Pharmacovigilance and Medication Error Reporting Systems:

Overview of FDA's Pharmacovigilance and Medication Error Reporting Systems

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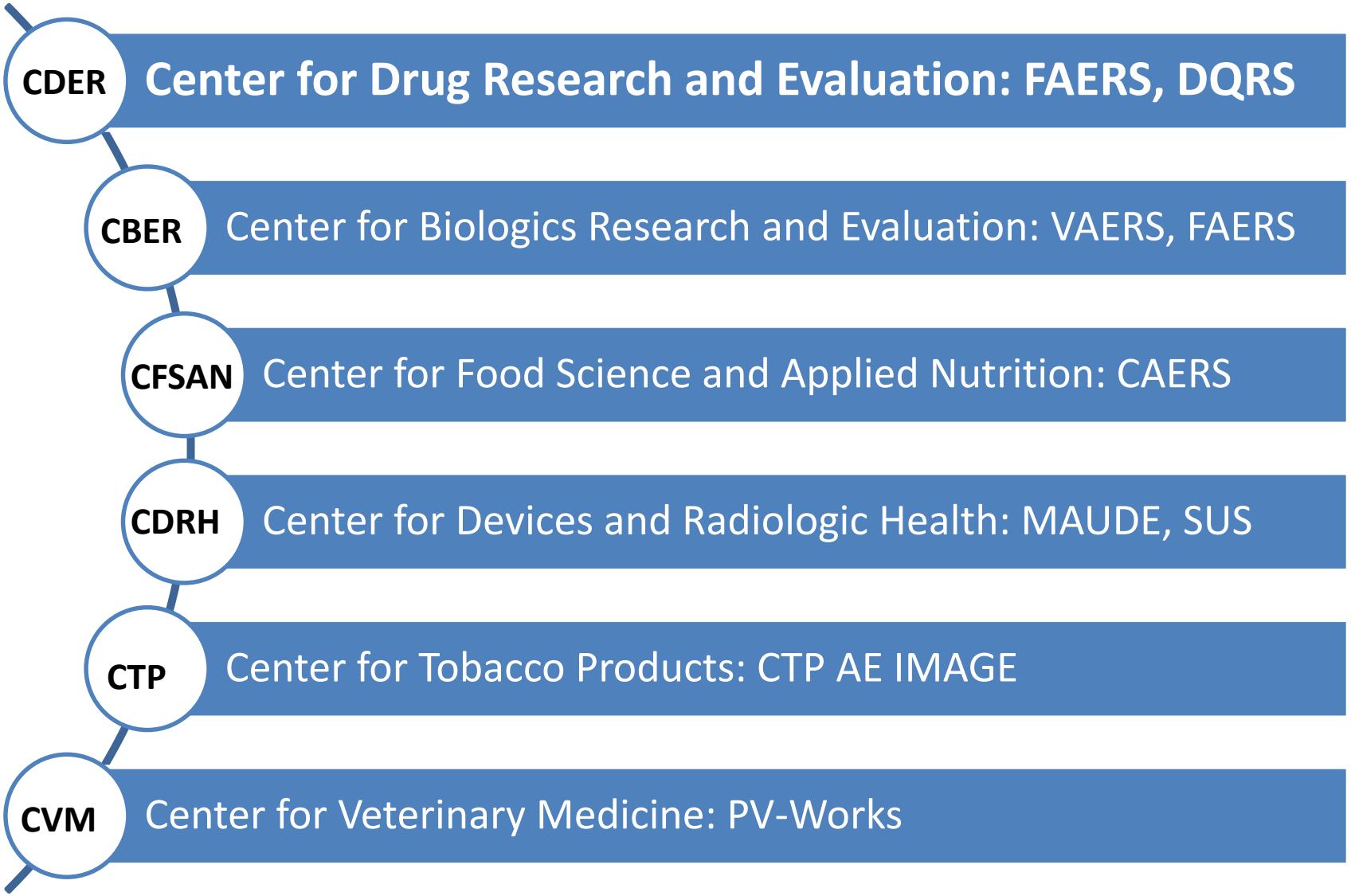
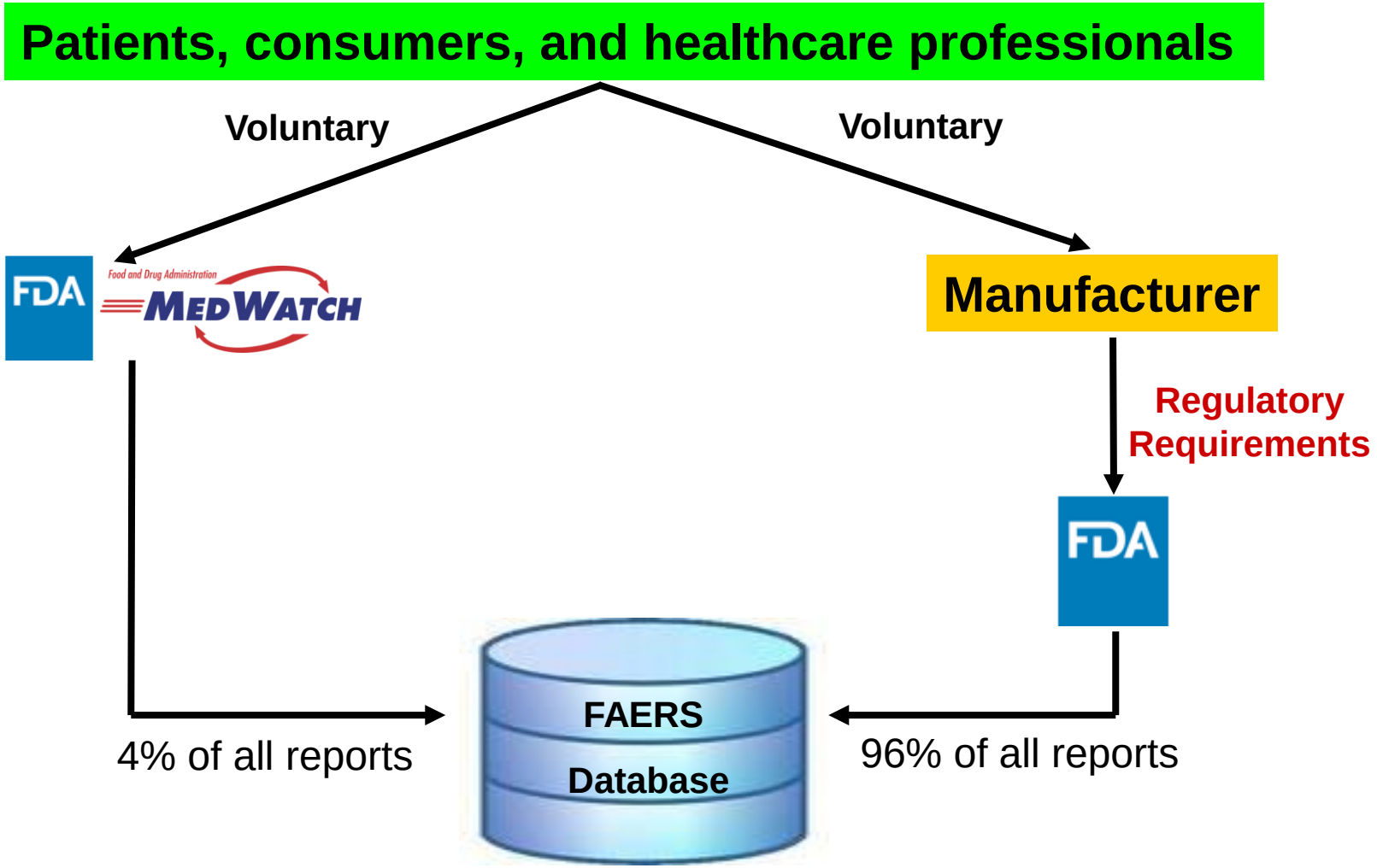
Medication Errors are a Global Public Health Burden

FDA Centers and Reporting Systems



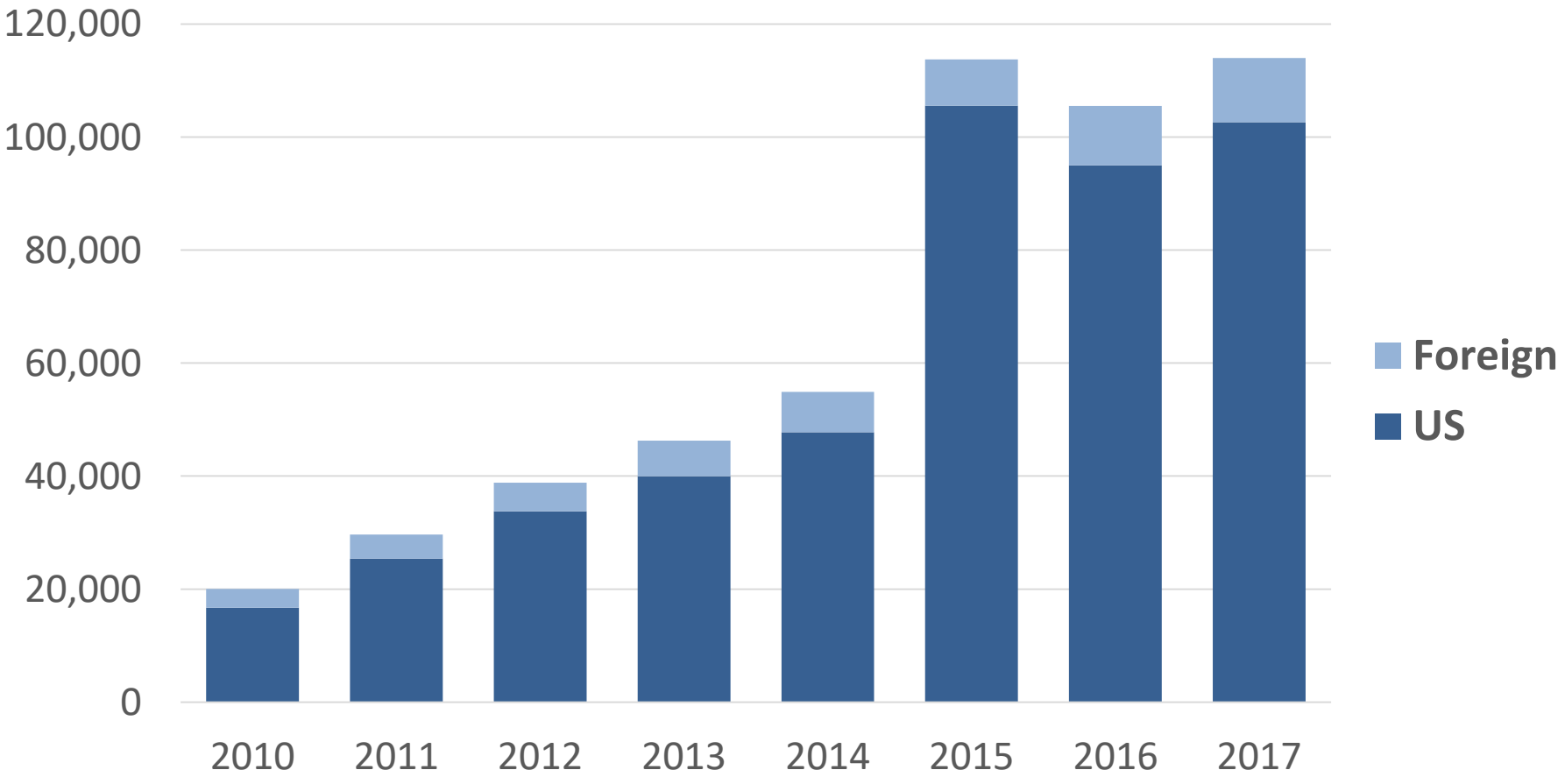
How Postmarketing Reports Get to FDA



Role of the Division of Medication Error Prevention and Analysis (DMEPA)

- Located within CDER (Center for Drug Research and Evaluation)
- Dedicated solely to medication error prevention and analysis for drug products
- Perform premarket reviews and postmarket pharmacovigilance for assigned drug products
- Use FAERS (FDA Adverse Event Reporting System) as primary source for postmarket monitoring of medication errors

Number of Medication Error Reports in FAERS*



*Based on the MedDRA SMQ *Medication errors (narrow)*, V21

Medication Error Signal Detection and Analysis

- Focus on US FAERS reports (non-US products may have different labeling, practice settings, etc.)
- Form partnerships with patient safety organizations, USP, and other drug safety stakeholders
- Host teleconferences and collaborate with other regulatory agencies and FDA Centers
- Review periodic safety reports submitted by industry
- Evaluate and implement tools to use machine learning technology, predictive analytics, and other data sources

Challenges With Medication Error Pharmacovigilance

- ✓ Different medication error terminology, reporting requirements, labeling and product design, clinical practices
- ✓ Incomplete reports/lack of reporting forms tailored to capture medication error information
- ✓ Accurate product identification
  - Nomenclature (e.g., acetaminophen vs paracetamol, biosimilar suffixes)
  - Products with the same proprietary name but different ingredients
- ✓ Inconsistent and ambiguous coding of medication errors
- ✓ Identifying and reviewing labeling from other countries
- ✓ Timely sharing of information

FDA is modernizing the medication error/adverse event reporting system

- FDA Adverse Event Reporting System (FAERS) is the primary source used by FDA for surveillance of medication errors and adverse events associated with drugs and therapeutic biologicals.
- FDA has started the development of FAERS II, which will provide a modernized surveillance system, and allow for enhanced and unified data analytics and a signal management lifecycle solution

FDA is exploring artificial intelligence techniques for medication error analysis

- FDA receives more than 100,000 U.S. reports annually associated with suspected medication errors
- Medication error information in the reports is subject to ambiguous and inconsistent coding
- FDA analysts are often required to manually extract relevant information such as the root cause from the report narrative
- FDA pilot study found that Natural Language Processing could improve the quality of coded medication error information, and extract relevant text from medication error reports

FDA's Sentinel System has been used for medication error analyses

- Sentinel provides real-world evidence from a large population dataset
- Currently used for investigating medication error signals. Two examples include Brilinta-Brintellix name confusion and Methotrexate wrong frequency dosing errors.
- Depending on type of medication error, Sentinel may:
  - Address limitations of medication error underreporting and incomplete reports submitted to FAERS
  - Assess trends for the impact of labeling revisions and other regulatory actions
  - Determine incidence, patient populations at risk, outcomes, stage in the medication use system where an error originated, and contributing factors for the error

Conclusions

- Medication errors are a global public health burden
- There is a need for harmonization, especially in the areas of:
  - Medication error reporting (to capture relevant information)
  - Product identification
  - Medication error terminology and coding
- The timely sharing of information is imperative for medication error prevention and analysis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