

DEPARTMENT OF HEALTH AND HUMAN SERVICES. Food and Drug Administration.

[Docket No. FDA–2021–N–0275] Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions; Public Workshop. June 7, 2021

Presentation by Larry Aubry

- Background: MMEs are increasingly being used to indicate abuse and overdose potential and to set thresholds for prescribing and dispensing of opioid analgesics. CDC guideline cited a dose threshold of 90MME per day based on correlation to abuse and overdose deaths.
- Presentation Purpose: Present findings of the nature and strength of the relationship between Opioid Rx Daily Dosage  $\geq$  90 MME per day with abuse and overdose deaths (opioid Rx, any opioid and total).
- Method: Correlation & Linear Regression of Opioid Rx Daily Dosage  $\geq$  90 MME per day to:
  - Abuse (Opiate/Opioid Treatment Admissions)
  - Opioid Rx Overdose Deaths
  - Any Opioid Overdose Deaths
  - Total Overdose Deaths

# Opiate/opioid Treatment Admissions (Abuse) as a Function of Prescribed Opioid Daily Dosage $\geq 90$ MME per 100 persons 2006-2018

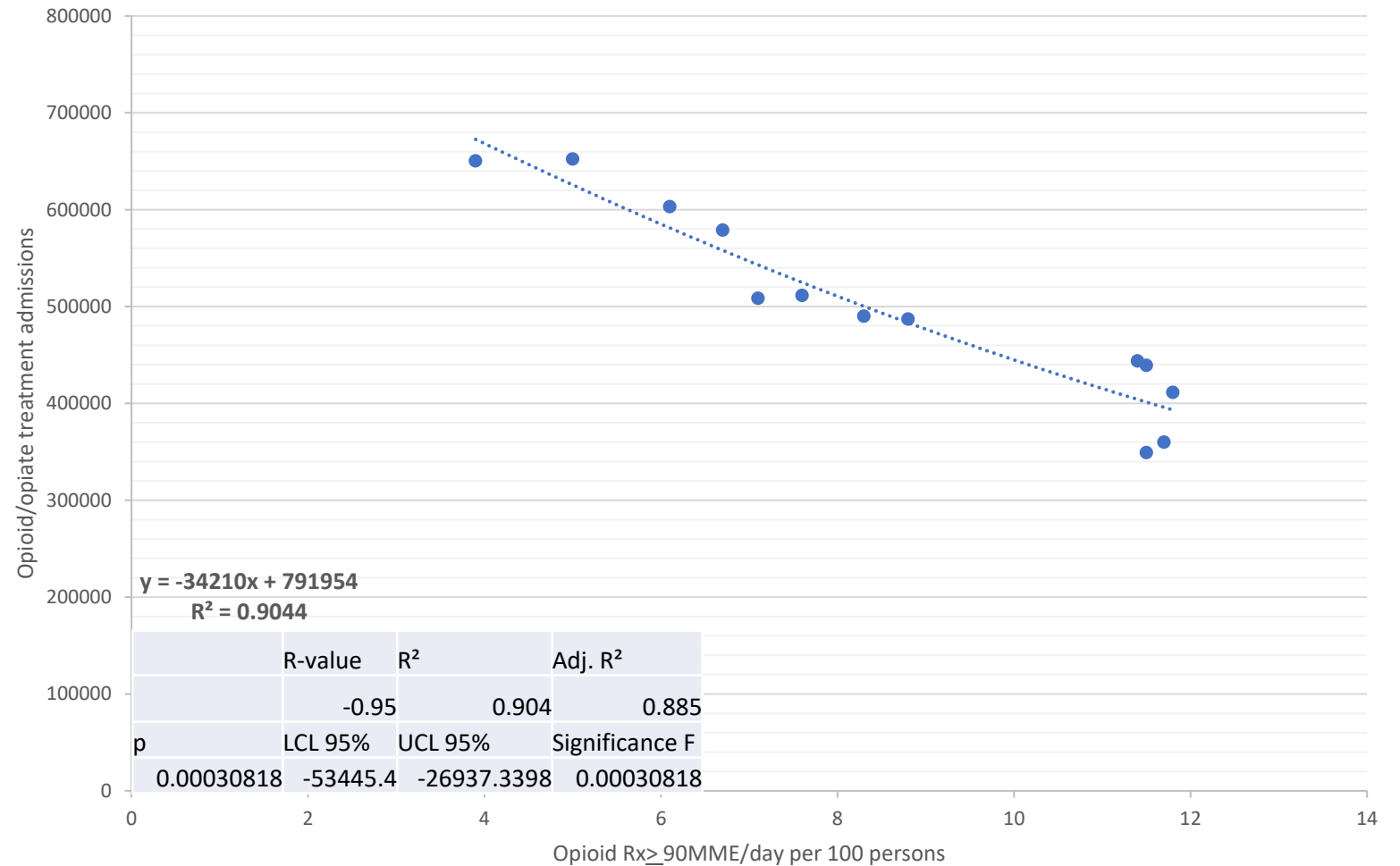
Opioid Rx  $\geq 90$ MME/day -66% to 3.9 per 100 persons

Opiate/Opioid admissions climbed by 86% to +650,000.

Inverse/negative correlation

Opiate/opioid treatment admissions cited as a measure of abuse by CDC.

Opiate/opioid Treatment admissions as a function of Opioid Rx  $\geq 90$ MME/Day. 2006-2018



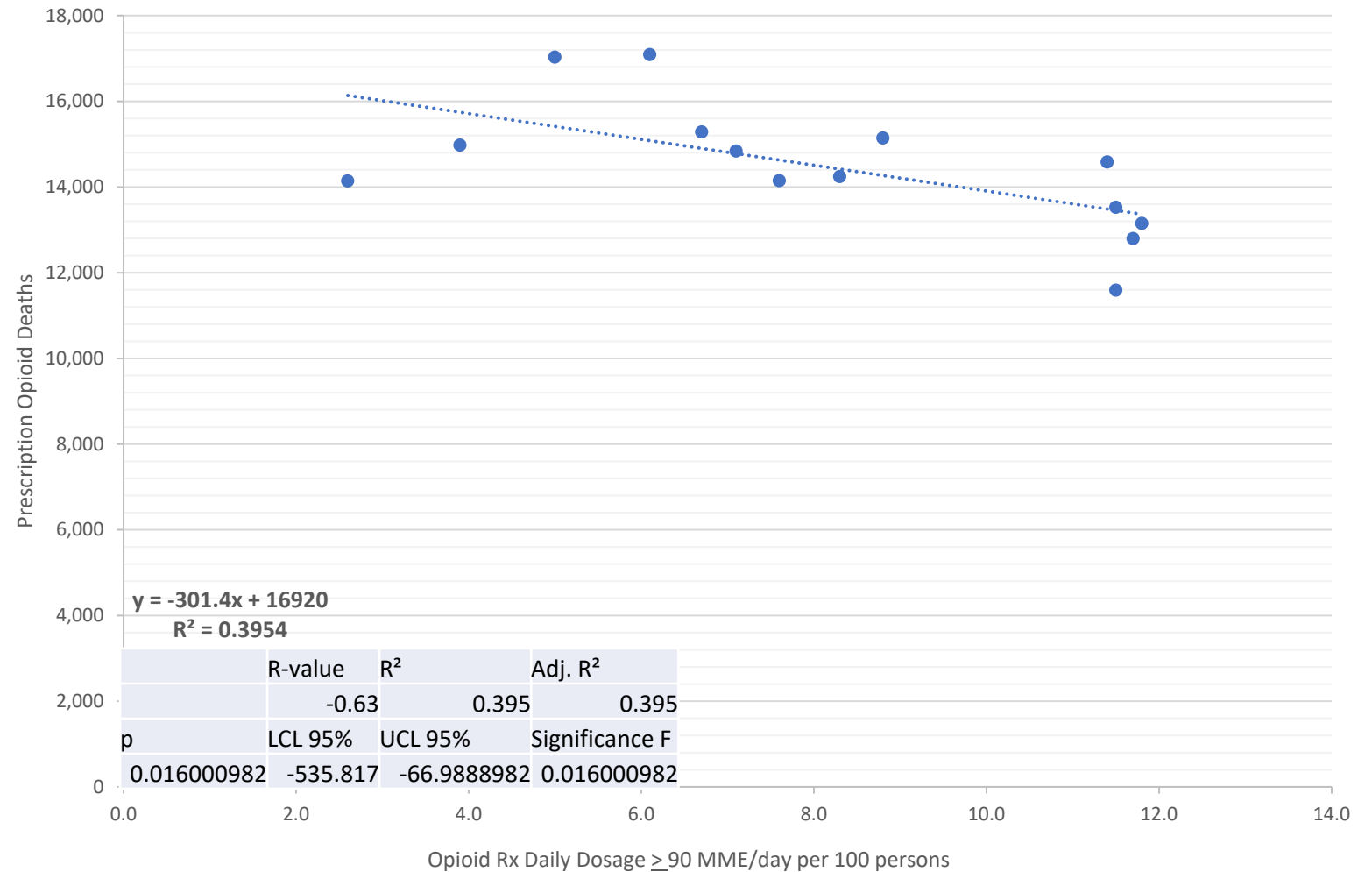
# Prescription Opioid Overdose Deaths as a Function of Prescribed Opioid Daily Dosage $\geq 90$ MME per 100 persons 2006-2019

Opioid Rx  $\geq 90$  MME/day -77.4% to 2.6 per 100 persons

Prescription Opioid Deaths +22% to 14,139.

Inverse/negative correlation

Prescription Opioid deaths as a Function of Opioid Rx Daily Dosage  $\geq 90$  MME/Day. 2006-2019



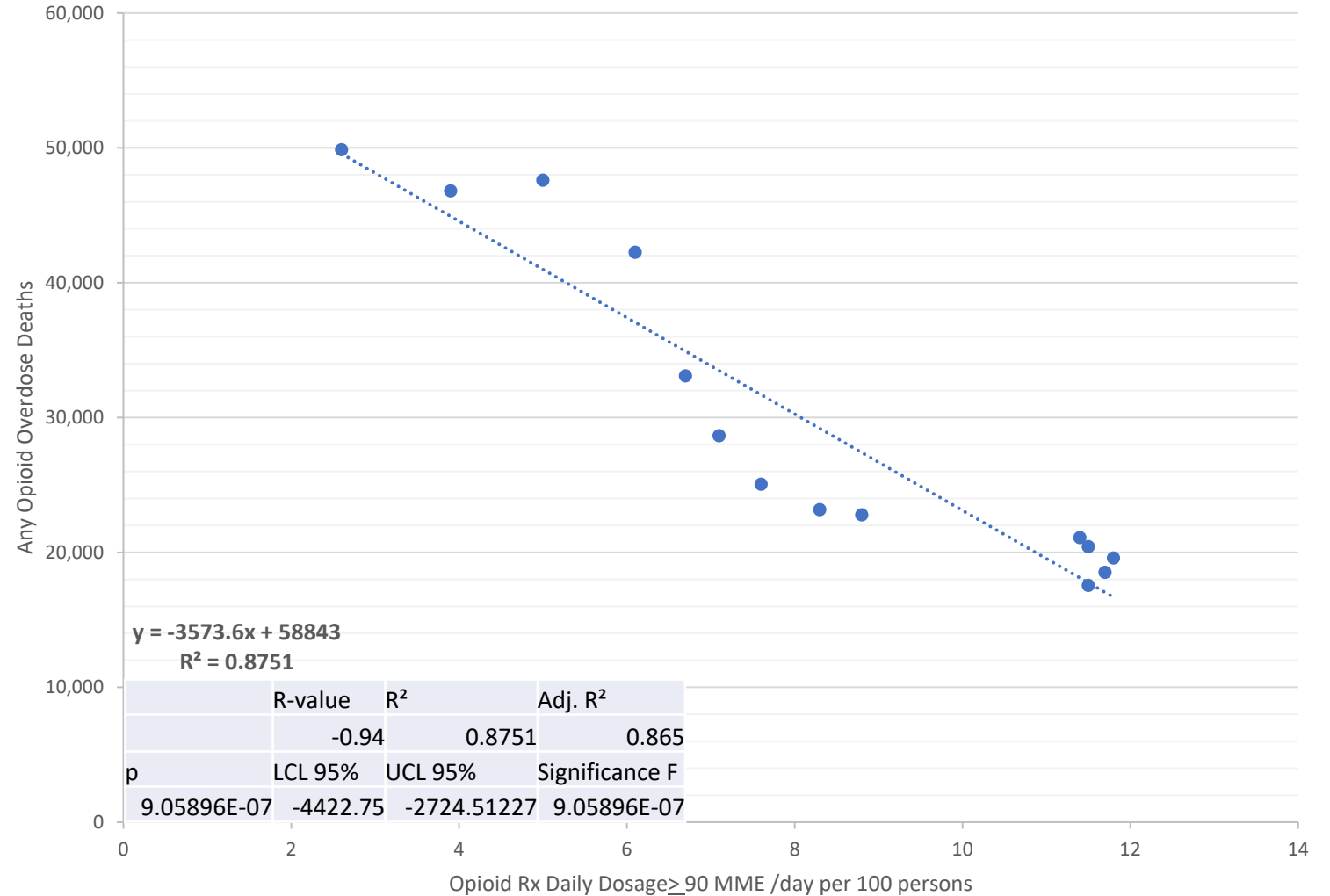
# Any Opioid Overdose Deaths as a Function of Prescribed Opioid Daily Dosage $\geq$ 90 MME per 100 persons 2006-2019

Opioid Rx  $\geq$  90MME/day: -77.4% to 2.6 per 100 persons

Any Opioid Overdose Deaths: +184.2% to 49,860.

Inverse/negative correlation

Any Opioid Overdose Deaths as a Function of Opioid Rx daily dosage  $\geq$  90MME/Day. 2006-2019



# Total Overdose Deaths as a Function of Prescribed Opioid Daily Dosage $\geq 90$ MME per 100 persons 2006-2019

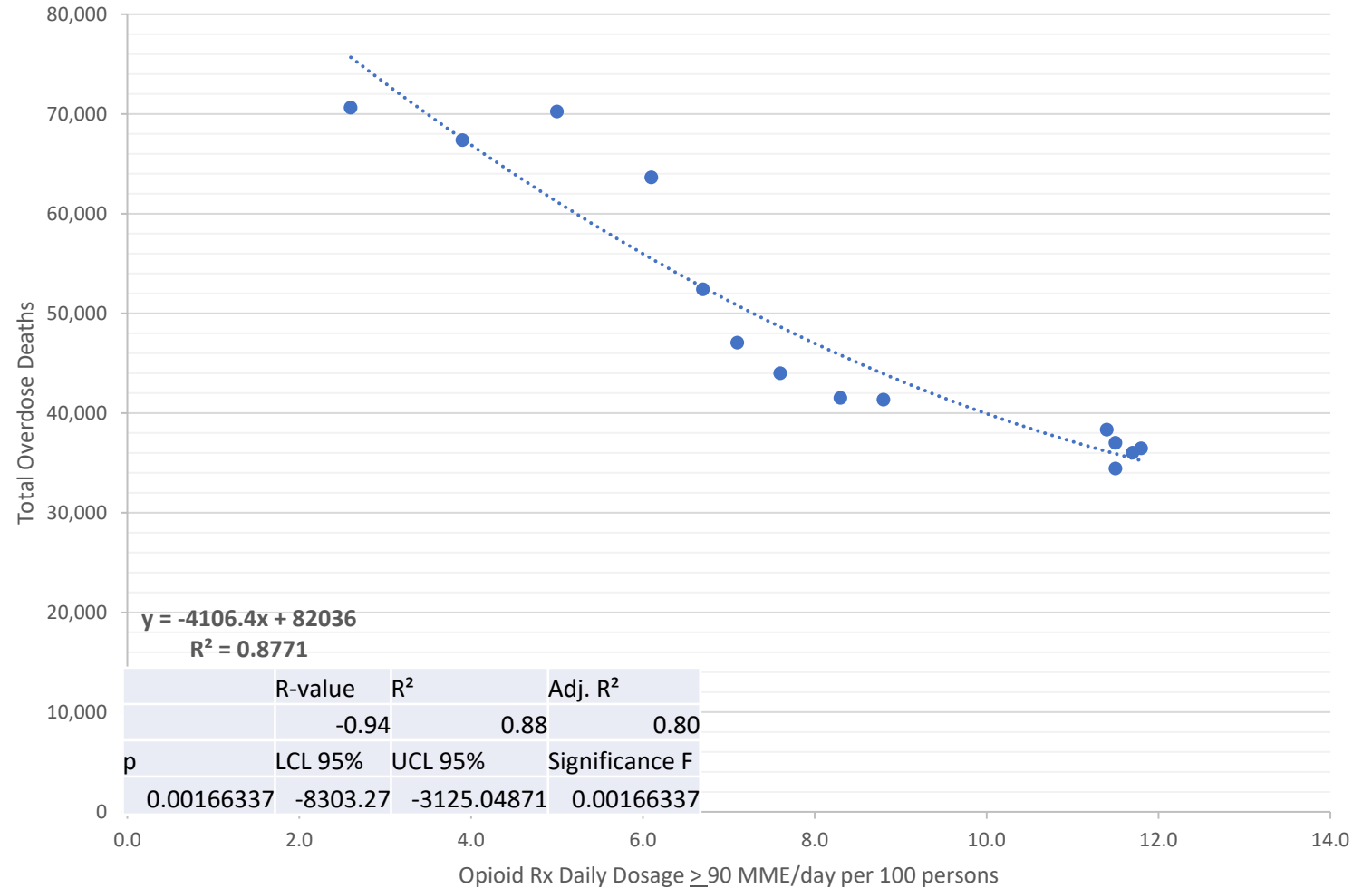
Opioid Rx  $\geq 90$  MME/day: -77.4% to 2.6 per 100 persons

Total Overdose Deaths: +105.2% to 70,630.

October 2019 to 91,862 deaths in October 2020

Inverse/negative correlation

Total Overdose Deaths as a Function of Opioid Rx Daily Dosage  $\geq 90$  MME/Day. 2006-2019



# Results and Conclusion

- Even simple linear regression is sufficient to illustrate the inverse patterns in the data.
- The current use of MMEs to indicate abuse and overdose potential and to set thresholds for prescribing and dispensing of opioid analgesics is unfounded based on current data and, as such, unfairly deprives patients of a legitimate treatment option (i.e., prescription opioid pain relievers).

# Appendix

- **Description of Data:**
- [Overdose Deaths \(National\)](#): The overdose data was sourced from [Overdose Death Rates | National Institute on Drug Abuse \(NIDA\)](#), National Drug Overdose (OD) Deaths, 1999-2019, Source: CDC WONDER, Multiple Cause of Death (Detailed Mortality)
- **Opioid Prescribing (National)**: The opioid analgesic medication prescribing data was sourced from IQVIA® Transactional Data Warehouse as shown in Annual Surveillance Report of Drug-Related Risks and Outcomes United States CDC National Center for Injury Prevention and Control and IQVIA™ Xponent 2006-2018. Data extracted in 2019. <https://www.cdc.gov/drugoverdose/pdf/pubs/2019-cdc-drug-surveillance-report.pdf>.
- [Opiate/opioid treatment admissions \(National\)](#): 2006-2008 data sourced from Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set (TEDS): 2000-2010. National Admissions to Substance Abuse Treatment Services. DASIS Series S-61, HHS Publication No. (SMA) 12-4701. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012. [Treatment Episode Data Set \(TEDS\) 2000 - 2010 \(samhsa.gov\)](#)
- **Opiate/opioid treatment admissions (National)**: 2008-2018 data sourced from Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. *Treatment Episode Data Set (TEDS): 2018. Admissions to and Discharges From Publicly Funded Substance Use Treatment*. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020. [2018 TEDS Annual Report \(samhsa.gov\)](#)