



# The importance of Pharmacovigilance

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# Outline

Definition of PV

Why is PV important

Examples of when PV would have been helpful



# Definition of PV

”Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.”<sup>(1)</sup>



# Why is PV important

- To minimize harm (not eliminate)
- To understand harm (and then prevent)
- To maintain confidence (of all players)



# Are vaccines not always safe?



# Yellow fever vaccination of US military troops

2.5 Million vaccinated

-> 26 thousand cases of hepatitis

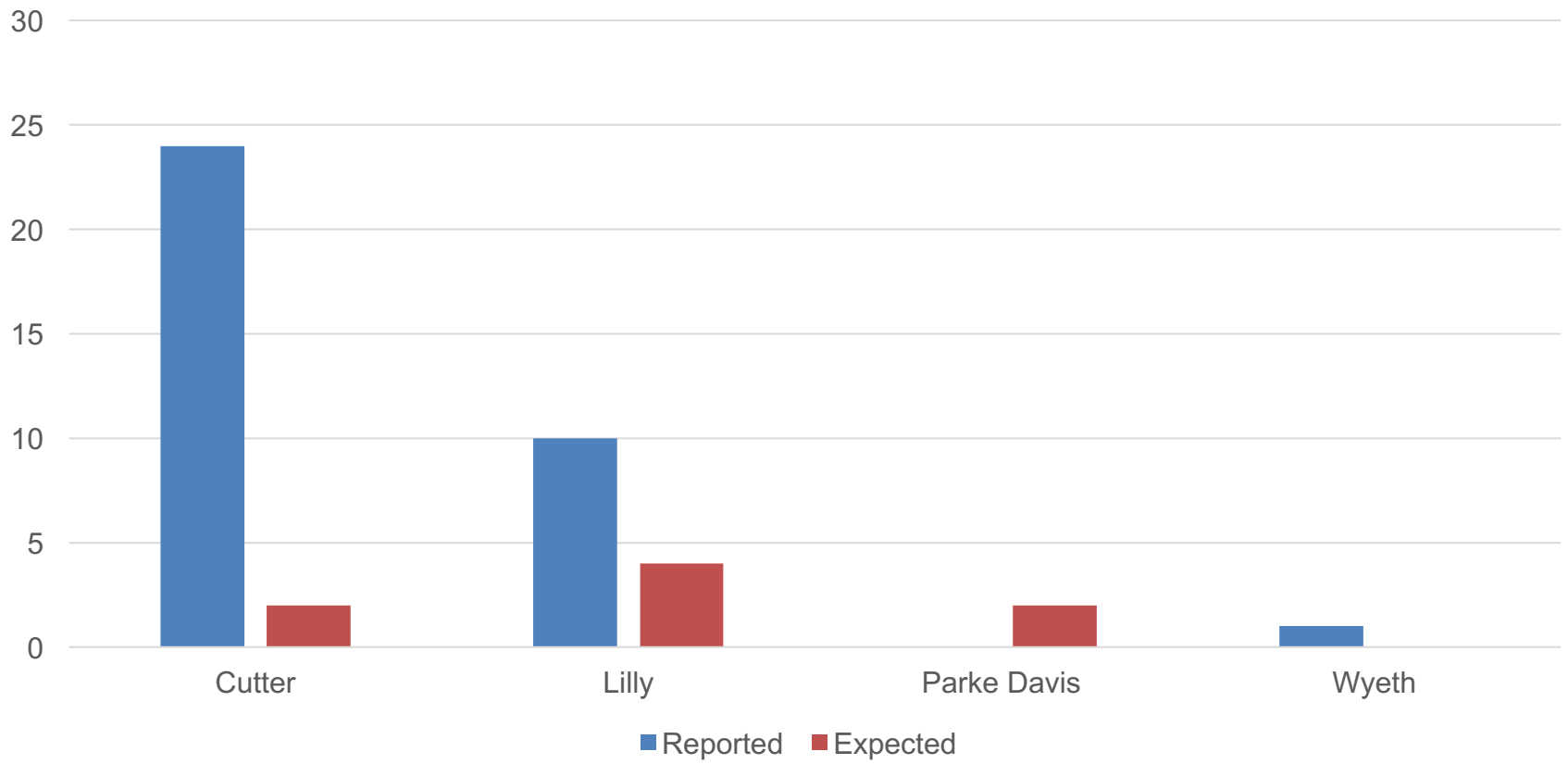
-> 62 deaths <sup>(2)</sup>

Shown to be HepB related



# Cutter incident (3)

Poliomyelitis cases in school clinics, April-May 1955





# References

- (1): The importance of pharmacovigilance. WHO 2002
- (2): Lancet 1942; 73: 1110
- (3): Nathanson, N.; Langmuir A. D. The Cutter Incident. Poliomyelitis following Formaldehyde-Inactivated Poliovirus Vaccination in the United States during the Spring of 1955. II. Relationship of Poliomyelitis to Cutter Vaccine. American Journal of Hygiene 1963 Vol.78 No.1 pp.29-60