

Women In Science Scholars Program Annual Meeting Highlights October 2, 2023

Rizzo Center, Chapel Hill

Marilyn Foote-Hudson, Executive Director of the North Carolina GlaxoSmithKline Foundation welcomed everyone and shared the agenda for the day.

Marilyn highlighted the Women in Science Scholars program was developed to mentor scholars, specifically to support their academic growth and development while plotting a successful STEM career.

Marilyn referred to the scholars as the next generation of innovators and critical thinkers, and we can't wait to see all that you will accomplish!

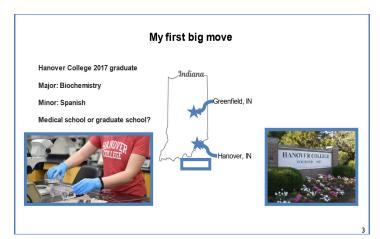


Marilyn recognized the mentors and introduced them to the scholars as these are your "tall friends". She noted the recent NC GlaxoSmithKline Foundation Child Health Recognition Lifetime Achievement Award recipient had conveyed "It's good to have tall friends in deep water", a quote the award recipient's grandfather stated often. Marilyn encouraged the scholars to seek out the knowledge of their mentors, and to know they also had "tall friends" in this program.

Marilyn recognized the scholars, faculty and staff attending and gave a special welcome to Dr. Margaret Dardess, PhD, JD, Chairman of the NC GlaxoSmithKline Foundation, and the President of the Foundation Dr. George Abercrombie, RPh. A warm welcome was given to Dr. Tim Wilson, PhD, a University of North Carolina at Chapel Hill professor and encouraged the scholars to talk with him about research opportunities in his lab.

Marilyn introduced the keynote, Rebekah Dickmander. She is currently finishing her graduate work at The University of North Carolina at Chapel Hill in the lab of Dr. Nat Moorman.

Rebekah Dickmander presented **"From Farm to Pharmaceuticals"**. She highlighted her early days growing up in a small town in Indiana on a farm. She shared the anxiety involved at leaving the comfort of her family and small town to attend college. She



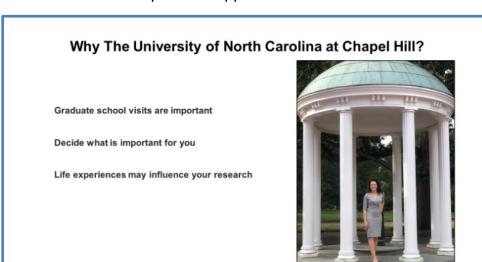
shared the impact of her high school biology teacher's influence and joining the science academic club. With the assistance of scholarships in lacrosse and track, she completed her undergraduate studies in biochemistry and minor in Spanish at Hanover College.

Graduation with her undergraduate degree came with more decisions and opportunities.

Missed deadlines in the college application process resulted in her taking a gap year. During that year, she worked to save for college. While working, she was offered a leadership role, but turned it down to go on to college.

She noted some key points that helped her make decisions:

- In an interview, remember you may be a good fit for the position, but is the position a good fit for you.
- Learn how to learn, quickly and efficiently.
- Hard work pays off.
- Make a list to prioritize opportunities.

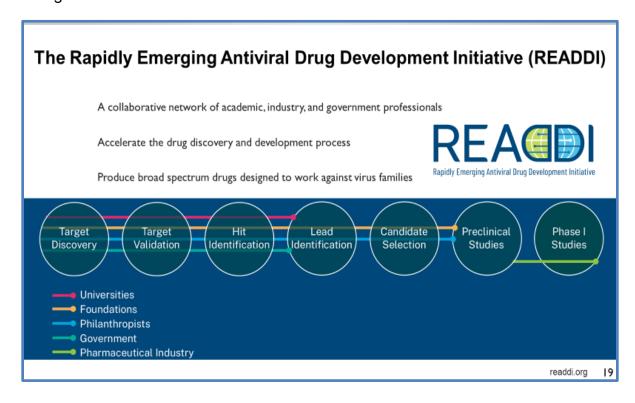


After applying to many of the top PhD programs in the US, she accepted the program at the University of North Carolina at Chapel Hill. All the research labs would have been a good fit, but it allowed her to

decide where she really wanted to focus her research. Working and learning in Dr. Nat Moorman's lab combines microbiology and immunology, lots of collaboration with other likeminded students, successes, and failures. She noted with research there will always be failures. She encouraged the scholars to remember her key learnings:

- Don't take failures personally, be resilient.
- All experiments will not be successful, continue to look for a new route.
- Embrace failures and challenges, your knowledge will grow.
- Don't be timid, ask questions.
- Keep an open mind.

The pandemic created an opportunity for her to expand her skills. She worked in the Rapidly Emerging Antiviral Drug Development Initiative (READDI) where she developed and optimized cell-based assays. These assays are used for testing antiviral compounds against multiple families of pre-pandemic viruses in efforts to develop broad acting antivirals small molecules.



This led to her applying and being awarded The Chu Family Foundation Scholarship for Early Career Women in Science in 2023 for her work in antiviral research and drug development. In conclusion, Ms. Dickmander advised scholars to be open to various roles, working with multidisciplinary teams, and using their background and training to understand other areas of expertise.

Marilyn thanked Bekah and invited everyone to lunch.

Debra Lake, MS and Leslie Driver, Pharm D presented "Pharmaceutical Marketing Application and Approval in the US". STEM educational backgrounds were featured in the process of bringing a drug to market. Walking through the drug approval steps begins with understanding the role of the US Food and Drug Administration (FDA) and the various laws, regulations and guidances that are followed to bring new compounds to market.

Using a mock pharma company, the path to regulatory approval was presented along with the specific stages and milestones throughout the process. This complex path relies on many individuals, including STEM career professionals, to accomplish this work.

The requirements for submission of an Investigational New Drug

Regulatory Considerations During Drug Development: An Overview PACs, safety changes/ updates INTERACT/ Pre-Pediatric Planning End of Phase II IND/IND (PREA and BPCA) Meeting Global considerations Pre-submission meetings of File and Sponsor Prepare Submission, Plan for safety Update

(IND) application to FDA based on non-clinical data, safety data, and drug formulation

New Drug Application (NDA) Application in which a sponsor/applicant seeks approval by the FDA to market a drug Components of NDA including CMC, Nonclinical, Clinical, labeling, tradename, risk management plan, patents 60 days to determine "fileability" of the application User fees of up to \$4 million USD Must be prepared for inspections of clinical investigator sites and proposed manufacturing sites (primary and secondary) Presentation of Application to Advisory Committee — public forum and recommendation for approval or not

information were explored in addition to the progression through different phases of clinical trials in humans – a process that can take many years. Upon completion of the trials, the applicant may submit a New Drug Application (NDA) to FDA. The parts of an NDA were discussed, including clinical and non-clinical data, chemistry and manufacturing information, and product labeling. Once the drug has been reviewed and approved by FDA, the work of the company is not complete. The various

regulatory activities conducted by the company during the approved drug's lifecycle were also examined.

The presentation concluded by sharing advice to those interested in a career in pharmaceutical industry, including being open to the various roles, working with multidisciplinary teams, and using one's background and training to understand other areas of expertise.

The afternoon sessions included time for the mentors and scholars to talk in small groups, and a session for faculty and staff was led by Herman Holt, PhD, Interim Provost and Vice Chancellor for Academic Affairs, University of North Carolina Asheville.

Marilyn requested attendees to share their favorite session and any learnings before adjourning the meeting. She also encouraged everyone to "Save the Date" March 1, 2024 for the Spring Conference. Please contact Dawn.L.Lloyd@gsk.com with any questions.