Fall 2025 Budget Reduction Feedback for the UNL Department of Statistics

I am writing this letter to highlight the importance of the discipline of statistics (specifically the role of statistics in drug development), express the impact the Department has had on me, and make my voice heard in hopes to prevent the abolishment of the Department of Statistics at UNL.

Why are statisticians needed in the pharmaceutical industry and regulatory agencies (e.g. FDA)?

As a Biostatistician at a pharmaceutical company (Novartis), I provide expert support and technical knowledge to ensure the scientific integrity and validity for clinical drug development. I provide statistical support for regulatory drug submissions to the FDA including planning, analysis, and reporting of clinical safety and efficacy summaries. At Novartis "*Our teams work on critical solutions for the problems of tomorrow*" to "*deliver medicines to patients to meet a medical need*" ([Meet the Novartis Biostatistics Team in Analytics](#)).

Eric Gibson (head of Advanced Quantitative Sciences at Novartis) writes: "*Scientists in every discipline are generating data more rapidly than ever before, resulting in an increasing need for statistical skills at a time when there is decreasing visibility for the field of statistics. Resolving this paradox requires stronger statistical leadership to guide multidisciplinary teams in the design and planning of scientific research and making decisions based on data. It requires more effective communication to non-statisticians of the value of statistics in using data to answer questions, predict outcomes, and support decision-making in the face of uncertainty. It also requires a greater appreciation of the unique capabilities of alternative quantitative disciplines such as machine learning, data science, pharmacometrics, and bioinformatics which represent an opportunity for statisticians to achieve greater impact through collaborative partnership*" ([Leadership in Statistics: Increasing Our Value and Visibility](#)).

Statisticians are leaders and play a critical part in ensuring the right data are collected to make informed decisions on the overall risk/benefit of a new drug. Better put: *"The role of statisticians in regulatory science is more pivotal than ever. As the pharmaceutical landscape becomes increasingly intricate, statisticians are not merely adapting, and they are leading. Through expanded technical expertise, deeper engagement with regulators, and active collaboration across sectors, statisticians are poised to drive meaningful innovation while preserving scientific integrity throughout the lifecycle of clinical development"* ([The Evolving Role of Statisticians in Regulatory Science](#)).

FDA statisticians review New Drug Applications by analyzing clinical data, evaluating clinical studies, and performing statistical reviews to ensure drug safety and efficacy. Their role encompasses evaluating scientific data, applying statistical principles for benefit-risk assessments, conducting independent statistical research, and ensuring adherence to regulatory guidelines for public health protection.

How has my UNL education helped set me up for success?

As a graduate student (2005-2010), I was approached by my PhD advisor Walt Stroup, professor and Chair of the Department of Statistics at the time, with the opportunity to become a member along with him of the Product Quality Research Institute (PQRI) Stability Shelf Life Working Group (SSL WG) to expand their initial research on shelf life estimation. I accepted this opportunity and was able to work along with members of industry, academia, and FDA to assess the current methodologies for shelf life estimation of pharmaceutical products. This research led to my dissertation topic and completion of my PhD requirements.

The UNL faculty's extensive knowledge and expertise proved vital in helping me communicate statistical aspects to the SSL WG, allowing me to bridge the gap between academic/statistical theory and real world problems in ways non-statisticians could understand. The opportunity to become a member of the SSL WG provided valuable experiences in collaborative research and impact outside the UNL community.

The Department of Statistics provided me the academic background and developed my consulting skills, allowing me to analyze data from clinical trials and successfully explain statistical concepts to drug developers and researchers at Novartis. My education provided invaluable influence on my professional development and involvement in bringing several new drugs to market at Novartis.

In summary, the UNL Department of Statistics plays a crucial role in training statisticians like me to fulfill the need for statisticians to make informed decisions about data across numerous industries; there is a great need for trained statisticians especially in the pharmaceutical and regulatory industries. I therefore strongly recommend you reconsider abolishing a department that has produced (and will continue to produce) graduates who go on to make critical impacts on the world in which we live.

Sincerely,

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