Career Opportunities at FDA

From a regulatory scientist perspective

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Disclaimers

1. The views expressed in this presentation are those of the speaker and do not necessarily represent the official position of the U.S. Food and Drug Administration.

2. I am not a head hunter

3. I am not from FDA personnel office

What to cover

- Introduction
- FDA: A dynamic organization
- Overview of career opportunities at CDER/FDA
- What are the basic requirements to become a regulatory scientist or reviewer
- What do I do as a regulatory reviewer
- Summary of regulatory reviewer positions
- How to apply for a regulatory scientist position

Introduction

- FDA: >10,000 employees with a budget >$2 billion, comprising chemists, pharmacologists, physicians, microbiologists, pharmacists, lawyers, and many other professions and support staff members.
- Center of Drug Evaluation and Research (CDER):
- CDER performs an essential public health service by ensuring that safe and effective drugs are available to improve the health of people in the United States.
- CDER regulates over-the-counter (OTC) and prescription drugs, including biological therapeutics and generic drugs.

When/what is CDER involved

- Drug development/investigational phase
  Investigational New Drug Application (IND)

- Pre-market review phase
  New Drug Applications (NDA)
  Biologic License Applications (BLA)
  A*bbreviated* NDAs (ANDA) for generic drugs

- Post-approval phase

CDER Workload (Yearly)

- INDs (research & emergency) receipts = >700
- Approved NDAs = 125 (entirely new = 25-35)
- Approved Efficacy Supplements = 130
- Manufacturing Supplements = 2,000
- Adverse Events = 1,000,000

Generic Drug Workload (Yearly)

- Approved ANDA = 500
- Tentatively Approved = 100
- ANDA Receipts = 1000
- Chemistry Supplements Received = 3600
- Labeling Supplements = 2000

FDA: A dynamic organization

Prescription Drug User Fee Act (PDUFA)

- To speed up drug review times without compromising standards
  Pharmaceutical companies pay user fees for the review of their new drug application which FDA uses to add review staff and shorten review time

- PDUFA I started in 1992, renewed four times 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), and 2012 (PDUFA V)

- PDUFA V covers October 1, 2012 and September 30, 2017

FDA: A dynamic organization

- **Generic Drug User Fee Act (GDUFA):** Established 2013

  Generic drug submission: 320 in 2001 to 946 in 2011
  Backlog of nearly 3,000 generic drug applications

  Estimated savings through generic drug use: $192 billion in 2011

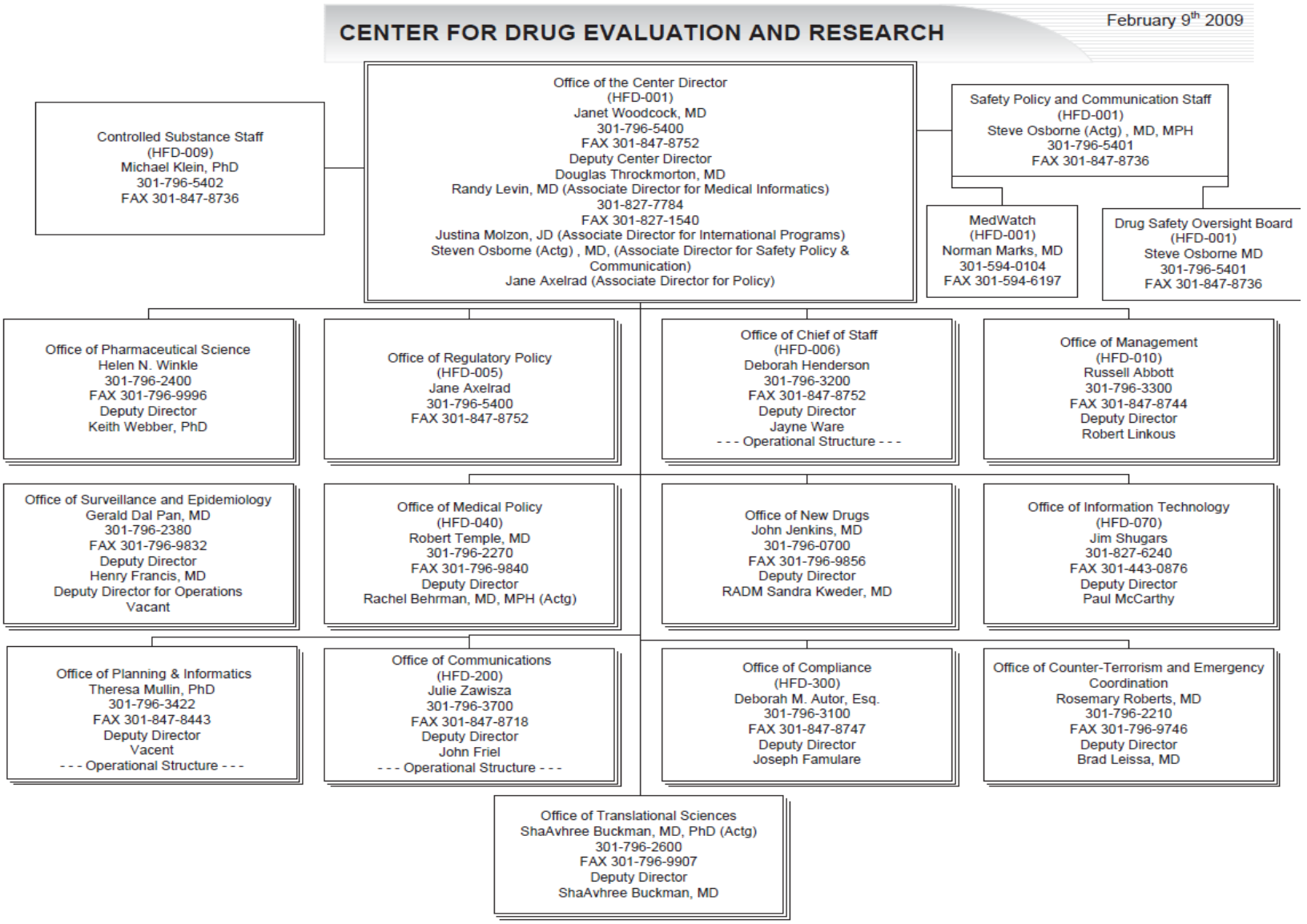
- **Biosimilars**

  Biosimilar User Fee Act (BsUFA) passed July 2012 – effective Oct. 1, 2012

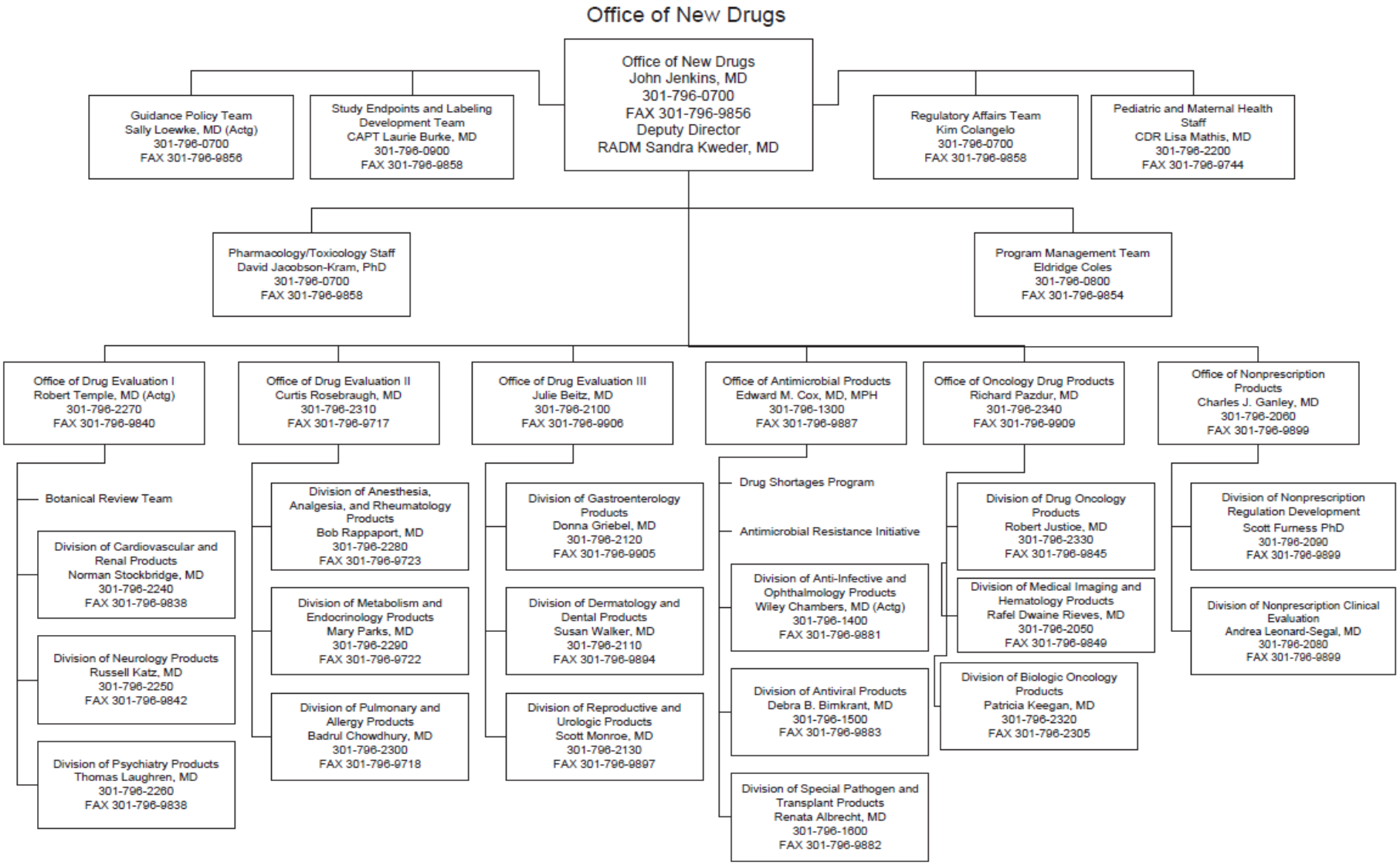
  Review primarily conducted by the Office of New Drugs and the Office of Biotechnology Products

  Estimated to save $42-108 billion in its first 10 years

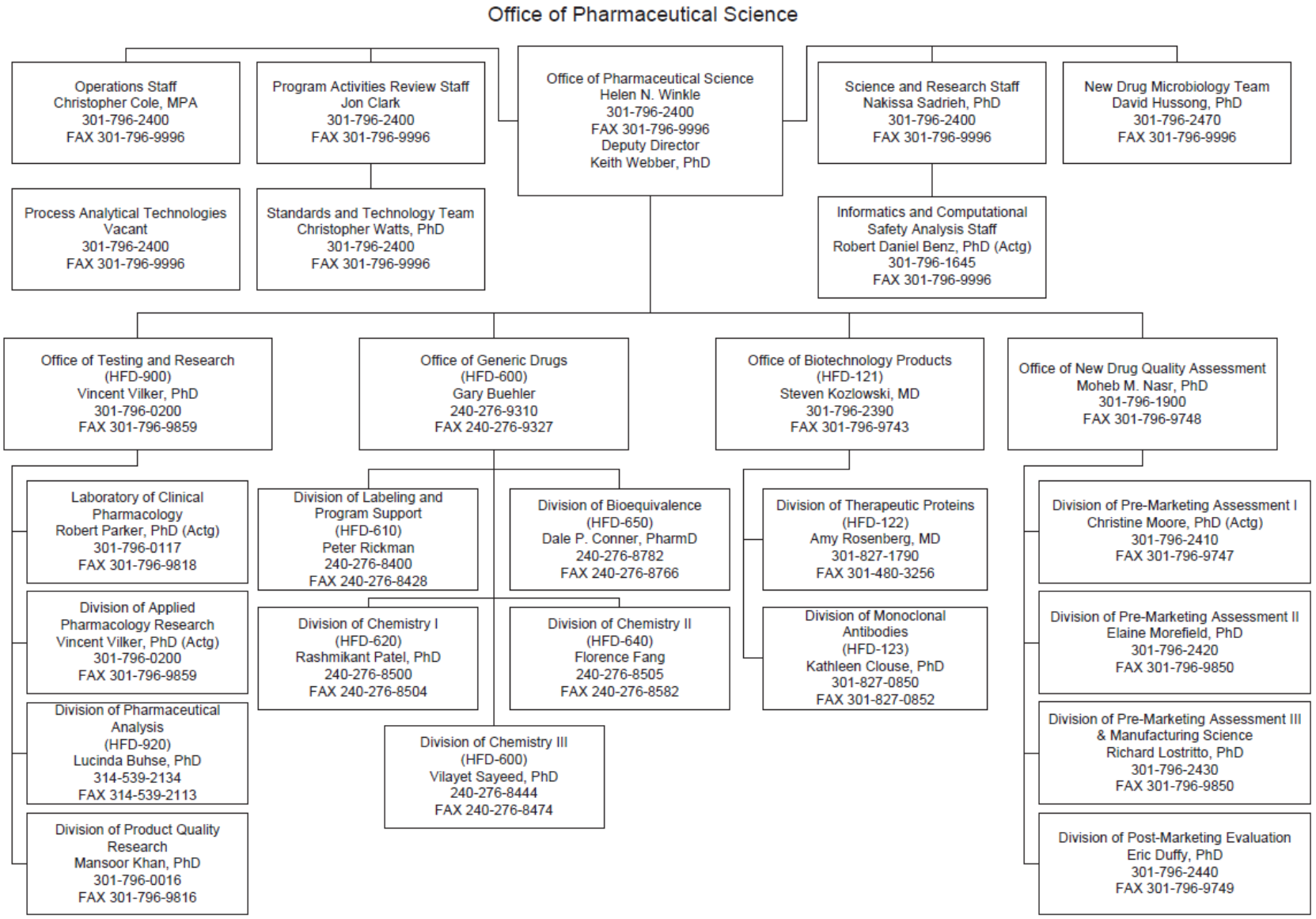
CDER Organization Charts



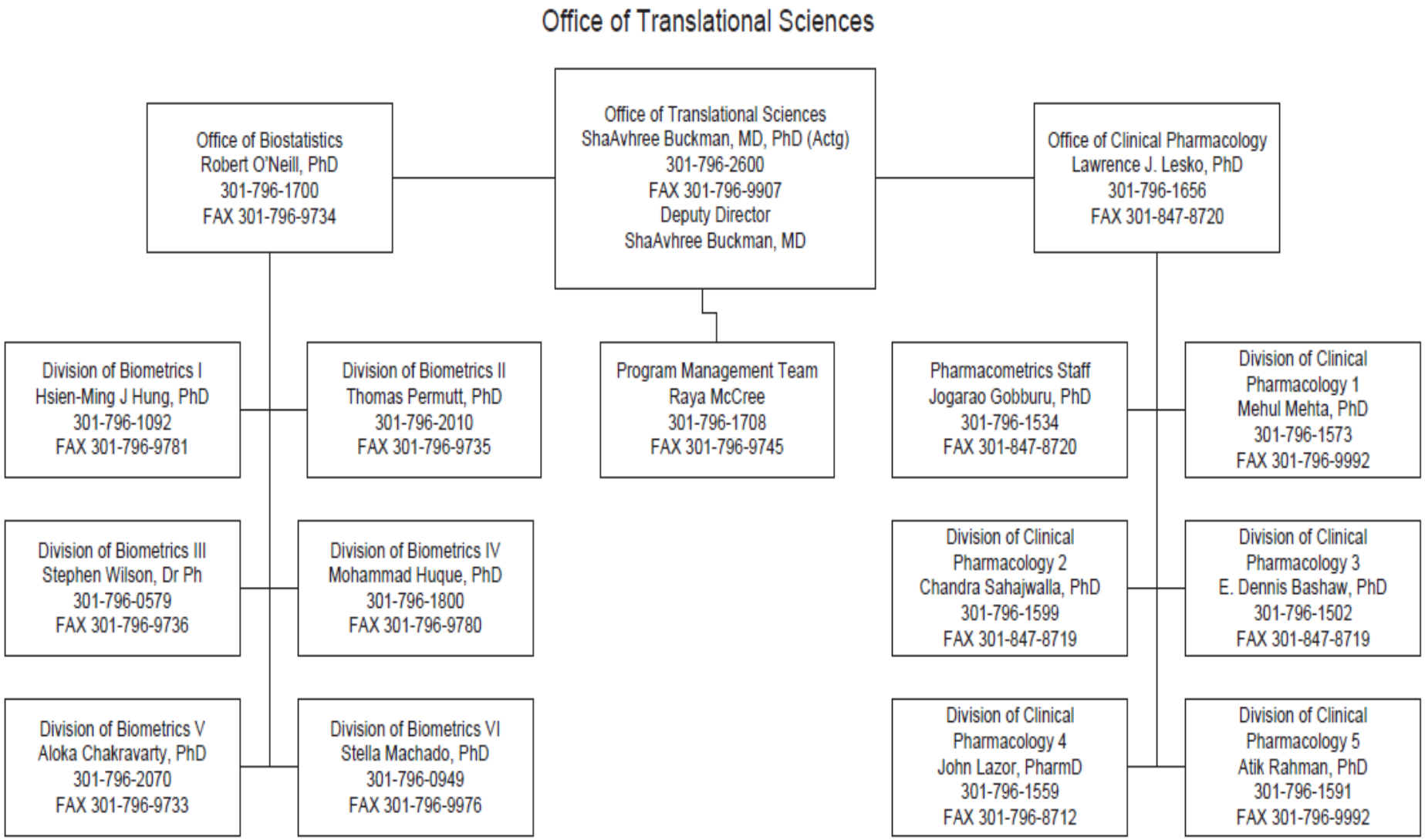
CDER Organization Charts



CDER Organization Charts

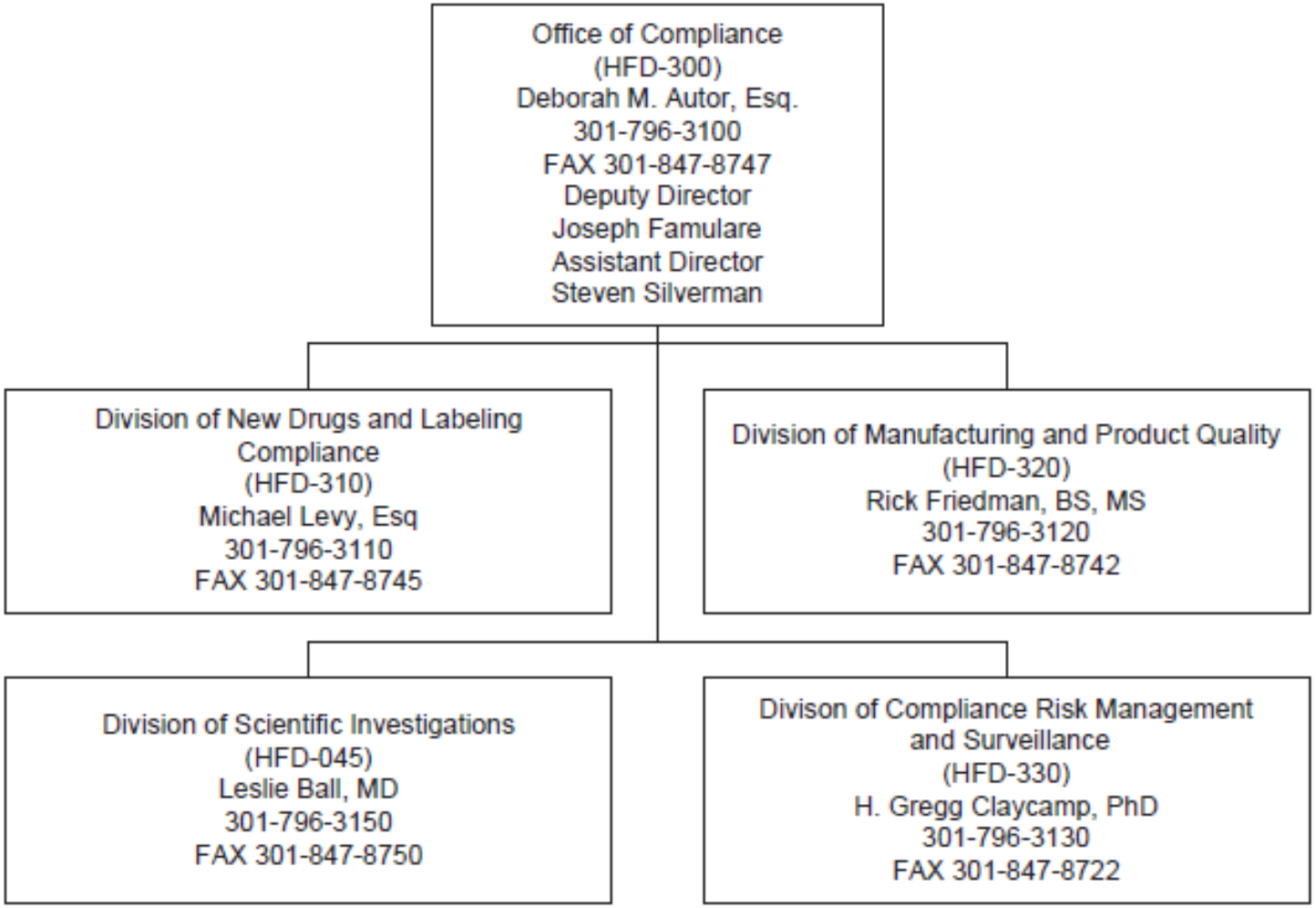


CDER Organization Charts



CDER Organization Charts

Office of Compliance



Careers at CDER

- **Reviewers or regulatory scientists**

- Pre-market review team:
  - Medical Officer/Physician
  - Project Manager
  - Chemist
  - **Pharmacologists/Toxicologist**
  - Statistician
  - Clinical Pharmacologist
- Post-market review team:
  - Epidemiologist
  - Risk Management specialist
  - Safety evaluator

Careers at CDER

- Evaluate data submitted by sponsors of an Investigational New Drug Application (IND) and New Drug Applications (NDA) to support the marketing of a drug.

- Evaluate portions of INDs/NDAs related to their particular discipline. Determine the scientific validity of manufacturers' tests, drug safety and efficacy claims.

Careers at CDER

- **Physicians.** (Various medical specialties)
- Basic qualification is a Doctor of Medicine.
- Graduates of foreign medical schools must be Educational Commission for Foreign Medical Graduates (ECFMG) certified.
- Board certification/eligibility in a medical specialty and experience in conducting clinical trials are highly desired for these positions.
- Physicians may also be paid an additional Physician Comparability Allowance up to $24,000 (depending on years of Federal experience).
- GS14 - GS15

Basic requirements for regulatory scientists

- **Pharmacologist - 0405**

  A degree in an appropriate biological, medical, veterinary, or physical science, or in pharmacy that included at least 30 semester hours in chemistry and physiology and 12 semester hours in pharmacology.

- **Toxicologist - 0415**

  A degree in toxicology or an appropriate discipline of the biological, medical, or veterinary sciences that included at least 30 semester hours in chemistry, biochemistry, or physiology, and 12 semester hours in toxicology.

- A doctorate degree in a relevant scientific discipline with at least two years post-doctorate experience is highly desired.

- Civil Service or Commissioned Corp is limited to U.S. Citizens. Permanent resident aliens (Green card holders) and others with visas that legally permit such employments may be hired through the Service Fellowship or Staff Fellow/Visiting Scientist Programs.

What do I do as a regulatory reviewer

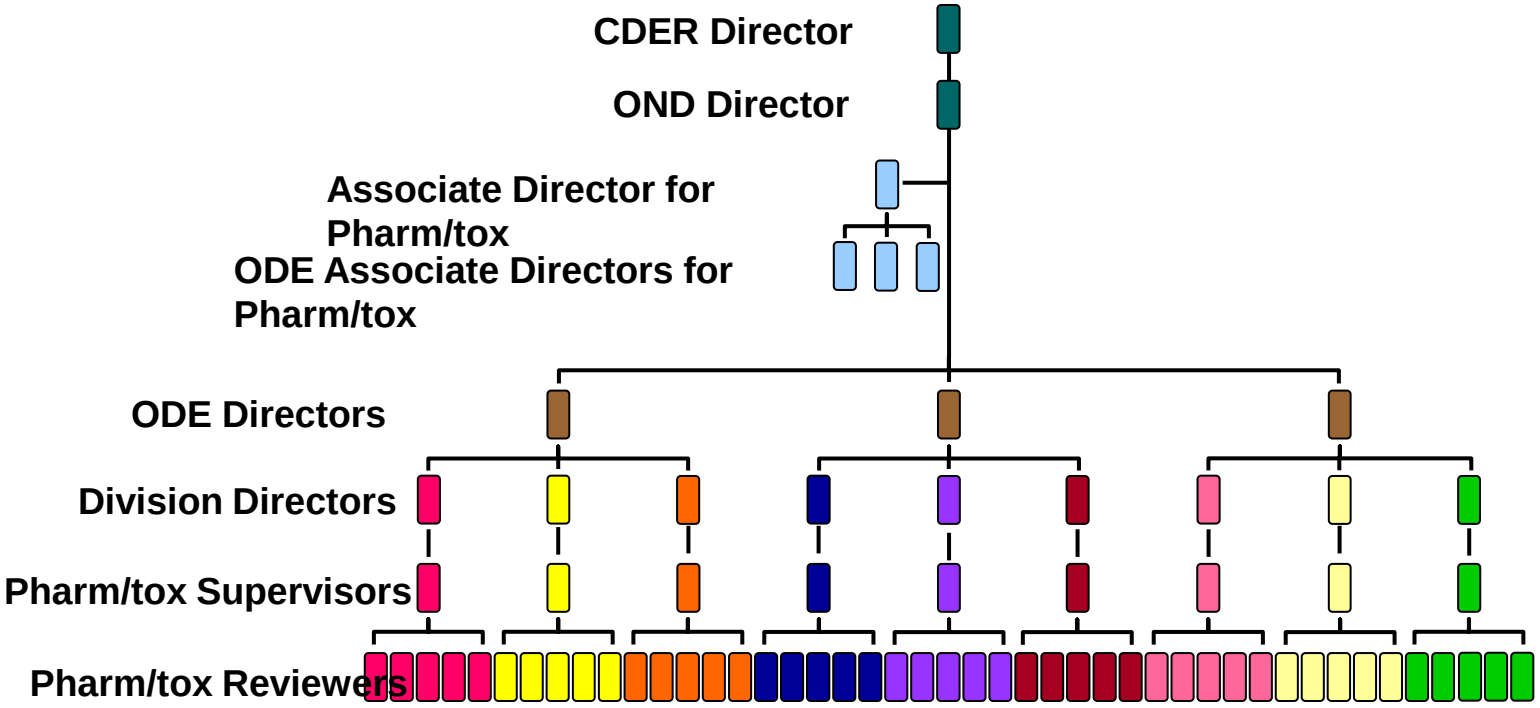
- Pharmacology and toxicology reviewers
  Review nonclinical data or animal studies

Cynomolgus monkey

Rhesus monkey

Pharm/tox reviewer in CDER

Pharm/tox reviewer



Role of pharmacologist or toxicologist

- Assess the safety and efficacy of a drug based on the animal data submitted by the sponsor
- Predict how effects and/or toxicity in animals will correlate to the effects and/or safety in humans.

Pharmacologist or toxicologist

- Pre-IND
- New IND 30-day safety assessment
- Industry meetings
- Special protocol assessments
- Consults (areas of expertise)
- NDA: comprehensive review / drug labeling
- Interact with other disciplines including clinical, chemistry, clinical pharmacology, statisticians…

Pharmacology or toxicology Review

- **PHARMACOLOGY**
- Primary and secondary pharmacodynamics (mechanism of action)
- Safety pharmacology

- **PHARMACOKINETICS/TOXICOKINETICS**
- Absorption, Distribution, Metabolism, Excretion

- **TOXICOLOGY**
- Single-dose toxicity (not required, but still seen)
- Repeat-dose toxicity
- Genetic toxicology
- Carcinogenicity
- Reproductive and developmental toxicology
- Local tolerance
- Special toxicity

Pharmacologist or toxicologist

- **COMMUNICATE**
  written and oral

- **REVIEW**
  Evaluate all evidence using our knowledge, expertise, and judgments

- **RECOMMEND**
  Provide our expertise and recommendation to the review team

Benefits

- **GS12 - GS13**
- **Annual Leave:** 13, 20, or 26 days of annual leave a year depending on the length of service
- **Sick Leave:** 13 days a year
- **Holidays:** 10 federal holidays a year
- **Health Insurance**
- **Life Insurance:** A low-cost life insurance available to the federal employees
- **Retirement:** Covered by the Federal Employees Retirement System (FERS).

Project Manager position

- **Consumer Safety Officers (Regulatory Health Project Managers)**
- Perform management and liaison responsibilities throughout the lifecycle of a new drug application.
- In addition, they serve as the regulatory expert on the review team, advise team members on regulatory requirements, and coordinate information with pharmaceutical industry officials.
- Qualifications: a degree or combination of courses in the fields of biological science, chemistry, pharmacy, nursing, physical science, food technology, nutrition, medical science, epidemiology, engineering, veterinary medical science, or related scientific fields.
- Project management experience in the health care/pharmaceutical industries is highly desired for these positions.
- GS5 - GS13

How to apply

- **By word of mouth**

- **Applying for a job through USAJOBS**

FDA website

Post your resume online

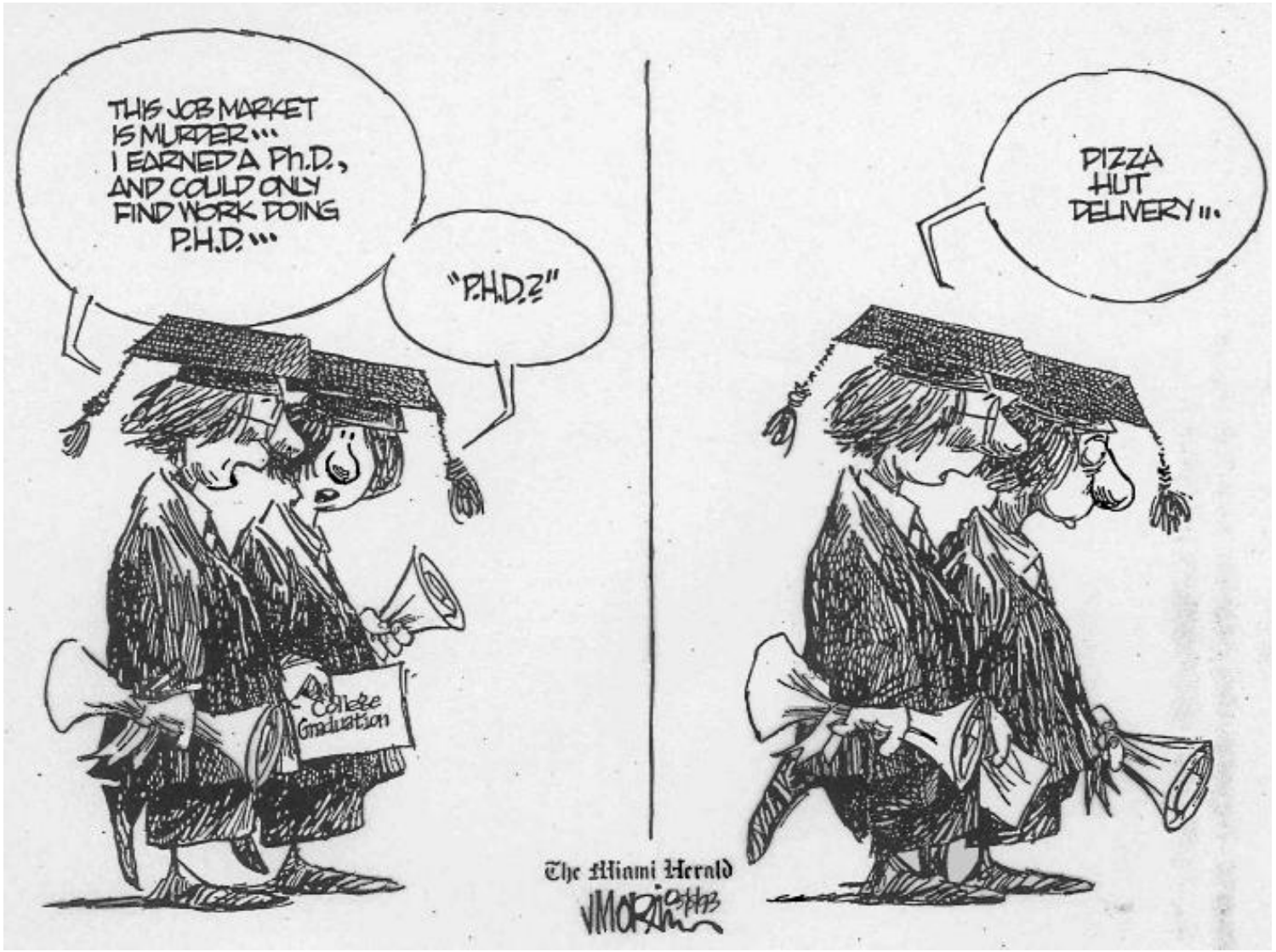
Receive automated Job Alerts

Create your own account

View the current job openings

- **A few tips**

Good luck


THIS JOB MARKET IS MURDER!!! I EARNED A Ph.D., AND COULD ONLY FIND WORK DOING P.H.D.!!!
"P.H.D.?"
College Graduation
PIZZA HUT DELIVERY!!
The Miami Herald

Thank you for your attention

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