

JUDITH A. SHINOGLA AWARD LECTURE: MENTAL HEALTH POLICY AND FDA WARNINGS

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The Hilltop Institute
analysis to advance the health of vulnerable populations



EMPLOYMENT SUPPORTS FOR THOSE WITH SERIOUS MENTAL ILLNESS...

- Schizophrenia, bipolar, disability, Medicaid/Medicare, serious functional impairment. 4.1% of US population (SAMHSA, 2013)
- Employment rates only about 15% (Bond and Drake, 2014; Salkever et al. 2007, 2014)
- Two thirds of persons with SMI have employment as a goal (Bond and Drake, 2014; Frounfelker et al. 2011; Ramsay et al. 2011; Watkins et al. 2011)
- Evidence-based (Kinoshita, 2013; Steinwachs et al., 2014)
- Benefits of working: financial (societal and individual), self-esteem, social integration

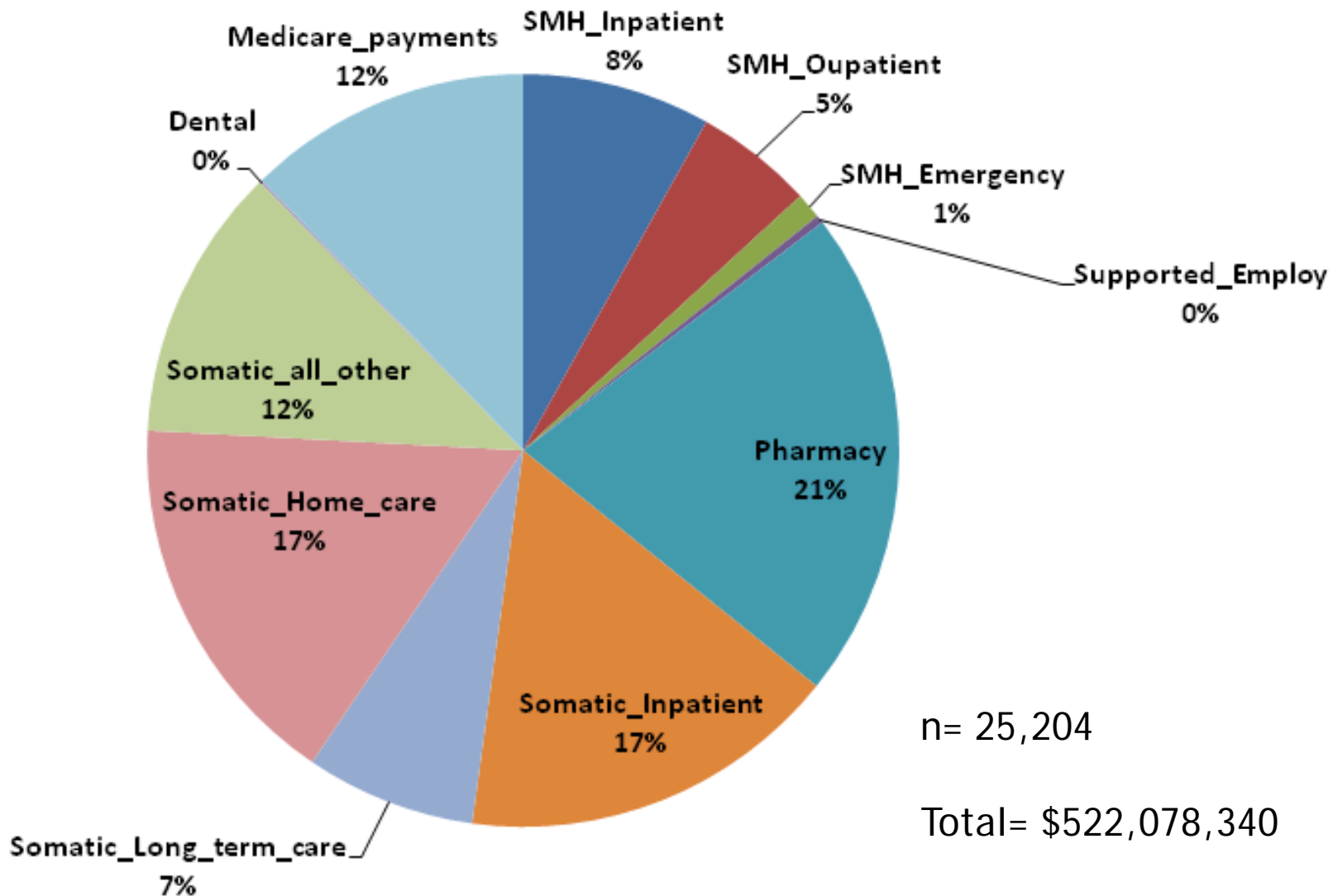


NIMH GRANT STUDYING SUPPORTED EMPLOYMENT...

- ◉ Study Maryland Medicaid implementation of evidence-based supported employment implementation that dates back to 2002
- ◉ Source Data: administrative records from 2001 to 2010, Department of Labor and Licensing, federal earning reports, BHA administrative and outcomes and Authorization records
- ◉ Questions being addressed...
 - Uptake, population characteristics?
 - Earnings? (DLLR and federal earnings reports)
 - Correlates to fidelity?
 - Functioning?
 - Utilization of other Medicaid services?
 - Costs?



MEDICAL COSTS FOR OUR SMI SAMPLE IN FY2004...




REDUCING ASTHMA MORBIDITY...

- 823,000 Marylanders diagnosed
 - 11,474 Hospitalizations
 - 39,834 Emergency room visits
 - 67 Deaths
 - Prevalence of asthma among adults—
 - Baltimore City 18.6%
 - Maryland 13.9%
- } \$99 million

Source: Maryland Asthma Control Program,
August, 2011; figures pertain to 2009



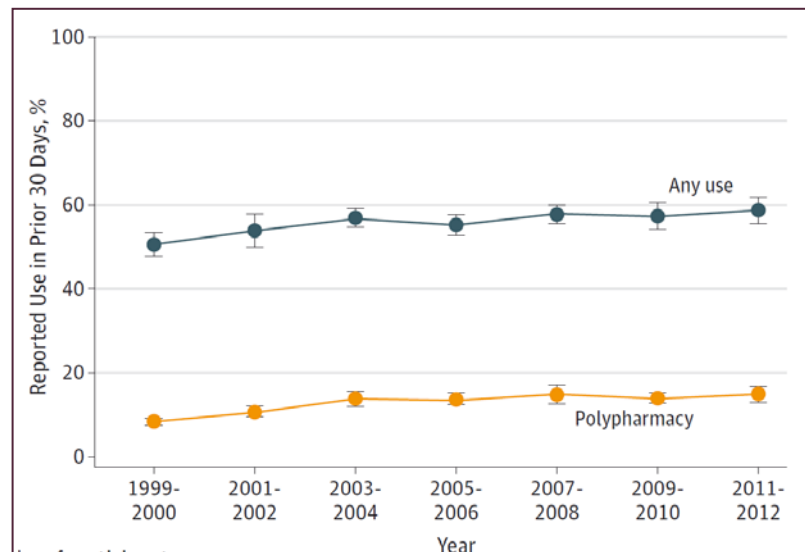
PRIMARY/SECONDARY PREVENTION, COST BENEFIT ANALYSIS...

- Target population: Medicaid children in Baltimore City with Asthma
- Intervention: 
 - Pest, dust, allergen (e.g., tobacco smoke) abatement
 - Mold removal/leak repair
 - Heating/cooling system repairs, weather proofing
 - Medication counseling
- Design: 240 interventions, matched controls from Medicaid system
- Evaluation: Do cost savings in Medicaid and energy use offset intervention within 12 months?
 - Secondary outcomes: missed work and school days



PHARMACEUTICALS MATTER...

- Antipsychotics (clozapine, Zyprexa), Antidepressants (Prozac), Stimulants (Ritalin)...
- “Return on investment” of 10 to 1 (Cremieux *et al*, 2007).
- \$234 billion in 2008 up from \$40 billion in 1990. 10¢ of every health care \$ (not including professional fees) (Hartman *et al*, 2010).
- Kantor *et al*, 2015: 60% of adults use at least 1 Rx.

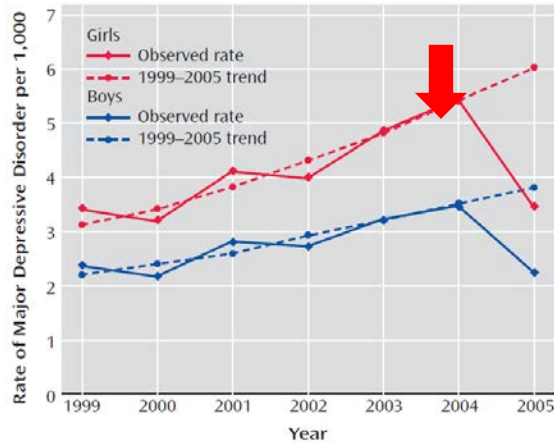


THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) MATTERS...

- Principal gate-keeper with exceptional power and reputation (Carpenter, 2010; Szalados, 2007; Babiarz & Pisano, 2008)
- 1. Pre-clinical -> 2. Clinical -> 3. Pivotal clinical -> **APPROVED!** -> 4. **Post-marketing surveillance**
- Problems: sample size, indications.
 - Vioxx/Bextra (\$3 billion in sales pulled from market)
 - Antidepressants (SSRIs)- Warning on suicidality in youths issued October (Weissert & Weissert, 2006)
- FDA Admendment Act (P.L. 110-85), 2007-2012

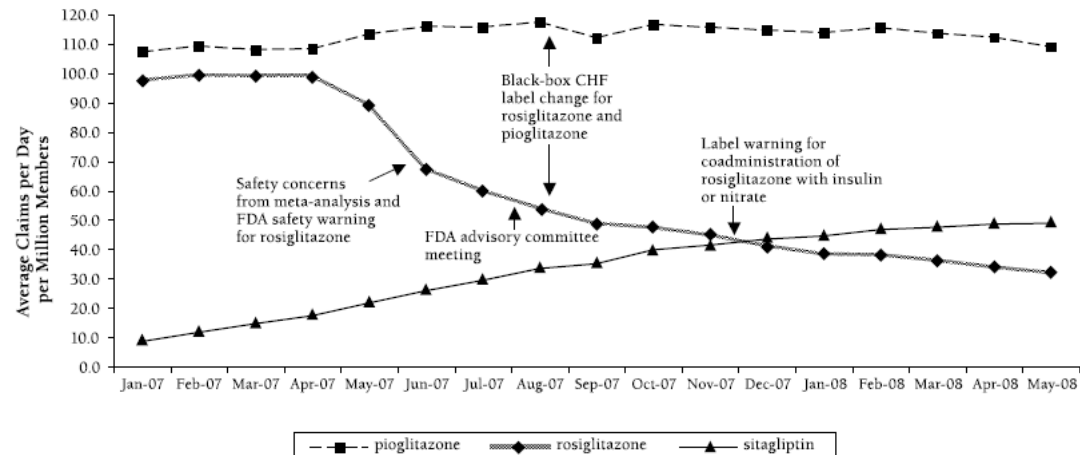


SOME WARNINGS MATTER...



Libby et al, 2007:
antidepressants → suicidality

Starmer et al,
2008:
Avandia (diabetes
medication) →
cardiovascular



NEWS MATTERS...AND FOR HEALTH INFORMATION

- ◉ Agenda setting (McCombs, 2005; Iyengar & Kinder, 1987)
- ◉ Meta-analysis (Grilli *et al*, 2002)
- ◉ Smoking rates (Clegg *et al*, 2008)
- ◉ Suicide copy-cat (Ishii, 1991; Hagihara *et al*, 2007)
- ◉ “Mixed” quality coverage includes warning dissemination (Barry and Busch, 2010; Shih *et al*, 2008; Comis, 2015; Speers *et al*, 2004)



CAN I PUT IT ALL TOGETHER IN A TESTABLE MODEL?

○ 4 warnings

- Antidepressants (SSRIs) → suicidality (2003)
- Rosiglitazone (diabetes) → heart attack (2007)
- Chantix (smoking) → suicidality, aggression, anxiety, etc. (2009)
- Leukotriene Inhibitors (asthma and allergies) → agitation, aggression, anxiousness, dream abnormalities and hallucinations, depression, insomnia, suicidality and tremor

○ Model: Use-Drug = $f\{\text{lagged}(\text{Warning-News})\}$



METHODS

- Get time series from published literature or from Maryland Medicaid data
- Select major news content from news source databases using searches for drugs that treat condition (e.g., depression or asthma) and use term “safety” or “efficacy”
- Count and code those articles for:
 - Orientation (heightening concern or not)
 - Front page
 - FDA and/or Warning mention
 - Length
 - Media type (broadcast vs. print)
 - Valence
 - Quality (Schwitzer)

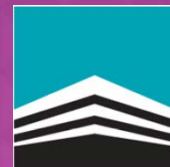


HEALTHNEWSREVIEW YOUR HEALTH
NEWS WATCHDOG



STORY REVIEWS

NEWS RELEASE REVIEWS



EARLY RESULTS

Variable	Coef.	<i>p</i>	<i>R</i> ²	<i>df</i>	article count	Notation
% of new child dep. where PCP RX'd an antidep.	-0.22	<0.001	0.31	49	587	
Rosiglitazone Claims Per Million Members (diabetes)	-2.4	0.14	0.14	17	97	n.s., revise with Medicaid data
Chantix RX count (smoke)	-13	0.039	0.09	46	51	
Montelukast RX count (asthma)	-175	0.09	0.37	46	105	Trend, Seasonal adjustment

Basic model: 2 month lag of news coverage articles that heighten concern



NEXT STEPS...

- Form of models...
 - Lag structure (autocorrelation)
 - Diminishing effects with time
- Test other variables beside direct reporting on articles that heighten concern (e.g., front page placement, length, valence)
- Granger causality...
- Limitations
 - Errors of omission (e.g., DTC, drug approval issues, physician letters)
 - Selected warnings...



POLICY IMPLICATIONS...

- Health education, health communication
- Managing risk of complex situations which impact many
 - Risk communication by the FDA and other agencies with similar, limited policing authority
- Optimizing and leveraging journalism
 - Foundation of democracy (Overholser & Jamieson, 2005)
 - Media is a key source of information for most of us





FOR MORE INFORMATION...

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RISK CONCENTRATED AMONG YOUNG, BALTIMORE CITY, MEDICAID ENROLLEES

Hospitalizations

Asthma Hospitalization Rates (per 10,000)
Baltimore City vs. Maryland, 2009

Age	Baltimore City		Maryland	
	n	Rate	n	Rate
Children 0 - 4 yrs	367	80.9	1,834	48.2
5 - 17 yrs	425	41.3	1,400	17.4
< 18 yrs	792	* 50.7	2,976	25.4
Adults 18 - 64 yrs	1772	44.1	5867	9.5
65+ yrs	383	50.9	2,087	30.0
≥ 18 yrs	2155	42.9	7954	13.2
Total	2947	47.2	11,474	19.8

Emergency Department Visits

Asthma Emergency Department Visit Rates (per 10,000)

Baltimore City		Maryland	
n	Rate	n	Rate
2,317	510.6	7,443	195.6
5,197	313.2	11,077	114.7
5,514	* 360.2	18,520	136.1
6,718	166.3	20,296	56.3
253	33.6	1,018	14.7
6,971	144.1	21,314	50.3
12,485	203.3	39,834	72.3

>>50% of payments for these services for youth <18 years old are made by Medicaid

Source: Maryland Asthma Control Program, August, 2011; figures pertain to 2009

