

# **Report to the Science Board**

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## Vision

Top quality regulatory science will  
improve regulatory decisions,  
regulatory consistency and speed  
the approval of new products

## Science Board Recommendations

- Scientific leadership and investment: partnerships and priorities
- Scientific recruitment and retention
- IT infrastructure and its scientific integration

## Three principles which guide scientific strategy

- Principle #1: The FDA cannot do it alone - the FDA should partner more and smarter.
- Principle #2: FDA must enhance its core scientific expertise
- Principle #3: The FDA scientific strategy must be preemptive

## Task 1: Develop Science Strategy:

### Overview

- Identify overarching scientific vision and priorities for the agency.
- Identify critical problems and roadblocks to achieve these priorities, develop hypothesis driven research to solve these problems.
- Identify timetables, deliverables, and budgets.

## Task 1: Develop Science Strategy:

### Priority areas identified by Centers

- Rapid detection methods
- Biomarkers to predict safety and efficacy
- Adverse event detection
- Innovative clinical trial designs
- Personalized therapies and nutrition
- Understanding microbial contamination
- Technologies in manufacturing science

## Task 1: Develop Science Strategy: Projects in priority areas

Rapid detection	<input type="checkbox"/>	
Biomarkers	<input type="checkbox"/>	
AE detection	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Clinical trial design	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> ORA
Personalized therapies & nutrition	<input type="checkbox"/>	<input type="checkbox"/> NCTR
Microbial contamination	<input type="checkbox"/>	<input type="checkbox"/> CFSAN
Manufacturing science	<input type="checkbox"/>	<input type="checkbox"/> CDRH
		<input type="checkbox"/> CBER

## Task 1: Develop Science Strategy: Next Steps

- Assess integration and collaboration among Center priorities.
- Complete the identification of projects that will move forward these scientific priorities.
- Request Science Board review of this scientific plan.

## Task 2: Develop workforce to implement strategy

## Task 2: Develop workforce: Commissioner's fellowship program

- >1000 applicants for 50 slots: physicians, scientists, biomedical engineers, epidemiologists...
- 2 yr program:
  - Hypothesis-driven regulatory science project
  - Curriculum in FDA law and policy, leadership, ethics, biostats, epi, clinical trial design, exposure to science in Centers, risk assessment.

## Task 2: Develop workforce: Commissioner's fellowship program: project examples

- epigenetics in breast cancer—science and regulation
- bacterial virulence factors in food toxicity
- anti-cytokine therapeutics – cytokine signals that affect FDA regulatory decisions
- bioequivalence studies of generic and innovator drugs
- drug and hormone residues in animal tissues
- cardiac electrophysiology and device regulation
- regenerative medicine
- aquacultured fish diseases
- medwatch: risk assessment and communication
- ethical issues in pediatric studies before the FDA

## Task 2: Develop Workforce: Deliver key tools to enable research and career development

- Quarterly FDA wide science symposia: (Nov = bioinformatics; April = nanotech)
- Enhance library capabilities: from ~150 to 2000 through Science Direct
- Fund quarterly distinguished speaker series.
- Establish new Journal of Regulatory Science.
- Establish science writer's symposium.
- Work with Oncology Program to develop career development plan.

Task 3: Insure that IT infrastructure serves the needs of science and scientists

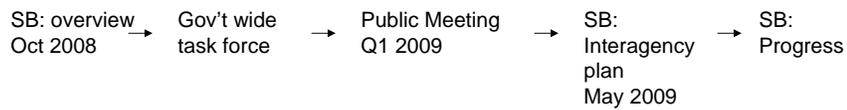
- Report from Dr. Kim that Dr. McNeil will present later this morning.

Task 4: Tackle urgent problems using state of the art scientific approaches

- Rapid detection of *Salmonella*
- The next “melamine” – economically motivated adulteration – economic bioterrorism
- BPA and the Science Board

Task 4: Rapid Detection of Contaminants:  
Scientific Strategy (draft)

**Salmonella Rapid Detection**



**Economically Motivated Adulteration**



FDA in 21th Century: the job of the FDA  
has changed drastically and permanently

- Overseas production of drugs, devices and food.

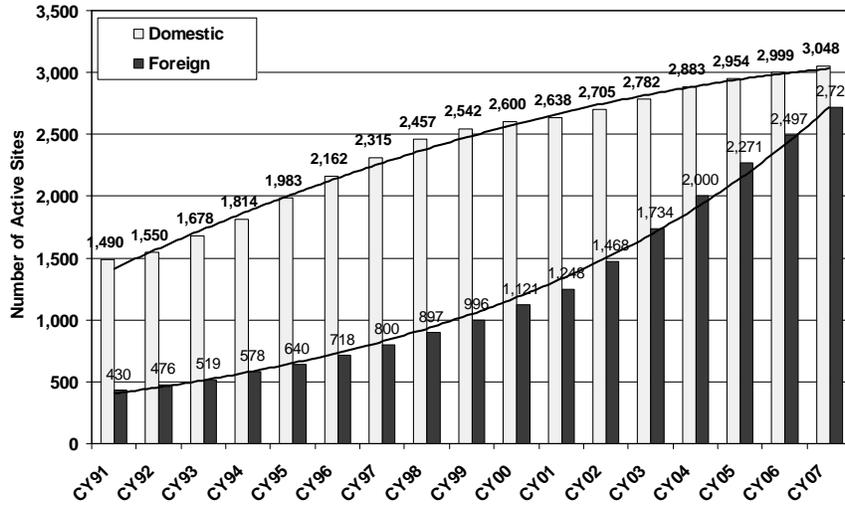
FDA in 21th Century: the job of the FDA has changed drastically and permanently

- Overseas production of drugs, devices and food.
  - Bioterrorism.
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FDA in 21th Century: the job of the FDA has changed drastically and permanently

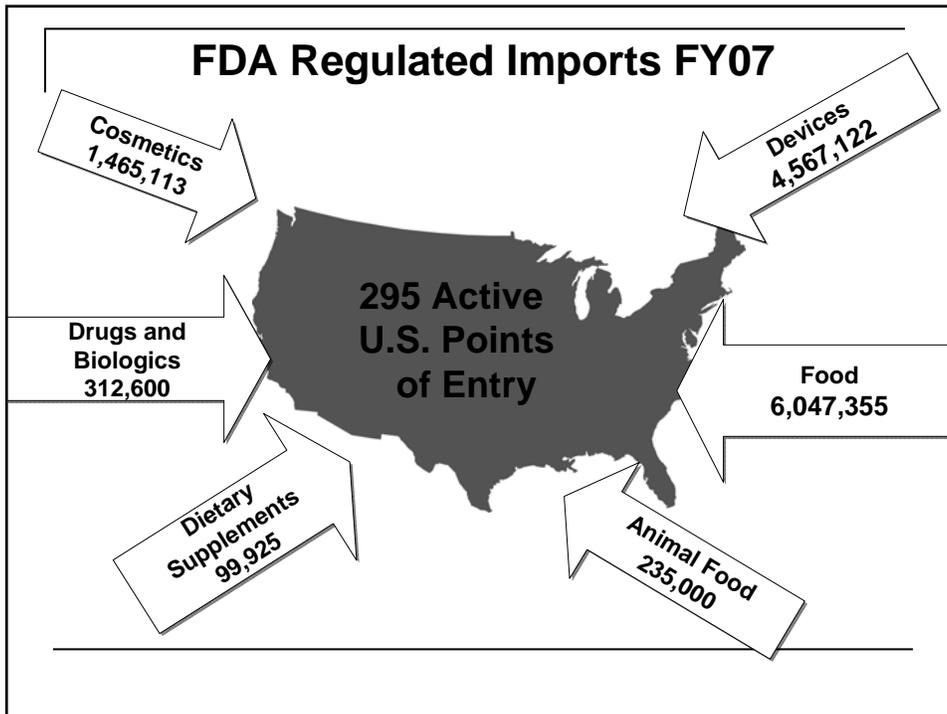
- Overseas production of drugs, devices and food
  - Bioterrorism
  - The rate of change of technology has vastly accelerated.
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### FDA Registered Domestic and Foreign Manufacturing Sites\*



\* Sites active on 5/31/2008 with at least one product listed

### FDA Regulated Imports FY07



How can Regulatory Science contribute to protecting people in the face of increased foreign production of foods and medical products?

- Evaluate entire life cycle of drug, device or food, thereby identifying problems at the source, not at the border. Manufacturing science.
- Algorithms for risk-based assessment /inspection.
- Enhance and make field-ready techniques of rapid identification contaminants.
- Enhance product tracking methodologies - informatics for supply chain.

Final thoughts