California Department of Public Health

Department of Toxic Substances Control

Centers for Disease Control and Prevention

MEMORANDUM OF UNDERSTANDING

Among

HEALTH AND HUMAN SERVICES AGENCY
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
DIVISION OF ENVIRONMENTAL AND OCCUPATIONAL DISEASE CONTROL
ENVIRONMENTAL HEALTH LABORATORY BRANCH

And

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF TOXIC SUBSTANCES CONTROL
ENVIRONMENTAL CHEMISTRY LABORATORY

And

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL CENTER FOR ENVIRONMENTAL HEALTH
DIVISION OF LABORATORY SCIENCES

September 23, 2008

I. PURPOSE:

The purpose of this Memorandum of Understanding is to describe a cooperative relationship among the three organizations above (California Department of Public Health (CDPH) Environmental Health Laboratory Branch, Department of Toxic Substances Control (DTSC) Environmental Chemistry Laboratory, and Centers for Disease Control's (CDC) Division of Laboratory Sciences (DLS) of the National Center for Environmental Health) with respect to laboratory support for the California Environmental Contaminants Biomonitoring Program.

II. BACKGROUND:

In 2005, Representative Nancy Pelosi, Democratic Leader of the House of Representatives, wrote to Dr. Julie Gerberding, Director of the Centers for Disease Control and Prevention, to request a description of the assistance that

CDC could offer California as the state implements its biomonitoring program. In her response, Dr. Gerberding provided the following examples of assistance: training in analytical methods and collecting, processing, and shipping human samples for analyses; analysis of up to 500 human samples for a one-time community-based type of survey; and assistance in testing for specific chemicals of concern in one additional chemical-specific study involving up to 200 participants.

In 2006, the California Environmental Contaminant Biomonitoring Program (CECBP) was authorized by Senate Bill (SB 1379) (Perata, chapter 599, Statutes of 2006). SB 1379 directs the CECBP to provide for the systematic collection and chemical analysis of human biological specimens, such as blood and urine, in a representative sample of Californians. The legislation also directs the CECBP to incorporate, as appropriate, the methods utilized by the CDC in its National Biomonitoring Program as well as for its *National Report on Human Exposure to Environmental Chemicals*.

III. DEFINITION OF SCOPE:

The participating CDC and California laboratories share a common interest in utilizing biomonitoring as a means to assess human exposure to environmental chemicals.

CDC's DLS has, for more than three decades, been conducting biomonitoring measurements in representative samples of the US population. These national surveys have determined which chemicals enter people's bodies, how much of those chemicals are actually present and how the amounts of those chemicals may be related to health effects. CDC's DLS also has keen interest in stronger state biomonitoring programs and currently provides analytical assistance to several research studies in California that involve biomonitoring.

California's new biomonitoring program is similarly planning to determine baseline levels of environmental contaminants in a representative sample of Californians. In addition, the program will begin to plan for and then conduct community-based studies. Thus, the CECBP will be able to track statewide exposure trends over time, as well as to investigate highly exposed communities. In addition, the program will assess effectiveness of public health efforts and regulatory programs to reduce exposures of Californians to specific chemical contaminants.

The participating federal and state laboratories recognize that laboratory measurements are the basis of our biomonitoring programs. Furthermore,

measuring chemicals in people is very challenging and requires high levels of experience and training as well as substantial and sustainable funding.

CDC's willingness to enter into a partnership with California focused on laboratory biomonitoring is consistent with CDC's interest in furthering state biomonitoring activities and can provide enormous benefit to the state's program as it builds laboratory capability and capacity. The California Legislature is reluctant to expand programs that cannot demonstrate the ability to leverage additional support through non-state in-kind contributions, including commitments from the federal government. As such, a commitment from the CDC's DLS to California's biomonitoring program would be extremely useful at this time to help sustain and further the state's biomonitoring activities.

IV. SUBSTANCE OF AGREEMENT:

Training

Using Analytical Methods. Scientists at CDC's DLS agree to train laboratorians from California's state biomonitoring program in the analytical methods used to measure levels of trace metals and organic pollutants in people. The specific analytical methods for training would be chosen to meet the highest priority testing needs of the California biomonitoring program and would be limited by the training resources available for this purpose as determined by CDC. Training would be conducted at various intervals in Atlanta at CDC's DLS. All travel, lodging, and meals for the California laboratorians would be the responsibility of the state.

Collection, Processing, and Shipping Human Samples for Analysis. Integral to biomonitoring is the proper collection, processing, storage, and shipping of human samples that are analyzed for studies or health investigations. CDC's DLS would provide training in these processes for state laboratory staff as appropriate. Training would be conducted at CDC's DLS with follow-up site visits by CDC staff to the state laboratories. All travel, lodging, and meals for the California laboratorians would be the responsibility of the state.

Analysis of Samples

CDC's DLS agrees to provide in-kind services to the California laboratories for the analyses of samples for the following purposes:

Proficiency testing. DLS will assist California laboratories by providing proficiency-testing materials to evaluate the quality of biomonitoring measurements. These proficiency-testing materials will include selected quality-control pools, standards (also known as calibrators), and split-sample analyses. DLS will make every effort to assist with acquiring isotopically labeled standards, recognizing that cost confers some limitation on direct provision of these standards. DLS will assist California with the interpretation of proficiency-testing results as needed. Recognizing the requirement of Clinical Laboratory Improvement Amendments (CLIA) certification for biomonitoring measurements, DLS will provide to California its CLIA-type method descriptions, the DLS Policies and Procedures Manual (containing DLS CLIA procedures), and other information about best laboratory practices and procedures used to meet CLIA requirements.

Testing for Community and Special Studies and Exposure Incidents.

Community-Based Study. DLS will provide analytical services for a one-time community based type survey of up to 500 human samples in a California subpopulation. The analyses will be limited to ten chemical analytical groups of concern in the state (e.g., metals, pesticides, phthalates, PCBs, PAHs, tobacco smoke, PBDES, polyfluoroalkyl chemicals). The state would be responsible for reporting and interpreting test results.

Special Study. DLS will provide analytical services for one chemical-specific study in California. The services will support a study of up to 200 participants. The state would be responsible for reporting and interpreting test results.

Exposure-Incident Response. DLS will provide assistance to California in responding to unusual chemical exposure incidents. DLS will provide analytical services to test human samples for analytes that it can test for and for which the California laboratories cannot. DLS would be expected to test samples from approximately twenty of the most highly exposed individuals. For analytes that the California laboratories can test for, DLS would perform repeat tests on samples with high values analyzed by the California laboratories. The state would be responsible for reporting and interpreting test results.

Outcomes as Measures of Impact

CDC's DLS and the California laboratories agree to communicate regularly for the purpose of sharing information and outcomes of joint biomonitoring efforts. Shared outcomes would include reports and peer-reviewed publications.

V. PERIOD OF AGREEMENT:

This Memorandum of Understanding will remain in effect as long as all three agencies agree that it should.

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California Department of Public Health
Health and Human Services Agency

9-23-08

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10/9/08

Howard Frumkin, M.D., Dr. P.H. — Date
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