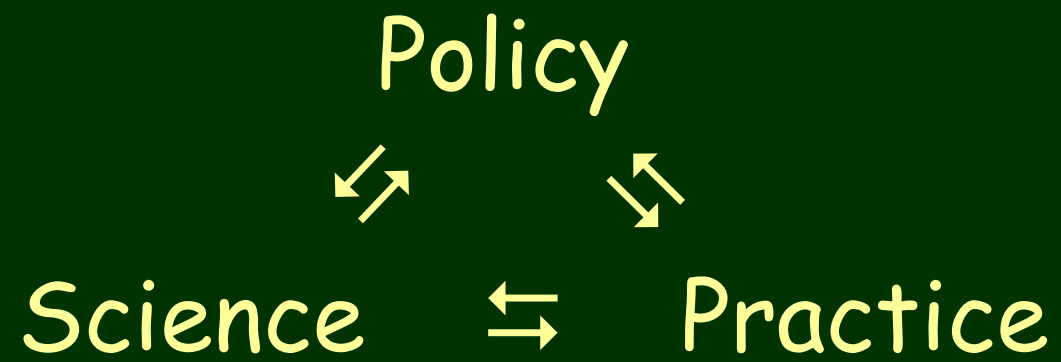
 - CATIE, CUTLAS, EUFEST
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Past environment:

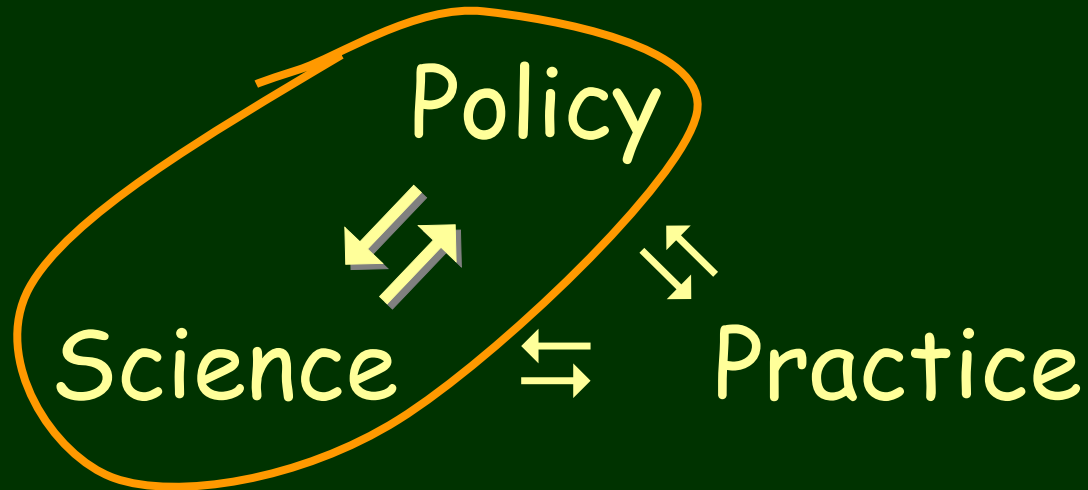
Science ↔ Practice



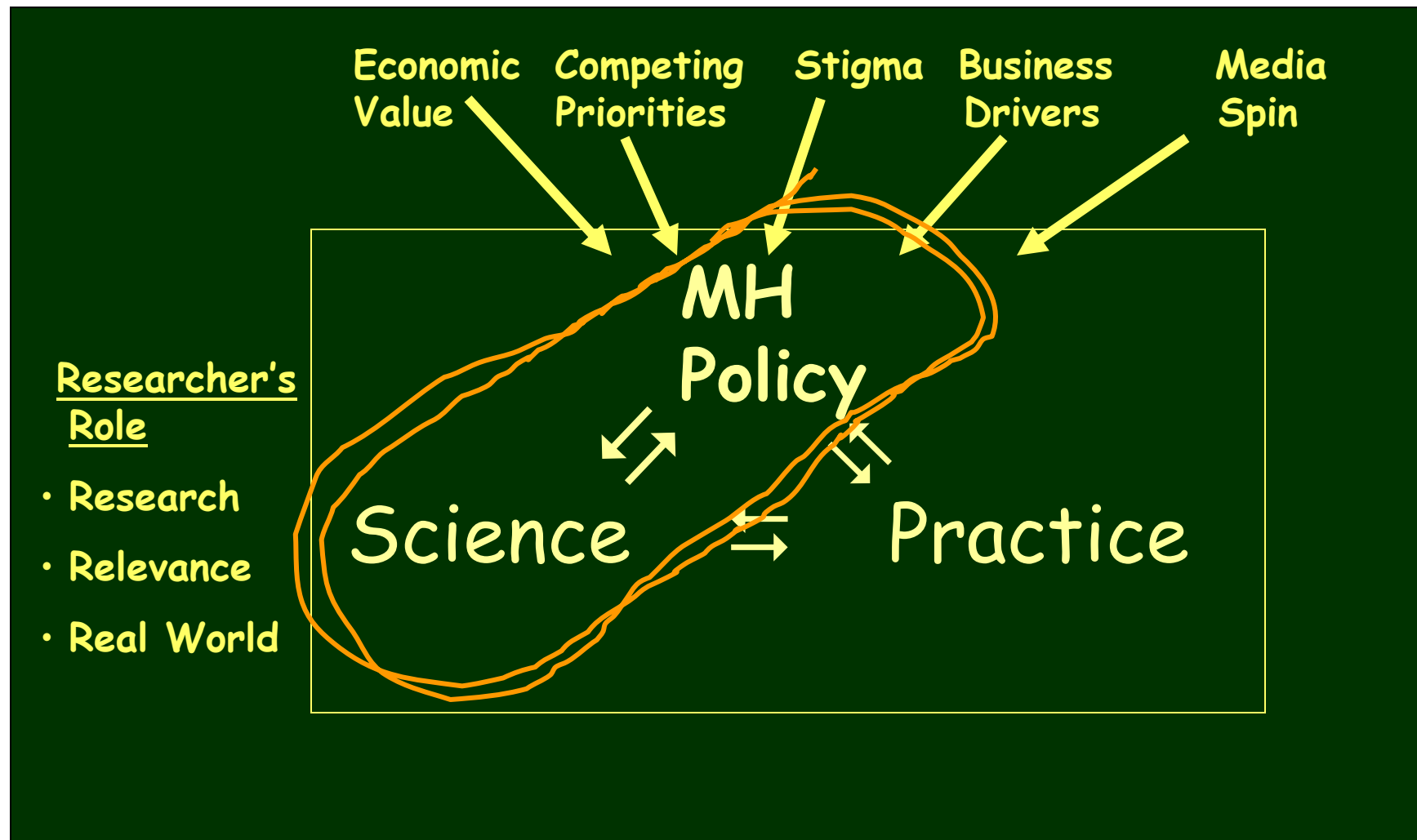
Current environment:



The influence of scientific data on practice increasingly depends on its relevance to policy decision makers.



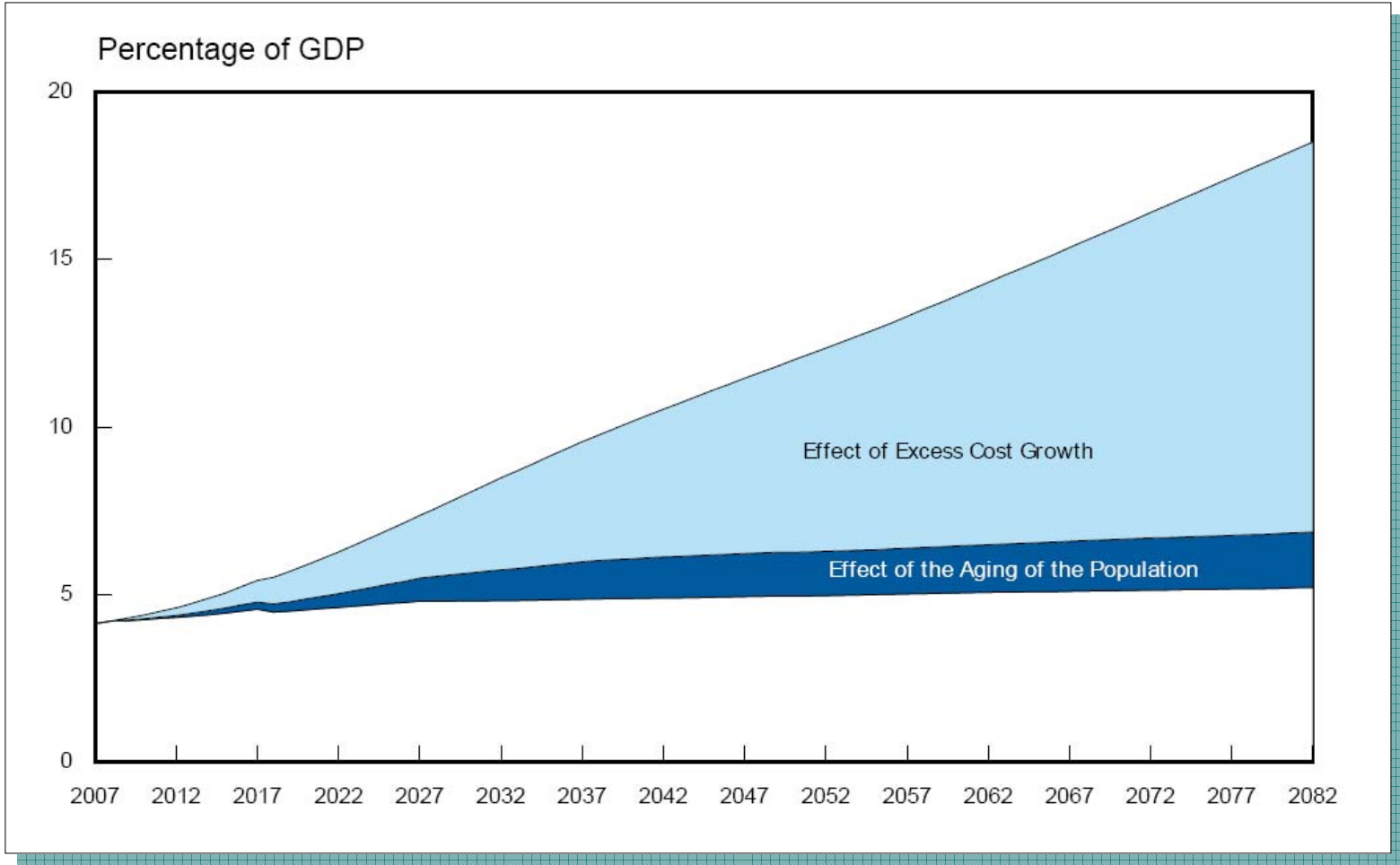
Mental Health Policy Environment:



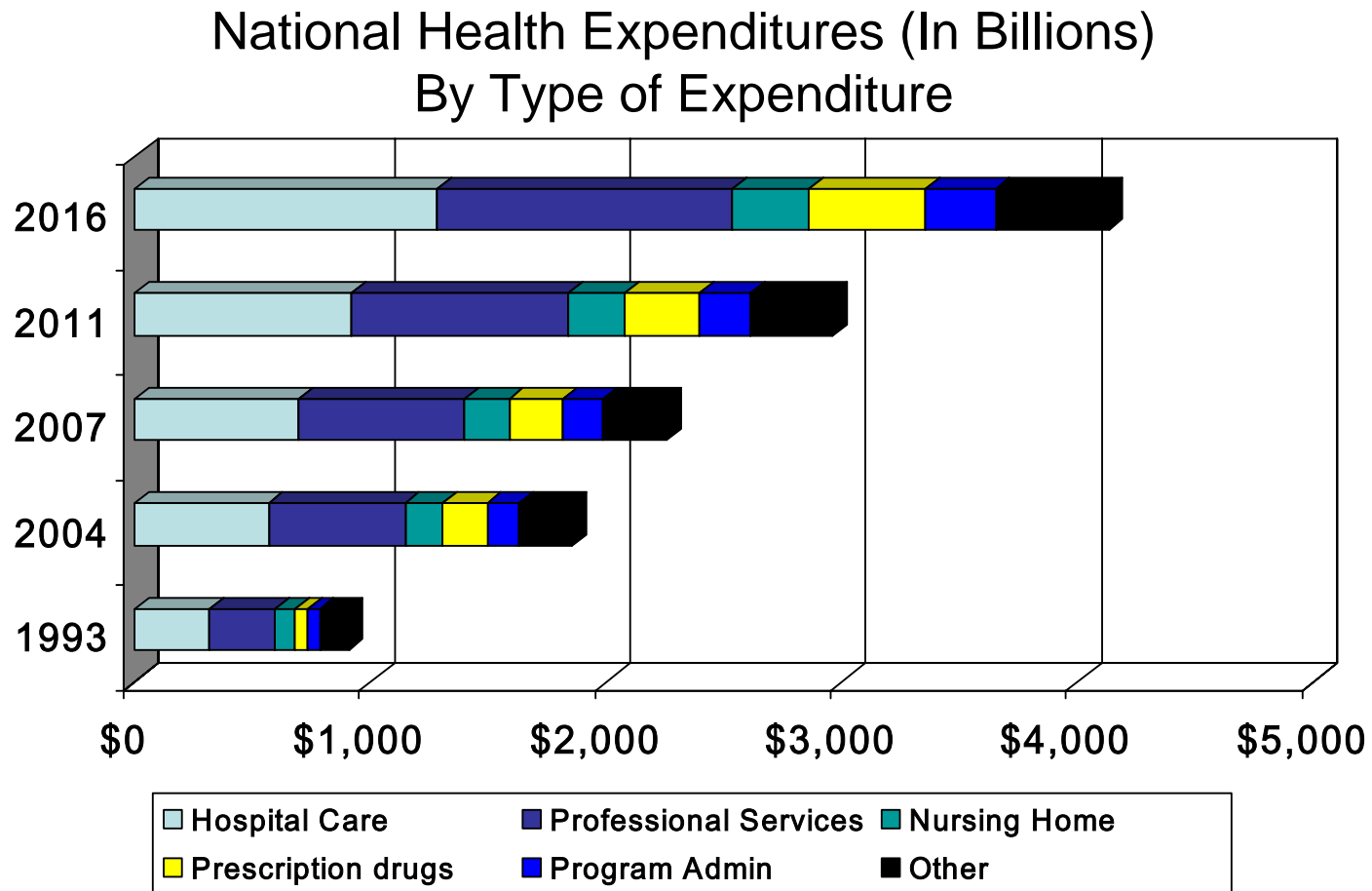
CBO: Health Care Spending Analysis and Projections

CBO Director Peter Orszag, testimony before the Senate Budget Committee on the rising costs of health care to, January 29, 2008

- **Technological change in health care is the primary driver of health care cost (and not population aging).**
 - **It is the rising cost of the health care that is the underlying cause of the nation's long-term fiscal challenge.**
 - **Spending on Medicare and Medicaid are projected to increase from today's 4 percent of GDP to 19 percent of GDP in 2082.**
 - **Total US spending on health care will reach 49 percent of GDP in 2082 - up from today's 16 percent.**
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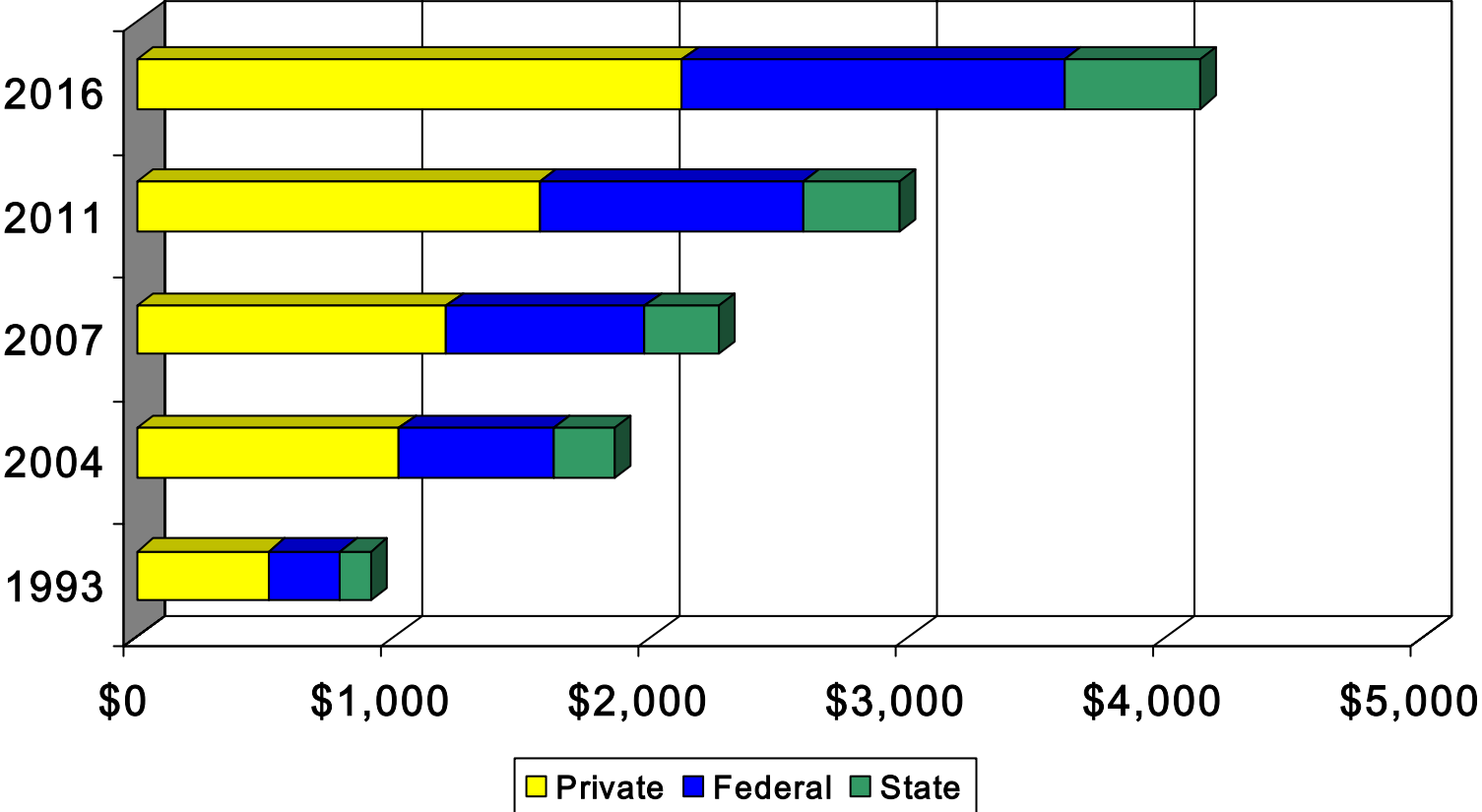
National Health Expenditures projected to double by 2016



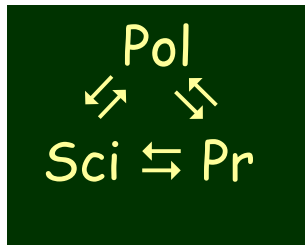
Source: Centers for Medicare and Medicaid Services

National Health Expenditures projected to double by 2016

National Health Expenditures (In Billions) By Source of Funds



Source: Centers for Medicare and Medicaid Services



- How should the field of CNS clinical trials research respond to the changing equilibrium of policy-driven medical practice?
 - The available clinical trials database does not address the data needs of health policy decision makers. What do policy makers need from clinical researchers? What does our field need to do differently?
 - Example: CATIE is a milestone in retooling the mental health clinical trials enterprise for policy relevance. What can we learn from CATIE? How should our field move beyond CATIE, to the next level of policy relevant clinical effectiveness research?
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1. What are the health policy questions that CATIE has tried to address?
 2. What was successful and what was unsuccessful about the methodology used to address these questions?
 3. What are the reasons for discrepancies in interpretation?
 4. What are the implications of the results from CATIE for mental health policy?
 5. What lessons has CATIE provided for future comparative effectiveness trials in terms of questions, design, implementation of study, analysis, interpretation and dissemination of results?
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