Building a National Framework for the Establishment of Regulatory Science for Drug Development

Objectives

- To engage public and policy community in a discussion of regulatory science- challenges and opportunities
- To increase awareness of inadequate funding of regulatory science and the impact upon development of new therapies
- To bring clarity to priorities and strategies going forward

FDA Science and Mission at Risk

Report of the Subcommittee on Science and Technology

Prepared For
FDA Science Board

November 2007

Charge to Science Board

Appoint a Subcommittee to assess whether science and technology at FDA can support current and future core regulatory functions and decision-making

Uniqueness of this Review

- 100th Year Anniversary of FDA
- Unprecedented scientific advances to reduce regulatory uncertainty
- Increasingly complex product reviews based upon scientific advances and globalization
- Increased scrutiny of Agency by all stakeholders
- Unprecedented opportunities to leverage expertise and resource needs with external partners
- Decline in funding in real dollars
- Only the second time Agency has been reviewed as a whole entity
- Committee composition

Demands of FDA have soared.
resources have not!

FDA Impact vs Investment

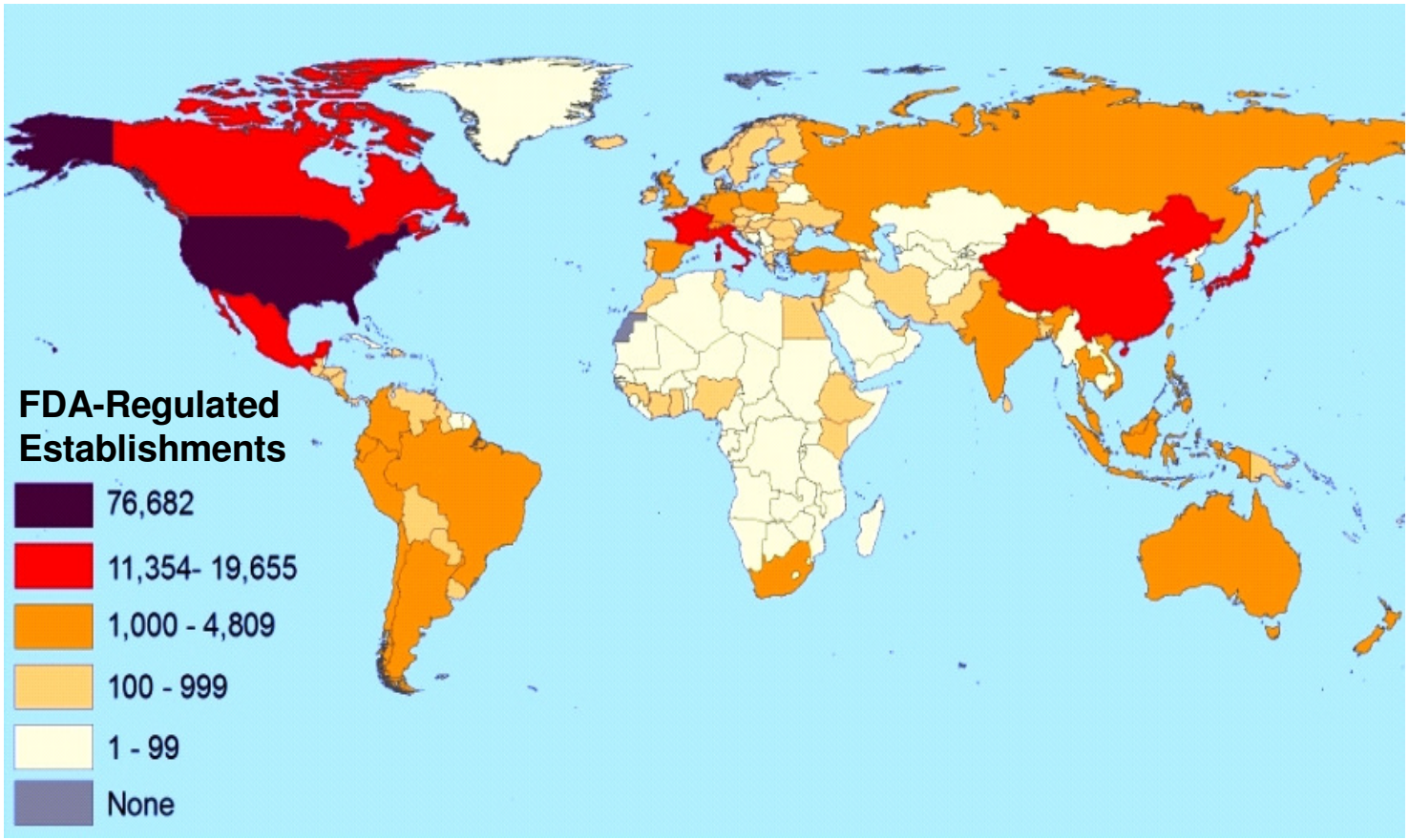
Impact

- **Integral to national economy and security**
- **Regulates $1trillion in consumer products or 25 cents of every consumer $ expended annually in this country**

Investment

- **Appropriated budget for 2007=$1.6 billion (in other words less than the budget for Montgomery County School District)**
- **Each American currently pays ~1 ½ ¢/day**

The Breadth of FDA Responsibilities by Number of Establishments



Source: FDA 10/02/07

Subcommittee Conclusion

Science at the FDA is in a precarious position *("hanging on by its fingernails"):* the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities

Impact of deficiency profound precisely because science is at the heart of everything FDA does!!

(Reprinted) JAMA, January 9/16, 2008-Vol. 299, No.2

History of Agencies in Constant 1999 Dollars ($000)

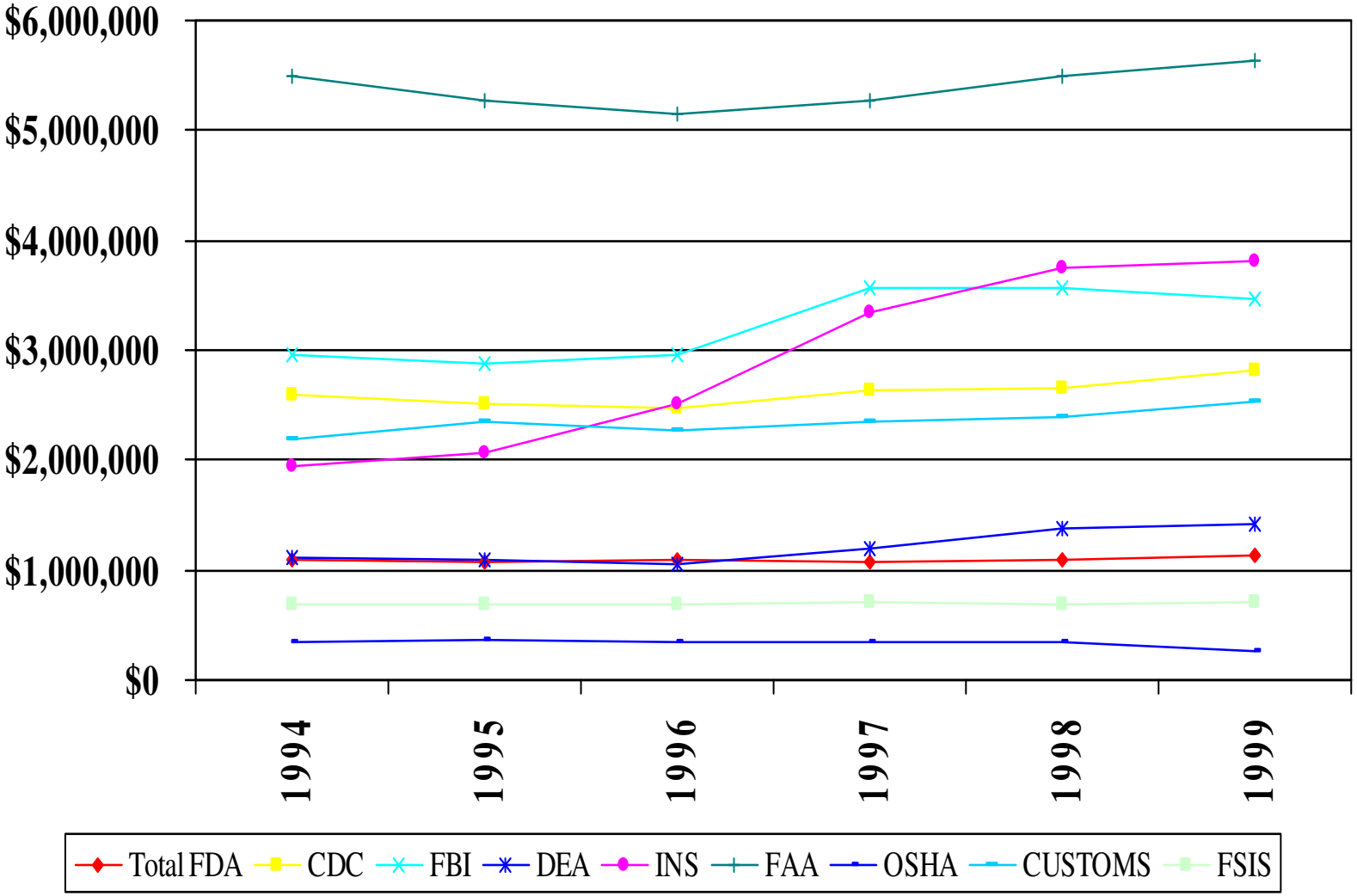
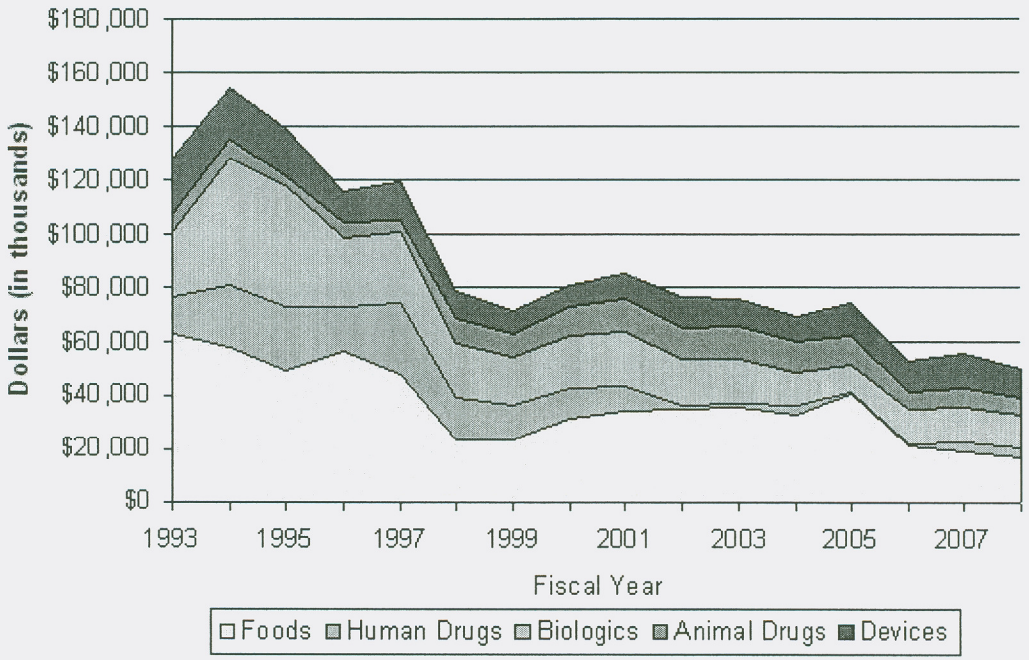


Figure 4. FDA Research in Five Activity Areas (Constant FY2000 $)



Source: RAND Corporation RaDiUS database, November 7, 2007.

Funding the Critical Path Initiative 2006 – 2009*

Fiscal year	Amount
2006	$750,000 (external grant)
2007	$5,940,000
2008	$13,500,000
2009	$6,000,000

*Launched March, 2004 but no funding until 2006.

Major Findings

- **Fire-fighting regulatory posture instead of proactive regulatory science**
- **Unable to keep up with scientific advances (systems biology, wireless healthcare devices, nanotechnology, medical imaging, robotics, cell- and tissue-based products, regenerative medicine, and combination products)**

Major Findings (con'd)

- **FDA cannot fulfill its surveillance mission because of inadequate staff and IT resources to implement cutting-edge approaches to modeling, risk assessment and data analysis**

- **Lack of coherent scientific vision, structure, and consistent external peer review**

- **Weakened scientific base [laboratory research (CDER, CBER, NCTR) and training, including visiting scientists]**

FDA cannot fulfill its mission because its scientific workforce does not have sufficient capacity and capability

- **Capacity**
- **Recruitment and retention challenges**
- **Insufficient investment in professional development**

Recommendations: Immediate Priorities

- **Provide significant and sustainable resources, especially for scientific infrastructure**
- **Rebuild scientific base of CFSAN and CVM and their related inspection and enforcement functions**
- **Immediately implement the IOM recommendations for improving drug safety, as well as those made by the Subcommittee working group on Surveillance/Biostatistics**

Highest Priority: Establish new Scientific Organization with Strong Scientific Leadership in all Senior Positions

- Chief Scientific Officer with sole responsibility being oversight of scientific infrastructure and reporting directly to the Commissioner with budget authority
- Establish an External Board of Scientific Counselors for each Center
- Deputy Director for Science in each center
- Director of Extramural Collaborations and Training for each center

- Develop a program to manage "new science" - establish the Incubator for Innovation in Regulatory and Information Science (IIRIS)

Recommendations

- **Provide significant and sustainable resources**
- **Rebuild CFSAN and CVM scientific base and their related inspection and enforcement functions**
- **Develop a program to manage "new science" - establish the Incubator for Innovation in Regulatory and Information Science (IIRIS)**
- **Immediately implement the IOM recommendations for improving drug safety, as well as those made by the Subcommittee working group on Surveillance/Biostatistics**

Key Advances at FDA

- **Increased funding, plus**
  - **Supplemental appropriations for sciences ($270 mil) in 2008**
- **FDAAA—new authorities, $$ to support those authorities, esp. drug safety**
- **Chief Scientist (Commissioner's Fellows)**
- **Large recruitment effort (1300 new employees in 2008, almost 800 of which are new positions)**
- **NIH/FDA enhanced interactions**
- **Others**

Where Do We Go From Here?

QUESTIONS….

Reagan-Udall Foundation for the Food and Drug Administration

A Critical Part of the Solution

Scope of Mission

- **Taking into consideration FDA's Critical Path reports and priorities:**
  - **identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness of devices, biologics, and drugs, and the safety of foods, food ingredients, and cosmetics,**
  - **establish goals and priorities to meet these unmet needs**
- **Includes post-approval safety and effectiveness**
- **Covers science for all FDA-regulated product areas**

Foundation Duties Include:

- **Authority for grants, contracts, MOUs, cooperative agreements with:**
  - **scientists and entities, which may include FDA**
  - **universities and university consortia**
  - **public-private partnerships**
  - **industry**
  - **other foundations and charitable institutions**
- **Hold or sponsor public meetings**
- **Provide objective clinical and scientific information to the FDA**

Public Accountability

- **Foundation:**
  - **Bylaws published in Federal Register**
  - **Recipients/partners must report progress to Foundation annually**
  - **Foundation must report annually to Congress and FDA on activities and progress, with specific accounting of funds, and information on how results of Foundation activities might be used by FDA for product review and regulation**

- **FDA:**
  - **Report to Congress annually on incorporation of Foundation research results into regulatory and product review activities**

Funding….

- **Foundation projects will be privately funded**

- **Requirement for FDA to transfer $500K - $1.25 million / year to the Foundation**
  - **Limited to operations/administration of Foundation, not to support projects**
  - **Currently suspended**