Medical Devices: Innovation and Regulation

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AdvaMed Submissions Workshop 2003

FDA and Change

"You won't recognize FDA a year from now"

Secretary Tommy Thompson

2002

Performance Based Budgeting

NOT MEASURING UP

Why Managers Are Failing To Measure Their Programs' Results

By MOLLIE ZIEGLER

measure their results ended up with an av-
ercentage funding increase of 1.2
. By comparison, programs that
easure their results — regardless
her those results were good or bad
much better. Programs deemed to
ective in achieving their results, for
e, received on average a 6.6 percent
increase.

e evaluation expands — OMB will
percent of federal programs each
til all are assessed for the fiscal
dget — the scrutiny will increase.
cause the same evaluation method
used on similar programs in differ-
artments, programs will go head to
see which perform better. Entire
ms could be cut and have their
applied to better-performing pro-
grams.

And although it is more important than ever for managers to be able to measure their programs' results, most are not able to. Managers faced two main obstacles last year in demonstrating their programs' results: poor measures or lack of data. More than nine out of 10 did not develop appropriate measures with which to measure

pose, it could not. It didn't have the data to indicate it was meeting its goals.

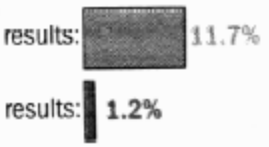
OMB assessed 234 programs last year — 20 percent of all federal programs — in its first attempt to base budgeting decisions upon programs' performance. More than half of those pro-

performance first.
Page 6

Guidance: A new assessment tool puts focus on results.
Page 7

THE PENALTY

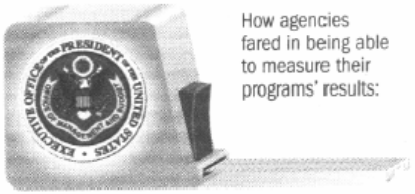
Programs that could not measure results received far smaller funding increases than other programs for fiscal 2004. How average percentage funding increases compare:



SOURCE: President Bush's Fiscal 2004 Budget Request

GRAPHIC BY MARCIA STAIMER

NO RESULTS MEASURED



How agencies fared in being able to measure their programs' results:

Agency	Programs demonstrating results	Programs not demonstrating results
Small Business Administration	0	4
Office of Personnel Management	0	2
General Services Administration	0	5
Agriculture	1	12
Environmental Protection Agency	1	10
Army Corps of Engineers	1	4
Justice	2	7
Homeland Security	2	7
Veterans Affairs	1	2
Labor	3	6
Education	8	10
Housing and Urban Development	3	3
Interior	8	7
Health and Human Services	18	12
Treasury	5	3
State*	11	6
NASA	2	1
Energy	21	10
Commerce	8	2
Defense	11	1
Transportation	4	0
Social Security Administration	2	0

* Includes programs of Agency for International Development and other international affairs agencies

Changes: CDRH

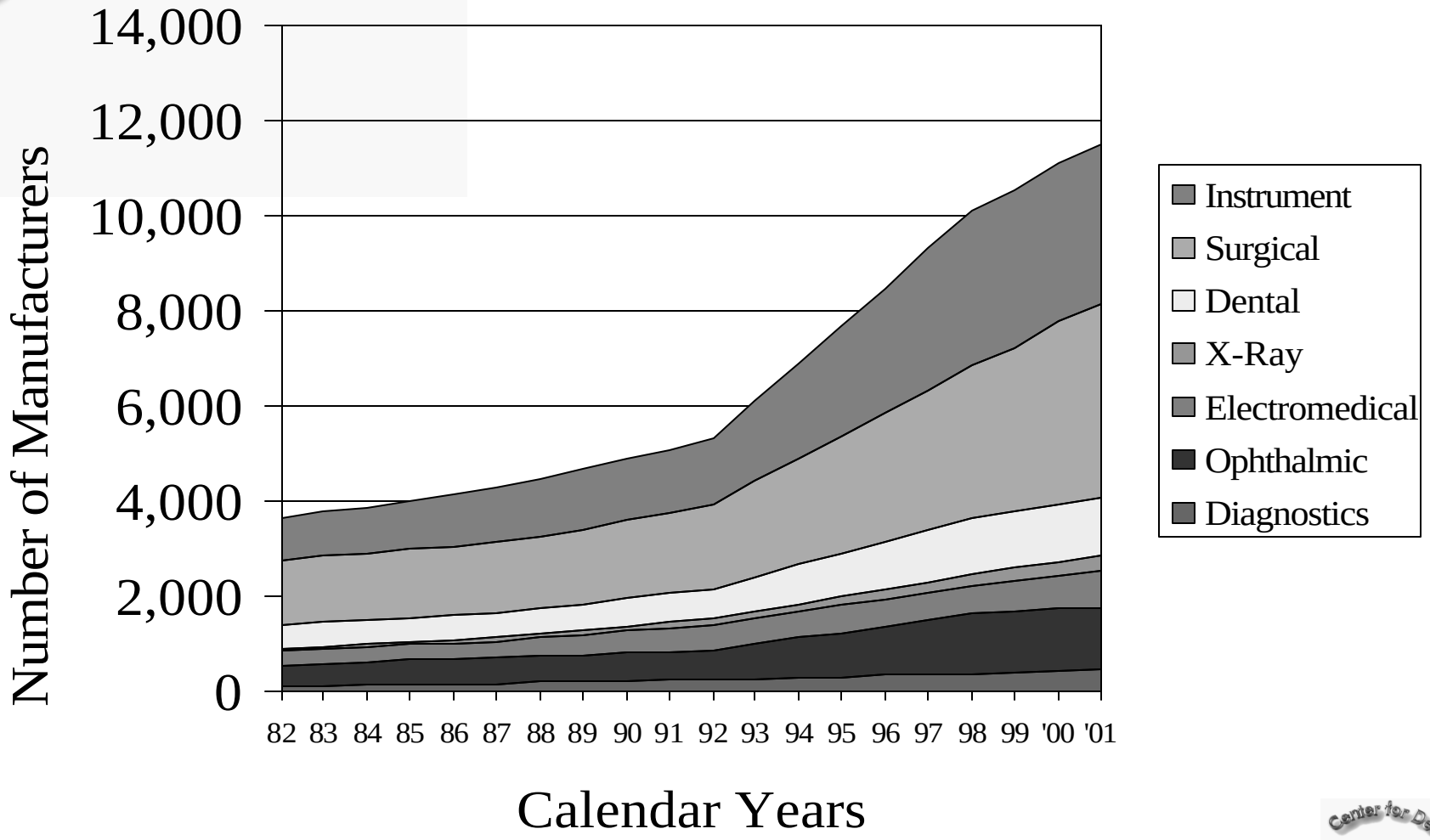
FDAMA Implementation

- Least Burdensome

Medical Device User Fee and Modernization Act of 2002 (MDUFMA)

- Resources
- Statutory Changes

Device Industry Growth by Device Group



Note: 1998 & 2001 used Dun & Bradstreet Data; Other years used Dept. of Commerce Data to include secondary products..

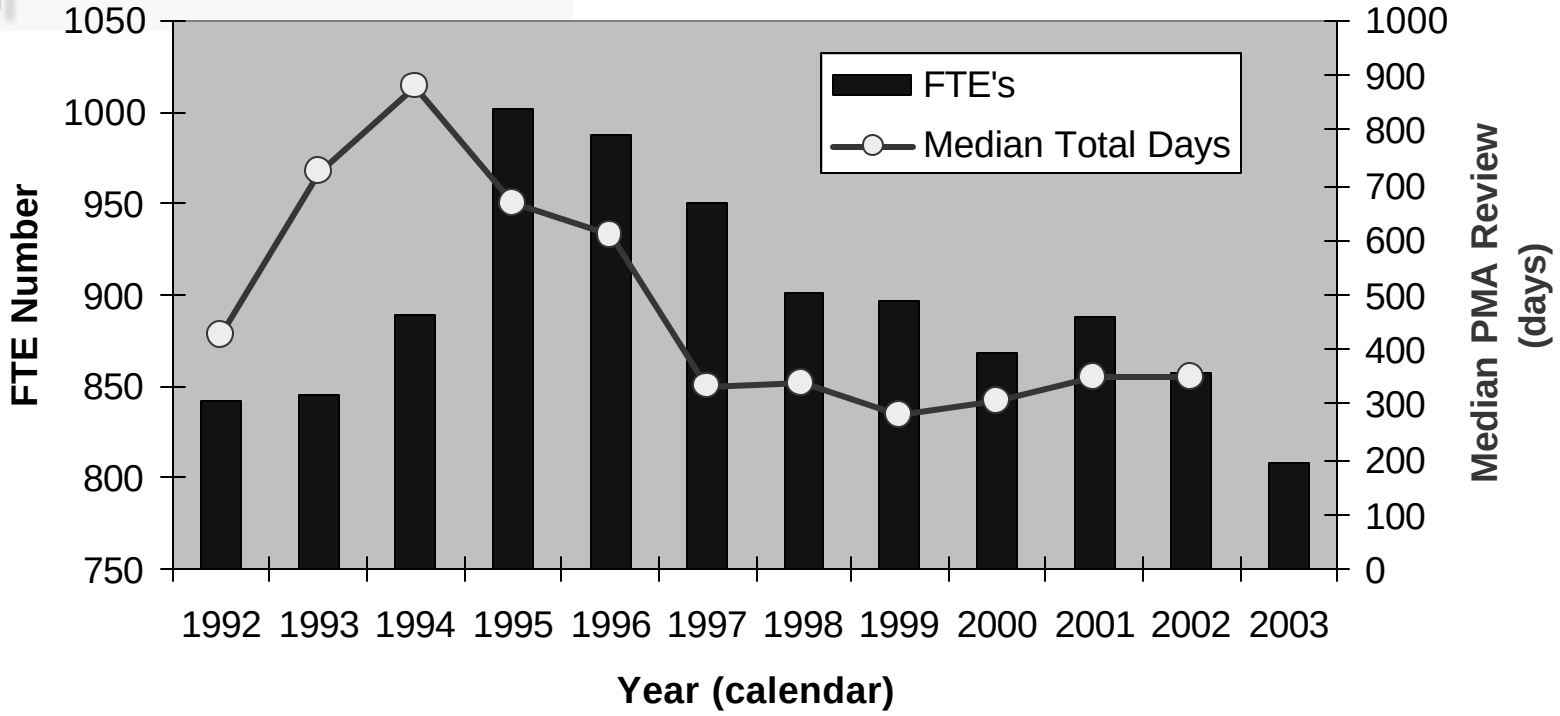
Medical Device Program

CDRH: Types and numbers of submissions

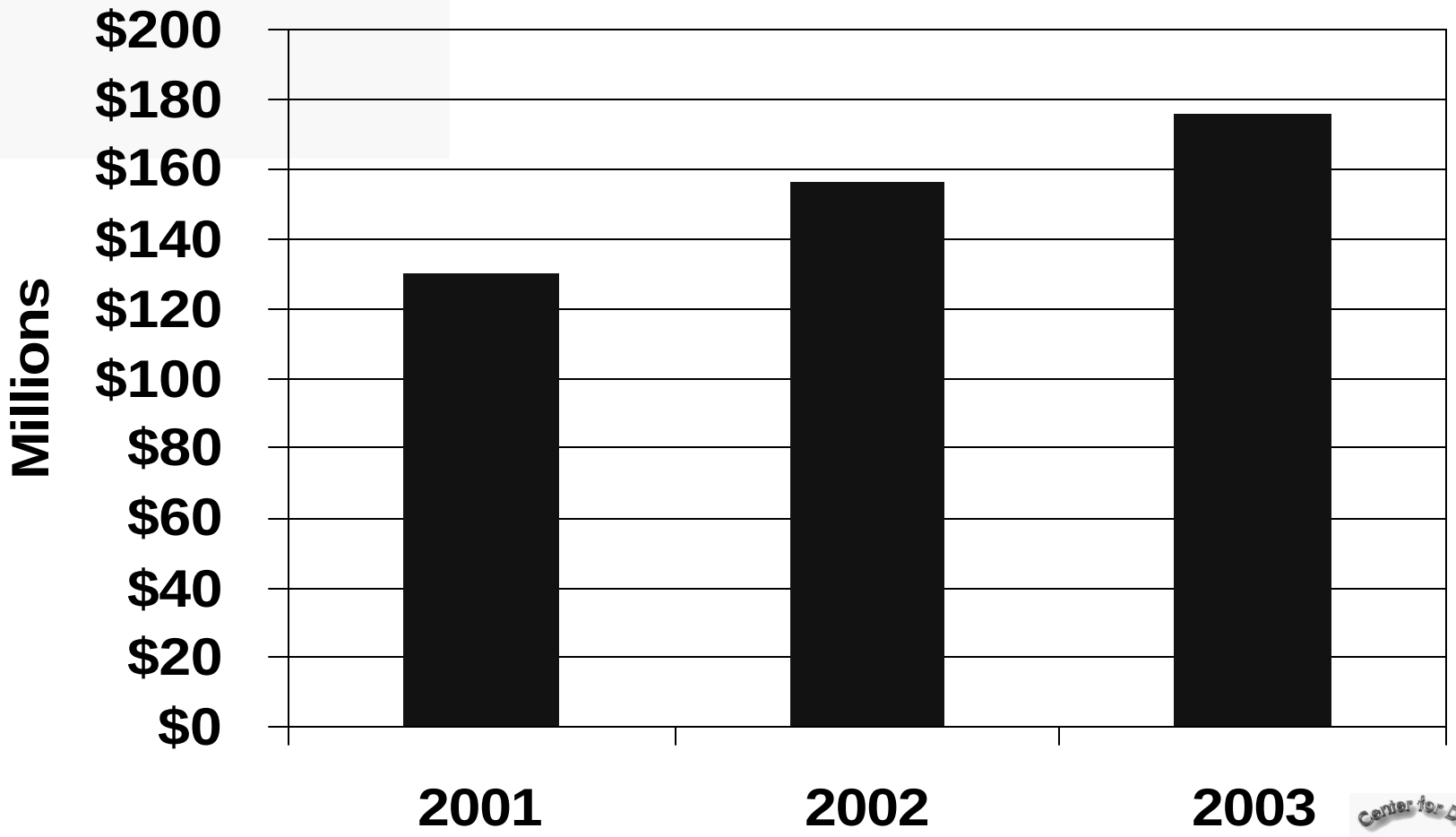
TYPE OF SUBMISSION	FY1997	FY1998	FY1999	FY2000	FY2001	FY2002
Original PMAs	66	47	60	67	70	48
PMA Supplements	409	513	552	545	641	644
Original IDEs	297	322	304	311	284	312
IDE Amendments	223	226	275	240	206	252
IDE Supplements	3,776	4,277	4,127	4,388	4,811	4,724
510(k)s *(10% with clinical Data)*	5,049	4,623	4,458	4,202	4,248	4,320
Original HDE	4	8	12	11	5	5
HDE Supplements	0	0	4	10	16	16
Total	**9,824**	**10,016**	**9,792**	**9,774**	**10,281**	**10,321**

Performance

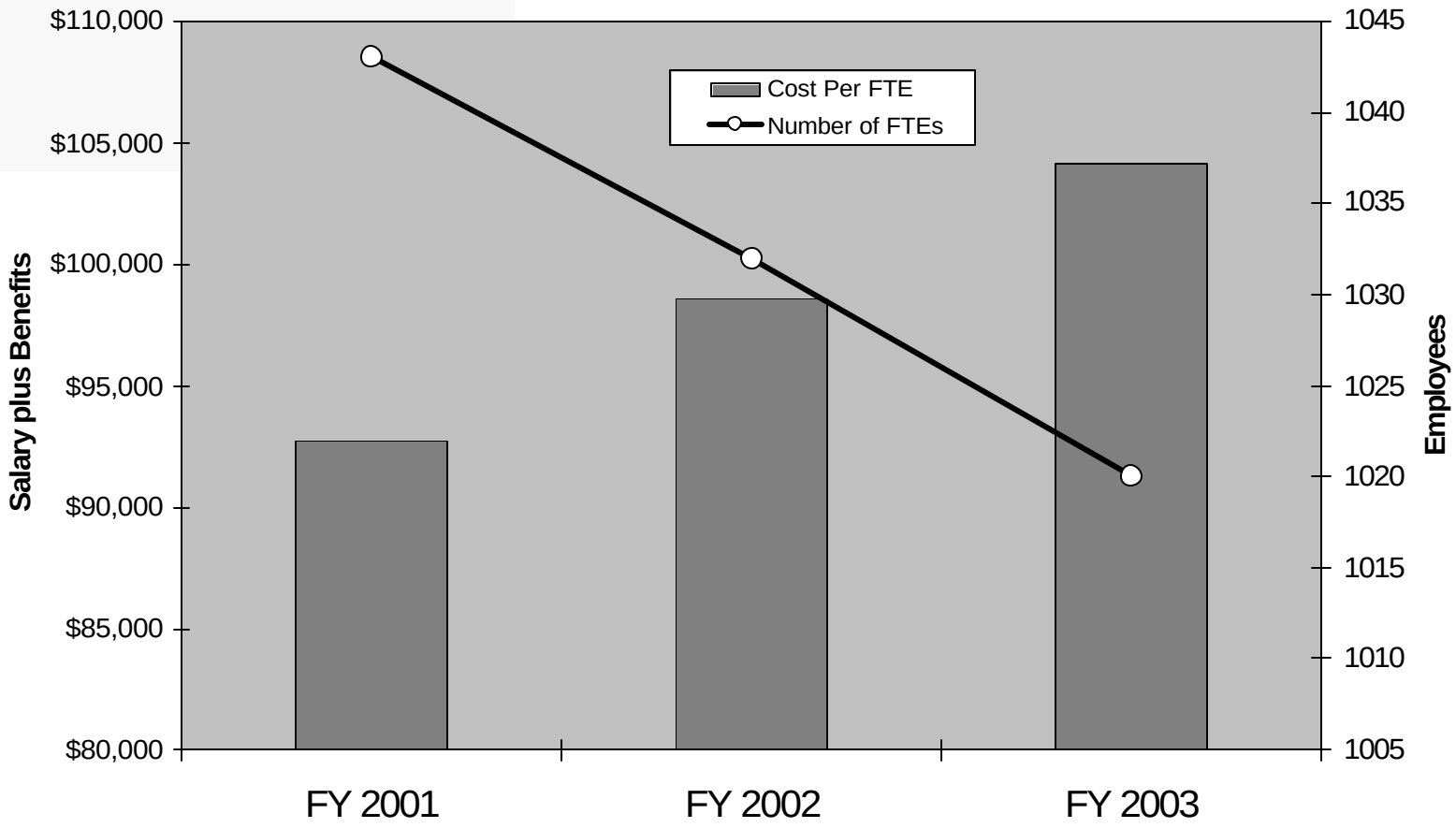
PMA Review Times and Number of FTE's



Device Program Budget



Center Staff Costs



Note: these staff reductions are above and beyond the 8% reduction (about 100 FTE's) that occurred between 1995 – 2000)

Performance 2002 vs. 2001

FDA Times are slipping

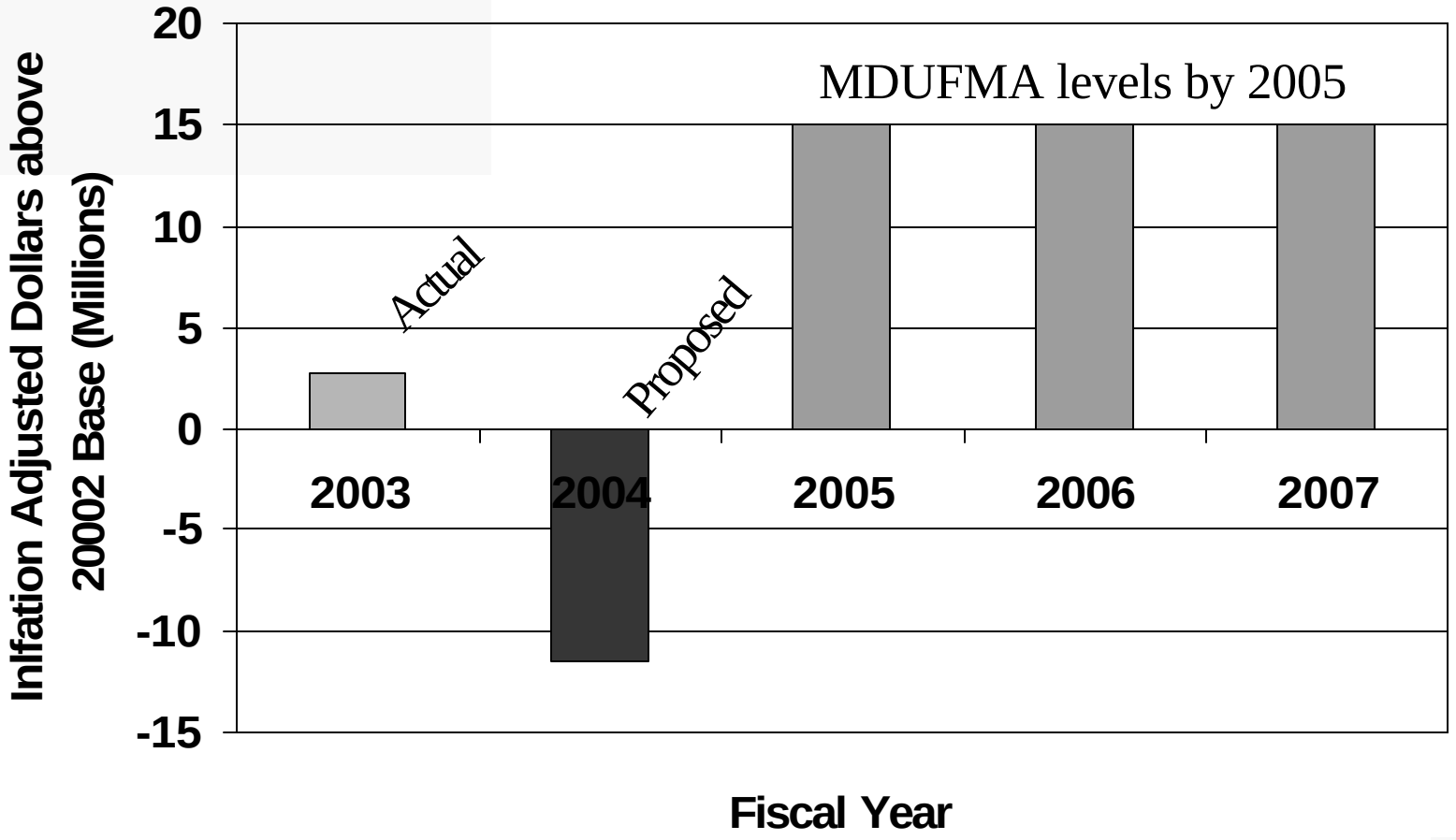
- Although 25% fewer standard PMA's were approved they took 2 days longer to approve
- Modular PMA reviews took 74 days longer
- Expedited reviews took 72 days longer
  - 86 days longer than a standard PMA
- 510(k) reviews took 4 days longer
- Shortage of field resources delayed some approvals
- Meetings more difficult to schedule

2003 CDRH Budget Increases

… the details

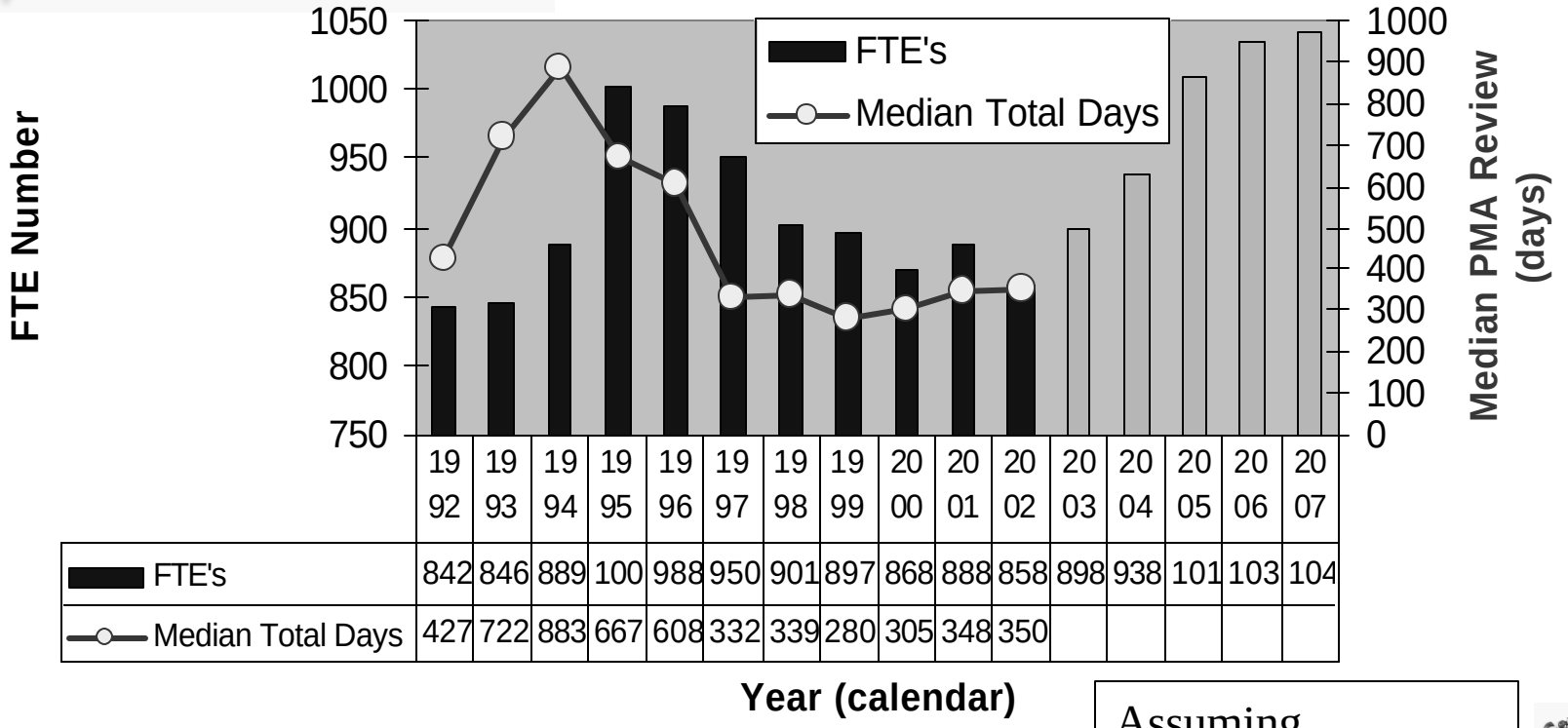
	Pay Raise	Counter-terrorism	MedSun
Center	$3726	$1284	$1500
Field	$1447	$3638	0

MDUFMA Appropriation Levels



Performance

PMA Review Times and Number of FTE's



	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
FTE's	842	846	889	100	988	950	901	897	868	888	858	898	938	101	103	104
Median Total Days	427	722	883	667	608	332	339	280	305	348	350					

Year (calendar)

Assuming appropriations on track by 2005

Legislation: MDUFMA

User Fee's

- Tiered Fee Scale for small manufacturers
- Performance Targets
  - Priority review
  - PMA's and supplements
  - 510(k)'s
- Predictable income
  - No disincentive for down-classification
  - Different from PDUFA where income fluctuates with workload

Legislation: MDUFMA

Changes and Issues:

- Combination Products
- Third Party Inspection
- External Experts
- Re-Use of Single Use Devices
- Devices for Children
- Breast Implants

Changes: CDRH

Medical Device User Fee and Modernization Act of 2002 (MDUFMA)

- Resources
- Statutory Changes

CDRH Strategic Plan

- Office of IVD
- Knowledge Management
- Score Cards

Organizational Changes: CDRH

New Leadership

- Office of Device Evaluation
  - Dan Schultz, M.D., Director
- Office of in Vitro Drug Products
  - Steve Gutman, M.D., Director
- Office of Surveillance and Biometrics
  - Susan Gardner, Ph.D. Director
- Office of Science and Technology
  - Larry Kessler, Ph.D., Director
- Office of Systems Management
  - Ruth Clements, Director
- Office of Compliance
  - Tim Ulatowski, Director

CDRH Medical Device Fellowship Program

Physicians

- Visiting Scholar – senior level clinicians, surgeons
- Fellow - physician during fellowship training
- Resident – physician during residency training
- Medical student
- Consultant – generally off-site experts available for consultation

Engineers

- Visiting Scholar – senior level engineer
- Consultant – generally off-site experts available for consultation
- Students
- Biomedical Engineering Co-op Program
- Engineering internships

Others

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Strategic Plan

How to implement ?

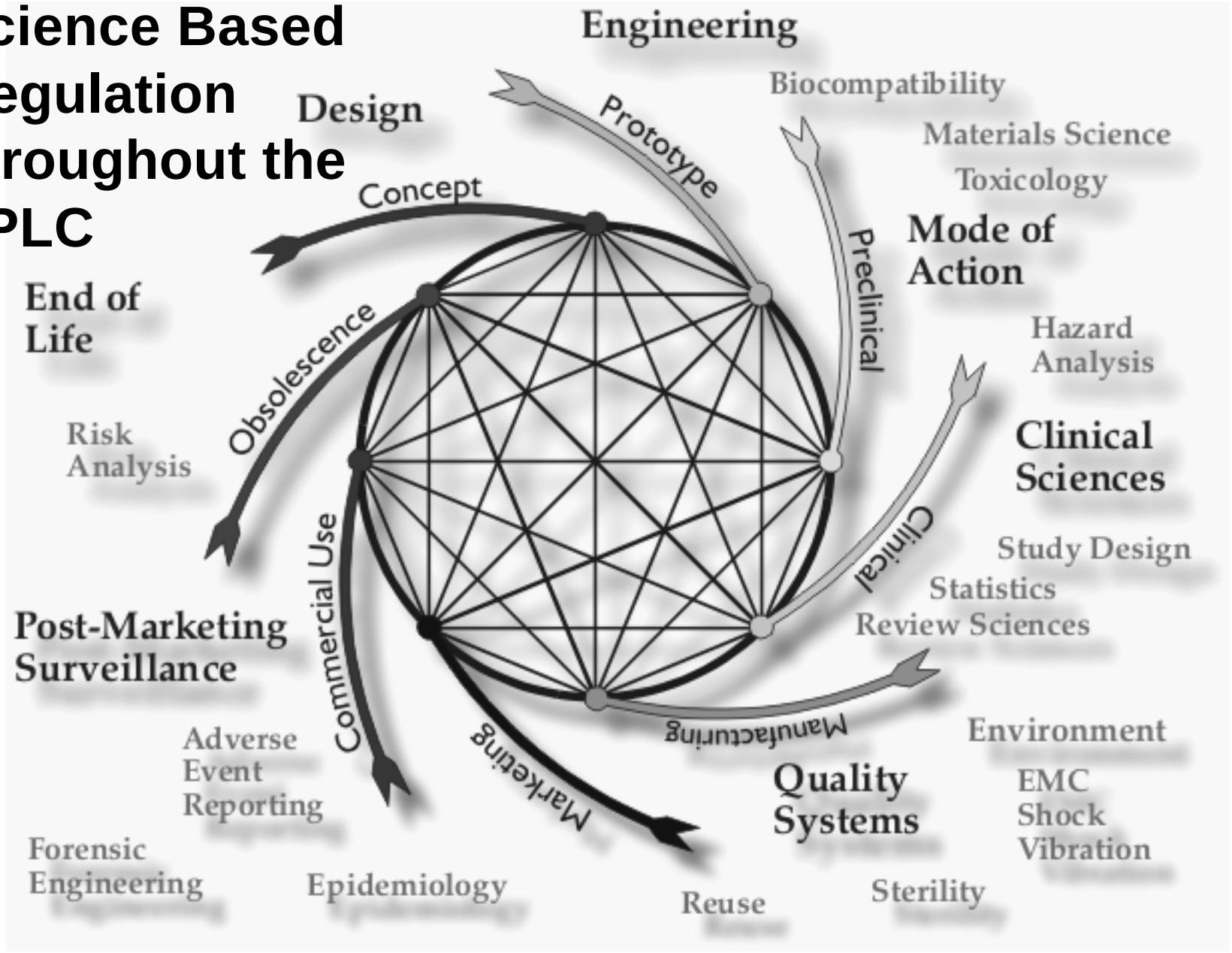
- Goal Area work groups and projects
- Center-Wide Score Cards
  - Link the Strategic Goal Areas to ***Key Results Areas*** (KRA's)
  - Measure performance in each KRA with ***Key Indicators*** (KI's)
  - Recruit:
    - Measurement team to develop KI's
    - Score Card Trainers to develop specific organizational score cards

Center for Devices and Radiological Health

Mission:

CDRH promotes and protects the health of the public by ensuring the safety and effectiveness of medical devices and the safety of radiological products.

Science Based Regulation throughout the TPLC



Performance Scorecards

Key Results Areas

- Public Health Protection
- Public Health Promotion
- Operational Accountability
- Stakeholder Collaboration
- Workforce Excellence
- Strategic Directions

Performance Scorecards

Key Results Areas and Key Indicators

1. Public Health Protection
   - Monitoring Index: Identifying Hazards
   - Follow-up and Resolution Index: Timely and effective
2. Public Health Promotion
   - Timely Marketing of New Products
3. Operational Accountability
   - Application Review Timeliness Index
   - Application Review Quality Index
   - Inspection Index

Performance Scorecards

Key Results Areas and Key Indicators

4. Stakeholder Collaboration
   - Collaborative Meeting Index
   - External Expertise Engagement Index
5. Workforce Excellence
   - Development Index
6. Vision Attainment
   - Total Product Life Cycle
   - Global Products — Global Quality

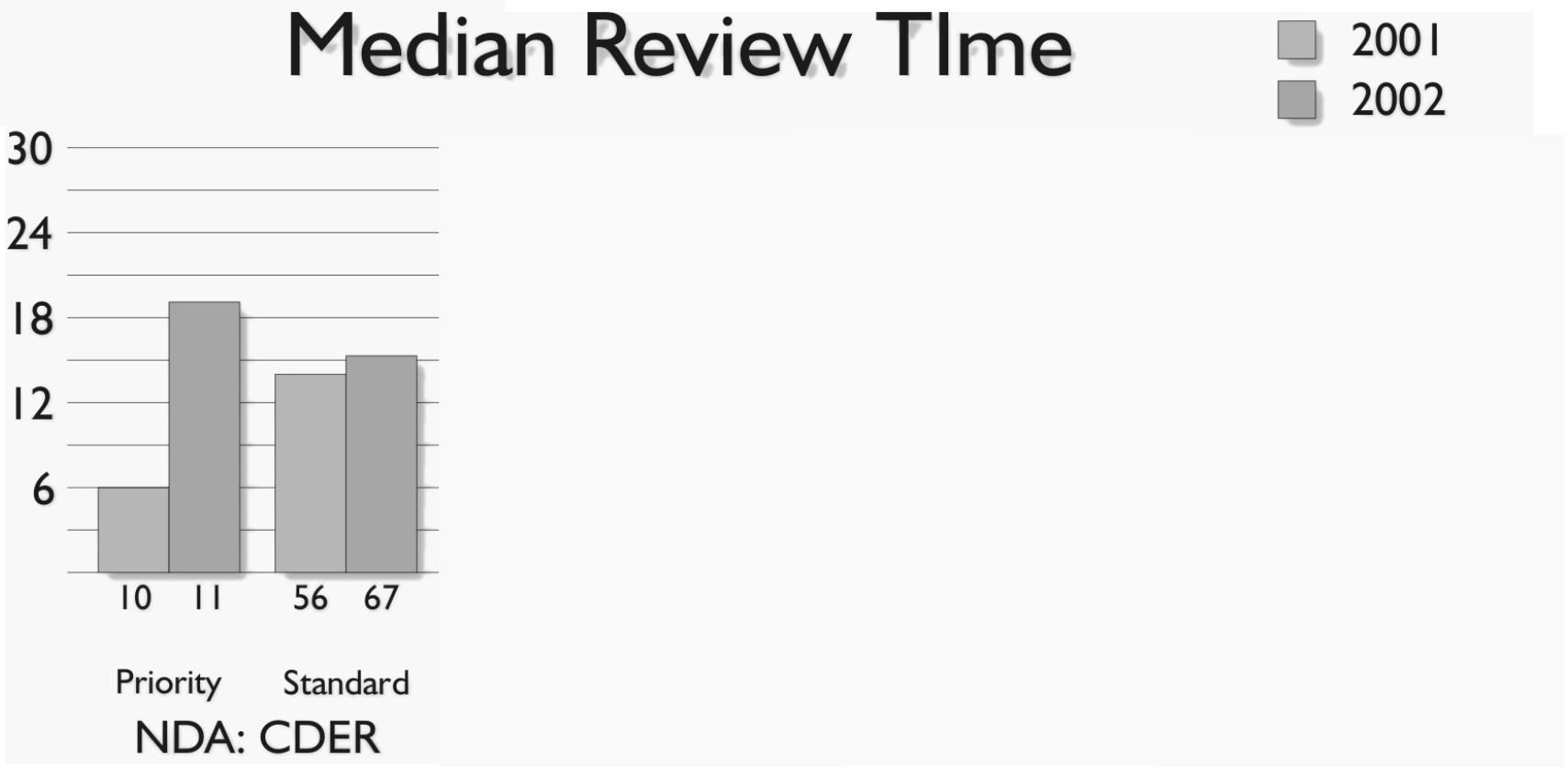
Changes: Therapeutic Centers

CDER / CBER Merger of
- Biological Therapeutics

Office of Combination
- Products

Commissioners
- Premarket Initiatives

Review Performance 2001 - 2002



Commissioner Mark McClellan, M.D., Ph.D.

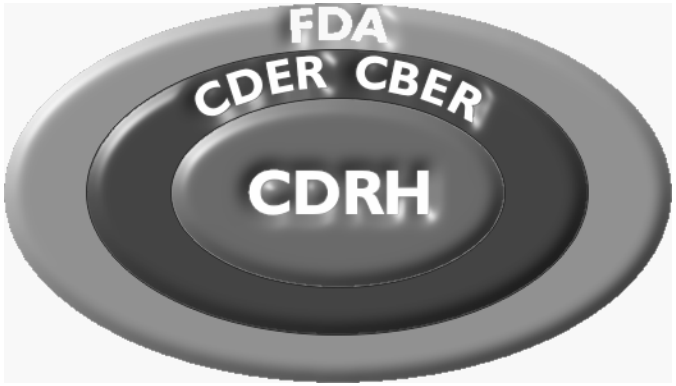
Improving Innovation in Medical Technology: Beyond 2000

- Eliminate multiple Review cycles
- Instituting a quality systems for pre-market review
- Illuminate the regulatory path for novel products

Changes: FDA

Commissioner's Strategic Objectives

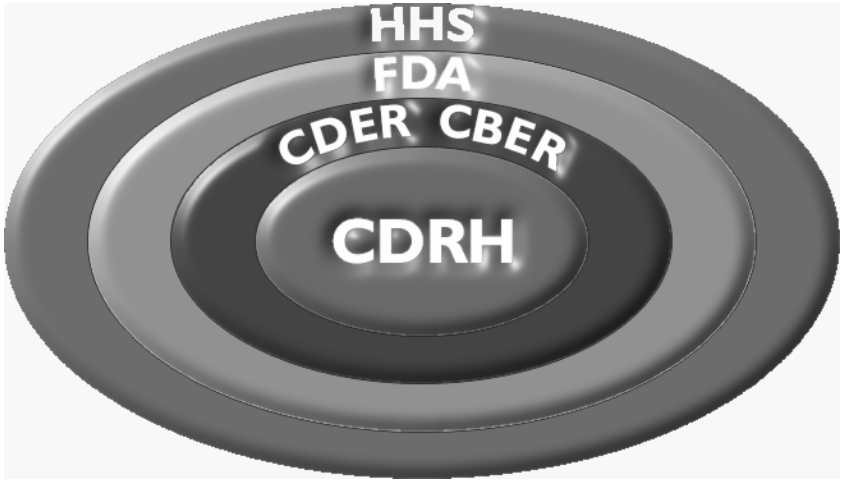
- Strong FDA
- Counter-Terrorism
- Informed Consumers
- Patient Safety
- Risk Management



Changes: HHS

One HHS

- CMS – FDA MOU on Data sharing
- Disease – Specific initiatives
  - Diabetes
  - Obesity



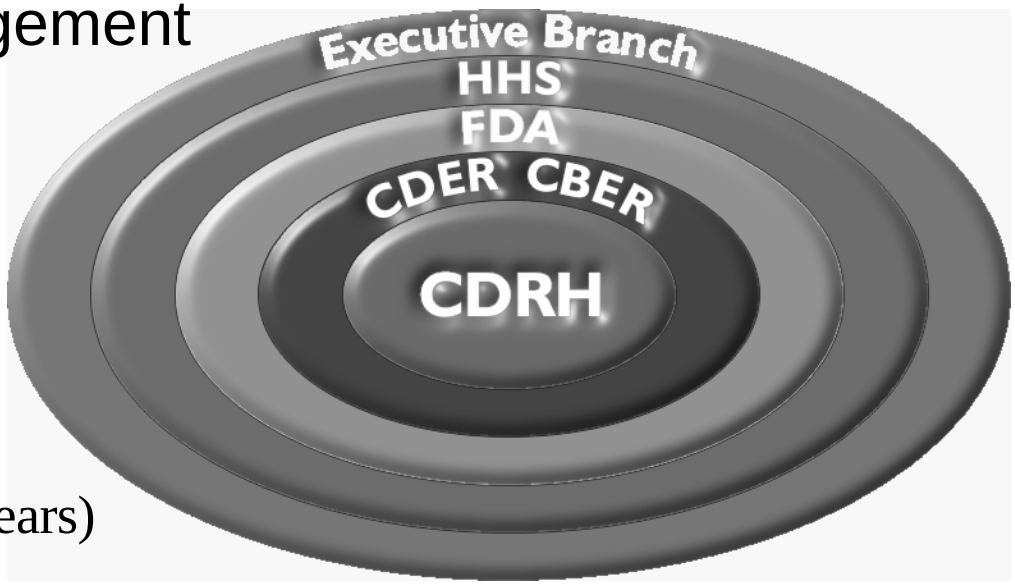
Management Consolidation

- Human Resources
- Core IT Services

Changes: Executive Branch Wide

President's Management Agenda

- Performance Contracts
- Outsourcing (Target: 25% of Federal workforce in 2 years)
- Delayeringing
- Administrative Consolidation
- Performance Based Budgeting



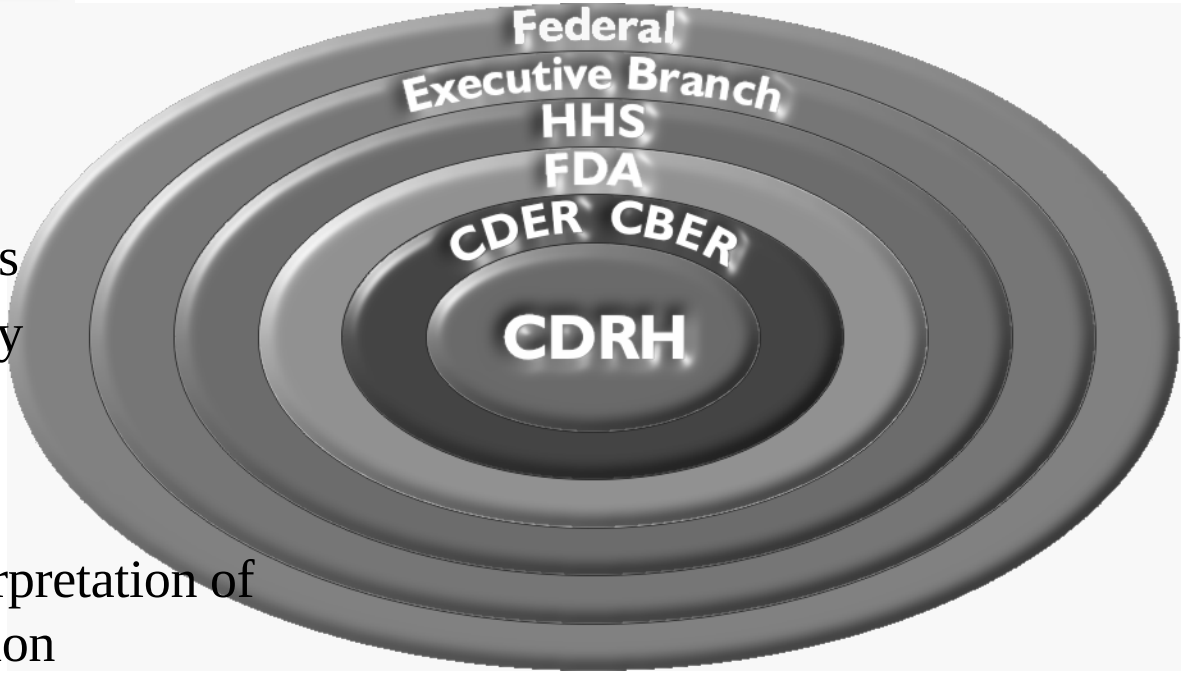
Changes: Federal

Congress

- MDUFMA
- Appropriations
- Mammography

Courts

- Narrower interpretation of FDA jurisdiction



Changes: International

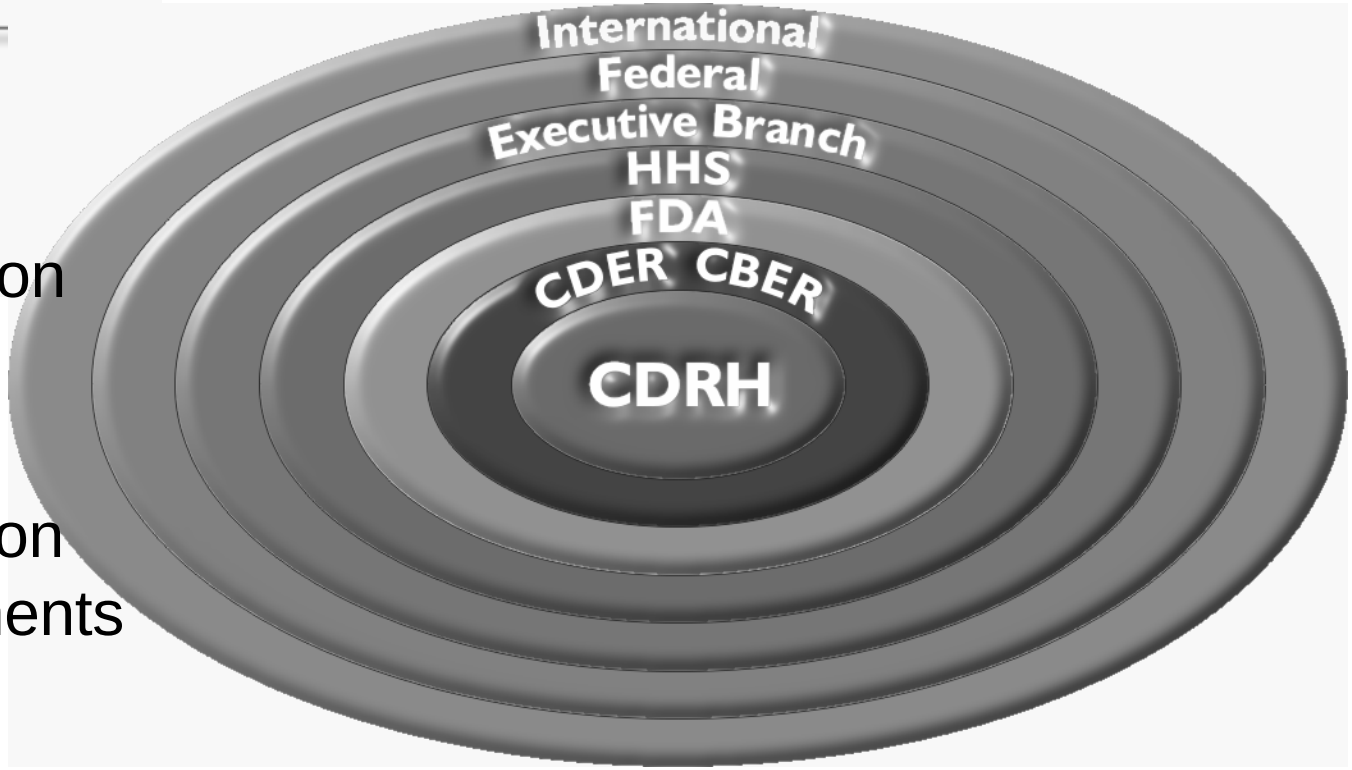
Standards

Harmonization

Mutual
Recognition
Agreements

Trade Agreements

Imports



Globalization

Global Standards

Global Quality

Global Market

Means Global Regulation

- Quality system standards differ
- Premarket requirements differ
- Regional perspectives differ
- Reimbursement decisions differ
- Increasing volume and diversity of imports
- More U.S. manufacturers are using foreign clinical trials

Global Harmonization Task Force

Four study groups:

- Regulatory Requirements / Premarket Review
- Device Vigilance / Post-Market Surveillance
- Quality System Requirements and Guidance
- Auditing

www.ghtf.org

For medical devices …

… there is nothing new about New