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FOREWORD FROM THE GUEST EDITOR

Reproductive and Other Health Effects of Semiconductor Work: The Semiconductor Health Study

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This issue presents the results of a large, multidisciplinary investigation of reproductive and other health outcomes in the semiconductor industry. Each manuscript has been peer reviewed by reviewers selected by the *Journal* without input from the guest editor or the manuscript authors. Only manuscripts that were found to be acceptable by the reviewers are published in this volume.

I am particularly pleased that this volume contains manuscripts covering the broad spectrum of disciplines brought together for this investigation. Juxtaposition of the industrial hygiene/exposure-assessment papers with manuscripts on laboratory and epidemiologic methods and epidemiologic findings provides an uncommon sequence of articles allowing insight into the diverse disciplines involved in this investigation. It also is of value to the reader wishing to understand the inter-relationships of those disciplines in an occupational epidemiology investigation.

Several unique and innovative methods were developed and/or applied to the field investigation in this study, ranging from the assessment of complex occupational exposures, to the handling of biologic samples collected in the field, to the recruitment of study participants and communication of study results to the participants, other industry employees, and the public. The first noteworthy innovation was creation of an independent Scientific Advisory Panel by the Semiconductor Industry Association (SIA). The Panel, under the leadership of Dr. Patricia Buffler, was composed of academic professionals from multiple disciplines. They reviewed all aspects of the investigation from selection of the proposal during competitive funding, through to interpretation and reporting of results. Other Panel members, whom we gratefully thank, were Drs. Mark Cullen, Phillip Enterline, Robert Spear, Robert Harris, and Don Mattison. The Scientific Advisory Panel also played an extremely valuable role in communicating with the industry about the specific requirements for an adequate scientific investigation and critically reviewed the study progress, providing the investigators with valuable advice and assistance throughout this lengthy and complex study. The structure and role of a Scientific Advisory Panel, functioning as it did in

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this study, is a worthy model for maintaining independence of research funded by industry (Cullen et al., 1994). With the limited federal funding available for occupational health research, such models might well be emulated by other industries.

The raison d'être for this investigation and inter-relationships of the various study components are described in the paper by Schenker and coworkers. This paper also synthesizes and analyzes the separate study component results in terms of the biologic plausibility of the findings. By design, this investigation had separate epidemiologic components and the similar findings from those independent components greatly strengthen the conclusion of causality in the observed association of spontaneous abortion (SAB) and semiconductor fabrication work. The conclusion derives additional support from the very similar findings in a simultaneous but independent investigation of IBM employees (Gray et al., 1993).

Studying adverse reproductive health outcomes in the semiconductor industry was a challenge to exposure assessment because of the large number of potential hazards in fabrication rooms (fabs), and the generally low levels of chemical agent air concentrations in the fabs. The challenge was increased by the wide variety and geographic dispersion of study sites across the country and the rapid technologic changes in this industry. The innovative approach employed in exposure assessment for this study is described in the paper by Hammond and coworkers. This efficient, logical, and systematic approach serves as a model for studies in other industries with diverse and complex occupational exposures. The remaining papers in the industrial hygiene/exposure-assessment section address patterns of chemical use and exposure control in the semiconductor industry, and specific methods for characterizing exposures of subjects in this study.

The historical cohort component methods and overall risk of SAB for fabrication workers are described in the paper by Beaumont and coworkers. Analysis of SAB in relationship to specific agent exposures is described in the paper by Swan and coworkers. The historical cohort component was designed to have adequate study power to address the primary study hypothesis of an increased risk of SAB associated with fabrication room work per se. The large sample size also allowed a more detailed analysis of SAB risk with exposure to specific workplace agents. The methods used in this analysis, described by Swan and coworkers, are particularly noteworthy.

The prospective cohort investigation was designed to provide objective, independent assessment of SAB via analysis of daily urine collections from women working in the industry who might become pregnant. As such, this component of the study also provided confirmation with a very different study approach of the findings from the historical cohort, which depended on recall of SAB and verification by medical records or physician assessment. The application of laboratory techniques developed for use in infertility clinics to a large-scale epidemiologic investigation required development or modification of methods for specimen collection, sample handling, and analyses, and is described in the article by Lasley and coworkers. The prospective design of this study component permitted analysis of menstrual cycle characteristics and fecundability as well as early fetal loss, as described in the accompanying papers by Gold and Eskenazi and coworkers. Normative values for these outcomes in the nonfabrication workers and the comparative methods used in this investigation are important contributions to the usual volunteer and clinic-based populations for reproductive health studies.

The cross-sectional component of this study primarily addressed nonreproductive outcomes. Because resources allocated to the cross-sectional investigation were

relatively few, the study sites were widely dispersed geographically, and little data existed on the multiple potential adverse health outcomes in this industry (e.g., respiratory, musculoskeletal, dermatologic), this component used a broad, questionnaire-based approach to assess symptom and disease prevalence and risk factors. Despite the absence of physiologic testing, this method identified several factors associated with increased symptom or disease risk and is deserving of more detailed followup investigation.

Recent attention has focused on the importance of communication with study participants in epidemiologic studies. Many important communication and ethical issues in an industry-based reproductive health study are addressed in the manuscript by Saiki and coworkers. Some of these issues included maintenance of confidentiality when communicating with potential study participants, methods for communication in a multicultural and multilingual workforce, direct communication of study results to participants by the investigators, the format of study result presentation, and resources for subjects with questions about the study or their individual results. Study investigators made substantial efforts so that all employees at participating company sites received a letter from the principal investigator describing the study results. In addition, participants in the prospective cohort and all workers who had personal industrial hygiene monitoring received individual reports of those results. The investigators also responded to individual questions by any participants and made medical referrals, if necessary.

Support for this large investigation was provided primarily by the Semiconductor Industry Association to the Division of Occupational/Environmental Medicine and Epidemiology at the University of California, Davis. I thank the SIA and SIA Worker Taskforce for their ample cooperation and support of this endeavor, and specifically Lee Neal and Craig Modahl. I and my coinvestigators appreciate the generous and capable help of the Scientific Advisory Panel. I also acknowledge the cooperation, time, and support of the companies participating in this study, and especially the assistance of human resource and industrial hygiene personnel at those companies.

A large research staff including field coordinators, interviewers, coders, lab technicians, and programmers contributed to this study. I thank my coinvestigators for their outstanding effort and hard work, Ann Lavallee and the rest of the UC Davis administrative staff for clerical assistance, Ann Halstead for technical editing, and the Labor Occupational Health Program in Berkeley for professional advice. Subcontracts for research were arranged with the University of Massachusetts Medical Center; the University of California, Berkeley; the Western Consortium for Public Health; and the California Public Health Foundation. I appreciate the effort provided by the many people at these institutions who worked on this study.

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