Future Spending for Prescription Drugs Used for Mental Health and Substance Use Disorders: Does the Past Portend the Future?

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Presented at the annual meeting of the American Public Health Association
Washington, DC
November 05, 2007

Acknowledgements

- Katie Levit (Thomson Medstat), Rita Vandivoort (SAMHSA), and Jeff Buck (SAMHSA)
- SAMHSA and Thomson Medstat for interest and funding

Purpose of Project

- Part of a larger SAMHSA-sponsored study to project trends in spending on mental health and substance abuse (MHSA) treatment in the United States.
- The primary purpose of this presentation:
  - Aim 1) Present new estimates on MHSA prescription drug spending from 1986 – 2003;
  - Aim 2) Explore qualitatively factors with potential to influence future use and spending of prescription drugs used to treat mental health disorders

Why Prescription Drugs? They're used… a lot.

- For many MHSA disorders, prescribed psychotherapeutic agents are the predominant form of treatment
  - 8.1% of US population used MHSA drugs in 2001 *(Zuvekas, 2005)*
    - In 2005, antidepressants most commonly Rxed drug class (118 M Rxs) *(CDC, 2007)*
  - For substance abuse disorders, prescription drugs less commonly used for treatment…but that trend is changing

Why Prescription Drugs? They cost… even more.

- In 2003, total MH treatment spending=$100.3 Billion
  - $23.3 B for prescription medications *(Mark et al, 2007a)*
- 80% of growth in MH drug spend during 1996-2001 explained by:
  - SSRIs and other novel antidepressants (+52%)
  - Atypical antipsychotics (+28%)
  - Anticonvulsant 'mood stabilizers' (+9%)
  - Anxiolytics (+7%)
  - Stimulants (+4%) *(Zuvekas, 2005)*
- In 2003, total SA treatment spending =$20.7 Billion
  - $98 Million for prescription medications *(Mark et al, 2007b)*

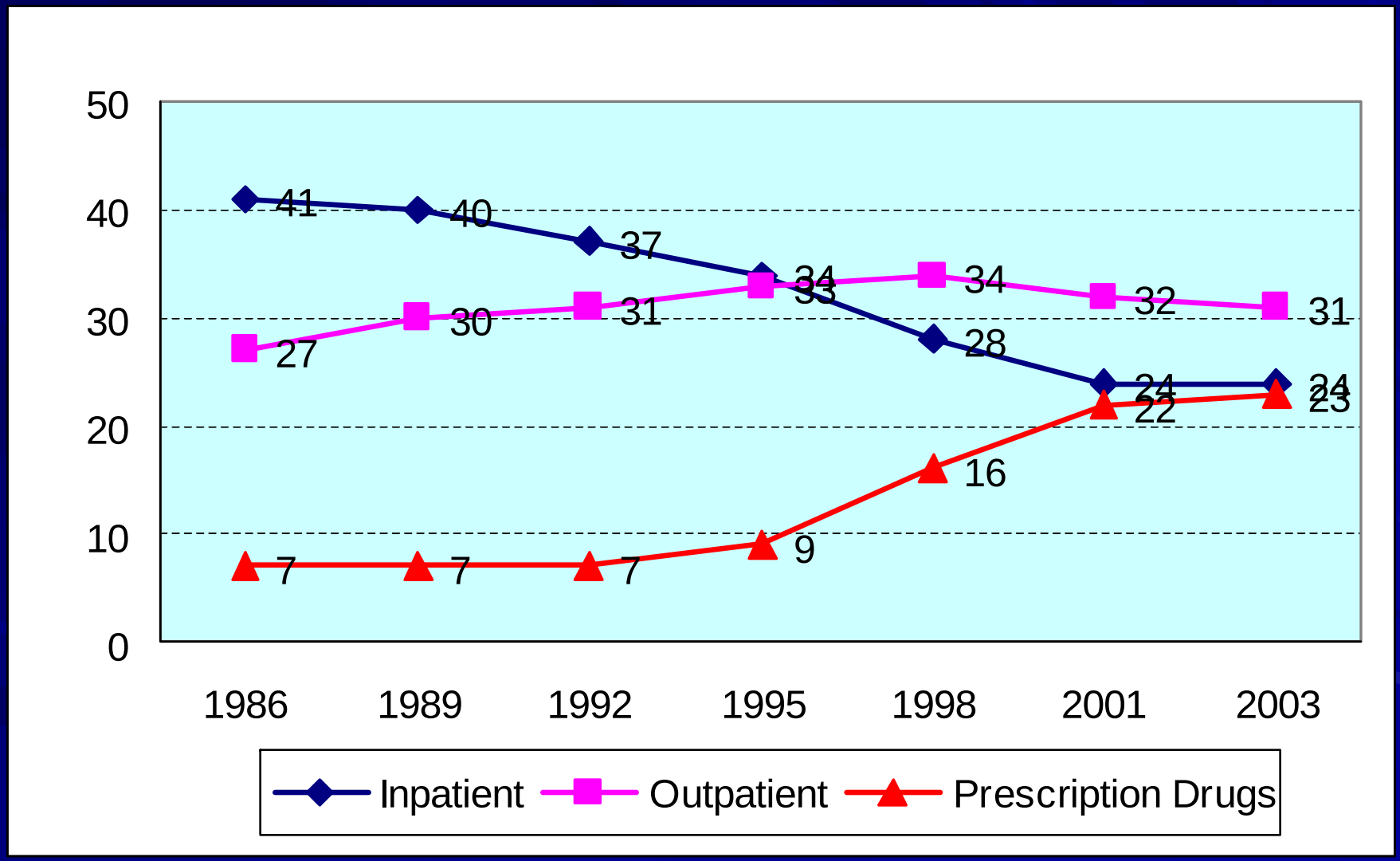
Methods

- Quantitative: Consistent with National Health Expenditures Accounts (NHEA) methods. Uses Survey of Mental Health Organizations and National Survey of Substance Abuse Treatment facilities, as well as other databases (eg, NIS, NAMCS, MEPS)
  - Data from 1986 - 2003
- Qualitative: Review of theoretical, clinical, economic, and policy published literature, as well as ‘white’ and ‘grey’ documents

Findings

- Total MH spending increased from $33 B in 1986 to $100.3 B in 2003 *(Mark et al, 2007a)*
  - As proportion of total MH spending, Rx drug spending rose from 7% in 1986 to 23% in 2003
  - MH prescription spending increased 14.9% (versus 12.5% for total Rx spending)
  - Per capita MH spending: $205 (1986) to $345 (2003) (inflation-adjusted 2003 dollars)
- Total SA Rx spending increased from $24 M in 1986 ➔ $98 Million in 2003 *(Mark et al, 2007b)*
  - 12.3% annual increase, but < 1% of total SA spending

Percent Distribution of Expenditures for Mental Health Treatment

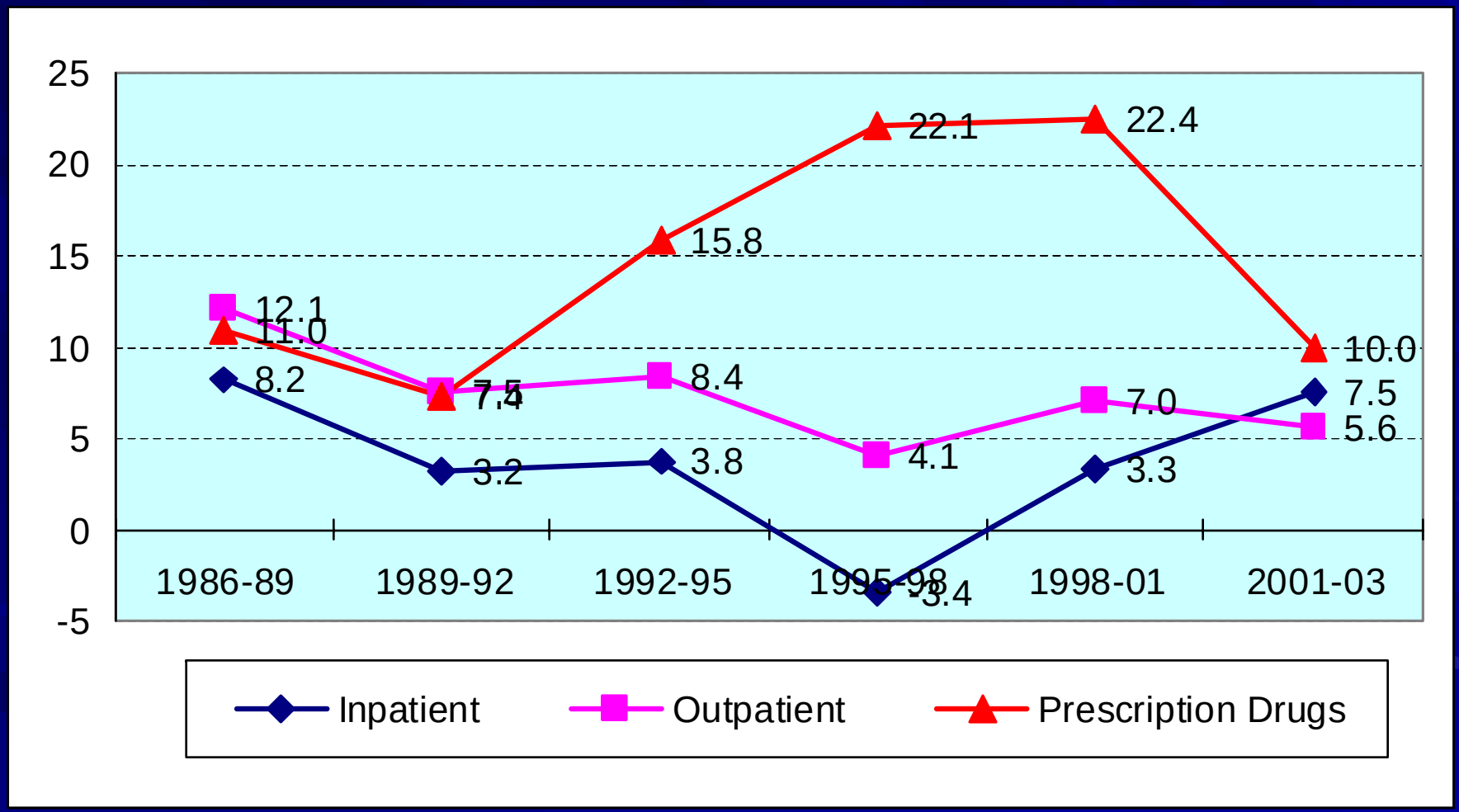


So one would expect…

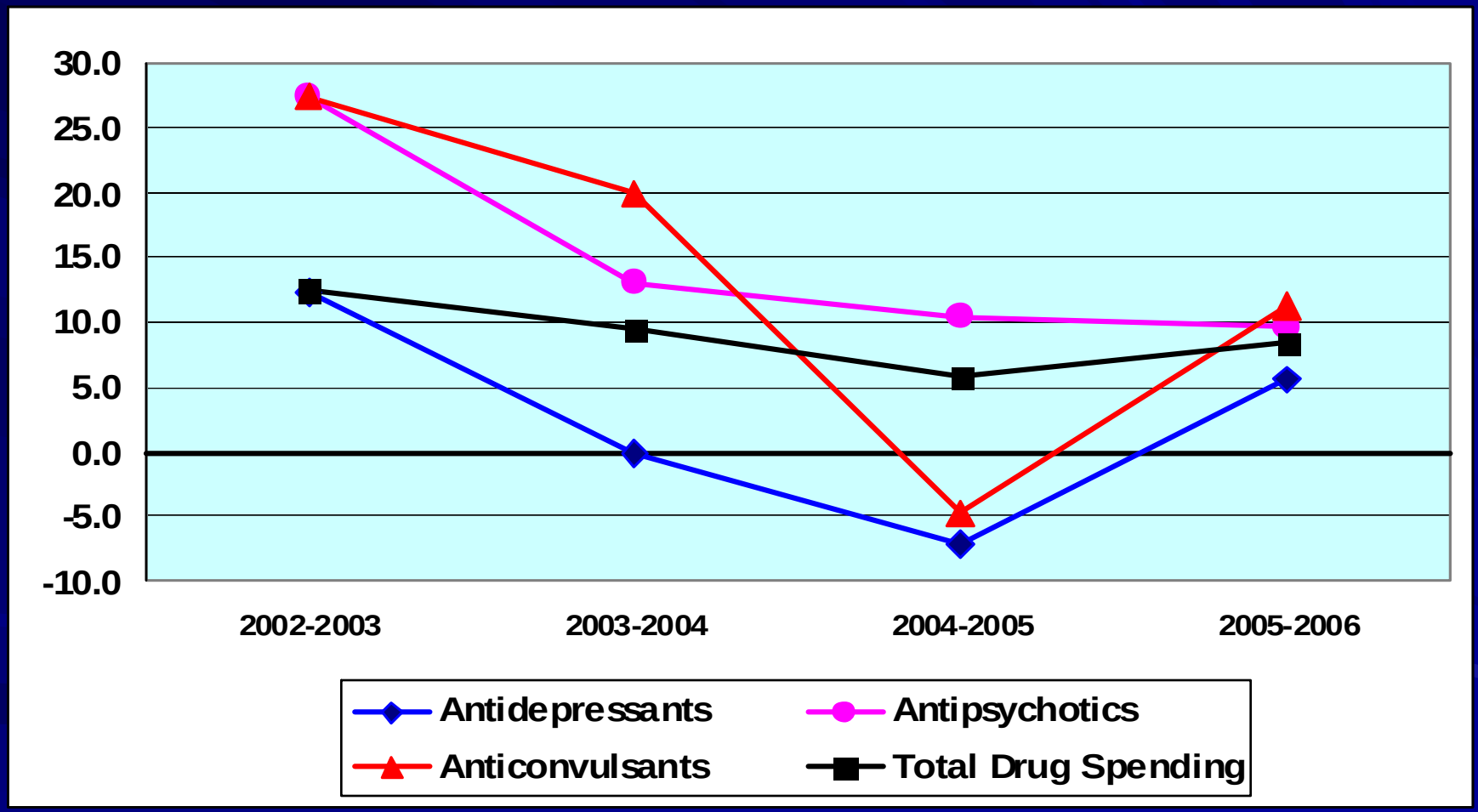
- To see double-digit increases in prescription drug spending over the next few years…

RIGHT?????

Average Annual Growth Rates in Expendituresfor Mental Health Treatment



Trends in Average Annual Growth Rates for Total and Select MH Therapeutic Classes



IMS, 2007

What Will Influence Future Trends?

- Many possible drivers, but focus on four:
  - Safety and effectiveness
  - Patent expiration
  - Drug development
  - Off-label use and treatment augmentation

Drug Safety

- 'Black-box' safety warnings on three MH drug classes
  - Antidepressants: Suicide in pediatrics
  - Antipsychotics: dementia in elderly; atypicals and diabetes
  - Stimulants: cardiac problems and sudden-death
- Do such warnings actually influence prescribing patterns?
  - Pediatric antidepressant users down 18%
  - Olanzapine sales down 3% with diabetes warning
- The use of methadone, buprenorphine and other opioid agonist and antagonists for SA treatment have abuse potential themselves

Clinical Efficacy and Effectiveness

- As new information becomes available about the utility of specific drugs in treating problems, subsequent use and spending may be affected
  - CATIE: Older, less expensive antipsychotics may be comparably tolerable and efficacious as newer – and more expensive – atypical antipsychotics ➔ interpreted by some payors in formulary and benefit design considerations
  - SSRI/SNRI antidepressants more efficacious than older drugs in treating major depression in adults
    - But perhaps not better than older agents and behavioral interventions for mild/moderate depression
- Some evidence that naltrexone no better than placebo in treating chronic, severe ETOH dependence
  - Ditto for acamprosate versus naltrexone and/or cognitive behavioral intervention

Patent Expiration and Availability of Generic Alternatives

- There are generic alternatives available in all MH therapeutic classes
- Antidepressants: 9/12 'novel' antidepressants have generics (including paroxetine)
  - Sertaline and escitalopram have generics in pipeline
  - Only duloxetine (Cymbalta®) has solid patent protection
- Antipsychotics: clozapine only generic atypical
  - 2008: risperidone
  - 2011: Olanzapine, quetiapine
  - 2012: ziprasidone
  - 2014: aripiprazole
- Regarding SA drugs, methadone, naltrexone and disulfiram have generic equivalents

Drug Development – What's in the Pipeline for MHSA Drugs?

- Fueled by marked advances in understanding of brain structure and chemistry
- General consensus that US Pharma is in bit of dry spell regarding new drug development
- Average cost to bring new drug to market = $868 million
- Top 3 most costly classes:
  - Cancer
  - Respiratory
  - Neurologic (includes psychiatric, anticonvulsants)

Drugs Under Development: Anxiety/Depression (n=60)

- 10 for anxiety, 20 for depression, and 30 for both
- Some novel chemicals: Triple-reuptake inhibitors, agents that target melatonin, tachykinin, corticotrophin relaxing factor, but many are existing MH medications seeking new indications and/or dosage forms
  - Examples:
    - Desvenlafaxine (metabolite of venlafaxine)
    - Selegiline (MAOI transdermal patch)
    - Agomelatine (melatonergic agent)
    - Gepirone ER® (serotonin-1A partial agonist)

Rosack, 2006

Drugs Under Development: Psychotic/Bipolar Disorders (n=40)

- Most are new dosage forms or “me-too” drugs with slightly modified chemical structures
- Examples:
  - Paliperidone (long-acting metabolite of risperidone) – just approved
  - Mifeprostone (long-acting IM maintenance for BP and psychosis)
  - Bifeprunox® (partial dopamine/serotonin agonist) *Rosack, 2006*

Drugs Under Development: Substance Use Disorders

- Opioid abuse focusing on non-opioid drugs
  - Lofexidene (congener of clonidine used in HTN)
  - Corticotropin Releasing Factor (CRF) antagonists
- Cocaine abuse:
  - Vaccines (TA-CD)
  - Selective Dopamine (D1) antagonists (DAS-431) as aerosol, IV, and transdermal formulations
- Cannabinoid receptor antagonists (e.g., SR141716)
- Most efforts are on new uses for already-marketed drugs
  - Atypical Antipsychotics
  - Bromocriptine
  - SSRI and other antidepressants
  - Anticonvulsant mood stabilizers

‘Off-Label’ Use and Treatment Augmentation

- 1 in 7 medications prescribed off-label
  (Radley et al, AIM, 2006)
  - 31% of psychiatric medications
  - 46% of anticonvulsant medications
- Treatment augmentation (i.e., drugs used to ‘boost’ effectiveness of other MHSA drugs) increasing
  - No real evidence base for most poly-therapy

Other Factors

- Expansion of benefits
  - MMA Part D
  - New parity provisions
- Diffusion and Adoption:
  - MH drugs: Widely diffused, widely adopted
  - Substance use treatments: not diffused, not adopted
- Advances in basic sciences and understanding of how mental health disorders manifest themselves (and how drugs work)
- Changes in screening and treatment, including improved financing and access
- Advances in non-drug treatment and whether covered by insurers
  - Vagus nerve stimulation
  - Transcranial magnetic stimulation

Conclusions

- MHSA treatment spending increased over past decade, due largely to increased spending on MHSA drugs
  - BUT… marked increase in MH drug spending shows evidence of abating
- Likely stimulants to increased spending:
  - Increase in demand due to baby-boom cohort and expansion to pediatrics
  - New drugs in pipeline
  - Increased coverage and reimbursement for MH drugs
  - Increased off-label use
  - Increased DTCA and other marketing
- Likely impediments to increased spending:
  - Increase in generic use
  - Increase in use of older therapeutic alternatives
  - Documentation of reduced safety/effectiveness
  - Increased implementation of use and cost-control strategies

THANK YOU!

- Questions? Comments? Please contact me at:

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