About the Authors – Team Enigma

- We are a group of independent researchers with experience in:
  - Pharmaceutical R&D and manufacturing
  - Clinical trials
  - Pharma industry regulations
  - Data analyses and modeling
  - Statistics
- Located worldwide, conducting independent analyses of the same data
- Financially and politically independent
- We are not afraid to think for ourselves and speak up

Why does this matter?

- All drugs are poisons, it is a matter of dosing, application and risk/benefit:
  - Warfarin (blood thinner) – its other application is rat poison
  - Chemotherapy agents for cancer are highly toxic

- Mass produced food, beverages, vitamins, supplements, homeopathic products, etc:
  - If you drank a can of beer from your favorite brand and the result was 300% different from previous time, would you drink that beer again?

That's why product consistency matters!

FDA Good Manufacturing Practices (GMP): 21CFR210.1

- High quality, consistency and purity standards for drugs/vaccines:
    - Expectation that every new lot/batch is "almost the same" as all previous lots
    - Expectation that vaccines from different manufacturers for a disease indication are "the same" or interchangeable product
- Current FDA GMP regulations were developed after several adulterated or poorly tested products poisoned and killed 100s of people (early 1900's to 1960's)
- "The failure to comply ...shall render such drug to be adulterated ...shall be subject to regulatory action".
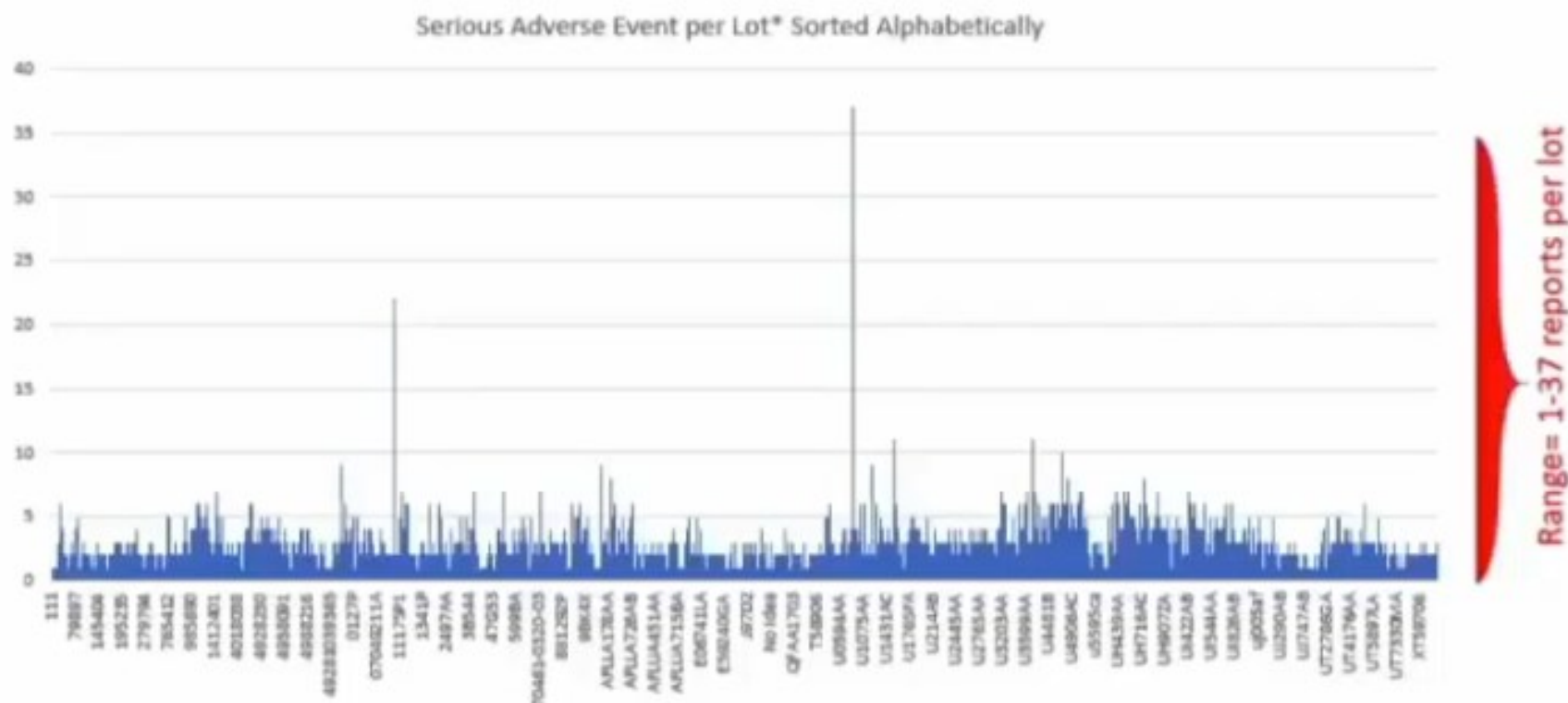
VAERS Data: Covid 19 mRNA Vaccines vs Seasonal Flu Vaccines

Seasonal Flu Vaccines	Covid 19 mRNA Vaccines
9 injectable products	3 injectable products
10+ manufacturers	3 manufacturers (Pfizer, Moderna, Janssen)
10+ years of data	<12 months of data
22,334 manufacturing lots*	24,945 manufacturing lots*
9,429 Serious Adverse Events**	47,239 Serious Adverse Events**
906 deaths**	7,335 deaths**

*Unvalidated – i.e. lots that are present in VAERS database, not complete list, contains typos. This does not matter when comparing two datasets that have the same error-prone data.
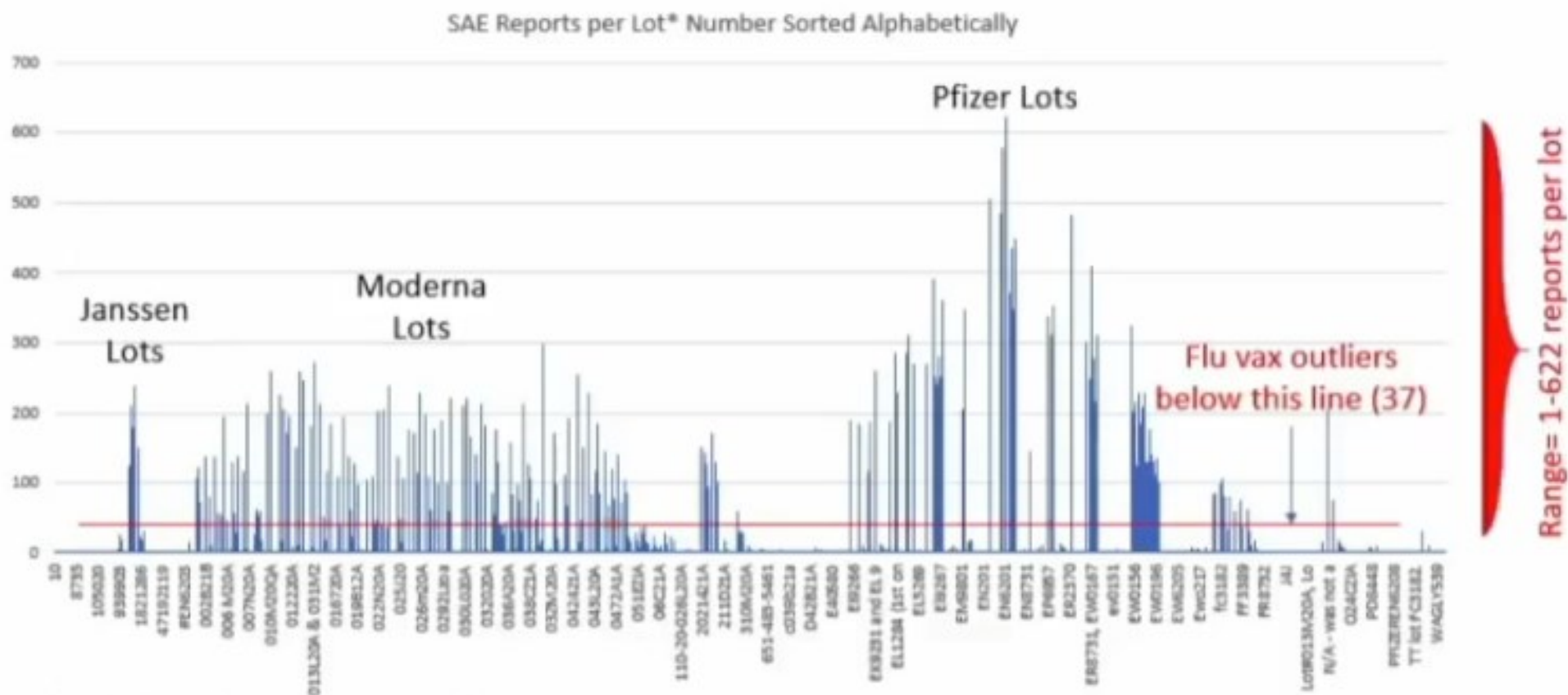**Numbers of events reported to VAERS in each category

Flu Vaccines: Consistent product across many manufacturers, lots, years, only 2 outliers

Serious Adverse Event per Lot* Sorted Alphabetically

Range= 1-37 reports per lot

*Includes lots with non-zero SAE Reports only, N= 5,797 Lot Numbers

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Covid Vaccines: Does this look like the same consistent product by manufacturer and by lot?

SAE Reports per Lot* Number Sorted Alphabetically

Pfizer Lots

Janssen Lots

Moderna Lots

Flu vax outliers below this line (37)

Range= 1-622 reports per lot

*Includes lots with non-zero SAE Reports only, N= 4,122 Lot Numbers

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