Experiences at the FDA
Careers Workshop
Department of Mathematics
University of Pittsburgh

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FDA/CDER/OTS/OB/DB6

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Disclaimer

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Before coming to Pitt

• Born in the UK, but grew up in New Zealand.
• Attended the University of Canterbury,
  • Earned bachelors degrees in mathematics and performance music
  • And an MA in mathematics
• Came to Pittsburgh in 1998 to study at CMU.
  • Completed an MS in Pure and Applied Logic.
• Transfered to Pitt in 2000 to continue PhD.
• Graduated in 2006.
Research area

- This is really hard to explain.
- Thesis title: A sheaf theoretic approach to measure theory.
- I think I am a logician, but logicians think I am a geometer, and geometers probably think I’m an analyst.
- This makes a jobsearch difficult.
Who I worked with

- My principal advisor was Steve Awodey, a philosophy professor at CMU.
- The chair of my committee was Bob Heath.
- I also worked closely with Paul Gartside and Chris Lennard.
Other activities in the Department

- Of course, I worked as a TA.
- I was the first computer/IT coordinator.
- Worked as calculus lab coordinator.
- Student rep on Departmental IT committee.
- This is funny, since I’m not especially good with computers.
- Also managed the Wednesday afternoon Departmental Teas.
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Mission

• Regulate food (but not meat), pharmaceuticals (human and animal), medical devices, cosmetics, and tobacco.
• Ensure safety and efficacy.
• “To protect and promote the public health”.
• Regulation of tobacco is a new responsibility for the FDA.
• The CTP’s mandate is to implement the Family Smoking Prevention and Tobacco Control Act.
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History

- Began (1862) as the Division of Chemistry in the Department of Agriculture.
- Modern role starts with 1906 *Federal Food and Drugs Act*.
- Changed name to Food, Drug, and Insecticide Administration in 1927, and to FDA in 1930.
- Began regulating for safety and efficacy with 1938 *Food, Drug, and Cosmetic Act*.
- Moved to the Federal Security Administration (1940), to the Department of Health, Education and Welfare (1953), and to the DHHS in 1980.
- 1992 *Prescription Drug User Fee Act* (PDUFA), renewed every five years, governs timelines and procedures for drug approvals.
- PDUFA also allows the FDA to charge fees to sponsors, in order to fund operations.
Organizational structure

- Most of the scientific work at the FDA is done in seven *Centers*.
- These centers, (together with some Offices) are divided among five large *Offices*.
- The offices:
  - Office of the Commissioner
  - Office of Foods
  - Office of Medical Products and Tobacco
  - Office of Global Regulatory Operations and Policy
  - Office of Operations.
- The centers:
  - Center for Drug Evaluation and Research (CDER)
  - Center for Biologics Evaluation and Research (CBER)
  - National Center for Toxicological Research (NCTR)
  - Center for Devices and Radiological Health (CDRH)
  - Center for Tobacco Products (CTP)
  - Center for Veterinary Medicine (CVM)
  - Center for Food Safety and Applied Nutrition (CFSAN).
Current role (Drugs)

- **Drug approval**
  - All drugs intended for market in the US must be approved by the FDA.
  - The FDA independently reviews all data from the sponsor’s studies.
  - This data are generally patient level, and therefore proprietary.
  - The FDA can request additional information.
  - The FDA can withhold approval, or can mandate additional studies after approval.

- **International regulatory science**
  - Ensure that standards are transparent – sponsors must know what is expected of them.
  - Coordinate with regulatory agencies in other nations.
The campus

- The main campus is in White Oak, Maryland, just outside the Capital Beltway.
- Currently under construction. The first buildings were occupied in 2003 and 2005. Construction is expected to be complete in 2017.
- Currently about 5,500 employees on site.
- Finished campus should accommodate about 8,900 employees.
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Size and structure

- Housed in CDER. (There are smaller groups of statisticians in other Centers).
- Seven divisions (DB1–DB7) of approximately 20 statisticians each.
The review divisions

- DB1–DB5 are the *review divisions*.
- Each is associated with three or four medical review divisions in the Office of New Drugs (OND).
- For example, DB1 is associated with the *Division of Cardio-Renal Medical Products*, the *Division of Neurology Products*, and the *Division of Psychiatry Products*.
- Reviewers in these Divisions analyze anew the data submitted by sponsors to these Medical Divisions, and critique the sponsors’ statistical analyses.
- They are part of comprehensive interdisciplinary review teams.
- Research that they conduct generally grows out of problems faced in these reviews.
DB7: The safety division

• Works closely with the Office of Surveillance and Epidemiology (in CDER).
• Primarily focused on reviewing post market safety trials.
• The conduct of these trials is not settled science, so the reviews are more idiosyncratic.
• A new Division, only founded in 2009.
Division of Biometrics 6

- A number of different, largely unrelated teams:
  - Pharmacology/Toxicology
  - QT studies
  - Generic Drugs
  - Biosimilars
  - Chemistry/Manufacturing
Reviewing rodent carcinogenicity studies

- Most New Drug Applications (NDAs) include results from long term (two year) studies in mice and rats.
- These studies have consistent designs: two sexes, one control group, three treated groups.
- Analyze submitted data for evidence of carcinogenic effects.
- The main statistical issues are dealing with multiple endpoints, rare events, and small sample sizes.
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Improving rodent carcinogenicity studies

- Adjusting the statistical method we use.
- Adjusting the study design.
Exact methods for rare events

- Developing methods for dealing with saw-tooth power curves.
- Developing exact methods for two sample tests.
Data standards

- Data standards are necessary for the automated analysis of data.
- The SDTM (Study Data Tabulation Model) is just being adopted by sponsors.
- The SEND (Standard for Exchange of Non-clinical Data) is the non-clinical analogue of SDTM; it will be adopted soon.
- I have also been involved in developing a data standard for stability studies.
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Statistical jobs outside of CDER

- Other Centers also employ some statisticians, but none as many as CDER.
- There is a large group in CDRH.
- There are also reasonably large groups in CBER and NCTR.
- There is a very small group in CVM, and a new group is forming in CTP.
Positions for mathematicians

- One would have thought that there would be considerable demand at the FDA for mathematicians with experience in pharmacodynamics.
- But as far as I can tell, there are no mathematical biologists currently working in CDER.
- The Office of Pharmaceutical Science seems to rely on laboratory analyses.
- Likewise, CDRH employs a number of physicists, but I am unaware of any mathematicians working there.
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Eligibility

• Mathematical Statisticians must have a graduate degree, usually a PhD, in a mathematical discipline, and have taken at least five statistics courses (undergraduate or graduate).

• Courses taught do not count.

• Jobs are open to non-citizens. Non-citizens can be sponsored for an H-1B visa, but CDER will not currently sponsor an application for Legal Permanent Residence (a “Green Card”). You may apply independently under the National Interest Waiver.

• Some promotion opportunities are available only to citizens.
Desirable attributes for applicants

- Skills in statistics, especially biostatistics. (With the exception of data analysis experience, these are fairly easy skills for a mathematics PhD to acquire.)
  - Experience with data analysis.
  - Familiarity with statistical software (especially SAS or R).
  - Knowledge of biostatistical techniques such as logistic regression, case-control analysis, and survival analysis.
- The ability to communicate with nonstatistical scientists (especially physicians).
  - Note that communication involves both the ability to express ideas and the ability to listen.
  - It also includes the ability to write reports.
- Integrity.
- Reliability.
Recruitment

• Jobs are advertised through the USAJobs.gov website.
• Recruitment also occurs at the ENAR and JSM conferences.
• Recruitment for OB is carried out at the Division level.
The interview process

• Similar to an academic interview.
• Give a talk on your research, relevant to the FDA.
• Mine was on fuzzy logic.
• Meet with prospective Division director, and other members of prospective Division.
• Atmosphere is generally relaxed; my luggage (including my interview suit!) was lost on the flight to Washington, and I had to go through my interview wearing jeans and a tee-shirt. I still got the job.
Orientation

- Paperwork can take a long time to process.
- Orientation is generally conducted at the Center level.
- There are many orientation activities – not completed until second year of service.
- Background checks.
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Working at the FDA

- The working environment is relaxed and friendly.
- Flexible work schedules.
- In many respects it is a lot like an academic setting.
- There are many opportunities for ongoing training.
- Research tends to be quite narrowly focused, and is secondary to the review work.
Hot areas of statistics at FDA

- Missing data
- Meta-analyses
- Multiple endpoint testing
- Bioinformatics and genomics
- Non-inferiority studies
- Safety