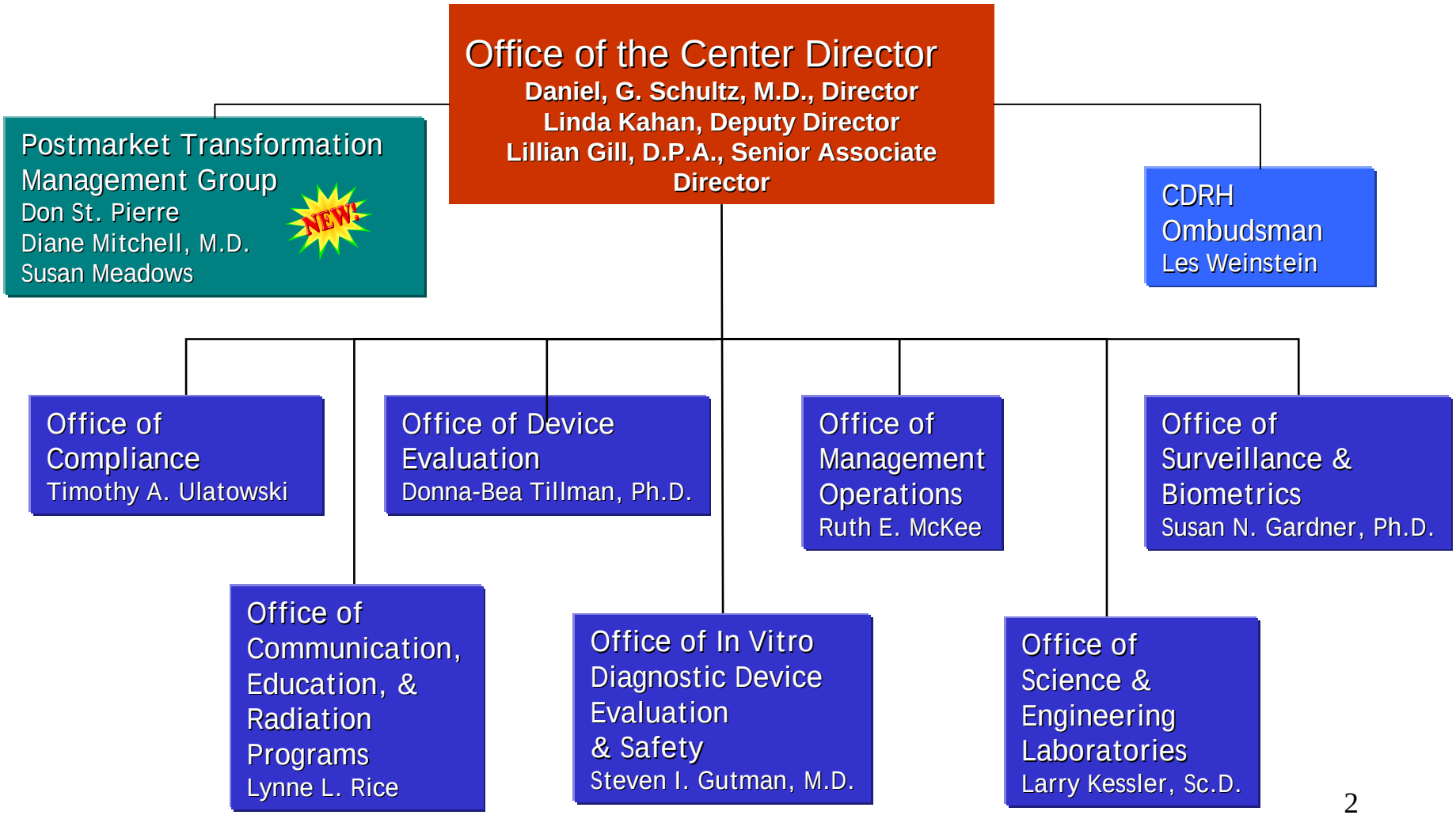
AFDO Annual Conference
San Antonio
June 18, 2007

Les Weinstein, Esq.
Ombudsman
Office of the Center Director
Center for Devices and Radiological Health
FDA

CDRH's Organizational Chart

CDRH is a team of over 1,000 dedicated, highly skilled, and internationally respected public health employees



CDRH Mission

Getting safe and effective devices to market as quickly as possible…

… while ensuring that devices currently on the market remain safe and effective.

Helping the public get science-based accurate information about medical devices and radiological products needed to improve health

Ombudsman

- Receives and investigates complaints about a government agency and mediates or otherwise resolves disputes between that agency and the public
- Resolves disagreements at an early stage before they escalate
  - Alternative Dispute Resolution (ADR)
  - Conciliation, mediation, arbitration, and negotiation

CDRH Ombudsman

- **Provides focus to existing appeal & dispute resolution mechanisms**
  - **some informal and others more formal**
- **Gets involved in any stage of CDRH's decision making processes**
- **Accessible to industry, easing the way to be heard**

CDRH Ombudsman

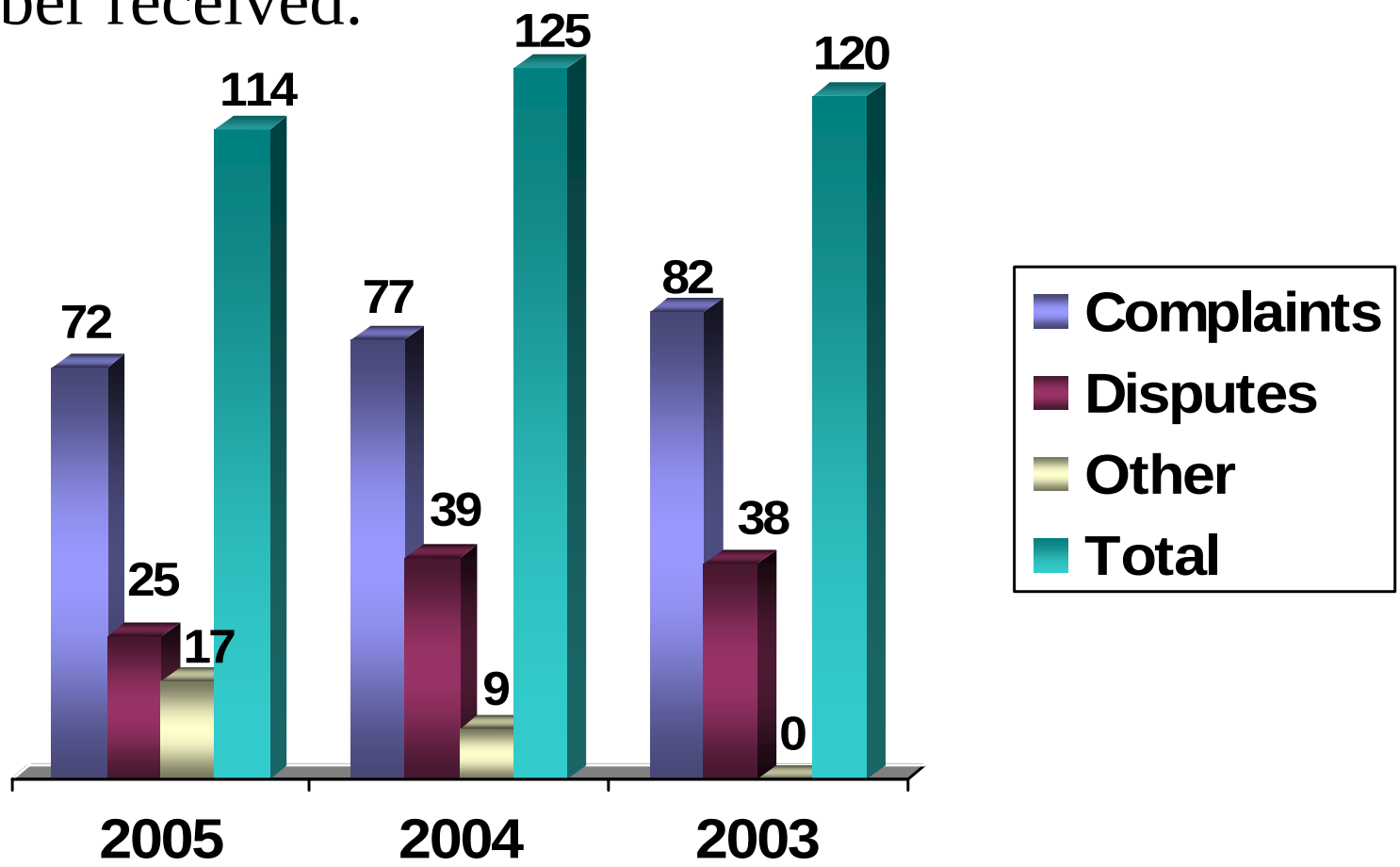
- **Strategizes options available to challenge or appeal**
- **Shuttle diplomacy**
- **Informal/behind the scenes**
- **Attends meetings of companies and CDRH**
- **Facilitates equitable resolution**
- **Promotes and supports fairness, accountability and equity**

CDRH Ombudsman

- **Catalyst to get CDRH staff to take a second look**
- **Are laws and regulations being applied consistently?**
- **Are policies and procedures in conformance with the law?**
- **Neutral and impartial**
- **Pledge of confidentiality**
- **Grassroots liaison**

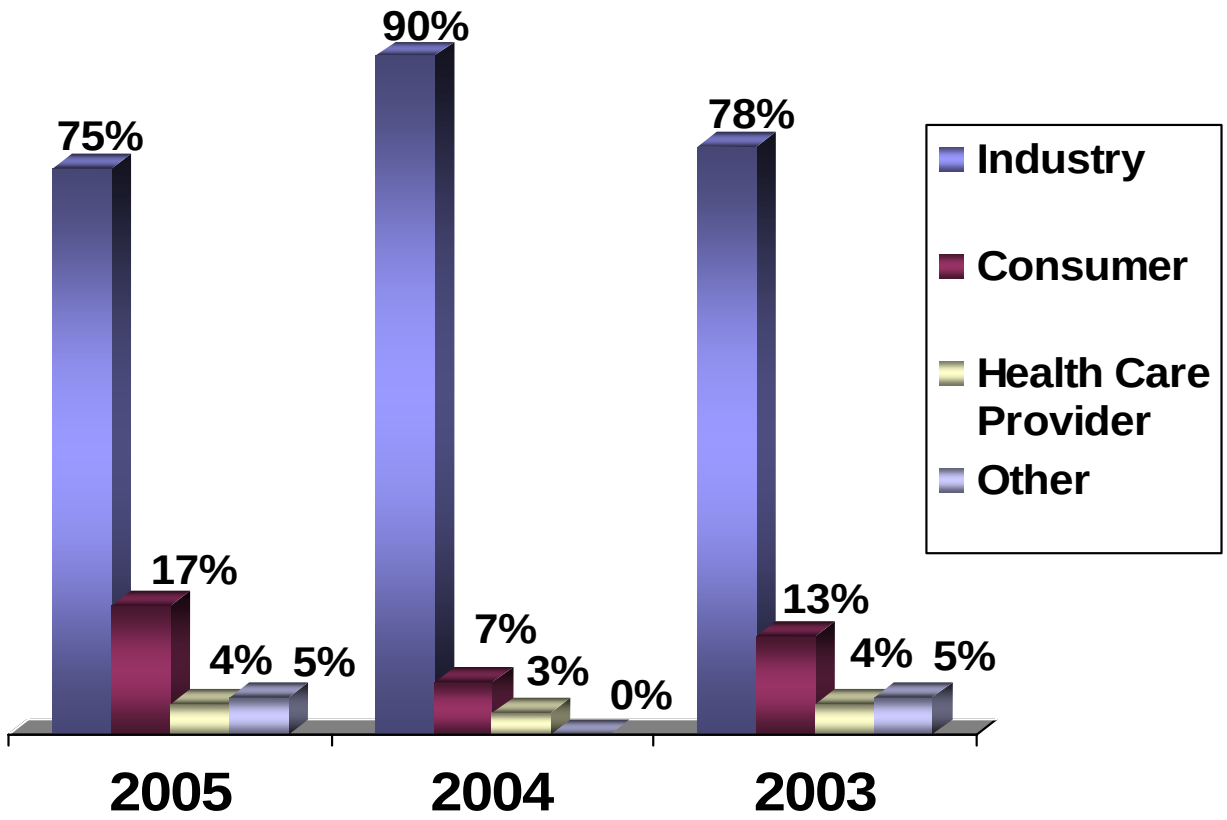
Complaints and Disputes

Number received:



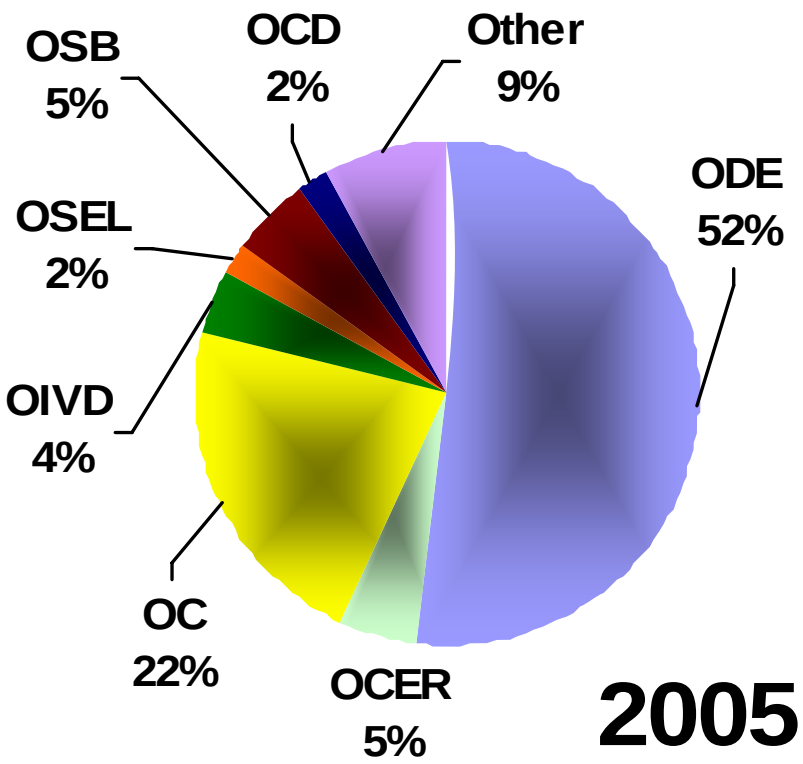
Complaints and Disputes

Source of contacts:



Complaints and Disputes

Office involved or referred to:



Office of the Center Director (OCD)
Office of Compliance (OC)
Office of Communication Education, and Radiation Programs (OCER)
Office of Device Evaluation (ODE)
Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)
Office of Science and Engineering Laboratories (OSEL)
Office of Management Operations (OMO)
Office of Surveillance and Biometrics (OSB)

Complaints and Disputes

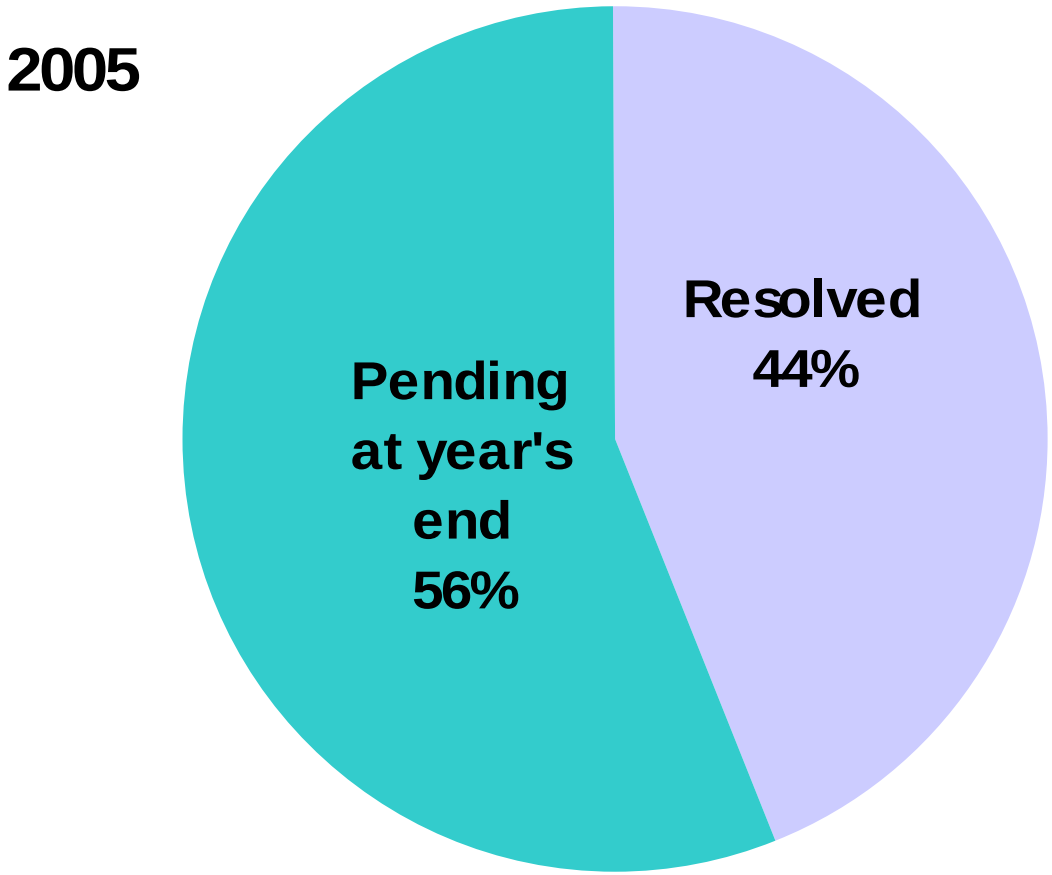
Most common subjects	
510(k)	16%
Adverse Events/MDR	9%
Imports	8%
PMA	7%
IDE	6%
513g	5%

Complaints and Disputes

Most common reasons by rank
1. Miscommunication or lack of communication
2. Data, testing requirements to support a premarket submission; "least burdensome"
3. Lack of timeliness (of approval/clearance; setting up meetings; returning phone calls, etc.)
4. Safety concern/issue
5. Various policies and procedures
6. Level playing field (claim of unequal treatment)
7. Difficult or unhelpful employee
8. Freedom of Information Act (FOIA)

Complaints and Disputes

Status, excluding those referred outside CDRH, withdrawn or had no follow-up by complainant:



Medical Devices
Dispute Resolution Panel

- **FDAMA – Section 404**
  - **Additional, more focused procedure for timely review of scientific disputes between FDA and sponsor, applicant or manufacturer**
  - **Independent expertise of outside clinicians/scientists**
  - **Congressional intent: fair, impartial and timely hearing**

Dispute Resolution Panel

- FDA amended 21 CFR 10.75
- Guidance on Resolving Scientific Disputes: A Guide to Use of Dispute Resolution Panel
  - Issued 7/2/01

Dispute Resolution Panel

- **Eight members:**
  - **Five standing members**
    - **3 voting members with broad scientific/medical backgrounds**
    - **1 non-voting industry representative**
    - **1 non-voting consumer representative**
  - **Three voting temporary members chosen to hear a particular dispute**

- **Makes recommendation to Center Director**
  - **Who can concur, concur with exception(s), or not concur**

Dispute Resolution Panel

- **Has met only three times in six years to resolve a dispute, all re: approvability of PMA**
  - **September 2001: voted approvable**
  - **December 2006: voted not-approvable**
  - **April, 2007: voted not-approvable**

- **Much more common for company to appeal up the supervisory chain using 21 CFR 10.75**

How to Contact the CDRH Ombudsman

- **Les Weinstein**

  Office of the Center Director
  Center for Devices and Radiological Health
  U.S. Food and Drug Administration
  9200 Corporate Blvd. (HFZ-5)
  Rockville MD 20850

  Phone: 240-276-3962
  Fax: 240-276-3961
  email: Les.Weinstein@fda.hhs.gov
  website: http://www.fda.gov/cdrh/ombudsman/index.html

CDER Ombudsman

- **Handles complaints and formal and informal dispute resolution**
- **Jurisdictional issues: drug/device & drug/biological products**
- **Drug development assistance**
- **Contacts from industry, consultants and consumers**

CDER Ombudsman

- **Subject of complaints**
  - **Irregularities & fraud in clinical trials & promotional activities; manufacturing violations**
  - **Urging approval or disapproval/rescission of certain drug therapies**
  - **Unwanted emails from on-line pharmacies**
  - **Direct-to-consumer advertising**
  - **IPledge program administered by Covance**

CDER Ombudsman

- **Types of cases and allegations**
  - **Unethical clinical research including IRB issues**
  - **Off-label promotion and violitive manufacturing**
  - **Review/drug development delay**
  - **Unfair handling of an issue by CDER**
  - **FOIA backlog**

How to Contact the CDER Ombudsman

- **Virginia Behr**

  Acting Ombudsman (HFD-1)
  Center for Drug Evaluation and Research
  U.S. Food and Drug Administration
  Suite 700
  5515 Security Lane
  Rockville MD 20852

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  email: cderombudsman@fda.hhs.gov
  website: http://www.fda.gov/cder/ombud/default.htm