

An Evolving Fellowship Program in an Ever-Changing Industry

In 1983, a paper written by clinical professor Heyward Hull, PharmD, and colleagues from academia and industry appeared in the *American Journal of Pharmaceutical Education* making the case that pharmacy was changing and that pharmacy education needed to change with it.

Pharmacists were expanding beyond their traditional roles as dispensers of drugs and were taking positions on school faculties and in the pharmaceutical industry. In his paper, titled “Training the ‘Clinical Scientist’ Through a Combined Industrial-Academic Fellowship,” Hull argued that with the increasing interest in drug-related research by clinical pharmacists, schools needed to focus on medical, legal and regulatory issues associated with clinical drug trials that were not being taught in pharmacy graduate programs. At the same time, pharmaceutical companies were demanding professionals with more advanced skills and knowledge in clinical research and drug development that, at the time, were not a part of the pharmacy school curriculum.

And so, Hull and faculty colleague **Wayne Pittman (’72 BSPharm, ’78 MS)** from the UNC Eshelman School of Pharmacy created the postgraduate fellowship program to meet the needs of students, industry, and academia. Today, the program has grown to include industry-sponsored fellowships in drug development and clinical research and in pharmacokinetics/pharmacodynamics in addition to academic fellowships in oncology, HIV pharmacology and heart failure.

“This program’s been around a long time thanks to the dedication of our faculty and the longstanding commitment of our industry partners,” said Bob Dupuis, PharmD, a clinical associate professor and the fellowship program’s director. “The program has flourished, even in some challenging economic times.”

“For those of us in research, it’s a gift”

Initially the School partnered with Burroughs Wellcome (now GlaxoSmithKline) to offer a program in clinical drug research and drug development methodology by using pharmaceutical industry, with university and hospital research facilities as the classrooms. As fellows went through that program—which was the first of its kind in the country—and into industry, they shared their experience with their employers. More companies, such as PPD, United Therapeutics,

Quintiles and King Pharmaceuticals, have joined in, allowing the School to expand the fellowship program. Another fellowship was added for this coming year with biopharma company UCB.

“The School is really invested,” Dupuis said. “And on the industry side, there’s great support. Many of our industrial partners are former fellows or scientists who have worked with our fellows.”

The program has 15 to 20 fellows at any given time. Each year, eight to 12 fellows are chosen to enter the program from nearly 100 applicants. Fellows receive two year appointments. During the first year in the program, fellows are primarily engaged in clinical research and complete some specialty coursework in experimental design and data analysis, as well as in pharmacokinetics. Industry fellows spend the second year working at the companies that sponsor their fellowships, where they learn first-hand about clinical drug development. Academic fellows continue at the UNC Eshelman School of Pharmacy during the second year, focusing on clinical research in their specific area.

“We build a foundation for them in clinical research,” Dupuis said. “They gain hands-on experience and learn how to run clinical trials. Clinical research is a complicated process that starts with the study concept and proceeds from protocol development to IRB approval, subject recruitment, study conduct, data analysis, presentation of results, and finally publication of the results. The fellow is involved in every step.”

During the two-year program, fellows give back to the School in a number of ways. Principally, they provide faculty with eager professionals who want to learn about research and bring with them a variety of educational backgrounds and different perspectives.

“For those of us in research, it’s a gift,” said Herb Patterson, PharmD, who is vice chair for research and graduate education in addition to overseeing the academic heart failure fellowship. “We recruit and work with some incredibly talented pharmacists who come into the program—bright, enthusiastic young people—and teach them about research. In exchange, they share their talents with us for two years.”

The School’s partners in industry also benefit. While there is certainly an altruistic component to companies’ involvement, they also are

Jill Henry, a drug development fellow, counsels Carlton Spivey at the UNC Heart Center at Meadowmont in Chapel Hill.



looking to identify top-notch employees. The fellowship program provides fellows with a year of academic experience and then a year of work experience at the company.

“Scientists in industry will always be doing cutting edge research,” Patterson said. “Because of the program we offer, I believe fellows completing our program will always have opportunities in industry even though there may be fewer clinical research positions available. I’d like to think our fellows will be very competitive for these positions. There’s

always going to be a need for well-trained clinical scientists.”

Answering industry’s needs

Throughout the program’s history, the focus has been on PharmD-trained fellows although there have been some with other degrees. This year, Dupuis said, the program has a MD fellow with the UCB fellowship.

However, while the program has changed to adapt to the times, it’s never deviated from its initial mission – to train the next genera-

tion of clinical scientists.

“We’ve been doing this for 30 years,” Patterson said. “The program continues to evolve and we have been very successful. And if you look at where the fellows have gone — most in industry, some in academia, some in regulatory — they’re strong proponents of the program and our best ambassadors. We have a strong national reputation so we attract the best candidates for our program. We clearly have one of the premier fellowship programs in the country!”

Fellowships Offer Multiple Disciplines to Serve Industry and Academia

The **Clinical Research and Drug Development Fellowship** seeks to provide an orientation to all aspects of the drug development process, including experience in developing, reviewing, and composing protocols, study reports, and regulatory submissions and exposure to the selection, set-up, and monitoring of clinical sites participating in Phase I/ II/III and/or pharmacokinetic studies.

Pharmacokinetic/Pharmacodynamic Fellows participate in clinical pharmacokinetic, pharmacodynamic, transport and/or metabolism studies with faculty at the School and with members of the Clinical Pharmacology group at Quintiles Inc. or with the Clinical Pharmacokinetics, Modeling and Simulation group at GlaxoSmithKline. These fellows design, initiate and conduct pharmacokinetic/pharmacodynamic studies and develop skills in pharmacometric data analysis and presentation in reports, regulatory submissions, and published manuscripts.

The **Oncology Fellowship** is intended to develop independent research skills for a career in academics. Experience with clinical trials (phase I pharmacokinetic, multicenter phase II-IV), preclinical model systems (cell culture), analytical techniques (HPLC) and molecular techniques (Westerns and PRC) are available. Fellowship activities include protocol development with IRB submission, data collection and analysis with pharmacokinetic and/or statistics programs, and oral and written presentation.

HIV Pharmacology Fellows are prepared to become independent researchers in anti-infective clinical pharmacology. Specific research areas include antiretroviral pharmacokinetics/pharmacodynamics and pharmacogenetics. These fellows will gain experience in all areas of translational research, from grant-writing to manuscript submission and are expected to present research findings at scientific meetings.

The **Heart Failure Pharmacotherapy Fellowship** provides extensive research experience in cardiovascular pharmacotherapy, with a special emphasis on heart failure and cardiovascular pharmacokinetics and pharmacodynamics. A multidisciplinary team approach including medicine, pharmacy, and nursing is applied to research and management of heart failure.



Fellow Elizabeth McNeely reviews medications with patient William Flynn before he meets with his doctor at the UNC Heart Center at Meadowmont.

30 Years of Fellows: Where Are They Now?

Debbie Montague '81 ('77 BSPHarm, '81 MS, '06 PharmD), Senior Clinical Specialist, UNC Hospitals

Lucy Allen '82 ('79 BSPHarm), Project Manager, Quintiles

Jim Mannion '83, President, CEO, and Founder, Galleon Pharmaceuticals

Karl Donn '83 ('85 MS, '87PharmD), Vice President, Drug Development, Parion Sciences

Judy Bryson '83

Jill Slater '84

Michael Dalton '84, Founding partner, Gnomon Group, FDA liaison for 22nd Century Limited

Michael King Jolly '84, Senior Vice President of Drug Development Partnerships, NovaQuest

Linda Winship Manning '85 ('82 BSPHarm), Section Head for Home Care Product Safety and Regulatory Affairs, Procter & Gamble

Ann Talton Lee '86 ('84 PharmD), Director, GlaxoSmithKline

Ramadas Balasubramanian '87

Brenda Jameson '87

Karol Krueger LaCroix '87 ('83 BSPHarm), Project Manager, GlaxoSmithKline

Betty Hussey '89 ('83 BSPHarm, '87 PharmD), Director of Clinical Pharmacology, GlaxoSmithKline

David Bremseth '89, Consultant, Independent Medical Device

Ingrid Lewis '90 ('88 PharmD), Vice President Informatics, Medkeeper

Tom Lampkin '90, Director of Clinical Development Cancer Metabolism Drug Development Unit, GlaxoSmithKline

Carl Roland '91, Senior Director of Neurosciences Medical Development, King Pharmaceuticals

Jeanne M. Bertch '91

Doug Figg '92, Head, Molecular Pharmacology Section, Senior Scientist, National Cancer Institute, Medical Oncology Board

Brian Wagner '92, Freelance Account Supervisor Consultant pharmaceutical advertising and marketing industry *

Pamela Barrett Sarver '92 ('89 PharmD)

Shelly Gray '92, Professor of Pharmacy,

University of Washington

Becky Nagle '93

Ed Liao '93, Consultant, Boehringer Ingelheim *

Jyoti Patel Jankowsky '93

Stephen O'Quinn '93, Director of Marketing for Wellbutrin-XL, GlaxoSmithKline *

David Hermann '93, Senior VP Early Development & Pharmacometrics, Great Lakes Drug Development, Inc

Patricia Warner Jacob '93, Senior Regional Medical Scientist II, Clinical Development and Medical Affairs North America, GlaxoSmithKline *

David Martin '94, Senior Vice President of Drug Development and Regulatory Affairs, Tobira Therapeutics, Inc.

George Foose '94

Jacqueline G. Nolen '94, Assistant Professor, Feik School of Pharmacy, University of the Incarnate Word *

Lynn Fitzgerald '94

Kristen Jones Letrent '94, Director of Global Medical Communications and Medical Affairs, Pfizer Oncology

Michael J. Koronkowski '94, Clinical Assistant Professor of Pharmacy Practice, UIC

Kellie Schoolar Reynolds '94, Deputy Director, Division of Clinical Pharmacology 4, Office of Clinical Pharmacology, Center for Drug Evaluation & Research, FDA *

Margaret Britto '94, Senior Research Pharmacokineticist, Clinical Pharmacology, Quintiles

Jamie Blose '95, Clinical Drug Development, Elcelyx Therapeutics, Vice President, NovaQuest *

Penny Shelton '95

Denise Rhoney '95, Department of Pharmacy Practice Associate Professor, Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University

Patrick Wire '95, Director of Regulatory Affairs, GlaxoSmithKline

Valerie Brooks '95 ('89 BSPHarm, '93 PharmD)

Katy H.P. Moore '95 ('93 PharmD), Director of Clinical Pharmacokinetics Modeling and Simulation, GlaxoSmithKline

Stephen Letrent '95 ('98 PhD), Clinical Oncology, Vice President, Asset Team Leader

Did you complete a post-graduate fellowship at the School and would like to get back in touch with your peers? The PAA is helping to organize a fellowship reunion on June 17, 2011.

If you'd like to be notified of reunion plans or if you can help us get in touch with other past fellows, contact the PAA at paa@unc.edu.

Clinical Development and Medical Affairs, Pfizer

Deborah Copeland '96

Gary Hoel '96

Melissa Ellis '96, Research Scientist, GlaxoSmithKline *

Paul Meisner '96, Senior Director, King Pharmaceuticals

Tracy Eatmon Thomason '96 ('92 BSPHarm, '94 PharmD), Adjunct Professor, UNC Eshelman School of Pharmacy

Mary Beth Mann Wire '96, Clinical Pharmacokineticist, GlaxoSmithKline

Ben Lee '97

Kristin M. Williamson '97 ('94 PharmD), National Director of Neurology and Psychiatry, US Medical

Rob Kustra '97, Associate Director of Development Sciences, GlaxoSmithKline

Elizabeth Migoya '97 ('87 BSPHarm, '95 PharmD), Director of Early Stage Development, Merck Research Lab *

Yazdi K. Pithavala '97, Director of Clinical Pharmacology, Pfizer

Ed Brewer '98, Medical Science Liaison, Medical Affairs, Otsuka American Pharmaceutical, Inc.

Jodi Decker '98 ('96 PharmD)

Amy Mewborn Meadowcroft '98 ('93 BSPHarm, '95 PharmD), Director, Clinical Development, Business Lead for Clinical Study Planning Initiative, GlaxoSmithKline

Jeannine McCune '98 ('95 PharmD),

Associate Professor Department of Pharmacy,
University of Washington

Katie Graham Lyons '98, Owner and
Director of Medical Content, Consulting
Services, LLC

Jeffrey Fischer '98, Manager of PK
Automation Services, Pharsight, Inc.

Joi Odishaw Dunbar '98, Director
of Clinical Pharmacology, Infinity
Pharmaceuticals

Kristine Radomski Crews '98,
Translational Research Laboratory Director,
Pharmaceutical Sciences
Department, St. Jude Children's Research
Hospital

Angela Donahue '99, Director of
Product Management, PPD, Inc.

Donald Graff '99, Clinical Research
Scientist, Celerion

Katie Graham '99

Michael Kotlyar '99, Associate Professor,
Department of Experimental and Clinical
Pharmacology, University of Minnesota *

Jodi Weidler '99, Senior Director,
Oncology, Biomarker Clinical Development/
Medical Affairs, Monogram Biosciences

**Kim Parnell '99 ('94 BSPHarm, '96
PharmD)**, Associate Director of Clinical
Research, Johnson & Johnson Pharmaceutical
Research

Odin Naderer '99, Director of
Infectious Diseases, Discovery Medicine,

GlaxoSmithKline

Tracy Allen Fischer '99, Manager of
U.S. Regulatory Affairs, GlaxoSmithKline

Min Song '99

Paul N. Mudd '99, Director of Clinical
Pharmacology Modeling/Simulation,
GlaxoSmithKline

Sarah Roberts '00

**Stephanie Faucette '00 ('95 BSPHarm,
'97 PharmD)**, Clinical Pharmacokinetic
Manager, Sepracor *

**Jo Ellen Rodgers '00 ('94 BSPHarm, '96
PharmD)**, Clinical Assistant Professor, UNC
Eshelman School of Pharmacy

**John Rublein '00 ('91 BSPHarm, '97
PharmD)**, Clinical Scientist Abbott Virology,
Abbott Laboratories

Karl Gotzkowsky '00, Senior Director of
Product Development, United Therapeutics

**Kim Hollar '00 ('92 BSPHarm, '97
PharmD)**, Clinical Science Manager in
Virology, Abbott Laboratories

Matthew Lamb '00

Chee Ng '00, Principal Scientist in
Department of Discovery Medicine and
Clinical Pharmacology, Bristol-Myers Squibb *

Julie Kim '01

Michael Watkins '01, Manager of
Clinical Development MDC Clinical
Respiratory U.S., GlaxoSmithKline *

Monica Johnson '01

Naumann Chaudry '01, Director of

Medical Affairs, Pfizer *

Stacy Shord '01, Oncology Group for
FDA *

Christina Hill-Zabala '01, Manager
of Global Strategic Planning of Stiefel,
GlaxoSmithKline

Scott Pescatore '01, Region Europe
Brand Lead-Oncology, Novartis

**Mary Jayne Kennedy '01 ('95
BSPHarm)**, School of Pharmacy, Virginia
Commonwealth University

Daphne H. William '01, Senior Clinical
Pharmacokineticist, GlaxoSmithKline *

Bindu P. Murthy '01, Assistant
Director, Clinical Pharmacokinetics, Clinical
Pharmacology and Experimental Medicine,
Johnson & Johnson Pharmaceutical Research
and Development *

Heather Tangeman '02

Sheri Hoyler Arndt '02, Senior Medicate
Writer, Abbott Laboratories *

**Craig R. Lee '02 ('00 PharmD, '06
PhD)**, Assistant Professor, UNC Eshelman
School of Pharmacy

Sunila Reddy '02, Associate Director
of Clinical Research, Liver Diseases, Gilead
Sciences

Seth Berry '02, Clinical Pharmacologist,
Quintiles *

Susan Ford '02, Clinical Pharmacologist,
GlaxoSmithKline *

Kimberly Dombrook-Lavendar '03

Kevin Haynes '03, Adjunct Professor
of Epidemiology, University of Pennsylvania
School of Medicine

Michael Lim '03, Therapy Area Director,
Immuno-Inflammation and Respiratory
CPSSO, GlaxoSmithKline

Aliou Ousmanou '03, Senior Project
Manager, PPD, Inc.

Alison Lyke '03 ('01 PharmD),
Dermatology resident, MUSC

Amanda H. Corbett '03, Clinical
Assistant Professor, UNC Eshelman School
of Pharmacy

Kevin Laliberte '03, Senior Director of
Product Development, United Therapeutics
Corp.

Christine M. Brandquist '03, Senior
Manager of Clinical Pharmacology, Celerion *

Leslie Davidson Kalvass '04

Lisa Patel '04 ('01 PharmD), Health
Services Research Consultant with Family
Health International

Jennifer Park '04, Clinical Program Lead,



Fellows and faculty members gather at a Durham Bulls game in July 2010.

Fellowship Provides Training, New Opportunities

When **Linda Winship Manning '82 BSPPharm** decided to change career paths late in her undergraduate years, she turned to a fellowship at the School to help her prepare for conducting clinical research in industry. Five years later, when she had to leave the pharmaceutical industry, her experience from that same fellowship again paid off.

Manning says she knew back in junior high that she wanted to be a pharmacist but couldn't decide which area of pharmacy she wanted to pursue. By the end of her time as an undergraduate in Chapel Hill, she was leaning toward industry and wanted to get into sales and marketing, but she needed 100 more internship hours the summer before she was to take the pharmacy boards. Her sister, who was a physician in Richmond, Va., helped get her into a pharmacy-services clinic there. That experience opened Manning's eyes to the opportunities with clinical pharmacy.

"I became very interested in disease management and the interaction with patients," Manning said. "My preceptor began talking to me about using my clinical skills and interests by pursuing a PharmD degree. By the completion of my hours with him he convinced me."

After receiving her PharmD at the Medical College of Virginia, Manning returned to Chapel Hill for the School's fellowship in drug development and clinical research. She split her time between classes

in Chapel Hill and working at Burroughs Wellcome (now GlaxoSmithKline) in Research Triangle Park.

"I spent a year there writing protocols and monitoring studies for new drugs," Manning said. "Since it was jointly with Burroughs and UNC, I had the opportunity to go to UNC and take classes. I also wanted to make sure I wanted to go into industry, so I did one last clinical rotation in the ICU at UNC Hospital my last month and decided I wanted to get a job in industry. The fellowship showed me that there was a way to bridge my newfound interest in clinical pharmacy with my desire to work in the pharmaceutical industry."

Following her fellowship in 1984 and 1985, Manning spent four years as a clinical project coordinator for A.H. Robins Co. in Richmond. She then relocated to Austin, Texas, when her husband enrolled in graduate school. With no industry positions for her

to pursue in Austin, her fellowship training helped land her a position in academia — on the faculty of the University of Texas' College of Pharmacy, where she was a clinical assistant professor. While there, Manning also directed a Phase I drug studies unit.

"Because I'd done my fellowship in clinical research and worked, I was adequately trained to take on a role like that," she said.

"I felt like it was difficult to get a job in industry and clinical research without experience," she said. "I felt very fortunate to have the fellowship. It gave me a great heads up over others applying for a job. I knew what the job was, and I'd had a year's worth of training under my belt."

In 1994 Manning made the move back into industry, joining Procter & Gamble, where she has worked for the past 17 years, most recently as section head for home care product safety and regulatory affairs.



Photo by John Zhu

Linda Manning and her daughter Emily on a visit to the School.

Clinical Research Program Manager, GlaxoSmithKline *

Andrew C. Nelsen '04, Manager of Global Medical Affairs, United Therapeutics

Jill M. Herendeen '04, Regulatory Affairs, Oncology Therapeutic Area, Amgen

Pinal Shah '04, Project Manager, PPD, Inc.

Adam M. Persky '04, Clinical Associate Professor, UNC Eshelman School of Pharmacy

Ya-Chi Chen '05, Associate Clinical Director, Hoffman-La Roche *

Eric E. Williams '05, Associate Attorney, Barnes and Thornburg LLP

Jason M. Collins '05, Clinical Science Specialist (Consultant), Cardiovascular, US Medical Affairs, Genentec

Rosa F. Yeh '05, Director of Pharmacokinetics Laboratory, Seattle Cancer Care Alliance

Brendan Johnson '05, Principal Clinical Pharmacokineticist/Clinical Pharmacology Modeling & Simulation, GlaxoSmithKline

Kathryn A. Gillis '06, CRS, Novartis

Hiba L. Tappouni '06 ('04 PharmD), Senior Medical Project Manager, Gilead Sciences

Kristen D. Rollins '06 ('04 PharmD), Clinical Research Scientist Corp., United Therapeutics *

Christine M. Walko '06, Clinical Assistant Professor, UNC Eshelman School of Pharmacy

Nabil Uddin '06, Associate Director of Clinical Programs, Seaside Therapeutics

Lakshmi S. Wasist '06, Clinical Pharmacokineticist, Clinical Pharmacokinetics/Modeling & Simulation, GlaxoSmithKline

Todd E. Dumas '06, Clinical Pharmacokineticist, Quintiles

Larry W. Buie '07 ('05 PharmD), Pharmacy Resident, UNC Hospitals *

Michael J. Kardas '07, Global Project Lead Manager, Stiefel, GlaxoSmithKline

Julie Brumer Dumond '07, Research Assistant Professor, UNC Eshelman School of Pharmacy

Manoli Vourvahis '07, Associate Director, Clinical Pharmacology-Infectious Disease (HIV), Pfizer

Ted Shih '07, Clinical Scientist, Genentech

Amar A. Mehta '07, Lawyer/Associate, Jones Day/Pharmaceutical Patent Litigation

Grant W. Hogeland '07, Pharmacokineticist II, Clinical PK/PD, Early Clinical Development, Quintiles

Kan Lu '08, Postdoctoral Research Fellow, UCLA *

Sunita Paul '08, Site Manager, Johnson and Johnson Pharmaceutical Research and Development

Thomas H. Cho '08 ('06 PharmD)
Katarina Ilic '08 Assistant Professor, Dept. of Pharmacology, School of Pharmacy, University of Belgrade, Serbia

Sarah J. Schrieber '08, Clinical Pharmacologist, FDA

Ngoc "Betty" Ngo '08, Research Scientist, Quintiles

Sandra L. Goss '08, Clinical Pharmacokineticist, Abbott Laboratories

Almasa Bass '09, Senior Scientist, Pharmacokinetics and Clinical Research, King Pharmaceuticals Research and Development, Inc.

Shriya Bhushan '09

Tedi Soule '09, Clinical Quality

Assurance Auditor, PPD

Ryan M. Criste '09, Research Scientist, MedImmune

Angela Y.C. Yu '10, Post-approval pharmacovigilance group, PPD, Inc. *

Dustan P.M. Byrd '10, Research Scientist, PPD, Inc.

Ninh (Irene) La-Beck ('08 PharmD), Assistant Professor, Texas Tech University HSC

Amanda E. Jones Jenkins '10 ('08 PharmD), Research Scientist, United Therapeutics

Colleen M. Lemmon '10 Clinical Development Manager of Oncology, GlaxoSmithKline

John S. An '10 ('01 PharmD), Regulatory Intelligence Manager of Global Regulatory Affairs, PPD

Kyle J. Ellis '10, Clinical Science Manager for Pharmaceutical Strategic Initiatives, PSI

Yingxin Li '10

Ahsan N. Rizwan '10, Lead Pharmacokineticist Clinical Pharmacokinetics and Pharmacodynamics, Quintiles

Kevin Brown ('07 PharmD), Pharmacist, UNC Hospitals

Noelia Nebot, 2nd year fellow with GlaxoSmithKline

Austin Combest, 2nd year fellow with PPD

Justin Koteff, 2nd year fellow with

GlaxoSmithKline

Meredith Howell ('09 PharmD), 2nd year fellow with United Therapeutics

Bryant Tran, 2nd year fellow, GlaxoSmithKline

Mark Walsh, 2nd year fellow in academic hematology and oncology

Rachael Kendrick, 1st year fellow with Quintiles

Teodora Dumitrescu, 1st year fellow with Quintiles *

Catherine Denton, 1st year fellow with GlaxoSmithKline

Erick Borg, fellow in Clinical Research and Drug Development

Jessica L. Adams, HIV Pharmacology Fellow with UNC Eshelman School of Pharmacy

Jill Henry, fellow in Clinical Research and Drug Development

Savannah Steele, current fellow

Key: * denotes last known employment
To update your record or one of a friend or colleague, email paa@unc.edu.



Fellows Day 2008