ALLIANCE FOR A STRONGER FDA

www.StrengthenFDA.org

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All of FDA's stakeholders working together for a strong, well-funded FDA

FDA: Underfunded, Vitally Important

- **FDA relatively small, underfunded for decades**
- **Agency appropriated $2.5B to oversee:**
  - 100% of drugs, vaccines, medical devices, personal care products and 80% of our nation's food supply
  - Products that are nearly 25% of all consumer spending
- **Strong FDA essential to U.S. economy, jobs, balance of trade; critical to homeland security**
- **Unlike other U.S. regulatory agencies, all stakeholders (including industry) support increased funding for the agency**

FDA Responsibilities Grow Each Year

- **Increases in funding have prevented crisis; but not fully supported growing responsibilities**
  - **From Congress:**
    - New laws: biosimilars (2010), food safety (2011), drug and device innovation and safety (2012)
    - Pending mandates: track and trace, compounding
  - **From other sources:**
    - Globalization
    - Scientific complexity
    - Growth of industry

FDA Especially Vulnerable to Cutbacks

- **FDA is a staff-intense organization**:
  - more than 80% staff costs,
  - little grant and contracting to cut
  - rent and utilities are fixed costs--paid first
- **If cuts occur:**
  - food will be less safe and consumers may die,
  - drug and device approvals will be slower, conflicting with promises made to consumers and companies,
  - problems with imports and globalization will become more numerous (2100 fewer food inspections, per WH)

Food Safety Modernization Act

FSMA Signed into Law—January 2011

Fundamental Overhaul of Food Laws

Risk-Based Inspections

Change from Re-active to Pro-active System

Acceleration of Inspections

Safer Food Supply

Reduced Foodborne Illness

New Drug and Device Laws

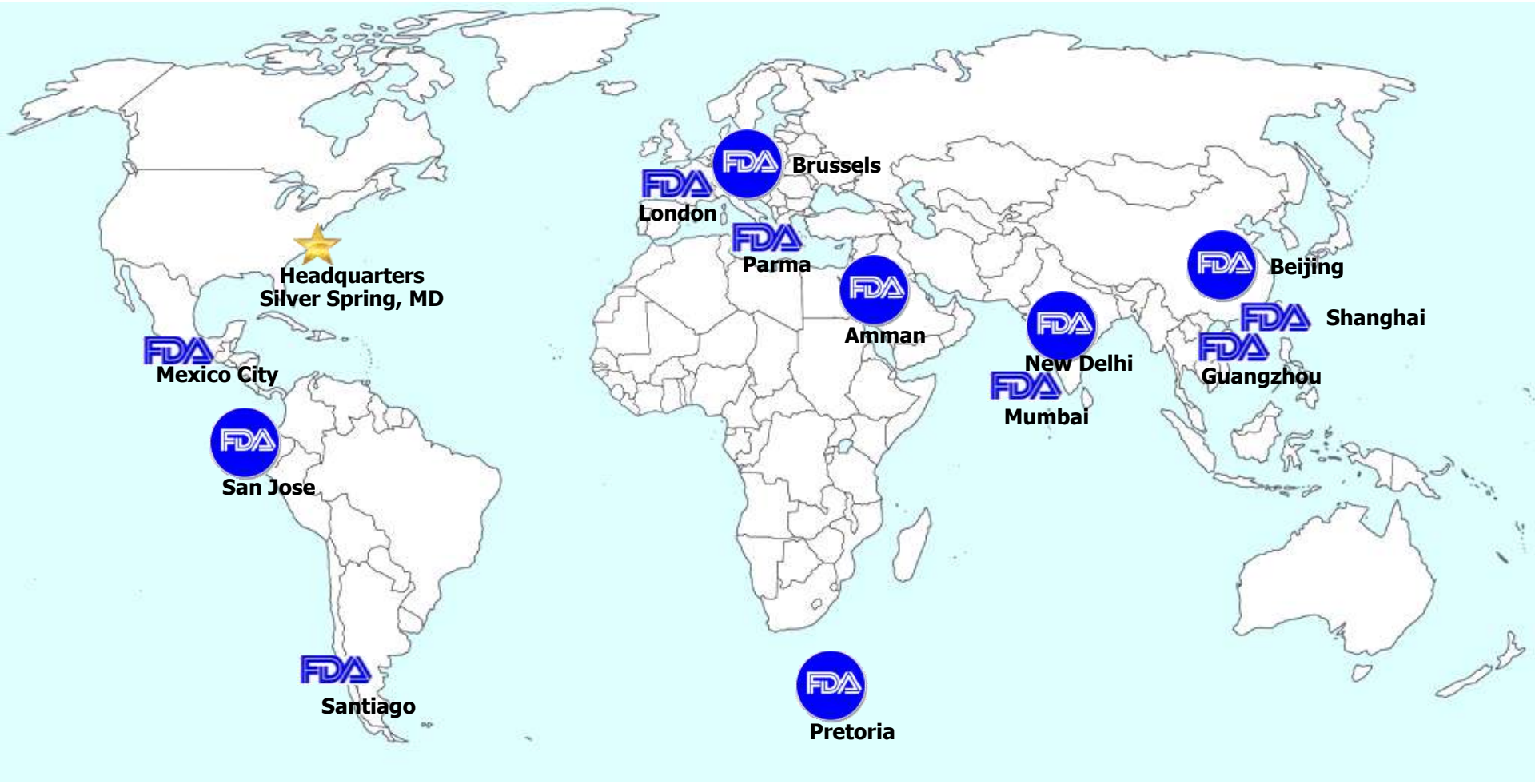
- **Biologics Price Competition and Innovation Act**
  - BPCIA signed into law March 2010
  - First fully new drug approval pathway in 30 years
  - Creates competition in $100B+ biotech drug market
- **FDA Safety and Innovation Act**
  - FDASIA signed into law July 2012
  - Overhauls drug and device approval processes
  - Dozens of new rules and programs to implement
- **3 new laws in 3 years; more expected in 2013**

Globalization Transforms FDA Mission

Massive increase in need for safety inspections:

- **Food Imports**: 10% annual increase from 2005-2011
  - 10-15% of all food consumed in U.S. is imported
  - Nearly 2/3 of fruits and vegetables are imported
  - 80% of seafood is imported
- **Device Imports**: 10% annual increase from 2005-2011
  - 50% of all medical devices used in the US are imported
- **Drug Imports**: 13% annual increase from 2005-2011
  - 80% of API used in the U.S. are manufactured abroad
  - 40% of finished drugs are manufactured abroad

FDA Foreign Offices (more coming)



Scientific Complexity & Medical Products

Drugs, Devices, Vaccines, Diagnostics:

All Involve More Complex Science

- Sponsors Need More Meeting Time and Other Feedback from FDA
- Product Applications Require More Patients, Study Sites, Analysis
- Enhanced Timeliness and Consistency of Product Review
- Expansion of Pre- and Post-Market Safety
- Sustain and Increase Core Programs That Enhance Innovation, Speed Approvals

Safe and Effective Medical Products to Meet Patient Needs

Drug Protocol Complexity & Execution Burden Increasing!

All Therapeutic Areas, All Phases	00 – 03	04-07	08-11	Percent Change 00-11
Unique medical and compliance procedures per protocol (median)	20.5	28.2	30.4	**48%**
Total procedures per protocol (median)	105.9	158.1	166.6	**57%**
Total investigative site work burden (median units)	28.9	44.6	47.5	**64%**
Total eligibility criteria	31	49	46	**58%**
Median study duration in days	140	154	175	**25%**
Median number of CRF pages per protocol **(CRF = case report forms)**	55	180	171	**227%**

Source: Getz, Campo, Kaitin. Variability in Protocol Design Complexity by Phase and Therapeutic Area, DIJ 2011 45(4); 413-420
Tufts Center for the Study of Drug Development

A strong FDA benefits all Americans

Patients, consumers, health professionals, industry....and the whole world benefits, too.

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