



U.S. Food and Drug Administration

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U.S. Food and Drug Administration

FDA Overview
November 2011

Jarilyn Dupont, J.D.
Director of Regulatory Policy
Office of the Commissioner, Office of Policy



Overview Briefing

- Background on FDA
 - Mission
 - Organization
 - Scope of Responsibility
- Major Issues Confronting FDA
 - Medical Product Safety
 - Medical Product Review & Innovation
 - Food/Feed Safety
 - Import Safety
 - Regulation of Tobacco Products



Fast Facts About FDA

- Science-Based Regulatory Agency
- Organized by Product Area
- 223 Field Offices Around U.S.
 - 13 Field Laboratories
- Approximately 11,516 Employees
- Physicians, Pharmacologists, Toxicologists, Microbiologists, and Other Scientific Professionals, Lawyers, Analysts, Administrative
- \$ 4.36 Billion Annual Budget (Requested FY 2012)



FDA Mission

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.



FDA Organization: Office of the Commissioner

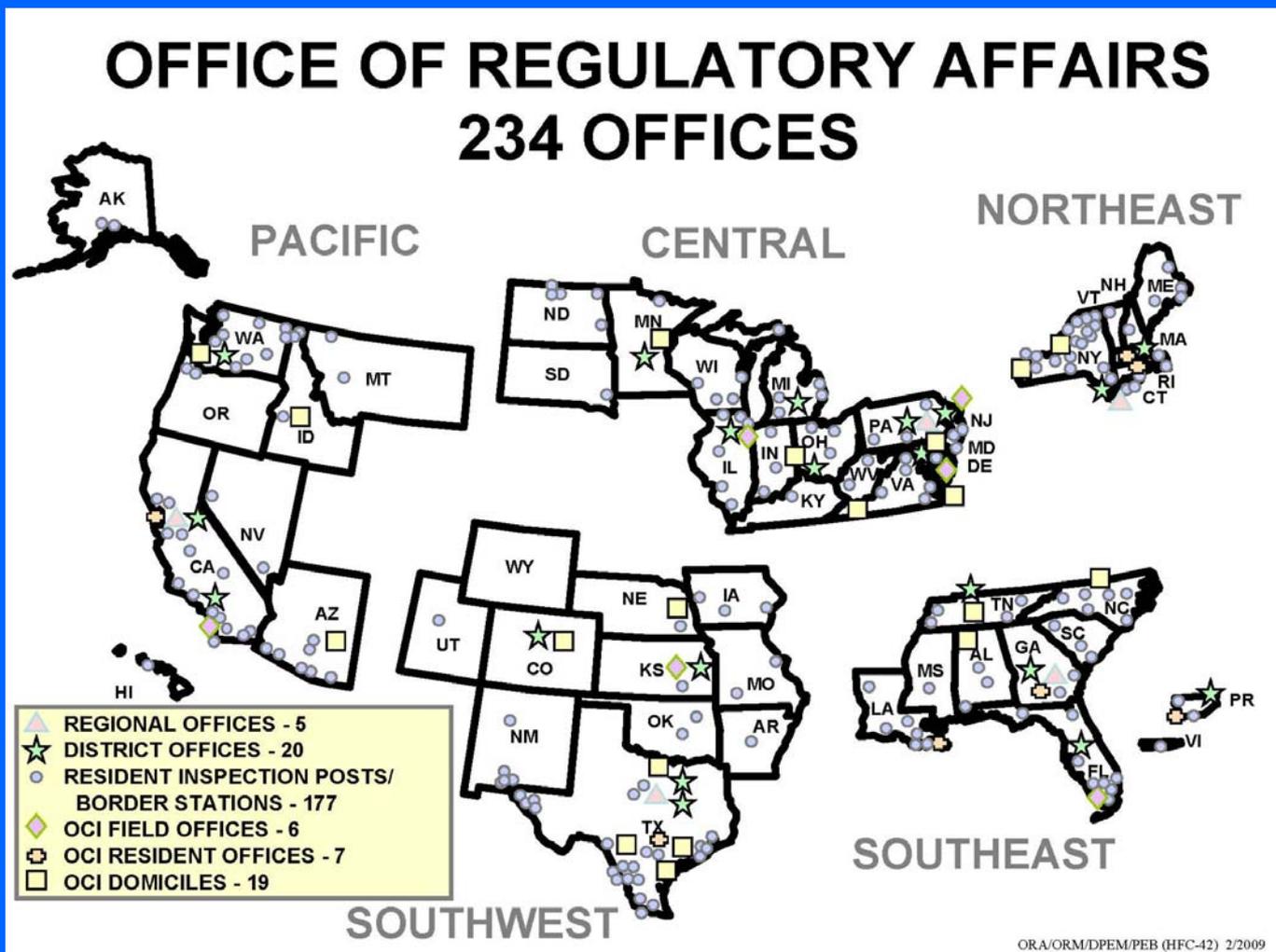
- Commissioner of Food and Drugs: *Margaret A. Hamburg, M.D.*
- Counselor to the Commissioner: *John M. Taylor III, J.D.*
- Chief Counsel: *Elizabeth Dickinson, J.D. (Acting)*
- Associate Commissioner for Legislation: *Jeanne C. Ireland*
- Associate Commissioner for Policy and Planning: *David Dorsey, J.D. (Acting)*
 - Assistant Commissioner for Policy: *Leslie Kux, J.D. (Acting)*
- Associate Commissioner for Office of External Affairs: *Virginia Cox*
- Chief Scientist: *Jesse Goodman, M.D., MPH*
- Director of Office of Women's Health: *Marsha Henderson, M.C.R.P. (Acting)*
- Director of Office of Minority Health: *Michelle Yebosh, DrPH (Acting)*
- Associate Commissioner of Office of Operations: *Caroline Lewis*
- Deputy Commissioner of Office of Foods: *Michael R. Taylor, J.D.*
- Deputy Commissioner of Office of Medical Products and Tobacco: *Stephen P. Spielberg, M.D., Ph.D.*
- Deputy Commissioner of Office of Global Regulatory Operations and Policy: *Deborah M. Autor, J.D. (Acting)*
- Director of Office of Special Medical Programs: *Jill H. Warner, J.D. (Acting)*
- Associate Commissioner of Office of International Programs: *Mary Lou Valdez*



FDA Organization

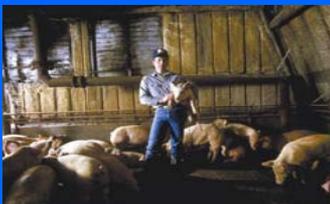
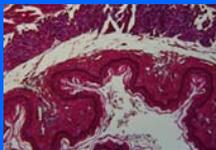
- Center for Biologics Evaluation and Research
 - Karen Midthun, M.D.
- Center for Drug Evaluation and Research
 - Janet Woodcock, M.D.
- Center for Devices and Radiological Health
 - Jeffrey Shuren, M.D., J.D.
- Center for Food Safety and Applied Nutrition
 - Michael M. Landa, J.D. (Acting)
- Center for Tobacco Products
 - Lawrence Deyton, M.D., M.S.P.H.
- Center for Veterinary Medicine
 - Bernadette M. Dunham, D.V.M., Ph.D.
- National Center for Toxicological Research
 - William Slikker Jr., Ph.D.
- Office of Regulatory Affairs
 - Dara Corrigan, J.D. (Associate Commissioner for Regulatory Affairs)

FDA Locations Around the US



Scope of FDA's Mission

- Food
- Drugs
- Vaccines/Blood
- Dietary Supplements
- Animal Foods & Drugs
- Toxicological Research
- Biotechnology
- Medical Devices/
Radiological Products
- Cosmetics
- Tobacco Products



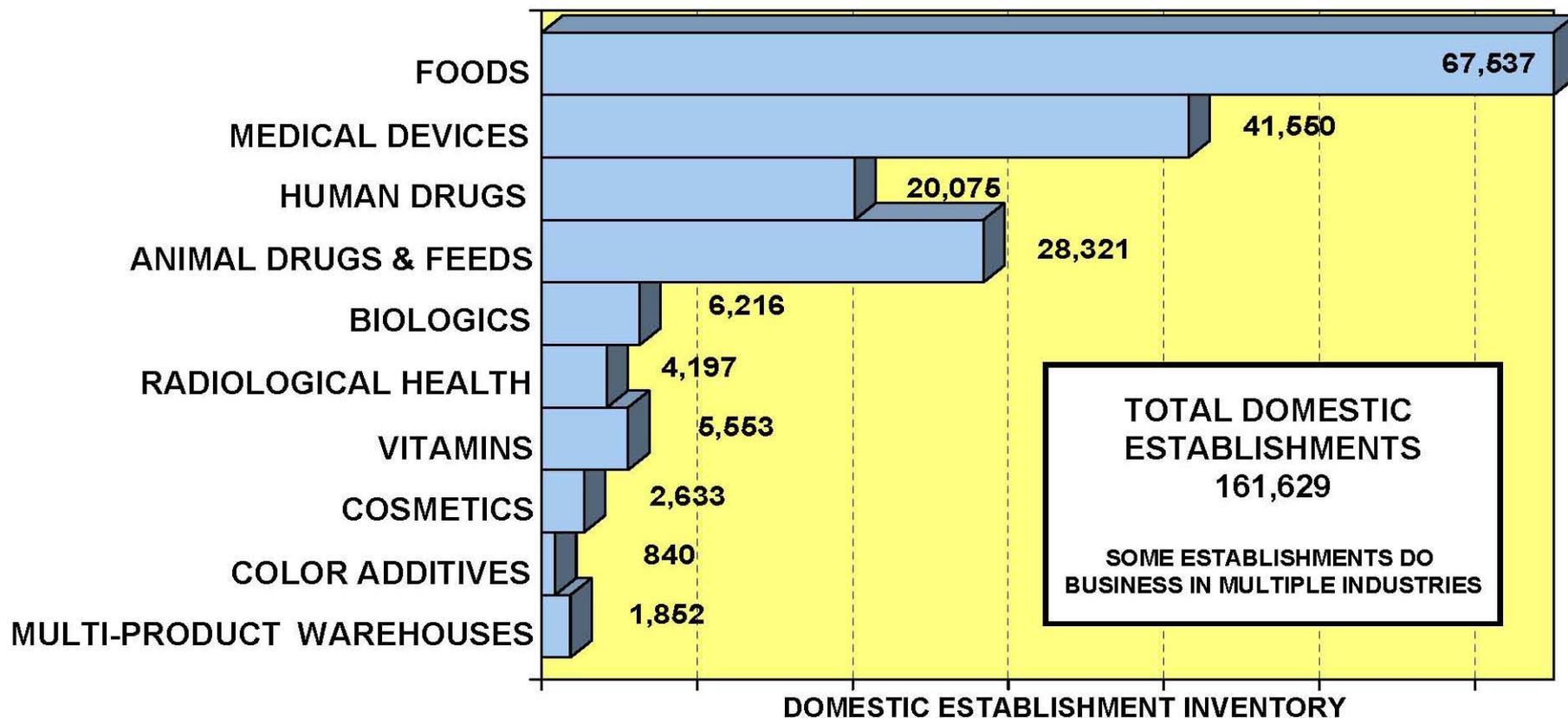


What FDA Does Not Regulate

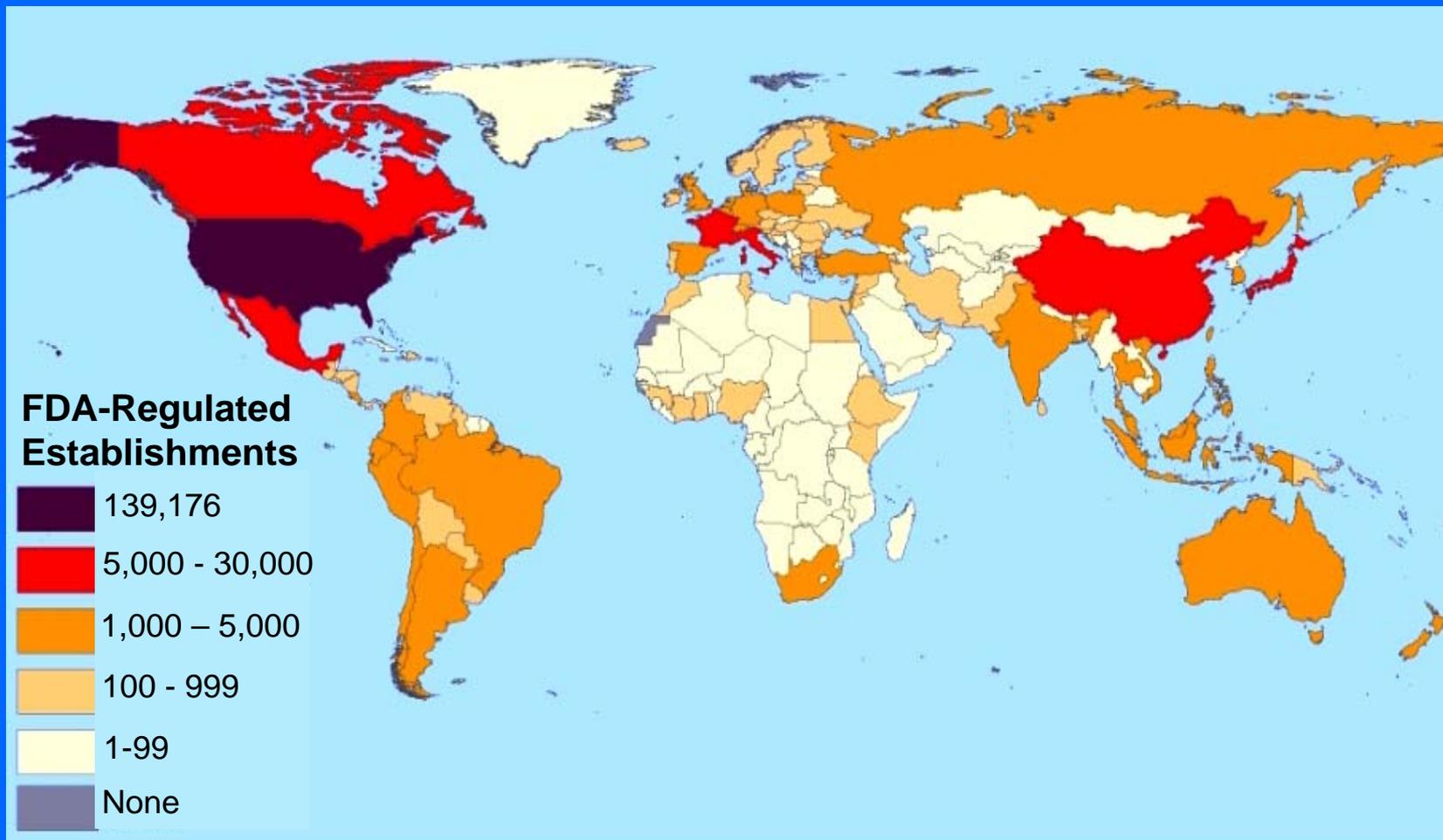
- Advertising (except prescription drugs and devices) (FTC)
- Alcohol (ATF) (some joint regulation)
- Consumer Products (e.g. household goods, toys) (CPSC)
- Drugs of Abuse (controlled substances) (DEA)
- Health Insurance (Medicare/Medicaid) (CMS)
- Meat and Poultry (USDA)
- Pesticides (EPA establishes tolerance levels; USDA and FDA enforce)
- Water (EPA develops standards, FDA regulates labeling and safety)

Domestic Industry is Extensive

Establishments under FDA's Regulatory Authority (as of 2/3/2010)



FDA covers over 300,000 Establishments in More Than 230 Countries

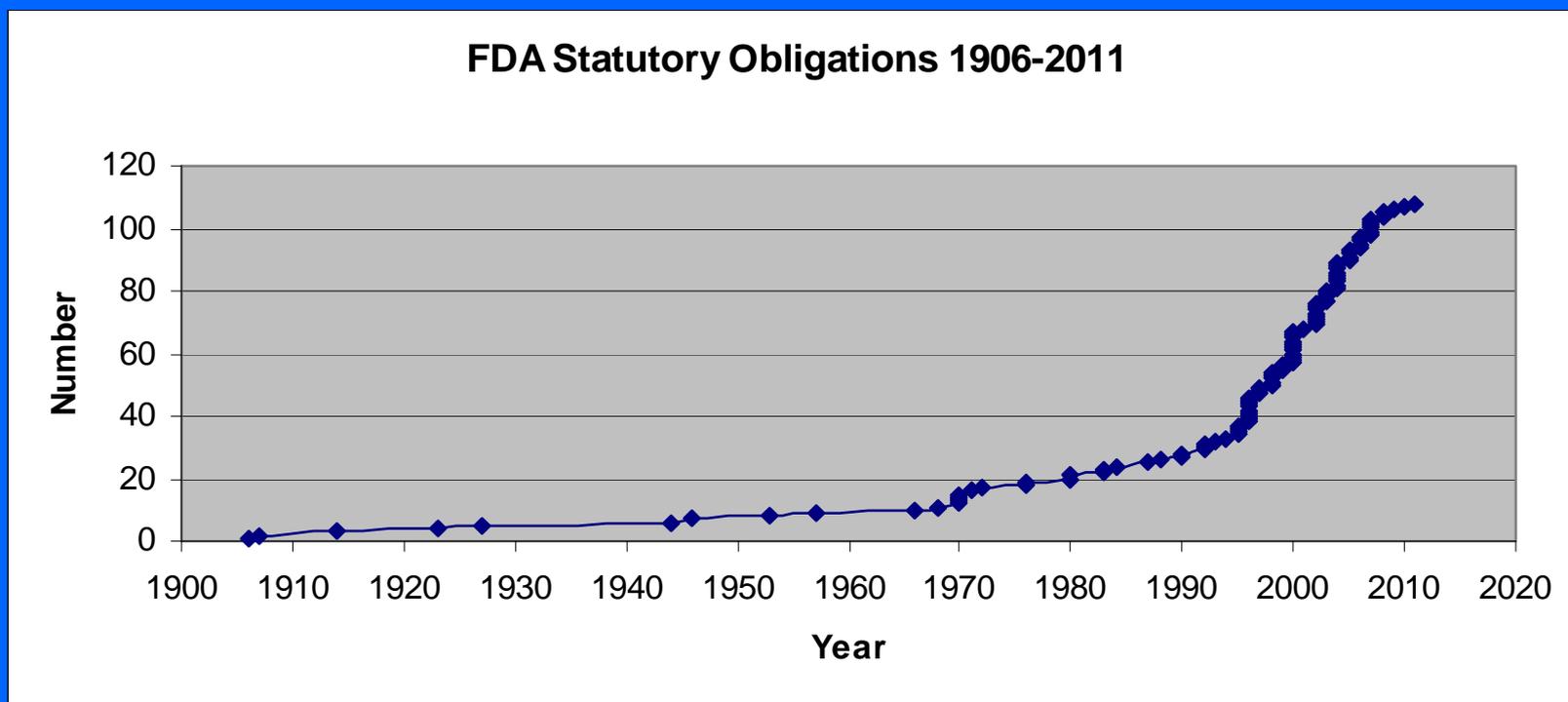




Regulatory Science

- **Regulatory science** is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.
- FDA's challenge: apply advances and innovations in regulatory science to particular agency actions and articulate our regulatory stance for regulated parties as we ensure our actions are for the benefit of the public health.
 - **Existing (and non-existing) regulations:** adapting to considering new scientific methods may mean new rulemaking.
 - **Guidances:** implementation recommendations and clarifying statutory provisions are useful for new science.
 - **Statutory Enactments:** often require science-based practices, and may need rulemaking, guidance, and/or analysis/support.
 - **Reports/Reviews of FDA practices:** including Institute of Medicine, Government Accountability Office, Office of Inspector General, Congressional Oversight Reports

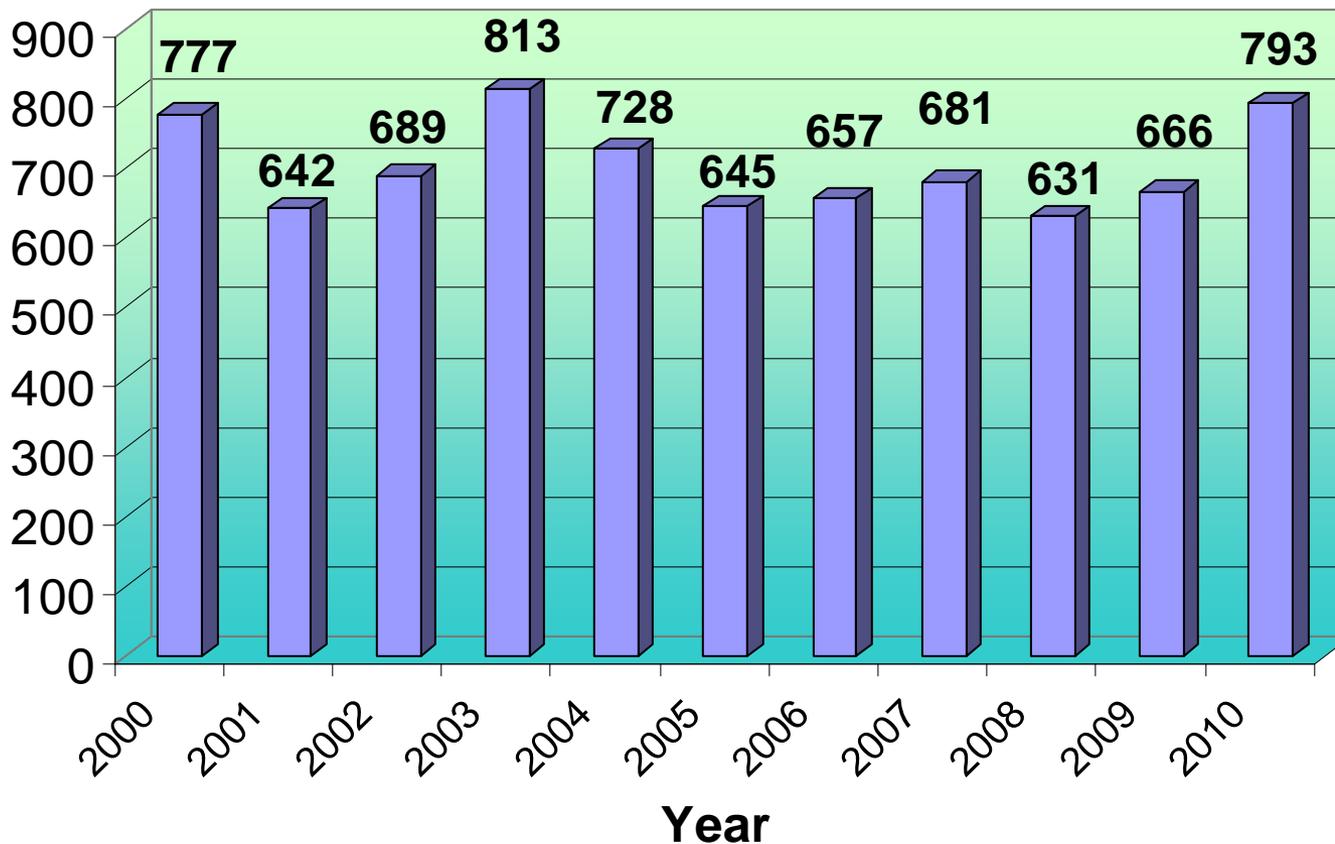
FDA Statutory Obligations



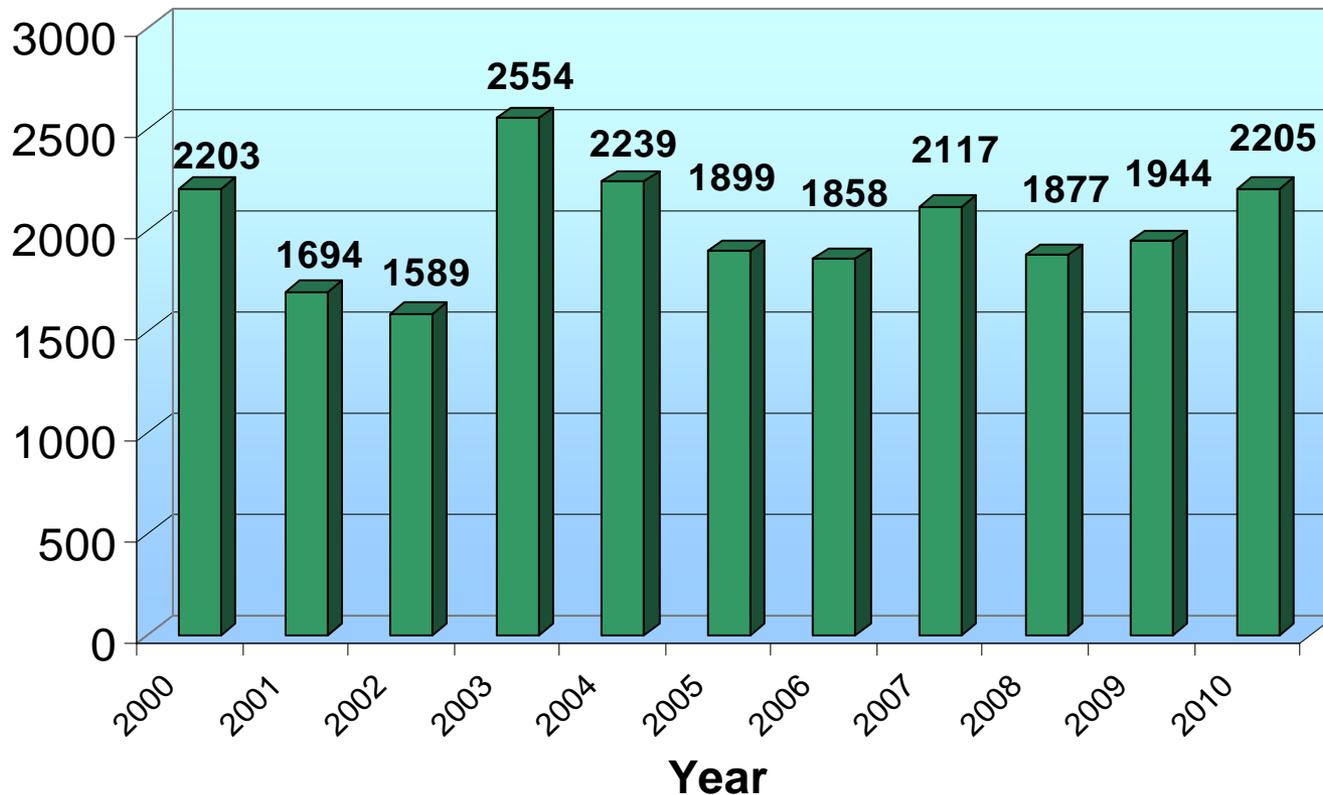


- 1906 - Federal Food and Drugs Act (repealed 1938)
- 1907 - Meat Inspection Act
- 1914 - Federal Trade Commission Act
- 1923 - Filled Milk Act
- 1927 - Import Milk Act
- 1944 - Public Health Service Act
- 1946 - Trademark Act of 1946
- 1953 - Reorganization Plan 1
- 1957 - Poultry Products Inspection Act
- 1966 - Fair Packaging and Labeling Act
- 1968 - Radiation Control for Health & Safety Act
- 1970 - National Environmental Policy Act
- 1970 - Controlled Substances Act
- 1970 - Controlled Substances Import and Export Act
- 1970 - Egg Products Inspection Act
- 1971 - Lead-Based Paint Poisoning Prevention Act
- 1972 - Federal Advisory Committee Act
- 1976 - Government in the Sunshine Act
- 1976 - Food, Drug and Cosmetic Act (FD&C)
- 1980 - Infant Formula Act
- 1980 - Government Patent Policy Act of 1980
- 1983 - Federal Anti-Tampering Act
- 1983 - Orphan Drug Act
- 1984 - Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act)
- 1987 - Prescription Drug Marketing Act (PDMA)
- 1988 - Generic Animal Drug and Patent Term Restoration Act
- 1990 - Safe Medical Devices Act (SMDA)
- 1990 - Nutritional and Educational Labeling Act (NLEA)
- 1992 - Mammography Quality Standards Act (MQSA)
- 1992 - Medical Device Amendments
- 1992 - Prescription Drug User Fee Act
- 1993 - NLEA regulations
- 1994 - Animal Medicinal Drug Use Clarification Act
- 1994 - Dietary Supplement Health and Education Act
- 1995 - Federal Reports Elimination and Sunset Act
- 1995 - Unfunded Mandates Reform Act
- 1995 - The Paperwork Reduction Act
- 1996 - Freedom of Information Act (FOIA)
- 1996 - Safe Drinking Water Act Amendments
- 1996 - Animal Drug Availability Act
- 1996 - Food Quality Protection Act
- 1996 - Economic Espionage Act of 1996
- 1996 - Electronic Freedom of Information Improvement Act
- 1996 - Comprehensive Methamphetamine Control Act
- 1996 - Health Insurance Portability and Accountability Act (HIPAA)
- 1996 - Drug-Induced Rape Prevention Punishment Act
- 1997 - Food & Drug Administration Modernization Act (FDAMA)
- Better Pharmaceuticals for Children Act
- PDUFA II
- 1998 - Antimicrobial Regulation Technical Corrections Act
- 1998 - Sec. 615 Ag. Research, Extension and Education Reform Act
- 1998 - MQSA Reauthorization
- 1998 - Sec. 654, Omnibus Approps. (Family Impact Assessments)
- 1998 - Seafood HACCP Regulation
- 1999 - Government Employees Training Act
- 1999 - Fed. Financial Assistance Management Improvement Act
- 2000 - Responsible for Clinical Laboratory Improvement Amendments (CLIA)
- 2000 - Approps Act (FDA) - FY 2001
- Medicine Equity and Drug Safety Act
- Prescription Drug Import Fairness Act
- 2000 - Approps. Act (HHS)
- Sec. 516, HPV-Condom Labeling Review
- 2000 - Ryan White AIDS Care Act
- 2000 - Date Rape Drug Prohibition Act
- 2000 - Children's Health Act
- 2000 - Technology Transfer Commercialization Act
- 2002 - Farm Security & Rural Investment Act
- 2002 - Bioterrorism Act
- PDUFA III
- 2002 - Best Pharmaceuticals for Children Act
- 2002 - Rare Diseases – Orphan Product Development
- 2002 - E-Government Act
- 2003 - Mosquito Abatement for Safety and Health Act
- 2003 - Animal Drug User Fee Act
- 2003 - Pediatric Research Equity Act (PREA)
- 2003 - Medicare Prescription Drug and Modernization Act
- 2004 - Minor Use and Minor Species Animal Health Act
- 2004 - Food Allergen Labeling and Consumer Protection Act
- 2004 - Medical Devices Technical Corrections Act
- 2004 - National Defense Authorization Act
- 2004 - AIDS (PEPFAR)
- 2004 - Project BioShield
- 2004 - Anabolic Steroid Control Act
- 2004 - MQSA Reauthorization
- 2004 - Homeland Security Presidential Directive (HSPD) #12, Identification Standard
- 2005 - Protecting America in the War on Terror Act
- 2005 - Patient Safety & Quality Improvement Act
- 2005 - Medical Device User Fee Stabilization Act (MDUFSA)
- 2005 - Stem Cell Therapeutic and Research Act
- 2006 - Combat Meth Act
- 2006 - Labeling of trans fatty acids
- 2006 - Pandemic and All-Hazards Preparedness Act
- 2006 - Dietary Supplement and Nonprescription Drug Consumer Protection Act
- 2007 - Prescription Drug User Fee Amendments
- 2007 - Medical Device User Fee Amendments
- 2007 - Pediatric Medical Device Safety and Improvement Act
- 2007 - Pediatric Research Equity Act
- 2007 - Best Pharmaceuticals for Children Act
- 2007 - Food and Drug Administration Amendments Act
- 2008 - Animal Drug User Fee Amendments
- 2008 - Animal Generic Drug User Fee Act
- 2009 - Family Smoking Prevention and Tobacco Control Act
- 2010 - Patient Protection and Affordable Care Act
- 2011 - Food Safety Modernization Act

FDA Documents Published 2000 - 2010



FDA Published Pages 2000 - 2010





Regulations and Other Federal Register Documents Published 2010

Updated as of December 31, 2010

	CBER	CDER	CDRH	CFSAN	CTP	CVM	OC	ORA	NCTR	Total
Final Rules*	0	4	10	6	2	58	6	0	0	86
Direct Final Rules:			2		1	2				5
Final Rules:		4	8	6	1	56	6			81
Interim Final Rules:										0
Tentative Final Rules:										0
Proposed Rules	1	2	6	4	3	4	1	0	0	21
Proposed Rules:	1	2	6	3	2	3				17
ANPRMs:				1	1	1	1			4
Notices**	18	128	62	34	17	28	379	20	0	686
FDAAA of 2007	0	0	0	0	0	0	0	0	0	0
Number of Published Federal Register Documents:	19	134	78	44	22	90	386	20	0	793
Number of Published Federal Register Pages:	45	363	236	155	99	154	1118	35	0	2,205

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* Includes New Animal Drug Application approvals and Medical Device reclassifications.

** Includes all types of FR Notices (i.e., advisory committee meeting notices, public workshops, paperwork notices, notices of availability, etc...)

Regulations and Other Federal Register Documents Published 2011

Updated as of August 31, 2011

	CBER	CDER	CDRH	CFSAN	CTP	CVM	OF	OC	ORA	NCTR	Total
Final Rules*	2	4	14	7	3	28	2	4	0	0	64
Direct Final Rules:					1	1					2
Final Rules:	2	4	14	7	2	27		4			60
Interim Final Rules:							2				2
Tentative Final Rules:											0
Proposed Rules	1	5	7	7	2	0	0	1	0	0	23
Proposed Rules:	1	4	7	7	2			1			22
ANPRMs:		1									1
Notices**	13	87	59	14	8	14	6	280	20		501
FDAAA of 2007								1			1
Number of Published Federal Register Documents:	16	96	80	28	13	42	8	286	20	0	589
Number of Published Federal Register Pages:	39	298	218	170	200	69	29	668	35	0	1,726

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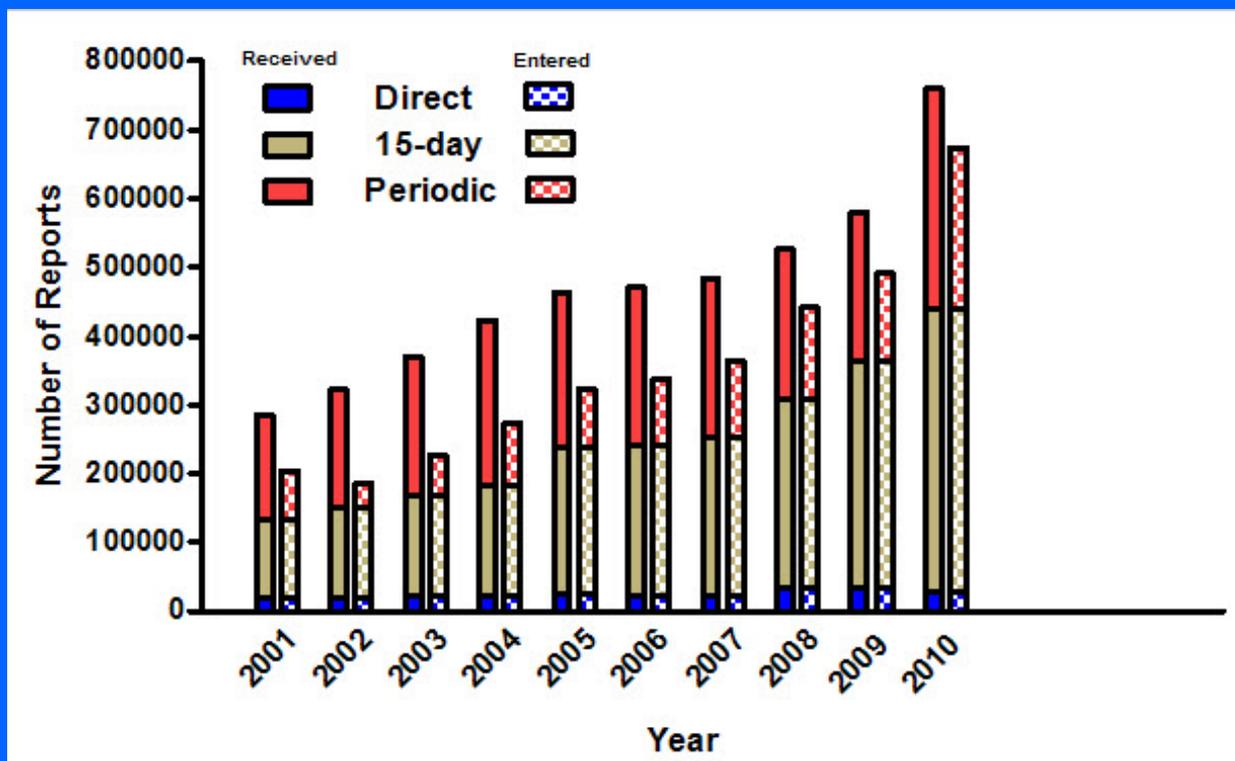


Major Issues Confronting FDA

- Medical Product Safety
- Medical Product Review & Innovation
- Food/Feed Safety
- Import Safety
- Regulation of Tobacco Products

Medical Products Safety

Serious Adverse Drug Event Reports to FDA Grew Almost 80% Between 2000 and 2010





Approved Risk Evaluation and Mitigation Strategies (REMS)

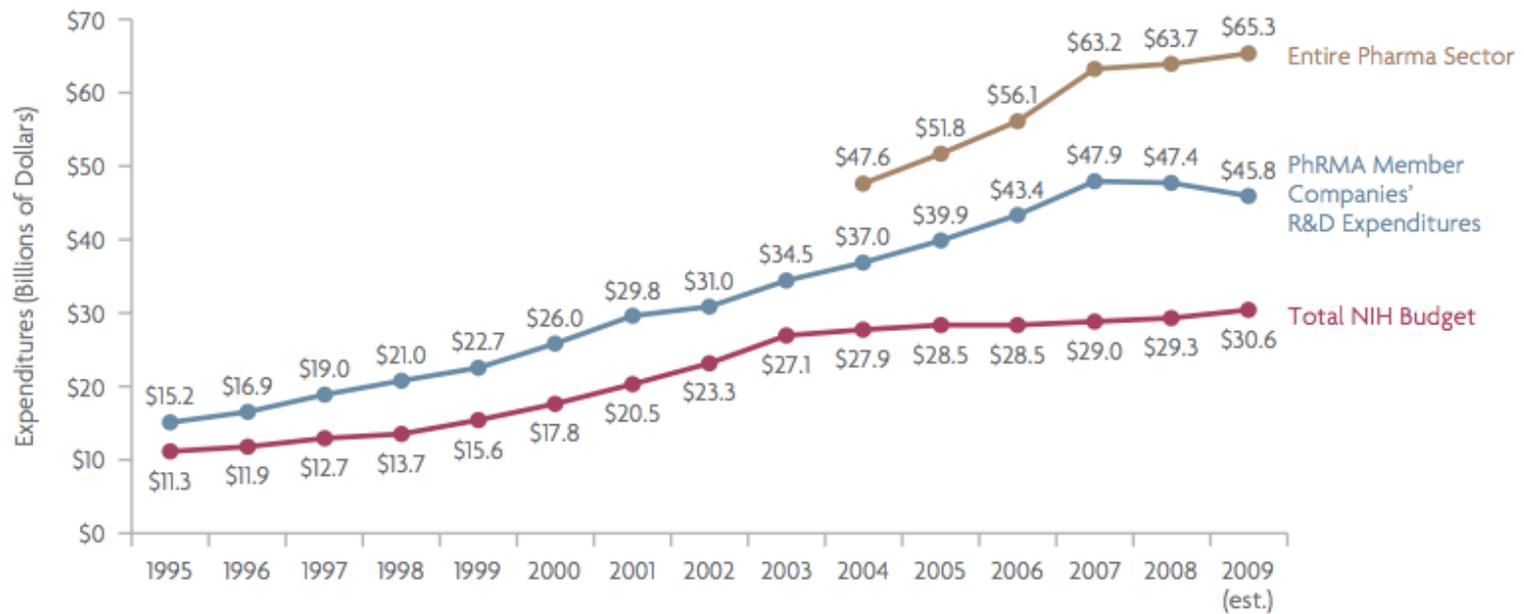
- For most approved products, labeling and routine reporting requirements are sufficient, but some products require additional measures to ensure risks are mitigated and benefits are preserved.
- FDAAA gave FDA the authority to require a REMS from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.
- All REMS must include a timetable for submission of assessments of REMS. Other REMS components may include: medication guides (21 CFR 208), patient package inserts, communication plans to health care providers, elements to ensure safe use, and/or an implementation system.
- ~114 drugs/biological products currently have approved REMS



The Sentinel Initiative

- Launched on May 22, 2008
- Goal is to create and implement a national, integrated, electronic system for monitoring medical product safety.
- Enables FDA to query multiple, existing data sources for information about medical products.
- Strengthens FDA's ability to monitor a product throughout its life cycle enhancing the protection and promotion of public health.
- Achieved with minimal transfer of data to ensure the protection of patient information.
- FDA's pilot program, "Mini-Sentinel," is up and running, with data about 99 million individuals, 2.9 billion prescription drug dispensings, and 2.4 billion unique medical encounters.
- <http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm>

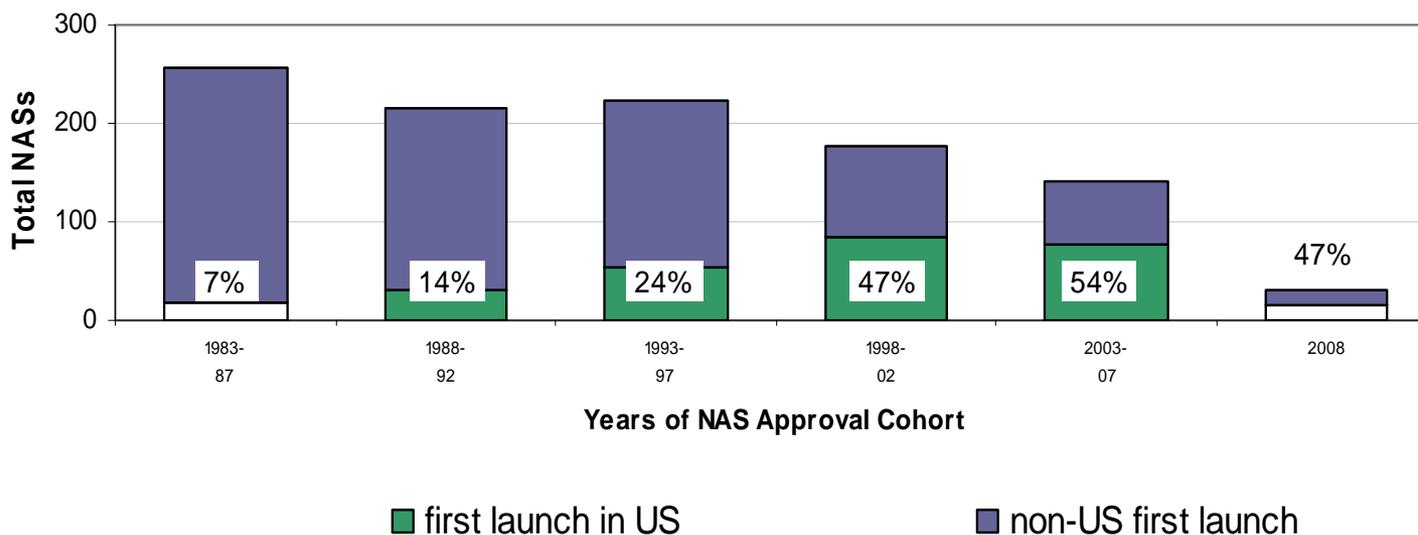
Private and Public R&D Spending



Source: Burrill & Company, PhRMA, NIH Office of Budget¹⁰

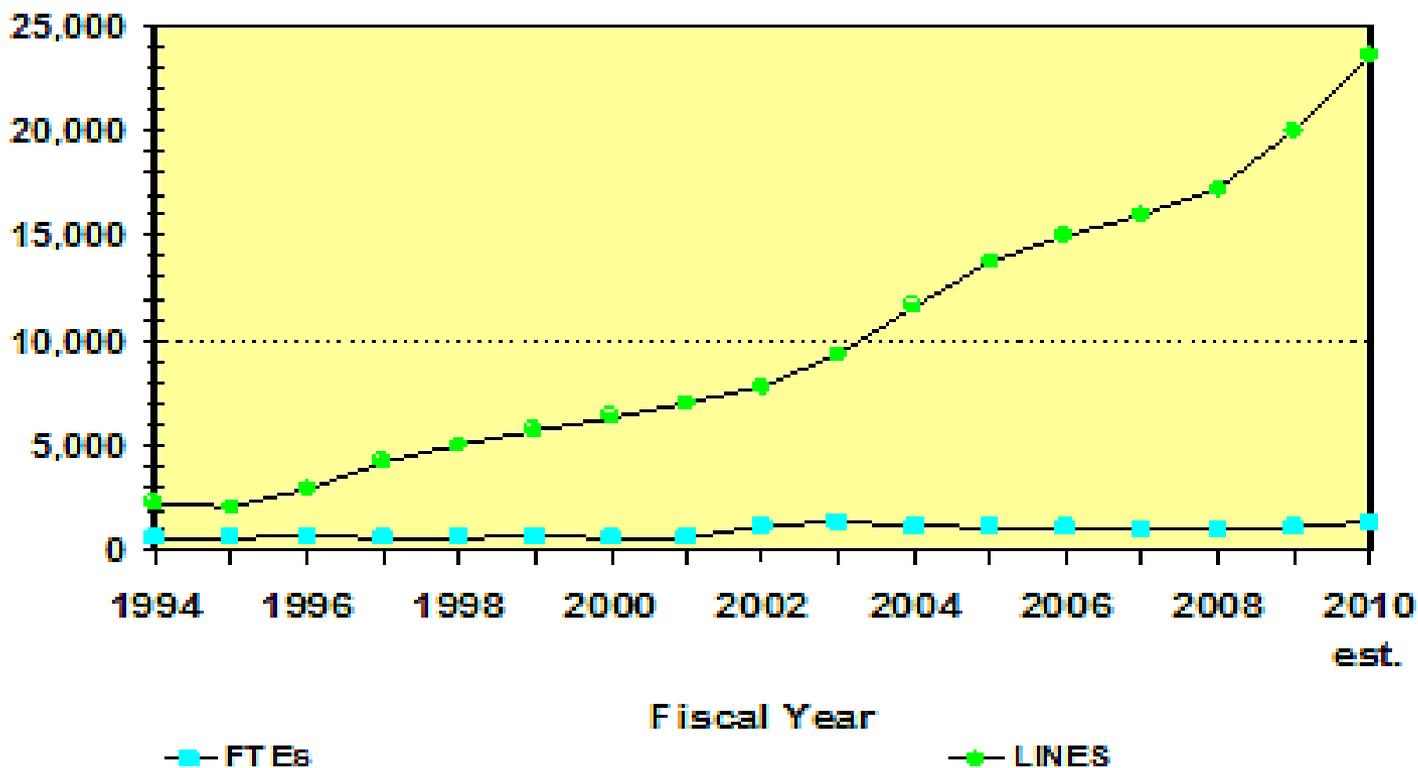
New Approvals Launched World-wide

US Share of NASs First on World Market
(US% in bars)



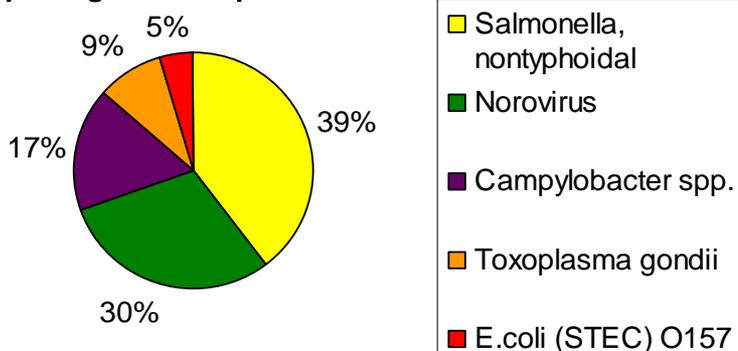
Personnel Vs. Line Entries

Import Volume History vs. Import FTE History (FTE include Foreign Inspections)

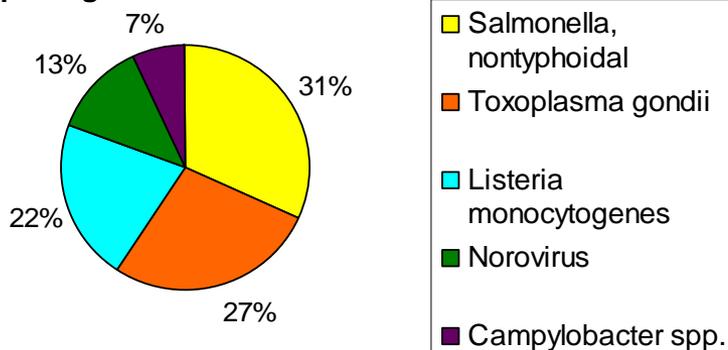


Foodborne Disease Burden Estimates

Top 5 pathogens - hospitalizations



Top 5 pathogens - deaths

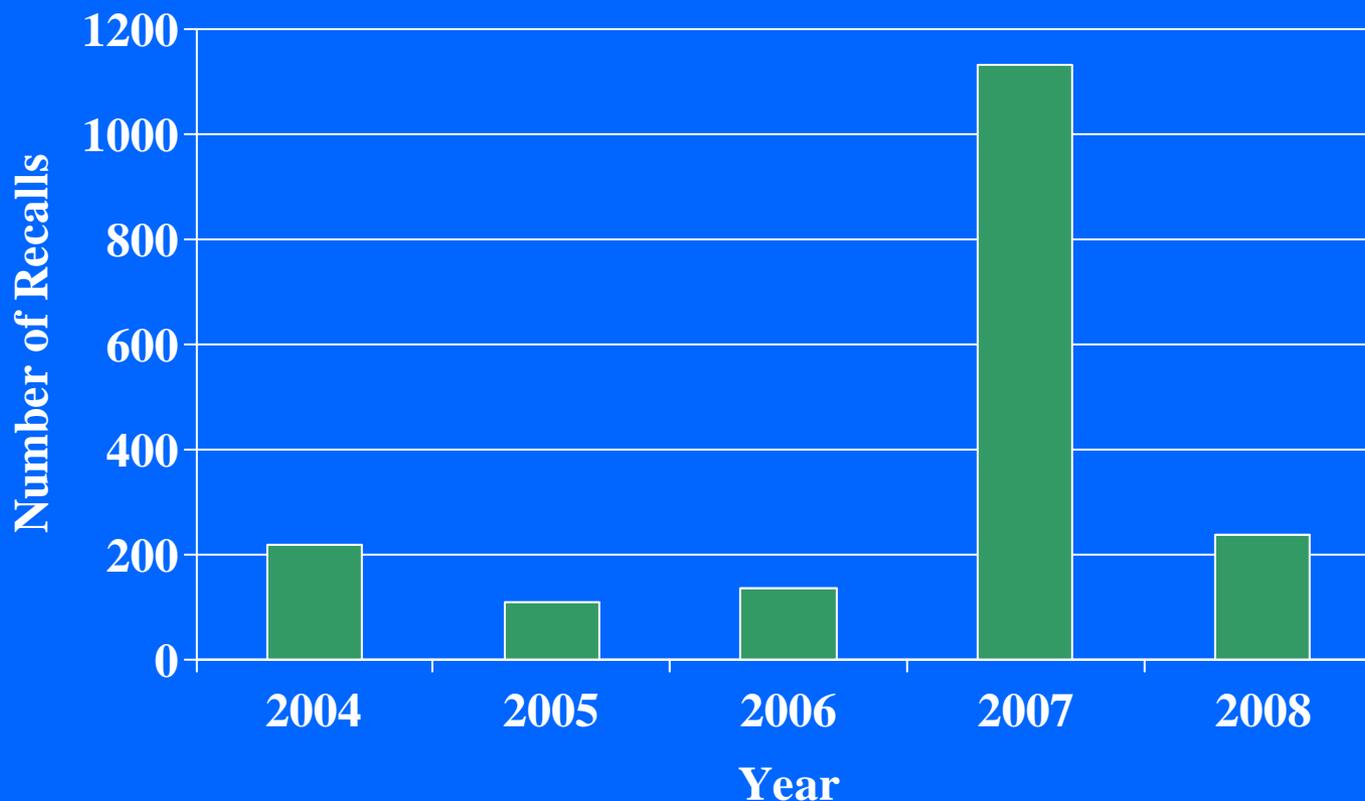


~48 Million sickened; 128,000 hospitalized; 3,000 die each year (CDC estimates from 2011)

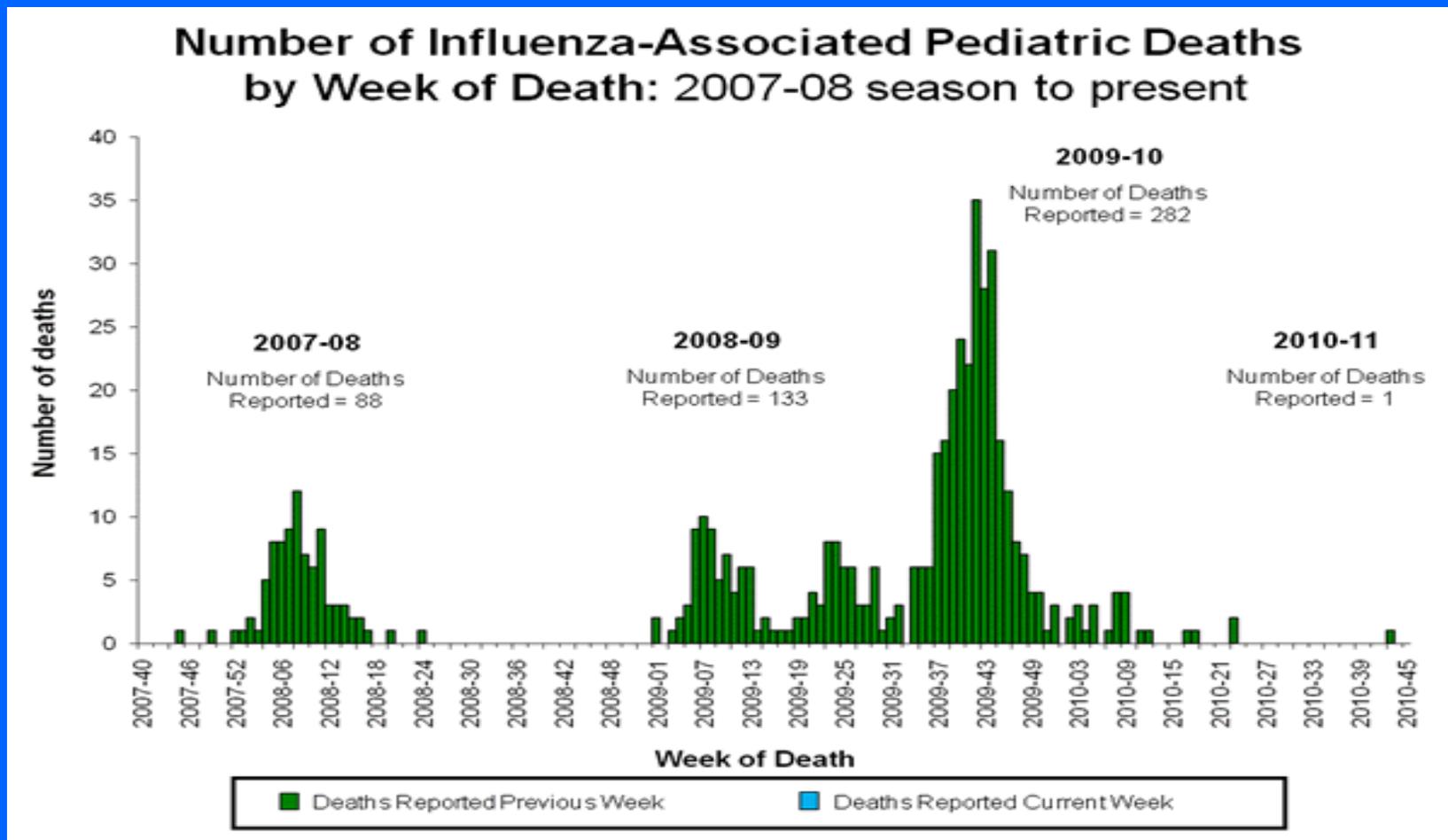
1 in 6 Americans each year gets sick by consuming contaminated foods or beverages

31 known pathogens cause 20% of foodborne illnesses; unspecified agents cause the remaining 80%

Number of Pet Food Recalls before and after Enactment of FDAAA in 2007



Impact of Swine Flu on Children



Overall Flu Statistics

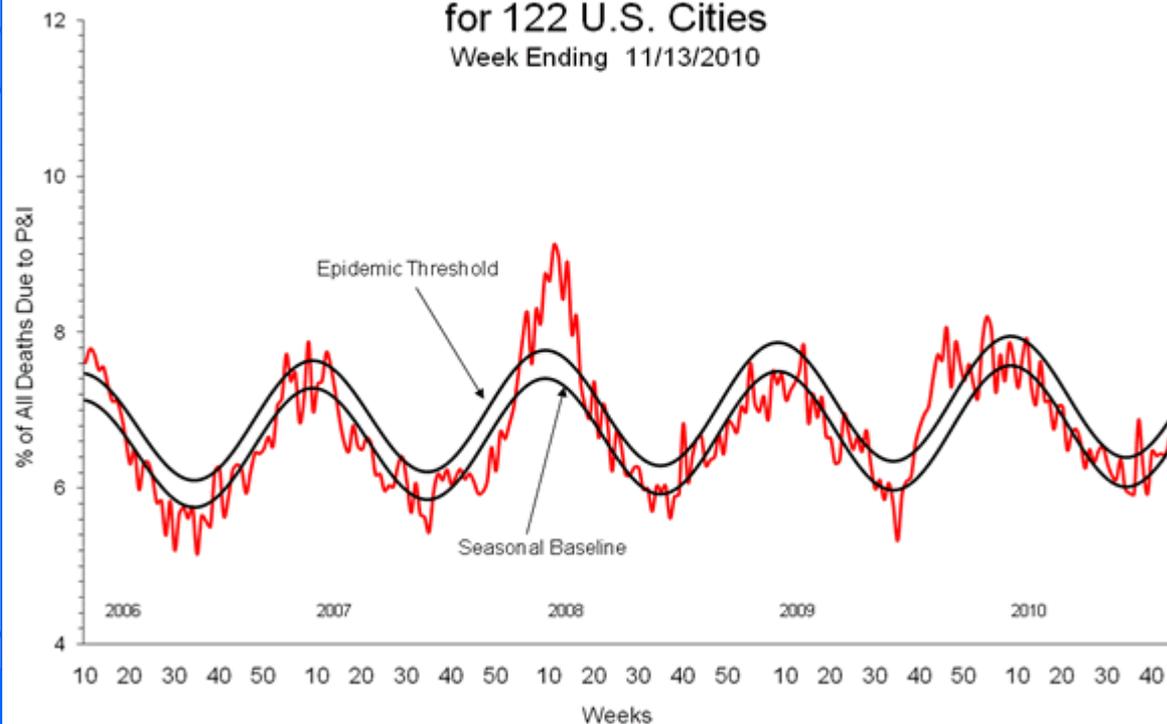
Flu Virus Type/Subtype by Region, 2008–09

Region	A(H1)	A(H3)	B
New England	65.73	11.17	23.09
Mid-Atlantic	68.34	6.46	25.2
East North Central	69.55	5.9	24.55
West North Central	81.48	3.06	15.46
South Atlantic	66.61	5.26	28.12
East South Central	69.34	2.93	27.73
West South Central	66.04	4.62	29.35
Mountain	60.46	30.85	8.7
Pacific	75.29	8.02	16.68
United States	68.25	7.36	24.39

Pneumonia and Influenza Mortality

for 122 U.S. Cities

Week Ending 11/13/2010



Tobacco Use in the United States

- Leading preventable cause of death in the United States
- Approximately 443,000 deaths yearly from smoking and exposure to second-hand smoke
- An estimated 8.6 million smokers have at least one serious illness due to smoking
- Smokers die 13-14 years earlier than nonsmokers
- An annual \$193 billion in lost productivity and medical costs is attributed to tobacco use





Regulating Tobacco Products

- On June 22, 2009, FDA was given the authority to regulate tobacco products with the signing of the Family Smoking Prevention and Tobacco Control Act, and the FDA Center for Tobacco Products was established.
- FDA has made advances in tobacco product regulation since the Tobacco Control Act was passed:
 - 2009 - banning flavored cigarettes
 - 2010 - restricting youth access to tobacco products, banning misleading advertising claims to communicate products are not safer, and establishing new smokeless tobacco warnings to advertise health risks
 - 2011 - issuing new cigarette health warnings to highlight product dangers.

