Science Board to the Food and Drug Administration
via Videoconference
June 14, 2022

QUESTIONS

1. How might a public health agency assess the unique toxicological safety questions raised by a substance (e.g., cannabinoids), likely used for pharmacological (e.g., psychoactive) effects, outside the context of an approved drug?

   Consider the following potential scenarios:

   - Known or predicted pharmacological activity that raises toxicological concerns
   - Lack of substantial history of safe use directly relevant to the context of use
   - Variability in product quality and composition, particularly variability in the concentration of active constituents
   - Consumer ability to self-administer without practical limitations to dosage

2. If consumers have broad access to a substance (e.g., cannabinoids), likely used for its known or predicted pharmacological (e.g., psychoactive) effects, outside of the context of an approved drug, what approaches might a public health agency use to manage, mitigate, or communicate potential harm?

   Consider the potential scenarios above.