

**LSRO Report: The Health Effects of Dental Amalgam**

**REVIEW AND ANALYSIS OF THE LITERATURE  
ON THE POTENTIAL ADVERSE HEALTH EFFECTS OF  
DENTAL AMALGAM**

**SUPPLEMENT**

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### **PREFACE**

The Life Sciences Research Office, Inc. (LSRO) provides scientific assessments of topics in the biomedical sciences. Reports are based on comprehensive literature reviews and the scientific opinions of knowledgeable investigators engaged in work in relevant areas of science and medicine. This LSRO report was developed for the Trans-agency Working Group on the Health Effects of Dental Amalgam. The Trans-agency Working Group is composed of representatives from the National Institutes of Dental and Craniofacial Research (NIDCR) of the National Institutes of Health, the Center for Devices and Radiological Health of the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, and the Office of the Chief Dental Officer of the Public Health Service. The report was supported and governed in accordance with Prime Contract No. N01-DE-12635 between NIDCR and BETAH Associates, Inc. and Subcontract No. 03001NIDC between BETAH Associates, Inc. and LSRO.

LSRO engaged an Expert Panel to provide scientific oversight and direction for all aspects of this project. Expert Panel members were appointed based on their qualifications, experience, judgment, and freedom from significant conflict of interest, with due considerations for balance and breadth in the appropriate scientific disciplines. No member of the Expert Panel expressed a public opinion on the potential adverse health effects of dental amalgam prior to or during the review period. LSRO retained full and final authority for the selection of the independent Expert Panel that was chosen with the concurrence of the LSRO Board of Directors. The Sponsor was offered, but refused comment on the final composition of the Expert Panel.

The Expert Panel convened five times (two two-day meetings, one one-day meeting, and two conference calls) to consider the peer-reviewed, primary scientific and medical literature published since the beginning of 1996 that contributed to an understanding and evaluation of the potential adverse human health effects that may be caused by dental amalgam. The Expert Panel considered literature recommendations and comments submitted by the public in response to the Federal Register Request for Information on Dental Amalgam (Docket No. 03N-0169). Additional written testimony was accepted by the Expert Panel throughout the review period. Although not required as part of the contractual Scope of Work, a meeting was held on December 12, 2003 where the Expert Panel received verbal and written testimony from interested stakeholders. The Expert Panel also heard from and interacted with scientific experts who presented information about the absorption, distribution, metabolism, and excretion of mercury; the material properties of dental amalgam; and ongoing clinical trials studying the health effects of dental amalgam in children. Comments and further information were solicited from these scientists both before and after the December meeting. Information about the review process, including meeting agendas, presentations, and minutes as well as a listing of the Expert Panel members, was made publicly available at the LSRO web site.

The LSRO staff and members of the Expert Panel considered all of the available information when drafting the report and provided additional documentation and viewpoints for incorporation into the final report. Although not required to fulfill the

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contractual Scope of Work, LSRO engaged three independent external reviewers to evaluate a draft of the report. This external review process was requested by the Expert Panel. The comments that were provided by these reviewers were discussed by the Expert Panel and where appropriate, were incorporated into the report. The final report was reviewed and approved by the Expert Panel and the LSRO Board of Directors. On completion of these reviews, the Sponsor was given the opportunity to check the report for technical errors, but refused comment.

The report was prepared and edited by Amy M. Brownawell, Ph.D. Each draft was revised and amended by the Expert Panel. The inclusion of the names of the Expert Panel, others who assisted in preparation of this report, and the LSRO Board of Directors in Appendix A, does not imply that each individual endorsed all of the statements in this report. The report was developed independently of the Trans-agency Working Group and conclusions drawn therein do not necessarily represent the view of the Transagency Working Group, NIDCR, or any of their representatives or employees. The LSRO accepts full responsibility for the study conclusions and accuracy of the report.

Michael Falk, Ph.D.  
Executive Director  
Life Sciences Research Office, Inc.

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### Articles Considered by the Expert Panel

All peer-reviewed human, animal, and *in vitro* studies published between January 1, 1996 and December 31, 2003 that investigated the biochemical, behavioral, and/or toxicological effects resulting from exposure to dental amalgam, mercury vapor ( $\text{Hg}^0$ ), inorganic mercury ( $\text{Hg}^{2+}$ ), or organic mercury (methyl and ethylmercury) were considered. The Expert Panel and LSRO were not asked by the Sponsor to review studies that evaluated the dental or material properties of dental amalgam, compared the risks and benefits of alternative replacement materials *versus* dental amalgam, or considered the environmental consequences of dental amalgam disposal. Papers dealing with these topics were, therefore, excluded because they were beyond the scope of the project. Letters, comments, news articles, editorials, lectures, and other non peer-reviewed documents were also excluded. Approximately 961 articles were identified as broadly meeting these inclusion criteria and were considered during the course of the review. The references of these studies comprise this Report Supplement.

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