Conflict of Interest Statement

• I have no COI with any pharmaceutical or health care technology company
• Chair, Medical Advisory Panel for Pharmacy Benefits Management, Department of Veterans Affairs
• Co-Director VA Center for Medication Safety
• Member, FDA Drug Safety Board
Background: 2016 VA Statistics

• Veterans
  – 8.8 million enrollees
  – 6.3 million patients treated
  – 4.9 million pharmacy users

• 7 million outpatient opioid RXs (30-day Eqv)
• 1.2 Million unique VA patients rec opioid FY 2016
• $99.3 M outpatient opioid drug expenditures
VA and the Opioid Crisis

- VA is 100% committed and supportive of efforts to improve the safe and effective use of opioids
- VA has demonstrated our ongoing commitment to improving the safe use of opioids with a multi-faceted approach
Veterans Dispensed An Opioids And A Benzodiazepine Over Time

<table>
<thead>
<tr>
<th>Quarter</th>
<th>FY12 Q1</th>
<th>FY13 Q2</th>
<th>FY13 Q3</th>
<th>FY13 Q4</th>
<th>FY14 Q1</th>
<th>FY14 Q2</th>
<th>FY14 Q3</th>
<th>FY14 Q4</th>
<th>FY15 Q1</th>
<th>FY15 Q2</th>
<th>FY15 Q3</th>
<th>FY15 Q4</th>
<th>FY16 Q1</th>
<th>FY16 Q2</th>
<th>FY16 Q3</th>
<th>FY16 Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Veterans</td>
<td>122,633</td>
<td>120,955</td>
<td>120,076</td>
<td>118,197</td>
<td>116,739</td>
<td>111,969</td>
<td>108,158</td>
<td>106,378</td>
<td>102,100</td>
<td>93,352</td>
<td>88,762</td>
<td>84,470</td>
<td>80,492</td>
<td>74,887</td>
<td>70,717</td>
<td>64,899</td>
</tr>
<tr>
<td>Difference</td>
<td>-9,323</td>
<td>-2,779</td>
<td>-2,988</td>
<td>-2,988</td>
<td>-1,628</td>
<td>-3,047</td>
<td>-6,080</td>
<td>-4,702</td>
<td>-3,200</td>
<td>-8,881</td>
<td>-4,292</td>
<td>-3,922</td>
<td>-1,508</td>
<td>1,000</td>
<td>5,983</td>
<td>5,002</td>
</tr>
</tbody>
</table>

62,810 fewer Veterans
Veterans On Opioid Therapy Long-Term Over Time

438,329 Veterans in Q4 FY12

145,426 fewer Veterans

292,903 Veterans in Q4 FY16
Veterans Dispensed Greater Than Or Equal to 100 MEDD

<table>
<thead>
<tr>
<th>Quarter</th>
<th>FY12</th>
<th>FY13 Q1</th>
<th>FY13 Q2</th>
<th>FY13 Q3</th>
<th>FY13 Q4</th>
<th>FY14 Q1</th>
<th>FY14 Q2</th>
<th>FY14 Q3</th>
<th>FY14 Q4</th>
<th>FY15 Q1</th>
<th>FY15 Q2</th>
<th>FY15 Q3</th>
<th>FY15 Q4</th>
<th>FY16 Q1</th>
<th>FY16 Q2</th>
<th>FY16 Q3</th>
<th>FY16 Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vets (#)</td>
<td>59,499</td>
<td>59,112</td>
<td>58,235</td>
<td>57,523</td>
<td>56,831</td>
<td>55,362</td>
<td>53,536</td>
<td>52,368</td>
<td>51,534</td>
<td>49,356</td>
<td>47,221</td>
<td>45,768</td>
<td>44,327</td>
<td>42,635</td>
<td>40,616</td>
<td>37,984</td>
<td>35,645</td>
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</tbody>
</table>
Thoughts about Abuse-Deterrent Opioid Formulations

• VA Pharmacy supports the development of abuse-deterrent opioid formulations for opioid products including generic formulations

• VA probably leads the nation in our integrated approach to addressing the opioid crisis
Thoughts about Abuse-Deterrent Opioid Formulations

• The great majority of Veterans receiving opioids are at no risk for diversion, or misuse by crushing, snorting, smoking, or IV use or prescription opioids

• Converting *all* opioids to abuse-deterrent formulations would be quite costly to VA
  – VA is not opposed to spending $$ for clinically effective interventions. $1.2 B FY 2016 on Hep C treatments alone
Abuse-Deterrent Opioid Formulations
Cost Implications to VA

• What if VA converted all our long-acting Morphine to Xtampza?

<table>
<thead>
<tr>
<th></th>
<th>FY 2016 $$$</th>
<th>Xtampza Conversion $</th>
<th>Difference</th>
<th>Increase in Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine SR</td>
<td>$5,062,838</td>
<td>$340,748,059</td>
<td>$335,685,221</td>
<td>67.3 x Increase</td>
</tr>
</tbody>
</table>
Abuse-Deterrent Opioid Formulations
Cost Implications to VA

- Generic Oxycodone SR in VA is abuse-deterrent. What is the difference in cost for generic Oxy to Xtampza?

<table>
<thead>
<tr>
<th></th>
<th>FY 2016 $$</th>
<th>Xtampza Conversion $$</th>
<th>Difference</th>
<th>Increase in Cost (e.g. difference in generic to brand)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone SR</td>
<td>$18,152,289</td>
<td>$35,986,769</td>
<td>$17,834,380</td>
<td>2.0 x Increase</td>
</tr>
</tbody>
</table>
Abuse-Deterrent Opioid Formulations
Potential Budget Impact to VA

• Analysis of oxycodone SR and morphine SR represent ends of spectrum. Most opioids in VA are with inexpensive products.

• Potential budget impact:

<table>
<thead>
<tr>
<th>FY 2016 Opioid Expenditures</th>
<th>Conversion of all VA Opioids to Deterrent Product (16.2 x increase)</th>
<th>Increase in Budget to cover the Expense Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>$99.3M</td>
<td>$1.61B</td>
<td>$1.51B</td>
</tr>
</tbody>
</table>
# Abuse-Deterrent Opioid Formulations: Cost Implications

Non-VA Patients on Opioids

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Embeda 30/1.2mg BID (MSO4/Naltrexone)</td>
<td>$543.55 (# 60) Kroger</td>
<td>30 mg BID</td>
<td>$42.95 (# 60) Walmart</td>
</tr>
<tr>
<td>Zohydro ER 30 mg BID (Hydrocodone)</td>
<td>$499.99 (# 60) Kroger</td>
<td>30 mg BID</td>
<td>$42.95 (# 60) Walmart</td>
</tr>
<tr>
<td>Hysingla ER 60 mg QD (Hydrocodone)</td>
<td>$595.23 (# 30) Kroger</td>
<td>30 mg BID</td>
<td>$42.95 (# 60) Walmart</td>
</tr>
<tr>
<td>Xtampza ER 18mg BID (Oxycodone)</td>
<td>$385.12 (# 60) Kroger</td>
<td>30 mg BID</td>
<td>$42.95 (# 60) Walmart</td>
</tr>
</tbody>
</table>
Likely Outcomes for Mandating Universal Abuse-Deterrent Opioid Formulations

• Dramatic increase in costs for opioid for patients, and health-care systems (¿ 10-fold cost increase?)
  – The overwhelming majority of which are not at risk for injection/ snorting/ illicit delivery
• Decrease in overdose by prescription opioids (although unintended overdose will continue with intended oral intake)
• Concomitant increase in heroin overdose
• “Arms Race” to overcome abuse-deterrent opioids illicitly
Mandating Universal Abuse-Deterrent Opioid Formulations- Questions

• Would the excess $$ to pay for abuse-deterrent products (for most patients where it is not necessary) be better spent for drug treatment centers? For VA, 5-10x increase would mean estimated $300-$900M/year; at 16.2 x, $1.51B

• Or, use excess $$ to implement the recommendations of the CDC for prescribing of opioids?

• Or, use excess $$ to provide universal coverage of naloxone rescue kits, and education?
Abuse-Deterrent Opioid Formulations
Conclusions

• VA Pharmacy favors widespread availability for both product formulations (e.g. abuse-deterrent products, and current products)
• Physicians should be able to prescribe either product formulation (current products, or abuse-deterrent products), based on clinical assessment of risk for abuse/diversion
• Mandatory use of abuse-deterrent formulations will have staggering costs
Thank You

- (Any questions for clarification?)