



FDA Science and Mission at Risk

Report of the
Subcommittee on Science
and Technology

Prepared For
FDA Science Board

November 2007

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**

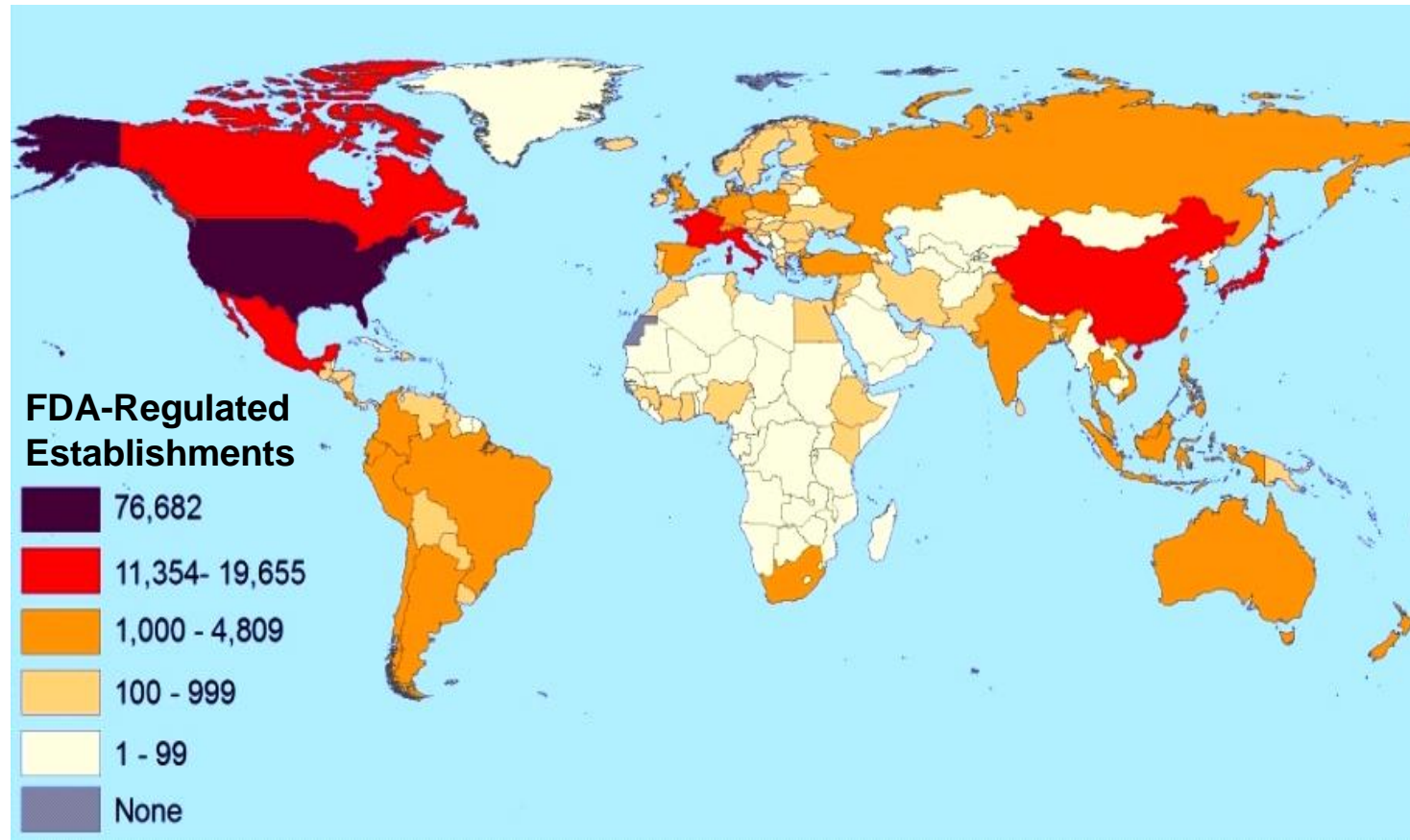
Science and Technology Subcommittee

- Gail Cassell (chair)*
- David Altshuler
- Barbara Alving
- Les Benet
- Bruce Burlington
- Robert Califf
- Thomas Caskey
- Joan Chesney
- David DeMets
- Susan Desmond-Hellman
- Susan Ellenberg
- Garret Fitzgerald
- Robert Goldstein
- Alfred Gilman
- Lee Hood
- Peter Hutt
- Evan Kharasch
- Sang Kim
- Cato Laurencin
- Julia Lane
- Jeff Leiden
- Barbara McNeil*
- Glen Morris
- Phillip Needleman
- Robert Nerem
- Dale Nordenberg
- Marc Overhage
- Jim Riviere
- Allen Roses*
- Eve Slater
- John Thomas
- Roy Vagelos
- Cathy Woteki

*Member FDA Science Board

**Demands of FDA have soared.
Resources have not!**

The Breadth of FDA Responsibilities by Number of Establishments



Source: FDA 10/02/07

FDA Impact

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

Subcommittee Conclusion

Science at the FDA is in a precarious position: the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities

Major Findings

- **Fire-fighting regulatory posture vs instead 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

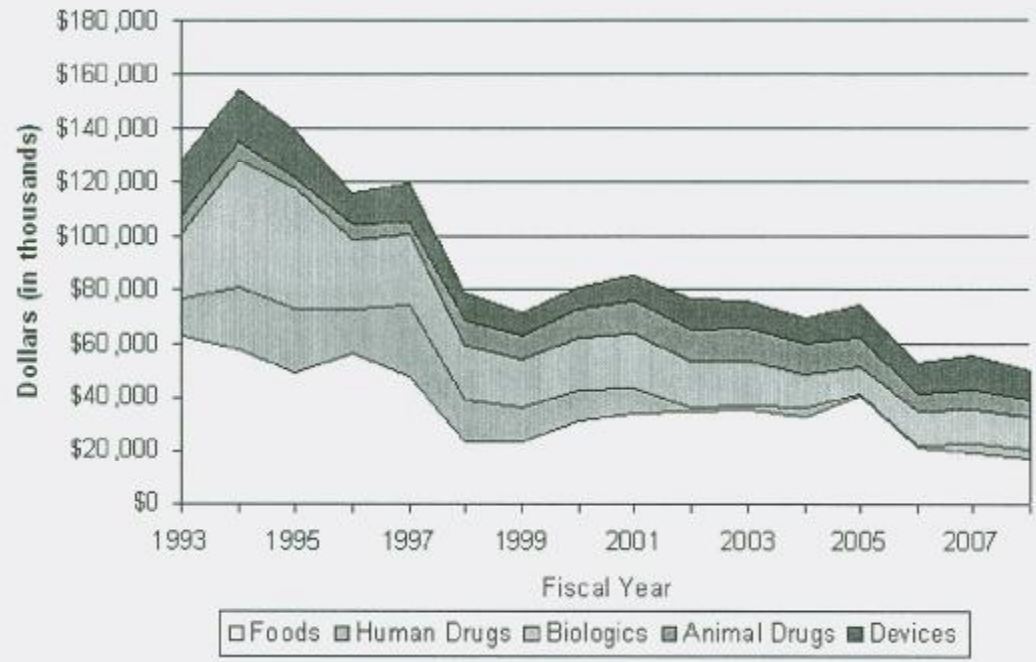
- **Capacity**
- **Recruitment and retention challenges**
- **Insufficient investment in professional development**

Funding the Critical Path Initiative 2006 – 2008*

<u>Fiscal year</u>	<u>Amount</u>
2006	\$750,000 (external grant)
2007	\$5,940,000
2008	\$13,500,000

*Launched March, 2004 but no funding until 2006.

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



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

Response

- **Science Board**
- **FDA**
- **News Media**
- **Congress**
- **Obama Transition Team**
- **New Commissioner and Chief Scientist**



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

Why Von Eschenbach Bucked Bush: The Fight Over FDA Funding



New York Times...“Commissioner did what has never been done before in 100 plus years of the agency.”

FDA for Stronger Alliance...“Visible transition point” came during Energy & Commerce Oversight & Investigations Subcommittee hearing called in response to FDA Science Board Report”