

AMDM 2016 Focus Meeting

FDA PACIFIC REGION COMPLIANCE UPDATE

Agenda

- Overview of FDA's Inspections
- Overview of Enforcement Statistics
- Questions



Overview of FDA Inspection & Enforcement Statistics Fiscal Year 2015

- Inspections
- Warning Letters
- Seizures
- Injunctions
- Recalls
- Import Refusals

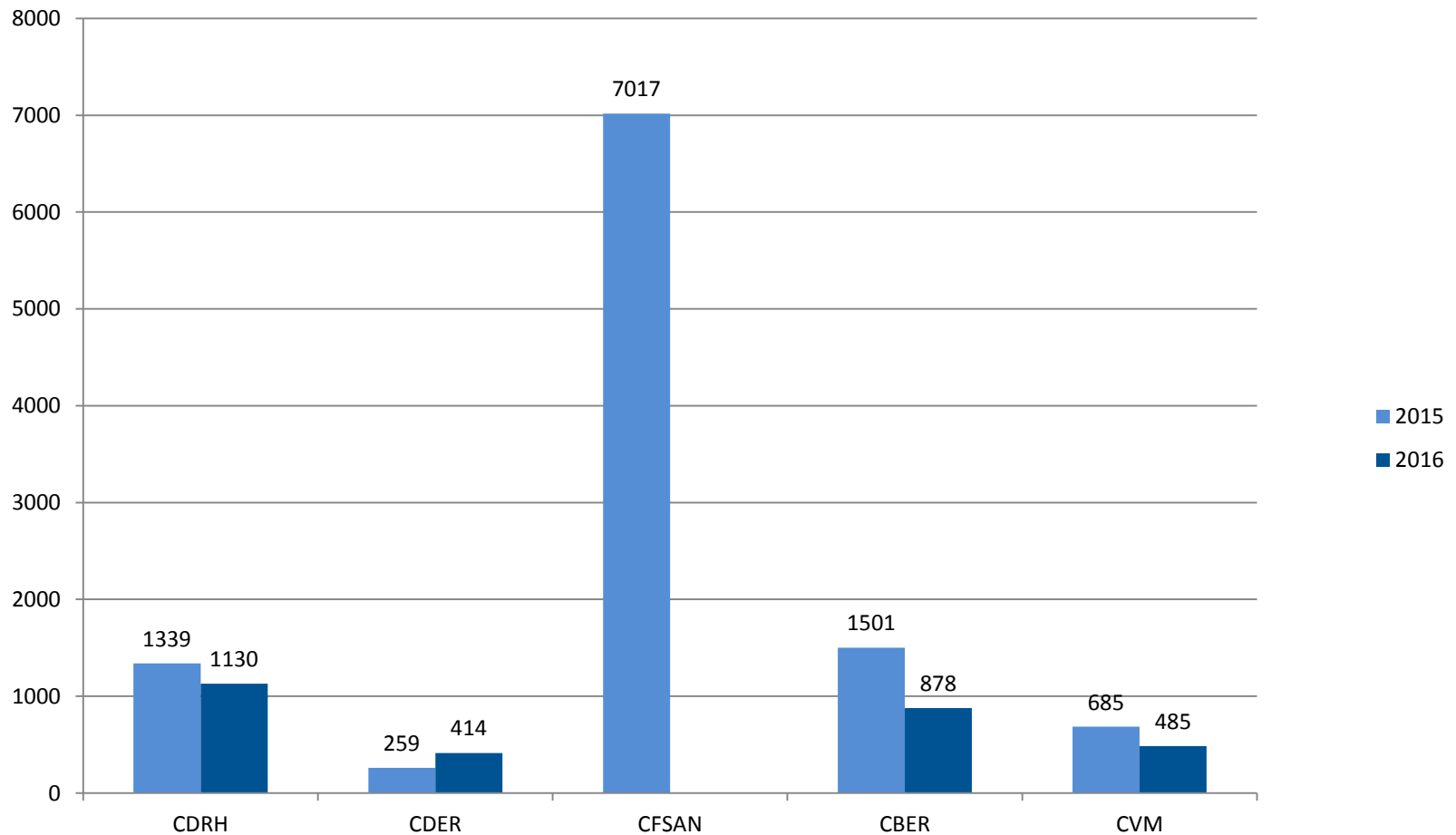
FDA Enforcement Statistics

Fiscal Year 2015

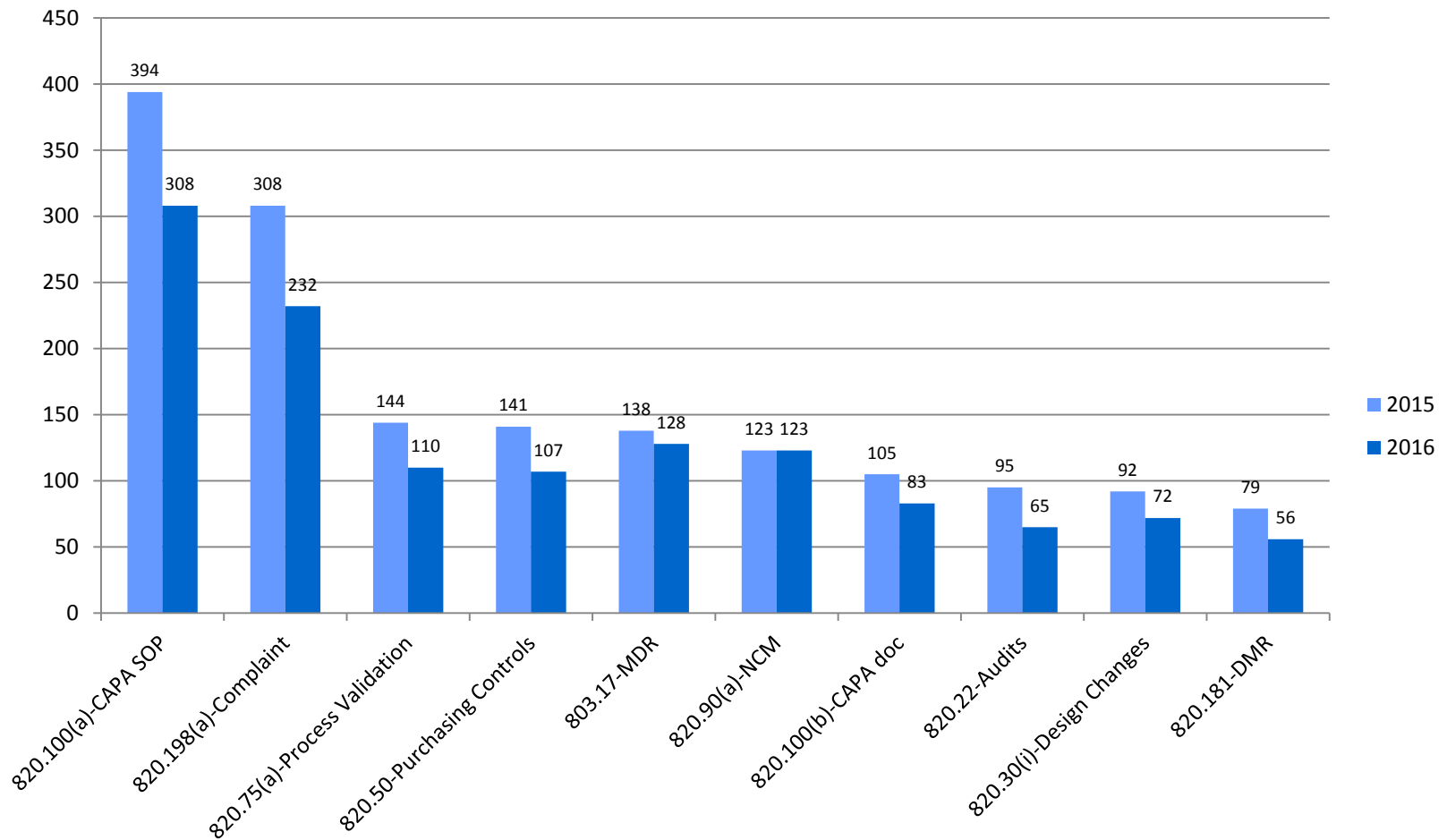
1 [8]	Seizures
21 [32]	Injunctions
17 (14 drugs/3 foods)	Debarments
17, 232 [14,145]	Warning Letters
2,789	Recalls
38,116	Inspections
29,432	Import Refusals

FDA Domestic Inspections Summary

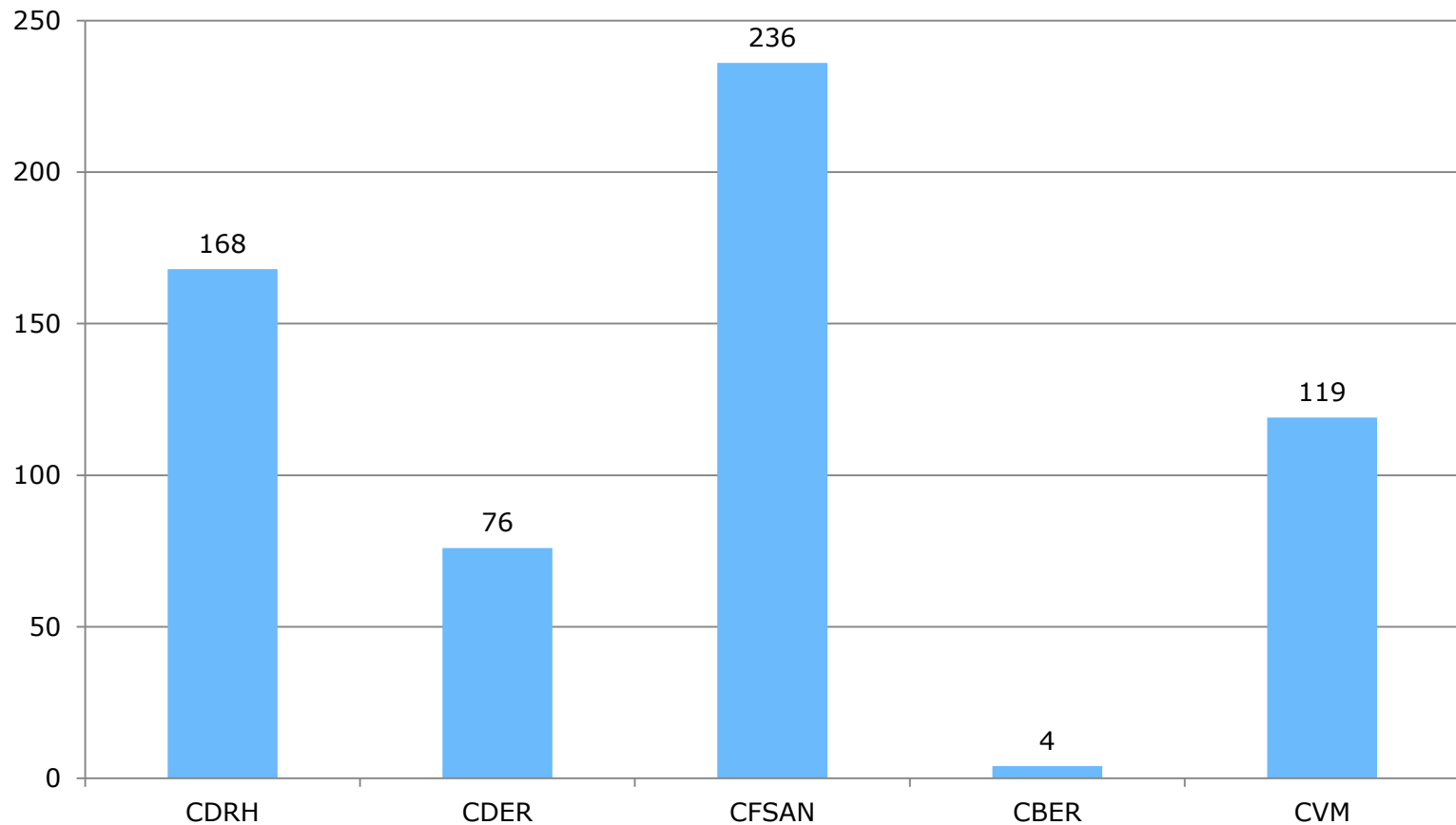
Fiscal Years 2015



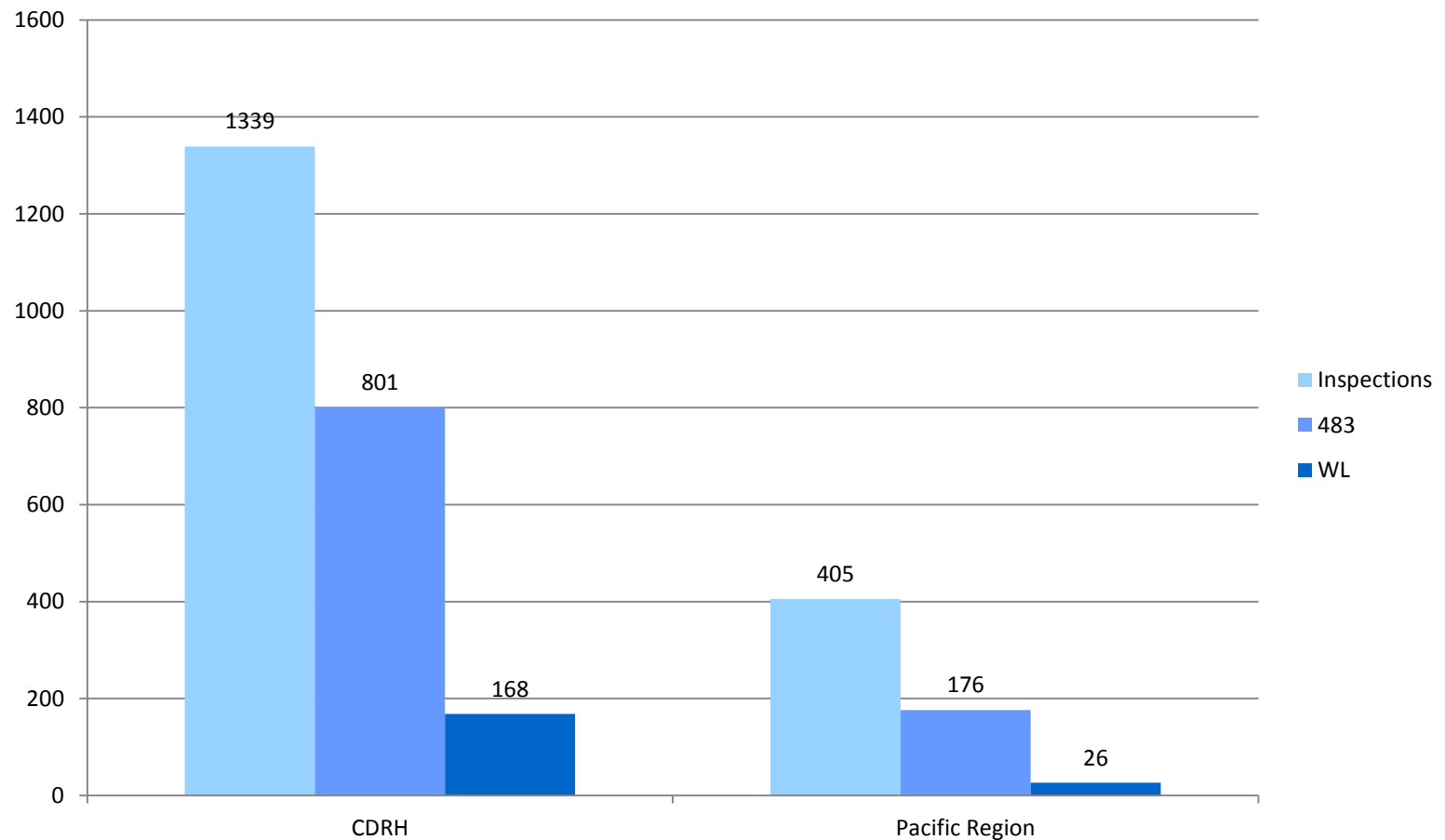
Top Device Citations-Foreign & Domestic in 2015 & 2016



Warning Letters by FDA Center Fiscal Year 2015 – Exclude CTP

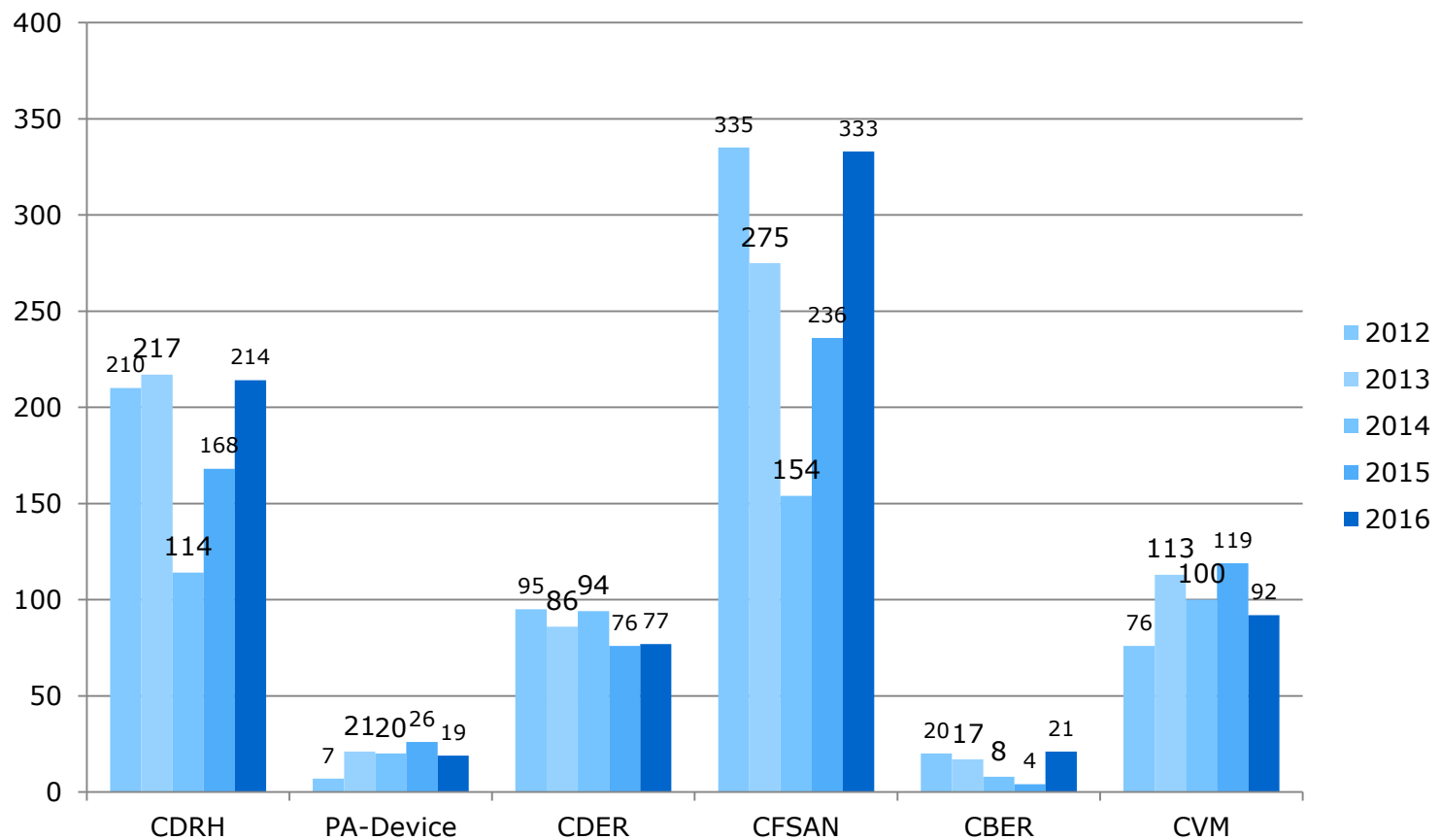


Device Domestic Inspections Resulting in WL - Fiscal Year 2015

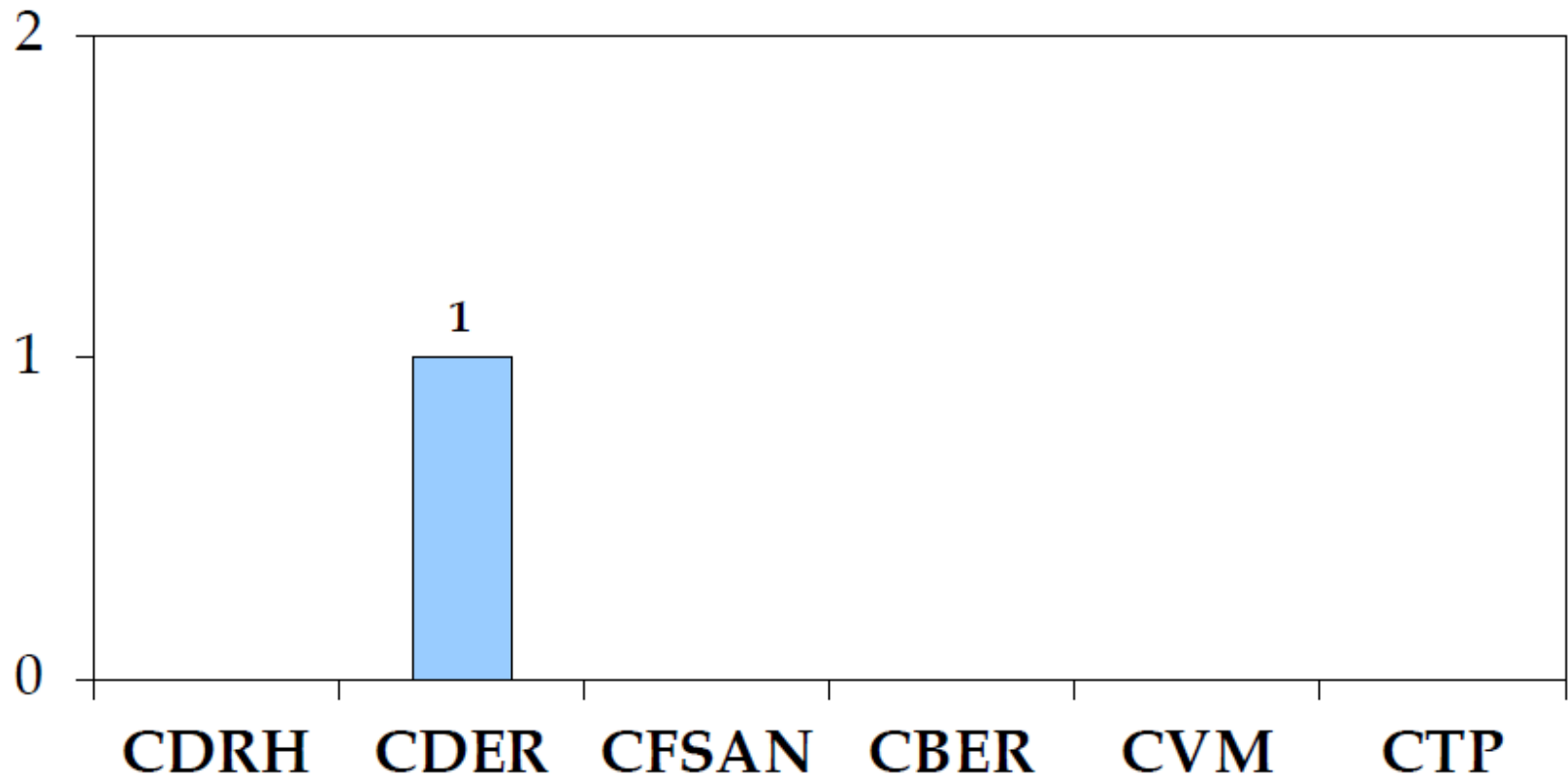


FDA Warning Letters

Fiscal Years 2012-Sep. 30, 2016

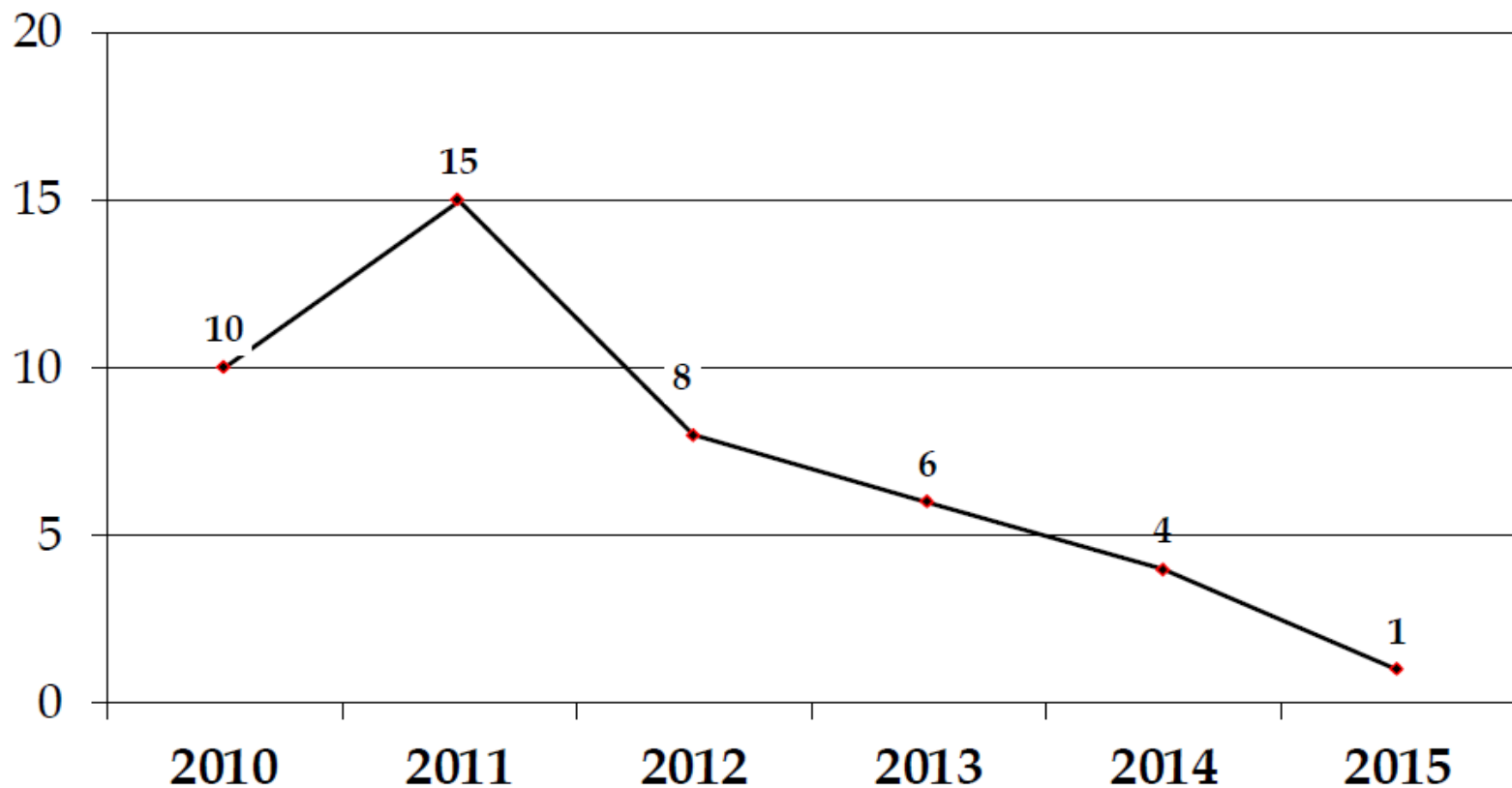


Seizures by FDA Center Fiscal Year 2015

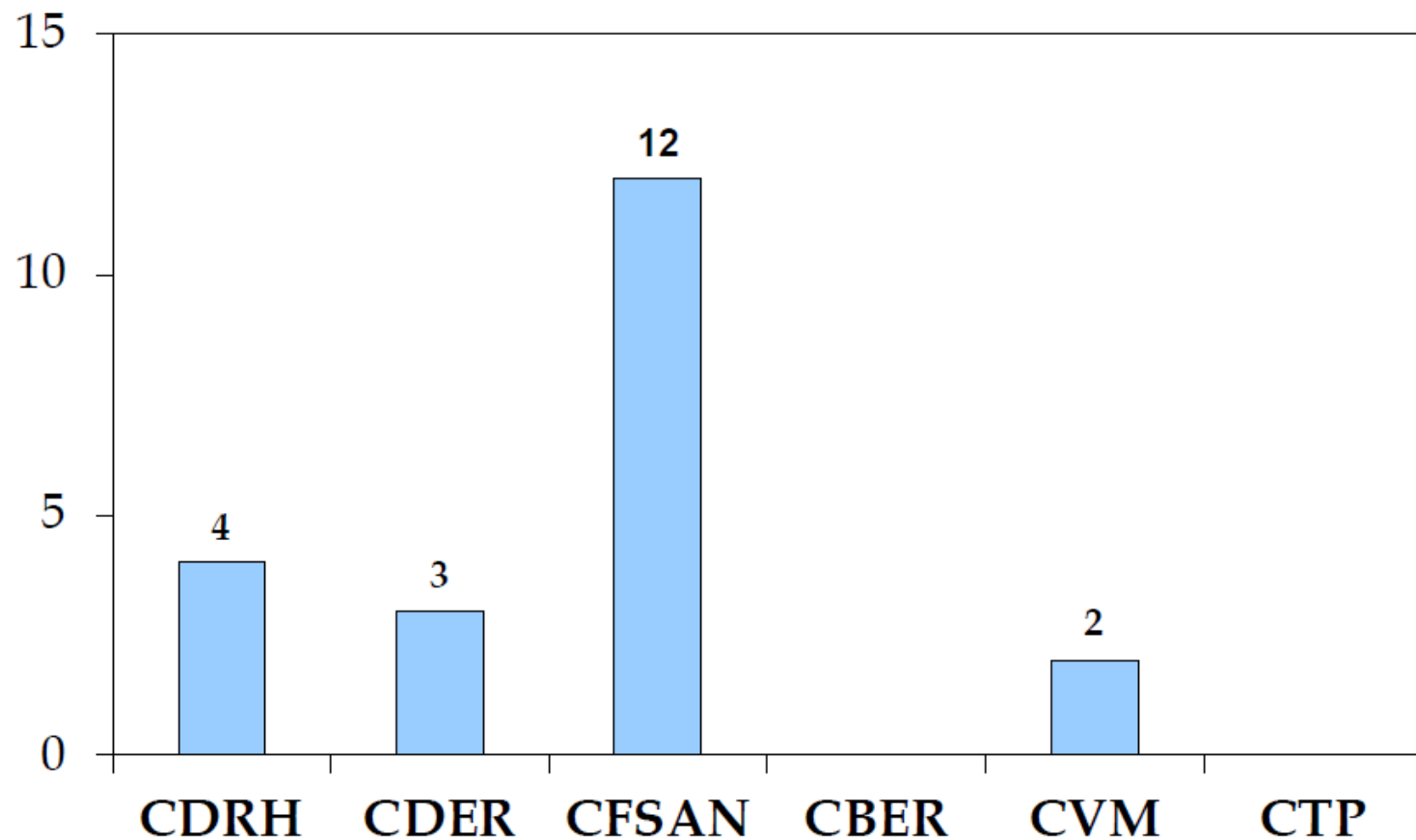


FDA Seizures

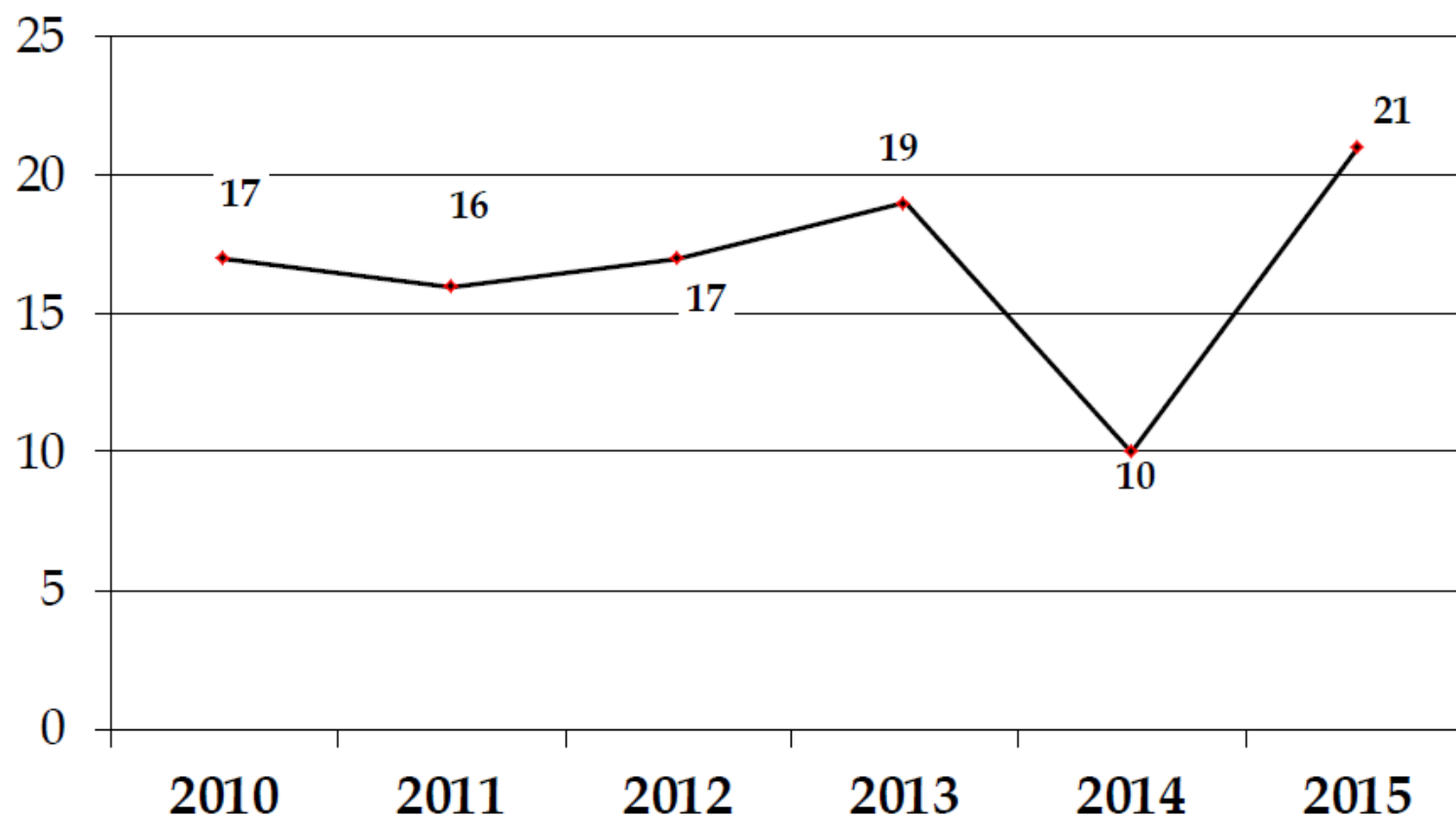
Fiscal Years 2010-2015



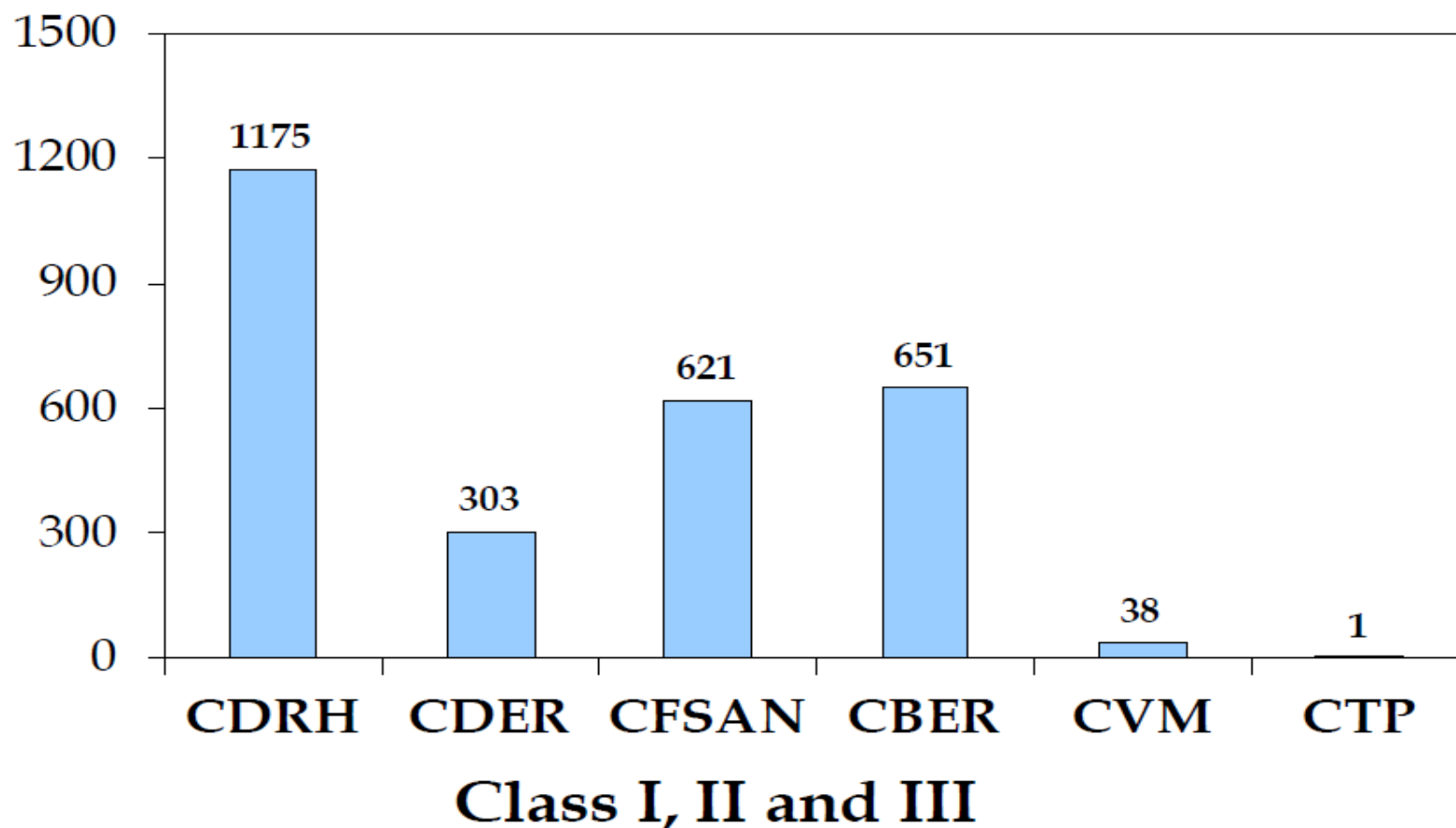
Injunctions by FDA Center Fiscal Year 2015



FDA Injunctions Fiscal Years 2010-2015

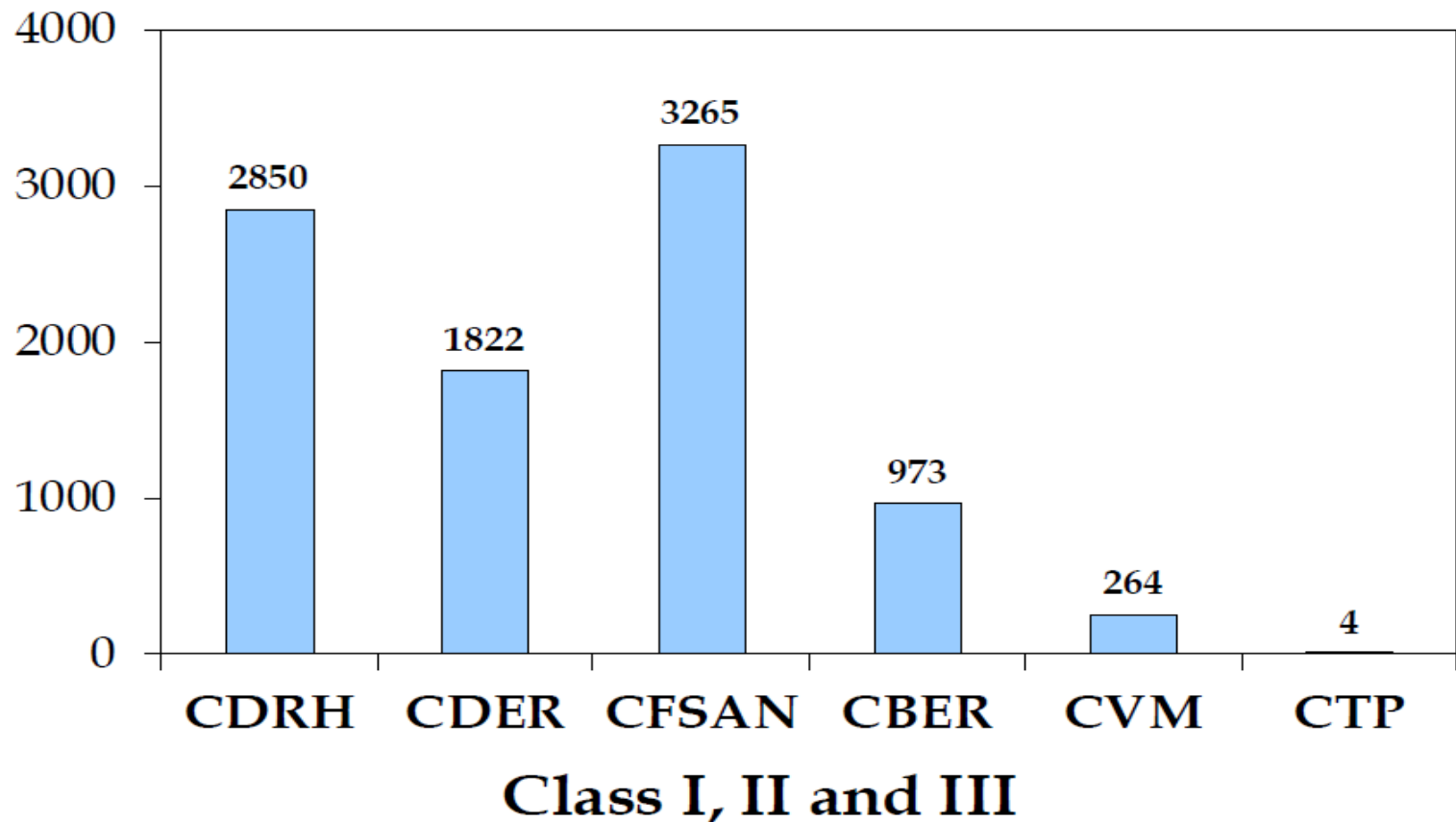


Total Recall Events by FDA Center Fiscal Year 2015

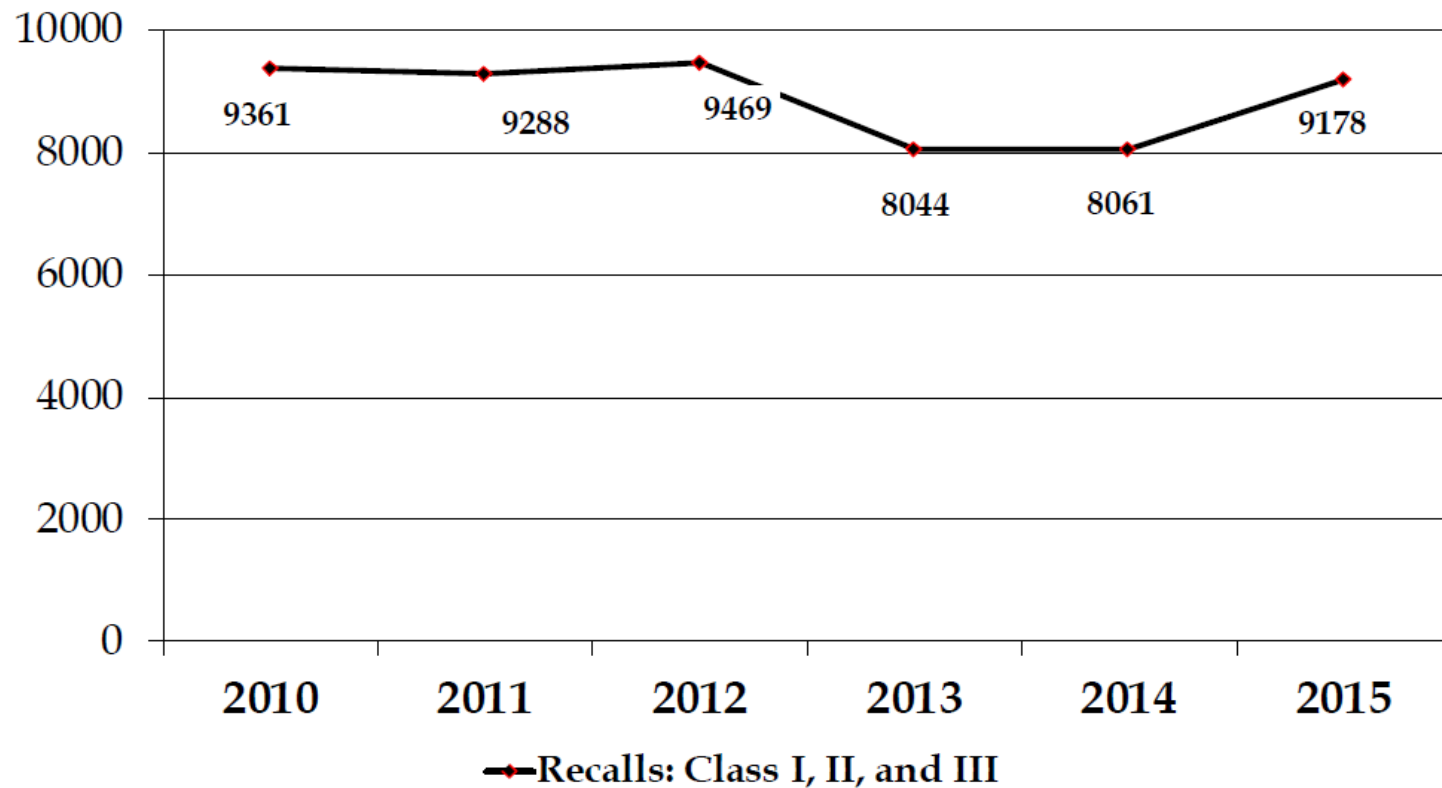


Total Recalled Products by FDA Center

Fiscal Year 2015

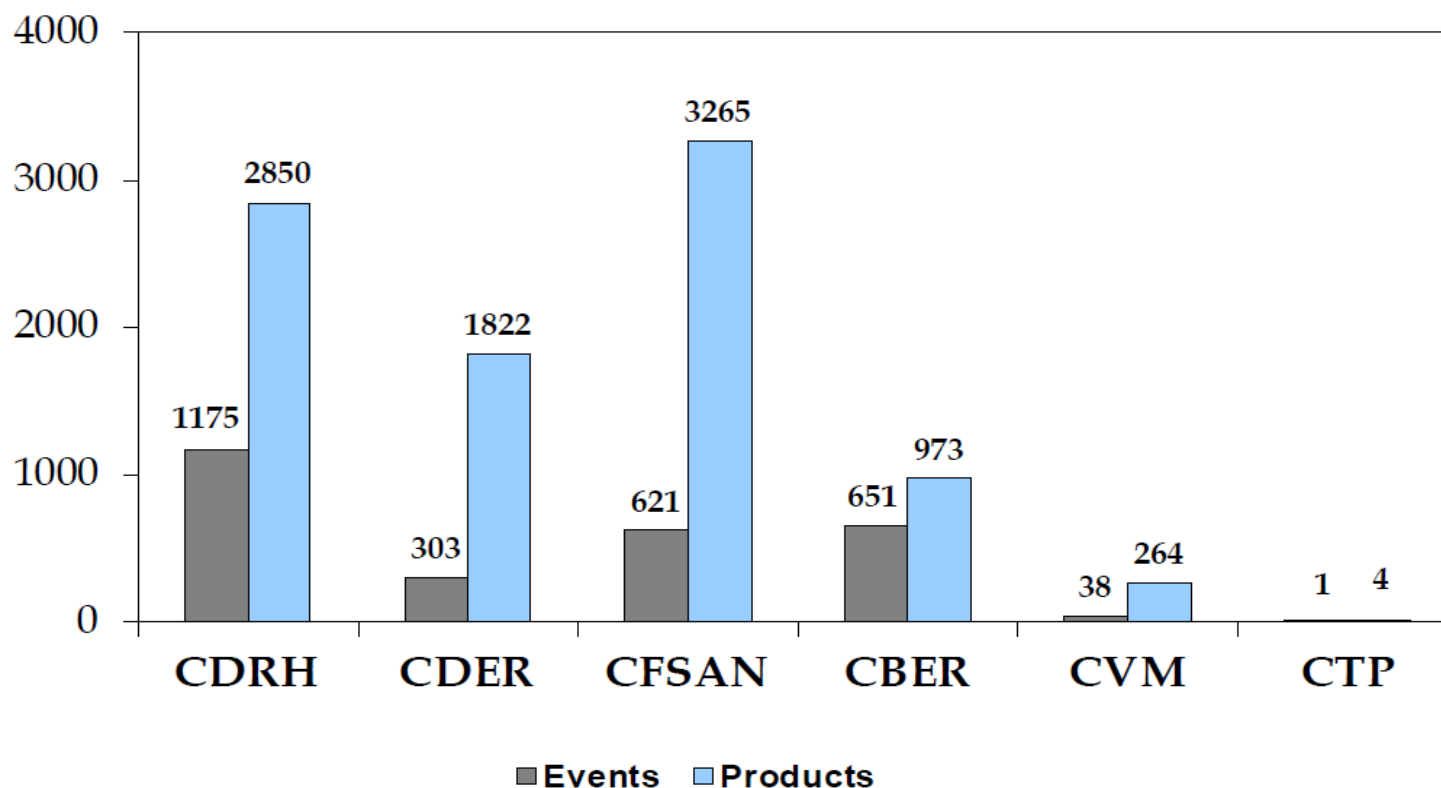


Recalled Products – All Centers Fiscal Years 2010-2015



FDA Recalls By Center – All Classes

Fiscal Year 2015



Recalls: Definition of Class I, II and III

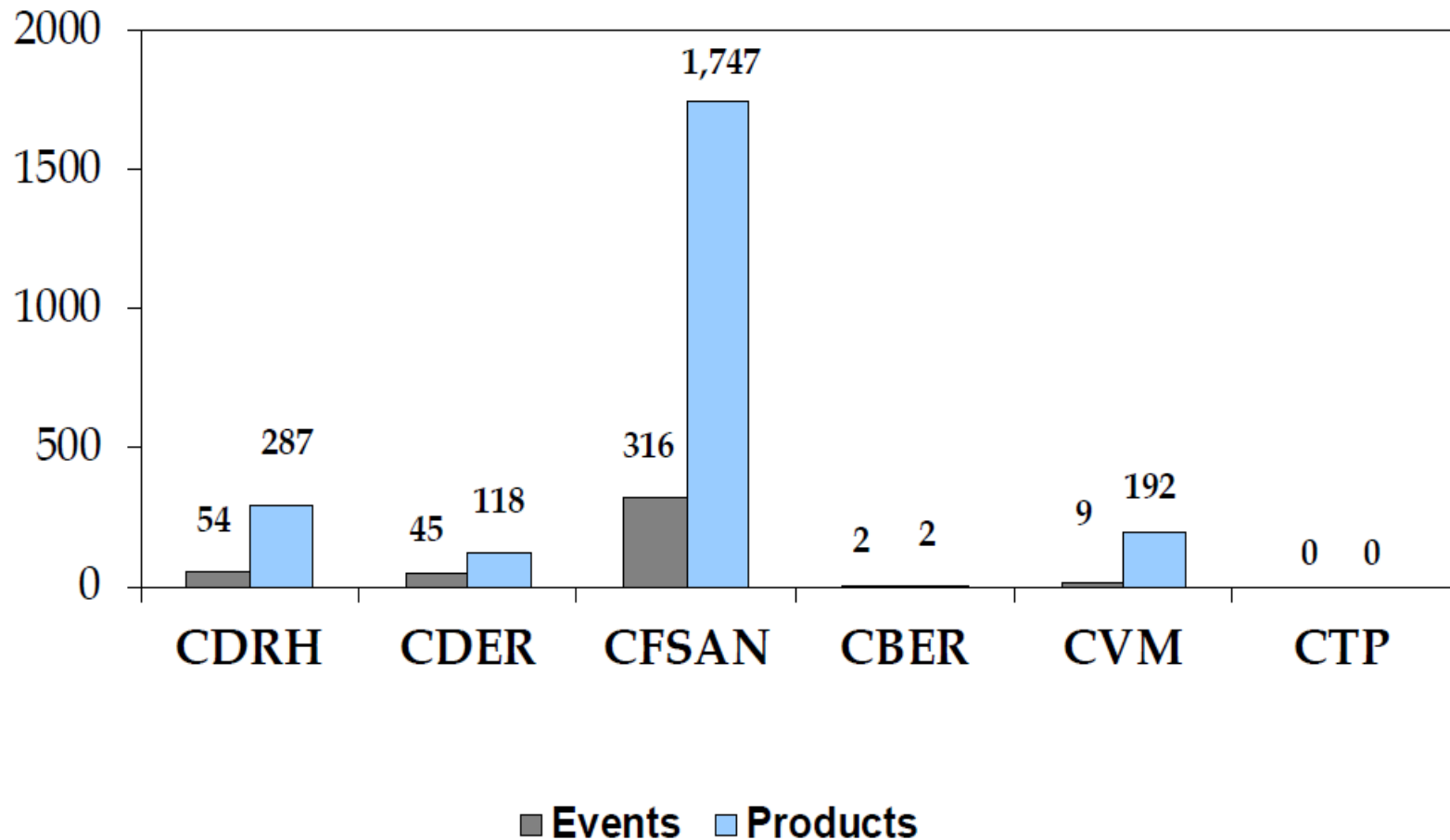
Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

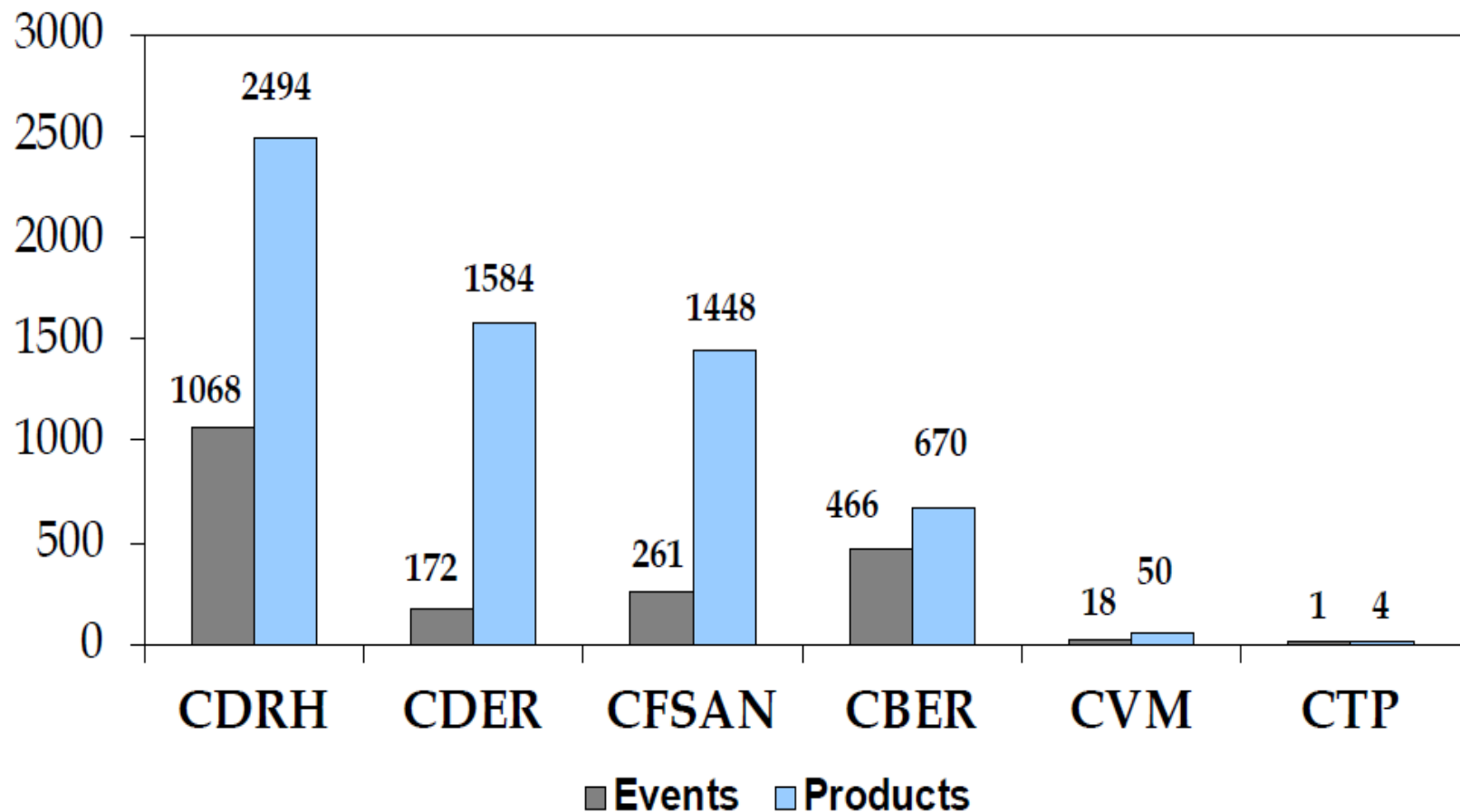
FDA Recalls – Class I By Center

Fiscal Year 2015



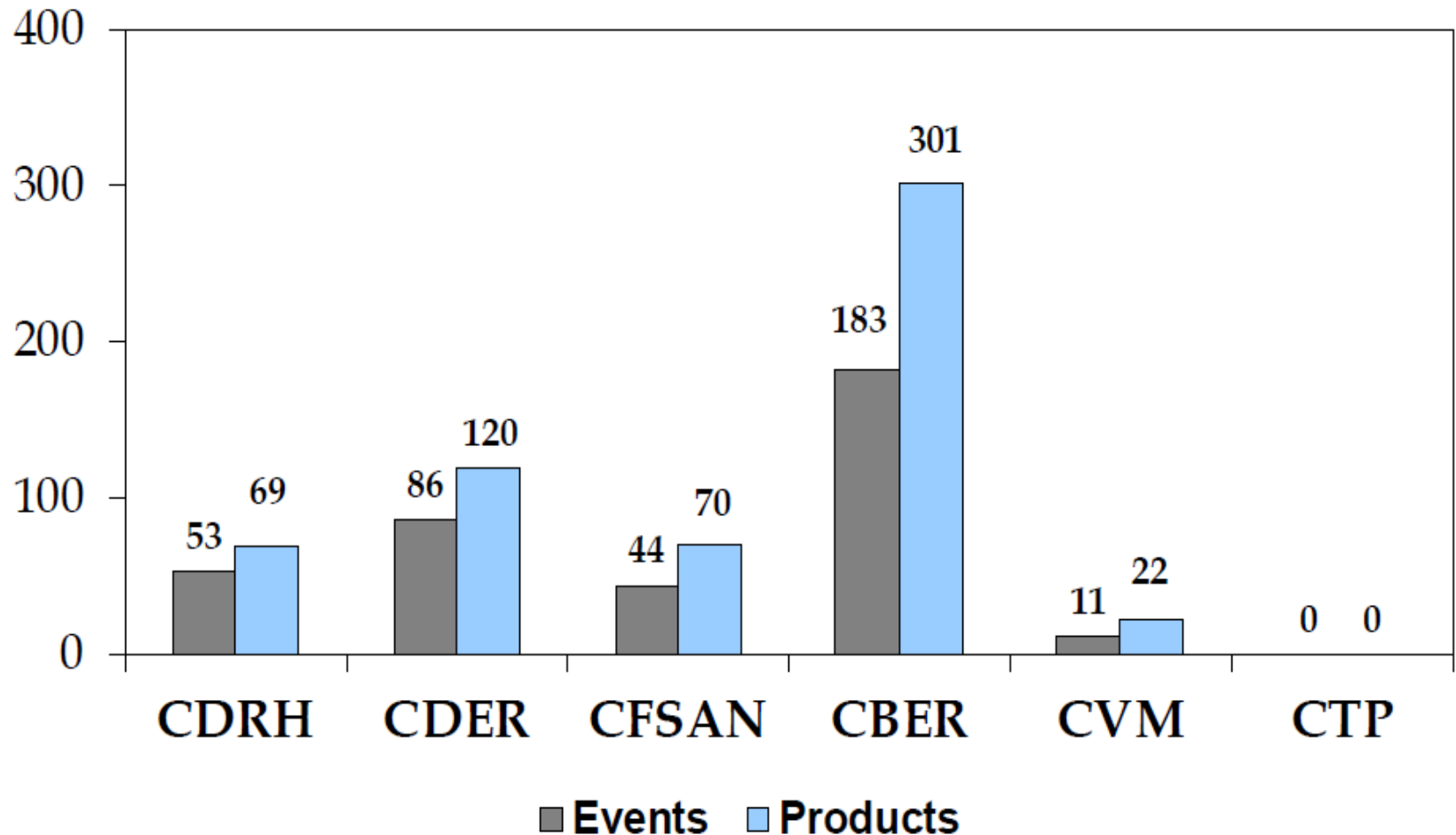
FDA Recalls – Class II By Center

Fiscal Year 2012



Recalls – Class III By Center

Fiscal Year 2012



Import Refusals Fiscal Year 2015

