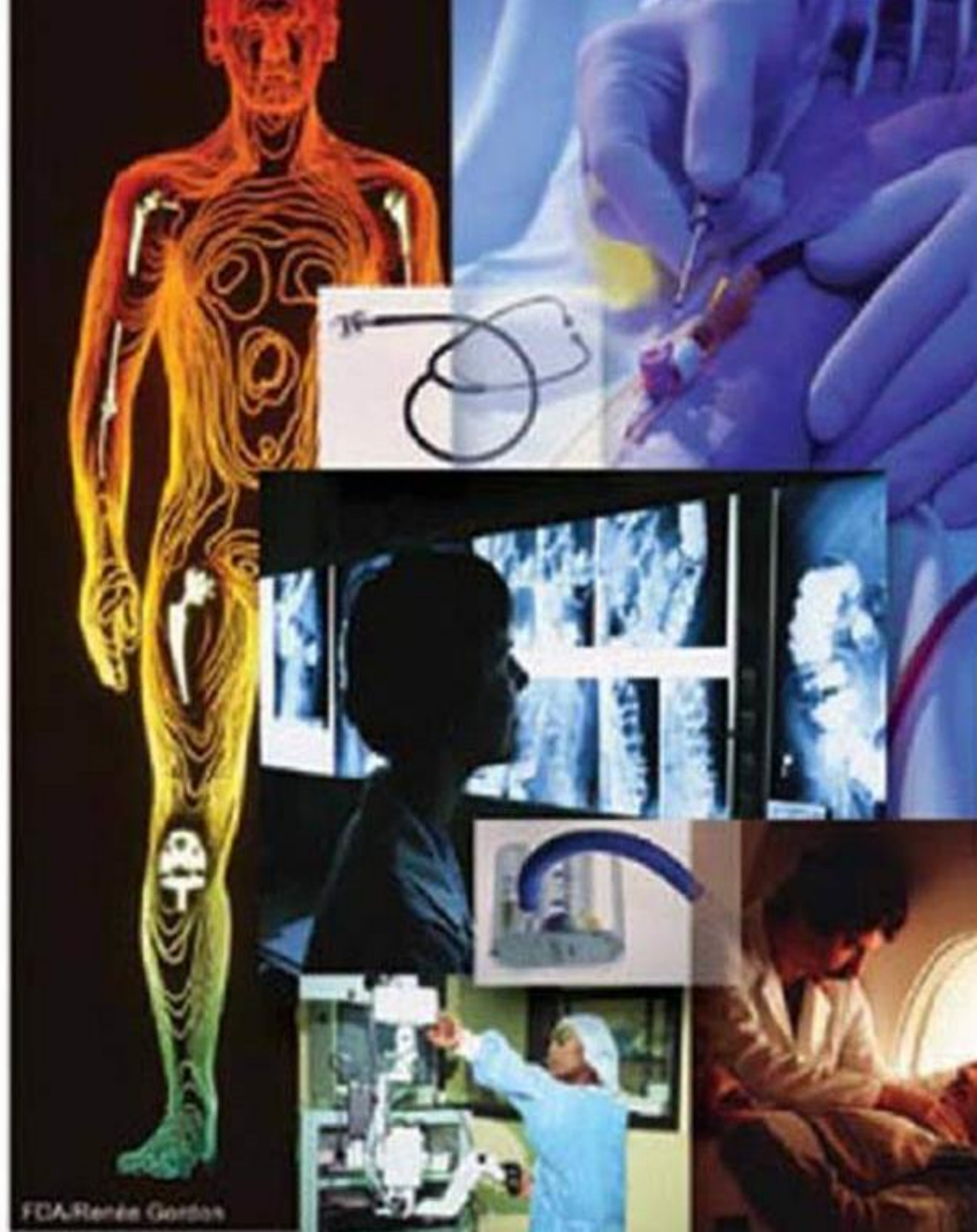
2013 ODE Update

Center for Devices and Radiological Health



2013 Strategic Priorities

Priority 1. Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

Priority 2. The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.

Priority 3. U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device. approval or clearance

Priority 4. Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.

Priority 5. Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

Priority 6. Strengthen Our Workforce and Workplace

PRIORITY 1.

PATIENTS IN THE U.S. HAVE ACCESS TO HIGH-QUALITY, SAFE, AND EFFECTIVE MEDICAL DEVICES OF PUBLIC HEALTH IMPORTANCE FIRST IN THE WORLD.

Strategy 1.1. Strengthen our pre-market review programs

Strategy 1.2. Strengthen and streamline the clinical trial enterprise

Strategy 1.3. Advance adoption of connected health care

Strategy 1.4. Strengthen the regulatory pathway from product concept to patient access

Strategy 1.5. Further develop CDRH's Personalized Medicine Program

PRIORITY 2.

THE U.S. IS THE WORLD'S LEADER IN REGULATORY SCIENCE, MEDICAL DEVICE INNOVATION AND MANUFACTURING, AND RADIATION-EMITTING PRODUCT SAFETY.

Strategy 2.1. Strengthen our national regulatory science infrastructure

Strategy 2.2. Strengthen CDRH's Radiological Health Program

PRIORITY 3.

U.S. POST-MARKET SURVEILLANCE QUICKLY IDENTIFIES POORLY PERFORMING DEVICES, ACCURATELY CHARACTERIZES REAL-WORLD PERFORMANCE, AND FACILITATES DEVICE APPROVAL OR CLEARANCE.

Strategy 3.1. Strengthen our national system for medical device post-market surveillance

PRIORITY 4.

DEVICES ARE LEGALLY MARKETED IN THE U.S. AND REMAIN SAFE, EFFECTIVE, AND OF HIGH-QUALITY.

Strategy 4.1. Advance the Case for Quality Initiative

Strategy 4.2. Establish a Voluntary Compliance Improvement Pilot Program

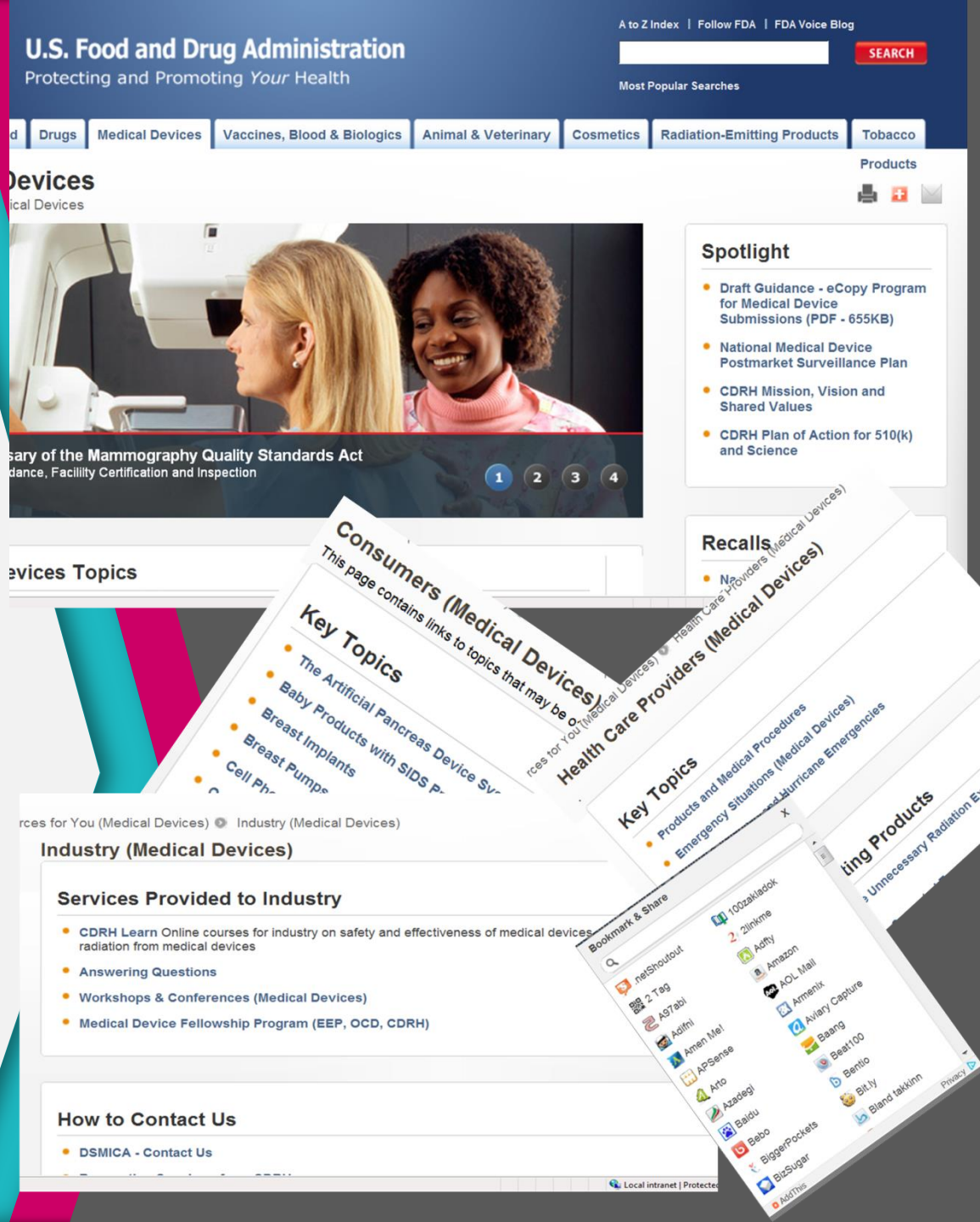
Strategy 4.3. Address challenges associated with globalization

PRIORITY 5.

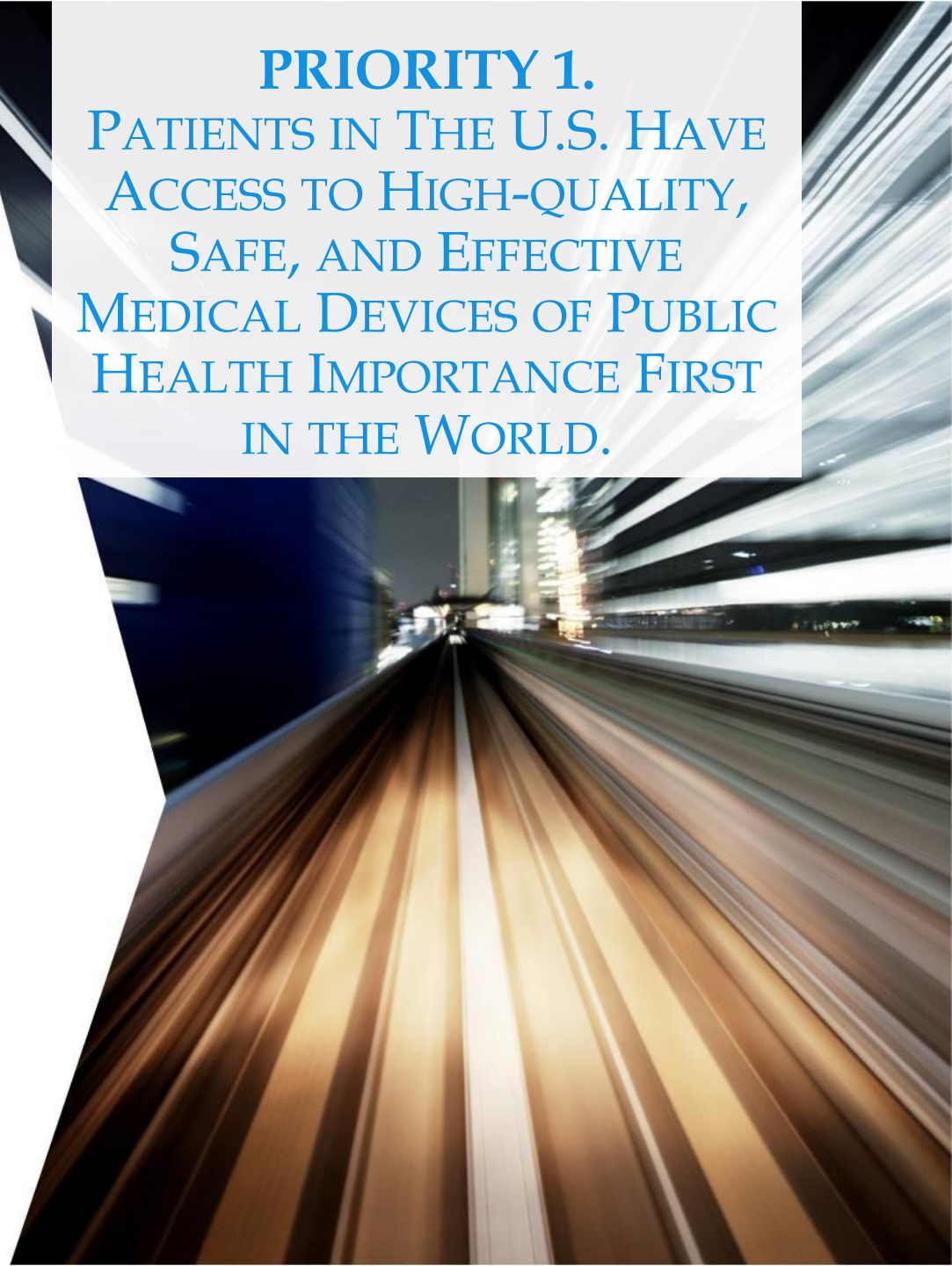
CONSUMERS, PATIENTS, THEIR CAREGIVERS, AND PROVIDERS HAVE ACCESS TO UNDERSTANDABLE SCIENCE-BASED INFORMATION ABOUT MEDICAL DEVICES AND USE THIS INFORMATION TO MAKE HEALTH CARE DECISIONS.

Strategy 5.1. Improve the accessibility and usefulness of device labeling

Strategy 5.2. Explore the use of social media for gathering and sharing information with external constituents



PRIORITY 1.
Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.



Strategy 1.1. Strengthen our pre-market review programs

Goal 1.1.1. In 2013, CDRH will continue implementation of the plan of action to strengthen pre-market review.

Goal 1.1.2. By December 31, 2013, CDRH will take steps to modernize the infrastructure and processes for the review of pre-market applications.

Strategy 1.2. Strengthen and streamline the clinical trial enterprise

Goal 1.2.1. By September 30, 2013, CDRH will take steps to reduce the time and cost associated with the conduct of clinical trials in the U.S. while maintaining patient protection.

Strategy 1.3. Advance adoption of connected health care

Goal 1.3.1. By September 30, 2013, CDRH will advance the adoption of connected health care by fostering innovative solutions and technology.

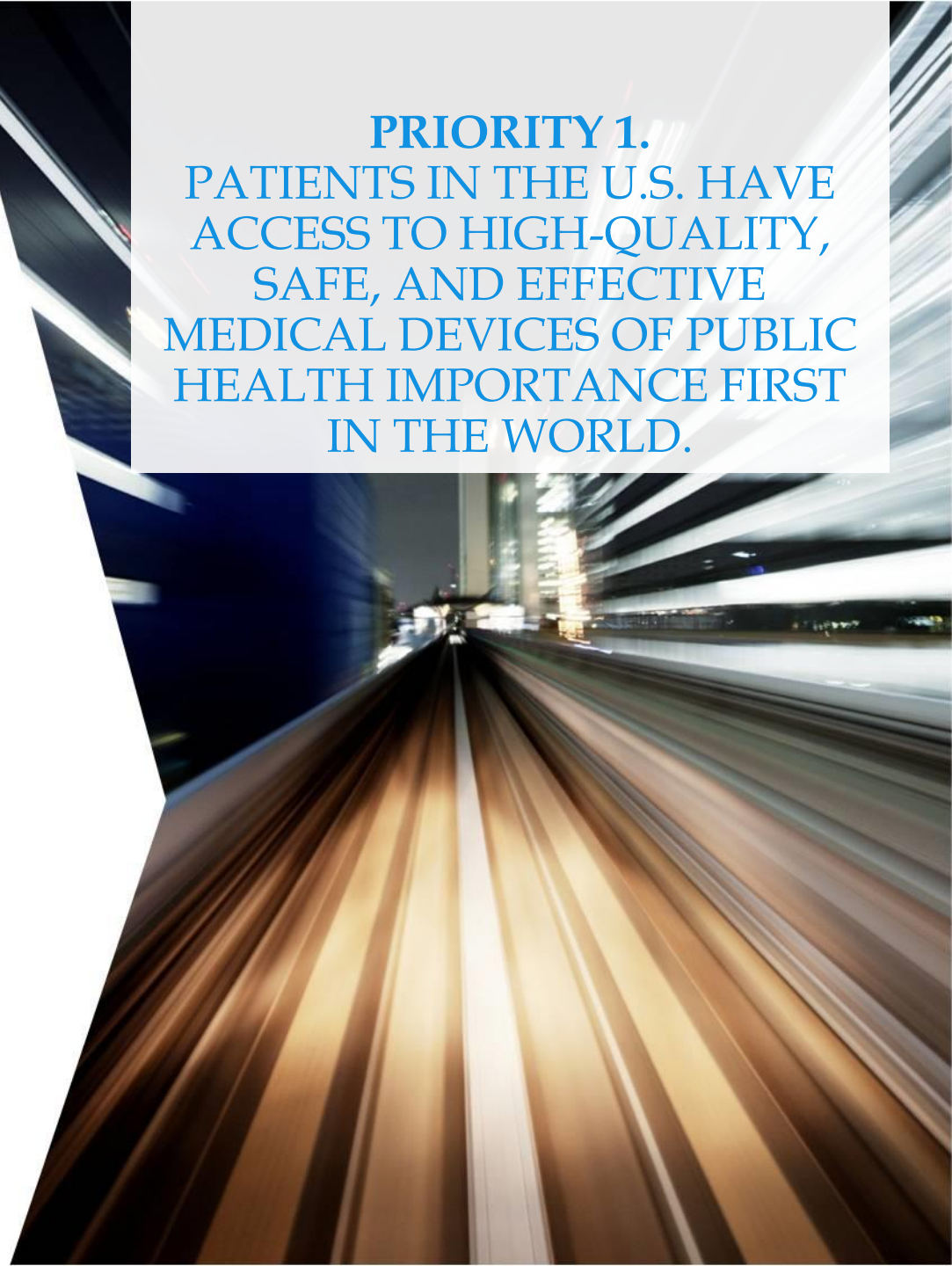
Strategy 1.4. Strengthen the regulatory pathway from product concept to patient access

Goal 1.4.1. By September 30, 2013, CDRH will take steps to streamline the pathway from FDA approval to reimbursement.

Strategy 1.5. Further develop CDRH's Personalized Medicine Program

Goal 1.5.1. By September 30, 2013, CDRH will take steps to enhance the field of personalized medicine by defining the appropriate regulatory paths for diagnostic devices that are intrinsically tied to a therapeutic and for novel diagnostic devices.

PRIORITY 1.
PATIENTS IN THE U.S. HAVE ACCESS TO HIGH-QUALITY, SAFE, AND EFFECTIVE MEDICAL DEVICES OF PUBLIC HEALTH IMPORTANCE FIRST IN THE WORLD.



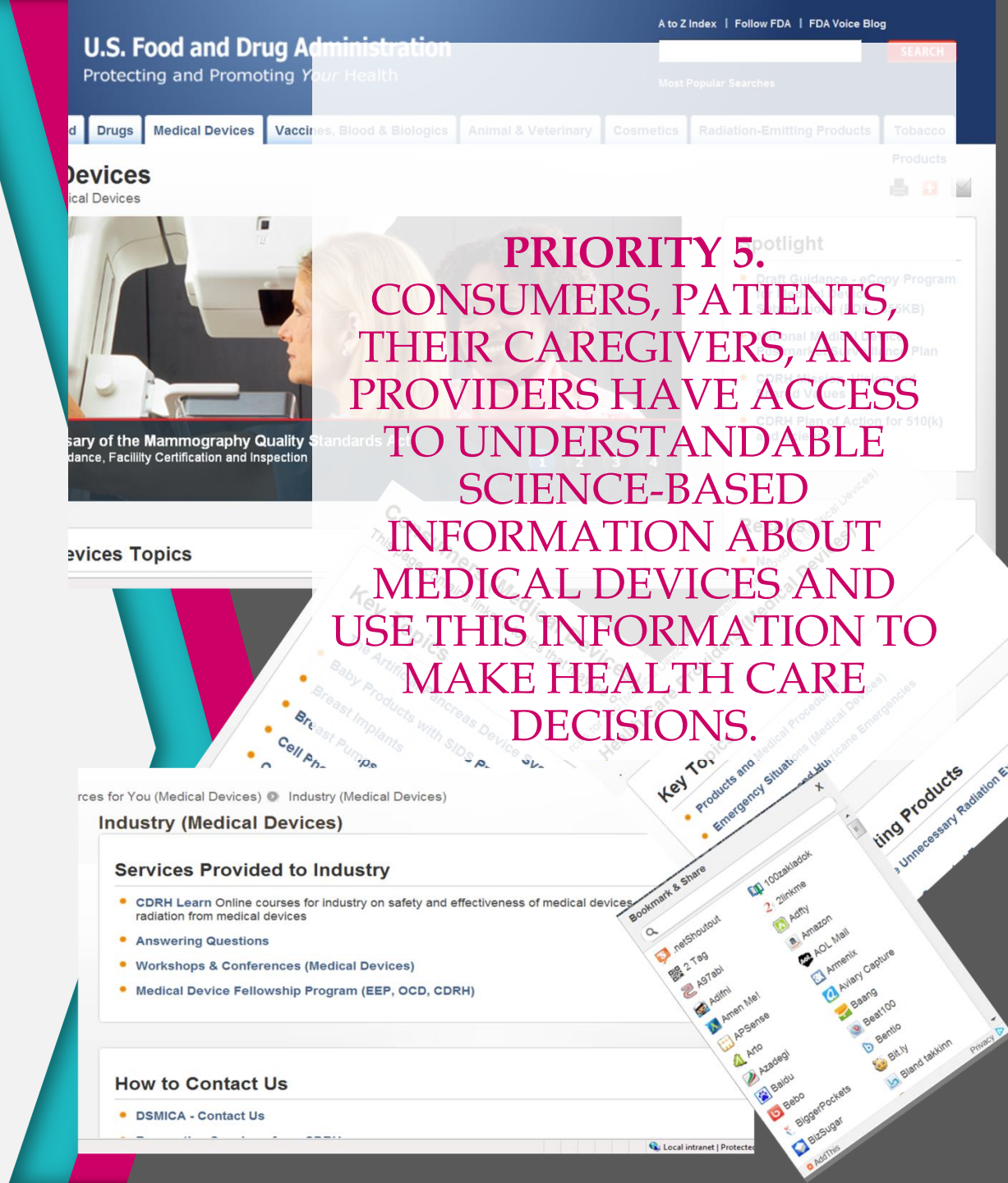
Strategy 5.1. Improve the accessibility and usefulness of device labeling

Goal 5.1.1 By September 30, 2013, CDRH will propose initiatives to improve consistency, usefulness, and accessibility of labeling for home use devices.

Goal 5.1.2. By June 30, 2013, CDRH will assess device user needs to determine adequacy of current labeling practices and initiate discussion about content and format of device labeling.

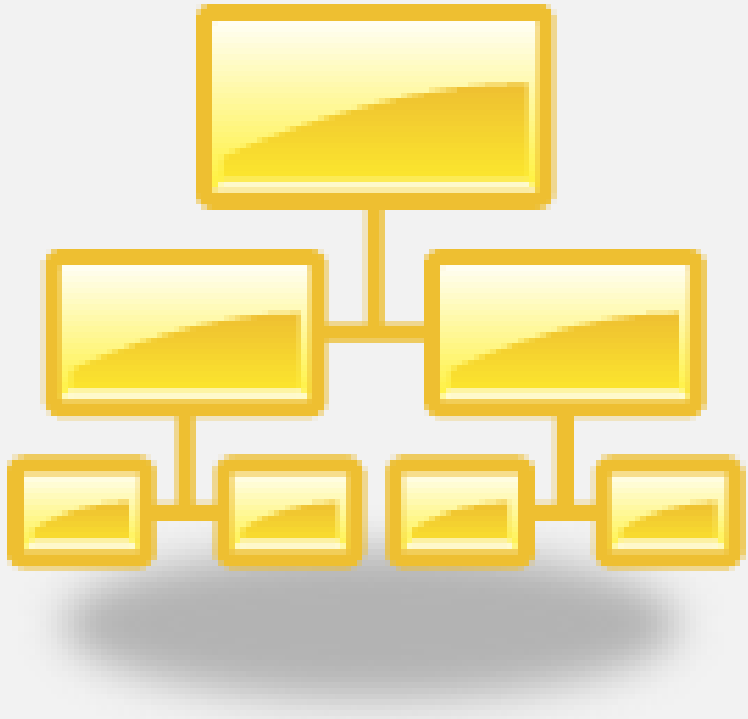
Strategy 5.2. Explore the use of social media for gathering and sharing information with external constituents

Goal 5.2.1. By September 30, 2013, CDRH will take steps to incorporate the use of social media into CDRH communication processes.



PRIORITY 5.
CONSUMERS, PATIENTS, THEIR CAREGIVERS, AND PROVIDERS HAVE ACCESS TO UNDERSTANDABLE SCIENCE-BASED INFORMATION ABOUT MEDICAL DEVICES AND USE THIS INFORMATION TO MAKE HEALTH CARE DECISIONS.

Reorganization Update



ODE Updates

- The Office of Device Evaluation reorganized on November 1, 2012 . The intent behind ODE's reorganization was to:
  - Allow the branches to become more focused on a less diverse
  - Better manage workload
  - Accommodate the new MDUFA hires

- There are two newly created divisions :
  - Division of Surgical Devices
  - Division of Neurological and Physical Medicine Devices

- 12 new branches were created across all 7 review divisions:
  - Division of Surgical Devices – 4 new branches
  - Division of Neurological and Physical Medicine Devices – 3 new branches
  - 5 original Divisions will add a total of 5 new branches
- Division of Cardiovascular Devices implement PMA/HDE manufacturing review and recall evaluation responsibilities starting February 1, 2013.

Office of Device Evaluation

Christy Foreman - *Director*
Jonette Foy - *Deputy Director for Engineering and Science Review*
Barbara Zimmerman - *Deputy Director for Premarket Operations*
Markham Luke - *Deputy Director* for *Clinical*
Melissa Burns - *Associate Director for Regulations and Guidance (Acting)*
Randall Brockman - *Associate Director, Chief Medical Officer (Acting)*

Program Operations Staff
PMA Section - Nicole Wolanski
IDE Section – Vacant
510 (K) Section – Marjorie Shulman

Program Management Office
Kathryn Appler – *Director*
Sharyn (Lesa) Dowtin – *Deputy Director*

Division of Anesthesiology, General Hospital, Respiratory Infection Control, and Dental Devices (DAGRID)

Anthony Watson – Director
Tejashri Purohit-Sheth– Deputy Director
Kwame Ulmer – Deputy Director

Anesthesiology Devices Branch (ANDB)

Lester Schultheis - ***Branch Chief***

- Anesthetic catheters
- Hyperbaric chambers
- Oximeters
- Airway monitoring systems
- Gas analyzers

General Hospital Devices Branch (GHDB)

Richard Chapman - ***Branch Chief***

- Clinical electronic thermometers
- Hypodermic needles
- Intravascular catheters

Respiratory Devices Branch (RPDB)

Vacant - Branch Chief

- Ventilators
- Nebulizers
- Tracheobronchial catheters
- Portable oxygen units
- Oxygen generators

Infection Control Devices Branch (INCB)

Elizabeth Claverie - ***Branch Chief***

- Patient examination gloves
- Sterilization wrap
- Sterilization process indicator
- Surgeon's gloves

•Dental Devices Branch (DEDB)

Susan Runner - ***Branch Chief***

- Endosseous dental implant
- Endosseous dental implant abutment
- Bone grafting material
- Intra-oral devices for snoring
- Dental cement
- Tooth shade resin material

Division of Cardiovascular Devices (DCD)

Bram D. Zuckerman– Director
Owen Faris– Deputy Director
Matthew Hillebrenner – Deputy Director
Vacant – Deputy Director

Cardiac Diagnostics Devices Branch (CDDB)
Linda Ricci - Branch Chief

- Blood pressure monitors
- Implantable hemodynamic
- Electro-Physiology monitors
- Arrhythmia detectorsElectrocardiogram
- Multiparameter monitors
- Diagnostic catheters

Cardiac Electrophysiology Devices Branch (CEDB)
Felipe Aguel - *Branch Chief*

- Ablation catheters
- Ablation surgical instruments
- Mapping catheters

Circulatory Support Devices Branch (CSDB)
Fernando Aguel - Branch Chief

- Ventricular assist devices
- Total artificial hearts
- Cardiopulmonary bypass
- Autotransfusion
- Compressible limb sleeves
- Cardiopulmonary resuscitation devices

Interventional Cardiology Devices Branch (ICDB)
Melissa Torres - *Branch Chief (Acting)*

- Coronary stents
- PTCA catheters
- Coronary atherectomy, embolectomy
- Aortic coarctation stents

Division of Cardiovascular Devices (… continued)

Bram D. Zuckerman– Director
Owen Faris– Deputy Director
Matthew Hillebrenner – Deputy Director
Vacant – Deputy Director

Implantable Electrophysiology Devices Branch (IEDB)
Mitchel Shein - ***Branch Chief***

- Pacemakers
- Defibrillators
- Cardiac resynchronization therapy
- Nerve stimulators

Peripheral Interventional Devices Branch (PIDB)
Lisa Lim - Branch Chief

- Stents
- Atherectomy catheters
- Embolic protection
- Angioplasty catheters

Structural Heart Device Branch(SHDB)
Sonna Patel-Raman - ***Branch Chief***

- Replacement heart valves
- Heart valve repair devices
- Cardiac occluders
- Balloon valvuloplasty
- Adhesion barriers
- Pericardial patches

Vascular Surgery Devices Branch (VSDB)
Kenneth Cavanaugh - ***Branch Chief***

- Endovascular grafts
- Vascular surgical sealants
- Vascular surgical grafts
- IVC filters
- Vascular embolization

Division of Neurological and Physical Medicine Devices (DNPMD)

Victor Krauthamer Director (*Acting*)
Joyce Whang – Deputy Director (*Acting*)

Neurostimulation Devices Branch (NSDB)
Vacant - Branch Chief

- Deep brain stimulation systems
- Spinal cord stimulation systems
- Implanted peripheral nerve stimulation systems
- Vagus nerve stimulation systems
- Permanently implanted electrodes.

Neurodiagnostic and Neurosurgical Devices Branch (NNDB)
Quynh Hoang - *Branch Chief*

- Cerebral-spinal fluid shunts
- Stereotactic equipment
- Neurosurgical lasers
- Diagnostic Electromyography and Nerve Conduction Velocity Devices
- Dura Matter Substitutes and Sealant

Physical Medicine and Neurotherapuetic Devices Branch (PNDB)
Vacant – Branch Chief

- Neuro-psychiatric devices
- Wheelchairs and powered scooters
- Transcutaneous electrical nerve stimulators
- Powered muscle stimulators
- Bone growth stimulators
- Cutaneous electrodes
- Therapeutic infrared heat lamps
- Therapeutic massagers
- Functional electrical (neuromuscular) stimulators
- Diathermy (shortwave and ultrasound)
- Shockwave generators for pain relief

Division of Ophthalmic and Ear, Nose' and Throat Devices (DOED)

Malvina Eydelman– Director
Kesia Alexander– Deputy Director
Eric Mann – Deputy Director

Contact Lenses and Retinal Devices (CLRD)

Denise Hampton - Branch Chief

- Contact lens,
- Lens case
- Intraocular fluid
- Ophthalmic eye shield

Diagnostic and Surgical Devices Branch (DSDB)

Brad Cunningham - *Branch Chief*

- Optical coherence tomography
- Ophthalmic/fundus camera
- Ophthalmoscope
- Transcorneal electrical stimulation

Intraocular and Corneal Implants Branch (ICIB)

Tina Kiang - *Branch Chief*

- Ophthalmic clip
- Ophthalmic conformer
- Artificial eye
- Lacrimal system repair devices

Ear, Nose, and Throat Branch (ENTB)

Srinivas Nandkumar - *Branch Chief*

- Cochlear implants
- Auditory brainstem implants
- Implantable middle ear hearing devices
- Implantable hearing aids
- Hearing aids
- Tinnitus maskers

Division of Orthopedic Devices (DOD)

Mark Melkerson – Director
Peter Rumm – Deputy Director (On Detail to DSD)
Erin Keith – Deputy Director

Joint Fixation Devices Branch One (JFDB1)

Vacant- ***Branch Chief***

- Joint prostheses
- Orthopaedic patient match guides
- Fracture fixation 1
  - Suture anchors
  - Bone fixation fasteners (pins)
  - Nail/blade/plate combination

Joint Fixation Devices Branch Two (JFDB2)

Elizabeth Frank - Branch Chief

- Joint prostheses
- Arthroscopes
- Ortho manual surgical instruments
- Ortho powered surgical instruments
- Fracture fixation 2
  - Bone plates
  - Bone screws
  - Pediatric plates

Restorative and Repair Devices Branch (RRDB)

Laurence Coyne ***- Branch Chief***

- Bone cements
- Bone morphogenetic proteins
- Bone void fillers
- Hyaluronic acid injectables
- Ligaments

Anterior Spine Devices Branch (ASDB)

Anton Dmitriev - Branch Chief

- Anterior/anterolateral plates
- Vertebral body replacements
- Total disc replacements

Posterior Spine Devices Branch (PSDS)

Ronald Jean - ***Branch Chief***

- Posterior/Pedicle Screws Systems
- Facet Screw Systems
- Spinous Process

Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD

Benjamin Fisher– Director
Joyce Whang – Deputy Director (On Detail to DNPMD)
Herbert Lerner – Deputy Director

Obstetrics/GynecologyDevices Branch (OGDB)

Elaine Blyskun - *Branch Chief*

- Assisted reproduction devices
- Urogynecologic surgical mesh
- Laparoscopic and hysteroscopic instrumentation
- Adhesion barrier products
- Endometrial ablation systems
- Vaginal lubricants
- Fetal evaluation/surgery
- Pessaries/dilators/perineometers

Urology and Lithotripsy Devices Branch (ULDB)

Glenn Bell - *Branch Chief*

- Urethral bulking agents for urinary incontinence
- Drug-coated catheters and stents
- Implanted urethral stents
- Implanted prosthesis
- Lithotripters

Renal Devices Branch (RNDB)

Carolyn Neuland - *Branch Chief*

- Dialysis
- Extracorporeal blood treatment
- Transplant solutions and systems
- Body composition analyzers
- Catheter lock solutions

Gastroenterology Devices Branch (GEDB)

Jeff Cooper - Branch Chief

- Obesity
- Ingestible video cameras
- Feeding tubes

Division of Surgical Devices (DSD)

Mark Melkerson – Director (Acting)
Peter Rumm – Deputy Director (Acting)
Vacant – Deputy Director

General Surgery Devices Branch One (GSDB1)
Neil Ogden - *Branch Chief*

- Surgical lasers
- Low level lasers
- Infrared (solid state sources)
- Light based imagining

•General Surgery Devices Branch Two (GSDB2)
Josh Nipper/Long Chen - Branch Chief

- Manual surgical instr.(includes ortho)
- Powered surgical instr. (includes ortho)
- Hypo/hyperthermia devices (surgical cooling)
- Electrosurgical devices

- **Plastics and Reconstructive Surgery Devices Branch One (PRSB1)**

David Krause - *Branch Chief*

- Sutures
- Hemostatic agents
- Breast implants
- Silicone contouring – implants
- Liposuction
- Surgical meshes
- Surgical sealants

- **Plastics and Reconstructive Surgery Devices Branch Two (PRSB2)**

Jiyoung Dang - Branch Chief

- Wound dressings
- Soft tissue fillers
- Surgical sealants
- Dermal replacements
- Wound healing – stimulators
- Skin adhesives

OIR Updates

OIR, the Office of In Vitro Diagnostics and Radiological Health, formerly known as the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), reorganized on Oct. 1, 2012.

Two Divisions with integrated regulatory responsibilities aligned by product area were created:

- Division of Mammography and Quality Standards (DMQS)
- Division of Radiological Health (DRH).

OIR will also add branches to each division to improve the supervisor to staff ratio and ensure consistency with the organizational structure of other Offices within the Center.

Center Updates

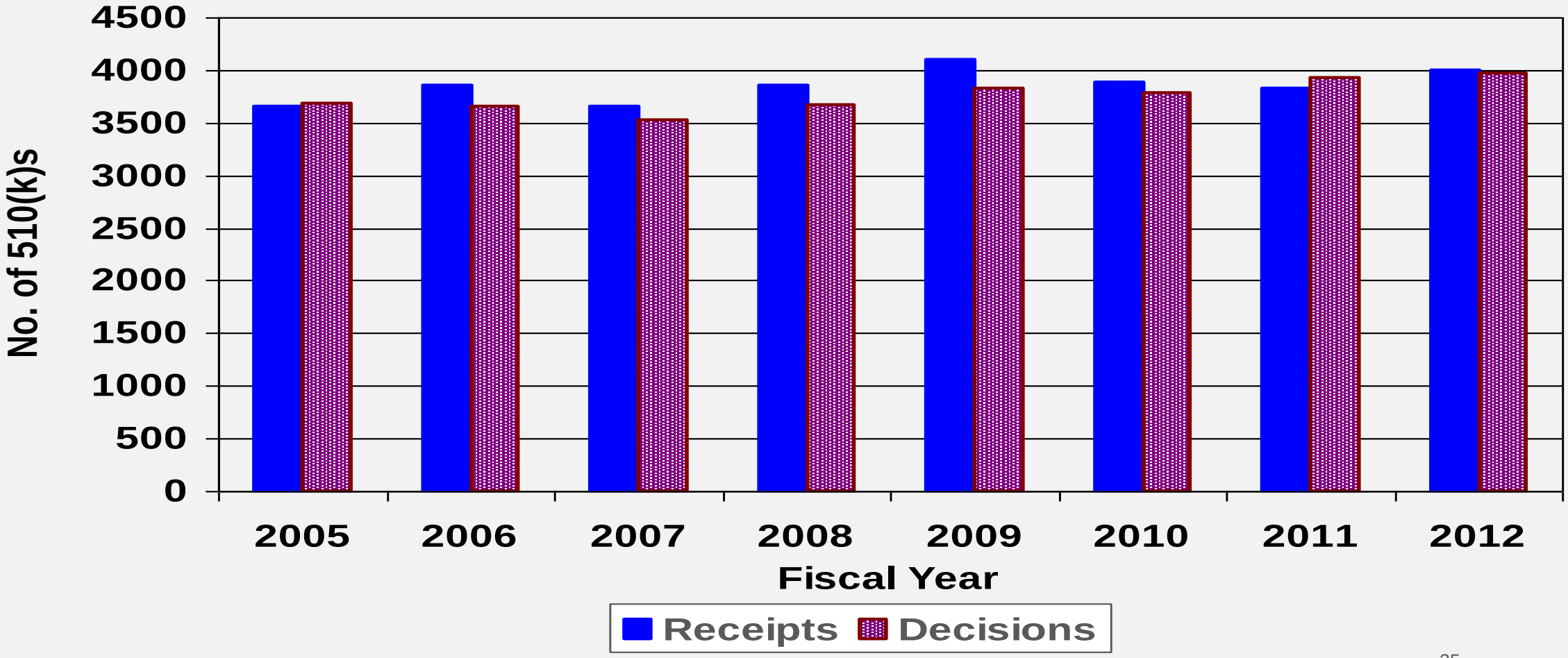
- Associate Director for Innovation
  Murray Sheldon

- Director for Knowledge Management
  Ramin Assa

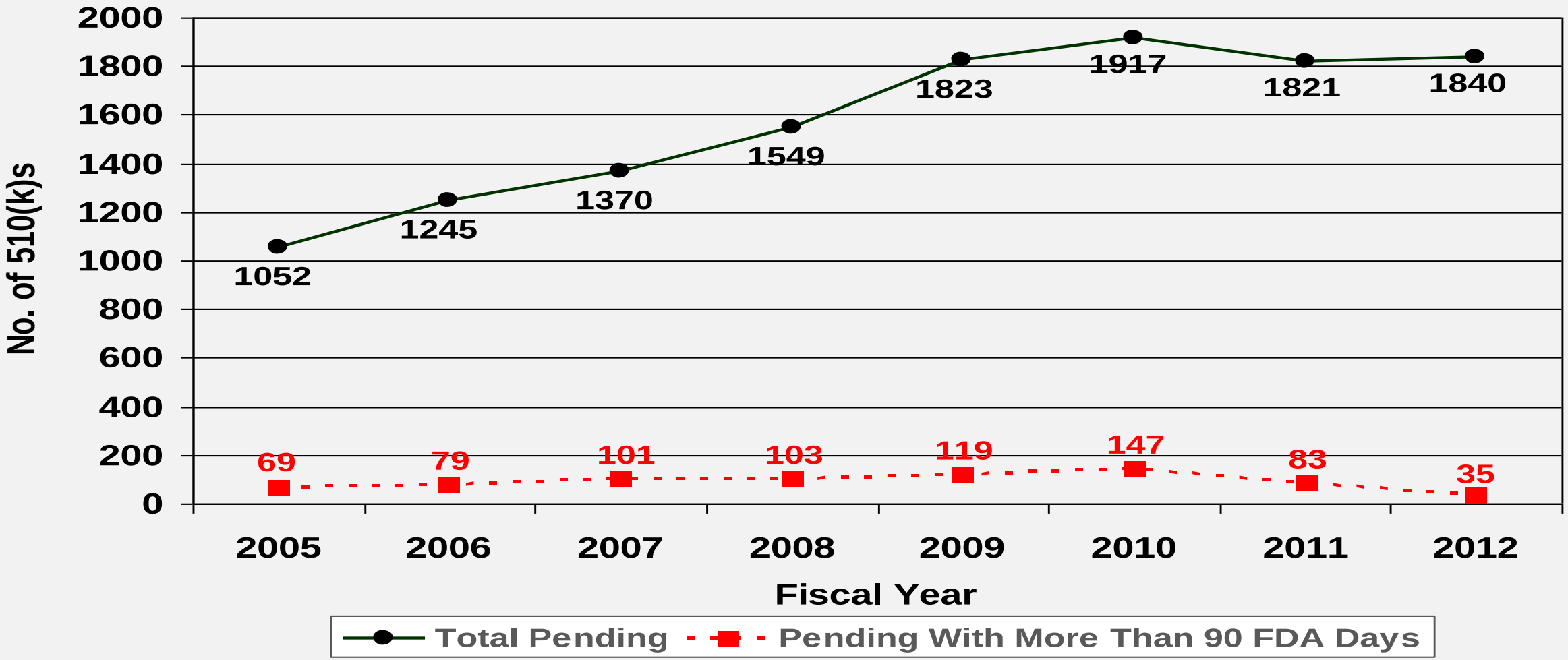
  Getting the right information to the right people at the right time.

Performance Updates

510(k) Receipts and Decisions

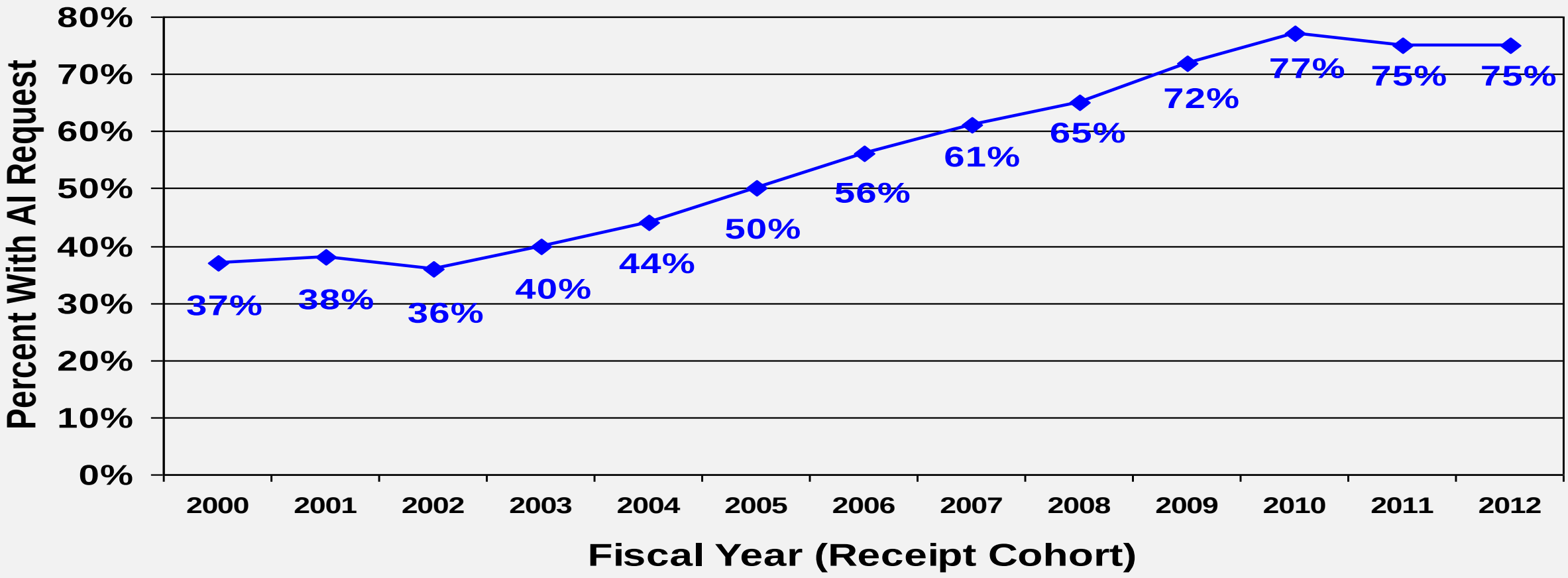


510(k)s Pending* at End of Year

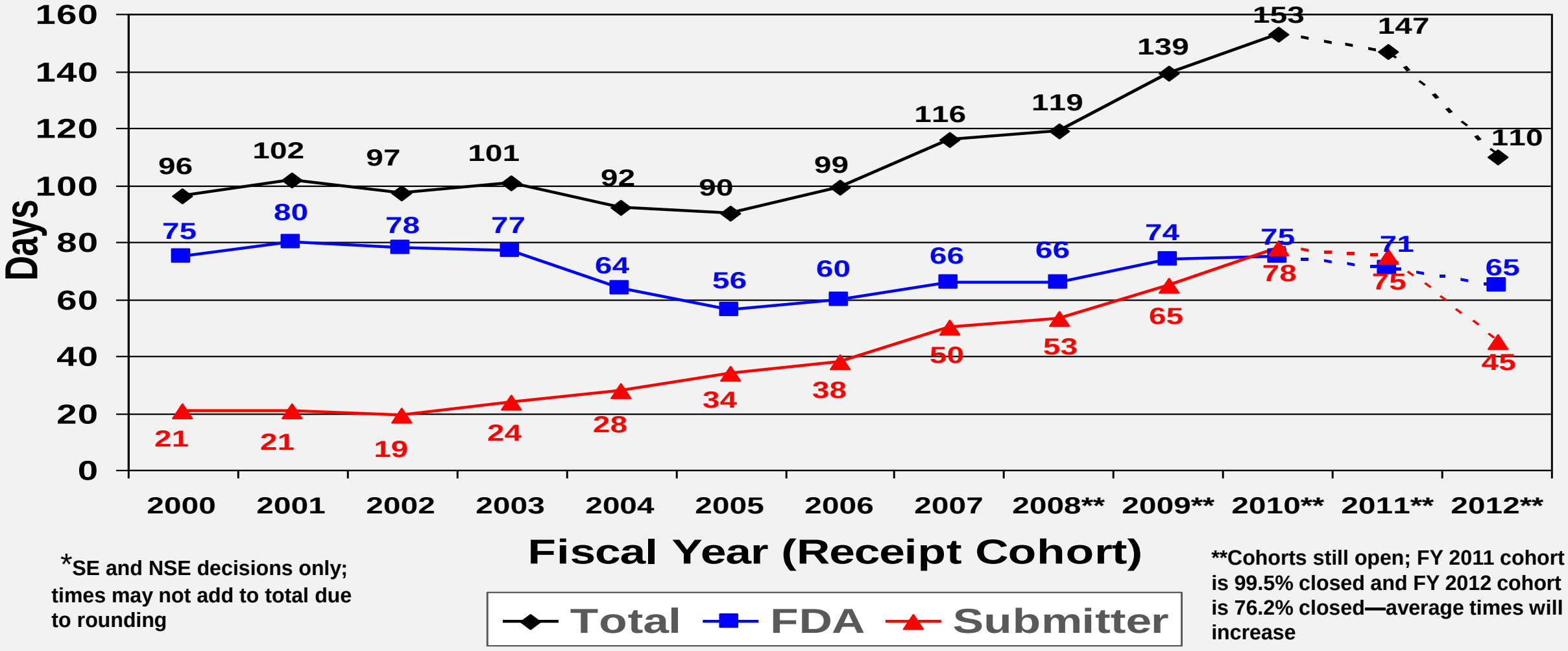


*Under review or on hold

Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



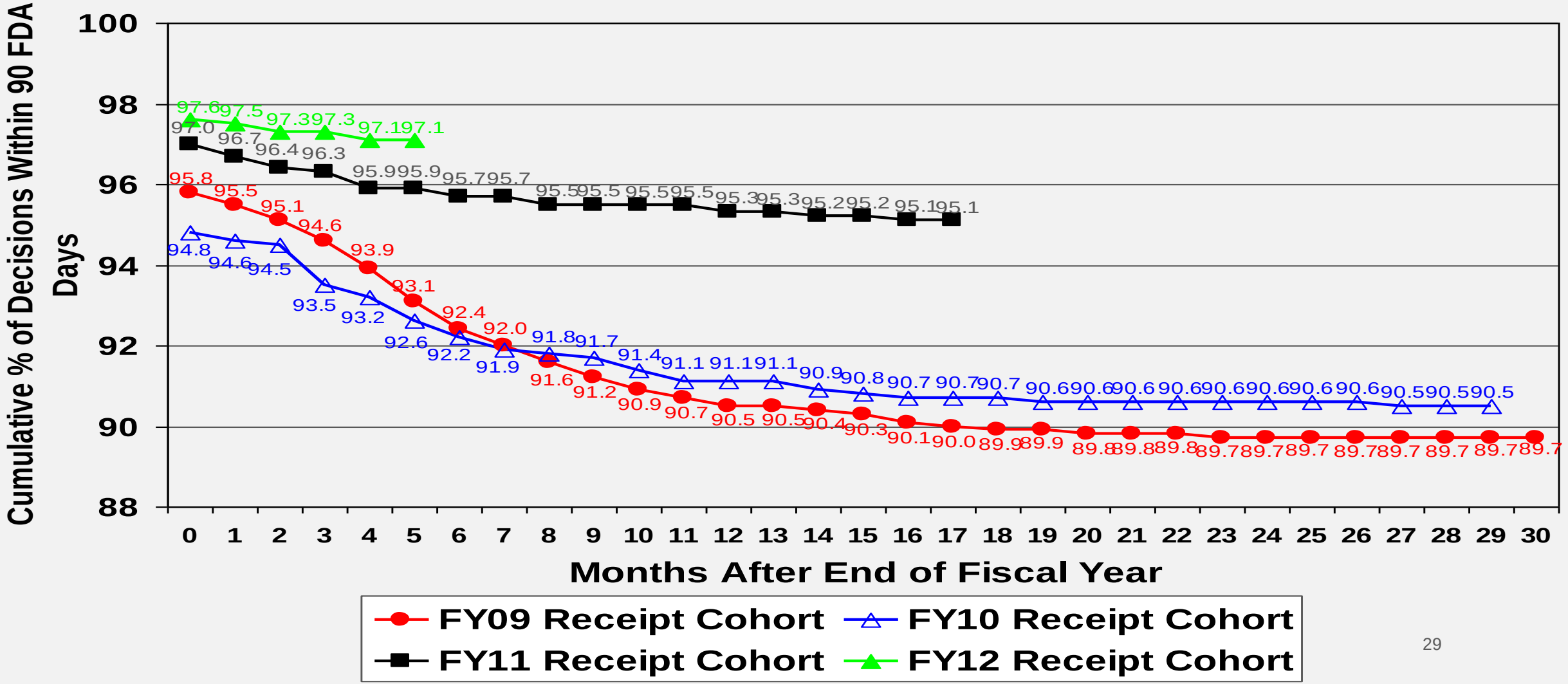
Average Time to Decision: 510(k)s* (Receipt Cohorts as of December 31, 2012)



*SE and NSE decisions only; times may not add to total due to rounding

**Cohorts still open; FY 2011 cohort is 99.5% closed and FY 2012 cohort is 76.2% closed—average times will increase

Trend in 510(k) Tier 1 Goal Performance
- Comparison of FY09 - FY12 Receipt Cohorts -



Percent of 510(k)s Determined to be Substantially Equivalent (SE)