Joint Meeting of the Dental Products Panel (CDRH) and the Peripheral and Central Nervous System Drugs Advisory Committee (CDER) - September 6-7, 2006 (Summary)

The joint committee met on Wednesday, September 6, and Thursday, September 7, 2006, in Gaithersburg, MD, to discuss and make recommendations to FDA on its draft white paper regarding the potential adverse health risks associated with exposure to mercury in dental amalgam. The joint committee was comprised of 24 panelist including consultants.

On the first day, the joint committee heard presentations from a materials expert on the properties of dental amalgam, from officials from Health Canada and the Medical Products Agency (Sweden) on the scientific basis for the regulation of dental amalgam in their respective countries, and from the FDA on how the US has regulated amalgam and has performed risk assessments over the years. The first day concluded with 5 hours of public testimony including a talk by the honorable Congresswoman Diane Watson of California.

The second day added two hours of pubic hearing. In total 52 speakers presented in approximately 7 hours. The panel then deliberated on a series of questions the FDA had posed on its draft white paper review of the amalgam literature.

To the question of whether the white paper "objectively and clearly presented the current state of knowledge about the exposure and health effects related to dental amalgam," the panel voted "no" by a 13-7 margin. Some of the reasons cited by the majority were that the paper was limited and scope and had knowledge gaps particularly regarding exposure limits.

To the question of whether the white paper's conclusions were "reasonable" the panel also voted "no" by the same 13-7 margin. Some of the reasons cited by the majority were that no conclusion could be drawn because the evidence was often contradictory and that conclusions based on a limited search should not be made.

The joint committee concluded with personal recommendations by the members. These include that FDA should :

- Consider informed consent for patients receiving amalgam
- Consider labeling changes restricting its use in pregnant woman and children
- Revisit the white paper to include a broader search, include data from other countries, and provide the rationale for study exclusion
- Study the pharmacokinetics of mercury
- Consider the relevancy of the "precautionary principle."
- Not make any rash decisions by having the pubic remove their amalgams because it appears that this problem may affect only a small segment of the population.

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A complete transcript will be available at:
http://www.fda.gov/ohrms/dockets/ac/cdrh05.html#DentalProducts

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