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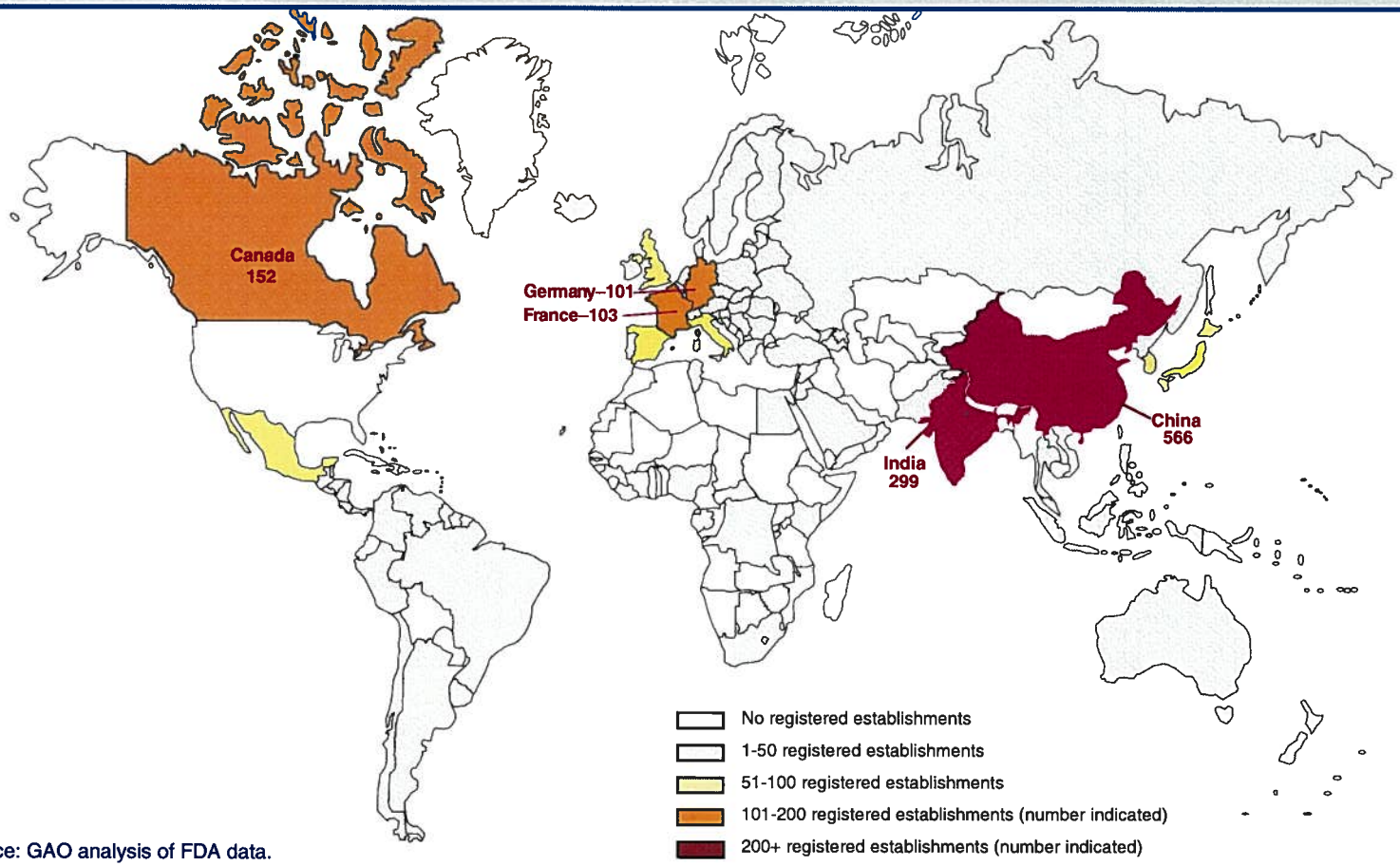
DRUG SAFETY: Preliminary Findings Suggest Weaknesses in FDA's Program for Inspecting Foreign Drug Manufacturers

Testimony Before the
Subcommittee on Oversight and Investigations,
Committee on Energy and Commerce,
House of Representatives

Statement of Marcia Crosse, Director, Health Care

Foreign Establishments Registered to Manufacture Drugs for the U.S. Market, by Country, Fiscal Year 2007



Source: GAO analysis of FDA data.

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FDA Data Used to Estimate the Number of Foreign Establishments Subject to Inspection

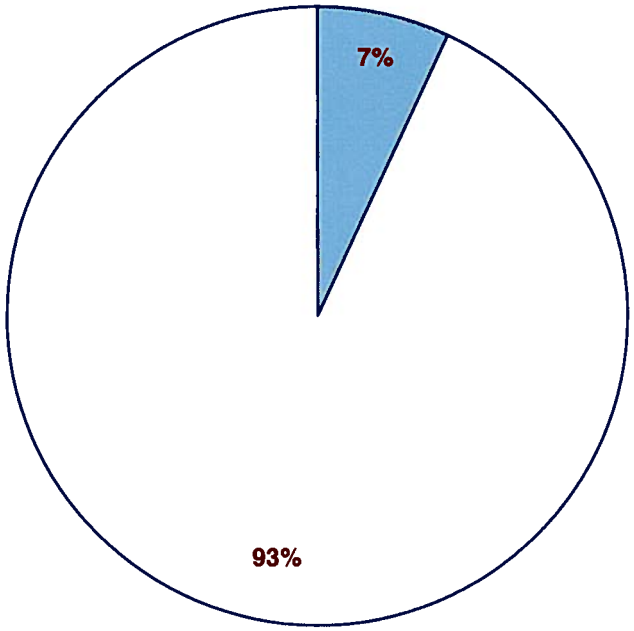
Drug Registration and Listing System (DRLS):

- Contains information on about **3,000** foreign establishments registered to manufacture drugs for the United States.
- FDA does not routinely verify the information provided by establishments.

Operational and Administrative System for Import Support (OASIS):

- Contains information showing that about **6,800** foreign establishments had drugs imported into the United States.
- OASIS may artificially inflate the number of foreign establishments.

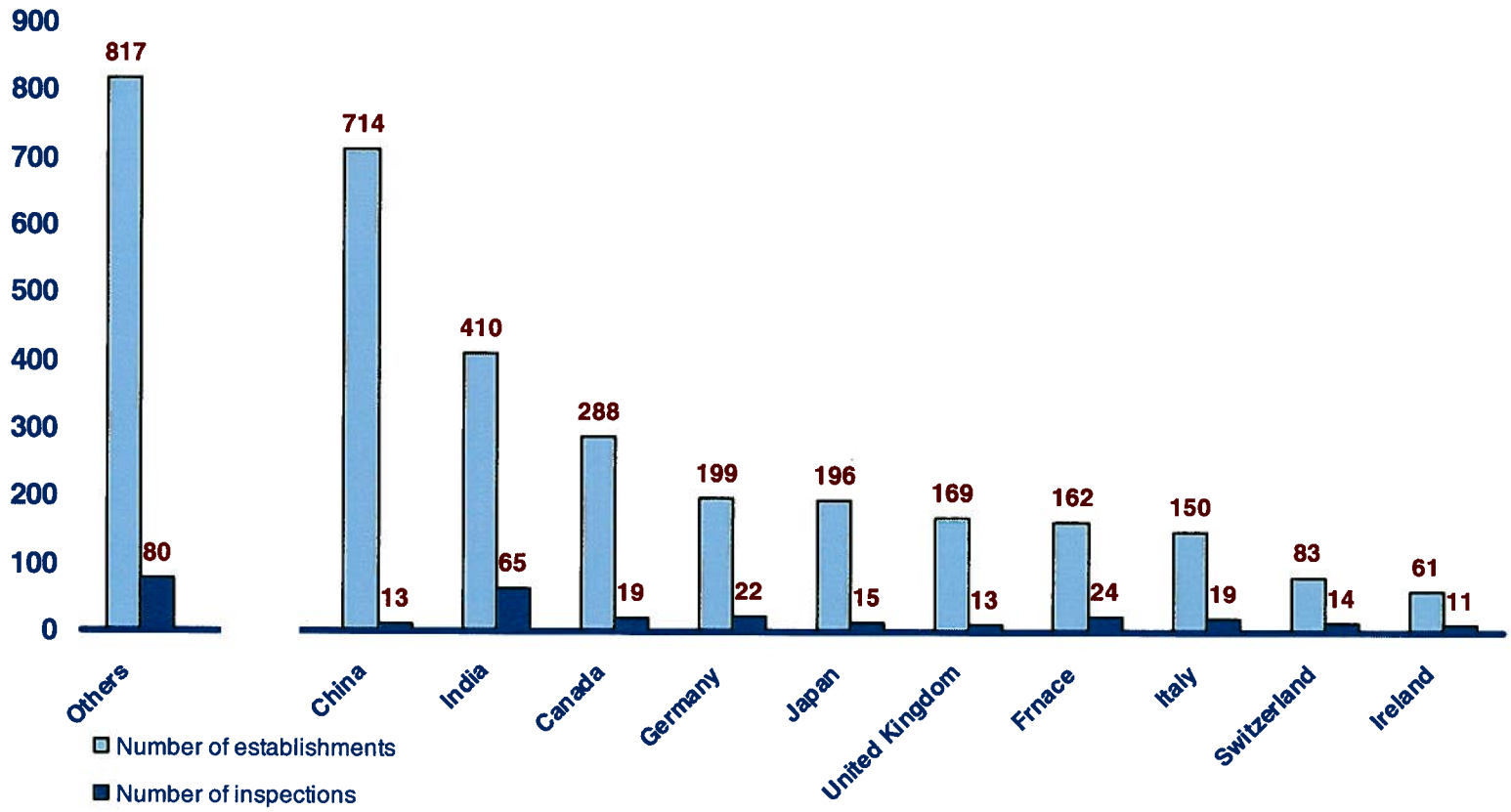
Estimated Percentage of Foreign Establishments Inspected Each Year



- Inspected
- Not Inspected

Source: GAO analysis of FDA data.

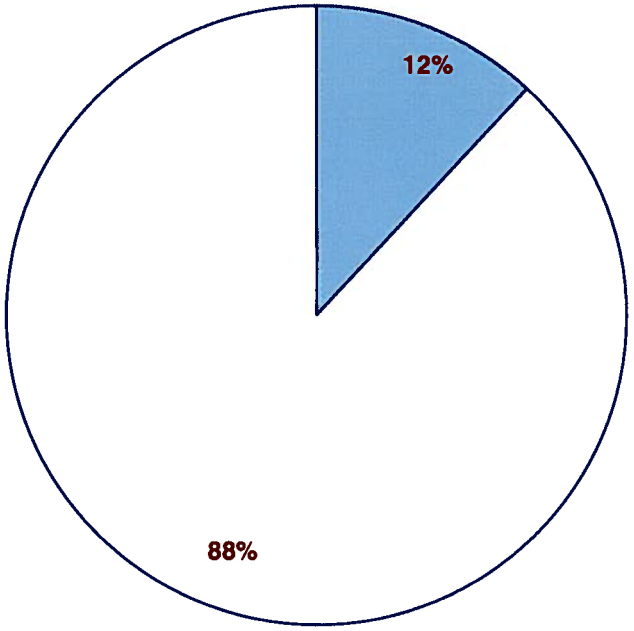
Number of Foreign Establishments and FDA Inspections for the 10 Most Frequently Inspected Countries, Fiscal Year 2007



Source: GAO analysis of FDA data.

Foreign Preapproval and Routine Surveillance Inspections, Fiscal Years 2002—2007

Foreign Inspections

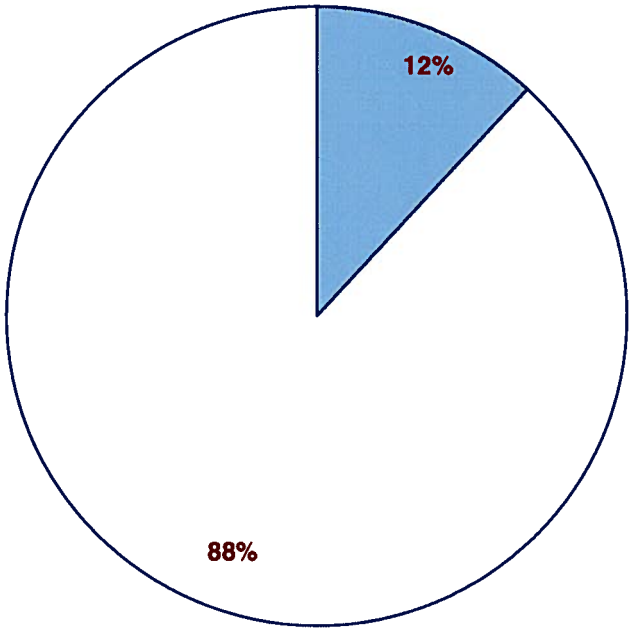


- Inspected for routine surveillance purposes
- Inspected for preapproval purposes

Source: GAO analysis of FDA data.

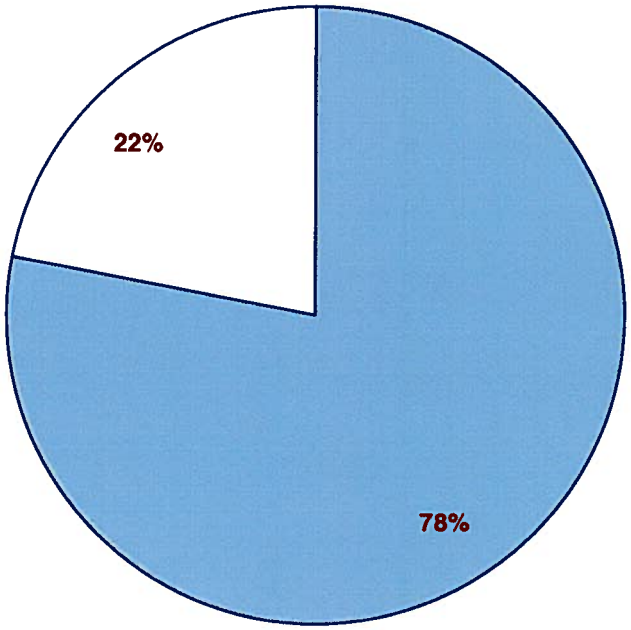
Foreign and Domestic Preapproval and Routine Surveillance Inspections, Fiscal Years 2002—2007

Foreign Inspections



- Inspected for routine surveillance purposes
- Inspected for preapproval purposes

Domestic Inspections



- Inspected for routine surveillance purposes
- Inspected for preapproval purposes

Source: GAO analysis of FDA data.

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Circumstances Unique to Foreign Inspections

- FDA asks staff to volunteer for foreign inspections
- Arrival at facility cannot be unannounced
- Lack of flexibility to easily extend inspection
- Language barriers