Panel questions for Dr. Brian King

Question 1: Is the FDA-CTP able to use research on a *class* of products in the Premarket Tobacco Product Application process for *individual* products. If so, for what parameters exactly?

Question 2: How does the FDA-CTP handle situations in which there is disagreement in the literature; for example, longitudinal cohort studies generally finding e-cigarette use in one period leads to higher youth cigarette use in another, and natural experiment research generally finding that e-cigarette availability reduces youth cigarette use?

Question 3: How is the FDA-CTP transparent with the scientific community currently about their use of research in evaluating Premarket Tobacco Product Applications? Could this be improved in any way?

Question 4: When determining whether to authorize a new product, how does the FDA-CTP use research to weigh potentially opposing benefits and harms to different populations (e.g., youth vs. adults)?

Question 5: Are there any examples of decisions or statements FDA-CTP has made that were either incorrect, or are outdated based on new evidence? What are channels for researchers to inform the FDA-CTP of possible errors in regulatory decision-making, and what would the process look like for the FDA-CTP to fix these?

Question 6: What does the FDA-CTP see as the benefits and disadvantages of convening a tobacco-specific special emphasis panel, rather than using standard National Institutes of Health study sections, in reviewing grant applications? Could giving investigators a choice, or otherwise providing a mixed review strategy, lead to the funding of higher-quality science?

Question 7: What types of research from international settings, if any, does the FDA-CTP use in making regulatory decisions?