Presentation to the American Spice Trade Association

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Alliance for a Stronger FDA
180 Members and Growing

The Alliance for a Stronger FDA:

- comprised of 180 members,
- unites a broad base of patient groups, consumer advocates, biomedical researchers, health professionals and industry to work to increase FDA‘s appropriations.

It is supported by leading public health advocates, including three former HHS Secretaries and seven former FDA Commissioners.

The Food and Drug Administration

- Promotes and protects the public health by ensuring consumers have access to safe foods and safe and effective medical products, including drugs, biologics and medical devices.
- It is one of the world‘s most admired consumer protection agencies and is widely respected for its leadership in science-based regulation.
- FDA-regulated products account for almost 25 cents of every consumer dollar spent in the United States.

FDA Budget Basics

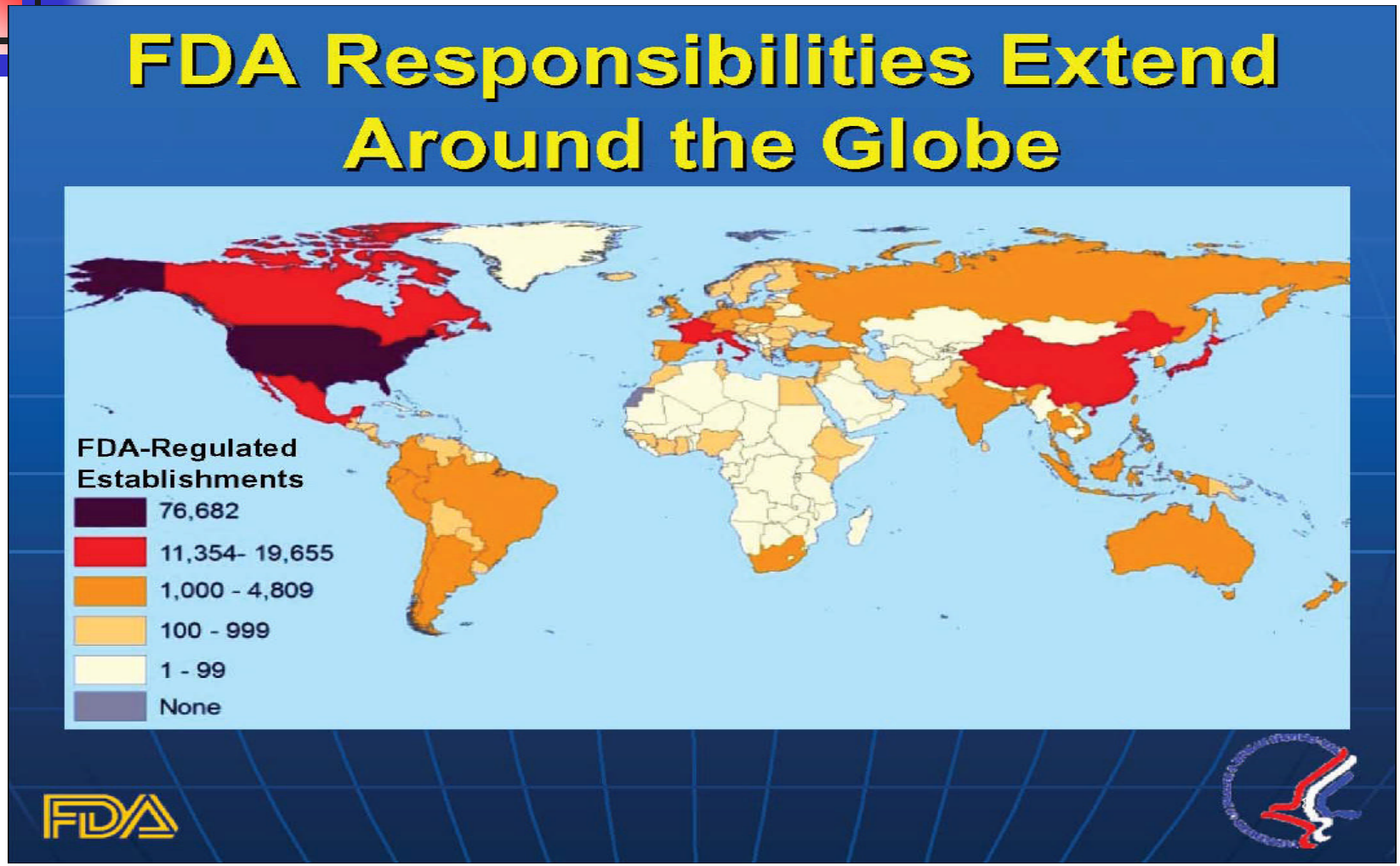
- FDA's budget is relatively small: $1.7B appropriated; $550M in user fees
- 83% of FDA costs are staff-related: salary, benefits, rent, supplies, telecom, travel, etc.
- FDA's appropriation must increase about $100 million per year to "stay even" with increased costs (anything less results in decreased staff and programming)
- New responsibilities, increased scientific complexity, globalization grow, while FDA's base erodes

FDA Receives Less Funding than its Local School District

	FY07CR	FY08	FY09
Montgomery County (MD) Public Schools	**$1.85B**	**$1.98B**	**$2.07B**
FDA (appropriated funds)	**$1.57B**	**$1.72B**	**$1.86B**

http://montgomeryschoolsmd.org/about
Alliance for a Stronger FDA—September 2008 www.StrengthenFDA.org

...Yet It's Reach is Global



The Problem

- Diminished resources in the face of increasing workload and new responsibilities
- Declining public confidence
- Erosion in public health protection
- Slowed innovation @ patient expense
- Competitive disadvantage in world economy

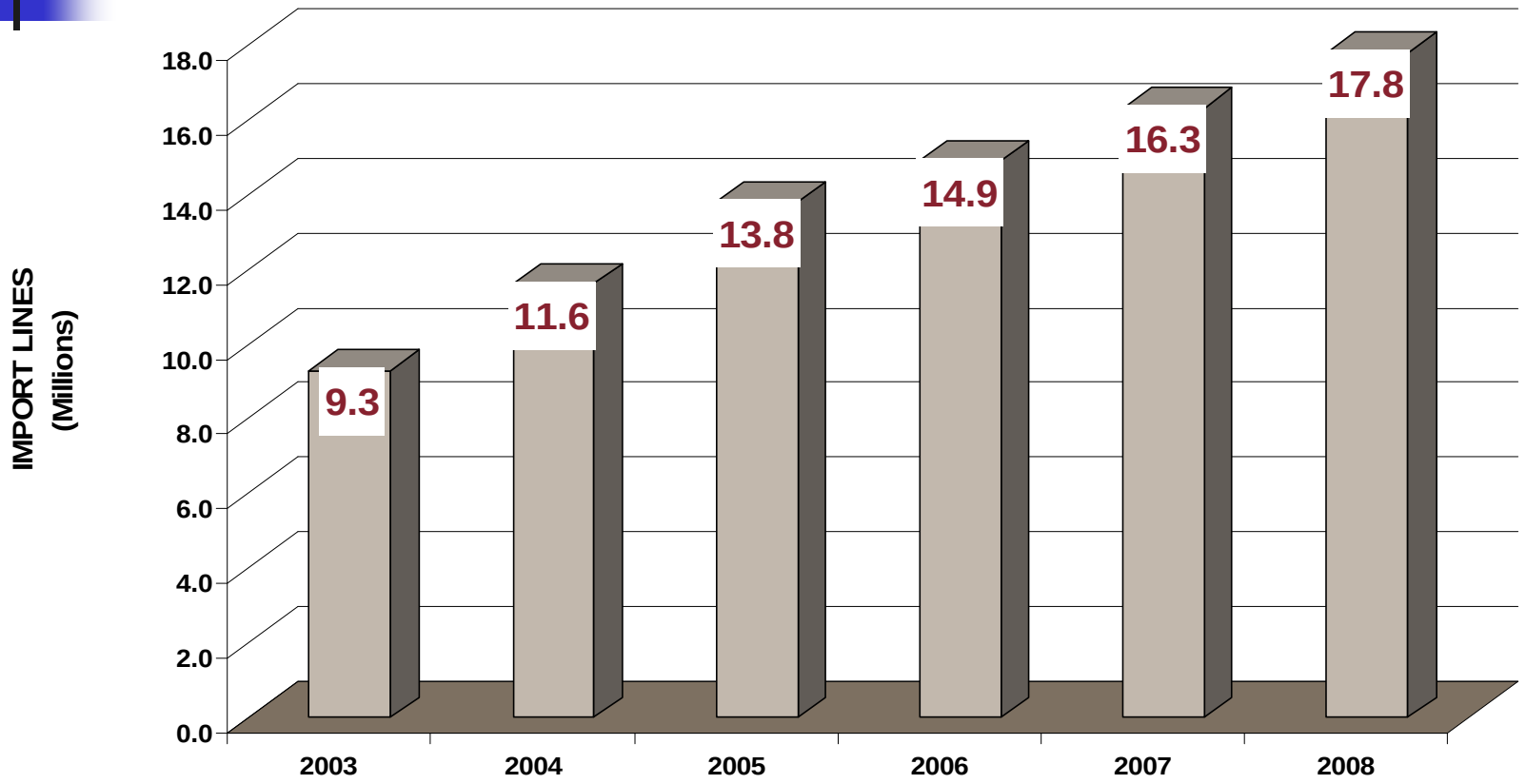
Widespread Awareness of Critical Deficiencies

- The Institute of Medicine, GAO, and FDA Science Board have highlighted deficiencies in the FDA's ability to carry out its responsibilities.
- The Science Board report (December 2007) is particularly clear that the fundamental source of problems is chronic underfunding.
- No systemic improvement is likely without resources to: increase food science and inspection capacity, further fund drug and device approval and safety monitoring, and upgrade critical information technology systems.

Congress Keeps Adding Responsibilities,1996-2006

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)
1997 - Better Pharmaceuticals for Children Act
1997 - PDUFA II
(Family Impact Assessments)
1998 - Antimicrobial Regulation Technical Corrections Act
1998 - Sec. 615 Ag. Research, Extension and Education Reform Act
1998 - MQSA Reauthorization
1998 - Sec. 654, Omnibus Approps
.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
2000 - Medicine Equity and Drug Safety Act
2000 - 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
2001 - Animal Disease Risk 2002 - Medical Device User Fee and Modernization Act (MDUFMA)
2002 - Hatch-Waxman-Amendments
2002 - Drug Importation Report
2002 - Farm Security & Rural Investment Act
2002 - Bioterrorism Act
2002 - 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 Ac
2005 - Stem Cell Therapeutic and Research Act
2006 - Combat Meth Act

Total Import Volume of FDA Regulated Products



The number of line entries is a measure of the number of places from which products are flowing into the US, and it indicates the relative volume of imported products that are subject to FDA regulation.

The Solution

- Strengthen FDA‘s ability to operate a modern, scientifically-based regulatory program
- Provide resources to rebuild the infrastructure and assure the safety of foods and cosmetics and the safety and efficacy of drugs and medical devices.

What Would New Resources Accomplish?

- Foods
  - Address gaps in food safety oversight with enhancements in inspection, auditing, and compliance
  - Promote health and wellness
  - Speed approvals for safe new products and technologies for food
  - Enhance scientific and policy programs, including risk assessment, risk management, and analysis
  - Promote globalization through harmonized, science-based food standards
  - Provide leadership in food defense

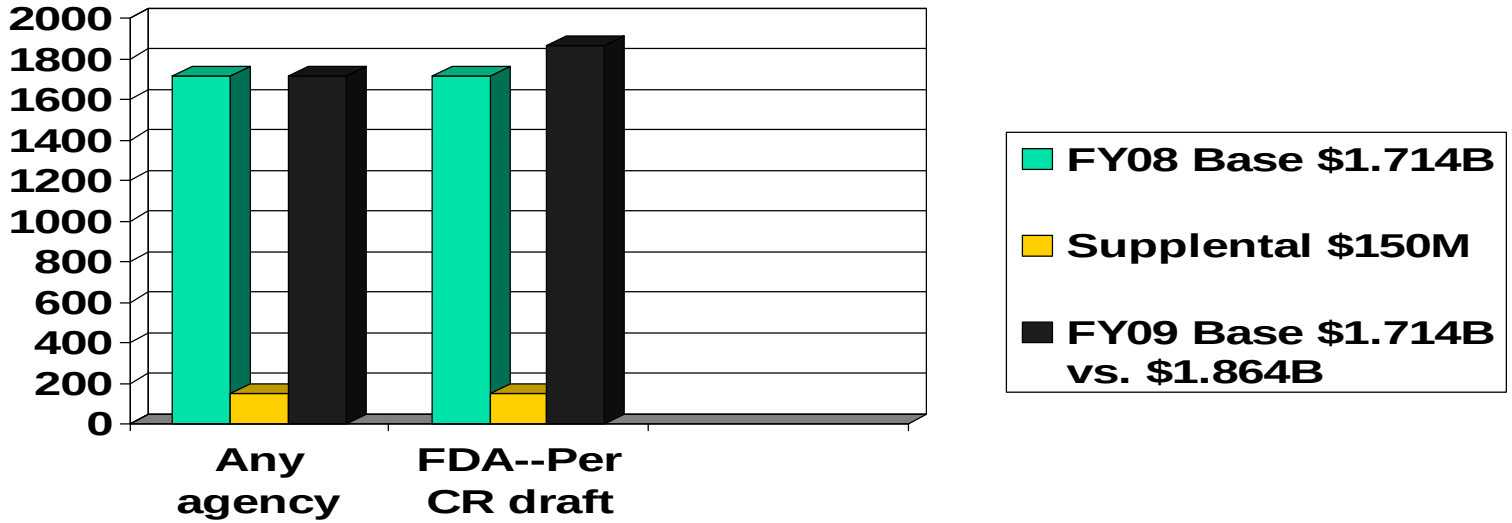
Imports – The Need

- New paradigm
- Shift responsibility from FDA border inspection to prevention
- Responsibility/accountability across supply chain
- FDA resources to oversee , inspect foreign countries, develop new technologies

House, Senate, Administration Agree on Needs at FDA

- Administration requested $50M increase for FY 2009, then added $275M more after Commissioner provided "professional judgment"
- House S/C recommends $325M, offset by FY 2008 supplemental
- Senate Committee recommends $330M increase
- Unanimity made possible special positioning of FDA in FY 2009 continuing resolution
- Agency gets new funds; almost no others do

FY 2009 CR—
Consequences for FDA



For almost all agencies:
Dec. 2007 omnibus = FY 09 CR base, regardless of supplement

Per CR language for FDA:
Dec. 2007 omnibus + supplemental = FY 09 CR base

Impact of Supplemental on FDA in FY 09 and FY 10

- FDA spent almost none of its $150M supplemental in FY 08 and these funds remain available in FY 08
- FY 09 CR lets FDA spend through March 6, 2009, as if its FY 08 base was $1.864B.
- Assuming straight-line after March 6, 2009, FDA will have $300M to spend in FY 09 ($150M + $150M)
- Challenge for FDA is that only half the monies it spends in FY 09 will be reflected in its base going forward to FY 10.

Working Without a Commissioner

- FDA is extraordinarily complex, every move has worldwide consequences, many unintended
- FDA had acting commissioner for half of Bush Administration...a worrisome trend
- Challenge to identify a new Commissioner, get him/her confirmed quickly, and help them get a team in place
- Six months would be a serious problem; a year without a leadership team could be disastrous
- Not about competency of FDA civil service leadership
- Many decisions can't or won't be made without a permanent, confirmed Commissioner.

A strong FDA benefits all Americans:

Patients, consumers, health professionals, industry

....and the whole world benefits, too.