

Panel questions for Dr. Brian King

Question 1:

- **Introduction:** The FDA-CTP's Premarket Tobacco Product Application process requires applicants to provide product-specific scientific evidence that the product is appropriate for public health for it to be authorized for legal sale in the US. However, the FDA-CTP generally funds (and researchers generally conduct) research on a class of products rather than individual products, leading to some uncertainty in how class-specific evidence is used in evaluating individual products.
- **Question:** 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:

- **Introduction:** The FDA-CTP has funded substantial research using Population Assessment of Tobacco and Health (PATH) data and longitudinal cohort studies to find that e-cigarette use in one period is associated with more dangerous tobacco product use in another period. Some have argued that this shows a "gateway," However, this conclusion contrasts with youth smoking rates falling to virtually zero during a decade with e-cigarette availability, and declining faster than ambitious public health objectives. Additionally, most quasi-experimental studies find that restricting e-cigarette use increases youth cigarette use.
- **Question:** 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:

- **Introduction:** Our understanding is that new tobacco products that were not on the market by Aug 8, 2016 need to be authorized for marketing by the FDA-CTP through their Premarket Tobacco Product Application process. To date, the FDA-CTP has authorized 23 e-cigarette products from 3 companies, and has rejected millions of applications.
- **Question:** 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)?
- **Chat:** Here is a link to authorized products: <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>.

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:

- **Introduction:** FDA-CTP grant applications are reviewed by a tobacco-specific special review panel, which is in contrast to the typical process of National Institutes of Health grant applications being sent to a standing study section that is generally methods-focused rather than topic-focused.
- **Question:** 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:

- **Introduction:** E-cigarette research is conducted globally, with important differences in culture, regulation, and policy across countries and even within countries. To the best of our knowledge the FDA-CTP follows National Institutes of Health rules regarding the funding of international research, but less clear is if international research, while not fundable by the FDA, can be used in their regulatory activities.
- **Question:** What types of research from international settings, if any, does the FDA-CTP use in making regulatory decisions?