ALLIANCE FOR A STRONGER FDA

www.StrengthenFDA.org

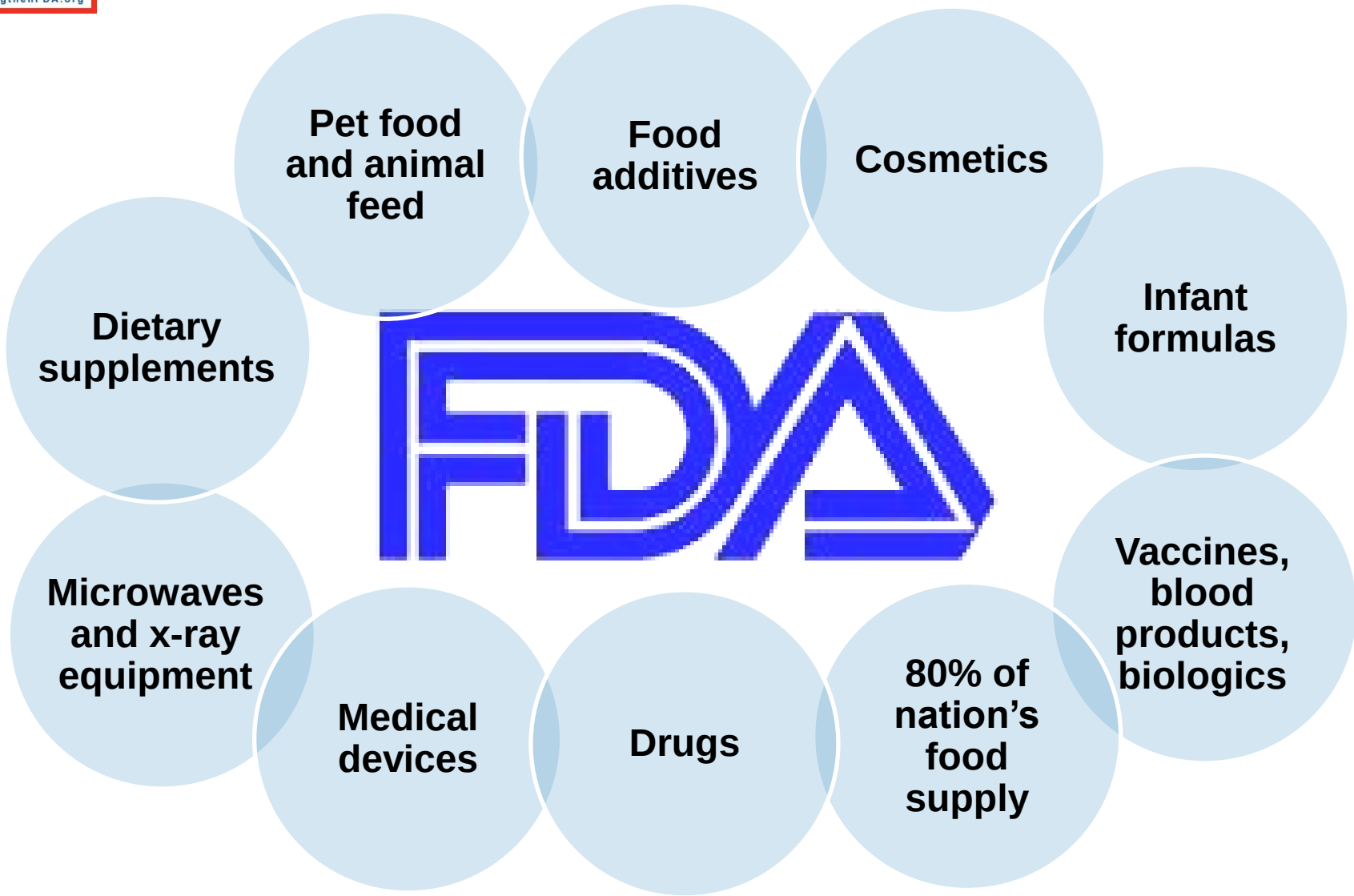
March 2013

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, cosmetics 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 Regulates . . . 25% of Consumer Spending



FDA Responsibilities Grow Each Year

Increases in funding have prevented crisis… but not fully supported growing responsibilities

FROM CONGRESS

- Tobacco control (2009)
- Biosimilars (2010)
- Food Safety (2011)
- Drug and device innovation and safety (2012)

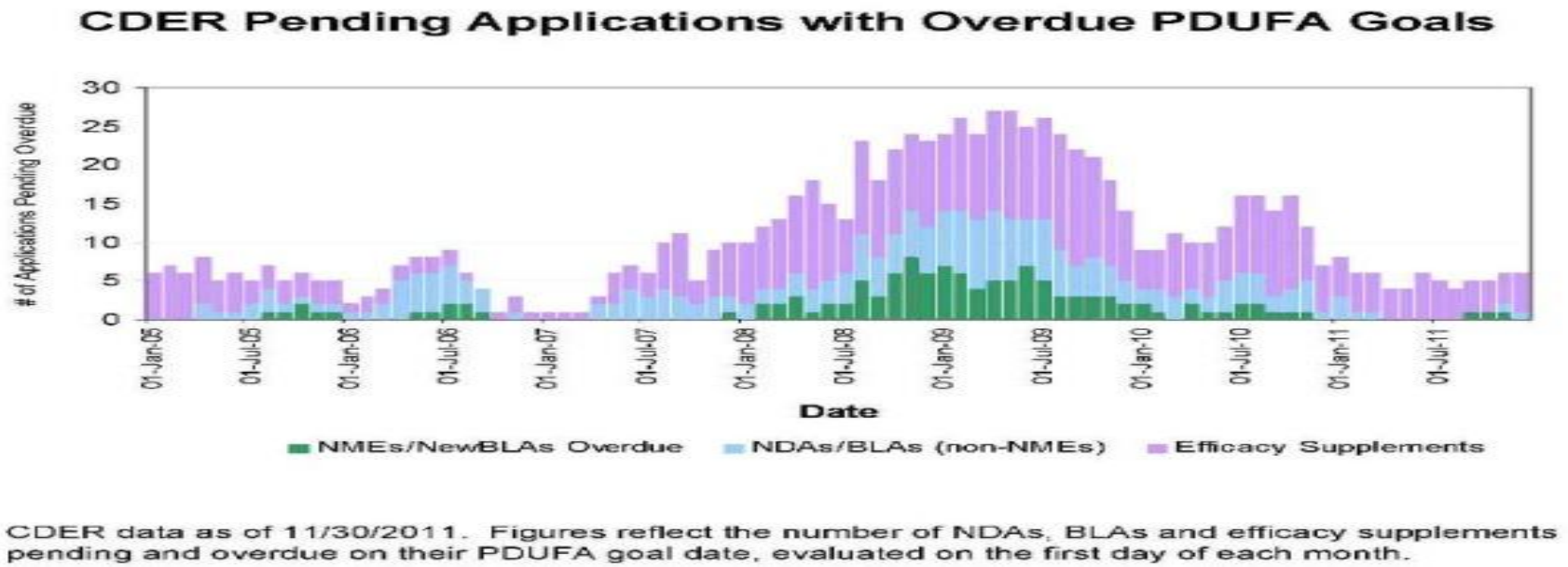
Possible 2013: compounding, counterfeiting/track & trace, and drug shortages

OTHER ADDITIONAL RESPONSIBILITIES

- Globalization
- Scientific complexity
- Promoting innovation
- Public health emergencies
- National security
- Growth of industry

New Laws Add Costs; Impact Existing Responsibilities

- FDA Amendments Act of 2007 added a slew of new responsibilities and created a funding shortfall.
- FDA's reviews slowed substantially for two years.



CDER data as of 11/30/2011. Figures reflect the number of NDAs, BLAs and efficacy supplements pending and overdue on their PDUFA goal date, evaluated on the first day of each month.

- **New laws: enormous resources to implement; permanently increase agency responsibilities.**

Barely Staying Ahead of County Schools

- In FY 07, FDA received less than the Montgomery County School system, where the agency is located.
- FDA's big gains since 2007 are being eroded

	FY 07	FY 08	FY 09	FY 10	FY 11	FY 12	FY 13
MC Public Schools	**$1.85 billion**	$1.98 billion	$2.07 billion	$2.20* billion	$2.10 billion	$2.09 billion	**$2.170 billion**
FDA appropriated funds	**$1.57 billion**	$1.72 billion	$2.04 billion	$2.35 billion	$2.45 billion	$2.51 billion	**Post-sequester: $2.395 billion**

http://montgomeryschoolsmd.org/

* Reflects approximately $80 million added to pay debt service on a one-time basis.

FDA Especially Vulnerable to Cutbacks

- **FDA is a staff-intense organization**:
  - more than 80% staff costs,
  - rent and utilities are fixed costs--paid first
  - little grant and contracting to cut
- **If cuts occur (sequester, FY 13, or FY14):**
  - food will be less safe and consumers may be hurt,
  - 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)

Sequestration Takes $209 Million Away

Sequestration	FY 13 Continuing Resolution (thru 3/27/13)	Less Sequester Amounts	Net Amount
Budget Authority Appropriations	$ 2.521 billion	$ 126 million	$ 2.395 billion
User Fees (including tobacco and generics user fees)	$ 1.647 billion	$ 82 million	$ 1.565 billion
Totals	$ 4.168 billion	$ 209 million (rounded)	$ 3.960 billion (rounded)

The loss of $209 million will be met by fewer inspections, short-staffing of FDA offices/functions, cuts to training and travel (critical for inspections and international standard-setting) and cancelling contracts and grants.

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

New Import Program

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 $ 60B+ 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
- **4 major 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

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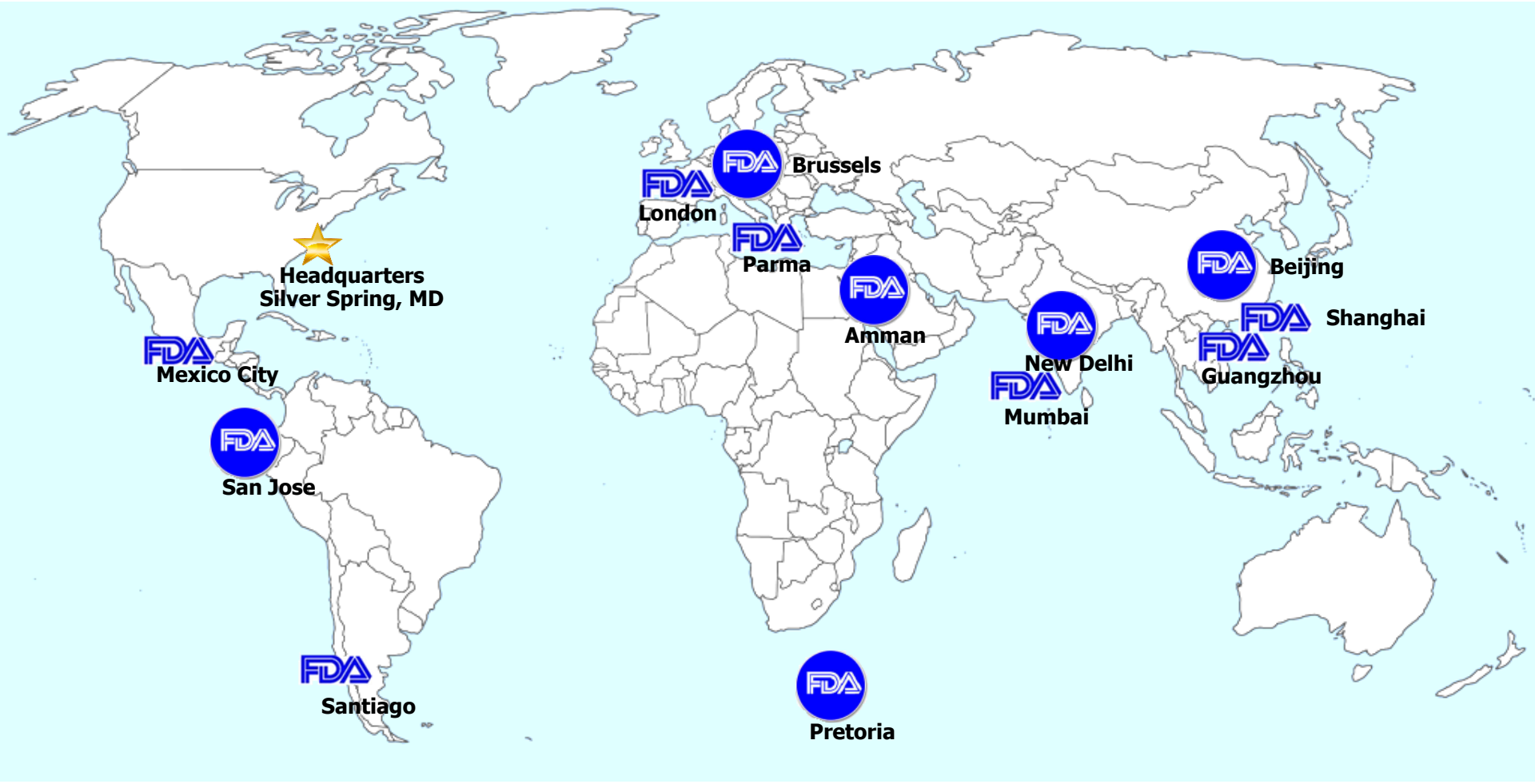
FDA Foreign Offices (more coming)



Scientific Complexity & Medical Products

Drugs, Devices, Vaccines, Diagnostics, Cosmetics:

All Involve More Complex Science

Sponsors Need More Meeting Time; Other Feedback from FDA

Applications Require More Patients, Study Sites, Analysis

Enhanced Timeliness and Consistency of Product Review

Expansion of Pre- and Post-Market Safety

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		08-11	% Change 00-11
Unique medical and compliance procedures per protocol (median)	20.5		30.4	**48%**
Total procedures per protocol (median)	105.9		166.6	**57%**
Total investigative site work burden (median units)	28.9		47.5	**64%**
Total eligibility criteria	31		46	**58%**
Median study duration in days	140		175	**25%**
Median number of CRF pages per protocol **(CRF = case report forms)**	55		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

Conclusion

The U.S. Food and Drug Administration:

- **broad mandate for a relatively small agency**
- **core function of government**
- **mission and responsibilities are increasing**
- **needs funding to transform into a 21st century regulatory agency**

FDA should be a priority…and deserves exceptional status when appropriations decisions are made

A strong FDA benefits all Americans

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

For more information, contact:

Ladd Wiley, Executive Director
lwiley@StrengthenFDA.org
202-887-4083

Steven Grossman, Deputy Exec. Director
sgrossman@StrengthenFDA.org
301-539-9660