

Abuse -Deterrent Opioid Formulations

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October, 2016

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

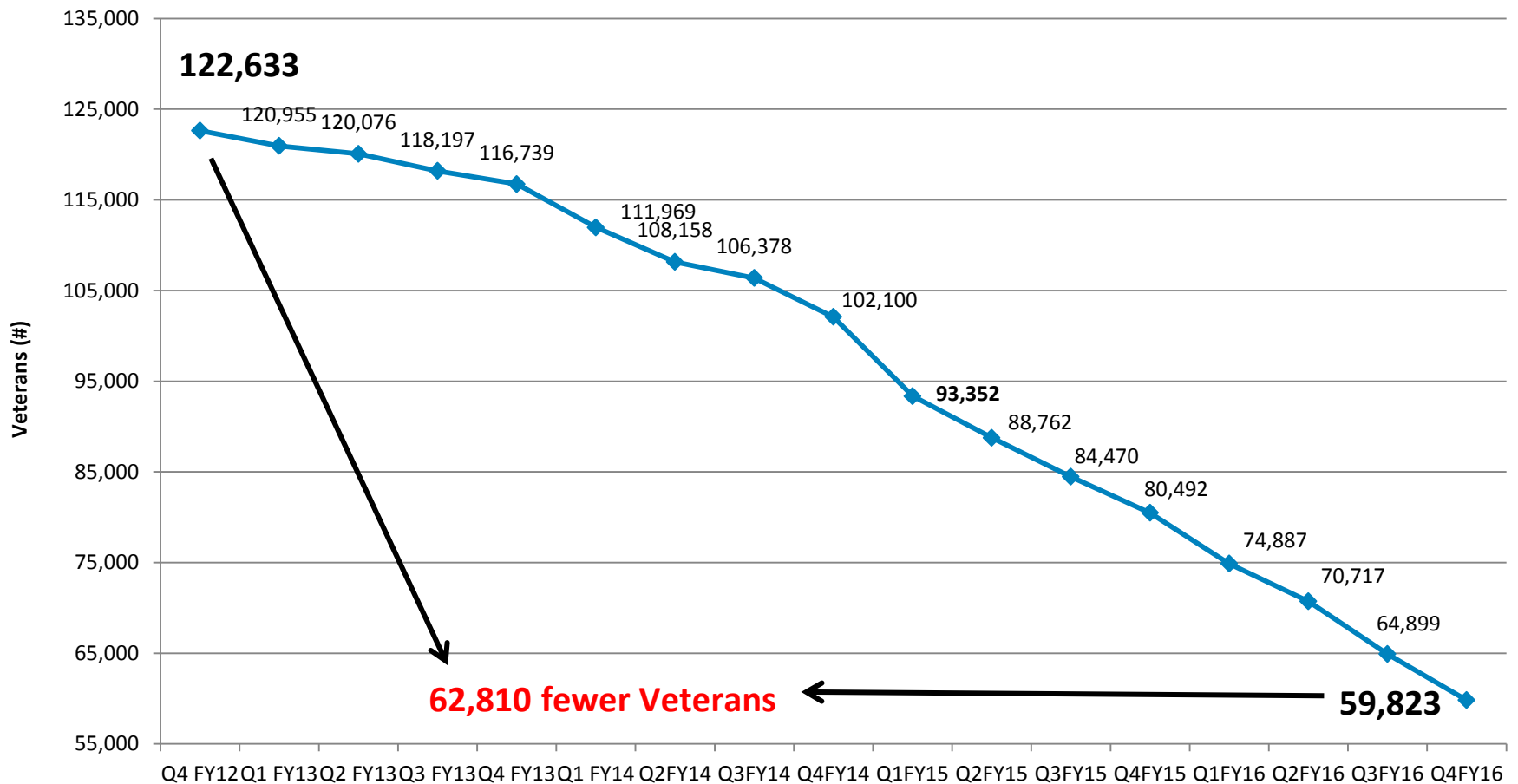
Background: 2016 VA Statistics

- 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

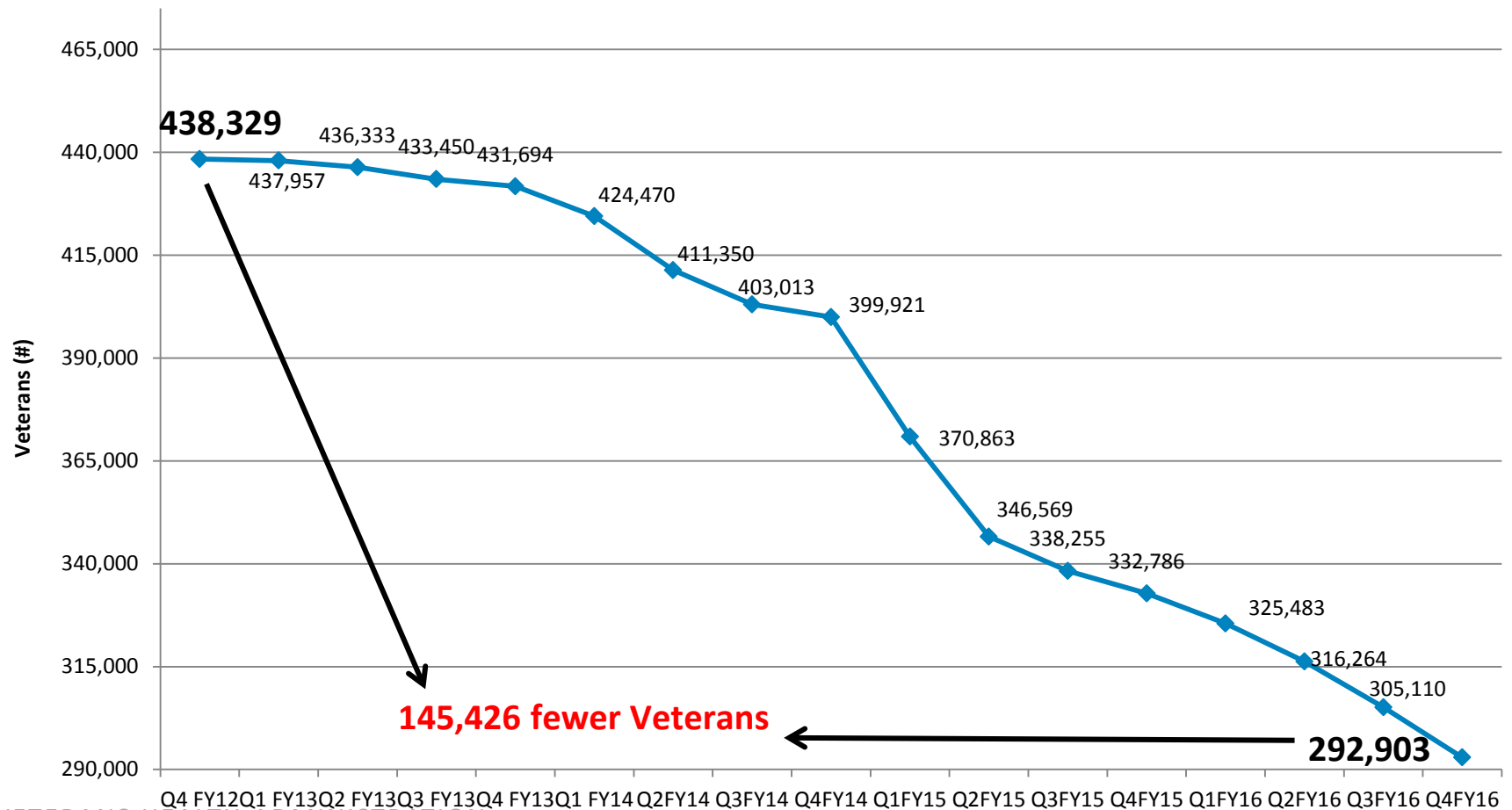
VA and the Opioid Crisis

- **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

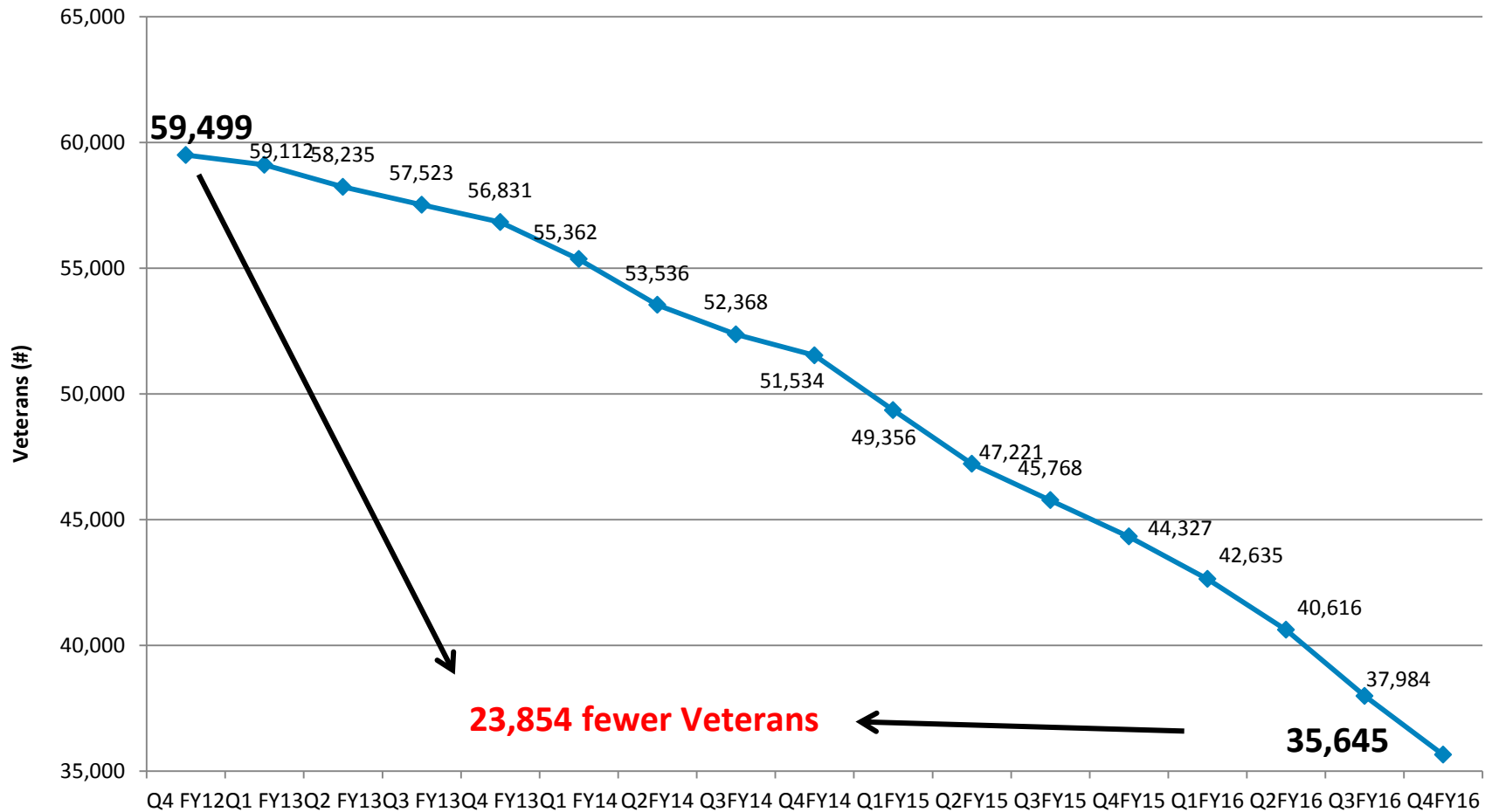
Veterans Dispensed An Opioids And A Benzodiazepine Over Time



Veterans On Opioid Therapy Long-Term Over Time



Veterans Dispensed Greater Than Or Equal to 100 MEDD



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?

	FY 2016 \$\$	Xtampza Conversion \$	Difference	Increase in Cost
Morphine SR	\$5,062,838	\$340,748,059	\$335,685,221	67.3 x Increase

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Cost Implications to VA

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

	FY 2016 \$\$	Xtampza Conversion \$\$	Difference	Increase in Cost (e.g. difference in generic to brand)
Oxycodone SR	\$18,152,289	\$35,986,769	\$17,834,380	2.0 x Increase

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:

FY 2016 Opioid Expenditures	Conversion of all VA Opioids to Deterrent Product (16.2 x increase)	Increase in Budget to cover the Expense Required
\$99.3M	\$1.61B	\$1.51B

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Cost Implications: Non-VA Patients on Opioids

Drug/ Dose	GoodRx Cost Best Price 10/25/2016	Equivalent Morphine SR	GoodRx Cost Best Price 10/25/2016
Embeda 30/1.2mg BID (MSO4/Naltrexone)	\$543.55 (# 60) Kroger	30 mg BID	\$42.95 (# 60) Walmart
Zohydro ER 30 mg BID (Hydrocodone)	\$499.99 (# 60) Kroger	30 mg BID	\$42.95 (# 60) Walmart
Hysingla ER 60 mg QD (Hydrocodone)	\$595.23 (# 30) Kroger	30 mg BID	\$42.95 (# 60) Walmart
Xtampza ER 18mg BID (Oxycodone)	\$ 385.12 (# 60) Kroger	30 mg BID	\$42.95 (# 60) Walmart

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?

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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?)