FDA U.S. FOOD & DRUG ADMINISTRATION

"FDA Adverse Events Reporting System Public Dashboard"

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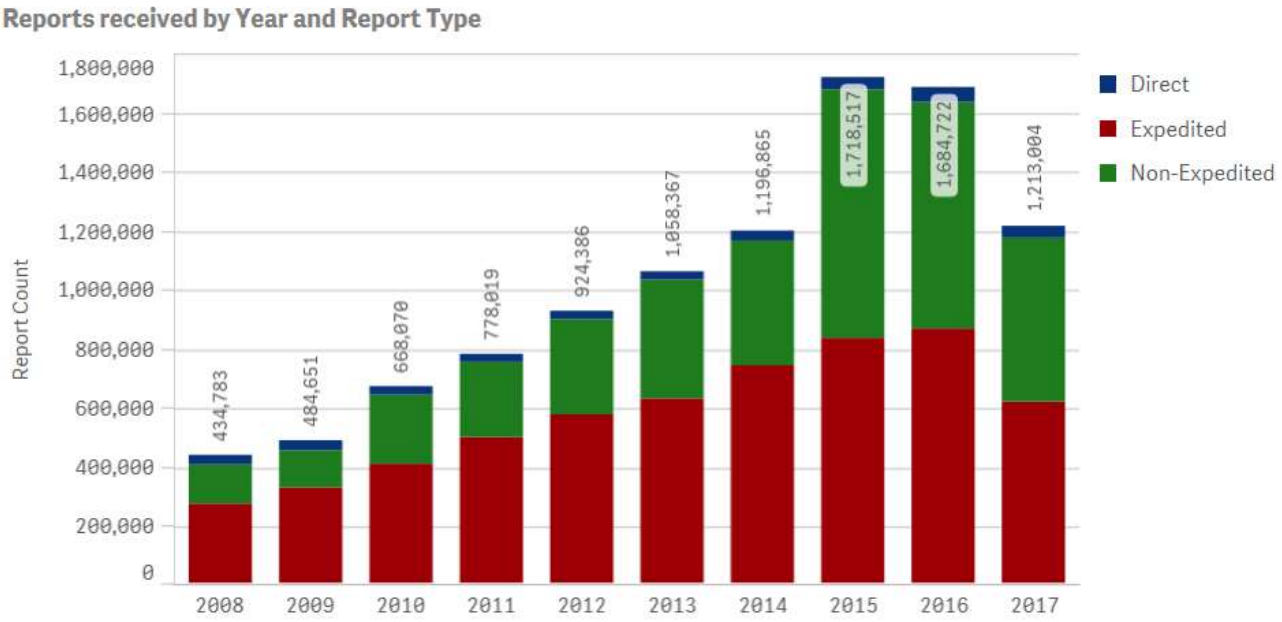
BACKGROUND

The FDA Adverse Event Reporting System (FAERS) is a database that contains spontaneous adverse event reports that are submitted to FDA from the product manufacturer or directly from the consumer, healthcare professional, or other reporter. The database supports the FDA's post marketing safety surveillance program for drug and therapeutic biologic products.

The database consists of more than fourteen (14) million reports since 1969 to August 2017. Each year, FDA receives over one (1) million adverse events and medication error reports associated with the use of drug or biologic products. Existence of a report does not establish causation.



OBJECTIVE

FDA provides information to the public in an accessible and transparent manner. This new FAERS dashboard will give the public a more user friendly platform for accessing FAERS reports and making adverse event data more accessible and transparent to the general public.

FAERS data outlets for public:

JSON File(s)

openFDA

Open FDA

FAERS Quarterly Data Extracts (QDE)

FAERS Public Dashboard

The FAERS Public Dashboard will be an interactive application, which will enable the public to search for information related to adverse events reported to the FDA by the pharmaceutical industry, healthcare providers and consumers.

KEY POINTS TO CONSIDER

- **Data Quality**
  - There are many instances of duplicative reports and some reports do not contain all the necessary information.

- **Existence of a report does not establish causation**
  - There is no certainty that a suspected drug caused the adverse events.
  - Adverse events may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or occurred for other reasons.
  - The information in these reports reflects only the reporter's observations and opinions.

- **Information in reports has not been verified**
  - Submission of a report does not mean that the information included in it has been medically confirmed.

KEY POINTS TO CONSIDER

- **Rates of occurrence cannot be established with reports**
  - The number of adverse events should not be used to determine the likelihood of a side effect occurring.
  - Factors such as the time a product has been marketed and publicity can influence reporting.

- **Patients should talk to their doctor** before stopping or changing how they take their medications

- **Patient Outcomes received in FAERS**
  - A reported serious outcomes does not necessarily mean that the suspect product(s) named in the report was the cause of these outcomes.

FAERS data by themselves are not an indicator that the drug is causing the reported adverse events.

PREVIEW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