



FDA Commissioner's Fellowship Program

<http://www.fda.gov/commissionersfellowships/default.htm>



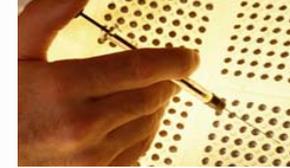
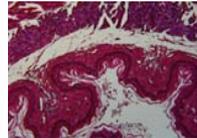
Fast Facts About FDA

- Science-Based Regulatory Agency
- Organized by Product Area
- 223 Field Offices Around U.S.
 - 13 Field Laboratories
- Over 12,000 Employees
- Physicians, Pharmacologists, Toxicologists, Microbiologists, and Other Scientific Professionals
- \$ 3.2 Billion Annual Budget (Proposed FY 2010)



Scope of FDA'S Mission

- *Food*
- *Drugs*
- *Vaccines/Blood*
- *Dietary Supplements*
- *Animal Foods & Drugs*
- *Toxicological Research*
- *Biotechnology*
- *Medical Devices/
Radiological Products*
- *Cosmetics*



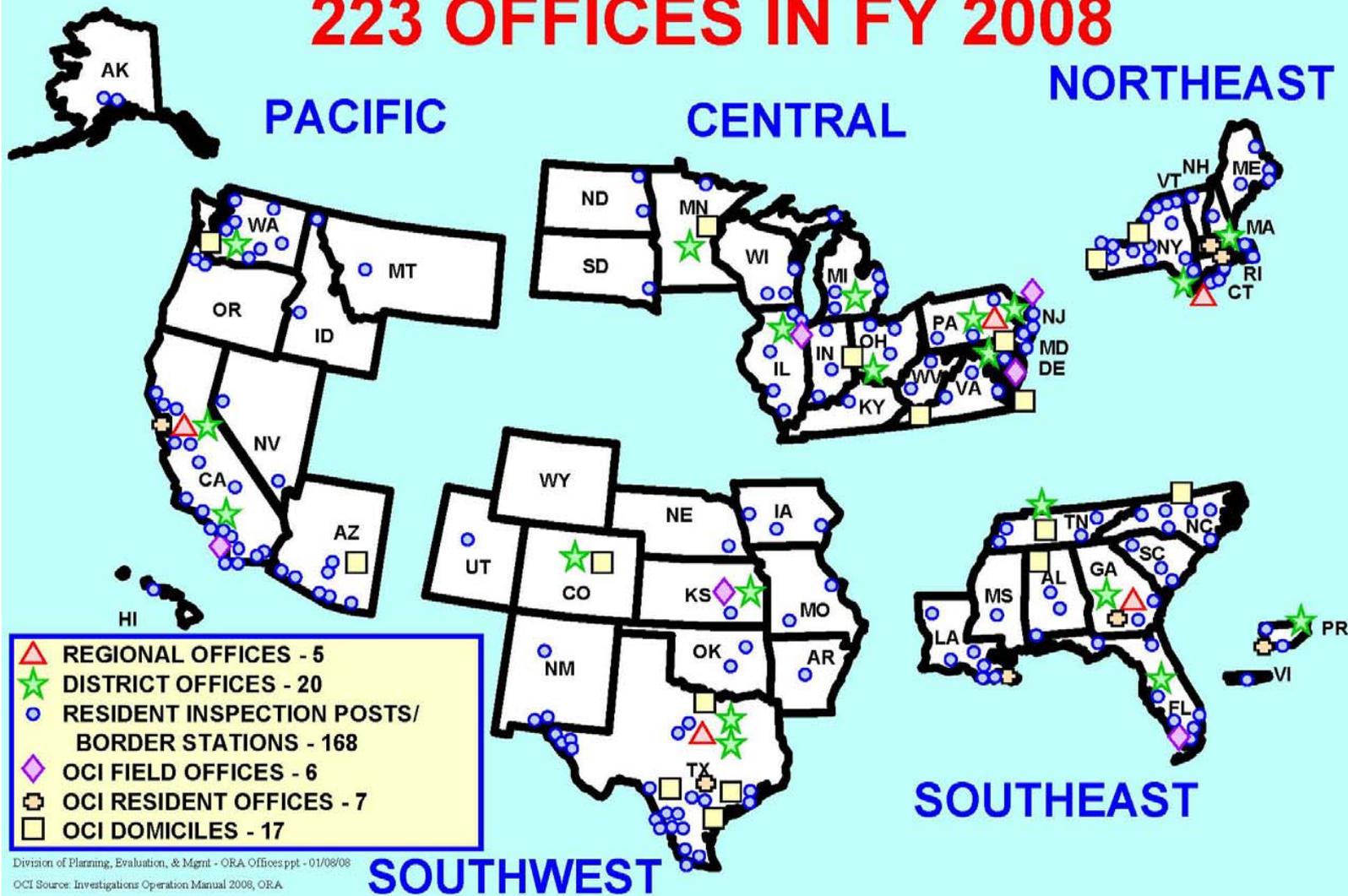


FDA

COMMISSIONER'S

Fellowship Program

223 OFFICES IN FY 2008



Protecting Public Health Through Science and Regulation



FDA

COMMISSIONER'S Fellowship Program

FDA White Oak Campus, Silver Spring, MD



Protecting Public Health Through Science and Regulation



“Chain of Command”



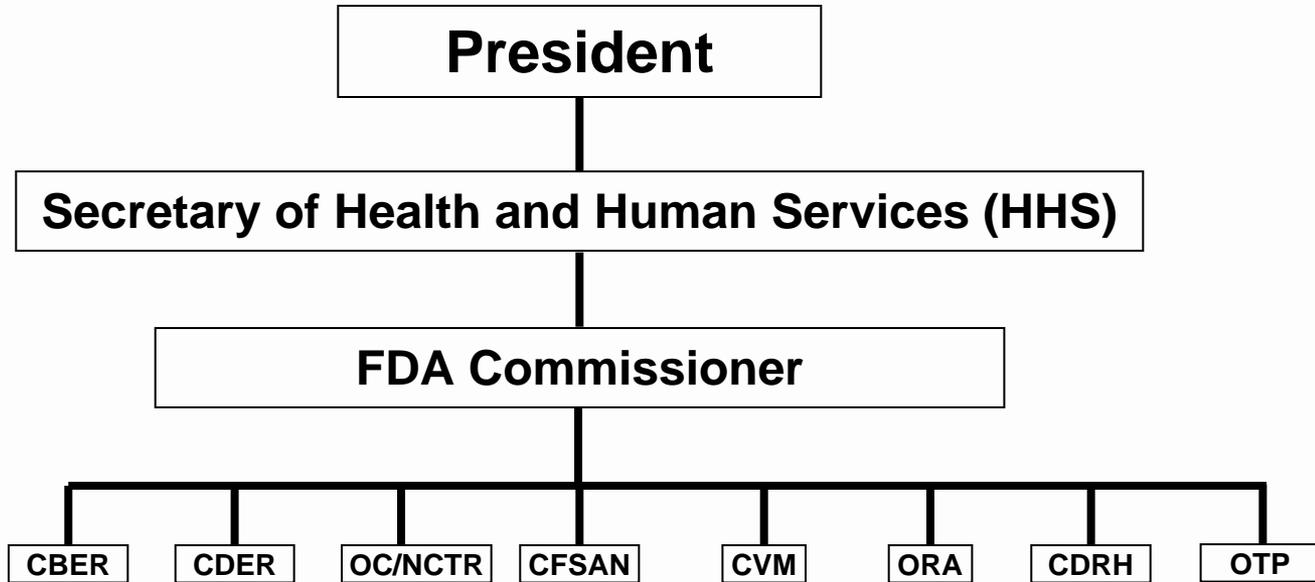
Pres. Barack Obama



Sec. Kathleen Sebelius



Commissioner
Dr. Margaret Hamburg



FDA Offices and Centers



Centers and Offices

- **Center for Devices and Radiological Health (*CDRH*)**
- **Center for Biologics Evaluation and Research (*CBER*)**
- **Office of the Commissioner (*OC*)**
- **Center for Drug Evaluation and Research (*CDER*)**
- **Center for Veterinary Medicine (*CVM*)**
- **Center for Food Safety and Applied Nutrition (*CFSAN*)**
- **National Center for Toxicological Research (*NCTR*)**
- **Office of Regulatory Affairs (*ORA*)**
- **Office of Tobacco Products (*OTP*)**



What you want to know about the Commissioner's Fellowship

- **1. What is the fellowship about?**
- **2. Duties and day-to-day activities?**
- **3. Who can apply and how does one obtain this fellowship?**



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FDA Commissioner's Fellowship Program

Overview



Vision from the Fellowship Program

- Best and brightest, new science and scientists
- Challenge convention
- Exposes Fellows to all FDA centers and offices
- A program for Preceptors as well as Fellows

- Dr. Torti, Report to the Science Board, 2/24/2009



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COMMISSIONER'S Fellowship Program

General:

<http://www.fda.gov/commissionersfellowships/default.htm>

- **2-Year Program (October 2010 – October 2012)**
- **Rigorous Didactic Coursework**
 - Specific to concepts related to the FDA
- **Regulatory Science Research Project**
 - Under the supervision of an established FDA Preceptor



The Fellowship Program

Curriculum and Projects



Semester 1: Core Introductory Courses

- FDA and Public Policy
- FDA Law
- Negotiation and Influencing
- Ethics and Decision Making
- Beyond Our Borders
- Conflict Management Skills
- Briefing the Boss: Presenting to Senior Executives
- Building Leadership Credibility
- Decision Making for Leaders



Semester 2:

- Statistical Methods and Applications
- Population Science/ Epidemiology
- Clinical Trial Design and Evaluation

Summer Session:

- Investors View of Drug Development
(An MBA Course)



Semester 3: Core Functions and Science of The Centers and Offices

- Devices and Radiological Health
- Foundations of Toxicology
- Understanding Biologics and Their Evaluation
- Understanding Drugs and Their Evaluation
- Food and Nutrition Safety
- Surveillance and Operations
- Animal and Human Health: An Inseparable Link



Semester 4:

- Process Control Engineering and Chemistry
- Risk Assessment / Risk Management
- Case Studies in Translational and Regulatory Science
- Elective (to be determined)



Research Project:

A hypothesis driven project guided by a senior FDA Preceptor:

- Detailed research proposal
- Oral presentation and final report
- 60-70% time
- Can be regulatory or laboratory based



Project Examples:

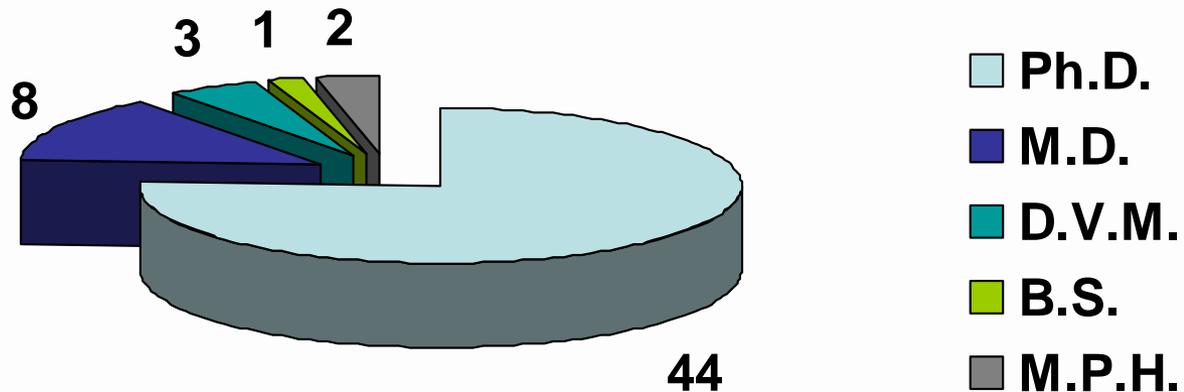
- *International Clinical Trials Harmonization in Medical Device Regulations for Human Participant Protections (CDRH)*
- *Engineering HIV Protein gp120 for the Rational Design of an HIV Vaccine (CBER)*
- *Science Policy and Outreach in Regenerative Medicine (OC)*
- *Mechanisms of Oncogenesis - Investigation of p53 and Interacting Pathways for Targeted Therapy and Biomarker Potential (CDER)*
- *Disposition of Selected Veterinary Drugs in Edible Aquatic Species (CVM)*
- *Development of a Rapid Approach for Identification of Foodborne Bacterial Pathogens (CFSAN)*
- *Ahead of the Challenge - Setting up a Regulatory Standard for Proteomics Data Submission and Evaluation (NCTR)*

Inaugural Class – 2008



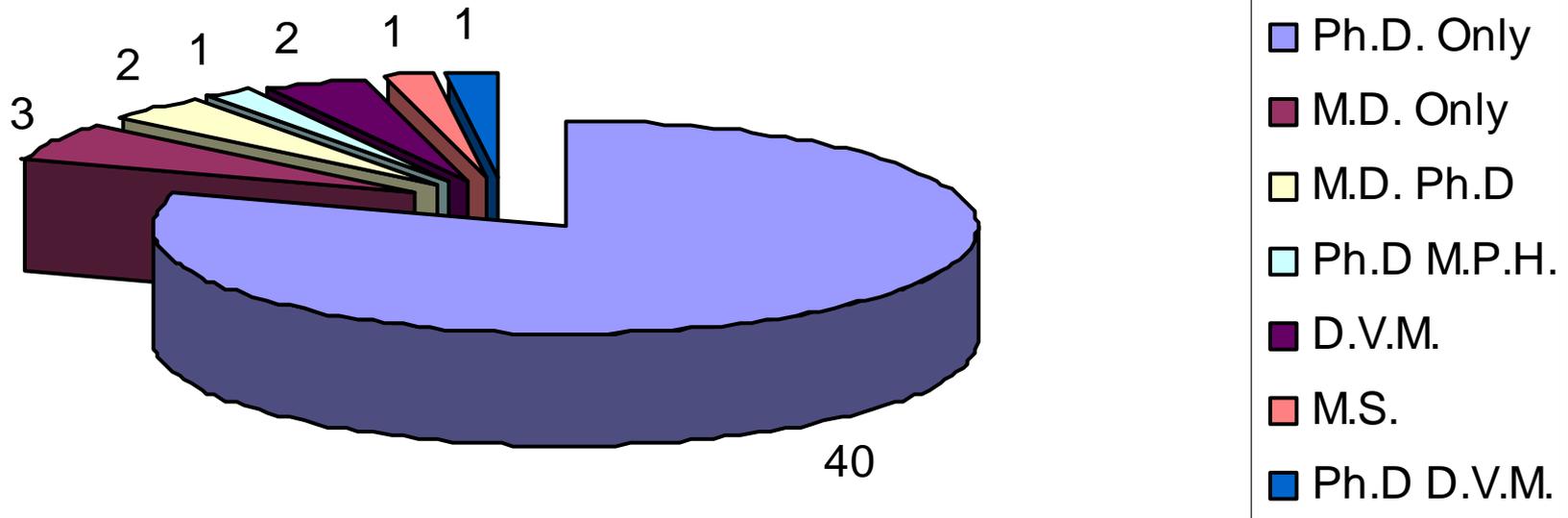


Class 2008 Degree Breakdown





Class 2009 Degree Breakdown





The Fellowship Program

The Application



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- **1. What is the fellowship about?**
- **2. Duties and day-to-day activities?**
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Eligibility:

- **US Citizen**
 - Non-citizens must be admitted to the U.S. for permanent residence before the program start date
- **M.D., D.O., D.V.M., D.D.S., D.P.M., Pharm. D., or Ph.D.**
 - All PhD requirements must be completed by 9/30/10
 - M.S or B.S. in Engineering may be accepted



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What You Need to Do.....

- Permanent residence if you are not a U.S. Citizen.
- Verification of foreign degree if your degree is completed outside of U.S.
- Electronic copy of your Resume/CV in Word, Word Perfect, or PDF.
- Three references and their contact information.
- Personal Statement
 - Your educational and professional experience
 - What has driven you to apply to the FDA Commissioner's Fellowship program.
 - What you would bring to the FDA
 - How you believe this fellowship will help you reach your short and long term career goals.
 - One page, single-spaced, 12-point font.
- Electronic copy of your transcripts
 - Unofficial transcripts are acceptable.
- Select up to ten preceptors from the list who you would be interested in working with.

Protecting Public Health Through Science and Regulation



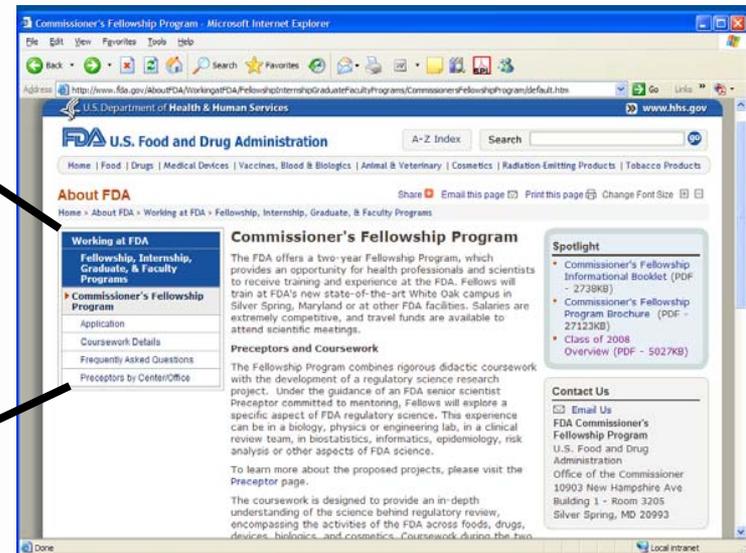
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Fellowship Program

All the Information is on our website

Working at FDA
Fellowship, Internship, Graduate, & Faculty Programs
► Commissioner's Fellowship Program
Application
Coursework Details
Frequently Asked Questions
Preceptors by Center/Office



<http://www.fda.gov/commissionersfellowships/default.htm>

Protecting Public Health Through Science and Regulation



Key Dates

- December 15 – April 15 – Applications Accepted
- June – Interviews
- June – July – Applicants Notified of Their Standing
- October – Program Start Date



Pay and Benefits

<http://www.fda.gov/jobs/default.htm>

- Stipend will be determined by Human Resources.
 - Expected range is \$65,000 - \$110,000
- Federal Government Health Insurance Programs
- Federal Government Retirement Programs (TSP)
- 2 weeks/year Vacation
- 2 weeks/year Sick leave
- No Housing Allowance or Relocation Assistance
- No Student Loan Repayment



Questions?

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