A View from Inside Pharmaceutical Development: Perspective on Career Paths

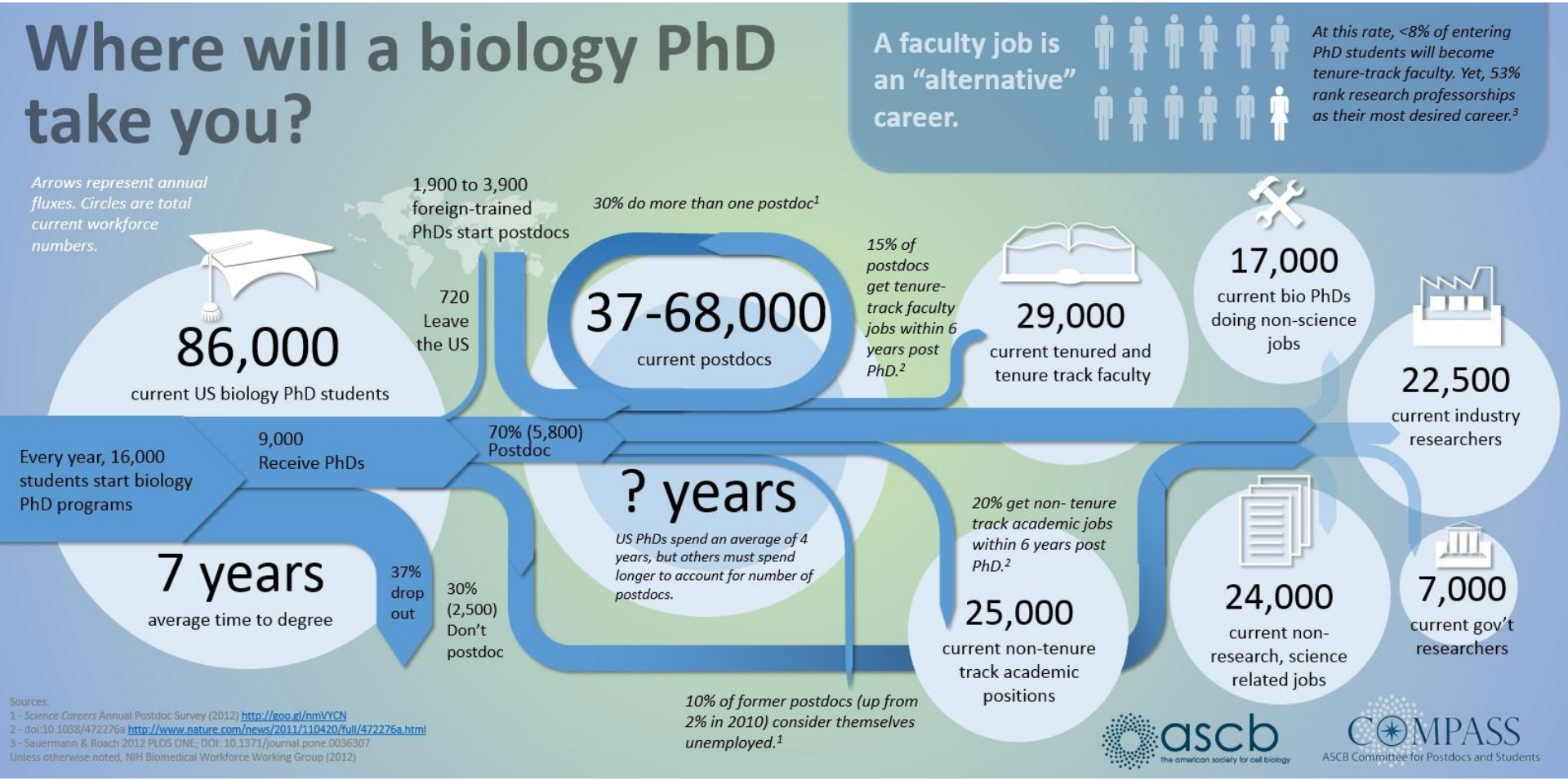
Disclaimer

The views, comments and thoughts in today's presentation about working in pharmaceutical industry do not represent Merck: *Merck Research Laboratories (MRL)* or *Merck Sharpe & Dohme (MSD).* They are the opinions of each speaker.

Outline

- Welcome
- Introduction of Speakers / Careers they represent
- Split into 2 group: half tour, half stay for Q&A
- Switch activities: tour / Q&A
- Conclusions

Future Jobs in Academics?



- Carrie Markgraf
- Discovery Program Lead and Compound Leader

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Carrie Markgraf: Background

Schering-Plough
Schering-Plough
Safety
NeuroPharmacology

MERCK
Merck
Toxicology

Internet Search

The University of Texas Health Science Center at Houston
UT Houston
Brain Injury In Vivo Models

Lab Association

Marion Merrell Dow
Discovery-
Stroke &Brain Injury In Vivo Models

Personal Networking

University of Miami
Post Doc
Neurology

University of Miami
Post Doc-Psych

Middlebury
Middlebury College
Biology / Psychology majors

Proximity

The University of Vermont
University of Vermont
MD, PhD—Exp't Psych

Lab Association

Public

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Positions in Drug Discovery

- High School / College education: Lab technician
  - $27-35K[a]
- B.S. / B.A.: Scientists / Biologist
  - $40-71K[a]
- PhD: Principal Scientist, Senior Principal Scientist
  - $75-95K starting + annual bonus $5000-$10,000[a]
  - Average $138K + annual bonus ~20% salary + stocks[a]
  - Head of laboratory
  - Responsible for running compounds in your assay / model
  - Analyzing / reporting results
  - Participating in teams to represent your area of expertise
  - Keeping management informed of progress, issues, upcoming milestones
  - Attend scientific meetings, publish papers when approved

a: American Association of Pharmaceutical Scientists, 2013 report

Positions in Preclinical Development

- Laboratory positions
  - PhD, DVM: Lab Head, Principal Scientist, Sr. Principal Sci.
  - Starting salary 75-95K starting + annual bonus $5000-$10,000[a]
  - Average $150K + annual bonus ~20% salary + stocks[a]
  - Oversee assays run in your lab, develop new assays to address issues, keep current with literature and competitors' technologies
  - Manage colleagues in lab

- Non-laboratory scientific positions
  - PhD, DVM: Study Director, Compound Leader
  - Starting salary 75-95K starting[a] + annual bonus; Average $150K + bonus ~20%
  - Design and oversee studies (SD) or a compound's program (CL)
  - Requires knowledge of GLP regulations and of broad nonclinical development
  - Develop study design, analyze & interpret data for standard and investigative studies
  - Write sections of documents for FDA, EMA etc. that will support clinical trials
  - Keep management apprised of issues and upcoming milestones, presentations

a: American Association of Pharmaceutical Scientists, 2013 report

Other Positions

- Project Management
  - Co-leads project team
  - Tracks all activities and keeps all parts moving on time
  - BA/BS, MA, PhD. PMP certification preferred
  - $91-165K, average $126K + bonus[a]
- Regulatory Affairs
  - Interacts with regulatory authorities in all countries
  - Knowledge of regulations, sets strategies for advancing a compound
  - $75-85K starting salary[a]
- Scientific Writer
  - Works with Study Director or Research Physician to write sections of regulatory documents (IND, IMPD, NDA, study protocol)
  - Scientific Writing certificate
- Medical Science Liaison
  - Liaison with outside experts in academics, hospitals
  - Develop relationships with Key Opinion Leaders (KOL) in disease area
  - $100-$150K + bonus/stocks[a]

a: American Association of Pharmaceutical Scientists, 2013 report

Conclusions

- Variety of positions within pharmaceutical industry, both laboratory-based and non-lab based

- Industry offers opportunity to work in multi-disciplinary teams and have real impact on bringing new human medicines to market
  - Good scientific support with resources necessary to do the job
  - Typically, regular hours (8-4) with additional effort for important regulatory interactions, for example with FDA
  - Well-paid, good benefits, smart and interactive colleagues

- Challenges include finding company with compatible style of management
  - Attend a lot of meetings
  - Mergers, change of management or disease area are out of your control

Melissa Tice, Ph.D.
Executive Director
Global Regulatory Affairs

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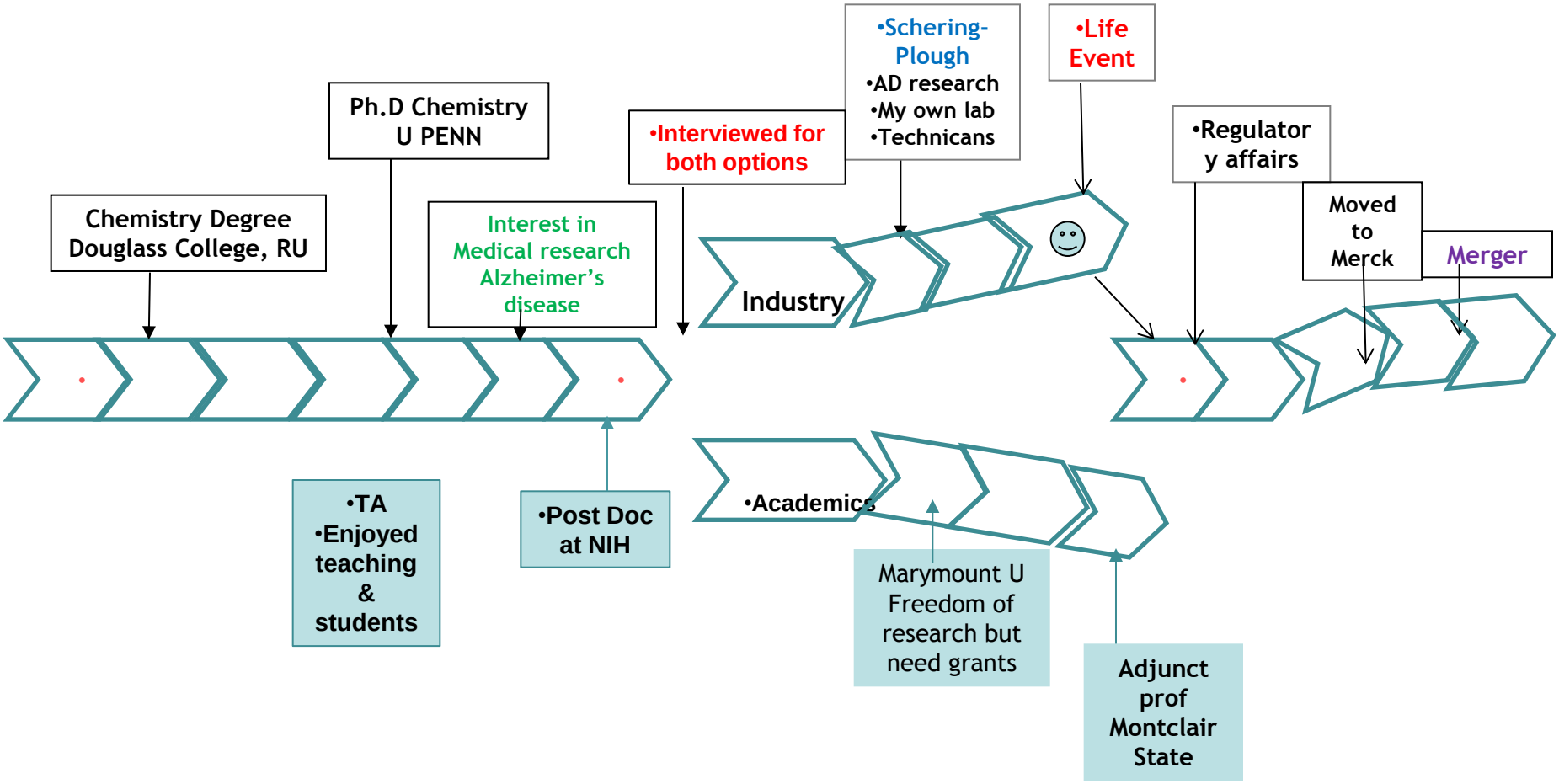
Career Path-Alternate Options

Start on one path-straight ahead...then choices, option and changes occur that can direct you in multiple paths---stay open to the possibilities



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What does one do in Regulatory Affairs?

- Based on experience your role can change over time
- Based on your role domestic or International focus determines amount of global travel and health agency interactions
- Provide regulatory leadership and guidance
  - to product development and global regulatory teams
  - develop global strategy, coordinate and lead agency interactions and respond to inquiries from health agencies.
    - Recent accomplishment obtained US approval for Keytruda
  - expected to stay current with your therapeutic area; regulatory guidances, research findings, new data and products
    - Interact with Health agencies
    - Interact with Merck subsidiary personnel-work as a Global regulatory team
    - Attend research conferences

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- Karen Dingley
- Compound Leader

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Karen Dingley

- Principal Investigator (Compound Leader)
- Pharmacokinetics, Pharmacodynamics and Drug Metabolism Department (PPDM)
- At Merck since 2005
- Role: Department representative on Discovery and Development teams

- Function on teams: To understand and optimize the ADME properties of compounds so that they have a high POS for success in humans
- Work primarily focused on preclinical data: in vitro and in vivo
  - Plan/schedule studies
  - Interpret data
  - Present data to team/management
  - Write up data in regulatory documents

Figure. Transporters are key determinants of drug ADME properties.

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•Prior Research Background

UNIVERSITY of York

CALIFORNIA REPUBLIC

Lawrence Livermore National Laboratory

- PhD in Biology, in field of chemical carcinogenesis
- Had opportunity to collaborate with Lawrence Livermore National Laboratory in CA to use Accelerator Mass Spectrometry (AMS) to study metabolism of environmental carcinogens in humans
  - Post Doc at Lawrence Livermore National Laboratory that lead to a Senior Scientist Position
  - Collaborated with groups from academia and industry from all over world to use AMS
  - Spent several years writing grants to fund research
  - Networking at ACS meeting led to current role at Merck

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- Krupali Prevete
- Program Coordinator

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Program Development

Therapeutic Area Lead (TAL)

- Responsible for a particular Therapeutic Area (e.g. Cardiovascular, Infectious Disease, Biologics/Vaccines, Woman' Health, Neuro)
- Oversee/advise CL on their programs
- Responsible for all regulatory and internal documents within assigned area
- Requires an advanced degree (e.g. Ph.D. in relevant field, D.V.M. (or equivalent Veterinary Medicine degree) with highly advanced level of knowledge and understanding of the drug discovery process.

Compound Leader (CL/DPL)

- Safety representative on the Early Development Teams and EDT and Product Development Teams
- Responsible for preclinical development strategy and risk
- Oversee design and timely reporting of SA studies to support clinical trials and marketing application
- Contribute to Regulatory/Internal documents
- Requires a Ph. D. in relevant field with advanced level of knowledge and understanding of the drug discovery process

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Program Coordinator (PC)

- PC's are considered operational experts in non-clinical drug development
- Coordinate all non-clinical studies and Regulatory submissions in SALAR
- Determine drug requirements for studies
- Provide monthly tracking in a pipeline management tool for the status, issues, and resolution plans on all active programs
- BS/BA degree in relevant area with commensurate experience

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- Lena Hofer
- Strategic Operations

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Career Options outside of Academia and Away from the Lab

April 29, 2015

Visit by Rutgers Graduate Students and Post-Docs

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Lena Hofer, PhD – Current Role and Responsibilities

- Biologics and Vaccines Strategic Operations
  - Deliver and manage strategic external contract research and manufacturing partnerships that complement our internal capabilities and advance the B&V pipeline
    - Work with external partners or CROs to develop and validate bioanalytical assays and manage analysis of preclinical and clinical serum sample analysis for drug level and immunogenicity
  - Proactive internal and external resource and financial management across B&V
    - Short-and long-term resource and capacity planning
    - Manage fluctuations in workload and manpower

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Career Path

- BS from Technical University Munich, Germany
- PhD: Max Planck Institute for Psychiatry, Munich, Germany: Role of Brain-Derived Neurotrophic Factor in Development of Chick and Rat Nervous System
- Post-docs at Yale and Rockefeller University
- Staff Scientist at Acorda Therapeutics
- Section Head at Novo Nordisk
- Various positions at Merck

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- Linda Hunt
- Scientific Writing

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SCIENTIFIC WRITING

Linda Hunt
Director, Submissions
Nonclinical Safety Assessment
(Toxicology/Pharmacology)

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Background - “Typical vs. Atypical”?

- Education - Varies
- Work History – Typically roots in lab/scientific area
- Skill sets – Organized, structured – yet flexible, adherence to deadlines, strong verbal and written communication skills, ability to ask clarifying questions, collaborative, willingness to be a “ghost writer”, understanding of the audience, “big picture perspective” and a bit of tenacity
- Knowledge of drug development process, health authority guidelines (FDA, ICH, EMEA, PMDA, etc.), and understanding of the “puzzle”

Scientific Writers in Pharma

The use of scientific writers varies within Pharma.
Authoring scientists are expected to be proficient writers. However, use of scientific writers may facilitate the authoring process in a number of areas: Medical Communications, Regulatory Affairs, Contributing Functional Groups (Toxicology, Toxicokinetics / Pharmacokinetics, etc.) by providing…

- Templates
- Document publishing standards required for electronic filing
- Regulatory guidance perspective / history
- Literature searches/reviews
- Editing/reviewing and consistency of approach/format
- Final review of concatenated e-files for registration documents

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Training, Courses and Certifications

- Review guidances on ICH and FDA websites
- Review Scientific Reviews for approved drugs (FDA website)
- **Nonclinical Safety Assessment: A Guide to International Pharmaceutical ...** edited by William J. Brock, Kenneth L. Hastings, Kathy M. McGown
- http://www.diahome.org/en-US/Meetings-and-Training/About-our-offerings/Certificate-Programs.aspx
- http://www.amwa.org/certification
- http://www.raps.org/education-training/online-learning/regulatory-medical-writing-bundle/

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