

Questions for Committee Consideration

- 1) Based on the peer-reviewed scientific literature, the draft FDA White Paper, and any other information, including the information you heard in the public session, please discuss the following topics, including any issues of quality, experimental design, or other attributes of specific studies that may affect the weight that should be given to conclusions drawn from them:

Questions for Committee Consideration

1a) Please discuss the direct evidence, if any exists, supporting or refuting the occurrence of adverse health effects from mercury vapor released from dental amalgam devices.

Questions for Committee Consideration

1b) Please discuss the indirect evidence (e.g., extrapolation from higher dose studies, animal studies), if any exists, supporting or refuting a link between dental amalgam devices and adverse neurological effects at the absorbed doses received from these devices.

Questions for Committee Consideration

- 1c) Please discuss the indirect evidence (e.g., extrapolation from higher dose studies, animal studies), if any exists, supporting or refuting a link between dental amalgam devices and adverse non-neurological effects at the absorbed doses received from these devices.

Questions for Committee Consideration

1d) Please discuss the indirect evidence (e.g., extrapolation from higher dose studies, animal studies) , if any exists, supporting or refuting a link between dental amalgam devices and adverse effects specific to vulnerable populations such as children and pregnant women at the absorbed doses received from these devices.

Questions for Committee Consideration

- 2) Does the draft FDA White Paper objectively and clearly present the current state of knowledge about the exposure and health effects related to dental amalgam?

Questions for Committee Consideration

- 3) Given the amount and quality of the information available for the draft FDA White Paper, are the conclusions reasonable?