Response to National Ambient Air Quality Standard (NAAQS) Science Evaluation

Solicitation Number: 582-13-32032

Prepared for
Texas Commission on Environmental Quality
TCEQ MC182
Attention: Lilia VanderWal
Procurements & Contracts
PO Box 13087
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April 22, 2013

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Tab 1: Solicitation Signature Page

SIGN YOUR RESPONSE IN THE SPACE BELOW Your signature binds you to everything in your Response, including the HUB Subcontracting Plan (HSP) **Failure to manually sign here will disqualify your Response** **With regard to the attached Response, including the HSP, Responder certifies and agrees:** • Responder's information is complete, true and complies with all requirements in the Solicitation; • Responder will promptly notify TCEQ of any relevant changes to the Response information; • Response terms including prices are fixed for 120 days from due date for Response; • Responder affirmatively waives confidentiality of all information including email addresses; • Responder will completely perform the terms of the Response (including the HSP and agreed amendments); • The person signing is authorized to sign and certify this Response for the Responder.	
Authorized Responder Signature Julie E Goodman	Date April 19, 2013
Responder Printed Name **Julie Goodman**	Responder Title **Principal**

Company Name: **Gradient**	Contact Name, Title: **Julie Goodman, Principal**
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Vendor ID Number: 04-3483677	Back-Up Contact, Title: **Sonja Sax, Senior Environmental Scientist**

PLEASE ENTER YOUR FEDERAL EIN: 04-3483677

For Questions, contact the TCEQ Contract Specialist: Lilia VanderWal at 512-239-1370 or via email: Lilia.vanderwal@tceq.state.gov.

For HUB questions, contact Laura Cagle at 239-1273, or via email: laura.cagle@tceq.texas.gov.
Exclusive Addresses for Delivery: (LABEL **INSIDE** AND **OUTSIDE** PACKAGES)

Mail Response to:	**Hand-deliver Response to:**	**Overnight/Express Response to:**
TCEQ MC182 **Attention: Lilia VanderWal** **Procurements & Contracts** **PO Box 13087** **Austin, Texas 78711-3087**	**TCEQ MC182** **Attention: Lilia VanderWal** **Procurements & Contracts** **12100 Park 35 Circle, Bldg. A, 3rd Floor** **Austin, Texas 78753**	**TCEQ MC182** **Attention: Lilia VanderWal** **Procurements & Contracts** **12100 Park 35 Circle, Bldg. A, 3rd Floor** **Austin, Texas 78753**

Tab 2: Statement of Qualifications – Gradient

Gradient has more than 20 years of experience evaluating the health effects of criteria pollutants, including ozone, and a highly skilled staff of principals, senior scientists, research associates, and administrative professionals available to support TCEQ's science evaluation of the NAAQS. As discussed in more detail below, Gradient staff members have broad experience writing and serving as reviewers for peer-reviewed papers and white papers; presenting at scientific conferences; testifying before Congressional committees, government agencies, and scientific panels; conducting weight-of-evidence (WoE) evaluations; and conducting, reviewing, or critiquing meta-analyses.

Table 2.1 provides general information regarding Gradient's qualifications. Following this are examples of projects related specifically to the health effects of ozone and other criteria pollutants (2.A), WoE evaluations (2.B), and meta-analyses (2.C). We also list published peer-reviewed publications and discuss our experience teaching graduate-level courses, presenting at scientific conferences, and testifying before US Senate and Congressional committees and scientific advisory panels (*e.g.*, Clean Air Science Advisory Committee, CASAC) on these and related topics. We have participated in all of these activities for well over three years.

Table 2.1 Gradient Qualifications

1.	Company/Institution/Organization's Name: **GradCo LLC d/b/a Gradient**
2.	Prime or Subcontractor: **Prime**
3.	Type of business organization: **LLC**
4.	Date established: **3/13/85**
5.	State of incorporation: **Massachusetts**
6.	Texas authorizations to conduct business: **None**
7.	Location of your company/institution/organization's headquarters and relevant branch offices: **Cambridge, MA (headquarters), and Seattle, WA**
8.	Total years of experience in successfully reviewing and critiquing ozone science: **25**
9.	Total years of experience in formal weight-of-evidence evaluations: **7**
10.	Total years relevant Contractor's experience: **28**
11.	Description of relevant company/institution/organization's experience: **See 2.A-D, below**
12.	Areas of Scope of Work responsible for: **Epidemiology, toxicology, exposure science, mode-of-action, public health, risk assessment**

2.A Ozone and Other Criteria Pollutants

Gradient has provided oral testimony and written white papers critically reviewing almost every draft of the ozone, particulate matter (PM), nitrogen dioxide (NO_2), and sulfur dioxide (SO_2) Integrated Science Assessments (ISAs), Risk and Exposure Assessments (REAs), and Proposed and Final Rules published by the US Environmental Protection Agency (US EPA) over the last five years. On several occasions, these US EPA documents have been edited to reflect our comments. Below, we describe some of these and other projects, and we list some of our peer-reviewed publications; scientific conference presentations; testimony and white papers submitted to US Senate and Congressional Committees, government agencies, and scientific panels; participation on advisory panels; courses and workshops we have taught, and journals for which we have been peer-reviewers. This work represents more than three years of experience in each of these domains.

Example Projects

Evaluation of Key Literature and Epidemiology Studies for Ozone NAAQS Review

Gradient evaluated literature and analyses that are being considered by US EPA in its review of the ozone NAAQS. We attended a workshop in which initial draft materials for the health effects section of the ozone ISA were presented. Gradient critically reviewed the key clinical and epidemiological studies identified from this workshop in anticipation of the ISA. These reviews were used in written and oral testimony to US EPA at public hearings following release of the draft ISA.

Highlights

- *Risk analysis*
- *Air quality*
- *Regulatory comment*

Evaluation of Susceptible Individuals in Clinical Air Pollution Studies

Gradient is conducting a quantitative analysis of controlled human exposure studies to address whether there is a subset of individuals who are susceptible to health effects of criteria air pollutants, but whose response is obscured by analyzing data at the group level. This issue bears on establishment of the NAAQS for criteria air pollutants. Gradient's analysis will be submitted to a peer-reviewed scientific journal.

Highlights

- *Nitrogen dioxide*
- *Ozone*
- *Sulfur dioxide*
- *Lung function*
- *Controlled human exposure studies*

Human Health Risk Assessment Framework Comments

Gradient assessed the US EPA's draft Framework for Human Health Risk Assessment (HHRA) to Inform Decision Making. We assessed the HHRA Framework in general, and compared it to US EPA's ongoing ozone analysis using seven topics discussed in the Framework: planning and "fit for purpose," WoE, transparency, reasonableness, consistency, at-risk factors, and uncertainty and variability.

Highlights

- *Regulatory comment*
- *US EPA guidelines*

Review of Ozone Cardiovascular Effects

When US EPA considered cardiovascular effects of ozone in its review of the NAAQS, Gradient critically evaluated the literature regarding whether the current available evidence support a causal association between ozone exposure and cardiovascular effects. Our evaluation included a review of epidemiological, controlled human exposure, and toxicological studies. The findings were presented at a conference.

Highlights

- *Cardiovascular health endpoints*
- *Epidemiology*
- *Toxicology*

Ozone Mortality Risk Assessment

Gradient performed an ozone mortality risk assessment using the latest version of US EPA's Environmental Benefits Mapping and Analysis Program (BenMAP) model. We evaluated the impact of alterative model inputs on ozone mortality estimates, including using alternative air quality inputs and health effects functions. Results of our analysis were presented to US EPA as part of its review of the ozone NAAQS. In addition, Gradient will present results in a peer-reviewed manuscript.

Highlights

- *BenMAP*
- *Air quality*

Ozone Exposure and Risk Assessment

Gradient performed an ozone exposure and risk assessment using the latest version of the US EPA Air Pollutants Exposure (APEX) model. We evaluated the exposure and risk model and conducted a series of sensitivity analyses to assess how alterative model inputs impact exposure and risk assessment results. Results of our analysis will be presented to US EPA as part of the current review of the ozone NAAQS and submitted to a peer-reviewed scientific journal.

Highlights

- *APEX*
- *Exposure assessment*

Commentary on the US EPA Benefits and Costs of the Clean Air Act Report from 1990 to 2020

Gradient reviewed and critiqued scientific information that was the basis for the 2011 US EPA document, "Benefits and Costs of the 2011 Clean Air Act Report from 1990 to 2020." Specifically, we reviewed the underlying assumptions and the uncertainties associated with US EPA's methodology. Based on our expertise in risk assessment, epidemiology, and statistics, we provided opinions on whether the then-current scientific data supported US EPA conclusions.

Highlights

- *Regulatory comment*
- *Criteria air pollutants*
- *Cost-benefit analysis*

Reconsideration of 2008 Ozone NAAQS Final Rule

Gradient critically reviewed the key clinical and epidemiological studies that formed US EPA's rationale for proposing to lower the 2008 ozone NAAQS. In a series of webinars with supporting materials, we presented the key issues in these studies and the manner in which the new ozone standards would affect communities. We presented our analysis to the US Office of Management and Budget (OMB), the Texas House of Representatives Committee on Environmental Regulation, and US EPA as part of a reconsideration request of the Final Rule.

Highlights

- *Air pollution*
- *Risk assessment*
- *Regulatory comment*
- *Webinar presentations*

Regulatory Comment on SO_2 Secondary NAAQS

Gradient developed comments on US EPA's "Proposed Rule for the Secondary NAAQS for Oxides of Nitrogen and Sulfur." Gradient commented on the scientific basis of the secondary NAAQS for SO_2, the possibility that the proposed NAAQS could lead to reductions in SO_2 emissions, and the potential benefits of sulfur and nitrogen emissions for agricultural and climate change. Our comments were submitted to the docket as a technical attachment to legal comments.

Highlights

- *Regulatory comment*
- *Secondary NAAQS*

Assessment of SO_2 NAAQS

Gradient critically reviewed US EPA's 2010 Final Rule for a Primary National Ambient Air Quality Standard for Sulfur Dioxide. Specifically, we evaluated US EPA's basis for its new 1-hour standard for SO_2. Focusing on the underlying epidemiology and clinical studies, we evaluated the factors guiding US EPA's analysis and the concentration at which a causal association between short-term SO_2 exposure and respiratory morbidity is supported. We summarized our opinions in a white paper provided as technical assistance for litigation.

Highlights
- *Epidemiology*
- *Clinical studies*
- *Regulatory comment*

Scientific Comments on PM NAAQS Proposed Rule

Gradient reviewed and critiqued scientific information on which the PM NAAQS Proposed Rule was based. Based on our expertise in risk assessment, epidemiology, and statistics, we provided opinions on whether then-current scientific data provide sufficient evidence to support a change to the PM standards. We provided written and oral testimony to US EPA at a public hearing.

Highlights
- *Regulatory comment*
- *Epidemiology*
- *Statistics*

Comment on Proposed NO_x Regulations

Gradient provided oral comments to the US OMB regarding US EPA's Proposed Rule for nitrogen oxides (NO_x). Specifically, we identified and discussed shortcomings of US EPA's assessment of clinical studies of NO_x. We also presented results from a peer-reviewed meta-analysis of the same data conducted by Gradient.

Highlights
- *Regulatory comment*
- *NAAQS*
- *Meta-analysis*
- *Criteria air pollutants*

Lead NAAQS Critique

Gradient provided oral comment at US EPA's public hearing on the Proposed Rule for the NAAQS for lead. We also prepared written comments on the Proposed Rule. Our comments focused on US EPA's process for reviewing the NAAQS and the methods US EPA used to derive the NAAQS.

Highlights

- *Public hearing*
- *Submission to US EPA Docket*

Lead NAAQS Staff Paper Review

Gradient prepared comments on the draft US EPA Staff Paper and HHRA associated with US EPA's review of the NAAQS for lead. Gradient also presented these comments at a CASAC public meeting in Washington, DC. Our comments focused on US EPA's case study of a secondary lead smelter. We commented on flaws in US EPA's emissions modeling, flaws in the estimated soil lead concentrations, the underestimation of the contribution of anthropogenic background lead, and the overestimation of the percent of exposure related to current air lead levels. US EPA addressed many of our comments in the final Risk Assessment and Staff Paper.

Highlights

- *Regulatory analysis*
- *CASAC presentation*
- *Secondary lead smelter*

Peer-reviewed Publications

Goodman, JE; Sax, S. 2013. "Letter by Goodman and Sax regarding article, 'Controlled exposure of healthy young volunteers to ozone causes cardiovascular effects.'" *Circulation* 127:e432.

Sax, S; Goodman, JE. 2013. "Equivocal evidence for confounding effects of components of particulate matter on the relationship between ozone and mortality [Letter]." *Am. J. Epidemiol.* (accepted).

Prueitt, RL; Goodman, JE. 2011. "The global burden of ozone on respiratory mortality: No clear evidence for association [Letter]." *Environ. Health Perspect.* 119(4):A158.

Goodman, JE; Dodge, DG; Bailey, LA. 2010. "A framework for assessing causality and adverse effects in humans with a case study of sulfur dioxide." *Regul. Toxicol. Pharmacol.* 58:308-322.

Goodman, JE; Chandalia, JK; Thakali, S; Seeley, M. 2009. "Meta-analysis of nitrogen dioxide exposure and airway hyper-responsiveness in asthmatics." *Crit. Rev. Toxicol.* 39(9):719-742.

Valberg, PA. 2004. "Is PM more toxic than the sum of its parts? Risk-assessment toxicity factors *vs.* PM-mortality 'effect functions.'" *Inhal. Toxicol.* 16(Suppl. 1):19-29.

Beck, BD; Mattuck, RL; Bowers, TS. 2002. "Adult:child differences in the intraspecies uncertainty factor: A case study using lead." *Hum. Ecol. Risk Assess.* 8:877-884.

Bowers, TS; Mattuck, RL. 2001. "Further comparisons of empirical and epidemiological data with predictions of the Integrated Exposure Uptake Biokinetic Model for lead in children." *Hum. Ecol. Risk Assess.* 7:1699-1713.

Valberg, PA; Watson, AY. 1998. "Alternative hypotheses linking outdoor particulate matter with daily morbidity and mortality." *Inhal. Toxicol.* 10:641-662.

Scientific Conference Presentations/Abstracts

Sax, SN; Lau, J; Goodman, J. 2012. "Evaluation of the BenMAP Model for Estimating Mortality Impacts of Lower Ozone Concentrations." Poster Presentation at the International Society of Exposure Science, Seattle, WA, October 28-November 1.

Prueitt, RL; Goodman, JE. 2011. "Evaluation of Adverse Effects on Human Lung Function Caused by Ozone." Presented at Society of Toxicology 50th Annual Meeting, Washington, DC. *Toxicologist - Supplement to Toxicological Sciences* 120(Suppl. 2):491.

Beyer, LA; Slayton, TM; Goodman, JE; Greenberg, GI; Hudson, TC; Beck, BD. 2008. "Evaluation of Key Information Informing the Basis of EPA's New Recommended Ozone Standard." Presented at the Society of Toxicology 47th Annual Meeting and ToxExpo, Seattle, WA, March 20.

Testimony Before US Senate or Congressional Committees

Goodman, JE. 2012. "Testimony regarding EPA's Assessment of Health Benefits Associated with $PM_{2.5}$ Reductions for the Final Mercury and Air Toxics Standards." Testimony before the Subcommittee on Energy and Power, US Congressional Committee on Energy and Commerce American Energy Initiative Hearing, Washington, DC, February 8.

Goodman, JE. 2011. "Testimony regarding Air Quality and Children's Health." Testimony before the Subcommittee on Clean Air and Nuclear Safety and the Subcommittee on Children's Health and Environmental Responsibility, US Senate Committee on Environment and Public Works Hearing, Washington, DC, June 8.

Rhomberg, LR. 1997. "Testimony on Analysis of Risk Assessment Used by the EPA in Support of Its Proposed Ozone Standards." Testimony before the Joint Hearing of the Health and Environment Subcommittee and the Oversight and Investigations Subcommittee, Commerce Committee, US House of Representatives, Washington, DC, May.

Testimony or White Papers Provided to Government Agencies and Scientific Panels

Goodman, JE. 2012. "Oral Testimony Before the CASAC Ozone Review Panel on the Third Draft Ozone ISA and First Draft Ozone REA." Report to American Forest and Paper Association. Submitted to US EPA, Clean Air Scientific Advisory Committee (CASAC), Ozone Review Panel, 2p., November 5.

Sax, SN. 2012. "Written and oral testimony before US EPA's Clean Air Science Advisory Committee (CASAC) regarding issues with the Third Draft Ozone Integrated Science Assessment (ISA)." Comments submitted to CASAC Ozone Review Panel, September 11.

Goodman, JE; Sax, S. 2012. "Comments on US EPA's 'Benefits and Costs of the Clean Air Act from 1990 to 2020' (Second Prospective Study)." Report to American Petroleum Institute, 57p., February 9.

Goodman, JE. 2012. "Oral Testimony Before the CASAC Ozone Review Panel on the Second Draft Ozone ISA (Clarifying Comment)." Report to American Petroleum Institute. Submitted to US EPA, Clean Air Scientific Advisory Committee (CASAC), Ozone Review Panel, 1p., January 10.

Goodman, JE. 2011. "Comments on Second Draft Ozone Integrated Science Assessment." Report to American Petroleum Institute. Submitted to US EPA Docket, EPA-HQ-ORD-2011-0050, December 29.

Goodman, JE. 2011. "Comments on First Draft Ozone Integrated Science Assessment." Report to American Petroleum Institute, 38p., May 2

Goodman, JE. 2011. "Oral Testimony Before the CASAC Ozone Review Panel on the Reconsideration of the 2008 Primary Ozone NAAQS." 2p., February 18.

Goodman, JE. 2011. "Comments to the CASAC Ozone Review Panel for the Reconsideration of the 2008 NAAQS." Report to American Petroleum Institute, 13p., February 7.

Goodman, JE. 2010. "Comments on the CASAC Particulate Matter Review Panel Draft Letter on the 'Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards - Second External Review Draft' (June 2010)." Report to American Petroleum Institute, 2p., August 25.

Sax, SN. 2010. "Written and oral testimony before US EPA's CASAC regarding issues related to the Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards." Comments were submitted to Docket No. EPA-HQ-OAR-2007-0492, May 7.

Goodman, JE; Sax, SN. 2010. "Comments on the Quantitative Health Risk Assessment for Particulate Matter, Second External Review Draft." Report to American Petroleum Institute, 41p., March 15.

Goodman, JE; Sax, SN; Bailey, LA. 2009. "Comments on the Risk Assessment to Support the Review of the PM Primary National Ambient Air Quality Standards External Draft Review." Report to American Petroleum Institute, 52p., November 4.

Goodman, JE. 2009. "Comments on the Epidemiology Evaluation in the Integrated Science Assessment for Particulate Matter Second External Review Draft." Report to American Petroleum Institute, 64p., October 13.

Goodman, JE. 2009. "Comments Presented at the October 5, 2009 Public Meeting of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter Review Panel regarding the Epidemiological Evaluation in the 'Integrated Science Assessment for Particulate Matter: Second External Review Draft (July 2009).'" Report to American Petroleum Institute, 11p., October 5.

Goodman, JE. 2009. "Comments on the "Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment."" Report to American Petroleum Institute, 2p., May 7.

Goodman, JE. 2009. "Risk and Exposure Assessment to Support the Review of the SO_2 Primary National Ambient Air Quality Standards (Second Draft)." Report to American Petroleum Institute, 12p., April 16.

Valberg, PA. 2000. "Review of Ambient Air Quality as it Relates to Proposed Emission Standards for Massachusetts Power Plants." Testimony before the Massachusetts Dept. of Environmental Protection, Boston, MA, July 26.

Scientific Advisory Panels

Goodman, JE. 2012. Invited Participant, International Life Sciences Institute (ILSI) Health and Environmental Sciences Institute Emerging Issue Workshop: Evaluating Causality in Epidemiology, October.

Goodman, JE. 2012. Invited Panel Member, "Using Mode of Action to Support the Development of a Multipollutant Science Assessment," US EPA Workshop.

Goodman, JE. 2012. Invited Participant on "Improving Science-Based Regulation," The George Washington University Regulatory Studies Center and the Center for Risk Science and Public Health, January.

Graduate-level Courses or Workshops

Rhomberg, LR. 1992. "Workshop on Mobile Air Toxics." Benzene Panel, Health Effects Institute, Monterey, CA, December.

Beck, B. 1988. Ozone Toxicology and Risk Assessment." Harvard School of Public Health, Boston, MA, October.

Beck, B. 1987. "Health Effects of Ozone." Harvard School of Public Health, Boston, MA, November.

Beck, B. 1987. "Key Issues in Addressing Adverse Effects of Ozone." University of Massachusetts, Amherst, MA, April.

Peer-reviewer

Gradient staff members have been editors and peer-reviewers for scientific for scientific journals over the past two decades. These journals include: *American Journal of Pathology; Atmospheric Environment; Cancer Epidemiology, Biomarkers & Prevention; Cancer Genetics and Cytogenetics; Cancer Research; Carcinogenesis; Clinical Cancer Research; Critical Reviews in Toxicology; Environmental Health Perspectives; Human and Experimental Toxicology; Inhalation Toxicology; Journal of the Air & Waste Management Association; Journal of Cellular Biochemistry; Journal of Exposure Analysis and Environmental Epidemiology; Journal of Exposure Science and Environmental Epidemiology: Journal of Human and Ecological Risk Assessment; Journal of Occupational and Environmental Medicine; Medical Journal of Australia; NeuroToxicology; Pharmacogenetics; Regulatory Toxicology and Pharmacology; Risk Analysis;* and *Toxicology and Applied Pharmacology.*

Julie Goodman was also an invited peer-reviewer for the TCEQ document, "Development Support Document for Nickel and Inorganic Nickel Compounds, Preliminary Draft, May 2009."

2.B Weight-of-Evidence Evaluations

Gradient has been at the forefront of the development of WoE evaluation methodology and has conducted and published the results of several WoE evaluations. In fact, US EPA office of Chemical Safety and Pollution Prevention recently recommended our framework for evaluating endocrine disruptors.[1] Below, we describe some of these projects, peer-reviewed publications, scientific conference presentations, testimony and white papers submitted to government agencies and scientific panels, courses and workshops we have taught, and participation on advisory panels, for a time span longer than three years.

Example Projects

Weight-of-Evidence Evaluation of Ozone and Cardiovascular Effects

Gradient is conducting a WoE evaluation of the association between ozone exposure and cardiovascular effects. We are using our own WoE framework to systematically review the relevant epidemiology, toxicology, and mechanistic datasets and contrast our analysis to the recent evaluation conducted by US EPA as part of its process for revising the ozone NAAQS. We are determining how differences between US EPA's WoE framework and our framework led to different conclusions. We anticipate that our analysis will be published in a peer-reviewed journal.

Highlights
- *WoE frameworks*
- *Criteria air pollutants*
- *Epidemiology*
- *Systematic review*

Acrylonitrile Weight-of-Evidence for Carcinogenicity

Gradient provided advice on how existing and planned research efforts would support a WoE analysis of the carcinogenic potential for inhalation exposure to acrylonitrile. Existing evidence included occupational epidemiology, animal bioassays, and studies of potential modes of action. In this scoping project, Gradient reviewed existing evidence and research, along with planned research, and facilitated a discussion about interpretation issues and possible avenues for a full WoE evaluation at a meeting of trade association members and supported researchers.

Highlights
- *Carcinogenicity*
- *Mode of action*
- *Epidemiology*
- *Inhalation toxicology*

[1] US EPA. 2011. "Weight-of-Evidence: Evaluating Results of EDSP Tier 1 Screening to Identify the Need for Tier 2 Testing." Office of Chemical Safety and Pollution Prevention, Endocrine Disruptor Screening Program, EPA-HQ-OPPT-2010-0877-0021. 47p., September 14.

Comment on US EPA's Preliminary Chlorpyrifos Risk Assessment

Gradient critiqued US EPA's preliminary human health risk assessment of chlorpyrifos released in June 2011. We worked with a team of experts focusing our contribution on issues related to US EPA's proposal to conduct a thorough WoE analysis of the available human, experimental animal, and mechanistic data for hazard identification. We provided key statements from US EPA's guidance documents and cited evaluations of previous US EPA chemical assessments, and publications of Gradient's hypothesis-based weight-of-evidence (HBWoE) approach to illustrate how US EPA could facilitate a more rigorous WoE analysis. Gradient provided written comments on these issues to US EPA.

Highlights

- *Regulatory comment*
- *Risk assessment*
- *Pesticides*

Comments for Science Advisory Board Weight-of-Evidence Methodology Review

Gradient collaborated with other consultants to produce oral and written comments on WoE questions for a meeting of the US EPA's Chartered Science Advisory Board (SAB) as it considered the report of the SAB's Dioxin Review Panel, which examined a recent draft US EPA assessment document. Gradient's comments critiqued US EPA's WoE evaluation of carcinogenicity and non-cancer toxicity in light of its own standards as quoted from US EPA guidelines and its Risk Characterization Handbook.

Highlights

- *SAB comments*
- *Dioxins*

Evaluation of Non-Cancer Health Effects of Dioxin

In the context of US EPA's health effects reassessment for dioxins, Gradient compiled a comprehensive set of relevant human studies and conducted a WoE evaluation of the epidemiological data available for selected health endpoints. We identified datasets suitable for performing quantitative dose-response evaluations and illustrated the impact of toxicity assessment choices and key sources of uncertainty on quantitative toxicity estimates. We will be submitting our WoE and quantitative dose-response analyses for publication in a peer-reviewed journal.

Highlights

- *Epidemiology*
- *Dose-response*
- *Uncertainty analysis*

Styrene Cancer Epidemiology

Gradient conducted a critical review of the National Toxicology Program (NTP) draft background document on the carcinogenic potential of styrene. We reviewed the bearing of individual occupational epidemiology studies and cohorts, as well as the toxicological and mode-of-action data, in a WoE analysis of whether styrene should be considered carcinogenic. We offered alternative WoE analyses for each cancer type noted by NTP and evaluated the consistency and coherence of the data. These analyses were presented as both oral and written testimony to NTP.

Highlights

- *Epidemiology*
- *Toxicology*
- *Mode of action*

Scientific Plausibility of Naphthalene and Human Carcinogenesis using a Hypothesis-Based Weight-of-Evidence Approach

Gradient reviewed the available toxicity studies and evaluated whether the weight of available evidence (structured using the HBWoE approach) supports the plausibility of naphthalene as a human carcinogen. We conducted a thorough literature review and summarized the uncertainties in the naphthalene carcinogenesis dataset. We prepared a manuscript summarizing the logic of inferences from these data when applied to the examination of potential human carcinogenicity; the manuscript was published in a peer-reviewed journal. Our client anticipates using this publication to help guide discussions with regulatory agencies regarding the importance of understanding the scientific uncertainty and weighing all of the evidence in development of an inhalation cancer toxicity criterion for naphthalene.

Highlights

- *Uncertainty*
- *HBWoE*

Peer-reviewed Publications

Rhomberg, LR; Goodman, JE; Prueitt, RL. 2013. "The weight of evidence does not support the listing of styrene as "reasonably anticipated to be a human carcinogen" in NTP's twelfth 'Report on Carcinogens.'" *Hum. Ecol. Risk Assess.* 19(1):4-27.

Prueitt, RL; Goodman, JE; Bailey, LA; Rhomberg, LR. 2011. "Hypothesis-based weight-of-evidence evaluation of the neurodevelopmental effects of chlorpyrifos." *Crit. Rev. Toxicol.* 41(10):822-903.

Rhomberg, LR; Bailey, LA; Goodman, JE; Hamade, A; Mayfield, D. 2011. "Is exposure to formaldehyde in air causally associated with leukemia? - A hypothesis-based weight-of-evidence analysis." *Crit. Rev. Toxicol.* 41(7):555-621.

Goodman, JE; Kerper, LE; Petito Boyce, C; Prueitt, RL; Rhomberg, LR. 2010. "Weight-of-evidence analysis of human exposures to dioxins and dioxin-like compounds and associations with thyroid hormone levels during early development." *Regul. Toxicol. Pharmacol.* 58(1):79-99.

Goodman, JE; Prueitt, RL; Dodge, DG; Thakali, S. 2009. "Carcinogenicity assessment of water-soluble nickel compounds." *Crit. Rev. Toxicol.* 39:365-417.

Goodman, JE; McConnell, EE; Sipes, IG; Witorsch, RJ; Slayton, TM; Yu, CJ; Lewis, AS; Rhomberg, LR. 2006. "An updated weight of the evidence evaluation of reproductive and developmental effects of low doses of bisphenol A." *Crit. Rev. Toxicol.* 36:387-457.

Scientific Conference Presentations/Abstracts

Prueitt, RL; Goodman, JE; Rhomberg, LR. 2013. "Hypothesis-Based Weight-of-Evidence Evaluation of the Human Carcinogenicity of Toluene Diisocyanate." In Society of Toxicology 52nd Annual Meeting, San Antonio, TX.

Prueitt, RL; Goodman, JE; Bailey, LA; Rhomberg, LR. 2012. "Hypothesis-based weight-of-evidence evaluation of the neurodevelopmental effects of chlorpyrifos." *Toxicologist* 126(1):309.

Bailey, LA; Goodman, JE; Rhomberg, LR. 2011. "Hypothesis-based Weight-of-Evidence Evaluation of Naphthalene: Carcinogenic Hazard Assessment and Mode of Action." Presented at Society of Environmental Toxicology and Chemistry (SETAC) North America 32nd Annual Meeting, Boston, MA, November 14.

Goodman, JE; Mayfield, DB; Bailey, L; Rhomberg, LR. 2011. "Weight-of-evidence evaluation of formaldehyde exposure and leukemia risk." *Toxicologist* 120(Suppl. 2):416.

Peterson, MK; Bailey, L; Dodge, DG; Goodman, JE; Valberg, PA. 2011. "A weight-of-evidence evaluation of asbestos exposure and mesothelioma risk among electricians." *Toxicologist* 120(Suppl. 2):414.

Dodge, D; Goodman, J; Beck, B. 2010. "Weight-of-evidence analysis of hydroquinone and leukemia." *Toxicologist* 114(1):111-112.

Goodman, JE; Rhomberg, LR. 2009. "A weight-of-evidence approach to evaluating epidemiological data on styrene cancer hazards." *Toxicologist* 108(1):248.

Rhomberg, LR; Goodman, JE; McConnell, EE; Sipes, IG; Witorsch, RJ; Slayton, TM; Yu, CJ; Lewis, AS. 2007. "An updated weight of the evidence evaluation of reproductive and developmental effects of low doses of Bisphenol A." *Toxicologist* 96(1):427.

Testimony and White Papers Submitted to Government Agencies and Scientific Panels

Goodman, JE. 2013. "Evidence-Based Evaluation of Styrene and Human Cancer." Presented at Review of the Styrene Assessment in the National Toxicology Program 12th Report on Carcinogens, Washington, DC, March 19-20.

Goodman, JE. 2009. "Comments on the Review of Epidemiology Data in the NTP 12th Report on Carcinogens Draft Styrene Profile." Report to American Composites Manufacturers Association, 34p., February 6.

Rhomberg, LR. 2008. "Testimony of Lorenz Rhomberg, Ph.D., before the Report on Carcinogens Expert Panel Meeting for Styrene, Research Triangle Park, NC." Report to National Marine Manufacturers Association, 1p., July 21.

Scientific Advisory Panels

Goodman, JE. 2012. Invited Participant, ILSI Health and Environmental Sciences Institute Emerging Issue Workshop: Evaluating Causality in Epidemiology, October.

Goodman, JE. 2012. Invited Panel Member, "Using Mode of Action to Support the Development of a Multipollutant Science Assessment," US EPA Workshop.

Goodman, JE. 2012. Invited Participant on "Improving Science-Based Regulation," The George Washington University Regulatory Studies Center and the Center for Risk Science and Public Health, January.

Graduate-level Courses, Workshops, and Presentations

Rhomberg, LR. Lectures in "Principles of Risk Assessment." American Chemical Society course, "Toxicology: Principles and Applications" or "Pharmacokinetics and Risk Assessment." (Ongoing annual or semiannual participation since 1989.)

Rhomberg, LR. Lectures in "Analyzing Risk." Continuing education course presented by the Harvard Center for Risk Analysis, Harvard School of Public Health. (Ongoing annual or semiannual participation since 1994.)

Goodman, JE. 2009 - Present. Harvard School of Public Health, Boston, MA, Adjunct Faculty Member. Department of Epidemiology. Co-instructor of course entitled, "Research Synthesis & Meta-Analysis."

Goodman, JE. 2012. "Systemic Reviews and Meta-Analysis, Use of Expert Elicitation to Inform Decisionmaking." Presented at Society for Risk Analysis 2012 Annual Meeting, San Francisco, CA, December.

Goodman, JE. 2012. "Survival Analysis & Meta-Analysis." Presented at New York Medical College School of Health Sciences & Practice, November 8.

Goodman, JE. 2011. "Synthesizing Evidence: An Introduction to Systematic Reviews, Meta-Analysis, and Expert Elicitation." Presented at the Society for Risk Analysis 2011 Annual Meeting, Charleston, SC, December.

Rhomberg, LR. 2011. "Overview of Approaches for Evidence-Based Decisionmaking." Presented as part of "Synthesizing Evidence: An Introduction to Systematic Reviews, Meta-Analysis, and Expert Elicitation" Workshop, Society for Risk Analysis Annual Meeting. Charleston, SC, December.
Rhomberg, LR. 2011. "Comparison of Strategies to Structure Weight-of-Evidence Evaluations." Presented as part of "Synthesizing Evidence for Evidence-Based Decisionmaking: Part 1" Symposium, Society for Risk Analysis Annual Meeting. Charleston, SC, December.

Rhomberg, LR. 2011. "Hypothesis-based Weight-of-Evidence Evaluation of Naphthalene: Carcinogenic Hazard Assessment and Mode of Action." Poster presented at Society of Environmental Toxicology and Chemistry (SETAC) North America 32nd Annual Meeting. Boston, MA, November.

Rhomberg, LR. 2011. "Applying weight-of-evidence concepts/approaches used in toxicology and risk assessments to benefit-cost analysis." Presented as part of "Theory, Science, and Statistics in the Use of Benefit-Cost Analysis" conference. Washington, DC, October.

Rhomberg, LR.. 2011. "Uncertainty, Weight of Evidence, and Hazard Identification." Presented at Public Health Risk Science and Management Course, George Washington University. Washington, DC, September.

Rhomberg, LR. 2011. Lectures in a course at the Technical University of Cyprus, April.

Rhomberg, LR. 2011. "Using a structured approach - Hypothesis-Based Weight of Evidence - in evaluating uncertainty about human cancer hazard potential." Presented at the Health Effects Institute. Boston, MA, April.

Rhomberg, LR. 2011. "Weight-of-Evidence Frameworks in the Regulatory Context: A Conceptual Comparison." Presented as part of the Symposium: "Solving the Weight of Evidence Problem: A Way Forward?" at the American Association for the Advancement of Science Annual Meeting. Washington, DC, February.

Rhomberg, LR. 2010. "Weight-of-Evidence: Using Screening and Other Data to Decide What Comes Next." Presented at Endocrine Disruptor Screening Program Seminar. Washington, DC, May.

Rhomberg, LR. 2010. "Hypothesis-Based Approaches to Weighing Information of Complex Datasets." Presented as part of a roundtable session at the Society of Toxicology 49th Annual Meeting. Salt Lake City, UT, March.

Rhomberg, LR. 2009. "Using a structured approach - Hypothesis-Bases Weight of Evidence - in evaluating uncertainty about human cancer hazard potential." Presented at Society for Risk Analysis Annual meeting. Baltimore, MD, December.

Rhomberg, LR. 2008. "Proposed Weight of Evidence Scheme for Applying MOA Frameworks." Lecture in a California Mode of Action Workshop, Characterizing Dose Response & Hazard. Sacramento, CA, May.

Rhomberg, LR. 2008. "Hypothesis-Based Weight of Evidence to Separate Qualitative and Quantitative Aspects of Uncertainty in Risk Assessment." Lecture in 2008 Toxicology and Risk Assessment Conference, The Complexity of Uncertainty: Dealing with Known Unknowns. West Chester, OH, April.

Rhomberg, LR. 2008. "A Framework for Weight of Evidence: Application to Endocrine Effects and the Low-Dose Hypotheses.'" Lecture in ISRTP Workshop: "Conducting and Assessing the Results of Endocrine Screening." Bethesda, MD, February.

Rhomberg, LR. 2007. "Uncertainty Characterization: The Role of Hypothesis-Based Weight of Evidence" in the symposium "Current Trends and Advancement in Environmental Chemical Risk Assessment." 28th Annual Meeting of the American College of Toxicology. Charlotte, NC, November.

Rhomberg, LR. 2007. "Hypothesis-Based Weight of Evidence and its Role in Characterizing Uncertainty in Risk Assessment." Presented as a Seminar for the New England Society of Risk Analysis. Boston, MA, October.

Goodman, JE. 2007. "Systematic Review and Meta-Analysis." Presented at Society for Epidemiologic Research 40th Annual Meeting, Boston, MA, June.

Rhomberg, LR. 2007. "Hypothesis-Based Weight of Evidence and its Bearing on Uncertainty Analysis in Risk Assessment." Presented at the 5th Meeting of the Committee on Improving Risk Analysis Approaches Used by the U.S. Environmental Protection Agency. Washington, DC, June.

Rhomberg, LR. 2007. "Uncertainty Characterization: The Role of Hypothesis-Based Weight of Evidence." Seminar given at LSRO's Center for Health Risk Analysis. Washington, DC, May.

Rhomberg, LR. 2007. "Characterizing Uncertainty in Assessing Perchloroethylene Cancer Risk" in the symposium "Perchloroethylene (PERC): Approaches to Evaluating Uncertainty in Health Risk Assessment." 32nd Annual Winter Meeting of the Toxicology Forum. Washington, DC, January.

Peer-reviewer

Gradient staff members have been editors and peer-reviewers for scientific for scientific journals over the past two decades. These journals include: *American Journal of Pathology; Atmospheric Environment; Cancer Epidemiology, Biomarkers & Prevention; Cancer Genetics and Cytogenetics; Cancer Research; Carcinogenesis; Clinical Cancer Research; Critical Reviews in Toxicology; Environmental Health Perspectives; Human and Experimental Toxicology; Inhalation Toxicology; Journal of the Air & Waste Management Association; Journal of Cellular Biochemistry; Journal of Exposure Analysis and Environmental Epidemiology; Journal of Exposure Science and Environmental Epidemiology: Journal of Human and Ecological Risk Assessment; Journal of Occupational and Environmental Medicine; Medical Journal of Australia; NeuroToxicology; Pharmacogenetics; Regulatory Toxicology and Pharmacology; Risk Analysis;* and *Toxicology and Applied Pharmacology.*

Julie Goodman was also an invited peer-reviewer for the TCEQ document, "Development Support Document for Nickel and Inorganic Nickel Compounds, Preliminary Draft, May 2009."

2.C Meta-analyses

Gradient has been at the forefront of advancing meta-analysis methodologies. For example. we were the first to use meta-regression to evaluate NO_2 human exposure studies. We also have used meta-analysis to evaluate toxicity data, which is rarely done. Below, we describe some of these projects, peer-reviewed publications, scientific conference presentations, testimony and white papers submitted to government agencies and scientific panels, courses and workshops we have taught, and participation on advisory panels, for a time span longer than three years.

Example Projects

Review of a Nickel Carcinogenicity Meta-Analysis

Gradient is reviewing a meta-analysis of respiratory cancer risk associated with inhalation exposure to nickel compounds. We are providing comments regarding the methods, limitations, and interpretation of the results. A key component to our analysis is the inclusion of epidemiology and the inhalation toxicology of nickel compounds data. Our technical comments will be incorporated into the analyses prior to the presentation of the study results at a scientific meeting and the submission of a manuscript for publication in a peer-reviewed journal.

Highlights

- *Epidemiology*
- *Nickel compounds*
- *Meta-analysis and meta-regression*
- *Respiratory cancer risk assessment*

Meta-analysis of Bisphenol A Exposures and Reproductive Effects

Gradient conducted a pilot meta-analysis of studies bearing on the ability of very low oral exposures to bisphenol A (BPA) to affect prostate weight in rodents. Building on previous Gradient analyses, we compiled relevant study data and used meta-analytical techniques and regression analysis to investigate the possibility of publication bias and evidence for a temporal trend in the data.

Highlights

- *Epidemiology*
- *Regression analysis*
- *Publication bias investigation*
- *Temporal trend investigation*

Nitrogen Dioxide Health Effects Evaluation

Gradient performed a meta-analysis of clinical studies to assess the concentration of NO_2 that causes airway hyper-responsiveness in humans. This issue bears on the NO_2 NAAQS promulgated by US EPA. Our analysis included an evaluation of the influence of several factors, including type of airway impact, exposure method (*i.e.*, chamber *vs.* mouthpiece), exercise, and allergy/asthma status on airway response to NO_2. Gradient's analysis was published in a peer-reviewed scientific journal.

Highlights

- *Meta-analysis*
- *Epidemiology*
- *Lung function*
- *Criteria air pollutants*
- *Controlled exposure studies*

Peer-reviewed Papers and Letters to the Editor

Hajifathalian, K; Gonzalez LA; Zacharias, DG; Goodman, JE. 2012. "A response to the article, 'A Meta-Analysis of Human Acellular Dermis and Submuscular Tissue Expander Breast Reconstruction,' by Kim *et al.*" *Plast. Reconstr. Surg.* In press.

Goodman, JE; Chandalia, JK; Thakali, S; Seeley, M. 2009. "Meta-analysis of nitrogen dioxide exposure and airway hyper-responsiveness in asthmatics." *Crit. Rev. Toxicol.* 39(9):719-742.

Scientific Conference Presentations/Abstracts

Goodman, JE. 2011. "Why Meta-Analyses and Systematic Reviews Come to Different Conclusions About Formaldehyde and Leukemia." Presented at the Society for Risk Analysis 2011 Annual Meeting, Charleston, SC, December.

Thakali, S; Chandalia, JK; Seeley, MR; Goodman, JE. 2010. "Meta-analysis of nitrogen dioxide effects on airway hyper-responsiveness in asthmatics: Effects of the types of airway challenge, exposure methods, and activities during exposure." Poster presented at the Society of Toxicology 49th Annual Meeting, Salt Lake City, UT.

Goodman, JE; Chandalia, JK; Thakali, S; Seeley, M. 2009. "Meta-Analysis of Controlled Nitrogen Dioxide Exposure Studies Assessing Airway Hyper-Responsiveness in Asthmatics." Presented at Society for Risk Analysis (SRA) Annual Meeting, Baltimore, MD, December 6-11.

Testimony and White Papers Submitted to Government Agencies and Scientific Panels

Goodman, JE. 2009. "Comments on US EPA's Proposed Revisions to the NO_2 NAAQS." Report to American Petroleum Institute, 6p., August 10.

Goodman, JE. 2009. "Analysis of NO_2-Associated Airway Hyper-Responsiveness." Report to American Petroleum Institute, 22p., February 10.

Goodman, JE. 2008. "Comments on Chapter 10 of the Final Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard." Report to American Petroleum Institute. Submitted to US EPA Docket. EPA-HQ-2006-0922, 13p., December 1.

Scientific Advisory Panels

Goodman, JE. 2012. Invited Participant, ILSI Health and Environmental Sciences Institute Emerging Issue Workshop: Evaluating Causality in Epidemiology, October.

Goodman, JE. 2012. Invited Panel Member, "Using Mode of Action to Support the Development of a Multipollutant Science Assessment," US EPA Workshop, May.

Goodman, JE. 2012. Invited Participant on "Improving Science-Based Regulation." The George Washington University Regulatory Studies Center and the Center for Risk Science and Public Health, January.

Graduate-level Courses, Workshops, and Presentations

Goodman, JE. 2009 - Present. Harvard School of Public Health, Boston, MA, Adjunct Faculty Member. Department of Epidemiology. Co-instructor of course entitled, "Research Synthesis & Meta-Analysis."

Goodman, JE. 2012. "Systemic Reviews and Meta-Analysis, Use of Expert Elicitation to Inform Decisionmaking." Presented at Society for Risk Analysis 2012 Annual Meeting, San Francisco, CA, December.

Goodman, JE. 2012. "Survival Analysis & Meta-Analysis." Presented at New York Medical College School of Health Sciences & Practice, November 8.

Goodman, JE. 2011. "Synthesizing Evidence: An Introduction to Systematic Reviews, Meta-Analysis, and Expert Elicitation." Presented at the Society for Risk Analysis 2011 Annual Meeting, Charleston, SC, December.

Goodman, JE. 2007. "Systematic Review and Meta-Analysis." Presented at Society for Epidemiologic Research 40th Annual Meeting, Boston, MA, June.

Peer-reviewer

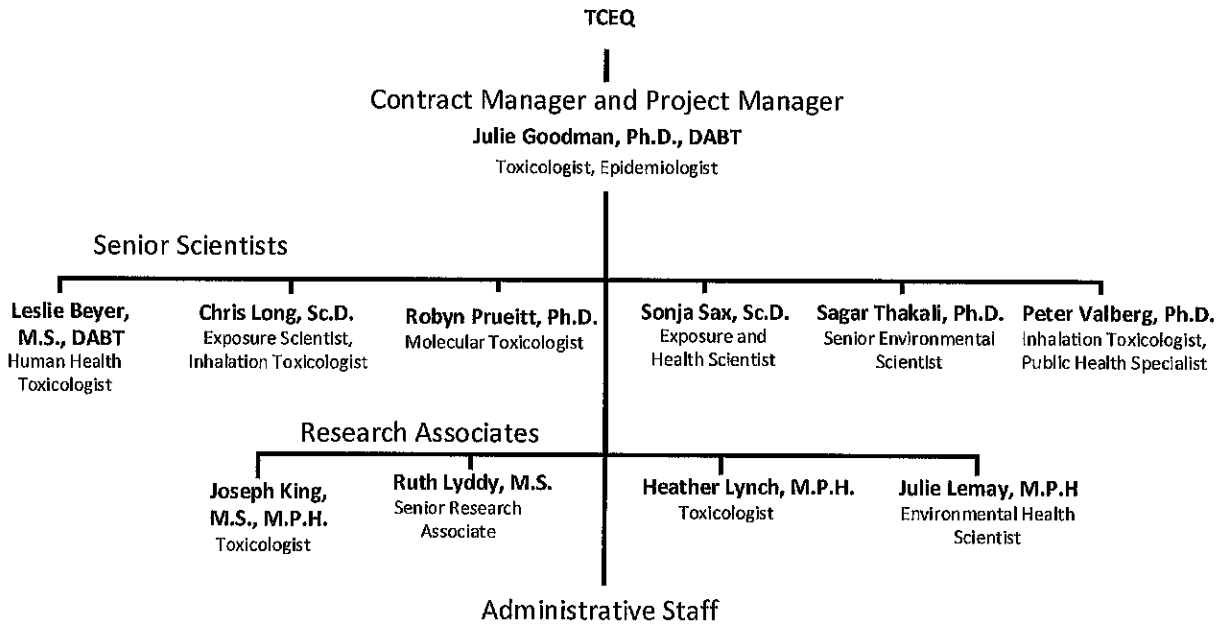
Gradient staff members have been editors and peer-reviewers for scientific for scientific journals over the past two decades. These journals include: *American Journal of Pathology; Atmospheric Environment; Cancer Epidemiology, Biomarkers & Prevention; Cancer Genetics and Cytogenetics; Cancer Research; Carcinogenesis; Clinical Cancer Research; Critical Reviews in Toxicology; Environmental Health Perspectives; Human and Experimental Toxicology; Inhalation Toxicology; Journal of the Air & Waste Management Association; Journal of Cellular Biochemistry; Journal of Exposure Analysis and Environmental Epidemiology; Journal of Exposure Science and Environmental Epidemiology: Journal of Human and Ecological Risk Assessment; Journal of Occupational and Environmental Medicine; Medical Journal of Australia; NeuroToxicology; Pharmacogenetics; Regulatory Toxicology and Pharmacology; Risk Analysis;* and *Toxicology and Applied Pharmacology.*

Julie Goodman was also an invited peer-reviewer for the TCEQ document, "Development Support Document for Nickel and Inorganic Nickel Compounds, Preliminary Draft, May 2009."

Tab 3 Statement of Qualifications – Key Personnel

Gradient has assembled a team of Senior Scientists, Research Associates, and Administrative Staff who meet or exceed the required qualifications and experience to work under this Contract. An organizational chart is provided below, followed by information about each project team member.

1 Contract Organizational Chart



2 Proposed Number of Personnel by Discipline, Function, and Designated Role

Table 3.1 Proposed Number of Personnel by Discipline, Function, and Designated Role

Role	General Expertise	Number of Personnel
Project Manager – Overall management of project resources, budget, and schedule; direct communications with TCEQ; ensure timely responses to TCEQ (including invoices); supervise technical and administrative implementation of the project; review work products for quality, completeness, and compliance with Contract requirements	Toxicology Epidemiology Risk Assessment Public Health	1
Senior Scientists – Scope and delegate work, critically review literature, conduct statistical and epidemiology analyses, oversee day-to-day project activities	Toxicology Epidemiology Risk Assessment Exposure Public Health	6
Research Associates – Critically review literature; conduct statistical and epidemiology analyses; summarize information in tables, figures, and text as appropriate	Toxicology Epidemiology Risk Assessment Public Health	3
Research Associate – Conduct literature searches and provide information services	Research and Information	1
Administrative Staff – Provide editorial review of work products	Editorial Review	2
Administrative Staff – Conduct administrative tasks	Administrative Services	2

3 Key Personnel

Table 3.2 Summary of Qualifications for Key Personne

Name	Julie Goodman	obyn Prueitt	Sagar Thakali
Team Member	Prime	Prime	Prime
Position Title:	Toxicologist, Epidemiolo	ular Toxicologist	Senior Environmental Scientist
Education	Ph.D., Toxicology, Johr Hopkins University Sc.M., Epidemiology, Jo Hopkins University S.B., Environmental Engineering, Massachus Institute of Technolog	Cell and Molecular University of Texas tern Medical Center at Dallas ogy, Pacific Lutheran University	Ph.D., Environmental Engineering, University of Delaware B.S., Civil Engineering, Swarthmore College B.A., Economics, Swarthmore College
Certifications	Diplomate of the Ameri Board of Toxicology		
Total Years of Relevant Contract Program Management Experience	7	N/A	N/A
Total Years of Relevant Project Management Experience	8	N/A	N/A
Total Years of Experience in Inhalation Toxicology of Ozone, $PM_{2.5}$, Lead, Sulfur Oxides, Nitrogen Dioxide, and/or Carbon Monoxide	6 years of experience crit reviewing and providi regulatory comment c inhalation toxicology of o NO_2, SO_2, and $PM_{2.5}$	experience critically ing and providing tory comment on toxicology of ozone and $PM_{2.5}$	Over 5 years performing statistical analysis (*e.g.*, meta-analysis), critically reviewing and providing regulatory comments on ozone and NO_2
Total Years of Experience in Epidemiology Studies of Ozone, $PM_{2.5}$, Lead, Sulfur Oxides, Nitrogen Dioxide, and/or Carbon Monoxide	6 years of experience crit reviewing and providi regulatory comment on ISAs, REAs, and Propose Final Rules for ozone, P SO_2, and NO_2	experience critically ing and providing tory comment on ogy studies of ozone and $PM_{2.5}$	Over 5 years performing statistical analysis (*e.g.*, meta-analysis), critically reviewing and providing regulatory comments on ozone and NO_2
Total Years of Experience in Formal Weight-of-Evidence analysis	6 years of experienc performing WoE analy	rs of experience ning WoE analyses	Over 5 years of experience supporting WoE analyses
Total Years of Experience in Meta-analysis	8 years of experienc conducting, interpreting critiquing meta-analyse years teaching meta ana	N/A	More than 5 years of experience performing and critically reviewing meta-analysis studies

Note: CVs are included at the end of Tab 3.

Tab 3.1 Contract Manager

Dr. Goodman will serve as Program Manager and Project Manager. She has been at Gradient for nine years and a Principal for more than five years. She has been the Program and Project Manager for over 100 projects, many of which were/are similar in scope and magnitude to this proposal. She will be the contact person authorized to legally bind Gradient for all issues regarding the Contract. She will be responsible for Gradient's project team acting in accordance with the Contract Documents and the HUB Subcontracting Plan. She will also be responsible for maintaining a complete and effective project team by formally requesting the addition or substitution of personnel and subcontractors, in accordance with Contract Documents.

Julie E. Goodman, Ph.D., DABT
Toxicologist, Epidemiologist

Dr. Goodman is an expert in toxicology, epidemiology, and assessing human health risks from chemicals in consumer products and the environment. Her primary responsibilities at Gradient include the analysis and interpretation of epidemiology and toxicity data, apparent disease clusters, and chemical exposures. Before joining Gradient, Dr. Goodman was a Cancer Prevention Fellow at the National Cancer Institute. She has authored original research articles, review articles, and book chapters on a wide variety of topics, including WoE analyses of several chemicals. She has presented scientific findings and analyses to community groups and regulatory and legislative bodies. Dr. Goodman is currently an adjunct faculty member in the Department of Epidemiology at the Harvard School of Public Health.

Areas of Expertise

Epidemiology

Toxicology

Occupational Exposures

Criteria Pollutants

Product Safety

Carcinogenesis

Risk Assessment

Education

Ph.D., Toxicology, Johns Hopkins University

Sc.M., Epidemiology, Johns Hopkins University

S.B., Environmental Engineering, Massachusetts Institute of Technology

Diplomate of the American Board of Toxicology

Tab 3.2 Project Manager

1 Dr. Goodman has worked specifically on ozone, $PM_{2.5}$, lead, SO_x, and NO_2 for six years. This work includes providing written comments and oral testimony regarding the ISAs, REAs, and Proposed and Final Rules for ozone, $PM_{2.5}$, SO_x, and NO_2. These comments have focused on controlled human exposure, epidemiology, toxicity, and mechanistic studies. She has provided similar testimony to the US Senate Committee on Environment and Public Works and the US Congressional Committee on Energy and Commerce. Dr. Goodman also has authored several peer-reviewed publications on these topics. These include a meta-analysis on the controlled human NO_2 exposure studies that US EPA evaluated, as well as the development of a framework for assessing causality and adverse effects, with SO_2 and lung function effects as a case study. She has also published several letters to the editor regarding papers evaluating criteria air pollutants and health effects.

Dr. Goodman has evaluated the toxicology and epidemiology of lead on several occasions. For example, she assessed whether epidemiology literature supports an association between low-level exposures to lead and IQ, and she also critically reviewed epidemiology literature to determine if the effects of lead and mercury on human neurological development are additive or synergistic.

Dr. Goodman has conducted several formal WoE analyses on substances – including BPA, chlorpyrifos, formaldehyde, naphthalene, ozone, nickel, toluene diisocyanate, and styrene – over the last seven years. She recently reviewed nearly 50 WoE frameworks that have been published in the primary literature and as agency guidance documents, articulating the best practices from among the spectrum of approaches. Dr. Goodman is currently evaluating the US EPA WoE framework in the ozone ISA, focusing on areas where more guidance is needed to ensure a transparent and balanced evaluation and proposing improvements to the framework based on other available WoE frameworks that best fit the purpose of a NAAQS evaluation.

Dr. Goodman has been teaching a graduate-level course, entitled "Research Synthesis & Meta-Analysis," at the Harvard School of Public Health for four years. She has also taught meta-analysis at two continuing education courses at the Society of Risk Analysis in 2011 and 2012, and she taught meta-analysis as part of an advanced epidemiology curriculum at the New York Medical College School of Health Science & Practice. She has published meta-analyses during this time, including one on NO_2 exposure and lung function. She has also worked with many of her students to help turn their class projects into manuscripts that have been (or are about to be) published in peer-reviewed journals.

2 Dr. Goodman received an S.B. in Environmental Engineering from the Massachusetts Institute of Technology, and both a Sc.M. in Epidemiology and a Ph.D. in Environmental Health Sciences/Toxicology from the Johns Hopkins Bloomberg School of Public Health. She was granted a Cancer Prevention Fellowship by the National Cancer Institute. Her additional training can be found on her *curriculum vitae* at the end of this section. She has been a Diplomate of the American Board of Toxicology since 2005. She has been the project manager for over 100 projects at Gradient, many of which were/are similar in scope and magnitude to this proposal. Dr. Goodman will be responsible for the overall management of project resources, budget, and schedule. She is always available by e-mail and will respond to TCEQ within one business day when contacted. She has both the technical and administrative expertise to manage this project. She will ensure correct invoices are sent monthly to TCEQ and will interact with the TCEQ project manager as necessary. She will take full responsibility for the quality, completeness, accessibility, and timeliness of deliverables and ensure they meet Contract requirements.

3 A *curriculum vitae* for Dr. Goodman is included at the end of this section.

GRADIENT

Julie E. Goodman, Ph.D., DABT
Principal
jgoodman@gradientcorp.com

Areas of Expertise

Epidemiology, toxicology, carcinogenesis, exposure assessment, dose-response analysis, weight-of-evidence analysis, product safety, risk assessment, risk communication

Education

Ph.D., Environmental Health Sciences/Toxicology, Johns Hopkins Bloomberg School of Public Health, 2002.

Sc.M., Epidemiology, Johns Hopkins Bloomberg School of Public Health, 2000.

S.B., Environmental Engineering, Massachusetts Institute of Technology, 1996.

Diplomate of the American Board of Toxicology, 2005.

Professional Experience

2004 – Present GRADIENT, Cambridge, MA
Principal. Environmental consulting practice consists of analysis and interpretation of epidemiology and toxicity data, apparent disease clusters, and chemical exposures to assess potential human health risks.

2009 – Present HARVARD SCHOOL OF PUBLIC HEALTH, Boston, MA
Adjunct Faculty Member. Department of Epidemiology. Co-instructor of course entitled, "Research Synthesis & Meta-Analysis."

2002 – 2004 NATIONAL CANCER INSTITUTE, Bethesda, MD
Cancer Prevention Fellow. Conducted a number of molecular epidemiology studies analyzing the relationships between inflammatory gene polymorphisms and colon cancer risk. Instrumental in the development of a powerful statistical tool for cancer risk assessment.

Continuing Education Courses and Other Training

- Systemic Reviews and Meta-Analysis, Use of Expert Elicitation to Inform Decisionmaking, Society for Risk Analysis 2012 Annual Meeting, San Francisco, CA, December 2012.
- Novel Statistical Challenges in Environmental Epidemiology Workshop, 3rd North American Congress of Epidemiology, Montreal, Canada, June 2011.
- Comparative Biology of the Lung, Society of Toxicology 49th Annual Meeting, Salt Lake City, UT, March 2010.
- Introduction to the Benchmark Dose Methodology and Interactive Application of US EPA's Benchmark Dose Software (BMDS), Version 2.1, Society for Risk Analysis 2010 Annual Meeting, Salt Lake City, UT, December 2010.
- Green Innovation for Business Conference (Moderator, Green Chemistry and Greenwashing Workshops), Boston, MA, June 2009.

- Scientific Workshop to Inform the Technical Work Plan for US EPA's Response to NAS Comments on the Health Effects of Dioxin Presented in US EPA's Dioxin Reassessment, Cincinnati, OH, February 2009.
- Decision-Making for Recommendations and Communication Based on the Totality of Food-Related Research, International Life Sciences Institute Workshop, Washington, DC, December 2008.
- 2008 Board of Health Certification Program, Massachusetts Association of Health Boards, Marlborough, MA, November 2008.
- What is Evolutionary Epidemiology? American College of Epidemiology Annual Meeting, Tucson, AZ, September 2008.
- Research Ethics in Studying Genes and the Environment in Diabetes among Ethnic Minorities, American College of Epidemiology Annual Meeting, Tucson, AZ, September 2008.
- Use of Data for Development of Uncertainty Factors in Non-Cancer Risk Assessment, Society of Toxicology 47th Annual Meeting, Seattle, WA, March 2008.
- International Society of Regulatory Toxicology and Pharmacology Workshop: Conducting and Assessing the Results of Endocrine Screening, Bethesda, MD, February 2008.
- Assessment of Abuse Liability and Physical Dependence, Northeast Chapter Society of Toxicology Annual Meeting, Groton, CT, October 2007.
- Practical Issues and Procedures for Preclinical Safety Testing, 2007 BioReliance Toxicology Technical Seminars, Boston, MA, October 2007.
- Introduction to Pharmacoepidemiology: Practical Applications and Analytic Methods, American College of Epidemiology 25th Annual Meeting, Ft. Lauderdale, FL, September 2007.
- SAS Programming I: Essentials, SAS Institute, Boston, MA, July 2007.
- Introduction to Bayesian Modeling of Epidemiologic Data, Society for Epidemiologic Research 40th Annual Meeting, Boston, MA, June 2007.
- Systematic Review and Meta-Analysis, Society for Epidemiologic Research 40th Annual Meeting, Boston, MA, June 2007.
- The Biology and Toxicology of the Peri- and Post-Natal Development, Society of Toxicology 46th Annual Meeting, Charlotte, NC, March 2007.
- Reproductive Toxicity Testing: Study Designs, Evaluation, Interpretation, and Risk Assessment, Society of Toxicology 45th Annual Meeting, San Diego, CA, March 2006.
- Project Managers Bootcamp I, PSMJ Resources, Inc., Cambridge, MA, April 2005.
- Development and Interpretation of Toxicokinetic Data for Risk and Safety Assessment, Society of Toxicology 44th Annual Meeting, New Orleans, LA, March 2005.
- Survival Analysis, Graduate Summer Institute of Epidemiology and Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, June 2003.
- Speaking on the Job, Cancer Prevention Fellowship Program, NCI, Rockville, MD, February 2003.
- Grants and Grantsmanship Workshop, Cancer Prevention Fellowship Program, NCI, Rockville, MD, January 2003.
- Spotted Gene Expression Microarray Workshop, Advanced Technology Center, NCI, Gaithersburg, MD, October 2002.
- Laboratory of Cellular Carcinogenesis and Tumor Promotion/Laboratory of Human Carcinogenesis/Laboratory of Experimental Carcinogenesis Interlaboratory Seminar, Monthly, 2002 to 2004.
- Division of Cancer Prevention, Office of Preventive Oncology Colloquia Series on Cancer Prevention Topics, Weekly, 2002 to 2004.
- Radiation Safety for Authorized Users, NIH Radiation Safety Branch, Bethesda, MD, September 2002.
- Molecular Prevention Course, NCI Summer Curriculum in Cancer Prevention, Rockville, MD, August 2002.
- Principles & Practice of Cancer Prevention and Control Course, NCI Summer Curriculum in Cancer Prevention, Rockville, MD, July to August 2002.

Professional Activities

- Keynote Speaker and Scientific Committee Member, Isocyanates & Health Conference, April 2013.
- Proposal Reviewer, National Science Foundation, 2013.
- Invited Participant, ILSI Health and Environmental Sciences Institute Emerging Issue Workshop: Evaluating Causality in Epidemiology, October, 2012.
- Invited Panel Member, "Using Mode of Action to Support the Development of a Multipollutant Science Assessment," USEPA Workshop, May 2012.
- Editorial Board Member, *Carcinogenesis*, 2012.
- Invited Participant on "Improving Science-Based Regulation," The George Washington University Regulatory Studies Center and the Center for Risk Science and Public Health, January 2012.
- Member, Massachusetts Environmental Justice Assistance Network, 2010 to Present.
- Board Member, American College of Epidemiology, 2010 to Present.
- Nominating Committee, Society of Toxicology, 2009 to 2011.
- Elected Member, Canton, Massachusetts Board of Health, 2008 to Present. (Chair, 2009 to 2010).
- Editorial Board Member, *The Open Biomarkers Journal*, 2008 to Present.
- Managing Editor, *Journal of Environmental Protection Science*, 2008 to 2010.
- Member, Canton, Massachusetts Medical Reserve Corps, 2007 to Present.
- Peer Reviewer, *Texas Commission on Environmental Quality, Development Support Document for Nickel and Inorganic Nickel Compounds, Preliminary Draft*, May 2009.
- Invited Observer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Volume 100, Meeting C: Metals, Particles and Fibres*, Lyon, France, March 2009.
- Abstract Awards Selection Committee, Risk Assessment Specialty Section, Society of Toxicology, 2008.
- Secretary/Treasurer, Risk Assessment Specialty Section, Society of Toxicology, 2007 to 2009.
- Editorial Board Member, *Journal of Environmental Protection Science*, 2007 to 2008.
- Guest Lecturer, Cancer Epidemiology, University of Maryland, 2004.
- Member, Cancer Prevention Fellowship Scientific Education Committee, NCI, 2003.
- Guest Lecturer, Xenobiotic Metabolism, Johns Hopkins Bloomberg School of Public Health, 2001 and 2002.
- Reviewer: *American Journal of Pathology; Cancer Epidemiology, Biomarkers & Prevention; Cancer Genetics and Cytogenetics; Cancer Research; Carcinogenesis; Clinical Cancer Research; Critical Reviews in Toxicology; Environmental Health Perspectives; Human and Experimental Toxicology; Inhalation Toxicology; Journal of Cellular Biochemistry; Journal of Exposure Analysis and Environmental Epidemiology; Journal of Human and Ecological Risk Assessment; Journal of Occupational and Environmental Medicine; Medical Journal of Australia; NeuroToxicology; Pharmacogenetics; Regulatory Toxicology and Pharmacology; Risk Analysis; Toxicology and Applied Pharmacology.*

Honors and Awards

- Best Overall Abstract, Risk Assessment Speciality Session, Society of Toxicology, San Antonio, TX, 2013.
- International Dose-Response Society Outstanding New Investigator Award, 2012.
- Top 10% Best Overall Abstracts in Risk Assessment, Risk Assessment Specialty Section, Society of Toxicology, Seattle, WA, 2008.
- Fellows Award for Research Excellence: $1,000 Travel Award, National Institutes of Health, Bethesda, MD, 2004.
- Honorable Mention Poster Presentation, Center for Cancer Research 4th Annual Fellows and Young Investigators Retreat, Williamsburg, VA, March 2004.
- Graduate Student Travel Award, Gordon Research Conference on Hormonal Carcinogenesis, 1999, 2001.
- Travel Award, 3rd World Congress on Alternatives and Animal Use in the Life Sciences, Bologna,

Italy, 1999.
- Howard Hughes Predoctoral Fellowship Award, 1997-2002.
- NIEHS Training Grant Graduate Fellowship Award, Johns Hopkins University, Baltimore, MD, 1996-1997.
- Tau Beta Pi, National Engineering Honor Society, 1995-1996.
- Chi Epsilon, National Civil Engineering Honor Society, 1994-1996.

Professional Affiliations

American College of Epidemiology; Society for Risk Analysis; Society for Risk Analysis New England Chapter; Society of Toxicology; International Dose-Response Society

Projects

Trade Organization: Provided written and oral comments on several occasions to the Clean Air Scientific Advisory Committee (CASAC) on human exposure, epidemiology, toxicology, and mechanistic studies and their bearing on US EPA's National Ambient Air Quality Standards (NAAQS) for particulate matter (PM), ozone, nitrogen oxides, and sulfur oxides.

Trade Organization: Assessed whether animal, mechanistic, and epidemiological data are consistent with the nickel ion bioavailability model, which asserts that the carcinogenicity of nickel-containing substances is based on the bioavailability of the nickel ion at nuclear sites of target respiratory epithelial cells. This analysis was published in a peer-reviewed journal.

Trade Association: Conducted two comprehensive critical weight-of-evidence reviews of studies bearing on the ability of very low bisphenol A exposures to affect reproduction and development *via* endocrine disruption. These analyses were published in a peer-reviewed journal and presented to several state legislative committees, all of which were considering bans on bisphenol A.

US EPA: Contributed to the design of a model describing several frequently encountered toxicity endpoints in terms of a series of progressive pathophysiological steps. This model will contribute to the application of the US EPA mode-of-action guidance for judging relevance to humans and for using precursor lesions and biomarkers in dose-response analyses.

Cleaning Product Company: Evaluated toxicity of chemicals in all-natural cleaning products.

Trade Organization: Conducted a survey of nearly 50 weight-of-evidence (WoE) frameworks to evaluate best practices for determining causation. Defined the key concepts of WoE analyses and their application to particular problems, and articulated the best practices from among the spectrum of approaches. This will be submitted for publication in a peer-reviewed journal.

Pesticide Company: Assessed whether epidemiology, toxicology, and mechanistic evidence support chlorpyrifos being a neurobehavioral toxicant in humans at relatively low exposure levels. Evaluated evidence using recently proposed frameworks for integrating human and animal data, as well as Gradient's hypothesis-based weight-of-evidence approach. This work was published in a peer-reviewed journal.

Municipality: In response to citizens' concerns, independently investigated whether there was an increased incidence of cancer in residents living near a municipal landfill. Communicated findings with city officials and residents at public meetings. This analysis was published in a peer-reviewed journal.

Trade Organization: Conducted a critical examination of a proposal by the National Academy of Sciences that linear low-dose extrapolation should be used for non-cancer and cancer endpoints as a default because measurement error in epidemiological studies linearizes dose-response curves. This analysis was published in a peer-reviewed journal.

Chemical Company: Assessed the potential toxicological and ecological effects of bisphenol A using a modification of the Green Screen method that was designed to advance the development of green chemistry. Modified the method to be risk-based, rather than hazard-based, by considering exposure information. For many endpoints, a weight-of-evidence approach was taken to integrate all the available data and to resolve conflicting information.

Law Firm: Evaluated the potential lung cancer and mesothelioma risks from exposure to chrysotile asbestos from brakes based on epidemiological studies of vehicle brake repair workers and mode-of-action and toxicology data.

Toy Distributor: Determined whether a toxicological evaluation of a toy was sufficient for determining children's health risks. Assessed the toxicity of a chemical found in the toy, potential routes of exposure, and possible health risks.

Electric Utility: Evaluated the scientific basis of health claims associated with air quality regulations that would impact an electricity generation facility. Compared air quality data in the area around the facility to health-based National Ambient Air Quality Standards.

Trade Organization: Assessed the EPA "Framework for Human Health Risk Assessment to Inform Decision Making" and compared it to EPA's ongoing ozone analysis. Focused on planning and "fit for purpose," weight of evidence, transparency, reasonableness, consistency, at-risk factors, and uncertainty and variability.

Trade Organization: Conducted a quantitative analysis of controlled human exposure studies to address whether there is a subset of individuals who are susceptible to health effects of criteria air pollutants at particular exposure levels, but whose response is obscured by analyzing data at the group level. This analysis will be submitted to a peer-reviewed scientific journal.

Electric Utility: Analyzed air monitoring data to determine the potential public health impacts of stack air emissions of fine particulate matter (PM), ozone, nitrogen dioxide, and sulfur dioxide.

Law Firm: Analyzed human health risks posed by chemicals measured in workplace indoor air that were alleged to have originated from groundwater contaminated by a nearby recycling facility. Focused on the epidemiology of the chemicals of concern at the levels measured in the workplace and the plaintiffs' health complaints, including cancer.

Law Firm: Reviewed specific exposure information and occupational epidemiology literature for a claim regarding a causal association between formaldehyde inhalation and acute myeloid leukemia.

Law Firm: Evaluated whether radiation should have been considered as a potential cause of an individual's mesothelioma. Analyzed both specific exposure information and toxicology and epidemiology literature on radiation and mesothelioma.

Trade Organization: Performed an ozone mortality risk assessment using US EPA's Environmental Benefits Mapping and Analysis Program. Evaluated mortality risks by conducting a series of sensitivity analyses to assess how alterative model inputs impact risk results. Presented our results to EPA and will submit them for publication in a peer-reviewed journal.

Smelter: Assessed whether smelter's permit would likely allow for SO_2 emissions that could lead to adverse health effects in the community.

Trade Association: Using the hypothesis-based weight-of-evidence approach, evaluated whether epidemiology, toxicology, and mechanistic evidence supports the plausibility of formaldehyde as a human leukemogen. This analysis was published in a peer-reviewed journal.

Chemical Companies: Calculated a benchmark dose (BMD) for an industrial chemical using US EPA's Benchmark Dose Software (BMDS). Assessed several dose-response models and evaluated the impact of using historical control data.

Trade Organization: Evaluated whether the weight of epidemiology, animal toxicity, mechanistic, and pharmacokinetic evidence indicates that toluene diisocyanate is a human carcinogen. This analysis will be submitted to a peer-reviewed journal.

Trade or Organization: Evaluated the latest version of the US EPA Air Pollutants Exposure (APEX) model by conducting a series of sensitivity analyses to assess how alterative model inputs impacted exposure and risk assessment results.

Trade Organization: Critically reviewed meta-analysis of respiratory cancer risk following inhalation exposure to nickel compounds. Provided comments regarding the methods, limitations, and interpretation of results throughout the conduct of this study.

Trade Organization: Conducted a pilot meta-analysis of studies bearing on the ability of very low oral exposures to bisphenol A (BPA) to affect prostate weight in rodents. Investigated the possibility of publication bias and evidence for a temporal trend in the data.

Trade Organization: Critically reviewed a draft European Union report on the state of the science regarding endocrine-disrupting chemicals. Assembled a panel of experts to determine whether the draft report constituted a complete and unbiased analysis of endocrine disruptors.

Trade Organization: Evaluated potential health risks from bisphenol A in epoxy-lined metal cans based on both the peer-reviewed scientific literature and regulatory agency risk assessments.

Trade Organization: Reviewed and critiqued the assumptions and uncertainties associated with the statistical models on which US EPA's 2011 Benefits and Costs of the Clean Air Act Report was based.

Trade Organization: Reviewed the basis for the California Environmental Protection Agency's proposal to list SO_2 as a Proposition 65 developmental and reproductive toxicant. Evaluated whether the underlying studies provided sufficient and robust evidence that SO_2 causes developmental and reproductive effects.

Trade Association: Reviewed and prepared comments on the American Conference of Governmental Industrial Hygienists' (ACGIH) proposed Threshold Limit Value (TLV) for manganese. Reviewed the methodology applied by ACGIH, compared the use of published regression analyses of manganese dose-response data to benchmark dose modeling of more recent data, and identified appropriate adverse effect levels of manganese in occupational studies.

Chemical Manufacturer: Reviewed the epidemiology and mode-of-action data on acetic anhydride and cancer using a systematic weight-of-evidence approach to determine whether the data are consistent with ACGIH cancer classification.

Law Firm: Evaluated epidemiology literature regarding present and future risks of cancer and non-cancer health effects in a group of individuals from inhalation exposures to tricholoroethylene (TCE) and perchloroethylene (PCE).

Law Firm: Evaluated the epidemiology literature regarding cancer and non-cancer health effects of benzene, dioxin, and pentachlorophenol. Conducted a cluster analysis to determine whether individuals residing in an area with alleged exposures had increased rates of several cancers and non-cancer health effects.

Chemical Company: Evaluated US EPA's proposed national emission standards for hazardous air pollutants (NESHAPs) for mercury from major industrial boilers. Evaluated the agency's statistical approach for establishing the maximum achievable control technology (MACT) limit and determined how alternative approaches would impact the MACT derivation.

Public Agency: Evaluated the variability in water lead levels and the association between water lead levels and blood lead levels in children.

Confidential Client: Evaluated the health effects associated with hexavalent chromium based on an assessment of the epidemiological literature. Also assessed the scientific rigor of an analysis of potentially exposed individuals' survey responses.

Trade Organization: Classified, summarized, and entered relevant lead studies into IUCLID (International Uniform Chemical Information Database) 5.2, a database for the intrinsic and hazard properties of chemical substances that companies can use to submit data under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation in Europe.

Trade Organization: Provided written and oral testimony to both the US National Toxicology Program (NTP) and its Board of Scientific Councilors regarding occupational epidemiology studies of styrene and their bearing on a weight-of-evidence analysis of whether styrene should be considered a human carcinogen.

Trade Organization: Developed scientifically sound approaches for incorporating human data into quantitative non-cancer risk assessment to support commentary on the ongoing US EPA revision of its dioxin assessment.

Trade Organization: Conducted meta-analyses and meta-regressions of airway hyper-responsiveness in asthmatic volunteers exposed to NO_2 in clinical studies. These analyses were published in a peer-reviewed journal and presented to CASAC and the US Office of Management and Budget in the context of US EPA's development of NAAQS for NO_2.

Pharmaceutical Company: Performed an in-depth analysis of the toxicology and epidemiology data of a specific drug to determine whether the company could have anticipated potential adverse side effects in humans.

Trade Organization: Assessed what constitutes an adverse health effect *vs.* normal biological variation (or adaption or compensation to stressors), and the role of statistics in assessing adversity. Used airway hyper-responsiveness to sulfur dioxide as a case study. This analysis was published in a peer-reviewed journal.

Trade Organization: Evaluated the associations between metal exposures and health outcomes using data from the National Health and Nutrition Examination Survey (NHANES), a program of studies of United States residents conducted at the Centers for Disease Control and Prevention (CDC).

Trade Organization: Conducted a weight-of-evidence assessment of exposure to soluble nickel compounds and respiratory cancer risk based on animal carcinogenicity, mode-of-action, and occupational epidemiology studies. This analysis was published in a peer-reviewed journal.

Trade Organization: Conducted a critical review of the US EPA Toxicological Review of 1,4-Dioxane in support of "Summary Information" provided in the Integrated Risk Information System (IRIS). In written comments to US EPA, proposed alternative methods to calculate the cancer slope factor and reference dose.

Law Firm: Evaluated the toxicology and epidemiology of several pesticides and whether there was evidence for a causal association with certain birth defects.

Law Firm: Assessed recent occupational epidemiological studies of manganese and their bearing on the reference concentration (RfC). This analysis was published in a peer-reviewed journal.

Law Firm: Assessed whether epidemiology literature supports an association between low-level exposures to lead and IQ.

Trade Organization: Determined whether linear low-dose extrapolation should be used for non-cancer endpoints. This analysis was published in a peer-reviewed journal.

Law Firm: Assessed appropriateness of statistical analyses used by the Ramazzini Foundation for comparing cancer incidence rates in rats treated with methyl tert-butyl ether (MTBE) and untreated rats. This analysis was published in a peer-reviewed journal.

Law Firm: Critically reviewed epidemiology literature of radium and osteosarcoma risk. Determined whether osteosarcoma rates were higher than expected in certain geographic regions in a southern state.

Law Firm: Critically reviewed potential health effects associated with exposure to heating oil from a basement spill.

Law Firm: Critically reviewed the epidemiology literature on the role of ionizing radiation in cancer risk in patients receiving radiation therapy, in nuclear energy facility workers, and in patients receiving Thorotrast treatments. This analysis was published in a peer-reviewed journal.

Chemical Company: Conducted a comprehensive review of the scientific literature on indoor dust levels of several flame retardants and an exposure assessment of each one. This analysis was published in peer-reviewed journal.

Consumer Product Company: Interpreted the results of two genotoxicity screening assays in light of their sensitivity and specificity.

Toy Manufacturer: Conducted failure analyses of children's toys to determine whether proper or improper use was likely to lead to physical harm. Made recommendations regarding ways to make the toys safer.

Chemical Manufacturing Plant: Evaluated the toxicology and epidemiology literature regarding mercury and determined whether levels in residential soil were above background and likely attributable to a nearby manufacturing plant.

Chemical Company: Conducted a critical review of neurodevelopmental toxicology studies of the flame retardant, decabromodiphenyl ether (BDE-209). This review was published in a peer-reviewed journal.

Petroleum Refining Company: Conducted an uncertainty analysis of the carcinogenicity of naphthalene using a hypothesis-based weight-of-evidence scheme. This analysis was published in a peer-reviewed journal.

Power Plant: Critically reviewed published epidemiology studies of health effects in children residing near coal-fired power plants or coal mines. These studies examined respiratory outcomes, birth defects, and effects on physical development.

Law Firm: Analyzed health effects – including fetal, infant, and total death rates and cancer rates – and certain vital statistics in a Montana county. Compared overall health status of the county to that of the state.

Trade Organization: Evaluated and applied an uncertainty analysis focused on dioxin exposure and health effects data from key toxicology and human biomonitoring-based epidemiology studies as part of a margin-of-exposure analysis. This analysis was published in a peer-reviewed journal.

Chemical Manufacturer: Served as an expert resource on the data, analyses, and proper interpretation for risk assessments of dioxin, furan, and dioxin-like PCB congeners measured by the University of Michigan in serum and associated house dust and soil samples of several hundred Michigan residents.

Law Firm: Evaluated the toxicology and epidemiology of glutaraldehyde and hydroquinone and whether there is evidence for a causal association with leukemia.

Trade Organization: Developed and refined a search strategy for the exposure and health effects of a chemical used in a manufacturing process using several databases, such as PubMed, Toxline, IRIS, and HSDB. Identified and screened relevant articles for inclusion in an electronic database, which included one- or two-sentence highlights for each article.

Hospitals: Participated in the evaluation of the potential for either acute or chronic adverse health effects due to a contaminant on surgical instruments used for medical procedures at several hospitals.

Industrial Consortium: Contributed to a toxicity and risk assessment in a class-action lawsuit by residents claiming adverse health effects from TCE and PCE in groundwater. Participated in a quantitative analysis of ingestion exposure, showering exposure, potential health risks, and proposed medical monitoring.

Cleaning Product Company: Designed methodology for testing the presence and activity of an enzyme in a cleaning product. Determined whether this enzyme was appropriate for the product.

Wood Treatment Plant: Analyzed dioxin and PCB congeners in individuals residing near a wood treatment plant and compared them to background levels reported by NHANES. Analyzed these compounds in soil, dust, and sediment to determine whether there were elevated risks of exposure.

Cleaning Products Company: Determined whether ingredients of several cleaning products, including floor strippers, could have caused or exacerbated several claimed health effects (such as respiratory effects) in individuals using the products or working in areas where the products were used.

Chemical Plant: Analyzed dioxin congener profiles and concentrations in serum, soil, and house dust, and oysters and sediment from a bay near a chemical plant. Compared these to background levels using publicly available data (*e.g.,* US EPA, NHANES, peer-reviewed literature) and assessed human health risks.

Small Business: Assessed whether cancer cases at a small business could be attributed to a common exposure.

Trade Association: Re-analyzed published rat testicular carcinogenicity data on MTBE using the Poly-3 statistical method to account for survival differences among treatment groups. This analysis was submitted to US EPA and published in a peer-reviewed journal.

Pesticide Company: Analyzed US EPA's use of the lower confidence limit on the BMD_{10} ($BMDL_{10}$) to determine a point of departure for the cancer risk of dimethylarsenic acid in humans. This analysis was submitted to US EPA.

Pharmaceutical Company: In the context of a patent infringement lawsuit, performed an independent analysis of efficacy and toxicity data from animal experiments to determine if claims in the patent could be challenged.

Research Organization: Critically reviewed epidemiology literature to determine if the effects of lead and mercury on human neurological development are additive or synergistic.

Health Effects Institute: Compiled and reviewed studies regarding chronic and acute toxicity guidelines for mobile source air toxicants.

Flame Retardant Company: Provided toxicological, database, and risk analysis support for product development of phosphorus-based flame retardant (FR) chemicals with low potential for health and environmental impact.

Manufactured Gas Plants: Contributed to an expert report regarding the historical releases of compounds associated with plant processes and the historical understanding of risk assessment, carcinogenesis, and the toxicity of these compounds.

Chemical Company: Contributed to the drafting of an evidence-based argument submitted to US EPA that demonstrated that acetonitrile should be delisted from the US EPA's Toxic Release Inventory (TRI).

Smelter: Reviewed general and company-specific historical knowledge of human and ecological toxicity of smelter contaminants for an insurance cost recovery case involving two US smelters.

Manufacturer: Summarized the cancer and non-cancer effects of cobalt and nickel for a company that fabricates tungsten heavy metal alloy products.

Trade Organization: Reviewed epidemiology studies assessing associations between bisphenol A (BPA) and several health effects.

Publications – *Journal Articles*

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Goodman, JE, Prueitt RL, Rhomberg, LR. 2013. "Hypothesis-Based Weight-of-Evidence Evaluation of the Human Carcinogenicity of Toluene Diisocyanate." Presented at the Isocyanates & Health Conference, April 3-4.

Seeley, MR; Goodman, JE. 2013. "Is There a Subset of Susceptible Individuals in Controlled Air Pollution Studies?" *Toxicologist* 132(1):414.

Prueitt, RL; Goodman, JE; Rhomberg, LR. 2013. "Hypothesis-Based Weight-of-Evidence Evaluation of the Human Carcinogenicity of Toluene Diisocyanate." *Toxicologist* 132(1):415.

Rhomberg, LR; Goodman, JE; Bailey, EA; Prueitt, RL. 2012. "Weight-of-Evidence Frameworks, Systems, and Tools: A Survey of Existing Approaches and Notes on Best Practices." Presented to the Society for Risk Analysis (SRA) Annual Meeting, December 9-12.

Sax, SN; Lau, JH; Goodman, JE. 2012. "Evaluation of the BenMAP Model for Estimating Mortality Impacts of Lower Ozone Concentrations." Presented at The 22nd Annual Conference of the International Society of Exposure Science (ISES), October 28-November 1.

Bailey, LA; Goodman, JE; Beck, BD. 2012. "Revised Reference Concentration for Manganese Oxide Based on Recent Epidemiology and Pharmacokinetic Studies." *Toxicologist* 96.

Peterson, MK; Goodman, JE. 2012. "Infant Risk and Exposure Assessment of Bisphenol A in Polycarbonate and 'BPA-free' Plastic Bottles." *Toxicologist* 96.

Prueitt, RL; Goodman, JE; Bailey, LA; Rhomberg, LR. 2012. "Hypothesis-Based Weight-of-Evidence Evaluation of the Neurodevelopmental Effects of Chlorpyrifos." *Toxicologist* 96.

Seeley, MR; Goodman, JE. 2012. "Is Sulfur Dioxide a Reproductive and Developmental Toxicant?" *Toxicologist* 96.

Bailey, LA; Goodman, JE; Rhomberg, LR. 2011. "Hypothesis-based Weight-of-Evidence Evaluation of Naphthalene: Carcinogenic Hazard Assessment and Mode of Action." Presented at the Society of Environmental Toxicology and Chemistry (SETAC) North America 32nd Annual Meeting, Boston, MA, November 14.

Prueitt, RL; Goodman, JE. 2011. "Evaluation of Adverse Effects on Human Lung Function Caused by Ozone." *Toxicologist* 95.

Peterson, MK; Bailey, LA; Dodge, DG; Goodman, JE; Valberg, PA. 2011. "A Weight-of-Evidence Evaluation of Asbestos Exposure and Mesothelioma Risk among Electricians." *Toxicologist* 95.

Goodman, JE; Mayfield, DB; Bailey, LA; Rhomberg, LR. 2011. "Weight-of-Evidence Evaluation of Formaldehyde Exposure and Leukemia Risk." *Toxicologist* 95.

Mattuck, RL; Seeley, MR; Reid, KR; Goodman, JE. 2011. "Human Health Risks from Exposure to 1,4-Butanediol in Craft Kit Beads." *Toxicologist* 95.

Dodge, DG; Pollock, MC; Sax, SN; Petito Boyce, C; Goodman, JE. 2011. "Risk Characterization of the Brominated Flame Retardant Decabromodiphenyl Ethane in Indoor Dust." *Toxicologist* 95.

Peterson, MK; Bailey, LA; Dodge, DG; Goodman, JE; Valberg, PA. 2010. "Risk Assessment of Mesothelioma Among Electricians." Presented at Society for Risk Analysis (SRA) Annual Meeting, Salt Lake City, UT, December 5-8.

Haber, LT; Prueitt, RL; Goodman, JE; Thakali, S; Patterson, J. 2010. "Report of a Workshop: An Evaluation of Hypotheses for Determining the Carcinogenic Potential of Nickel-Containing Substances." Presented at Society for Risk Analysis (SRA) Annual Meeting, Salt Lake City, Utah, December 5-8.

Goodman, JE; Kerper, LE; Petito Boyce, C; Prueitt, RL; Rhomberg, LR. 2010. "Weight of Evidence Exposures to Dioxins and Dioxin-Like Compounds and Associations with Thyroid Hormone Levels during Early Development." *Toxicologist* 94.

Prueitt, RL; Goodman, JE; Thakali, S. 2010. "An Evaluation of Hypotheses for Determining the Carcinogenic Potential of Nickel-Containing Substances." *Toxicologist* 94.

Dodge, DG; Goodman, JE; Beck, BD. 2010. "Weight-of-Evidence Analysis of Hydroquinone and Leukemia." *Toxicologist* 94.

Thakali, S; Chandalia, JK; Seeley, M; Goodman, JE. 2010. "Meta-Analysis of Nitrogen Dioxide Effects on Airway Hyper-Responsiveness in Asthmatics: Effects of the Types of Airway Challenge, Exposure Methods, and Activites During Exposure." *Toxicologist* 94.

Goodman, JE; Chandalia, JK; Thakali, S; Seeley, M. 2009. "Meta-Analysis of Controlled Nitrogen Dioxide Exposure Studies Assessing Airway Hyper-Responsiveness in Asthmatics." Presented at Society for Risk Analysis (SRA) Annual Meeting, Baltimore, MD, December 6-11.

Goodman, JE; Rhomberg, LR; Pruiett, RL. 2009. "A Weight-of-Evidence Analysis of the Human Carcinogenicity of Styrene." Presented at the Annual Meeting of the American College of Epidemiology, Silver Spring, MD, September 13-15.

Prueitt, RL; Goodman, JE; Dodge, DG; Thakali, S. 2009. "A Weight-of-Evidence Evaluation of the Carcinogenicity of Soluble Nickel." *Toxicologist* 93.

Goodman, JE; Rhomberg, LR. 2009. "Styrene and Cancer Risk in Humans." *Toxicologist* 93.

Beyer, LA; Beck, BD; Goodman, JE. 2009. "Background Rates of Lymphomas/Leukemias and Leydig Cell Tumors in Sprague Dawley Rats." *Toxicologist* 93.

Goodman, JE; Bailey, LA; Beck, BD. 2008. "Recent Occupational Studies of Manganese and their Bearing on the Reference Concentration (RfC)." Presented at the Annual Meeting of the American College of Epidemiology, Tucson, AZ, September 14-16.

Aylward, LL; Goodman, JE; Charnley, G; Rhomberg, LR. 2008. "A Margin of Exposure Approach to Assessment of Non-cancer Risks of Dioxins Based on Human Exposure and Response Data." Presented at the 28th International Symposium on Halogenated Persistent Organic Pollutants, Birmingham, England, August 17-22.

Goodman, JE; Bailey, LA; Beck, BD. 2008. "Recent Studies of the Health Effects of Manganese and the Implications for the Reference Concentration (RfC)." *Toxicologist* 92.

Dodge, DG; Haber, LT; Kopras, E; Goodman, JE; Pagan, I; Gift, JS; Rhomberg, LR. 2008 "Case Studies for the Development of a Pathophysiological Progression Model." *Toxicologist* 92.

Beyer, LA; Slayton, TM; Goodman, JE; Greenberg, GI; Hudson, TC; Beck, BD. 2008 "Evaluation of Key Information Informing the Basis of EPA's New Recommended Ozone Standard." *Toxicologist* 92.

Pagan, I; Haber, LT; Rhomberg, LR; Goodman, JE; Dodge, DG; Zhao, QJ; Foureman, GL. 2007. "Development of a Pathophysiological Progression Continuum Model for Selected Toxicological Endpoints." Presented at Society for Risk Analysis (SRA) Annual Meeting, San Antonio, TX, December 9-12.

Haber, LT; Rhomberg, LR; Goodman, JE; Dodge, DG; Zhao, QJ; Pagan, I; Foureman, GL. 2007. "Considerations Regarding the Structure and Application of a Pathophysiological Progression Model." Presented at Society for Risk Analysis (SRA) Annual Meeting, San Antonio, TX, December 9-12.

Dodge, DG; Zhao, QJ; Haber, LT; Goodman, JE; Pagan, I; Foureman, GL; Rhomberg, LR. 2007. "Case Studies for the Development of a Pathophysiological Progression Model." Presented at Society for Risk Analysis (SRA) Annual Meeting, San Antonio, TX, December 9-12.

Mechanic, LE; Luke, BT; Goodman, JE; Chanock, SJ; Harris, CC. 2007. "Polymorphism Interaction Analysis (PIA): A method for investigating complex gene-gene interactions." Presented at Approaches to Complex Pathways in Molecular Epidemiology, Santa Ana Pueblo, NM, May 30- June 2.

Goodman, JE; Gaylor, D; Beyer, LA; Rhomberg, LR; Beck, BD. 2007. "MTBE is Not Associated with a Statistically Significant Increase in Leydig Cell Tumors in Sprague-Dawley Rats." *Toxicologist* 91.

Rhomberg, LR; Goodman, JE; McConnell, EE; Sipes, IG; Witorsch, RJ; Slayton, TM; Yu, CJ; Lewis, AS. 2007. "An Updated Weight of the Evidence Evaluation of Reproductive and Developmental Effects of Low Doses of Bisphenol A." *Toxicologist* 91.

Beyer, LA; Goodman, JE; Seeley, MR; Slayton, TM; Beck, BD. 2007. "Carcinogenicity Evaluation of Methyl Tert-Butyl Ether (MTBE)." *Toxicologist* 91.

Zanetti, KA; Kahn, MA; Bowman, ED; Goodman, JE; Chanock, S; Harris, CC. 2007. "Compromised Complement System Increases Colon Cancer Susceptibility in African-Americans." *Proc. Am. Assoc. Cancer Res.* 48.

Schoen, A; Eldan, M; Goodman, JE; Beck, BD. 2006. "DMA_V-Induced Bladder Tumors: Unique Rat Susceptibility." *Toxicologist* 90.

Goodman, JE; Harris, CC. 2005. "*GST-T1, p53,* and *CASPASE-8* Polymorphisms and Colon Cancer Risk." *Toxicologist* 89.

Goodman, JE; Bowman, E; Chanock, S; Harris, CC. 2004. "Polymorphisms in ALOX and COX and Colon Cancer Risk." *Proc. Am. Assoc. Cancer Res.* 44.

Goodman, JE; Bowman, E; Chanock, S; Harris, CC. 2004. "ALOX & COX Polymorphisms & Colon Cancer Risk: Association with ALOX-5 G-1753A & G-1700A." Center for Cancer Research Fourth Annual Fellows and Young Investigators Retreat, Williamsburg, VA, March 9-11.

Sullivan, AE; Goodman, JE; Silber, PM; Yager, JD. 2004. "Correlation Between Catechol-*O*-Methyltransferase Genotype and Phenotype." *Toxicologist* 88.

Sullivan, AE; Goodman, JE; Yager, JD. 2003. "Catechol-O-Methyltransferase (COMT) and Catechol Estrogens in Breast Cancer." Presented at the 226th National American Chemical Society Division of Toxicology Meeting, New York, NY, September 7-11.

Goodman, JE; Sullivan, AE; He, P; Silber, PM; Yager, JD. 2003. "Correlation Between Catechol-O-Methyltransferase Genotype and Phenotype." AACR Molecular and Genetic Epidemiology of Cancer Conference Proceedings, Waikoloa, HI, January 18-23.

Goodman, JE; He, P; Yager, JD. 2002. "*COMT* Polymorphism and Catechol Estrogen Methylation in Breast Epithelial Cell Lines." *Proc. Am. Assoc. Cancer Res.* 45.

Goodman, JE; He, P; Yager, JD. 2001. "Kinetics of High and Low Activity Human Catechol-*O*-Methyltransferase Activity for Catechol Estrogen Methylation." *Proc. Am. Assoc. Cancer Res.* 42.

Lavigne, JA; Goodman, JE; Fonong, T; Odwin-DeCosta, S; He, P; Yager, JD. 2001. "The Effects of Catechol-*O*-Methyltransferase Inhibition on Catechol Estrogen Levels and Oxidative DNA Damage in MCF-7 Cells." *Proc. Am. Assoc. Cancer Res.* 42.

Goodman, JE; Lavigne, JA; Hengstler, JG; Helzlsouer, KJ; Yager, JD. 2000. "Catechol-*O*-Methyltransferase Polymorphism Not Associated with Ovarian Cancer." *Proc. Am. Assoc. Cancer Res.* 41.

Chen, JQ; Delannoy, M; Goodman, JE; Lavigne, JA; Odwin, SE; He, P; Yager, JD. 2000. "Enhanced Transcript Levels of Mitochondrial Genes, Respiratory Chain Activity, Bcl-2 Levels and Glutathione Distribution by Ethinyl Estradiol in Female Rat Hepatocytes." *Proc. Am. Assoc. Cancer Res.* 41.

Invited Lectures, Testimony, and Other Presentations

"A Hypothesis-Based Weight-Of-Evidence Approach to Evaluate the Human Carcinogenicity of Isocyanates." Presented at the Isocyanates & Health Conference, April 3, 2013.

"Using Epidemiology to Analyze Neurodevelopmental Toxicity across Species." Preseneted at the 52nd Annual Society of Toxicology (SOT) Meeting, March 14, 2013.

"Designing Case-Control Studies." Presented at New York Medical College School of Health Science & Practice, February 21, 2013.

"Designing Cohort Studies." Presented at New York Medical College School of Health Science & Practice, February 11, 2013.

"Systemic Reviews and Meta-Analysis," Presented in the Use of Expert Elicitation to Inform Decisionmaking Workshop, Society for Risk Analysis 2012 Annual Meeting, San Francisco, CA, December 2012.

"Survival Analysis & Meta-Analysis." Presented at New York Medical College School of Health Sciences & Practice, November 8, 2012.

"Overview of the Controversy Surrounding Bisphenol A Toxicity." Presented at the Biological Relevance and Health Concerns of Genotoxicity Conference, Newark, DE, October 24, 2012.

"Biological & Statistical Interaction." Presented at New York Medical College School of Health Sciences & Practice, October 11, 2012.

Testimony regarding "EPA's Assessment of Health Benefits Associated with $PM_{2.5}$ Reductions for the Final Mercury and Air Toxics Standards." Presented to the Subcommittee on Energy and Power, United States Congressional Committee on Energy and Commerce American Energy Initiative Hearing, Washington, DC, February 8, 2012.

"Synthesizing Evidence: An Introduction to Systematic Reviews, Meta-Analysis, and Expert Elicitation." Presented at the Society for Risk Analysis 2011 Annual Meeting, Charleston, SC, December 2011.

"Why Meta-Analyses and Systematic Reviews Come to Different Conclusions About Formaldehyde and Leukemia." Presented at the Society for Risk Analysis 2011 Annual Meeting, Charleston, SC, December 2011.

"The weight of evidence regarding bisphenol A and human health." Presented at the Society for Risk Analysis New England Chapter Meeting, Harvard School of Public Health, Boston, MA, December 2011.

Testimony regarding Air Quality and Children's Health. Presented to the Subcommittee on Clean Air and Nuclear Safety and the Subcommittee on Children's Health and Environmental Responsibility, United States Senate Committee on Environment and Public Works Hearing, Washington, DC, June 8, 2011.

"On babies, bottles, and bisphenol A." Presented at the Defense Research Institute (DRI) Toxic Torts and Environmental Law Seminar, New Orleans, LA, February 2011.

"Bisphenol A and Human Health: What Does the Science Show?" Presented at The Policy of BPA Event, American Enterprise Institute, Washington, DC, June 2010.

"Human Health Risk Assessment." Presented at Massachusetts Maritime Academy, Buzzards Bay, MA, May 2010.

"The Science Behind the Reconsideration of the Ozone NAAQS." Presented as part of the webinar, How Will EPA's New Ozone Standards Affect Your Community?, April 2010.

"Weight-of-Evidence Analysis of Reproductive and Developmental Health Effects of Bisphenol A." Presented at the Nypro Bisphenol A (BPA) Information Event, Clinton, MA, March 2010.

"Everyday Exposures to Bisphenol A Do Not Cause Adverse Health Effects in Humans." Presented at Harvard Extension School, Environmental Management Program, Cambridge, MA, March 2010.

"New Developments in Exploratory Research on 'Estrogenicity' – Progress Toward Validation of New Endpoints and Testing Methods." Presented at the Society of the Plastics Industry's Food, Drug, and Cosmetic Packaging Materials Committee Winter Conference, Atlanta, GA, December 2009.

"Avoiding Potential Long-Term Liability through Risk Assessment for Material Selection." Presented at the 21st Annual Product Liability Conference, University of Wisconsin-Madison, Madison, WI, September 2009.

"Epidemiology and Risk Assessment." Presented at the Annual Meeting of the American College of Epidemiology, Silver Spring, MD, September 2009.

"Risk Assessment Techniques for Materials Selection." Presented as part of the Strategies for Substance Replacement in Products Webinar, May 2009.

"Investigation of Potential Cancer Clusters in Northampton, MA." Presented at John F. Kennedy School, Northampton, MA, September 2008.

"Did Chemicals in Your Product Cause John Doe's Disease? The Toxicologist Speaks." Presented at the 20th Annual Product Liability Conference, University of Wisconsin-Madison, Madison, WI, September 2008.

"Investigation of Potential Disease Clusters in Northampton, MA: Progress Update." Presented at Robert K. Finn Ryan Road School, Northampton, MA, October 2007.

"Investigation of Potential Disease Clusters in Northampton, MA." Presented at Robert K. Finn Ryan Road School, Northampton, MA, May 2007.

"Single Nucleotide Polymorphisms (SNPs), Inflammation and Colon Cancer." Presented at the Cancer Prevention Fellowship Program Seminar Series, NCI, Rockville, MD, February 2004.

"The Epidemiology of Inflammation and Colon Cancer." Presented at the Laboratory of Human Carcinogenesis Meeting, NCI, Bethesda, MD, December 2003.

"Macrophage Migration Inhibitory Factor (MIF) in Inflammatory Bowel Diseases." Presented at the Laboratory of Human Carcinogenesis International Workshop, Bethesda, MD, September 2003.

"Chronic Inflammation and Colon Cancer Risk." Presented at the Cancer Prevention Fellowship Program Seminar Series, NCI, Rockville, MD, June 2003.

Tab 3.3

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Tab 3.4 Other Personnel including Senior Scientists and/or Research Associates

Senior Scientists

Ms. Leslie Beyer, Dr. Chris Long, Dr. Robyn Prueitt, Dr. Sonja Sax, Dr. Sager Thakali, and Dr. Peter Valberg will scope and delegate work, critically review literature, conduct statistical and epidemiology analyses, and oversee day-to-day project activities. They will be responsible for assembling the first draft of white papers and manuscripts before final approval by the Project Manager. Each individual's expertise is discussed below, along with their years of experience and work performed at Gradient. For this proposal, each person will work specifically in his or her area of expertise. *Curriculum vitae* for the senior scientists are included at the end of this section.

Leslie A. Beyer, M.S., DABT
Human Health Toxicologist

Ms. Beyer is a senior project manager and toxicologist with more than 20 years of experience working at Gradient. Her areas of expertise include environmental health, occupational health and safety, litigation support, project management, and risk assessment. Her projects have covered a variety of topics, including substantiation of structure-function claims for dietary supplements; historical toxicology of vinyl chloride, benzene, and lead; and review and interpretation of toxicological and epidemiological literature and data. She evaluates the significance of occupational and residential exposures, conducts health risk assessments for cancer and non-cancer endpoints, and assesses health effects from exposure to environmental chemicals. Ms. Beyer conducts in-depth technical analyses on a range of projects involving product liability and chemical exposures (*e.g.*, MTBE, dioxin, perchloroethylene, ozone, chromium). For example, she has evaluated proposed NAAQS standards for ozone on an ongoing basis starting in 1995. She has presented these analyses at national meetings, including two presentations on ozone: "Evaluation of Key Information Informing the Basis of EPA's New Recommended Ozone Standard," presented at the 2008 Society of Toxicology annual meeting, and "Key Issues Raised by EPA's Proposed Ozone Standards and Supporting Analysis," presented at the 1997 Society for Risk Analysis annual meeting.

Areas of Expertise

Toxicology

Occupational Health

Litigation Support

Risk Assessment

Solvents

Historical Toxicology

Dietary Supplements

Education

M.S., Environmental Health Science, Harvard School of Public Health

B.S., Political Economy of Natural Resources, University of California at Berkeley

Diplomate of the American Board of Toxicology

Chris Long, Sc.D.
Exposure Scientist, Inhalation Toxicologist

Dr. Long is an expert in the area of indoor and outdoor air quality, with particular expertise in exposure assessment, inhalation toxicology, air pollution epidemiology, air sampling and measurement, and air modeling. He has more than 15 years of experience, 13 with Gradient, assessing exposures and health risks associated with airborne particulates (*e.g.*, diesel exhaust particulates, carbon black, latex aeroallergens, ambient sulfates and nitrates, sulfuric acid, asbestos, ambient ultrafine particles, engineered nanoparticles, lead and other trace elements, and bioaerosols) and a number of gaseous criteria and hazardous air pollutants, including carbon monoxide, ozone, hydrogen sulfide, SO_2, and benzene. Dr. Long's work routinely involves integrating information from exposure, toxicology, and epidemiology studies. Dr. Long's practice area also includes evaluating product safety, with specific interests in airborne exposures and engineered nanoparticles, and he is a technical editor of Gradient's nanotechnology newsletter, *EH&S Nano News*. Dr. Long has published approximately 20 peer-reviewed journal articles and book chapters in the general areas of indoor and outdoor air pollution, exposure assessment, and inhalation toxicology. Dr. Long's work on ambient PM exposures and health effects has been cited by US EPA in its reviews of PM health effects research. He is a member of the International Society of Exposure Science, Air and Waste Management Association, and American Chemical Society.

Areas of Expertise

Indoor/Outdoor Air Quality

Exposure Assessment

Air Sampling, Measurement, and Modeling

Risk Assessment

Particulate Matter

Nanotechnology

Education

Sc.D., Environmental Science & Engineering, Harvard School of Public Health

M.S., Environmental Engineering, Massachusetts Institute of Technology

A.B., Chemistry and Environmental Studies, Bowdoin College

Robyn Prueitt, Ph.D.
Molecular Toxicologist

Dr. Prueitt is an expert in human genetics, carcinogenesis, toxicology, and molecular epidemiology. At Gradient, her primary responsibilities include evaluating toxicology and epidemiology data for regulatory comment, human health risk assessment, WoE analyses, and litigation projects. She has five years of experience at Gradient evaluating inhalation toxicology and epidemiology data for ozone and PM and communicating her findings in comments to regulatory agencies and in published manuscripts. She also has five years of experience conducting comprehensive WoE analyses for multiple types of substances, including dioxins, pesticides, methanol, and diisocyanates, and she has authored several peer-reviewed publications describing these analyses.

Before joining Gradient, Dr. Prueitt worked as a research scientist at the Fred Hutchinson Cancer Research Center, where she designed and interpreted multi-species proteomic studies related to tumor biology and biomarker discovery. As a postdoctoral fellow at the National Cancer Institute's Laboratory of Human Carcinogenesis, Dr. Prueitt performed genomic and molecular epidemiologic studies of human cancer risk and progression. As a pre-doctoral student, she investigated genetic causes of human diseases using various molecular genetic techniques. Dr. Prueitt has authored multiple peer-reviewed articles in the fields of genetics, carcinogenesis, and toxicology.

Areas of Expertise

Toxicology

General and Molecular Biology

Human Genetics

Molecular Epidemiology

Carcinogenesis

Mode-of-Action Analyses

Education

Ph.D., Cell and Molecular Biology, University of Texas Southwestern Medical Center at Dallas

B.S., Biology, Pacific Lutheran University

Sonja N. Sax, Sc.D.
Exposure and Health Scientist

Dr. Sax is an environmental health scientist specializing in exposure assessment and health effects of environmental pollutants, including airborne gases and particles. For more than 10 years, Dr. Sax has been actively involved in the investigation of indoor and outdoor air quality problems. At Gradient for seven years, Dr. Sax has managed several large projects conducting critical evaluations of toxicology and epidemiology studies for regulatory comments and WoE analyses, as well as in the preparation of technical and expert reports. She has co-authored several publications related to her consulting work, presented at research conferences, and testified before Scientific Panels, including CASAC.

Prior to working at Gradient, Dr. Sax was a postdoctoral fellow at the Harvard School of Public Health, where she managed two large exposure assessment projects, wrote grants, and worked on data analyses and journal manuscripts. As a graduate student, Dr. Sax helped design, conduct, and manage an exposure project in New York City and Los Angeles, measuring indoor, outdoor, and personal concentrations of volatile organic compounds, carbonyls, $PM_{2.5}$, and particle-associated metals. Dr. Sax also conducted laboratory analyses, statistical analyses, and evaluation of collected data for publication of journal manuscripts.

Areas of Expertise

Exposure Assessment

Indoor/Outdoor Air Quality

Human Health Risk Assessment

Air Dispersion Modeling

Statistical Data Analysis

Education

Sc.D., Environmental Science and Engineering, Harvard School of Public Health

M.S., Environmental Health Management, Harvard School of Public Health

B.A., Biological Chemistry, Wellesley College

Sagar Thakali, Ph.D.
Senior Environmental Scientist

Dr. Thakali has more than 10 years of experience evaluating chemical bioavailability and toxicity in the environment. With six years of experience at Gradient, Dr. Thakali specializes in environmental risk and safety assessments of pharmaceuticals and personal care products, pesticides, and fracking and other industrial chemicals; regulatory ecotoxicity testing; chemical (and product) scoring and ranking; and statistical analyses (particularly meta-analyses). Dr. Thakali also provides technical and research expertise, litigation and statistical support, and oversight and management on various multi-disciplinary projects.

Dr. Thakali received his Ph.D. in Environmental Engineering from the University of Delaware where he developed the terrestrial biotic ligand models (TBLMs) to predict ecotoxicity of metals in soils. He has published several research papers in peer-reviewed journals and presented at professional conferences.

Areas of Expertise

Meta-analysis and Statistical Support

Environmental Chemistry, Fate, and Effects Modeling

Pharmaceuticals in the Environment

Personal Care Products Environmental Assessments

Environmental Regulations (REACH, EMEA, US EPA, FDA)

Education

Ph.D., Environmental Engineering, University of Delaware

B.S., Civil Engineering, Swarthmore College

B.A., Economics, Swarthmore College

Peter A. Valberg, Ph.D.
Inhalation Toxicologist, Public Health Specialist

Dr. Valberg is an expert in public health, human health risk assessment, inhalation toxicology, and modeling of human exposure to environmental chemicals. He has 35 total years of experience on the faculty of the Harvard School of Public Health and at Gradient; 20 of these are with Gradient. Dr. Valberg has provided air quality expertise to the US Department of Justice, US EPA, and National Academy of Sciences. He is the author of more than 100 scientific articles on biological effects of environmental exposures on humans and animals. Dr. Valberg's risk assessment expertise covers air pollutants, chemical exposures, biologicals, and radionuclides. His publications have covered a range of topics regarding inhalation toxicology of airborne particulates in the occupational and ambient-air settings. Recent projects have included evaluating airborne sulfate PM, diesel exhaust, and specific airborne substances such as metals, asbestos, sulfuric acid, and TCE. Integrating the WoE in these areas has involved analysis of toxicology studies, epidemiology studies, and meta-analyses. Dr. Valberg is frequently called upon to prepare and interpret health-risk findings for a variety of audiences, and he helps apply research results to the regulatory, litigation, and public policy arenas.

Areas of Expertise

Inhalation Toxicology

Modeling of Exposure

Airborne Pollutants and Particulates

Radiation and Radionuclide Risk

Risk Communication and Relative Risk

Nanotechnology, Nanoparticles

Education

Ph.D., Physics, Harvard University

M.A., Physics, Harvard University

M.S., Human Physiology and Inhalation Toxicology, Harvard School of Public Health

B.A., Physics and Mathematics, Taylor University

Research Associates

Mr. Joseph King, Ms. Julie Lemay, and Ms. Heather Lynch will critically review literature; conduct statistical and epidemiology analyses; and summarize information in tables, figures, and text, as appropriate. Ms. Ruth Lyddy will conduct literature searches and provide information services. Each individual's job title, expertise, licenses, and certifications are discussed below, along with their years of experience and work performed at Gradient. For this proposal, each person will work specifically in his or her area of expertise.

Joseph M. King, M.S., M.P.H.
Toxicologist

Mr. King is an environmental health scientist with experience in toxicology, human health risk assessment, epidemiology, and exposure assessment. Mr. King's primary responsibilities at Gradient include providing critical reviews of human toxicology and epidemiology studies and litigation support. He has seven months of experience at Gradient in this role; before joining Gradient, Mr. King worked on soil sampling projects and as a technical writing tutor for the Boston University School of Public Health.

Areas of Expertise

Human Health Risk Assessment

Toxicology

Epidemiology

Exposure Assessment

Public Health

Data Analysis and Interpretation

Education

M.S., Environmental Health, Boston University School of Public Health, 2012

M.P.H., International Health, Boston University School of Public Health, 2010

B.A., Philosophy & History of Math and Science, St. John's College (Annapolis, MD), 2003

Julie C. Lemay, M.P.H.
Environmental Health Scientist

Ms. Lemay is an environmental health scientist with extensive experience in human health risk assessment under federal and state regulations, epidemiology, exposure assessment, and managing databases for risk assessment and literature review projects. She also performs critical review of ecotoxicology and human epidemiology studies and provides litigation support. She has more than 10 years of experience in the field of environmental health, with two years at Gradient. Before joining Gradient, Ms. Lemay worked as a consultant and as a health assessor for the Massachusetts Department of Public Health, where she conducted public health assessments on landfills, waste sites, and other areas of public concern.

Areas of Expertise

Human Health Risk Assessment

Epidemiology

Exposure Assessment

Public Health

Data Analysis and Interpretation

Education & Certifications:

M.P.H., Environmental Health, Boston University School of Public Health, 2011

B.A., Political Science and Environmental Science, College of the Holy Cross, 2003

OSHA-Certified 40 Hours of Training in Hazardous Waste Operations and Emergency Response

Ruth R. Lyddy, M.S.
Research Associate

Ms. Lyddy is a senior information specialist with more than 18 years of experience in Gradient's Information Resource Center. She provides research services in current and historical aspects of environmental sciences, toxicology, health risk assessment, and regulatory affairs. Her areas of expertise include online computerized literature searching, Internet research, historical data research, document retrieval, and bibliographic database creation and management.

Areas of Expertise

Information Resources Management

Technical Data Research

Internet and Online Searching

Literature Research and Retrieval

Education

M.S., Library and Information Sciences, Simmons College, 1992

B.S., Mathematics, Tufts University, 1972

Heather N. Lynch, M.P.H.
Toxicologist

Ms. Lynch is an environmental health scientist and toxicologist with six years of experience, with one year at Gradient, in human health risk assessment of chemicals in consumer products and the environment. Her primary responsibilities at Gradient include critical review of toxicology and epidemiology studies for regulatory comment, human health risk assessment, and litigation support. She has been heavily involved in assessments of NAAQS pollutants, primarily for ozone and PM. Before joining Gradient, Ms. Lynch was a human health and toxicology consultant at ICF International, where she worked for nearly three years on large, chemical-specific risk assessments for several programs within the US EPA National Center for Environmental Assessment. While receiving her M.P.H., Ms. Lynch worked as a research assistant on an exposure assessment of indoor air contaminants in offices.

Areas of Expertise

Human Health Risk Assessment

Toxicology

Epidemiology

Public Health

Indoor/Outdoor Air Quality

Education & Certifications:

M.P.H., Environmental Health, Boston University School of Public Health, 2009

B.A., Environmental Studies, Knox College, 2006

Tab 3.5 Administrative Staff (Non-key)

Gradient scientists are supported by a team of administrative staff who have the experience, skills, and resources to meet project needs. We will have up to four people (Rachel Evans, Bethany Allen, Carla Walker, and Jasmine Lai) from a full team of administrative staff assistants assigned to this project to ensure that deliverables are of the highest quality, accurate, and timely. Our administrative professionals have strong organizational, management, and communication skills and are able to anticipate and solve problems. Typical responsibilities of our administrative staff include:

- Formatting and editing reports and other documents created in Word and Excel;
- Managing ingoing/outgoing mail and maintaining calendar and contacts;
- Arranging travel, internal and external meetings, and conference calls;
- Creating and editing PowerPoint presentation slides;
- Data entry and quality control;
- Maintaining tracking spreadsheets;
- Online research;
- Document management, production (copying, binding, *etc.*), and shipping; and
- Copying, filing, and other organizational work, as needed.

Addendum

Curriculum Vitae of Senior Scientists

GRADIENT

Leslie A. Beyer, M.S., DABT
Senior Environmental Health Scientist
lbeyer@gradientcorp.com

Areas of Expertise

Toxicology and epidemiology, litigation strategy and support, occupational health and safety, exposure assessment, historical toxicology, toxicity of adulterants in dietary supplements, GRAS determination, regulatory analysis and policy support, and project management.

Education

M.S., Environmental Health Science, Harvard School of Public Health, 1982.

B.S., Political Economy of Natural Resources, University of California at Berkeley, 1977.

Diplomate of the American Board of Toxicology (DABT).

Professional Experience

1993 – Present GRADIENT, Cambridge, MA
Senior Project Manager and Toxicologist. Review and interpret toxicological and epidemiological literature and data (*e.g.*, MTBE, dioxin, perchloroethylene, ozone, chromium). Develop strategy and prepare expert reports in support of litigation involving product liability and chemical exposures. Manage large, complex projects involving multiple staff and disciplines. Assess significance of occupational and residential exposures. Evaluate chemical toxicity, conduct health risk assessment for cancer and non-cancer endpoints, and assess health effects from multimedia exposure to environmental chemicals with special emphasis on solvents. Assess state of knowledge regarding risk assessment and toxicology (historical toxicology) (*e.g.*, creosote, vinyl chloride, benzene, lead). Evaluate health effects from dietary supplements in the context of structure-function claim and assess data for completeness for New Dietary Ingredient (NDI) submissions.

1988 – 1993 EASTERN RESEARCH GROUP, Lexington, MA
Project Manager and Senior Environmental Health Scientist. Managed multiple projects and contracts with US EPA. Conducted environmental health projects that evaluated risk assessment methodology issues, the health effects of various toxicants, and environmental databases.

1986 – 1988 HYGIENETICS, INC., Boston, MA
Project Manager. Managed asbestos abatement programs and developed Right-to-Know training programs.

1985 – 1986 DAVID GORDON ASSOCIATES, Newton, MA
Project Manager. Conducted source sampling and ambient air monitoring, and performed laboratory analysis.

1983 – 1985 HYGEIA INC., Waltham, MA
Project Manager and Industrial Hygienist. Implemented sampling protocols for toxic substances. Supervised asbestos removal projects.

1983 BOLT BERANEK AND NEWMAN, INC., Cambridge, MA
Project Manager and Industrial Hygienist. Conducted surveys to evaluate exposure to toxic substances and developed recommendations for remedial action.

Expert Testimony

Provided expert witness testimony in a litigation case involving the application of asbestos-containing fireproofing and the installation of asbestos-containing insulation in schools.

Professional Affiliations

Society of Toxicology; Phi Beta Kappa; American Herbal Products Association; American Industrial Hygiene Association

Projects – *Litigation Support and Toxicology Evaluation*

Impact of Fracking on Ozone Concentrations: Evaluated the impact of natural gas development using hydraulic fracking on levels of ozone in the air in New York. Compared estimates of ozone exposure from the fracking to background exposure and evaluated the health impacts of ozone.

Toxicity and Comparative Risk Evaluation for MTBE: Researched the basis of drinking water limits for MTBE. In addition, compared possible health risks from MTBE in drinking water to risks from other compounds (*e.g.*, radon, arsenic) in drinking water.

Nitrogen Dioxide Health Effects Evaluation: in the context of the nitrogen dioxide National Ambient Air Quality Standards (NAAQS) promulgated by US EPA, assisted with a meta-analysis of clinical studies to assess the concentration of nitrogen dioxide associated with airway hyper-responsiveness in humans .

Asbestos State of Knowledge: Analyzed scientific literature spanning several decades regarding knowledge of toxicity and exposure of asbestos used in various industries. Specifically, we evaluated actions taken by government, labor, and industry to understand, inform, and reduce the hazards posed by asbestos on ships to onboard personnel.

Litigation Support for Owners of Manufactured Gas Plants: Evaluated historical understanding of risk assessment, carcinogenesis, and the toxicology of compounds associated with manufactured gas plant (MGP) byproducts *(e.g.,* benzene, benzo(a)pyrene, naphthalene, phenols, cyanides). Wrote reports discussing implication for MGP owners' ability to anticipate the current concern of health effects stemming from exposure to low-level chemical concentrations in the environment. Conducted for dozens of sites in many states (*e.g.*, WI, MA, CA).

Chlorinated and Arsenical Pesticide Exposure and Toxicity Analysis: Provided technical support in the context of a toxic tort case filed by neighbors living in the vicinity of a former agricultural facility that conducted research on pesticides and herbicides. Analyzed the toxicity of five selected pesticides, and addressed whether the pesticides were likely responsible for the plaintiffs' health problems, especially in the context of possible exposure.

Historical State of Knowledge Regarding Toxicity of an Organochlorine Pesticide: For a toxic tort case, evaluated the historical state of knowledge from the 1940s into the 1970s regarding the toxicity of an organochlorine pesticide. Compiled communications between our client and its customers (*e.g.*, labels, bulletins) and addressed whether they were consistent with the state of knowledge.

Potential for Autoimmune Effects from Contact with Transmission Fluid: In a toxic tort case, evaluated medical records to determine whether there was a scientific relationship between exposure to automatic transmission fluid during a workplace accident, and the plaintiff's alleged health problems, which included lupus and dermatomyositis. Researched the health effects and medical literature bearing on the hydrocarbon chemicals in the transmission fluid.

Evaluation of Exposure of a Smelter Worker: Evaluated the need for medical monitoring of a smelter worker claiming exposure to heavy metals, including arsenic, nickel, and lead. Demonstrated that job entailed working with copper, which was almost pure, so that exposures to these metals would have been minimal.

Health Effects from Coal-fired Power Plants: Analyzed claims that sulfate particles and ozone formed from excess sulfur dioxide (SO2) and nitrogen oxide (NOx) emissions caused increased morbidity and mortality. The detailed assessment considered the degree of concordance between community air pollution epidemiological studies, toxicological studies, and occupational exposure studies; the uncertainties and inconsistencies in the available PM and ozone epidemiological studies; and the role of confounding factors on the interpretation of epidemiological findings.

Analysis of MTBE Carcinogenicity: Evaluated the reliability of the findings for tumor types in rodents exposed to MTBE (*i.e.*, Leydig cell tumors, leukemia/lymphoma, kidney tumors, and liver tumors), and their relevance to humans. Conducted a prevalence analysis and determined that Leydig cell tumors in rats was not statistically significantly increased when age was taken into account.

Structure-Function Claim Evaluation for Dietary Supplements: Conducted comprehensive literature searches, purchased the most relevant literature, reviewed the literature, and summarized each article/document in a tabular format, providing detailed information on the methods, findings, conclusions, strengths, and weaknesses. Compared this documentation to products' structure-function claims to assess degree of support provided.

Dioxin Health Impacts Near a Pigment Manufacturing Facility: Examined whether a manufacturing facility was responsible for health problems of residential neighbors. Compared dioxin congener pattern data from plaintiffs' blood serum to soils, house dust, sediments, shellfish, food, and other background sources. Also compared diseases with epidemiological and toxicological literature on dioxins (and some metals) and critiqued plaintiffs' experts reports and unorthodox approaches to exposure and risk assessment.

Toxicity Evaluation of Chemicals Found in Consumer Products: Evaluated the epidemiology studies for occupational exposure to chemicals, noting that initial findings of excess cancer (*e.g.*, prostate, bladder, leukemia), were not supported by later studies. Compared exposures and results to those in a community drinking contaminated water.

Health Effects from Diesel Emissions: Evaluated the possible health impacts of secondary nitrate particulate generated as a result of excess diesel emissions generated due to a delay in upgrading diesel engineer software. Critiqued the risk estimates regarding excess mortality, work loss days, *etc.*, due to the excess diesel emissions, determined that NOx particulate was not associated with most of the effects listed by Cal EPA (*e.g.*, asthma).

Evaluation of Health Effects from Galvanizing Emissions: Opposing experts claimed that the concentrations of lead and zinc decreased with distance from the plant in both soil samples and indoor dust samples collected in the homes of plaintiffs. Demonstrated that once lead dust data from homes with high lead paint concentrations were excluded, lead dust concentrations did not decrease with distance from the plant. Further demonstrated that outdoor soil showed no elevations of lead. Showed that the plaintiffs' blood lead modeling was flawed and, once corrected, did not show elevations in blood lead. Results presented at a Daubert hearing.

Evolving Historical Knowledge of Health Effects of Wood-Treating Chemicals: In a toxic tort case, evaluated industry's and a specific company's knowledge of health effects of wood-treating chemicals to their workers during the early 1900s to the present. Assessed the company's actions in terms of implementing appropriate industrial hygiene and epidemiology studies and in terms of the contemporaneous state of knowledge. Determined whether our client took proper steps to ensure worker health and safety according to prevailing knowledge and, by extension, whether the health of nearby residents (plaintiffs) was protected.

Critique State / ATSDR Site Evaluation: Assisted with the preparation of presentations and PR materials. Reviewed and commented on ATSDR/NJDEP health consultations regarding public health implications and cancer incidence at the site. Conducted a focused risk assessment for exposures at a creek. The risks were minimal and cancer risks were less than US EPA acceptable risk and below 10-6, the acceptable risk level for NJDEP.

Causation Evaluation for a Landfill: For a toxic tort case, which included a brain cancer cluster as well as other cancers and diseases (*e.g.*, lupus), summarized the toxicity information and the cancer classifications for multiple chemicals. Also summarized the epidemiology studies (primary literature) evaluating the association between cancer incidence and exposure to dioxin, arsenic, and benzene. Demonstrated plaintiffs' modeling was flawed, and that plaintiffs' expert reports conflicted.

Health Impacts of Glass Beads and Silica: Evaluated the toxicity data for the inhalation of glass beads and crushed glass, both of which are used as abrasive blasting agents, finding that silicosis has not associated with using glass beads. Also determined that a number of US agencies recommend the use of glass beads as an alternative to silica when abrasive blasting as a means of reducing exposure and avoiding the adverse health effects of silica.

Toxicity of PCE in Groundwater: In the context of litigation, reviewed scientific literature on cancer and noncancer toxicity of PCE and critiqued the causation arguments of the opponents' expert.

Risk Evaluation for Former Phosphorous Plant: Provided two written reviews of the draft ATSDR Public Health Assessment (PHA) for the site, which was a former phosphate ore processing and phosphorous production facility. Key issues addressed by Gradient at the site included: SO_2 and PM community air quality impacts, worker exposure issues, radionuclide contamination, and risk communication issues. Demonstrated that plaintiffs' experts misused industrial hygiene data.

Toxic Effects of Chromium in Plating: Evaluated whether laryngeal cancer or leukemia were related to chromium VI (Cr VI) exposure in a chrome plating operation and what exposures to Cr VI cause cancer (especially lung cancer in worker epidemiology studies). Using the available peer-reviewed literature, evaluated whether Cr VI was associated with laryngeal cancer or leukemia. Gradient also reviewed the underlying mechanisms of lung cancer related to Cr VI exposure, as well as the risk factors for laryngeal cancer.

Expert Testimony on the Historical Knowledge Regarding the Toxicity of PCE: Developed expert testimony on the historical knowledge regarding the toxicity (both cancer and noncancer) of perchloroethylene (PCE). Demonstrated that positive results in cancer bioassays in animals are consistent with negative results in humans (as seen in epidemiology studies), given the different mechanisms of metabolism in humans, rats, and mice. Evaluated the basis for remediation at the sites. Reviewed industry literature to determine the degree to which it reflected the medical and scientific knowledge regarding the human health risks.

MTBE in Drinking Water: Conducted an in-depth analysis of methyl tert butyl ether (MTBE) toxicity, reviewing the results for both animal and human studies. Quantified possible exposure to MTBE in drinking water and evaluated possible health effects and whether medical monitoring was warranted.

Risk Evaluation for Former MGP: In a toxic tort case, Gradient evaluated possible exposure to MGP contaminants in air and consumption of fish/shellfish to evaluate possible health risks to surrounding residents. Estimated the concentrations of MGP chemicals and PM_{10} both on-site and for the surrounding neighborhood during historical MGP operations using plant production records (1920-1952), standard US EPA-recommended emission factors from similar operations, and a US EPA-recommended air dispersion model (ISCST). Compiled historic sediment and soil data to assess potential residential exposures to polycyclic aromatic hydrocarbons (PAHs) due to incidental soil/sediment contact and ingestion and possible PAH uptake from consuming locally caught fish/shellfish.

Occupational Lead Exposure: Provided litigation support for a case in Texas involving plaintiffs who worked at a tile manufacturing plant where lead was a component of the glaze sprayed onto tiles. Evaluated claimed link between plaintiff exposures (primarily to lead), plaintiff medical test results, and plaintiff health problems (*e.g.*, neurological deficits, elevated blood pressure).

Evaluated Vinyl Chloride Toxicity and Testing: Evaluated the state of knowledge regarding vinyl toxicity and carcinogenicity in animals and humans. Also analyzed the use (and limitations) of animal testing, as well as the accepted protocols for testing toxic substances up through the 1970s.

Projects – *Risk Assessment/Toxicology Evaluation*

Human Health Risk Assessment: Assessed the draft US EPA issued Framework for Human Health Risk Assessment to Inform Decision Making (HHRA), and compared it to EPA's ongoing ozone analysis using topics discussed in the Framework (*e.g.* planning and "fit for purpose," weight-of-evidence, transparency, reasonableness, consistency, at-risk factors, and uncertainty and variability).

Ozone NAAQS Critique: Critiqued documents released by US EPA as part of its process for revising the National Ambient Air Quality Standards (NAAQS) for ozone, focusing on the underlying epidemiology and human exposure studies, and evaluating the causal associations between exposure to these pollutants and multiple health effects.

Risk Assessment on Site Related to Oil Production to Evaluate Property Damage: For a property damage case in Louisiana, evaluated human health risk at an industrial property to assess present and future risk. Opinions addressed whether plaintiffs' expert properly assessed and interpreted the risks for arsenic, lead, and barium in an analysis using US EPA and Louisiana Department of Environmental Quality (LDEQ) risk assessment protocols.

Analysis of NTP Cancer Bioassay for Goldenseal: Evaluated the results of the National Toxicology Program's (NTP's) two-year cancer bioassay for goldenseal (*Hydrastis canadensis*) and provided written comments to NTP. We assessed the degree to which the NTP's cancer classification was supported by the bioassay results by evaluating the dose response, coherence in findings, and background tumor rates reported in controls, among other parameters.

Sensitization from Fragrances: Assisted a consumer products company in evaluating potential human health risks and data needs associated with long-term, low-dose, dermal exposure to fragrances used in leave-on products such as skin cream and colognes, rinse-off products such as shampoos, and in clothes *via* laundry detergent or fabric softener. Reviewed the literature and analyzed how exposure-related variables could impact the sensitization potential of fragrances, and what information would be needed in order to assess risk and conduct risk assessment calculations for specific products.

Analysis of US EPA-Proposed Ozone NAAQS: In 2007, US EPA proposed to reduce the NAAQS standard for ozone from 0.08 ppm ozone to a concentration within the range of 0.070 to 0.075 ppm, based on recent findings in human health studies. Gradient analyzed US EPA's use of studies to support its proposed standard, and assessed the strength of a causal relationship for a number of endpoints. The analysis was used as part of regulatory comments submitted to US EPA by a trade association.

Data Sufficiency of a New Dietary Ingredient Submission to FDA: Analyzed test data to determine if they were adequate to support a New Dietary Ingredient (NDI) submission to FDA. Critically evaluated animal studies, mutagenicity bioassays, and clinical studies to assess their quality and relevance to the dietary supplement formulation (including dose). In addition, Gradient conducted a comprehensive literature search and "gap analysis" to determine whether the scientific information available was sufficient to support and NDI submission.

Dietary Supplement Literature Review: Managed and participated in project in which Gradient summarized and critically evaluated the technical content of over 100 articles addressing the effects on health of eating various foods (*e.g.*, berries, spinach, yogurt) and supplements (*e.g.*, seaweed extract, bromelain). The articles discussed numerous health endpoints, including cancer, diabetes, colitis, Crohn's disease, HIV, and blood cholesterol.

Levels of Mercury in Residences: Researched and reviewed the information on approaches to reoccupancy subsequent to residential mercury spills, determined the recommended levels of mercury in residential air (*e.g.*, ATSDR, NJ), and reviewed appropriate sampling methodology. Wrote two letters to the homeowner interpreting the concentrations measured in the basement of his home.

Exposure and Toxicity of Mobile-Source Air Toxics (MSATs): Reviewed and compiled toxicity and exposure information on MSATs for use by regulatory decision-makers in determining research needs and priorities. Summarized information on acute, chronic, and subchronic health effects (both cancer and noncancer) for the 21 MSATs, identifying the critical studies in the scientific literature on which key toxicity criteria were based. Oversaw compilation of ambient exposure data for the 21 MSATs from US EPA's Air Quality System (AQS) and other governmental databases, as well as recently published studies (*e.g.*, in-vehicle studies, large-scale modeling analyses). Agencies used this information to select key MSATs for additional research.

Health Effects of Indoor Air from MSATs: For 6 of the 21 US EPA MSATs, identified and summarized recent studies on their toxicity and measured concentrations in indoor air for use by the Federal Highway Administration (FHWA). Reviewed concentration data from 28 studies of indoor air environments, including "indoor" air in cars. Conducted a comprehensive literature search and compiled a summary of the most scientifically relevant recent available chronic (noncancer and cancer) and acute health effects information for each MSAT.

Development of Risk-Based Remedial Action Levels: Conducted risk assessments for residential areas surrounding a former MGP site and developed air action levels to use during site remediation. Evaluated risk to nearby residents whose yards and crawl spaces under their homes were contaminated with PAHs. Evaluated possible exposure *via* the volatilization of chemicals from tar suspected to underlay an athletic field in the neighborhood. Pathways evaluated included vegetable and soil ingestion, and inhalation of chemicals in outdoor and indoor air.

Evaluation of EPA's Proposed Ozone Standard: Evaluated EPA's support (1995) for a proposed change to the National Ambient Air Quality Standard for ozone. Assessed the validity and appropriateness of key health studies comprising the scientific basis for the proposed change, to determine the uncertainties associated with the dose-response modeling, and to ascertain the protectiveness of the standard. Evaluated the analysis that US EPA conducted in support of its proposed ozone standards: 0.07 - 0.09 ppm ozone, 8-hour average, 1-5 exceedances per year. Also evaluated hospital admissions studies.

Effects from Residential Exposure to Ozone: Evaluated the possible health impacts from ozone generated due to VOC emissions from a chemical manufacturing facility. Reviewed the literature on health effects from ozone exposure. Epidemiology studies, especially three large-scale, long-term prospective cohort studies conducted in the US, have shown that ozone was not associated with all-cause mortality (death), and hospital admission studies have reported mixed results.

Uptake of PAHs into Plants: Conducted a literature search and found that the transfer factors for PAHs and plants are small and range between 0.001 and 0.4, with the majority being lower than 0.01. Determined that the most important source of PAHs for plants is the atmosphere (not the soil), from where PAHs may enter plants *via* the gaseous phase or deposit bound to particles on plant surfaces.

Perchloroethylene (PCE) Risk Assessment, Chupai, Taiwan: Evaluated risk to residents exposed to PCE in water *via* ingestion and inhalation based on site-specific characteristics of water usage, house size, *etc.* Assessed site-specific characteristics, such as the role of Hepatitis B carrier status in PCE response.

Risk Assessment for Community near MGP Site in New Jersey: Using the primary literature, developed action levels for VOCs and particulates, which could be used during remediation to trigger a change in work activities prior to reaching unacceptable levels of chemicals in air.

Residential Exposure to 1,4-dioxane: Performed a site-specific risk assessment to evaluate residential exposure to 1,4-dioxane (dioxane) in groundwater. Using a conventional risk analysis, cancer risks were of potential concern. Using a margin of exposure analysis, which is appropriate for chemicals such as dioxane, whose carcinogenic effects appear to have a threshold, cancer risks were determined to be below levels of concern.

Residential Chlorinated Solvent Risk Assessment: Conducted a risk assessment for residents exposed to solvents in well water used to water gardens, fill swimming pools, and wash cars; the risks were very low and well within state (Michigan) screening levels, where applicable. Conducted a separate risk assessment to determine risk to construction workers digging a house foundation pit and a deep utility trench (wet) in a lot directly above the plume.

Health Risk from Wood Preservatives: Evaluated the toxicity and risk to workers and nearby residents from exposure to three wood preservatives: creosote, pentachlorophenol (PCP), and chromated copper arsenate (CCA). Wrote a report for each chemical, summarizing the chemistry and environmental fate and transport; exposure pathways; toxic effects; and the regulatory and advisory numbers. .

Health Risk from Cement Kiln Emissions: Determined that most concentrations of contaminants (in soil, water, and air) were consistent with background concentrations and/or regulatory levels. Determined that neither the sediment, the surface water, nor the corn showed any impact from the plant. Reviewed the results of an epidemiology study conducted locally.

Assessment of Health Risks from Lead in Tap Water: Assessed the potential impact on blood lead levels in children and adults of the small amount of lead leached from faucets into tap water, which was subsequently ingested. For adults the impact on blood lead levels was evaluated using Dr. Ellen O'Flaherty's model, and for children the IEUBK model was used and adapted to adequately reflect the transient nature of the exposure.

Historical Understanding of Lead Toxicity: Assisted in the preparation of expert report for litigation against company's insurers to recover costs associated with cleanup activities at a Superfund site in Idaho. The report discussed the understanding of lead toxicity from antiquity to the present, the development of risk assessment, the impact of lead on the ecology of the region, and the recent understanding that humans can be exposed to contaminants in soil through inadvertent soil ingestion.

Civil Suit Concerning the Ingestion of Trichloroethylene in Drinking Water: Provided assistance to a manufacturer in a class action suit filed by citizens whose drinking water wells had been contaminated with trichloroethylene and 1,1,1-trichloroethane. Evaluated the risk of health effects, established important background exposures to the two solvents, and evaluated the carcinogenicity data.

Assessment of Risks Stemming from the Use of Iron-Rich Material: Evaluated risk from exposure to IRM constituents such as antimony, cadmium, chromium, lead, mercury, nickel, and zinc. Exposure was evaluated for direct pathways (*e.g.,* soil, groundwater, and surface water ingestion) and indirect pathways – ingestion of vegetables grown in soils impacted by IRM and ingestion of animal products (milk, meat) from animals ingesting vegetation and soil impacted by IRM.

Validation of an Arsenic Exposure Model at a Mining and Milling Site through Urinalysis: Conducted risk and exposure assessment for adults and children in a gold mining community where tailings containing arsenic were buried in residential areas. Used the results of a urinalysis program to assess the validity of the exposure model and determined that exposure had been conservatively estimated.

Assessment of Risk for a Former Oil Refinery Site: Assessed risk to commercial workers, utility workers, and residents from exposure to petrochemicals in soil, groundwater, and air. Chemicals of concern included VOCs (*e.g.,* benzene), SVOCs (primarily PAHs), and inorganics (*e.g.,* mercury). Pathways evaluated included ingestion and dermal contact with soil, and inhalation of vapors migrating from subsurface soil into utility trenches.

PCB Risk from Ingesting Fish, Pacific Northwest: Evaluated cancer risk to residents from ingesting fish. Related PCB concentrations in sediment and English sole measured in 1984 to PCB concentrations in 1994 sediment samples using a site-specific bioconcentration factor. Determined appropriate fish ingestion rate based on surveys conducted in the immediate area, and by reviewing the extensive literature on the subject.

Risk Assessment Expertise to Help Develop Guidelines for Ohio's Cleanup Program: Prepared a report exploring the concept of acceptable risk and how the federal government has defined and applied it. Recommended appropriate target risk levels for both residential and occupational exposure scenarios for Ohio's Voluntary Cleanup Program. Recommended values to use for a number of exposure parameters in the risk assessment equation including a soil-to-dust transfer coefficient, an adult soil ingestion rate, and chemical-specific dermal absorption factors.

Risk Assessment for a Photo Imaging Site: Worked closely with the state to develop an acceptable screening protocol for the site. Compared site concentrations to state guidance numbers, background concentrations, and risk-based concentrations (RBCs). Evaluated risk associated with workers' exposure to chemicals in hot spots where concentrations exceeded the RBCs (cadmium, silver, and PAHs).

Evaluated ATSDR's Public Health Assessment for a Smelter Site: Conducted a detailed review of this document to assess its completeness and appropriateness for the site. Determined that a flawed RfD was used for zinc, exposure was based on a single maximum value, bioavailability of metals in soils was not considered, and site-specific data on the transfer of metals from soil to dust was not incorporated.

Site Risk Assessment: The risk assessment evaluated the risk separately for residents (both adults and children) who lived off-site, but may have recreated on-site; and for future residents (both children and adults) who may live on-site. Pathways evaluated included ingestion of soil, sediment, and surface water; groundwater ingestion; and dermal contact with groundwater and soil.

PCB Risk Assessment to Meet Clean Closure Requirements: The assessment evaluated future residential use of the area where houses may be built and groundwater wells may be drilled. Evaluated exposures, including leaching of PCBs to groundwater and subsequent ingestion in drinking water; soil ingestion; inhalation of PCBs; and dermal contact with PCB-containing soil.

Risk Assessment for Former Auto Manufacturing Site: Assessed the risk posed to five different groups of workers who may be exposed to chemicals in the soil and groundwater at the site. Chemicals of concern included metals, SVOCs (particularly PAHs), and VOCs. Risks at the site were driven by exposure to PAHs.

Risk Assessment for the Land Application of Sewage Sludge: Directed the compilation of a risk assessment that evaluated the impact of applying sewage sludge to both agricultural and nonagricultural land (*e.g.*, forests, reclamation sites, and public contact sites), for 14 pathways. The highly exposed individuals (HEIs) included humans, plants, and animals.

Workshop on Health Risks from Indoor Exposure to Gasoline Vapors: Attended the workshop and prepared a technical report on the levels of benzene and other volatile hydrocarbons in the home, the risk associated with exposure to benzene both at background and elevated levels, and US EPA regional approaches to assessing the risk to humans exposed to gasoline in the home.

Colloquium on Children as a Sensitive Subpopulation: Prepared a comprehensive report discussing the higher exposure that children have to some substances, the effect of children's longer remaining life span on increased incidence, metabolic differences in children, and higher sensitivity in children to the same internal dose (as adults).

Workshop on Toxicity Equivalency Factors for PCBs: Prepared a report on Toxicity Equivalency Factor (TEF) schemes for polychlorinated biphenyl (PCB) mixtures. Topics discussed included PCB mechanisms of action, PCB toxicity and exposure data, and analytical methods for measuring PCBs in human and environmental samples.

Ad Hoc Meeting on a Biologically Based Dose Response Model for Assessing Cancer Risks to Humans from Exposure to 2,3,7,8-TCDD: Prepared a summary report including the factors that must be accounted for in a biologically based risk assessment model for dioxin and the issues the meeting participants agreed on (*i.e.*, that TCDD is a promoter).

Workshop to Peer Review "Alpha-2μ-Globulin: Association with Renal Toxicity and Neoplasia in the Male Rat": Prepared a final workshop report summarizing the presentations and discussion on alpha-2μ-globulin accumulation and nephrotoxicity, mechanisms of carcinogenesis, design of studies for detection of toxic effects of CIGA, and risk assessment of nongenotoxic carcinogens.

Projects – *Environmental Health*

The Role of Health Research in Support of US EPA's Regulatory Programs: Prepared report describing US EPA's major regulatory programs, regulatory implementing regulations, rulemaking agenda, health research issues of utmost importance, and the research needed to address these issues.

Health Effects of Hazardous Air Pollutants (HAPs): Developed a detailed protocol and directed the compilation of a comprehensive data base containing the health effects of 173 hazardous air pollutants (HAPs) listed in the Clean Air Act Amendments (CAAA).

Inventory of Environmental Exposure Databases: Inventoried databases in the federal government to identify those containing environmental data that could be used in estimating human exposure to toxicants. Summarized results in a standard format. In addition, determined the chemicals included in each database and compiled them, by media and database, in a searchable data file.

Health Effects Research Laboratory Chemical Mixtures Strategy: Prepared a summary document that describes a research strategy for addressing important health issues in the study of chemical mixtures.

Support for US EPA Task Force for Comparative Risk Data and Methods Needs: Prepared a background report summarizing the comparative risk assessment reports and projects conducted by the Science Advisory Board and US EPA, both national and regional projects, and ideas on current and emerging comparative risk assessment data and methods.

Municipal Wastewater Disinfection Policy Development: Researched wastewater disinfection alternatives (*e.g.*, ozone, bromine chloride, and chloride dioxide), and determined the operation and maintenance issues, worker safety concerns, environmental impacts, and costs of using each disinfectant.

Colloquia on Uncertainties in Risk Assessment and Their Influence on Risk Management Decisions: Prepared a detailed technical and scientific report on the sources of uncertainty in risk assessments, methods for depicting and expressing uncertainty, approaches to quantitative uncertainty estimates, and the effects of uncertainty on risk management.

Lead-Based Paint Guidance Manual: Prepared a manual presenting technical guidelines for the testing and disposal of lead-based paint in HUD housing. The guidelines prescribe reliable testing methods for lead in paint and dust, safeguards to protect workers and building residents, and disposal methods.

Environmental Equity Workshop: Rewrote, critiqued, reorganized, and substantively edited the papers generated at the workshop. Topics included health risk from contaminated water by class and race, susceptibility to environmental pollutants among minorities, health status by social class and/or minority status, and community perspectives on health and research needs.

Analysis of Superfund Feasibility Studies (FS), Proposed Plans (PP), and Records of Decision (ROD) for Innovative Technology Selection: Provided technical support in analyzing approximately 225 documents to determine, for each site, what factors influenced the type of technologies selected.

In-Vessel Composting of Municipal Wastewater Sludge Handbook: Prepared technology transfer handbook describing in-vessel composting systems, and assessing their successes and failures.

Sludge Odor Control Guidelines: Assisted US EPA in developing a 100-page document describing odor control guidelines for large sewage sludge composting facilities. The document describes why sewage sludge composting produces odors, tells how to identify the odors and predict their movement, presents odor dispersion and scrubbing technologies, describes suitable monitoring, and presents case studies.

Evaluation of Laboratory Performance: Designed a statistical study to determine the intra-laboratory and inter-laboratory variation in the analyses of asbestos samples. Conducted sampling and managed round-robin analysis program in which multiple labs participated.

Health Research in the Federal Government: Surveyed the nature and scope of environmental health research conducted by several federal government agencies (*e.g.*, EPA, NIOSH, ATSDR), and summarized the results in a compendium document.

Projects – *Occupational Health & Safety*

Potential for Autoimmune Effects From Contact with Transmission Fluid: In a toxic tort case, an employee who was accidentally sprayed with transmission fluid, claimed that as a result, he had dermatomyositis and lupus. Gradient researched the toxicolgy literature to determine whether there was a credible link between transmission fluid and autoimmune diseases.

Degreaser Work Practices: Determined historical health and safety recommendations for working with degreasers containing perchloroethylene and trichloroethylene (*e.g.*, ventilation requirement, labeling, storage, solvent transfer, personal protective equipment).

Economic Analysis of the Revised General Industry Personal Protection Equipment (PPE) Standard, 29 CFR Part 1910.132-1910.14: Researched current PPE practices and prepared a cost-benefit and economic impact analysis for revisions to the OSHA standards for eye, face, head, and foot protection. Estimated the costs to industry of complying with new OSHA language, the benefits in terms of accident reduction expected from the changes, and the economic impacts to general industry. Performed numerous industry site visits as part of the data collection effort.

Economic Analysis of the OSHA Welding, Cutting, and Brazing Industry Standard: Evaluated the effects of revising the General Industry Standard for welding. The study encompassed the analysis of welding tasks throughout industry, the development and use of a database on welding accidents, the study of compliance costs, and the estimation of financial impacts.

Economic Evaluation and Environmental Assessment of Regulations Prohibiting Overboard Disposal of Nonbiodegradable Garbage: Investigated current waste disposal practices, determined the costs of various methods of compliance, defined the population of affected shipping and fishing interests, and estimated the environmental benefits of the regulation.

Assessment of Proposed Asbestos Regulation: Reviewed, critiqued, edited, and rewrote a document describing US EPA's methodology for analyzing the economic impact of a proposed program to regulate asbestos in public buildings the same way as asbestos is currently regulated in schools.

Process Safety Management Manual for Small Employers: Provided sections on how to conduct a process hazard analysis, the types of analysis techniques available, which techniques to use and why, examples of analyses, the costs of conducting these analyses, and how to set priorities.

Air Emission Evaluations: Evaluated numerous air emission problems, including collecting and analyzing samples and investigating possible sources of exposure and health effects of those exposures. Evaluations include machinists' exposure to oil mist, nitrosamines, and degreasing solvents; workers' exposure to gases and fumes from soldering and welding operations; and indoor air pollution surveys measuring organics, particulates, carbon dioxide, carbon monoxide, and formaldehyde.

New Jersey Turnpike Authority: Evaluated possible sources of adverse health effects reported by toll booth operators' by developing a questionnaire and conducting interviews, conducting a site investigation to identify possible toxicants/exposures, sampling for contaminants of concern (*e.g.*, carbon monoxide, lead, and organics), and evaluating the results.

Design and Implementation of Asbestos Removal Projects: For Center Plaza, managed asbestos abatement programs, including developing specifications, designing removal jobs, and inviting and evaluating bids, and negotiating prices. Supervised asbestos removal projects to ensure contractor compliance with contract documents, collected and analyzed air samples for asbestos, enforced regulations for worker health and safety, and conducted training sessions.

Asbestos Evaluation and Remediation: For the City of Manchester, NH, surveyed over 100 buildings to locate, sample, and evaluate asbestos. Developed recommendations regarding needed maintenance and remedial action, and assisted in designing removal projects. Supervised all removal projects to ensure compliance with regulations and contract provisions.

Indoor Air Quality Evaluations: Evaluated the indoor air quality for dozens of buildings including hospitals, schools, health centers, and offices buildings. The efforts included testing for total volatile organic compounds, particulates, carbon dioxide, carbon monoxide, and formaldehyde. In addition, the air exchange rates were measured and the adequacy of the ventilation system determined.

US EPA Indoor Air Quality Investigation at Waterside Mall: Evaluated EPA sampling results and wrote a case study assessing the indoor air quality problems experienced in US EPA's headquarters at Waterside Mall, including the health problems experienced by employees and the methods and results of the air and materials testing and ventilation surveys.

Indoor Air Quality Literature Search and Assessment: Performed a comprehensive computerized literature search for indoor air quality (IAQ) literature, and compiled the results in tables to indicate trends over the last 20 years.

Occupational Exposure to Asbestos: Conducted sampling to determine maintenance workers exposure to asbestos. Statistically analyzed results to determine compliance with OSHA regulations. Trained maintenance workers concerning the health hazards of asbestos, asbestos identification, paperwork methods (including glove bag removal and pipe repair), and the use of personal protective equipment.

"Right-to-Know" Training Programs: Developed and conducted "Right-to-Know" training programs including inventorying chemicals, evaluating their hazards, and conducting training sessions for industry. Also assisted in developing corporate implementation strategy.

Health and Safety Surveys: Conducted numerous in-depth health and safety surveys in manufacturing plants that fabricate gears, footwear, leather goods, computers, plastic products, roofing materials, metal fasteners, pickles, and potato chips.

System Hazard Analysis: Analyzed injection molding machines to determine the safety hazards the machines posed and the approaches that could be used to minimize those hazards.

Publications

Beyer, L; Greenberg, G; Beck, BD. 2013. "Evaluation of potential exposure to metals in laundered shop towels." *Hum. Ecol. Risk Assess.* In press.

Beyer, LA; Beck, BD; Lewandowski, TA. 2011. "Historical perspective on the use of animal bioassays to predict carcinogenicity: Evolution in design and recognition of utility." *Crit. Rev. Toxicol.* 41(4):321-338.

Lewis, AS; Beyer, LA; Langlois, CJ; Yu, CJ; Wait, AD. 2008. "Considerations in toxicology study design and interpretation: An overview." *Inside Aloe Online – The Official Publication of the IASC*, August 15.

Rhomberg, LR; Bowers, TS; Beyer, LA; Goodman, JE. 2008. "Comment on 'Residential and biological exposure assessment of chemicals from a wood treatment plant' by James Dahlgren *et al.*" *Chemosphere* 70(9):1730-1733.

Goodman, JE; Gaylor, D; Beyer, LA; Rhomberg, LR; Beck, BD. 2008. "Effects of MTBE on the reported incidence of Leydig cell tumors in Sprague-Dawley rats: Range of possible Poly-3 results." *Regul. Toxicol. Pharmacol.* 50:273-284.

Beyer, LA; Seeley, M; Beck, BD. 2003. "Evaluation of potential exposure to metals in laundered shop towels." *INJ,* winter. Accessible at http://www.inda.org/subscrip/inj03_4/p22-37-beyer.pdf.

Beyer, LA; Beck, BD. 1998. "Confronting challenges in integrated risk assessment." *Environ. Compliance & Litigation Strategy* 14(5):3-4.

Presentations

Beyer, LA; Greenberg, GI; Beck, BD. 2012. "Evaluation of Potential Exposure to Metals in Laundered Shop Towels." 2012. *Toxicologist* 126 (1) : 454. Abstract No. 2107. Presented at Society of Toxicology 51st Annual Meeting, San Francisco, CA, March 14.

Beyer, LA; Mattuck, RL; Thakali, S; Beck, BD. 2011. "A Comparative Risk Evaluation of MTBE and Other Compounds (Including Naturally Occurring Compounds) in Drinking Water in New Hampshire." Presented at Society of Toxicology 50th Annual Meeting, Washington, DC, March 8. *Toxicologist - Supplement to Toxicological Sciences* 120(Suppl. 2):418.

Seeley, M; Beyer, LA; Beck, BD. 2011. "Is MTBE genotoxic or mutagenic?" Presented at Society of Toxicology 50th Annual Meeting, Washington, DC, March 8. *Toxicologist - Supplement to Toxicological Sciences* 120(Suppl. 2):417.

Beyer, LA; Rhomberg, LR; Hamade, AK; Beck, BD. 2010. "Evaluation of Recent Information on Carcinogenicity of Perchloroethylene (PCE) in Humans." Presented at the Society of Toxicology 49th Annual Meeting and ToxExpo, Salt Lake City, UT, March 10.

Beyer, LA; Beck, BD; Goodman, JE. 2009. "Background Rates of Lymphomas/Leukemias and Leydig Cell Tumors in Sprague-Dawley rats." Presented at the Society of Toxicology 48th Annual Meeting and ToxExpo, Baltimore, MD, March 19.

Beyer, LA; Slayton, TM; Goodman, JE; Greenberg, GI; Hudson, TC; Beck, BD. 2008. "Evaluation of Key Information Informing the Basis of EPA's New Recommended Ozone Standard." Presented at the Society of Toxicology 47th Annual Meeting and ToxExpo, Seattle, WA, March 20.

Lewis, AS; Beyer, LA; Beck, BD. 2008. "Evaluating the Toxicological Significance of Endpoints from Human and Animal Studies: Using Perfluorinated Compounds (PFCs) as an Example." Presented at the Society of Toxicology 47th Annual Meeting and ToxExpo, Seattle, WA, March 18.

Beyer, LA. 2007. "Structure-Function Claim Development & Substantiation in a Competitive World." American Herbal Products Association Tele-Seminar: Structure/Function Claims: How to Craft Smart and Lawful Marketing Info and Labels. June 28.

Beyer, LA; Goodman, JE; Seeley, M; Slayton, TM; Beck, BD. 2007. "Carcinogenicity Evaluation of Methyl Tert-Butyl Ether (MTBE)." Presented at the Society of Toxicology 46th Annual Meeting and ToxExpo, Charlotte, NC, March 28.

Beyer, LA; Seeley, M; Beck, BD. 2007. "Margin of Exposure Analysis for MTBE in Drinking Water." Presented at the Society of Toxicology 46th Annual Meeting and ToxExpo, Charlotte, NC, March 28.

Beyer, LA; Goodman, JE; Rhomberg, LR; Gaylor, D; Beck, BD. 2007. "MTBE is not Associated with a Statistically Significant Increase in Leydig Cell Tumors in Sprague-Dawley Rats." Presented at the Society of Toxicology 46th Annual Meeting and ToxExpo, Charlotte, NC, March 28.

Beyer, LA; Long, CM; Beck, BD; Slayton, TM. 2006. "Ambient Concentrations of Benzene are Below Those Associated with Significant Cancer Risk." Presented at the Society of Toxicology 45th Annual Meeting, San Diego, CA, March 9.

Beyer, LA; Beck, BD. 2005. "Glass Bead Inhalation and Induction of Silicosis." Presented at the Society of Toxicology 44th Annual Meeting, New Orleans, LA, March 9.

Lewandowski, TA; Beck, BD; Beyer, LA; Rhomberg, LR. 2005. "A Historical Perspective on Long-term Animal Bioassays." Presented at the Society of Toxicology 44th Annual Meeting, New Orleans, LA, March 7.

Beyer, LA; Seeley, MR; Beck, BD. 2004. "Evaluation of Exposure to Metals on Reusable Shop Towels." Presented at the Society of Toxicology 43rd Annual Meeting, Baltimore, MD, March 22.

Beyer, LA; Beck, BD. 2003. "Derivation of Air Action Levels for Use in Monitoring During Site Remediation." Presented at the Society of Toxicology 42nd Annual Meeting, Salt Lake City, UT, March 13. *The Toxicologist* 72(S-1):395.

Beyer, LA; Beck, BD; Chan, KW. 2002. "Assessment of 'All Cancers' in Dioxin Epidemiology Studies." Presented at the Society of Toxicology 41st Annual Meeting, Nashville, TN, March 19. *The Toxicologist* 66(1):158.

Chan, KW; Beyer, LA; Beck, BD. 2002. "Assessment of Benzene Carcinogenic Potential in Humans." Presented at the Society of Toxicology 41st Annual Meeting, Nashville, TN, March 19. *The Toxicologist* 66(1):159.
Received award for "Best Posters in Risk Assessment" at 2002 Society of Toxicology Meeting.

Beyer, LA; Beck, BD; Maier, WE. 1999. "Is Perchloroethylene (Perc) a Probable Carcinogen in Humans?" Presented at the Society of Toxicology 38th Annual Meeting, New Orleans, LA, March 17. *The Toxicologist* 48(1-S):343.

Beyer, LA. 1998. "Classification of Perchloroethylene (Perc) as a Probable Human Carcinogen: Is it Supported by the Data?" Presented at the 8th International Congress of Toxicology (ICT VIII), Paris, France, July 6.

Beyer, LA; Beck, BD; Cohen, JT; Valberg, PA. 1997. "Key Issues Raised by EPA's Proposed Ozone Standards and Supporting Analysis." Presented at the Society for Risk Analysis Annual Meeting and Exposition, Washington, DC, December 8.

Beck, BD; Boardman, PD; Beyer, LA; Cohen, JT; Hiller, D. 1995. "Validation of an Arsenic Exposure Model at a Mining and Milling Site through Urinalysis." Presented at the Society for Environmental Geochemistry and Health International Arsenic Conference, San Diego, CA.

Cohen, JT; Beck, BD; Boardman, PD; Beyer, LA. 1995. "Use of an Arsenic Exposure Model at a Gold Mining and Milling Site." Presented at the Society for Environmental Geochemistry and Health International Arsenic Conference, San Diego, CA.

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Areas of Expertise

Air quality and environmental health, with expertise in exposure assessment, indoor/outdoor air pollution, inhalation risk assessment and toxicology, particulate matter, and air sampling/modeling.

Education

Sc.D., Environmental Health, Harvard School of Public Health, 2001.

M.S., Environmental Engineering, Massachusetts Institute of Technology, 1995.

A.B., Chemistry and Environmental Studies, *summa cum laude*, Bowdoin College, 1993.

Professional Experience

2000 – Present GRADIENT, Cambridge, MA
Principal Scientist, Air Quality & Environmental Health. Evaluate human exposures and health effects of environmental pollutants, specializing in airborne gases and particles. Investigate indoor and outdoor air quality problems, and perform air sampling and exposure modeling. Conduct human health risk assessments, consumer product safety assessments, and worker safety evaluations; review and interpret epidemiological and toxicological studies. Prepare technical analyses, expert reports, and risk communication materials. Co-director of Gradient's Nanotechnology Risk practice area and Associate Editor of Gradient's newsletter on the environmental health and safety of nanotechnology, *EH&S Nano News*.

1997 – 2000 HARVARD SCHOOL OF PUBLIC HEALTH, Boston, MA
Research/Teaching Assistant. Designed and conducted indoor air particle characterization study of Boston-area homes. Also served as teaching assistant for two graduate courses: Seminar in Risk Analysis, Management, and Communication and Air Pollution: Particles and Gases.

1995 – 1997 MENZIE-CURA & ASSOCIATES, INC., Chelmsford, MA
Environmental Scientist/Risk Assessor. Conducted human health and ecological risk assessments for state and federal hazardous waste sites. Modeled fate and transport of organic and inorganic contaminants in all environmental media. Responsibilities also included project management, proposal writing, and litigation support. Participated in environmental site assessments and field sampling activities of aquatic and terrestrial habitats. OSHA-certified 40-hour training.

1993 – 1995 MASSACHUSETTS INSTITUTE OF TECHNOLOGY, Cambridge, MA
Research Assistant. Conducted research in trace organic pollutant laboratory. Modeled the fate and transport of sewage-derived linear alkylbenzenes (LABs) in the Gulf of Maine.

1992 NASA GODDARD SPACE FLIGHT CENTER, Greenbelt, MD
Research Assistant. Selected as summer intern in Summer Institute on Atmospheric and Hydrospheric Sciences; worked with atmospheric scientists in GSFC's Atmospheric Chemistry and Radiation Branch. Used a photochemical box model to explore the potential for ozone depletion in the Northern Hemisphere stratosphere at middle and low latitudes.

Professional Activities

- Member of City of Cambridge Nanomaterials Advisory Committee (NAC).
- Invited technical peer reviewer for the *Journal of the Air & Waste Management Association, Environmental Science & Technology, Atmospheric Environment, Environmental Health Perspectives, Environmental Forensics, Science of the Total Environment, Journal of Occupational and Environmental Medicine, and Journal of Exposure Science and Environmental Epidemiology.*
- Invited member of the National Institute of Environmental Health Sciences (NIEHS) Special Emphasis Panel ARRA- Standardized Testing of Nanoparticles for Their Safety to Human Health
- Co-Editor, Dose-Response, Special Issue on Nanotoxicology, 2009-2010.

Awards/Honors

- US EPA STAR Graduate Fellow, 1998-2000.
- *Phi Beta Kappa.*
- Student abstract/presentation award at 1999 ISEA/ISEE Annual Conference in Athens, Greece.
- 2009 World of Coal Ash (WOCA) Poster Award for Excellence in the Field of Coal Ash Research.

Professional Affiliations

American Chemical Society (ACS); International Society of Exposure Science (ISES); Air & Waste Management Association (AWMA)

Projects

University of Washington: Analyzed $PM_{2.5}$ air quality data collected in the vicinity of a large construction project and assessed the health implications for children at the university's daycare center across the street from the project. Met with parents and staff of the daycare center to discuss findings from our evaluation. Made recommendations for additional air monitoring activities.

Personal Care Products Company: Conducted a safety assessment for synthetic amorphous silica (SAS), including nanoscale forms, used as an ingredient in a cosmetics product. Prepared a safety dossier consistent with 2012 guidance from the European Commission Scientific Committee on Consumer Safety (SCCS) for the safety assessment of nanomaterials in cosmetics.

Coal Processing Facility: For a toxic tort, analyzed ambient particulate matter monitoring data, assessing the appropriateness of the measurement method, how the measured levels compared to background exposure levels, and implications for potential community exposures to coal dust. Provided deposition and trial testimony.

Electric Power Research Institute (EPRI): Evaluated potential inhalation risks from mercury associated with the beneficial use of coal combustion products in wallboard, concrete, and structural fill. Characterized indoor off-gassing of Hg from building materials, as well as ambient mercury volatilization and wind-blown dust emissions for coal ash structural fills.

State of Maine: Wrote indoor sampling guidance for a trial guideline for protecting residents from inhalation exposure to indoor petroleum vapors released from home fuel oil spills.

Metropolitan District Commission (MDC): Performed mass balance calculations for mercury in Western Massachusetts' Wachusett and Quabbin Reservoirs. Wrote technical report on environmental Hg cycling.

Coal Producing Company: For multiple toxic tort cases alleging health claims associated impacts of coal slurry operations on drinking water from domestic wells, evaluated exposures and potential health risks associated with inhalation of low levels of hydrogen sulfide during water use. Assessed the health effects evidence for H_2S health effects and the relationship between H_2S odors and health effect levels.

Confidential Client: Prepared technical analysis of fate and transport of zinc and fluoride emissions in subsurface environment for an aluminum manufacturing facility. Evaluated fluoride toxicity to aquatic organisms and livestock and developed ambient water quality criteria based on US EPA guidelines.

Air Purifier Manufacturer: Evaluated potential exposures and health effects associated with usage of ozone-generator air purifiers. Reviewed extensive body of epidemiological studies of ozone health effects. Assisted client in development of health-related labeling for their products.

New Mexico Environment Department: Prepared an acute health risk assessment for measured and modeled concentrations of 80 airborne chemicals as detected or predicted for a suburb of Albuquerque, NM.

Large Midwestern Farm: Conducted air sampling and performed air dispersion modeling analysis to estimate the air quality impacts of H_2S emissions from a large Ohio hog farm.

Health Effects Institute: Compiled comprehensive database of outdoor and indoor exposure concentrations for US EPA-designated mobile source air toxics (MSATs).

Printer Manufacturer: Designed a comprehensive measurement program to assess potential exposures associated with use of a commercially available printer. Assessed toxicological significance of indoor air and surface wipe measurements.

USDOJ: In support of litigation, assessed the exposure potential and public health impacts associated with airborne releases of asbestos from asbestos cement pipe fragments in an Illinois wetland.

Private Law Firm: Provided litigation support regarding residual asbestos contamination associated with the World Trade Center disaster on several floors of a Manhattan commercial office building. Assessed the adequacy of the testing protocols used to support re-occupancy of the building, and evaluated the level of health protection provided by asbestos clearance levels.

Private Law Firm: For a wrongful death case, analyzed available data on particulate matter (PM) levels associated with wood combustion in outdoor wood-fired boilers (OWBs) and evaluated the health effects evidence linking woodsmoke exposure with acute myocardial infarction. Provided scientific opinions regarding the relative toxicity of woodsmoke PM as compared to other types of PM with respect to cardiovascular health outcomes.

Salem and Beverly Water Supply Board: Conducted a human health and ecological risk assessment to characterize risks associated with disposal of arsenic-contaminated water treatment plant sedimentation residuals in a marsh adjacent to the Wenham Lake Reservoir, which is the source of drinking water for the towns of Salem and Beverly, MA.

Private Law Firm: Assisted in assessment of potential exposures to lead in air and residential yard soils alleged to have been derived from former mine waste piles. Evaluated the potential for wind-blown dust emissions of lead from mining residuals and conducted air dispersion modeling analysis to estimate airborne dust deposition. Compared predicted deposition patterns with the observed lead measurements in residential yard soils.

Private Law Firm: Designed and implemented an indoor/outdoor $PM_{2.5}$ sampling program in residential homes near a large industrial facility to investigate source contributions to residential particulate matter exposures. Prepared expert reports and provided deposition testimony.

Electric-Power Generating Companies: Prepared technical analyses on exposures and potential health effects associated with particulate matter from airborne emissions of coal-fired electric utility power generating plants.

Engine Manufacturers Association: Conducted reviews of various scientific and regulatory reports pertaining to the $PM_{2.5}$ National Ambient Air Quality Standards, and prepared written comments.

Private Law Firm: Provided litigation support for a class action lawsuit involving alleged health and environmental damages at a large lake associated with mercury emissions from several coal-fired power plants. As part of this multidisciplinary effort, conducted an air modeling analysis of mercury emissions, dispersion, and deposition from the power plants using the US EPA regulatory air models CALPUFF and ISCST3 and used the model results to assess the power plant impacts relative to other local/regional/global mercury sources.

Oakland County, MI: Prepared technical analyses of $PM_{2.5}$ measurement and meteorological data in support of the Oakland County, MI petition for reconsideration of US EPA's $PM_{2.5}$ non-attainment designation.

Private Law Firm: Provided expert witness testimony regarding the standard of care related to air quality management at a primary lead smelter.

Private Law Firm: Conducted an analysis of the possible relationship between exposures to indoor latex aeroallergens in healthcare settings and risk of adverse health effects.

PG&E National Energy Group: Prepared a multi-pathway (inhalation of wind-blown dust and vehicle-generated fugitive dust, incidental ingestion, dermal contact) human health risk assessment evaluating potential exposures of nearby residents to trace metals from a coal ash disposal site. Prepared technical analyses and public communication materials regarding coal ash disposal and beneficial usage.

Large Electrical Utility: Performed a health risk evaluation of the possible relationship between measured airborne concentrations of sulfuric acid and sulfur dioxide in vicinity of a large coal-fired power plant and acute health symptoms (e.g., irritation of the eyes, nose, and throat; shortness of breath; asthma-like symptoms). Reviewed regulatory, medical, and research information on the potential health effects of sulfur dioxide and sulfuric acid. Prepared both a technical report and a public communication document.

International Carbon Black Association: Provided analyses of health effects data on carbon black, a manufactured substance generated as an airborne fine particulate aggregate of nano-sized subunits of elemental carbon. Reviewed toxicological and epidemiological studies of carbon black exposed populations, and evaluated the evidence for the carcinogenicity of carbon black. Co-authored a peer-reviewed publication summarizing the findings of our analysis.

Renewable Energy Company: Conducted a human health risk assessment to support the permitting process for a biomass burning power plant. Assessed potential cancer and non-cancer risks from inhalation of criteria air pollutants and air toxics in stack emissions from the plant.

Large Oil Refinery: Conducted review of a human health risk assessment conducted for communities nearby by to a large Canadian oil refinery. Identified health-protective standards and guidelines for refinery emissions, including for short-term SO_2 exposures.

Publications

Beck, BD; Long, CM; Seeley, MR; Nascarella, MA. 2012. "A special issue on nanomaterial regulations and health effects." *Dose Response* 10:306-307.

Long, CM; Sax, SN; Lewis, AS. 2012. "Potential indoor air exposures and health risks from mercury off-gassing of coal combustion products (CCPs) used in building materials." *Coal Combustion and Gasification Products* 4: 68-74.

Hesterberg, TW; Bunn, WB, III; Slavin, TJ; Malcore, J; Porter, ME; Harrison, EB; Grasso, NC; Long, CM. 2012. "Sustainability at Navistar: A model distinguished by sustainable innovation, proactive product stewardship, and sound science." *International Journal of Sustainable Strategic Management* 3(3): 248-268.

Hesterberg, TW; Long, CM; Bunn, WB; Lapin, CA; McClellan, RO; Valberg, PA. 2012. "Health effects research and regulation of diesel exhaust: an historical overview focused on lung cancer risk." *Inhalation Toxicology*. 24(S1):1-45.

McCunney, RJ; Muranko, HJ; Long, CM; Hamade, AK; Valberg, PA; Morfeld, P. 2012. "Carbon black." In *Patty's Toxicology, Sixth Edition* (Vol. 5). (Ed.: Bingham, E; Cohrssen, B), John Wiley & Sons, Inc., New York, NY, p429-454.

Hesterberg, TW; Bunn, WB; Valberg, PA; Long, CM. 2012. "Potential health effects of exposure to diesel engine exhausts." In *The Praeger Handbook of Environmental Health: Water, Air, and Solid Waste* (Vol. 3). (Ed: Friis, RH), Praeger, ABC-CLIO, LLC, Santa Barbara, CA, p185-212.

Valberg, PA; Long, CM. 2012. "Do brain cancer rates correlate with ambient exposure levels of criteria air pollutants or hazardous air pollutants (HAPs)?" *Air Quality, Atmosphere and Health*. 5:115-123.

Hesterberg, TW; Long, CM; Sax, SN; Lapin, CA; McClellan, RO; Bunn, WB; Valberg, PA. 2011. "Particulate matter in New Technology Diesel Exhaust (NTDE) is quantitatively and qualitatively very different from that found in Traditional Diesel Exhaust (TDE)." *J. Air & Waste Manage. Assoc.* 61(9): 894-913.

Rhomberg, LR; Chandalia, JK; Long, CM; Goodman, JE. 2011. "Measurement error in environmental epidemiology and the shape of exposure-response curves." *Crit. Rev. Toxicol.* 41(8):651-71.

Hesterberg, TW; Long, CM; Lapin, CA; Hamade, AK; Valberg, PA. 2010. "Diesel exhaust particulate (DEP) and nanoparticle (NP) exposures: What do DEP human clinical studies tell us about potential human health hazards of nanoparticles?" *Inhalation Toxicology* 22:679-694.

Hesterberg, TW; Bunn, WB; McClellan, RO; Hamade, AK; Long, CM; Valberg, PA. 2009. "Critical review of the human data on short-term nitrogen dioxide (NO_2) exposures: evidence for NO_2 no-effect levels." *Critical Reviews in Toxicology* 39(9):743-81.

Long, CM; Beck, BD. 2009. "Study of Chinese print workers claims to provide the first human evidence of the clinical toxicity of long-term nanoparticle exposures." *InterNano* [online newsletter]. Accessed from http://www.internano.org/content/view/306/1/, October 29.

Hesterberg, T; Valberg, P; Long, C; Bunn, W; Lapin, C. 2009. "Laboratory studies of diesel exhaust health effects: Implications for near-roadway exposures." *EM Magazine, Air & Waste Management Association*, 12-16.

Hesterberg, TW; Long, CM; Bunn, WB; Sax, SN; Lapin, CA; Valberg, PA. 2009. "Non-cancer health effects of diesel exhaust (DE): A critical assessment of recent human and animal toxicological literature." *Critical Reviews in Toxicology* 39(3):195-227.

Valberg, PA; Long, CM; Hesterberg, TW. 2008. Comment on the nanoparticle conclusions in Cruts *et al.* (2008), "Exposure to diesel exhaust induces changes in EEG in human volunteers." *Part Fibre Toxicol.* 5(1):10.

Long, CM. 2008. "Development and application of an exposure-based framework for assessing nanomaterial safety." In *Nanotechnology 2008: Life Sciences, Medicine & Bio Materials - Technical Proceedings of the 2008 NSTI Nanotechnology Conference and Trade Show, Volume 2*, p134-137.

Long, CM; Valberg, PA. 2007. Comment on "An assessment of risk from particulate released from outdoor wood boiler" by Brown *et al. Human and Ecological Risk Assessment* 13:681-685.

Valberg, PA; Long, CM; Sax, SN. 2006. "Integrating studies on carcinogenic risk of carbon black: Epidemiology, animal exposures, and mechanism of action." *Journal of Occupational and Environmental Medicine* 48(12):1291-1307.

Valberg, PA; Long, CM. 2006. Comment on "Vehicle self-pollution intake fraction: Children's exposure to school bus emissions." *Environmental Science & Technology* 40(9):3123.

Long, CM; Seeley, M; Beck, BD. 2005. "Tiny particles, large data gaps: A risk assessment perspective on nanotechnology." *Risk Policy Report* 12:12-14.

Long, CM; Sarnat, JA. 2004. "Indoor-outdoor relationships and infiltration behavior of elemental components of outdoor $PM_{2.5}$ for Boston-area homes." *Aerosol Science & Technology* 38(S2):91-104.

Sarnat, JA; Long, CM; Koutrakis, P; Coull, BA; Schwartz, J; Suh, HH. 2002. "Using sulfur as a tracer of outdoor fine particulate matter." *Environ. Sci. Technol.* 36:5305-5314.

Long, CM; Suh, HH; Kobzik, L; Catalano, PJ; Ning, Y; Koutrakis, P. 2001. "A pilot investigation of the relative toxicity of indoor and outdoor fine particles: *In vitro* effects of endotoxin and other particulate properties." *Environ. Health Perspect.* 109(10):1019-1026.

Long, CM; Suh, HH; Koutrakis, P. 2001. "Using time- and size-resolved particulate data to quantify penetration and deposition behavior." *Environ. Sci. Technol.* 25:2089-2099.

Gustafsson, Ö; Long, CM; MacFarlane, J; Gschwend, PM. 2001. "Fate of linear alkylbenzenes (LABs) released to the coastal environment near Boston Harbor." *Environ. Sci. Technol.* 25:2040-2048.

Long, CM; Suh, HH; Koutrakis, P. 2000. "Characterization of indoor particle sources using continuous mass and size monitors." *J. Air & Waste Manage. Assoc.* 50:1236-1250.

Menzie, CA; Freshman, JS; Long, CM. 1997. "Developing Environmentally Acceptable Endpoints for Soil Based on Ecological Considerations." In *Proceedings for the Air & Waste Management Association's 90th Annual Meeting & Exhibition, Toronto, Ontario*, June 8-13.

Presentations

Peterson, M; Valberg, P; Long, C. 2013. "The association of vascular disease with exposure to diesel exhaust." Presented at Society of Toxicology 52nd Annual Meeting, San Antonio, TX, March 10-14. *Toxicologist* 132(1):244.

Long, CM; Nascarella, MA; Valberg, PA. 2012. "Manufactured Carbon Black Differs in Physical-Chemical Properties and Biological Activity from Ambient Black Carbon, Soots, and Other Carbon-Containing Inhalable Particles." Poster Presentation at the 22nd Annual Conference of the International Society of Exposure Science (ISES), Seattle, WA, October 28-November 1.

Calabrese, PJ; Long, CM; Nascarella, MA; Niehaus, SE. 2011. "Nanotechnology Litigation to Come: A Case Study." One-hour audio briefing, Practising Law Institute (PLI), September 12.

Long, CM; Lewis, AS; Sax, SN. 2011. "Indoor Air Inhalation Risks of Mercury Off-gassed from Building Materials Containing Coal Combustion Products (CCPs)." Platform Presentation at the Air & Waste Management Association's Annual Conference & Exhibition, Orlando, FL, June 21-24.

Hesterberg, TW; Bunn, WB; Long, CM; Sax, SN; Valberg, PA; Lapin, CA. 2011. "New Technology Diesel Exhaust (NTDE) Is Distinctly Different From Traditional Diesel Exhaust (TDE)." Platform Presentation at the Air & Waste Management Association's Annual Conference & Exhibition, Orlando, FL, June 21-24.

Hesterberg, TW; Long, CM; Hamade, AK; Valberg, PA; Lapin, CA. 2011. "Human Health Risks of Diesel Exhaust Particulate (DEP): Implications for Engineered Nanoparticle (NP) Exposures." Platform Presentation at the Air & Waste Management Association's Annual Conference & Exhibition, Orlando, FL, June 21-24.

Hesterberg, TW; Long, CM; Sax, SN; Lapin, CA; Bunn, WB; Valberg, PA; McClellan, RO. 2011. "Human Health Hazards of Exposure to New Technology Diesel Exhaust (NTDE)" Poster Presentation at the Health Effects Institute (HEI) Annual Conference, Boston, MA, May 1-3.

Valberg, PA; Hesterberg, TW; Long, CM; Lapin, CA; Hamade, AK. "Human Clinical Studies of Diesel Exhaust Particulate and Implications for Nanoparticle Exposures." Poster Presentation at the 50th Annual Meeting of the Society of Toxicology, Washington, DC, March 6-10.

Valberg, PA; Long, CM. 2010. "Do Brain Cancer Rates Correlate with Ambient PM-levels or with Hazardous Air Pollutant (HAP) Concentrations?" Platform presentation at the 2010 American Association for Aerosol Research (AAAR) Air Pollution and Health Meeting, San Diego, CA, March 22-26.

Long, CM; Lewis, AS; Sax, SN. 2009. "Mercury Inhalation Risks in Indoor Air from Use of Coal Combustion Products (CCPs) in Building Materials." Poster Presentation at the World of Coal Ash (WOCA) 2009 Conference, Lexington, KY, May 4-7.

Lewis, AS; Sax, SN; Long, CM. 2009. "Mercury Inhalation Risks from Use of Coal Combustion Products (CCPs) as Structural Fill and from Disposal of CCP-Containing Wallboard and Concrete in Landfills." Poster Presentation at the World of Coal Ash (WOCA) 2009 Conference, Lexington, KY, May 4-7.

Sax, SN; Lewis, AS; Long, CM. 2009. "Inhalation Risks of Mercury from Use of Coal Combustion Products (CCPs) as Structural Fill and from Disposal of CCP Building Materials in Landfills." Poster Presentation at the 48th Annual Meeting of the Society of Toxicology, Baltimore, MD, March 15-19.

Long, CM; Lewis, AS; Sax, SN. 2009. "Inhalation Risks of Mercury in Indoor Air from Beneficial Use of Coal Combustion Products (CCPs) in Building Materials." Poster Presentation at the 48th Annual Meeting of the Society of Toxicology, Baltimore, MD, March 15-19.

Hesterberg, TW; Lapin, CA; Long, CM; Valberg, PA. 2009. "Diesel-Exhaust Particulate (DEP) and Nanoparticle (NP) Exposures: Can DEP Tell Us About Potential Health Risks of NP?" Poster Presentation at the 48th Annual Meeting of the Society of Toxicology, Baltimore, MD, March 15-19.

Long, CM; Valberg, PA. 2008. "How Close Are We to Predicting the Toxic Potential of Engineered Nanomaterials Based on Physical-Chemical Properties?" Platform presentation at the 2008 Annual Meeting of the Society of Risk Analysis (SRA), Boston, MA, December 10.

Long, CM. 2008. "Development and Application of an Exposure-based Framework for Assessing Nanomaterial Safety." Poster presentation at the 11th Annual Nano Science and Technology Institute (NSTI) Nanotechnology Conference and Trade Show, Boston, MA, June 1-5.

Long, CM; Hakkinen, PJ; Valberg, PA. 2007. "Do We Know Enough to Apply the 'No Exposure, No Risk' Paradigm in Safety Assessments of Nanotechnology-Based Consumer Products?" Platform presentation and Session Chair for Oral Session: Exposure Processes for Manufactured Nanoparticles at 2007 International Society of Exposure Assessment (ISEA) Annual Conference, Research Triangle Park, NC, October 14-18.

Long, CM; Drivas, PJ. 2007. "Characterizing Airborne Hydrogen Sulfide Exposure Levels near a Midwestern Concentrated Animal Feeding Operation (CAFO) Using Both Measurement Data and Air Dispersion Modeling." Platform presentation at 2007 International Society of Exposure Assessment (ISEA) Annual Conference, Research Triangle Park, NC, October 14-18.

Valberg, P; Sax, S; Long, C. 2006. "Inhalation Health Risk Assessment: Extrapolating from Macromaterials to Nanomaterials." Poster presentation at Overcoming Obstacles to Effective Research Design in Nanotoxicology, Cambridge, MA, April 24-25.

Beyer, LA; Long, CM; Beck, BD; Slayton, TM. 2006. "Ambient Concentrations of Benzene are Below Associated with Significant Cancer Risk." Presented at the Society of Toxicology 45th Annual Meeting, San Diego, CA, March 5-9.

Long, CM. 2005. "Measurement, Fate, and Exposure Potential of Ultrafine Particles in Indoor Air: Lessons Learned for Nanotechnology." Poster presentation at 2nd International Symposium on Nanotechnology and Occupational Health, Minneapolis, MN, October 3-6.

Long, CM. 2004. "Indoor Ultrafine Particle Exposures: Small Particles, Large Data Gaps." Poster presentation at 2004 International Society of Exposure Assessment (ISEA) Annual Conference, Philadelphia, October 17-21.

Valberg, PA; Long, CM. 2003. "Is PM More Toxic than the Sum of its Parts? Discordance between 'Effect Functions' for PM Mass *vs.* Risk-Assessment Toxicity Factors." Poster presentation at 2003 AAAR PM Meeting: Particulate Matter: Atmospheric Sciences, Exposure and the Fourth Colloquium on PM and Human Health, Pittsburgh, PA, March 31-April 4.

Long, CM; Beck, BD. 2002. "An Evaluation of Potential Human Exposures to Trace Metals and Radionuclides in Construction and Building Materials Containing Coal Combustion Products." Poster presented at 2002 International Society of Exposure Assessment (ISEA)/International Society of Environmental Epidemiology (ISEE) Annual Conference, Vancouver, BC, August 11-15.

Long, CM; Suh, HH; Koutrakis, P. 2001. "Understanding Indoor Exposures to Ambient Particulate Matter: Estimates of Penetration Efficiencies and Deposition Rates for Residential Homes." Poster presented at the 2001 Society for Risk Analysis Annual Meeting, Seattle, WA, December 2-5.

Sarnat, JA; Long, CM; Koutrakis, P; Suh, HH. 2001. "Evaluating Tracers of Ambient $PM_{2.5}$." Platform presentation at the ISEA 2001 Conference, Charleston, SC, November 4-8.

Long, CM; Suh, HH; Koutrakis, P. 2000. "Using Time- and Size-Resolved Particulate Data to Investigate Infiltration and Deposition Behavior." Platform presentation at the ISEA 2000 Conference, Monterey Peninsula, CA, October 24-27.

Long, CM; Suh, HH; Koutrakis, P. 2000. "Using Time- and Size-Resolved Particulate Data to Investigate Infiltration and Deposition Behavior." Platform presentation at the AWMA PM2000 Specialty Conference, Charleston, SC, January 24-28.

Long, CM; Suh, HH; Koutrakis, P. 2000. "Characterization of Indoor Particle Sources Using Continuous Mass and Size Monitors." Poster presentation at the AWMA PM2000 Specialty Conference, Charleston, SC, January 24-28.

Long, CM; Suh, HH; Koutrakis, P. 1999. "Characterization of Indoor Particulate Source Strengths Using Continuous Mass and Size Monitors." Platform presentation at 1999 Annual ISEE/ISEA Conference, Athens, Greece, September 5-8.

Bernays, WH; Vorhees, DJ; Long, CM; Eremita, P. 1997. "Trial Guideline for Protecting Residents from Inhalation Exposure to Petroleum Vapors." Poster presentation at 1997 Annual Meeting of the Society for Risk Analysis, Washington, DC, December 7-10.

Invited Presentations and Lectures

Long, CM. 2009. "Nanotechnology: What You Should Know to Avoid Liability." Lecture given at the 21st Annual Product Liability Conference, University of Wisconsin-Madison Department of Engineering Professional Development, September 22-24.

Lewis, AS; Long, CM; Sax, SN. 2009. "Evaluation of Mercury Risks from Building Materials Containing CCPs and Opportunities for Risk Communication." Presented at the American Coal Ash Association (ACAA) 2009 Membership Meeting "Advancing the Management & Use of Coal Combustion Products," Phoenix, AZ, January 20-21.

Long, CM. 2008. "The State of the Science on Exposure Assessment of Engineered Nanoparticles: Challenges, Progress, Opportunities." Invited presentation at the November 2008 meeting of the Society of Risk Analysis – New England Chapter (SRA-NE) on Nanomaterials, Nanotoxicology, and Risk Assessment, Boston, MA, November 19.

Long, CM. 2007. "Development and Application of an Exposure-Based Framework for Assessing Nanomaterial Safety." Speaker and panelist, NanoTX '07 Conference and Expo, Environmental, Health & Safety Summit, Dallas, TX, October 2-4.

Long, CM. 2006. "Particulate Matter Exposure Assessment: State of the Science and New Challenges." BU School of Public Health, Environmental Health Seminar Series, September 29.

Long, CM. 2006. "Air Quality Exposure Assessment: Challenges Posed by Ambient Particles and Engineered Nanoparticles." Massachusetts Institute of Technology (MIT) Course 1.082 Air Pollution, April 26.

Long, CM. 2006. "Indoor Ultrafine Particle Exposures: Small Particles, Large Data Gaps." Poster presentation at the US EPA Board of Scientific Counselors (BOSC) Science To Achieve Results (STAR)/Greater Research Opportunities (GRO) Fellowship Subcommittee Meeting, Washington, DC, March 2-3.

Long, CM; Sarnat, JA. 2003. "Infiltration Behavior of $PM_{2.5}$ Chemical Components: Implications for Exposure Assessment and Epidemiological Associations." Platform presentation at the Particulate Matter: Atmospheric Sciences, Exposure and the Fourth Colloquium on PM and Human Health, Pittsburgh, PA, March 31-April 4.

Robyn Prueitt, Ph.D.
Senior Health Scientist
rprueitt@gradientcorp.com

Areas of Expertise

Carcinogenesis, human genetics, molecular toxicology, molecular epidemiology of cancer risk.

Education

Ph.D., Cell and Molecular Biology, University of Texas Southwestern Medical Center at Dallas, 2001.

B.S., Biology, Pacific Lutheran University, 1994.

Professional Experience

2007 – Present GRADIENT, Seattle, WA
Senior Health Scientist. Provides expertise in support of human health risk assessment, regulatory comment, and toxic tort litigation. Reviews and evaluates toxicology and health-related data.

2006 – 2007 FRED HUTCHINSON CANCER RESEARCH CENTER, Seattle, WA
Staff Scientist. Managed studies of prostate cancer biomarker detection and glycoprotein mass spectrometry analysis. Designed and managed multiple large-scale prostate tumor xenograft studies.

2001 – 2006 NATIONAL CANCER INSTITUTE, Bethesda, MD
Post-doctoral Research Fellow. Investigated genetic susceptibility of cancer risk through molecular epidemiology studies. Managed multiple studies related to breast and prostate carcinogenesis. Performed genome-wide expression analysis of genes and microRNAs associated with prostate carcinogenesis.

Other Training

Epidemiology for Toxicologists, Society of Toxicology 47th Annual Meeting, Seattle, WA, 2008.

Public Health Toxicology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, 2007.

Principles of Clinical Pharmacology, National Institutes of Health, Bethesda, MD, 2004-2005.

Honors and Awards

NIH/NHGRI Institutional Training Grant Award in Genomic Science, 1997-2001.

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Projects

Trade Organization: Assessed whether animal, mechanistic, and epidemiological data are consistent with the nickel ion bioavailability model, which asserts that the carcinogenicity of nickel-containing substances is based on the bioavailability of the nickel ion at nuclear sites of target respiratory epithelial cells. This analysis was published in a peer-reviewed journal.

Trade Organization: Classified, summarized, and entered relevant studies of lead into IUCLID (International Uniform Chemical Information Database) 5.2, a database for the intrinsic and hazard properties of chemical substances that companies can use to submit data under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation in Europe.

Trade Organization: Provided written and oral comments on several occasions to US EPA on clinical and epidemiology studies and their bearing on US EPA's National Ambient Air Quality Standards (NAAQS) for ozone.

Trade Organization: Conducted a critical review and a weight-of-evidence assessment of causality based on animal carcinogenicity studies, mode-of-action studies, and occupational epidemiological studies of soluble nickel compounds and respiratory cancer risk. This analysis was published in a peer-reviewed journal.

Law Firm: Critically reviewed potential health effects associated with exposure to heating oil from a basement spill.

Trade Organization: Classified, summarized, and entered all relevant studies of bisphenol A into the toxicity section of IUCLID 5 (International Uniform ChemicaL Information Database), an electronic repository for the intrinsic and hazard properties of chemical substances that companies can use to submit data under the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) legislation in Europe.

Law Firm: Examined the underlying biological mechanisms for ionizing radiation-induced cancers, including those involving radiation in cigarettes. This analysis was published in a peer-reviewed journal.

Chemical Manufacturing Plant: Evaluated the toxicology and epidemiology literature regarding mercury and determined whether levels in residential soil were above background and likely attributable to a nearby manufacturing plant.

Law Firm: Provided litigation support regarding health effects associated with lead for a case involving exposures in the vicinity of a smelter facility.

Industrial Client: Provided technical support in the evaluation of cost allocation issues at an industrial site. Reviewed information regarding the nature and extent of contamination within the site and assessed factors that could be evaluated to apportion costs among potentially responsible parties.

Confidential Client: Compiled and reviewed studies regarding chemical-induced chromosome abnormalities.

Industrial Company: Summarized literature on toxicity studies of perfluorinated alkane acids.

Confidential Client: Reviewed current data on background levels of trichloroethylene in the environment.

Confidential Client: Performed literature review of chemical associations and alternative causes of claimed health effects in individuals exposed to PCBs.

Publications – *Journal Articles*

Goodman, JE; Prueitt, RL; Rhomberg, LR. 2013. "Incorporating Low-Dose Epidemiology Data in a Chlorpyrifos Risk Assessment." *Dose Response.* In press.

Rhomberg, LR; Goodman, JE; Prueitt, RL. 2013. "The Weight of Evidence Does Not Support the Listing of Styrene as 'Reasonably Anticipated to be a Human Carcinogen' in NTP's Twelfth Report on Carcinogens." *Hum. Ecol. Risk. Assess.* 19(1):4-27.

Prueitt, RL. 2011. "Lung function decrements with 0.06 ppm ozone exposure are of limited clinical and public health significance." *Am. J. Respir. Crit. Care Med.* 184:1421-1422.

Rhomberg, LR; Bailey, LA; Prueitt, RL. 2012. "Hypothesis-based weight-of-evidence evaluation of methanol as a human carcinogen." *Reg. Toxicol. Pharmacol.* 62:278-291.

Prueitt, RL; Goodman, JE; Bailey, LA; Rhomberg, LR. 2011. "Hypothesis-based weight of evidence evaluation of the neurodevelopmental effects of chlorpyrifos." *Crit. Rev. Toxicol.* 42(10):822-903.

Prueitt, RL; Goodman, JE. 2011. "The global burden of ozone on respiratory mortality: no clear evidence for association." *Environ. Health Perspect.* 119(4):A158.

Goodman, JE; Prueitt, RL; Thakali, S; Oller, AR. 2010. "The nickel ion bioavailability model of the carcinogenic potential of nickel-containing substances in the lung." *Crit. Rev. Toxicol.* 41:142-174.

Glynn, SA; Prueitt, RL; Ridnour, LA; Boersma, BJ; Dorsey, TM; Wink, DA; Goodman, JE; Yfantis, HG; Lee, DH; Ambs, S. 2010. "COX-2 activation is associated with Akt phosphorylation and poor survival in ER-negative, HER2-positive breast cancer. *BMC Cancer.* 10:626.

Rhomberg, LR; Goodman, JE; Kerper, LE; Petito Boyce, C; Prueitt, RL. 2010. "Weight-of-evidence analysis of human exposures to dioxins and dioxin-like compounds and thyroid hormone levels during early development." *Reg. Tox. and Pharmacol.* 58(1):79-99.

Prueitt, RL; Beck, BD. 2009. Commentary on "Toxicity Testing in the 21st Century: A Vision and Strategy." *Belle Newsletter* 15(3):3-5.

Goodman, JE; Prueitt, RL; Dodge, DG; Thakali, S. 2009. "Carcinogenicity assessment of water-soluble nickel compounds." *Crit. Rev. Toxicol.* 39:365-417.

Prueitt, RL; Goodman, JE; Valberg, PA. 2009. "Radionuclides in cigarettes may lead to carcinogenesis *via* p16(INK4a) inactivation." *J. Environ. Radioact.* 100(2):157-161.

Ambs, S; Prueitt, RL; Yi, M; Hudson, RS; Howe, TM; Petrocca, F; Wallace, TA; Liu, CG; Volinia, S; Calin, GA; Yfantis, HG; Stephens, RM; Croce, CM. 2008. "Genomic profiling of microRNA and messenger RNA reveals deregulated microRNA expression in prostate cancer." *Cancer Res.* 68(15):6162-6170.

Prueitt, RL; Yi, M; Hudson, RS; Wallace, TA; Howe, TM; Yfantis, HG; Lee, DH; Stephens, RM; Liu, CG; Calin, GA; Croce, CM; Ambs, S. 2008. "Expression of microRNAs and protein-coding genes associated with perineural invasion in prostate cancer." *Prostate* 68(11):1152-1164.

Wallace, TA; Prueitt, RL; Yi, M; Howe, TM; Gillespie, JW; Yfantis, HG; Stephens, RM; Caporaso, NE; Loffredo, CA; Ambs. S. 2007. "Tumor immunobiological differences in prostate cancer between African-American and European-American men." *Cancer Res.* 68(3):927-936.

Prueitt, RL; Boersma, BJ; Howe, TM; Goodman, JE; Thomas, DD; Ying, L; Pfiester, CM; Yfantis, HG; Cottrell, JR; Lee, DH; Remaley, AT; Hofseth, LJ; Wink, DA; Ambs, S. 2006. "Inflammation and IGF-I activate the Akt pathway in breast cancer." *Int. J. Cancer* 120:796-805.

Volinia, S; Calin, GA; Liu, CG; Ambs, S; Cimmino, A; Petrocca, F; Visone, R; Iorio, M; Roldo, C; Ferracin, M; Prueitt, RL; Yanaihara, N; Lanza, G; Scarpa, A; Vecchione, A; Negrini, M; Harris, CC; Croce, CM. 2006. "A microRNA expression signature of human solid tumors defines cancer gene targets." *Proc. Nat. Acad. Sci. USA*. 103:2257-2261.

Prueitt, RL; Chen, H; Barnes, RI; Zinn, AR. 2002. "Most X;autosome translocations associated with premature ovarian failure do not interrupt X-linked genes." *Cytogenet. Genome Res.* 97:32-38.

Prueitt, RL; Zinn, AR. 2001. "A fork in the road to fertility." *Nature Genet.* 27:132-134.

Prueitt, RL; Ross, JL; Zinn, AR. 2000. "Physical mapping of nine Xq translocation breakpoints and identification of XPNPEP2 as a premature ovarian failure candidate gene." *Cytogenet. Cell Genet.* 89:44-50.

McDaniel, LD; Prueitt, R; Probst, LC; Wilson, KS; Tomkins, D; Wilson, GN; Schultz, RA. 2000. "Novel assay for Roberts Syndrome assigns variable phenotypes to one complementation group." *American J. Med. Genet.* 93:223-229.

Publications – *Abstracts*

Prueitt, RL; Goodman, JE; Rhomberg, LR. 2013. "Hypothesis-based weight-of-evidence evaluation of the human carcinogenicity of toluene diisocyanate." Presented at Society of Toxicology 52nd Annual Meeting, San Antonio, TX. *Toxicologist* 132(1):415. Abstract No. 1951.

Prueitt, RL;Goodman, JE;Bailey, LA;Rhomberg, LR. 2012. "Hypothesis-Based Weight-of-Evidence Evaluation of the Neurodevelopmental Effects of Chlorpyrifos." Presented at Society of Toxicology 51st Annual Meeting, San Francisco, CA. *Toxicologist* 126 (1) :309. Abstract No. 1430.

Prueitt, RL; Goodman, JE. 2011. "Evaluation of Adverse Effects on Human Lung Function Caused by Ozone." Presented at Society of Toxicology 50th Annual Meeting, Washington, DC. *Toxicologist - Supplement to Toxicological Sciences* 120(Suppl. 2):491.

Haber, LT; Prueitt, RL; Goodman, JE; Thakali, S; Patterson, J. 2010. "Report of a Workshop: An Evaluation of Hypotheses for Determining the Carcinogenic Potential of Nickel-Containing Substances." Presented at the Annual Meeting of the Society for Risk Analysis, Salt Lake City, Utah.

Prueitt, RL; Goodman, JE; Thakali, S. 2010. "An Evaluation of Hypotheses for Determining the Carcinogenic Potential of Nickel-Containing Substances." *Toxicologist* 94.

Prueitt, RL; Goodman, JE; Dodge, DG; Thakali, S. 2009. "A Weight-of-Evidence Evaluation of the Carcinogenicity of Soluble Nickel." *Toxicologist* 93.

Prueitt, RL; Howe, TM; Ambs, S. 2006. "Nicotine-Induced Progression of Prostate Cancer through Activation of the Akt Signaling Pathway." Presented at the Annual Meeting of the American Association for Cancer Research.

Boersma, BJ; Howe, TM; Prueitt, RL; Chanock, S; Ambs, S. 2004. "Breast Cancer Risk Associated with Allele Variant Genes in the Estrogen Pathway." Presented at the Annual Meeting of the American Association for Cancer Research.

Prueitt, RL; Ross, JL; Zinn, AR. 1999. "Identification of a Premature Ovarian Failure Candidate Gene." Presented at the Annual Meeting of the American Society of Human Genetics.

Zinn, AR; Prueitt, RL; Papenhausen, PR; Roberts, VL; Ross, JL. 1999. "Short Stature and Premature Ovarian Failure Loci in Proximal Xp." Presented at the Annual Meeting of the American Society of Human Genetics.

McDaniel, LD; Prueitt, RL; Probst, L; Schultz, RA. 1997. "Evaluation of the Roberts Syndrome Complementing Factor in a Transient Cell Fusion Assay." Presented at the Annual Meeting of the American Society of Human Genetics.

GRADIENT

Sonja N. Sax, Sc.D.
Senior Environmental Scientist
ssax@gradientcorp.com

Areas of Expertise

Exposure assessment, human health risk assessment, air dispersion modeling, air sampling, epidemiology, toxicology, statistical analysis, probabilistic analysis, indoor/outdoor air pollution, volatile organic compounds, metals, particulate matter, and ozone.

Education

Sc.D., Environmental Science and Engineering, Harvard School of Public Health, 2003.

M.S., Environmental Health Management, Harvard School of Public Health, 1996.

B.A., Biological Chemistry, Wellesley College, 1991.

Languages

Spanish (primary), English (primary)

Professional Experience

2005 – Present GRADIENT, Cambridge, MA
Senior Associate. Evaluated human exposures and health risks associated with environmental pollutants. Conducted air dispersion modeling and exposure assessments. Provided technical support for human health risk assessments. Reviewed and interpreted epidemiological studies. Assisted in preparing expert reports, peer-reviewed publications, regulatory comments, and risk communications.

2003 – 2005 HARVARD SCHOOL OF PUBLIC HEALTH, Boston, MA
Postdoctoral Fellow. Managed two large exposure assessment projects, developed study protocols, organized field studies, and managed staff. Additional duties included writing grants, analyzing data, and publishing manuscripts in peer-reviewed journals.

1998 – 2003 HARVARD SCHOOL OF PUBLIC HEALTH, Boston, MA
Research/Teaching Assistant. Designed, conducted, and managed large air pollution exposure assessment studies of inner-city teenagers in New York City and Los Angeles; measured and analyzed indoor, outdoor, and personal concentrations of volatile organic compounds (VOCs), carbonyls, $PM_{2.5}$, and particle-associated metals. Teaching assistant for and introductory environmental health course.

1994 – 1997 HARVARD SCHOOL OF PUBLIC HEALTH, Boston, MA
Research Assistant. Proposed, designed, and implemented an indoor air quality study of a green community of homes.

1995 – 1995 ENVIRONMENTAL PROTECTION AGENCY, Boston, MA
Intern. Analyzed health effects data to assess the impact of ozone concentrations on hospital admissions in Massachusetts.

1991 – 1994 REPLIGEN CORPORATION, Cambridge, MA
Research Associate. Managed the peptide chemistry lab. Conducted research to improve the synthesis of peptides. Trained and supervised laboratory staff.

Professional Activities

Invited technical peer reviewer for *Journal of the Air & Waste Management Association, Journal of Exposure Science and Environmental Epidemiology,* and *Atmospheric Environment.*

Professional Affiliations

Air & Waste Management Association (AWMA), Society for Risk Analysis (SRA), Society for Risk Analysis New England Chapter (SRA-NE), International Society of Exposure Science (ISES)

Testimony

On September 11, 2012, provided written and oral testimony before US EPA's Clean Air Science Advisory Committee (CASAC) regarding issues with the Third Draft Ozone Integrated Science Assessment (ISA). Comments submitted to CASAC Ozone Review Panel.

On September 11, 2012, provided written and oral testimony before US EPA's CASAC regarding issues with the First Draft Ozone Risk and Exposure Assessment. Comments submitted to CASAC Ozone Review Panel.

On January 9, 2012, provided written and oral testimony before US EPA's CASAC regarding issues with the Second Draft Ozone ISA. Comments submitted to CASAC Ozone Review Panel.

On May 7, 2010, provided written and oral testimony before US EPA's CASAC regarding issues related to the *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards*. Comments were submitted to Docket No. EPA-HQ-OAR-2007-0492.

On March 10, 2010, provided written and oral testimony before US EPA's CASAC regarding issues with the *Quantitative Health Risk Assessment for Particulate Matter: Second External Review Draft*, released February 2010. Comments were submitted to Docket No. EPA-HQ-ORD-2010-3518.

Project Experience

Trade Organization: Provided written and oral comments on several occasions to the Clean Air Scientific Advisory Committee (CASAC) on human exposure, epidemiology, toxicology, and mechanistic studies and their bearing on US EPA's National Ambient Air Quality Standards (NAAQS) for particulate matter and ozone.

Electric-Power Generating Companies: Prepared technical analyses on exposures and potential health effects associated with particulate matter from airborne emissions of coal-fired electric utility power generating plants. Conducted air dispersion modeling and risk analyses using the HEM-3 model. Evaluated the results of the model and summarized the findings in a technical report submitted to the client.

Trade Organization: Performed an ozone mortality risk assessment using US EPA's Environmental Benefits Mapping and Analysis Program. Evaluated mortality risks by conducting a series of sensitivity analyses to assess how alterative model inputs impact risk results. Presented results to US EPA and prepared a manuscript to be submitted to a peer-reviewed journal.

Trade Organization: Evaluated the latest version of the US EPA Air Pollutants Exposure (APEX) model by conducting a series of sensitivity analyses to assess how alterative model inputs impacted exposure and risk assessment results.

Electric Power Research Institute (EPRI): Co-authored a report summarizing the human health and ecological health effects of molybdenum found in coal combustion products, focusing on the use of this information in risk assessment and current regulatory standards and criteria.

EPRI: Co-authored a review of the role of non-chemical stressors in cumulative risk assessment that was published in a peer-reviewed journal.

Manufacturing Client: Conducted an extensive literature search on the toxicity and health effects of cobalt and cobalt alloys found in dental materials. Compiled and summarized the literature to determine the potential health risks from potential exposures.

Manufacturing Client: Reviewed the scientific literature on indoor dust levels of and potential exposure to several flame retardant chemicals. Developed exposure estimates using probabilistic analyses and co-authored a peer-reviewed publication.

Battery Council International: In response to an OSHA request for information for re-evaluating standards for lead, analyzed lead particle size distribution data and prepared a white paper summarizing the results and discussing the implications for lead workplace standards.

Large Electrical Utility: Performed a health risk evaluation of the possible relationship between measured airborne concentrations of sulfuric acid and sulfur dioxide in the vicinity of a large coal-fired power plant and acute health symptoms (*e.g.*, irritation of the eyes, nose, and throat; shortness of breath; asthma-like symptoms). Reviewed regulatory, medical, and research information on the potential health effects of sulfur dioxide and sulfuric acid. Aided in the preparation of both a technical report and a public communication document.

International Carbon Black Association: As part of a team, provided analyses of health effects data on carbon black, a manufactured substance generated as an airborne fine particulate of elemental carbon. Reviewed toxicological and epidemiological studies of carbon black-exposed populations, and evaluated the evidence for the carcinogenicity of carbon black. Co-authored a peer-reviewed publication summarizing the findings.

Coal Processing Facility: For a toxic tort, analyzed ambient particulate matter monitoring data, assessing the appropriateness of the measurement method, how the measured levels compared to background exposure levels, and implications for potential community exposures to coal dust.

EPRI: Evaluated potential inhalation risks from mercury associated with the beneficial use of coal combustion products in wallboard, concrete, and structural fill. Characterized indoor off-gassing of mercury from building materials, as well as ambient mercury volatilization and wind-blown dust emissions for coal ash structural fills. Presented results at a conference meeting and co-authored a peer-reviewed paper.

Electric Utility: Evaluated the scientific basis of health claims associated with air quality regulations that would impact an electricity generation facility. Compared air quality data in the area around the facility to health-based National Ambient Air Quality Standards.

Trade Organization: Reviewed and critiqued the assumptions and uncertainties associated with the statistical models on which US EPA's 2011 *Benefits and Costs of the Clean Air Act Report* was based.

New Mexico Environment Department: Conducted air dispersion modeling using AERMOD software for a large mine tailings area in New Mexico to determine the air concentration contributions of various heavy metals from contaminated resuspended dust. Results were used to calculate risk from inhalation and were included in a comprehensive risk assessment for the area.

Law Firm: Provided technical support for determining health risks from vapor intrusion of contaminated soils into schools.

Smelter Company, Peru: Reviewed and provided comments on a health effects study conducted in Peru and written in Spanish.

Law Firm: Using AERMOD, conducted air dispersion modeling for a large manufacturing facility to determine air impacts of various volatile organic compounds from contaminated groundwater (area source) and from stack emissions (point sources).

Law Firm: In the context of litigation, conducted a comprehensive exposure and risk assessment of pesticide exposures *via* dermal, inhalation, and ingestion routes.

Pesticide Manufacturer: As part of a comprehensive program of risk assessment support to an industry research task force, evaluated the risks associated with background exposure to inorganic arsenic in food, water, and soil in the US using a probabilistic (Monte Carlo) exposure model and a margin of exposure (MOE) toxicity assessment approach. Results were published in the peer-reviewed literature.

Utility Air Regulatory Group: Provided a critical review of the scientific basis for revisions to the National Ambient Air Quality Standards for Ozone, specifically focusing on the epidemiological and human health evidence.

Connecticut Siting Council: Conducted in-depth review of most current health effects information of exposures to low-frequency magnetic fields from epidemiological, animal, and mechanistic studies. Provided detailed reviews of most recent literature in support of guidelines for power line siting projects.

Harvard School of Public Health: Helped design a large study to assess the exposures of volatile organic compounds (VOCs), carbonyls, $PM_{2.5}$, and particle-associated metals of inner-city teenagers in New York City and Los Angeles, measuring indoor, outdoor, and personal concentrations. Implemented a sampling and quality assurance plan for the project, including building necessary field equipment and testing different sampling methodologies for VOCs. Trained field personnel in field activities. Analyzed all carbonyl samples using solvent extraction techniques and an HPLC method that I developed and implemented to analyze the samples. Compiled field and analytical datasets to compute concentrations, developed statistical models for data analysis, prepared a final report for the funding agency, and prepared several manuscripts for peer-reviewed journals.

Harvard School of Public Health: Conducted an in-depth literature review to assess the research needs for the design and construction of healthy and sustainable housing. Proposed, designed, and implemented an indoor air quality study of a green residential community, including recruitment of participants, setup and collection of air pollution samples (VOCs, carbonyls, and NO_2), and analysis of samples. Compiled and analyzed data and prepared a final report that was presented and distributed to all participants, as well as at a conference (Indoor Air).

US EPA: Collected and analyzed Massachusetts's hospital admissions data to assess correlations with ozone levels and determine respiratory health impacts of ozone exposures based on epidemiological findings. Prepared a report on the health impacts of ozone in Massachusetts based on the findings. Results were presented at the Clean Air and Public Health Conference. Assisted in the organization of the conference and wrote the proceedings. Analyzed data from the Toxic Release Inventory to develop a profile of emissions from the plastics industry.

Publications

Sax, SN; Goodman, JE. 2013. Letter re: Equivocal evidence for confounding effects of components of particulate matter on the relationship between ozone and mortality [Letter]."*Am. J. Epidemiol.* In press.

Goodman, JE; Sax, SN. 2013. Letter re: article, 'Controlled Exposure of Healthy Young Volunteers to Ozone Causes Cardiovascular Effects.' *Circulation* 127(4):e432.

Long, CM; Sax, SN; Lewis, AS. 2012. "Potential indoor air exposures and health risks from mercury off-gassing of coal combustion products (CCPs) used in building materials." *Coal Combustion and Gasification Products* 4:68-74.

Lewis, AS; Sax, SN; Wason, SC; Campleman, SL. 2011. "Non-chemical stressors and cumulative risk assessment: An overview of current initiatives and potential air pollutant interactions." *Int. J. Environ. Res. Public Health.* 8(6):2020-2073.

Hesterberg, TW; Long, CM; Sax, SN; Lapin, CA; Bunn, WB; Valberg, PA; McClellan, RO. 2011. "Human health hazards of exposure to new technology diesel exhaust (NTDE)." *Toxicologist - Supplement to Toxicological Sciences* 120(Suppl. 2).

Dodge, DG; Pollock, MC; Sax, SN; Petito Boyce, C; Goodman, JE. 2011. "Risk characterization of the brominated flame retardant decabromodiphenyl ethane in indoor dust." *Toxicologist - Supplement to Toxicological Sciences* 120(Suppl. 2):271.

Petito Boyce, C; Lewis, AS; Sax, SN; Beck, BD; Eldan, M; Cohen, SM. 2010. Letter re: Xue *et al.* (2010) article addressing probabilistic modeling of dietary arsenic exposure and dose. *Environ. Health Perspect.* 118(8). E-pub ahead of print doi:10.1289/ehp.1002328.

Petito Boyce, C; Sax, SN; Dodge, DG; Pollock, MC; Goodman, JE. 2009. "Human exposure to decabromodiphenyl ether, tetrabromobisphenol A, and decabromodiphenyl ethane in indoor dust." *J. Environ. Protection Sci.* 3:75-96.

Hesterberg, TW; Long, CM; Bunn, WB; Sax, SN; Lapin, CA; Valberg, PA. 2009. "Non-cancer health effects of diesel exhaust (DE): A critical assessment of recent human and animal toxicological literature." *Crit. Rev. Toxicol.* 39:195-227.

Petito Boyce, C; Lewis, AS; Sax, SN; Eldan, ME; Cohen, SM; Beck, BD. 2008. "Probabilistic analysis of human health risks associated with background concentrations of inorganic arsenic: Use of a margin of exposure approach." *Human Ecol. Risk Asses.* 14:1159-1201.
****Winner of the HERA Human Risk Assessment Paper of the Year Award in 2008.**

Sax, SN; Koutrakis, P; Rudolph, PA; Cereceda-Balic, F; Gramsch, E; Oyola, P. 2007. "Trends in the elemental composition of fine particulate matter in Santiago, Chile, from 1998 to 2003." *J. Air Waste Manag. Assoc.* 57(7):845-855.

Valberg, P; Long, CM; Sax, SN. 2006. "Integrating studies on carcinogenic risk of carbon black: Epidemiology, animal exposures, and mechanism of action." *J. Occup. Environ. Med.* 48(12):1291-1307.

Sax, SN; Bennett, DH; Chillrud, SN; Kinney, P; Ross, J; Spengler, JD. 2006. "A cancer health risk assessment of a cohort of inner-city teenagers in New York City and Los Angeles." *Environ. Health Perspect.* 114(10):1558-1566.

Koutrakis, P; Sax, SN; Sarnat, JA; Coull, B; Demokritou, P; Oyola, P; Garcia, J; Gramsch, E. 2005. "Analysis of PM_{10}, $PM_{2.5}$, and $PM_{2.5-10}$ concentrations in Santiago, Chile, from 1989 to 2001." *J. Air Waste Manage. Assoc.* 55(3):342-351.

Sax, SN; Bennett, DH; Chillrud, SN; Kinney, PL; Spengler, JD. 2004. "Differences in source emission rates of volatile organic compounds in inner-city residences of New York City and Los Angeles." *J. Exp. Anal. Environ. Epidemiol.* 14:S95-S109.

Chillrud, SN; Epstein, D; Ross, JM; Sax, SN; Pederson, D; Spengler, JD; Kinney, PL. 2004. "Elevated airborne exposures to manganese, chromium and iron from steel dust in New York City's subway system." *Environ. Sci. Technol.* 38:732-737.

Kinney, PL; Chillrud, SN; Ramstrom*, S; Ross, J. 2002. "Exposures to multiple air toxics in New York City." *Environ. Health Perspect.* 110(Suppl. 4):539-546.

Presentations

Sax, SN; Lau, J; Goodman, J. 2012. "Evaluation of the BenMAP Model for Estimating Mortality Impacts of Lower Ozone Concentrations." Poster Presentation at the International Society of Exposure Science, Seattle, WA, October 28-November 1.

Long, CM; Lewis, AS; Sax, SN. 2011. "Indoor Air Inhalation Risks of Mercury Off-gassed from Building Materials Containing Coal Combustion Products (CCPs)." Platform Presentation at the Air & Waste Management Association's Annual Conference & Exhibition, Orlando, FL, June 21-24.

Hesterberg, TW; Bunn, WB; Long, CM; Sax, SN; Valberg, PA; Lapin, CA. 2011. "New Technology Diesel Exhaust (NTDE) Is Distinctly Different From Traditional Diesel Exhaust (TDE)." Platform Presentation at the Air & Waste Management Association's Annual Conference & Exhibition, Orlando, FL, June 21-24.

Hesterberg, TW; Long, CM; Sax, SN; Lapin, CA; Bunn, WB; Valberg, PA; McClellan, RO. 2011. "Human Health Hazards of Exposure to New Technology Diesel Exhaust (NTDE)." Poster Presentation at the Health Effects Institute (HEI) Annual Conference, Boston, MA, May 1-3.

Long, CM; Lewis, AS; Sax, SN. 2009. "Mercury Inhalation Risks in Indoor Air from Use of Coal Combustion Products (CCPs) in Building Materials." Poster Presentation at the World of Coal Ash (WOCA) 2009 Conference, Lexington, KY, May 4-7

Lewis, AS; Sax, SN; Long, CM. 2009. "Mercury Inhalation Risks from Use of Coal Combustion Products (CCPs) as Structural Fill and from Disposal of CCP-Containing Wallboard and Concrete in Landfills." Poster Presentation at the World of Coal Ash (WOCA) 2009 Conference, Lexington, KY, May 4-7.

Lewis, A; Sax, S; Thakali, S; Beck, BD. 2009. "Evaluation of Risk for Fetal Limb Defects from Occupational Exposure to Mancozeb and Ethylene Thiourea During Pregnancy." Poster presented at Society of Toxicology 48th Annual Meeting, Baltimore, MD, March 15-19.

Sax, SN; Lewis, AS; Long, CM. 2009. "Inhalation Risks of Mercury from Use of Coal Combustion Products (CCPs) as Structural Fill and from Disposal of CCP Building Materials in Landfills." Poster Presentation at the 48th Annual Meeting of the Society of Toxicology, Baltimore, MD, March 15-19.

Long, CM; Lewis, AS; Sax, SN. 2009. "Inhalation Risks of Mercury in Indoor Air from Beneficial Use of Coal Combustion Products (CCPs) in Building Materials." Poster Presentation at the 48th Annual Meeting of the Society of Toxicology, Baltimore, MD, March 15-19.

Valberg, P; Sax, S; Long, C. 2006. "Inhalation Health Risk Assessment: Extrapolating from Macromaterials to Nanomaterials." Poster presentation at Overcoming Obstacles to Effective Research Design in Nanotoxicology, Cambridge, MA, April 24-25.

Sax, S; Spengler, JD; Chillrud, S; Kinney, P. 2003. "Concentrations and Emission Rates of VOCs in New York City and Los Angeles Homes." Presented at the 13th Annual Conference of the International Society of Exposure Analysis (ISEA), Stresa, Italy.

Ramstrom*, S; Spengler, JD; Chillrud, S; Kinney, P. 2002. "Seasonal Variation in Indoor and Outdoor Concentrations of VOCs in New York City." Presented at the 9th International Conference on Indoor Air Quality and Climate, Monterey, CA.

Ramstrom*, S; Chillrud, S; Kinney, P; Spengler, J. 2002. "Personal Exposures to VOCs in a Population of Inner-City Teenagers in New York City: A Preliminary Health Risk Assessment." Presented at the ISEA/ISEE Conference, Vancouver, BC, Canada. Abstract in *Epidemiology* 13(4):365.

Ramstrom*, S; Chillrud, S; Aggarwal, M; Spengler, J; Kinney P. 1999. "Exposure Assessment of Urban Air Pollutants in Teenagers in New York City: Winter Study Results." Presented at ISEA/ISEE Conference, Athens, Greece. Abstract in *Epidemiology* 10(4):850.

Ramstrom*, S; Chillrud, S; Spengler, J; Kinney, P. 1999. "Field Validation of VOC Thermal Desorption Tubes by Triplicate Comparisons." Presented at ISEA/ISEE Conference, Athens, Greece. Abstract in *Epidemiology* 10(4):3020.

Ramstrom*, S; Spengler, JD. 1999. "A Pilot Study of VOCs, Aldehydes, and NO_2 Measurements in Environmentally Innovative Homes." Presented at the 8th International Conference on Indoor Air Quality and Climate, Edinburgh, Scotland. Volume 4:165.

Technical Reports

Kinney, P; Chillrud, SN; Sax, S; Ross, J; Pederson, D; Johnson, D; Aggarwal, M; Spengler, JD. 2004. "The Los Angeles TEACH Study." Final Report to the Mickey Leland Urban Air Toxics Research Center.

Kinney, P; Chillrud, SN; Ramstrom*, S; Ross, J; Pederson, D; Johnson, D; Aggarwal, M; Spengler, JD. 2002. "The New York City TEACH Study." Final Report to the Mickey Leland Urban Air Toxics Research Center.

Sonja N. Sax formerly Sonja S. Ramstrom

GRADIENT

Sagar Thakali, Ph.D.
Senior Environmental Scientist
sthakali@gradientcorp.com

Areas of Expertise

Human health and ecological risk assessments; Environmental chemistry, fate, transport, and effects of metals, pesticides, pharmaceuticals, and personal care products; REACH support; FDA and EMEA registration support; Environmental scoring and ranking; Green chemistry.

Education

Ph.D., Environmental Engineering, University of Delaware, 2006.

B.S., Civil Engineering, Swarthmore College, 1999.

B.A., Economics, Swarthmore College, 1999.

Professional Experience

2006 – Present GRADIENT, Cambridge, MA
Environmental Scientist. Provide technical and strategic support on environmental fate and effects evaluations and risk assessments for metals, organics, pesticides, pharmaceuticals, and personal care products; Provide guidance and oversight on regulatory fate and effects testing.

2000 – 2006 UNIVERSITY OF DELAWARE, Newark, DE
Research Associate. Conducted original research in soil organic matter properties, soil pore water metal speciation, and soil metal ecotoxicity. Developed models to predict copper and nickel ecotoxicity in soils. Supervised and managed undergraduate teaching laboratory and environmental chemistry laboratory operations.

Awards

- Research and Teaching Assistantship, University of Delaware, 2000-2006.
- Vivian B. Allen Scholar, Swarthmore College, 1995-1999.
- Sigma XI Research Grant, Swarthmore College, 1998.
- Dean's List, Harvey Mudd College, 1998.
- National Merit Scholar, Budhanilkantha School, 1985-1994.

Professional Affiliations and Activities

- Society of Environmental Toxicology and Chemistry (SETAC).
- Reviewer for *Science of the Total Environment* (2010) *Ecotoxicology and Environmental Safety* (2007, 2009), *Environmental Toxicology and Chemistry* (2006).
- Engineer in Training (EIT), PA, 1999.

Projects – *Pharmaceutical and Personal Care Products*

Global Pharmaceutical Company: Developed and implemented strategies to address the regulatory and scientific challenges associated with potential environmental risks of pharmaceuticals at a former manufacturing facility. Performed modeling and review of eco-toxicity for effects and exposures for active pharmaceutical ingredients (APIs) and/or their intermediates.

Global Personal Care Products (PCPs) Company: Developed a standard screening protocol to evaluate potential ecological risks from societal use of PCPs ingredients. The protocol relies on appropriate QSAR models and toxicity databases and enables a rapid screening of a large number of chemicals. The protocol is being used to screen and rank ingredients with respect to their potential environmental risks and to support "green" product claims.

Global Pharmaceutical Company: Developed and implemented strategies to address the regulatory and scientific challenges associated with the topic of Pharmaceuticals in the Environment (PIE). Performed environmental evaluations to develop wastewater treatment strategies for APIs and developed a sediment-water partitioning model to simulate an otherwise costly standard test (OECD 308).

Global Pharmaceutical Company: Developed a new fish estrogen receptor (ER) *in vitro* binding assay to evaluate the estrogenic potency of hormonally-active APIs and to better understand their potential impact on the aquatic organisms. Effluent guidelines that are protective of aquatic receptors in the receiving environment were set at pharmaceutical manufacturing facilities.

Global Pharmaceutical Companies: Guided and oversaw environmental fate and effects testing of APIs required for drug approval registration with the US FDA and the EMEA; prepared environmental fate and effects assessments to fulfill FDA and EMEA requirement for drug approval registration.

Projects – *Metals and Pesticides*

Global Energy Services Company: Performed human health and ecological risk assessments to facilitate a remedial strategy at a former mining site.

Nickel Producers Environmental Research Association (NiPERA): Reviewed exposure evaluations in epidemiological studies linking respiratory cancer to occupational nickel exposure. Identified potential exposure misclassifications due to various factors—including metal speciation and extrapolation of historical data. This review was published a peer-reviewed scientific journal.

Major Agriculture Company: Provided analyses on environmental fate and transport of an active ingredient in a pesticide to determine field exposure to human. The analyses focused on partitioning, transport, and degradation in soil, and foliar residue of the active ingredient and its main degradation products.

Metal Smelter in the Mid West: Designed, planned, and oversaw a field trial for an *in situ* remediation of lead-contaminated soils in residential areas; reviewed and analyzed the results, and provided recommendations. The *in situ* remediation was designed in consultation with US EPA as a non-intrusive and cost-effective alternative to excavation and back-filling to achieve the remediation goal in residential areas.

Major Utility Company: Performed literature reviews on ecological effects of arsenic and thallium in soil, water, and sediment. The review identified the most potent arsenic and thallium species and the most sensitive organisms, determined the environmental concentrations due to anthropogenic *vs.* natural background sources, compiled regulatory and recommended ecological criteria, and determined the potential for environmental effects.

International Copper Association (ICA) and Nickel Producers Environmental Research Association (NiPERA): Designed and conducted original research in modeling copper and nickel speciation and ecotoxicity; modeled copper and nickel speciation in soil pore water; developed the Terrestrial Biotic Ligand Model (TBLM) to predict soil copper and nickel ecotoxicity. The speciation studies and the TBLMs have been published in peer-reviewed journals.

Center for Study of Metals in the Environment (CSME): Investigated soil organic matter properties, surface and pore water metal speciation, and metal ecotoxicity in terrestrial systems; performed literature review of mercury speciation and measurement in support of data development for water quality criteria revision for wildlife protection for mercury.

Projects – *Others*

Global Energy Services Company: Reviewed a comprehensive hazard evaluation system for scoring and ranking of products that was newly developed by the energy services company. Reviewed and analysed the general approach of the hazard evaluation system, compared with other existing chemical hazard evaluation and product scoring/ranking systems, and performed sensitivity analyses to evaluate the system's robustness.

Global Commercial Cleaning and Hygiene Products Company: Developed a guidance document for proper disposal of cleaning and floor care products. Evaluated disposal to large centralized treatment plants (POTWs) and smaller decentralized systems (*i.e.*, septic systems) and described how the cleaning products could interfere with wastewater treatment processes if disposed improperly. Produced a manual to provide practical guidance for plant managers at facilities that use large product volumes and to help technical sales staff address clients' questions regarding proper product use and disposal practices.

Major Industry Trade Group: Reviewed literature and standard test methods to determine environmental fate and effects of vegetable oil products and recommended scientifically sound and suitable test methods for acceptance under various regulations and "green" products claims under various eco-labeling schemes.

Major Trade Associations for Petroleum Products and Utility Companies: Performed a meta-analysis of clinical studies to assess the concentration of nitrogen dioxide that causes airway hyper-responsiveness in humans. Our analysis included an evaluation of the influence of several factors, including type of airway impact, exposure method (*i.e.*, chamber *vs.* mouthpiece), exercise, and allergy/asthma status, on airway response to nitrogen dioxide. This analysis was published a peer-reviewed scientific journal.

Publications – *Peer-Reviewed*

Goodman, JE; Prueitt, RL; Thakali, S; Oller, AR. 2010. "The nickel ion bioavailability model of the carcinogenic potential of nickel-containing substances in the lung." *Crit. Rev. Toxicol.* 41:142-174.

Goodman, JE; Chandalia, JK; Thakali, S; Seeley, M. 2009. "Meta-analysis of nitrogen dioxide exposure and airway hyper-responsiveness in asthmatics." *Crit. Rev. Toxicol.* 39:719-742.

Goodman, JE; Dodge, DG; Prueitt, RL; Thakali, S. 2009. "Carcinogenicity assessment of water-soluble nickel compounds." *Crit. Rev. Toxicol.* 39:365-417.

Ponizovsky, AA; Thakali, S; Allen, HE; Di Toro, DM; Ackerman, AJ; Metzler, DM. 2008. "Effect of soil properties on nickel partitioning in soil solutions at low moisture content." *Geoderma* 145:69-76.

Thakali, S; Allen, HE; Di Toro, DM; Ponizovsky, AA; Rooney, CP; Zhao, FJ; McGrath, SP. 2006. "A terrestrial biotic ligand model. 1. Development and application to Cu and Ni toxicities to barley root elongation in soils." *Environ. Sci. Technol.* 40:7085-7093.

Thakali, S; Allen, HE; Di Toro, DM; Ponizovsky, AA; Rooney, CP; Zhao, FJ; McGrath, SP; Criel, P; Van Eckout, H; Janssen, C; Oorts, K; Smolders, E. 2006. "Terrestrial biotic ligand model. 2. Application to Ni and Cu toxicities to plants, invertebrates, and microbes in soil." *Environ. Sci. Technol.* 40:7094-7100.

Ponizovsky, AA; Thakali, S; Allen, HE; Di Toro, DM; Ackerman, AJ. 2006. "Effect of soil properties on copper release in soil solutions at low moisture content." *Environ. Toxicol. Chem.* 25:671-682.

You, SJ; Thakali, S; Allen, HE. 2006. "Characteristics of soil organic matter (SOM) extracted using base with subsequent pH lowering and sequential pH extraction." *Environ. Int.* 32:101-105.

Shoji, R; Mohri, S; Ono, Y; Thakali, S; Allen, HE. 2010. "Metal bioavailability to Barley (*Hordeum vulgare*) in soils amended with municipal solid waste incineration (MSWI) ash." (In preparation).

Thakali, S; Allen, HE; Di Toro. 2010. "Soil metal criteria development using the Terrestrial Biotic Ligand Model (TBLM) and Species Sensitivity Distributions." (In preparation).

Publications – *Other*

Beyer, LA; Mattuck, RL; Thakali, S; Beck, BD. 2011. "A comparative risk evaluation of MTBE and other compounds (including naturally occurring compounds) in drinking water in New Hampshire." *Toxicologist - Supplement to Toxicological Sciences* 120(Suppl. 2):418.

Haber, LT; Prueitt, RL; Goodman, JE; Thakali, S; Patterson, J. 2010. "Report of a Workshop: An Evaluation of Hypotheses for Determining the Carcinogenic Potential of Nickel-Containing Substances." Presented at Society of Risk Analysis Annual Meeting, Salt Lake City, UT, December 5-8, 1p.

Thakali, S. 2009. "Pharmaceuticals in the Environment." *Trends: Risk Science & Application*, Winter 2009, Gradient.

Thakali, S; Allen, HE; Di Toro. 2007. "Applying Terrestrial Biotic Ligand Model (TBLM) to Species Sensitivity Distributions." In *Biogeochemistry of Trace Elements: Environmental Protection, Remediation and Human Health.* (Eds: Zhu, Y; Lepp, N; Naidu, R. Tsinghua), University Press, Peoples Republic of China.

Allen, HE; Thakali, S; Ponizovsky, AA; Di Toro, DM; Rooney, CP; Zhao, FJ; McGrath, SP. 2006. "Predicting Toxicity of Metals in Soils – the Terrestrial Biotic Ligand Model." In *Proceedings of the 13th Meeting of the International Humic Substances Society. Karlruhe, Germany.* (Eds: Frimmel, FH; Abbt-Braun, G), July 30 – August 4, p61-64.

Thakali, S; Allen, HE; Di Toro, DM; Ponizovsky, AA; Rooney, CC; Zhao, FJ; McGrath, SP. 2005. "Developing a TBLM: Copper Effect on Barley Root Elongation." In *Proceedings of the 8th International Conference on the Biogeochemistry of Trace Elements*, Adelaide, Australia, April 3-7, p357-358.

Thakali, S; Allen, HE; Di Toro, DM. 2004. "Modeling the Effect of Dissolved Organic Matter on Copper Activity in Soil Solutions." In *Proceedings of the XII International Meeting of International Humic Substances Society*. Humic Substances and Soil and Water Environment. (Eds: Martin-Neto, L; Milori, DMBP; Da Silva, WTL), Sao Paulo, Brazil, July 25-30.

Allen, HE; Shi, Z; Thakali, S; Ponizovsky, AA; Metzler, DM; Di Toro, DM. 2003. "Partitioning of Metal between Soil and Soil Solution: A Key Process Controlling the Risk of Metals to Soil Organisms." In *Proceedings of the Copper 2003 - Cobre 2003 International Conference, Volume II.* (Eds: Lagos, GE; Warner, AEM; Sanchez, M), Santiago, Chile, November 30 - December 3, Canadian Institute of Mining, Metallurgy and Petroleum, p567-580.

Presentations

Thakali, S; Chandalia, JK; Seeley, MR; Goodman, JE. 2010. "Meta-analysis of nitrogen dioxide effects on airway hyper-responsiveness in asthmatics: Effects of the types of airway challenge, exposure methods, and activities during exposure." Poster presented at the *Society of Toxicology 49th Annual Meeting, Salt Lake City, UT.*

Chandalia, JK; Goodman, JE; Thakali, S; Seeley, MR. 2010. "Meta-analysis of airway hyper-responsiveness in asthmatics after nitrogen dioxide exposure." Platform Presentation at the *Society of Toxicology 49th Annual Meeting, Salt Lake City, UT.*

Prueitt, RL; Goodman, JE; Thakali, S. 2010. "An evaluation of hypotheses for determining the carcinogenic potential of nickel-containing substances." Poster presented at the *Society of Toxicology 49th Annual Meeting, Salt Lake City, UT.*

Lewis, A; Sax, S; Thakali, S; Beck, BD. 2009. "Evaluation of risk for fetal limb defects from occupational exposure to Mancozeb and ethylene thiourea during pregnancy." Poster presented at the *Society of Toxicology 48th Annual Meeting, Baltimore, MD.*

Prueitt, RL; Goodman, JE; Dodge, DG; Thakali, S. 2009. "A weight-of-evidence evaluation of the carcinogenicity of soluble nickel." Poster presented at the *Society of Toxicology 48th Annual Meeting, Baltimore, MD.*

Mori, C; Thakali, S; Tarrant, A; Sharma, M; Verslycke, T; Yekel, H. 2009. "Translating *in vitro* estrogenic assay results to ecological risk assessment." Poster presented at the *Society of Toxicology 48th Annual Meeting, Baltimore, MD.* ** **(Won Best Abstract award).**

Thakali, S; Sharma, M; Verslycke, T. 2008. "Environmental Safety Ranking Framework for Surfactants in Personal Care Products (PCPs)." Poster presented at *the Society of Risk Analysis (SRA) 2008 Annual Meeting, Boston, MA, December 7-10.*

Thakali, S; Verslycke, T; Tarrant, A; Sharma, M; Yekel, H. 2008. "Estimating the Relative Potency of Estrogen-like Active Pharmaceutical Ingredients to Ecological Receptors Using a Fish Estrogen Receptor Binding Assay." Platform Presentation at the *Society of Environmental Toxicology and Chemistry (SETAC) North America 29th Annual Meeting, Tampa, FL, November 16-20.*

Saxe, J; Thakali, S; Sharma, M; Pollock, M; Ward, T; Yekel, H. 2007. "Predicting the Environmental Fate of Active Pharmaceutical Ingredients in Sediments for regulatory Environmental Risk Assessments." *Society of Environmental Toxicology and Chemistry (SETAC) North America 28th Annual Meeting, Milwaukee, WI, November 11-17.*

Allen, HE; Thakali, S; Di Toro, DM. 2007. "Applying the Terrestrial Biotic Ligand Model (TBLM) to Species Sensitivity Distributions." *Society of Environmental Toxicology and Chemistry (SETAC) Europe 17th Annual Meeting, Portok Portugal, May 20-24.*

Allen, HE; Thakali S; Ponizovsky, AA; Di Toro, DM; Rooney, CP; Zhao, FJ; McGrath, SP. 2006. "Predicting Toxicity of Metals in Soil – The Terrestrial Biotic Ligand Model (TBLM)." *18th World Congress of Soil Science, Philadelphia, PA, July 9-15.*

Thakali, S; Allen, HE; Di Toro, DM; Ponizovsky, AA; Rooney, CP; Zhao, FJ; McGrath, SP; Criel, P; Van Eckout, H; Janssen, C; Oorts, K; Smolders, E. 2005. "Development of Terrestrial Biotic Ligand Models for Copper and Nickel Toxicity in Soils: Application for Plant, Invertebrate, and Microbial Tests." *Society of Environmental Toxicology and Chemistry (SETAC) North America 26th Annual Meeting, Baltimore, MD, November 13-17.*

Technical Reports

"Chemical Constituents in Coal Combustion Product Leachate: Arsenic." 2008. Electric Power Research Institute (EPRI), Palo Alto, CA, Southern Company, Birmingham, AL, American Electric Power (AEP), Columbus, OH, and South Carolina Electric and Gas Corporate Planning, Columbia, SC, 101550.

"Chemical Constituents in Coal Combustion Product Leachate: Thallium." 2008. Electric Power Research Institute (EPRI), Palo Alto, CA, 1016801.

"Assessment of Existing Methods and Data Development for revising Water Quality Criteria for Protection of Wildlife for Mercury." 2003. Project 99-ECO-2, Cadmus Group, Ottawa, ON.

Peter A. Valberg, Ph.D., Fellow ATS
Principal
pvalberg@gradientcorp.com

Areas of Expertise

Public health, inhalation toxicology, epidemiology, human health risk assessment, risk communication, indoor / outdoor air quality, comparative toxicology, modeling of human exposure and retained dose, health effects of ionizing and non-ionizing radiation.

Education

M.S., Human Physiology and Inhalation Toxicology, Harvard School of Public Health.

Ph.D., Physics, Harvard University, Graduate School of Arts and Sciences.

M.A., Physics, Harvard University

A.B., Physics and Mathematics, *summa cum laude*, Taylor University.

Professional Experience

2001 – Present (and 1990 – 1998) GRADIENT, Cambridge, MA
Principal. Environmental consulting practice includes inhalation toxicology, environmental health, human health risk assessment, use of epidemiology in public health decisions, health effects of airborne gases and particles, and health effects of ionizing and non-ionizing radiation.

1998 – 2000 CAMBRIDGE ENVIRONMENTAL, INC., Cambridge, MA
Senior Scientist.

1985 – 2000 HARVARD SCHOOL OF PUBLIC HEALTH, Boston, MA
Associate Professor of Human Physiology. (Adjunct, after 1990) Research work included: (1) human health effects of air toxics, (2) lung macrophage function measured with magnetic particles, and (3) lung deposition and clearance of radioactive tracer particles.

1987 INSTITUTE OF OCCUPATIONAL HEALTH, Helsinki, Finland
Visiting Researcher. Developed a magnetometric assay to be used for studying pulmonary macrophage function for lung cells lavaged from human subjects.

1984 INHALATION TOXICOLOGY RESEARCH INSTITUTE, Albuquerque, NM
Visiting Scientist. Examined the effect of exercise and hypercapnia on deposition, lung clearance, and lung distribution of inhaled radioactive aerosol.

1976 – 1985 HARVARD SCHOOL OF PUBLIC HEALTH, Boston, MA
Assistant Professor of Respiratory Physiology.

1970 – 1976 AMHERST COLLEGE, Amherst, MA
Assistant Professor of Physics.

Professional Activities

- National Academy of Sciences and National Research Council, Evaluating Health-Risk-Reduction Benefits of US EPA Regulations (2001 – 2003).
- Harvard School of Public Health: Research Advisory Committee Member for NIH-Sponsored Research on "Mechanisms of mortality/morbidity due to air particulate" (1997 – 2005).
- Member of the Committee on Man and Radiation (COMAR) (1999 – 2006).
- Health Effects Institute, Cambridge, MA, ad hoc reviewer (1984 – 1994).
- National Research Council, Commission on Life Sciences: Committee on Passive Smoking (1986 – 1988).
- Editorial Board, Journal of Aerosol Medicine (1987 – 2000).
- Center for Indoor Air Research, grant-application reviewer (1989 – present).
- NIOSH: Environmental Center Grants, Site Visit Delegation (1990).
- NIH Reviewer: Cardiovascular and Pulmonary Study Section, Radiation Study Section, and Health of the Population Study Section.
- DOE: Office of Health and Environmental Research, reviewer.
- Harvard Center for Risk Analysis: Review of Cellular Telephones (1994 – 1999).
- Physical and Biological Sciences Study Committee, Town of Needham Planning Board.

Professional Affiliations

Fellow of the Academy of Toxicological Sciences; Society of Toxicology (full member); International Society for Environmental Epidemiology; Society for Risk Analysis; Health Physics Society (full member); Sigma Xi • American Association for the Advancement of Science; American Conference of Governmental Industrial Hygienists (associate member)

Projects *(abbreviated)*

Carbon Black Manufacturers: Evaluated the toxicology and epidemiology of carbon black inhalation and ingestion.

Charter School in Washington, DC: Prepared a health risk assessment for the school board on the health risks of handling asbestos-containing materials that might release fibers.

City of Newton Health Department: Measured RF levels from a local transmitting antenna, reviewed RF field calculations, and provided scientific literature critique on RF health effects.

Confidential Client: Prepared a risk assessment for a Massachusetts landfill containing both chemical and radioactive waste and including multiple pathways of contaminant uptake by a trespasser.

Confidential Client: Prepared a model predictive of asbestos fiber drift and inhalation health hazard applicable to industrial processes where asbestos-containing materials are used.

Confidential Clients: Prepared an analysis of relative risks of TCE in drinking water *versus* health hazards from background levels of chemicals in air, water, and soil, as well as other routine risks to life and health.

Electric-Power Generating Companies: Prepared and delivered expert reports and public testimony on the potential health effects of airborne emissions from coal fired, gas-fired, oil-fired, and wood-fired electric utility power generating plants.

Electric Power Research Institute: Reviewed and analyzed the mechanisms by which biological systems may be affected by environmental electric and magnetic fields (EMFs). Organized a public workshop on the causes and characteristics of childhood leukemia.

Engine Manufacturers Association: Evaluated US EPA and California EPA health assessment documents on the potential carcinogenicity of diesel exhaust and ambient air particulate matter.

Harvard School of Public Health: Continuing Education for Professionals: Prepared material on special topics on inhalation toxicology for graduate students and health professionals. Presented lectures on risk assessment and risk communication.

Health Effects Institute: Prepared an analysis entitled "Ozone Molecular Dosimetry and Interaction with Biological Macromolecules."

Health Effects Institute: Organized, supervised, and documented a feasibility study for the Health Effects Institute initiating a national research program on the health effects of electric and magnetic fields.

Manufacturing Company: Analyzed multi-pathway human health risk for a site contaminated with polychlorinated biphenyls (PCBs) and chlorinated organic solvents. Analyzed experimental data to derive a fraction of PCBs that are picked up from concrete when touching the concrete.

Manufacturing Company/FUSRAP Site: Prepared a radionuclide health risk assessment and site management plan for site contaminated by nearby storage of uranium ore.

Massachusetts Department of Public Health: Prepared a public communications essays on what citizens can do to support improved air quality.

Medical Product Manufacturer: Prepared a risk assessment for air toxics produced during malfunction of a medical device used to assist breathing.

Michigan Occupational and Environmental Medical Association (MOEMA): Prepared and delivered a risk assessment tutorial for MOEMA's Continuing Education program.

Mining Company: Evaluated the epidemiological basis for the toxicity of arsenic in soils. Evaluated metals toxicity factors and site-specific bioavailability of metals.

National Institute of Environmental Health Sciences – Division of Research Grants: Reviewed grant applications for the Radiation Study Section Panel on Health-Effects Research.

National Institute of Environmental Health Sciences / Environmental Protection Agency: Asbestos Workshop, assisted in the review of the summary publication, "A Science-Based Examination of Asbestos and Related Mineral Fibers".

Navy Occupational Health and Preventive Medicine Program: Prepared and delivered seminars and workshops to US Navy medical personnel on the current research on EMFs.

New Mexico Environmental Department: Prepared a health risk assessment for measured and modeled concentrations of 80 airborne chemicals in Albuquerque, NM.

Refineries in US and Canada: Prepared a multi-pathway human health risk assessment for air emissions from petroleum refineries. The risk assessment process was monitored by task forces composed of regulators, educators, union members, and local officials.

School District on Long Island: Assessed possible environmental, occupational, and lifestyle risk factors for early-term miscarriage.

University of Denver: Analyzed the potential health impact of uranium disposal from munitions testing ("depleted uranium") as it was practiced in the 1960s and 1970s.

Uranium Mill: Evaluated the health implications of radioactive substance migration as predicted by different US EPA and DOE models.

US Department of Energy: Prepared a risk communication strategy for a nuclear test site where detonation of underground atomic devices had the potential to contaminate groundwater.

US Department of Justice: Prepared an analysis of the health hazards of the Love Canal Superfund site (Niagara Falls, NY).

US Department of Justice: Prepared a report and provided expert testimony on human toxicology with regard to soil contamination at a RCRA site.

US Department of Justice: Prepared reports and provided expert testimony in several different cases on asbestos, sulfuric acid, and airborne particulate inhalation toxicology.

US Environmental Protection Agency: Provided US EPA with a peer review (scientific critique) of the agency's draft guidance on risk assessment for VOC's present in household water..

US Environmental Protection Agency: Provided US EPA with a peer review (scientific critique) of the agency's draft reference concentration (RfC) methodology for risk assessment.

US Environmental Protection Agency: Analyzed the health risks of a remediation alternative at the Bloody Run Creek section of the Hyde Park Landfill superfund site (Niagara Falls, NY).

US Environmental Protection Agency, Health Effects Research Laboratory: Assisted in preparing a database of non-cancer health effects for 189 Hazardous Air Pollutants.

US Environmental Protection Agency, Environmental Criteria and Assessment Office: Evaluated research proposals on "Indoor and Ambient Air Risk Assessment Methodologies."

Utility: Analyzed the relationship between inhaled carbon monoxide concentration and blood carboxyhemoglobin. Performed sensitivity analysis on all the variables involved.

Waste Management Company: Evaluated health risks for a medical waste incinerator, including a multiple-pathway (ingestion, inhalation, dermal, mothers' milk) health risk assessment.

World Health Organization: Helped prepare a WHO research report on EMF health effects. Presented a lecture on EMF health effects at a WHO workshop in Geneva, Switzerland. Published review article on RF health effects.

Academic Research Projects *(abbreviated)*

National Heart, Lung, and Blood Inst.:	"Physical Determinants of Lung Function and Dysfunction."
National Heart, Lung, and Blood Inst.:	"Pulmonary SCOR: Chronic Diseases of the Airways."
National Cancer Institute:	"Magnetic Field Effects on Macrophages."
National Inst. of Environ. Health Sci.:	"Inhaled Particle Retention in Normal and Diseased Lungs."
National Heart, Lung, and Blood Inst.:	"Particle Location and Ingestion by Lung Macrophages."
National Inst. of Environ. Health Sci.:	"Factors Influencing Deposition of Inhaled Aerosols."

Publications – *Articles*

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McCunney, RJ; Muranko, HJ; Long, CM; Hamade, AK; Valberg, PA; Morfeld, P. 2012. "Carbon black." In Patty's Toxicology, Sixth Edition, Vol. 5. Ed.: Bingham, E; Cohrssen, B, John Wiley & Sons, Inc. 26p.

Hesterberg, TW; Bunn, WB; Valberg, PA; Long, CM. 2012. "Potential health effects of exposure to diesel engine exhausts." In *The Praeger Handbook of Environmental Health: Water, Air, and Solid Waste.* (Ed: Friis, RH), Praeger, ABC-CLIO, LLC, Santa Barbara, CA, p185-212.

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Valberg, PA; Bruch, J; McCunney, RJ. 2009. "Are rat results from intratracheal instillation of 19 granular dusts a reliable basis for predicting cancer risk?" *Regul Toxicol Pharmacol.* 54(1):72-83.

Hesterberg, TW; Valberg, PA; Long, CM; Bunn, WB; Lapin, CA. 2009. "Laboratory studies of diesel exhaust health effects: Implications for near-roadway exposures." *EM, Air & Waste Management Association Publication for Environmental Managers.* August. p. 13-16.

Goodman, JE; Nascarella, MA; Valberg, PA. 2009. "Ionizing radiation: a risk factor for mesothelioma." *Cancer Causes & Control.* 20:1237-1254.

Prueitt, RL; Goodman, JE; Valberg, PA. 2009. "Radionuclides in cigarettes may lead to carcinogenesis *via* $p16^{INK4a}$ inactivation." *J. Environ. Radioact.* 100:157-161.

Hesterberg, TW; Long, CM; Bunn, WB; Sax, SN; Lapin, CA; Valberg, PA. 2009. "Non-cancer health effects of diesel exhaust (DE): A critical assessment of recent human and animal toxicological literature." *Critical Reviews in Toxicology* 39(3):195-227.

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Abstracts & Reports *(list available on request)*

Invited Lectures *(past 10 years)*

6/28/12 "Inhalation toxicology input to the fine-particle National Ambient Air Quality Standard." Presentation to the United States House of Representatives Committee on Energy and Commerce, Washington, DC.

6/11/12 "Portals of Entry: Pulmonary Deposition and Clearance of Particles." To be presented in the course "*Comprehensive Industrial Hygiene*" Harvard School of Public Health, Boston, MA.

3/19/12 "Epidemiology of Diesel Exhaust: An Overview." Presented at the "*International Congress of Occupational Health*" Cancun, Mexico.

4/12/11 "Nanotechnology Products: Environmental Health and Workplace Safety." Presented in the Symposium: "Nanotechnology's Journey to Commercialization" University of Massachusetts, Lowell, MA.

6/14/10 "Portals of Entry for Workplace Chemicals / Lung Deposition and Clearance of Inhaled Particles." Presented in the course "*Comprehensive Industrial Hygiene: The Applications of Basic Principles*" Harvard School of Public Health, Boston, MA.

3/24/10 "Do Brain Cancer Rates Correlate with Ambient PM-Levels or with Hazardous Air Pollutant (HAP) Concentrations?" Presented at the AAAR Specialty Conference "*Air Pollution and Health: Bridging the Gap from Sources to Health Outcomes*," San Diego, CA.

6/23/08 "Routes of Entry into the Body: Pulmonary Deposition and Clearance of Particles." Presented in the course "Comprehensive Industrial Hygiene: Practical Applications of Basic Principles," Harvard School of Public Health, Boston, MA.

6/25/07 "Routes of Entry into the Body: Pulmonary Deposition and Clearance of Particles." Presented in the course "Comprehensive Industrial Hygiene: Practical Applications of Basic Principles," Harvard School of Public Health, Boston, MA.

3/29/07 "Non-linear Exposure-Response Relationships between Ambient PM_{10} and Daily Mortality." Presentation with Dr. T. Bowers at the Society of Toxicology Annual Meeting, Charlotte, NC. This presentation was selected as one of the *Top 12 Risk Assessment Abstracts at the SOT Meeting.*

11/7/06 "What is EMF? How EMF Interacts with Organisms." Presented at the Cyprus International Institute for the Environment and Public Health symposium on "Electromagnetic Fields: Sources, Health Effects, and Regulations, Nicosia, Cyprus.

6/19/06 "Pulmonary Deposition and Clearance of Particles." Presented in the course "Comprehensive Industrial Hygiene: Practical Applications of Basic Principles," Harvard School of Public Health, Boston, MA.

5/18/06 "Health Hazards of Nanoparticles." Presented at "A Mock Hearing: Environment, Health & Safety" at the NanoBusiness Alliance Meeting, New York City, NY.

4/25/06 "Inhalation Risk Assessment: Extrapolating from Macro-materials to Nano-materials." Overcoming Obstacles to Effective Research Design in Nanotoxicology, Cambridge, MA.

10/6/05 Panelist for: "A Reevaluation of the Association Between Diesel Exhaust Exposure and Lung Cancer." Air & Waste Management Association (AWMA) Specialty Workshop on "Diesel Exhaust," Chicago, IL.

6/20/05 "The Respiratory Tract as a Portal of Entry for Airborne Chemicals in the Work Environment." Lecture at the Harvard School of Public Health course on "Comprehensive Industrial Hygiene," Boston, MA.

6/16/05 "Electromagnetic Fields, Base Stations, and Wireless Networks: Exposures & Health Consequences." WHO Workshop, 15-16 June 2005, at the World Health Organization, Geneva, Switzerland.

2/11/05 "Generation of Charged Aerosols by High-Voltage Electric-Power Lines." American Association for Aerosol Research, Specialty Conference on Particulate Matter, Atlanta, GA.

2/4/05 "Magnetic Microparticles Detect and Probe Cytoplasmic Motions." Bioelectromagnetics Society Winter Workshop, Phoenix, AZ.

6/21/04 "Pulmonary Deposition and Clearance of Particles." Harvard School of Public Health Continuing Education course on "Fundamentals of Industrial Hygiene," Boston, MA.

1/27/04 "Quantitative and Qualitative Factors that Determine Health Risk: Explaining Risk to Judges, Juries, and Communities." Mealey's Water Contamination Conference, Pasadena, CA.

9/14/02 "Health Effects of Air Pollutants." Annual Scientific Meeting of the Michigan Occupational and Environmental Medicine Association "Current Topics in Occupational and Environmental Medicine," Frankenmuth, MI.

6/18/01 "Pulmonary Physiology, and Lung Deposition and Clearance of Particles." Harvard School of Public Health Continuing Education course on "Fundamentals of Industrial Hygiene," Boston, MA.

11/14/00 "Effects of Air Pollution on the Human Lung." Lecture in Tufts University course CEE 136, "Air Pollution," Medford, MA.

7/26/00 "Review of Ambient Air Quality as it Relates to Proposed Emission Standards for Massachusetts Power Plants." Testimony before the Massachusetts Department of Environmental Protection, Boston, MA.

1/10/00 "Useful Concepts in the Physics of RF." RF Safety: Science, Compliance and Communication, Electromagnetic Energy Association and the University of Texas Health Science Center, San Antonio, TX.

Manuscript Peer Reviewer for the Following Research Journals

American Industrial Hygiene Journal; American Journal of Physics; American Journal of Respiratory Cell and Molecular Biology; American Review of Respiratory Disease; Atmospheric Environment; Bioelectromagnetics; Biophysical Journal; Biorheology; Cell Biophysics; Chemical Research in Toxicology; Critical Reviews in Toxicology; Environmental Geochemistry and Health; Environmental Health Perspectives; Environment International; Environmental Science & Technology; Epidemiology; Experimental Lung Research; Fundamental and Applied Toxicology; Hepatology; Human and Ecological Risk Assessment; Human and Experimental Toxicology; IEEE Biomedical Engineering; IEEE Transactions on Plasma Science; International Journal of Radiation Biology; Journal of Aerosol Medicine and Pulmonary Drug Delivery; Journal of Applied Physiology; Journal of Applied Toxicology; Journal of Occupational and Environmental Hygiene; Journal of Occupational and Environmental Medicine; Journal of Occupational Medicine and Toxicology; Journal of the Royal Society Interface; Journal of Toxicology and Environmental Health; Nature; Nonlinearity in Biology, Toxicology, and Medicine; Radiation Research; Risk Analysis: An International Journal; Regulatory Toxicology & Pharmacology; Science; Tissue & Cell; Toxicology and Applied Pharmacology; Toxicological Sciences; USGS Environmental Geochemistry of Mineral Deposits (Reviews in Economic Geology series).

Tab 4: Past Performance – Gradient

Gradient has performed the same or similar work as described in this proposal. Please see a list of some of Gradient's recent and significant instances of past performance in Tab 2. This includes authoring peer-reviewed papers; being peer-reviewers for scientific journals; teaching graduate-level classes; presenting at scientific conferences; participating on scientific advisory panels; providing testimony before US Senate and Congressional committees; and presenting briefings or white papers for policymakers on NAAQS science, epidemiology, meta-analyses, and WoE analyses. We have provided two published papers and one white paper at the back of this section and on the enclosed CD. We are happy to provide more examples upon request.

4.1 American Petroleum Institute

a) Dr. Julie Goodman (617-395-5000) has worked under many contracts with the American Petroleum Institute (API) since 2009 (4 years). Mr. Ted Steichen (202-682-8568) has been our contact for most of this contracted work. All work was performed in Cambridge, MA, or Seattle, WA. As part of this work, Dr. Goodman provided written and oral comments on many occasions to CASAC on human exposure, epidemiology, toxicology, and mechanistic studies and their bearing on US EPA's NAAQS for PM, ozone, NO_x, and sulfur oxides (SO_x) (see Tab 2). In addition, Dr. Goodman has had several peer-reviewed manuscripts published and has presented scientific findings at research conferences as part of this contracted work (see Tab 2). Some of these contracts include:

Table 4.1 American Petroleum Institute Contracts

Title	Start Date	End Date	Contract #
Commentary on the US EPA Benefits and Costs of the Clean Air Act Report from 1990 to 2020	May 2011	Present	2011-105628
Air Pollutant NAAQS Risk Critique	November 2008	March 2010	2008-103853
Nitrogen Dioxide Health Effects Evaluation	April 2009	January 2010	2009-104291*
Ozone NAAQS Literature Review	January 2010	March 2013	2009-104509
Reconsideration of Ozone NAAQS Final Rule	May 2010	February 2013	2010-104947
Particulate Matter NAAQS Risk Critique	August 2009	March 2010	2009-104338
Comments on the US EPA Proposed Rule for Sulfur Oxides	August 2009	May 2010	2009-104344

*This project was co-funded by API and Utility Air Regulatory Group (UARG).

b) Client Information:

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c) Scope of Work

Commentary on the US EPA Benefits and Costs of the Clean Air Act Report from 1990 to 2020

Gradient reviewed and critiqued scientific information that was the basis for the 2011 US EPA document, "Benefits and Costs of the 2011 Clean Air Act Report from 1990 to 2020." Specifically, we reviewed the underlying assumptions and the uncertainties associated with the US EPA methodology. Based on our expertise in risk assessment, epidemiology, and statistics, we provided opinions on whether the then-current scientific data supported US EPA's conclusions.

Highlights
- *Regulatory comment*
- *Criteria air pollutants*
- *Cost-benefit analysis*

Air Pollutant NAAQS Risk Critique

Gradient critiqued various documents released by US EPA as part of its process for revising the NAAQS for NO_2, SO_2, and PM. We evaluated the agency's basis for decision-making regarding the NAAQS for these pollutants that are protective of public health. Focusing on the underlying epidemiology and human exposure studies, we evaluated the causal associations between exposure to these pollutants and multiple health effects. Gradient provided written and oral testimony to US EPA at several public hearings.

Highlights
- *Regulatory comment*
- *Epidemiology*
- *Human exposure studies*
- *Risk assessment*

Nitrogen Dioxide Health Effects Evaluation

Gradient performed a meta-analysis of clinical studies to assess the concentration of NO_2 that causes airway hyper-responsiveness in humans. This issue bears on the NO_2 NAAQS promulgated by US EPA. Our analysis included an evaluation of the influence of several factors, including type of airway impact, exposure method (*i.e.*, chamber *vs.* mouthpiece), exercise, and allergy/asthma status, on airway response to NO_2. Gradient's analysis was published in a peer-reviewed scientific journal.

Highlights
- *Meta-analysis*
- *NAAQS*
- *Epidemiology*
- *Criteria air pollutants*
- *Controlled exposure studies*

Ozone NAAQS Health Effects Review and Testimony

Gradient critiqued the rationale for US EPA's proposed reconsideration of the 2008 ozone NAAQS. We critically reviewed the key clinical and epidemiological studies on which US EPA relied. We also evaluated the key issues with the underlying human health data that formed the agency's basis for decision-making regarding its 2008 ozone standard. Gradient provided oral testimony regarding our analysis to US EPA and the Texas House of Representatives Committee on Environmental Regulation.

Highlights
- *Risk assessment*
- *Regulatory comment*
- *Air pollution*
- *Epidemiology*

Reconsideration of Ozone NAAQS Final Rule

Gradient critically reviewed the key clinical and epidemiological studies that formed US EPA's rationale for proposing to lower the 2008 ozone NAAQS. In a series of webinars with supporting materials, we presented the key issues in these studies and the manner in which the new ozone standards would affect communities. We presented our analysis to congressional staff, the US Office of Management and Budget (OMB), and US EPA as part of a reconsideration request of the Final Rule.

Highlights
- *Air pollution*
- *Risk assessment*
- *Regulatory comment*
- *Webinar presentations*

Particulate Matter NAAQS Risk Critique

Gradient critiqued several documents as part of US EPA's process for revising primary NAAQS for PM, including US EPA's 2009 ISA and its 2010 risk and policy assessments. We evaluated US EPA's basis for making decisions regarding a PM NAAQS that is protective of public health. Focusing on the underlying epidemiology studies, Gradient evaluated the causal associations between PM exposure and multiple health effects. Gradient provided written and oral testimony to US EPA at a public hearing.

Highlights
- *Regulatory comment*
- *Epidemiology*
- *Risk assessment*

Comments on the US EPA Proposed Rule for Sulfur Oxides

Gradient critically reviewed and submitted comments regarding US EPA's 2009 proposed rule for SO_x as part of its review for promulgating the NAAQS. We evaluated the agency's basis for proposing a short-term standard for SO_x. Focusing on the underlying epidemiology and clinical studies, Gradient evaluated whether there was a causal association between short-term SO_2 exposure and respiratory morbidity at exposures below the current NAAQS. Gradient provided oral testimony and written comments to US EPA.

Highlights
- *Epidemiology*
- *Clinical studies*
- *Testimony and regulatory comment*

d) Nature of Proposer's Responsibility: The proposer functioned as the prime contractor on all of these projects and was responsible for the successful completion of work.

e) Period of Performance: Beginning and end dates are shown in the Table 4.1. US EPA and CASAC comments submissions have hard deadlines, though these are often extended (*e.g.*, if US EPA is late releasing a NAAQS document). If US EPA extended deadlines for public comments, often our client deadlines were extended as well.

f) Dollar Value of the Contract: Confidential.

g) Subcontractors: None.

4.2 American Chemistry Council

a) Gradient has worked on several contracts with the American Chemistry Council (ACC) since 2000 (13 years). Many of these contracts involve(d) WoE analyses. The project managers at Gradient have most often been Dr. Lorenz Rhomberg and/or Dr. Julie Goodman (617-395-5000). Dr. Rick Becker (202-249-6405) and Dr. Steven Hentges (202-249-6624) have been our contacts for most of this contracted work. All work was performed in Cambridge, MA, or Seattle, WA.

Table 4.2 American Chemistry Council Contracts

Title	Start Date	End Date	Contract #
Weight of Evidence Best Practices	April 2012	Present	5374
Analysis of US EPA Proposed Ozone NAAQS	August 2007	July 2008	3918
Bisphenol A Weight-of-Evidence Update	November 2012	Present	5485
Comments for Science Advisory Board Weight-of-Evidence Methodology Review	May 2011	Present	5013
Weight-of-Evidence Review of EU Report on Endocrine Disruption	July 2011	November 2012	5077

b) Client Information:

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American Chemistry Council
700 Second Street, NE
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Phone: (202) 249-6405
Email: rick_becker@americanchemistry.com

c) Scope of Work

Weight-of-Evidence Best Practices Evaluation

Gradient conducted a survey to evaluate best practices for WoE analyses for determining causation. We reviewed nearly 50 WoE frameworks that have been published in the primary literature and as agency guidance documents and summarized and compared the key aspects of each. We defined the key concepts of WoE analyses and its application to particular problems and articulated the best practices from among the spectrum of approaches. We summarized our findings in a white paper.

Highlights
- *Mode of action*
- *Risk assessment*

Analysis of US EPA Proposed Ozone NAAQS

In 2007, US EPA proposed to reduce the NAAQS standard for ozone from 0.08 ppm to a concentration within the range of 0.070 to 0.075 ppm, based on recent findings in human health studies. Gradient analyzed US EPA's use of studies to support its proposed standard and assessed the strength of a causal relationship for a number of endpoints. This analysis was submitted to US EPA.

Highlights
- *Epidemiology studies*
- *Exposure and effect analysis*
- *Regulatory review*

Bisphenol A Weight-of-Evidence Update

Gradient updated previous analyses of studies examining low-dose exposure to BPA and its effects on reproduction and development in rodents. We used a WoE analysis method we developed previously to evaluate repeatability of outcomes across studies and consistency with an endocrine-modulation mode of action. We tabulated our results in combination with those of our previous analyses to present a comprehensive overview of the entire literature of low-dose effects of BPA. Our client used the results for risk communication in a variety of settings.

Highlights
- *Endocrine disruption*
- *Reproductive and developmental toxicity*

Comments for Science Advisory Board Weight-of-Evidence Methodology Review

Gradient collaborated with other consultants to produce oral and written comments on WoE questions for a meeting of the US EPA's Chartered SAB as it considered the report of the Dioxin Review Panel, which examined a recent draft US EPA assessment document. Gradient's comments critiqued the adequacy of the US EPA's WoE evaluation of carcinogenicity and non-cancer toxicity in light of its own standards as quoted from US EPA guidelines and its Risk Characterization Handbook.

Highlights

- *SAB Comments*
- *Dioxins*

Weight-of-Evidence Review of EU Report on Endocrine Disruption

Gradient critically reviewed a draft European Union (EU) report on the state of the science regarding endocrine-disrupting chemicals. We assembled and led a panel of experts to determine whether the draft report constituted a complete and unbiased survey of the most recent literature on endocrine disruptors. Our analysis identified variances from a sound, transparent, and methodologically appropriate survey of the science and WoE evaluation. Our critique was published as a letter to the editor in a peer-reviewed scientific journal.

Highlights

- *State of knowledge*
- *Literature review*

d) Nature of Proposer's Responsibility: The proposer functioned as the prime contractor on all of these projects and was responsible for the successful completion of work.

e) Period of Performance: Beginning and end dates are shown in Table 4.2. The vast majority of the time, we met deadlines. If at any time during the projects it appeared that Gradient would miss a pre-determined deadline, we contacted the client and got them a work product in time to meet their needs.

f) Dollar Value of the Contract: Confidential.

g) Subcontractors: For the WoE review of the EU report on endocrine disruptors, we assembled a team of experts. Gradient conducted the original review and sent it to the team for comments before we submitted the draft manuscript for publication. Gradient also drafted a response to reviewers, and the team reviewed and commented on this before we resubmitted the manuscript.

4.3 Utility Air Regulatory Group

a) Gradient has worked under several contracts with the Utility Air Regulatory Group (UARG) since 2007 (6 years), providing critical analysis of scientific documents related to the review of NAAQS for ozone, NO_x, and PM. The project managers at Gradient have often been Dr. Chris Long or Dr. Julie Goodman (617-395-5000). Ms. Lucinda (Cindy) Minton Langworthy has been our contact for most of the contracted work. Example projects are listed in the table below.

Table 4.3 Utility Air Regulatory Group Contracts

Title	Start Date	End Date	Contract #
Scientific Comment on US EPA Ozone Integrated Science Assessment	April 2011	October 2012	ASC/GRA/3
Nitrogen Dioxide Health Effects Evaluation	April 2009	January 2010	2009-104291*

*This project was co-funded by API and UARG.

b) Client Information:

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c) Scope of Work

Scientific Comment on US EPA Ozone Integrated Science Assessment

Gradient conducted an independent scientific analysis of the US EPA Integrated Science Assessment for Ozone and Related Photochemical Oxidants. Our work critiqued the US EPA assessment of the health effects literature for ozone, specifically focusing on US EPA's findings related to the causal linkage between short- and long-term exposures to ozone and mortality. Gradient's analysis was submitted as public comments to US EPA.

Highlights
- *Regulatory comments*
- *Mortality impacts*
- *Epidemiology*

Nitrogen Dioxide Health Effects Evaluation

Gradient performed a meta-analysis of clinical studies to assess the concentration of NO_2 that causes airway hyper-responsiveness in humans. This issue bears on the NO_2 NAAQS promulgated by US EPA. Our analysis included an evaluation of the influence of several factors, including type of airway impact, exposure method (*i.e.*, chamber *vs.* mouthpiece), exercise, and allergy/asthma status, on airway response to NO_2. Gradient's analysis was published in a peer-reviewed scientific journal.

Highlights
- *Meta-analysis*
- *Controlled exposure studies*

d) Nature of Proposer's Responsibility: The proposer functioned as the prime contractor on all of these projects and was responsible for the successful completion of work.

e) Period of Performance: Beginning and end dates are shown in Table 4.3. US EPA and CASAC comments submissions have hard deadlines, though these are often extended (*e.g.*, if US EPA is late releasing a NAAQS document). If US EPA extended deadlines for public comments, often our client deadlines were extended as well.

f) Dollar Value of the Contract: Confidential.

g) Subcontractors: None.

4.4 Toxicology Excellence for Risk Assessment

a) Dr. Julie Goodman (617-395-5000) received an honorarium from Toxicology Excellence for Risk Assessment (TERA) for serving as a peer-reviewer on the TCEQ document, "Development Support Document for Nickel and Inorganic Nickel Compounds, Preliminary Draft, May 2009." Her contact at TERA for this project was Jacqueline Patterson (513-542-7475).

b) Client Information:

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c) Scope of Work

Peer-Review of Proposed Nickel Regulations

TCEQ prepared the "Development Support Document for Nickel and Inorganic Nickel Compounds, Preliminary Draft, May 2009," which outlines the hazard assessment and dose-response processes used to derive exposure levels to nickel and inorganic nickel compounds below which cancer and non-cancer health effects are not likely to occur. A Gradient principal served on an expert external peer-review panel of this document, where she critically reviewed the methodologies and the toxicology and epidemiology studies on which they were based. These comments were considered by TCEQ as it finalized this document.

Highlights

- *Risk methodology review*
- *Epidemiology/toxicology evaluation*
- *Regulatory comment*

d) Nature of Proposer's Responsibility: The proposer functioned as a subcontractor to TERA. She reviewed the document and served on the peer-review panel.

e) Period of Performance: August 2009 - March 2010. All deadlines were met.

f) Dollar Value of the Contract: Confidential.

g) Subcontractors: None.