The Prescription Drug Abuse Crisis: 2015 Update

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Mississippi Professionals Health Program

7th Annual Mississippi Addiction Conference
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Todays speaker has no disclosure of real or apparent conflict related to the content of this presentation.
What is the MPHP?

- The designated physician health program for Mississippi.
- 501(c) (3) nonprofit subsidiary of the Mississippi State Medical Association (MSMA)
- Organized in 1978
- MPHP has assisted over 900 physicians to return to healthy, safe and productive medical practices
What is the Goal of MPHP?

- To provide a confidential, non-disciplinary recovery track for physicians who suffer from potentially impairing conditions or illnesses.
- To coordinate effective detection, evaluation, treatment, and aftercare monitoring of physicians with these conditions.
- To provide advocacy for the physician to safely practice medicine.
Objectives:

1) To describe the epidemiology of prescription drug abuse.

2) To identify factors which have contributed to prescription drug abuse in America.

3) To summarize risks of prescribing controlled substances for chronic, non-life threatening conditions.
Much of the content of this presentation was made possible by Andrew Kolodny, MD and his work with the Physicians for Responsible Opioid Prescribing

www.supportprop.org
US Consumption of Global Supply of Opioids: 2010

- 55% of all morphine
- 56% of all hydromorphone
- 80% of all oxycodone
- 99% of all hydrocodone
- Americans represent 5.2% of the earth’s population

(International Narcotics Control Board 2011 Report)
111 Tons Dispensed in 2010!!!

- 69 tons of pure oxycodone
- 42 tons of pure hydrocodone

(NSDUH, 2011 reported in CDC Vital Signs, January 2012)
Opioid Prescriptions Dispensed per Year (Oxycodone and Hydrocodone)
Health care providers wrote 259 million prescriptions for painkillers in 2012, enough for every American adult to have a bottle of pills.
Mississippi Consumption of Opioids

- #1 prescribed drug in Mississippi in 2012
- Hydrocodone/acetaminophen

(ProPublica Report, 2013)
Classes of Prescription Drugs

Opioids
CNS Depressants
Stimulants
Other Substances
Opioids

- Prescribed to alleviate pain

- Examples include:
  - Hydromorphone (Dilaudid®)
  - Hydrocodone (Vicodin® Lortab ®)
  - Oxycodone (OxyContin®)
The Eye of the Perfect Storm...
The use of opioids for chronic noncancer pain (CNCP)
How Did We Get In This Mess???
Introduction
of OxyContin: 1996

- Active ingredient: oxycodone
- Manufactured by Purdue Pharma
- $44 million in sales in 1996

(OxyContin Marketing Plan, 1999)
Purdue “aggressively” promoted the use of opioids for use in the “non-malignant pain market.”

Targeted primary care

“Risk of addiction much less than 1%.”

1998 training video sent to thousands of physicians

(OxyContin Marketing Plan, 1999; Purdue Pharma, Stamford, CN, 1999)
Opioids are safe and effective for chronic pain.

Opioid addiction is rare in pain patients.

Opioid therapy can be easily discontinued.

Opiophobia: causes patients to needlessly suffer
Pseudoaddiction:
- Describes patients who manifest aberrant, drug-seeking behavior.
- “Result of untreated pain, not addiction”
- Recommended treatment: dose escalation.
- Problem: how to differentiate from addiction or hyperalgesia?
- Is it legitimate?
OxyContin Sales 2010

- $3.1 billion in sales in 2010
- Over $17 billion in sales 2000-2010

(IMS Health, National Prescription Audit, Dec 2010)
Are opioids for chronic, noncancer pain safe and effective?
Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)

2001 (range 1 - 71)

- < 8
- 8 - 14
- 15 - 18
- 19 - 44
- 45 or more
- Incomplete data

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroine opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)

2003 (range 2 – 139)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opiates/synthetics admission rates, by State
(per 100,000 population aged 12 and over)

2007
(range 1 – 340)

< 8  8 - 14  15 - 18  19 - 44
Incomplete data

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Primary non-heroin opiates/synthetics admission rates, by State (per 100,000 population aged 12 and over)

2009
(range 1 – 379)

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.
Non-heroin opioid admissions, by gender, age, race/ethnicity: 2011

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 10.10.11.
Unintentional Drug Overdose Deaths
United States, 1970-2007

Source: CDC, Unintentional Drug Poisoning in the United States (July 2010)
Unintentional Drug Overdose Deaths
United States, 1970-2007

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Unintentional Drug Overdose Deaths
United States, 1970-2007

5th Vital Sign Implemented 2001

Source: CDC, Unintentional Drug Poisoning in the United States (July 2010)
PAIN
The Fifth Vital Sign

Assessment of pain should be as routine as checking other vital signs.
How Can You Stop Enabling Addiction in This System?

- If you are an emergency medicine physician and want to keep a job, it will be very difficult!
Unintentional Drug Overdose Deaths
United States, 1970-2007

Source: CDC, Unintentional Drug Poisoning in the United States (July 2010)
38,329 Deaths (All O.D. Deaths)

Source: CDC, Unintentional Drug Poisoning in the United States (July 2010)
43,982 Deaths (All O.D. Deaths)

CDC, Web-based Injury Statistics Query and Reporting System (2014)
Record high life expectancy: 78.8 years
Record low age-adjusted death rate
A great year, if you exclude opioid related mortality
(CDC, 2015 National Vital Statistics mortality data)
10 Leading Causes of Death in 2012

- Cancer: 169.0 (2011), 166.5 (2012)
- Chronic lower respiratory diseases: 42.5 (2011), 41.5 (2012)
- Stroke: 37.9 (2011), 36.9 (2012)
- Influenza and pneumonia: 15.7 (2011), 14.4 (2012)
- Suicide: 12.3 (2011), 12.6 (2012)
Injury Pyramid

For every opioid overdose death:

- 9 treatment admissions
- 35 ER visits for nonfatal overdoses
- 161 people with drug abuse or addiction
- 461 nonmedical users of opioids

(CDC MMWR, January 13, 2012)
Patients with mental health and substance abuse co-morbidities are more likely to receive chronic opioid therapy than patients who lack these risk factors.

(Edlund MJ, et al., 2010)
How Many Americans Have Chronic Pain?

- “moderate to severe chronic pain that limits activities and diminishes quality of life.”
- 25 million Americans
  (Annals of Internal Medicine. POSITION PAPER. 2015;162:295-300)
Are We Winning the War on Pain?

- How close are we to eradicating pain??
Are We Winning the War on Pain?

- The 2013 Burden of Disease study in the Journal of the American Medical Association (JAMA):
  “Americans suffered as much disability from back and neck pain in 2010 as they did in 1990 before the escalation in the prescribing of opioids.” (Murray, 2013)
A 2008 JAMA study found that:
“...from 1997 to 2005, there was no improvement in self-assessed health status, functional disability, work limitations, or social functioning among respondents with spine problems.” (Martin et al., 2008, p. 661)
Extremely powerful psychotherapeutic effects which are likely much stronger than the pain relieving effects.

Relieve the emotional distress of pain.

Excellent at relieving anxiety and treating depression for a limited time.

Treatment of choice for short-term, end of life situations.
Opium Wars....

...were not fought for the right to have pain relief!!!
Opioids for CNCP:
Quality of Evidence

- Patient Selection and Risk Stratification: low quality
- Initiation and titration of chronic opioid therapy: low quality
- Use in high risk patients: low quality
- ALL are based on low quality evidence.

(2009 American Pain Society Guidelines)
Opioids for CNCP: Quality of Evidence

- High dose therapy (≥120 morphine equivalents/day): low quality
- Driving and work safety: low quality
- Treatment of breakthrough pain: low quality
- ALL are based on low quality evidence.

(2009 American Pain Society Guidelines)
No prospective study has clearly demonstrated *long-term safety or long-term efficacy*, in terms of functional improvement.

No prospective study has clearly demonstrated *long-term analgesia*.

*Long-term benefits* for chronic pain have not been established.

(2009 American Pain Society Guidelines)
“Reliable evidence on methods to accurately assess the potential benefits of chronic opioid therapy (COT) is limited.”

(2009 American Pain Society Guidelines)
Efficacy of Opioids for Dental Pain After Wisdom Tooth Extraction?

- 2013 quantitative systematic review in the Journal of the American Dental Association
- “325 mg of acetaminophen (APAP) taken with 200 mg of ibuprofen provides better pain relief than oral opioids.”

(National Safety Council WHITE PAPER, 2014)
2013 journal article in *Spine*.

Patients “initially treated with opioids (for lumbar disc herniation) had a higher rate of surgery and a greater chance of being on opioids four years later but no significant change in overall outcome.

(National Safety Council WHITE PAPER, 2014)
Number Needed to Treat (NNT)

NNT to get 50% pain reduction

- Oxycodone 15: 4.6
- Oxycodone 10 + Acetaminophen 650: 2.7
- Naproxen 500: 2.7
- Ibuprofen 200+Acetaminophen 500: 1.6

(National Safety Council WHITE PAPER, 2014)
Prescription Drug Abuse Crisis

"Drug abuse and addiction are often insufficiently covered in medical school curricula..."  
*NIDA, November, 2009*
“A line in the sand that represents the edge of appropriate, professional conduct.”

(Gutheil and Gabbard, 1993)
7TH International Conference on Pain and Chemical Dependency

June 2007
I’m shocked to find that gambling is going on here!
Purdue Pharma Pays $634.5 Million

- US Senate investigation resulted in guilty plea on May 10, 2007
- Misled regulators, doctors and patients about the enormous addiction and abuse potential of OxyContin
Heroin

- Sold over the counter by German drug company Bayer in 1895 to cure morphine addiction
- “a non-addictive morphine substitute and cough suppressant”
- Heroin rapidly metabolizes into morphine.
Lilly

January 2009

$1.4 Billion
September 2009

$2.3 Billion
July 2012

$3 Billion
Johnson & Johnson
FAMILY OF CONSUMER COMPANIES

November 2013
$2.2 Billion
## Annual Profits in Billions

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<tr>
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</thead>
<tbody>
<tr>
<td>Johnson &amp; Johnson (U.S.)</td>
<td>$10,853</td>
<td>$9,672</td>
<td>$13,334</td>
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<td>Pfizer (U.S.)</td>
<td>14,570</td>
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<td>Novartis (Switzerland)</td>
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<td>Merck (U.S.)</td>
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<td>Roche (Switzerland)</td>
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<td>Sanofi-Aventis (France)</td>
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<td>AstraZeneca (UK)</td>
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<td>Eli Lilly (U.S.)</td>
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<td>4,348</td>
<td>5,070</td>
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<tr>
<td>Bristol-Myers Squibb (U.S.)</td>
<td>1,960</td>
<td>3,709</td>
<td>3,102</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>$83,892</strong></td>
<td><strong>$82,779</strong></td>
<td><strong>$72,258</strong></td>
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All foreign company data reported in IFRS except Sanofi-Aventis 2003 data calculated using US-GAAP. *Sanofi-Aventis 2003 data calculated by adding net income of Sanofi and Aventis. Foreign currency converted to U.S. dollars as of Dec. 31 of reported year.*
Medicare Part D Implemented in 2006
<table>
<thead>
<tr>
<th>Company</th>
<th>Net Profits (in billions of US dollars)</th>
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</thead>
<tbody>
<tr>
<td>Johnson &amp; Johnson</td>
<td>$105.8</td>
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<tr>
<td>Pfizer</td>
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<td>Novartis</td>
<td>$83.1</td>
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<td>Merck</td>
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<td>$27.7</td>
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<tr>
<td>Bristol-Myers Squibb</td>
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</tr>
<tr>
<td><strong>Total:</strong></td>
<td><strong>$711.4 BILLION</strong></td>
</tr>
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Why are prescription medications so expensive???

“Drug companies spend 19 times more on marketing than Research & Development.”

*(BMJ 2012; 345:e4348)*
New drugs classified according to whether they are scientifically innovative and whether they respond to unmet medical needs.

Half of the scientifically innovative drugs approved in the U.S. from 1998 to 2007 resulted from research at universities and biotech firms, not drug companies.

May 8, 2012

“allegations of a network of national organizations and researchers, (including physicians, pain societies and regulatory agencies) with financial connections to the makers of narcotic painkillers
May 8, 2012

...helped create a body of dubious information favoring opioids “that can be found in prescribing guidelines, patient literature, position statements, books and doctor education courses.”
July 25, 2012
Signed by 36 physician leaders
Request that FDA should prohibit the marketing of opioids for conditions in which their use has not been proven safe and effective.
Citizens Petition to FDA: July 2012

“To exercise its regulatory responsibility”

1. Strike the term "moderate" from the indication for non-cancer pain.
2. Add a maximum daily dose, equivalent to 100 milligrams of morphine for non-cancer pain.
3. Add a maximum duration of 90-days for continuous (daily) use for non-cancer pain.
September 10, 2013

“Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.”

ER/LA Opioids no longer indicated for moderate pain

Warnings about NAS
October 24, 2013

FDA to recommend to DEA to reschedule hydrocodone from schedule III to schedule II

“This determination comes after a thorough and careful analysis of extensive scientific literature, review of hundreds of public comments on the issue, and several public meetings...”
FDA Response: October 25, 2013

- Approves Zohydro ER
- Pure hydrocodone in capsule form, with no abuse deterrent
- FDA ignores Advisory Committee recommendation against approval
  - December 7, 2012
  - Voted 11-2 against approval
    (FDA News Release, October 2013)
Bob Rappaport, MD director of the FDA's Division of Anesthesia, Analgesia, and Addiction Products:

- "Many patients in the U.S. suffer from untreated or poorly treated chronic pain. Further limiting access to potential treatments is not the answer when new treatments are critically needed."
- "I firmly believe that the benefits of this product outweigh its risks,"

(FDA News Release, October 25, 2013)
Sources of Illicitly Used Prescription Drugs

- 21.2% single doctor
- 67% obtained by friends or relatives
  - 84% of these by a single doctor
- 4.3% drug dealer/stranger
- 0.1% internet

(2013 NSDUH)
Has anything changed?
Current Illicit Drug Use (All Drugs)

(NSDUH, 2013)
Current Illicit Prescription Drug Use

(NSDUH, 2013)

2002: 1.9% (7 Million)
2012: 2.7% (7 Million)
2013: 2.5% (6.5 Million)
2013 NSDUH
Current Illicit Prescription Drug Use: Age 12-17

- 2002: 4.0%
- 2013: 2.2%
- Downtrend... Finally!!!
Rate of Past Year Heroin Use Increasing

- 2003: 314,000 users
- 2012: 669,000 (80% increase in 5 years)
- 2013: 681,000
- Trending upward as prescription drugs become less available
- 75% of heroin users report previous abuse of opioid pain medication
Opioids for chronic, noncancer pain

American Academy of Neurology

“No substantial evidence for maintenance of pain relief over longer periods of time, or significant evidence for improved physical function.” (Franklin, 2014)
“The risks for chronic opioid therapy for some chronic conditions such as headache, fibromyalgia, and chronic low back pain likely outweigh the benefits.”

(Franklin, 2014)
NIH Pathways to Prevention Workshop: The Role of Opioids in the Treatment of Chronic Pain

“the premise that tolerance can be overcome by dose escalation is now seriously questioned.”

(Reubenen et al., 2015)
“Particularly striking to the panel was the realization that evidence is insufficient for *every* clinical decision that a provider needs to make about the use of opioids for chronic pain...”

(Reuben et al., 2015)
FDA approves Vyvance (Schedule II amphetamine) for Binge eating disorder
Effective January 30, 2015
Here we go again...
Thank You!
REFERENCES:


REFERENCES, CONT’D.


- Light DW, Lexchin JR. Pharmaceutical research and development: what do we get for all that money? BMJ. 2012; 345. e4348. Available at: http://www.bmj.com/content/345/bmj.e4348


OxyContin Marketing Plan, 1999. Purdue Pharma, Stamford, CN, 1999

Substance Abuse and Mental Health Services Administration. (2013). Results from the 2013 National Survey on Drug Use and Health: volume 1: summary of national findings. Rockville, MD: Substance Abuse and Mental Health Services Administration. Available at: http://store.samhsa.gov/home


REFERENCES, CONT’D.


- American Society of Addiction Medicine (ASAM): www.asam.org/
RESOURCES

- **American Society of Addiction Medicine (ASAM):**
  [www.asam.org/](http://www.asam.org/)

- **Centers for Disease Control and Prevention:**
  [www.cdc.gov/](http://www.cdc.gov/)

- **Centers for Disease Control, storage and disposal guidelines:**
  [www.cdc.gov/HomeandRecreationalSafety/poisoning/preventiontip.htm](http://www.cdc.gov/HomeandRecreationalSafety/poisoning/preventiontip.htm)

- **Mississippi Professionals Health Program:**
  [www.msphp.com](http://www.msphp.com)

- **National Institute on Drug Abuse (NIDA):**
RESOURCES

- Office of National Drug Control Policy (ONDCP): 

- Physicians for Responsible Opioid Prescribing: 
  [http://www.supportprop.org](http://www.supportprop.org)

- Scott Hambleton, MD; Medical Director, Mississippi Professionals Health Program; 408 West Parkway Place, Ridgeland, MS, 39157. (601)420-0240. 
  [shambleton@msphp.com](mailto:shambleton@msphp.com)

- Substance Abuse & Mental Health Services Administration (SAMHSA) 
  [www.samhsa.gov/](http://www.samhsa.gov/)

- US Drug Enforcement Agency (DEA): 
  [www.usdoj.gov/dea](http://www.usdoj.gov/dea)