

# Protecting Public Health in the Face of Real and Manufactured Scientific Uncertainty

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Forum on Environment and Cancer

March 1, 2022

THE  
TRIUMPH  
OF  
DOUBT

DARK MONEY  
AND THE SCIENCE  
OF DECEPTION

DAVID MICHAELS

# The Current State of Affairs

It is now standard operating procedure for corporations to ***manufacture scientific uncertainty*** about potential harms caused by their products or activities.

Much of this is accomplished using “product defense” consulting firms.

# Tobacco's Campaign to Manufacture Uncertainty

“Doubt is our product, since it is the best means of competing with the ‘body of fact’ that exists in the minds of the general public. It is also the means of establishing controversy.”

-Brown & Williamson Document No. 332506, 1969



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Reports on

# Tobacco and Health Research

Vol. 7 No. 1

March-April 1964

## IN THIS ISSUE

Babies of smokers, p. 1

Heart studies, p. 2

Virus studies, p. 3

There is diversity of opinion regarding tobacco use and health. Charges against tobacco are widely publicized, but less attention is given to materials which indicate that differing opinions exist. This publication reports some of these materials.

## Follow-up Study Sheds New Light on Smoking And Infant Survival

Small babies born of cigarette-smoking mothers are markedly less likely to die at birth than are small babies of non-smoking mothers, a University of California biostatistician has found.\*

In a study of 6,800 infants born at the Kaiser Foundation Hospital, Oakland, Calif., Dr. Jacob Yerushalmy confirmed earlier findings that smoking mothers have more babies weighing under 5 lbs. 8 oz. (2500 gm.) at birth than do non-smokers.

Among 3,189 babies of non-smoking white women, Dr. Yerushalmy found 112 (3.5 percent) underweight,

(Continued on page 2)

\*"Mothers, cigarette smoking, and survival of infants." *American Journal of Obstetrics and Gynecology*, February 1964.

## 'Lung Cancer Rare in Bald Men'

A relatively low incidence of lung cancer among bald men has been reported by two New Orleans physicians.\* In contrast, the study supported earlier findings that baldness is associated with "increased susceptibility to heart disease."

Drs. Morton Brown and Howard A. Buschner studied 225 control pa-

From 1908 to 1959 . . .

## Massive German Study Points to Occupational Hazards in Lung Cancer

An increase in lung cancer incidence in Germany has been found to be most marked in three groups of occupations exposed to air pollutants, a team of pathologists and statisticians has concluded.\*

Their report included observations of recent lung cancer cases as well as study of autopsy records as far back as 1908. They found lung cancer incidence was most prevalent in a major industrial area among these groups:

- 1) Outdoor workers (high and deep construction workers, agricultural workers);
- 2) Industrial workers and craftsmen doing industrial type work;
- 3) Persons exposed to the effects of modern vehicular traffic (chauffeurs, railroad workers, messengers, traffic policemen, salesmen, etc., exclusive of office workers).

A lower incidence of epithelial lung cancer was found among (4) "crafts-

men of the old type who work in small shops," and among (5) "domestic, warehouse, store, office and administrative workers, and also members of the teaching profession," the investigators reported.

These conclusions emerged from a six-year study of 1,229 cases of the disease, plus an analysis of more than 26,000 autopsy records reaching back to the year 1908, according to Prof. Dr. Reinhard Poche, chief physician, Pathological Institute, Düsseldorf Medical Academy. The project also involved university departments of pathology at Bonn, Solingen, Bethel, Bielefeld, Dortmund, Duisberg, Essen, Essen-Steele, Cologne-Merheim and Münster.

The records studied covered the patients' history, occupations, urban or rural residence, war record, internment record, smoking habits and histological diagnosis.

The increase is accounted for chiefly

as opposed to 25 percent among Negro controls. Among the lung cancer patients, however, only 11 percent of the whites were bald, and only 10 percent of the Negroes, the investigators report.

The highest incidence of baldness among the lung cancer patients was 16 percent in the group aged 60-70

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The book cover features a photograph of a large concrete dam with water cascading over its spillways into a waterfall. The background consists of a dense forest of evergreen trees, with snow-capped mountains visible in the distance under a clear blue sky. The title is printed in large, white, sans-serif font over the upper portion of the image.

# Why Scientists Disagree About Global Warming

The NIPCC Report on Scientific Consensus

Craig D. Idso · Robert M. Carter  
S. Fred Singer

# Diesel Exhaust in Miners Studies

DOI: 10.1093/jnci/djq936  
Advance Access publication on March 5, 2012.

Published by Oxford University Press 2012.

## ARTICLE

### The Diesel Exhaust in Miners Study: A Cohort Mortality Study With Emphasis on Lung Cancer

Michael D. Attfield, Patricia L. Schleiff, Jay H. Lubin, Aaron Blair, Patricia A. Stewart, Roel Vermeulen, Joseph B. Coble, Debra T. Silverman

Manuscript received February 14, 2011; revised October 12, 2011; accepted October 21, 2011.

**Correspondence to:** Patricia L. Schleiff, MS, Division of Respiratory Disease Studies, National Institute for Environmental Health Sciences, Research Triangle Park, NC 27709 (e-mail: pls1@rdsi.nih.gov).

**Background** Current information points to an association between diesel exhaust exposure and lung cancer mortality outcomes, but uncertainties remain.

**Methods** We undertook a cohort mortality study of 12 315 workers exposed to diesel exhaust at various mining facilities. Historical measurements and surrogate exposure data were used to derive retrospective quantitative estimates of diesel exhaust exposure for each worker. Standardized mortality ratios and internally derived hazard ratios were used to evaluate diesel exhaust exposure-associated risk. Analyses were restricted to recent exposure such as that occurring in the 15 years directly before time of death.

**Results** Standardized mortality ratios for lung cancer (1.26, 95% confidence interval [CI] = 1.03 to 1.54), and pneumoconiosis (12.20, 95% CI = 6.82 to 21.50) were elevated in the cohort compared with state-based mortality rates, but all-cause, black, and obstructive pulmonary disease mortality were not. Differences in risk between surface and underground workers initially obscured a positive diesel exhaust exposure-response relationship in the complete cohort, although it became apparent after adjustment for work-related factors. Lung cancer mortality increased with increasing 15-year lagged cumulative exposure, with the reference category (0 to <20  $\mu\text{g}/\text{m}^3\text{-y}$ ; 30 deaths compared with 5.01, 95% CI = 1.97 to 12.76) but declined at higher exposures. Average hazard ratios plateaued around 32  $\mu\text{g}/\text{m}^3$ . Elevated hazard ratios and evidence of exposure-response were observed for lung cancer and other work-related potentially confounding exposures in the models adjusted for exposure derivation.

**Conclusions** The study findings provide further evidence that exposure to diesel exhaust is associated with lung cancer and have important public health implications.

J Natl Cancer Inst 2012;104:869–883

DOI: 10.1093/jnci/djq934  
Advance Access publication on March 5, 2012.

Published by Oxford University Press 2012.  
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## ARTICLE

### The Diesel Exhaust in Miners Study: A Nested Case-Control Study of Lung Cancer and Diesel Exhaust

Debra T. Silverman, Claudine M. Samanic, Jay H. Lubin, Aaron E. Blair, Patricia A. Stewart, Roel Vermeulen, Joseph B. Coble, Nathaniel Rothman, Patricia L. Schleiff, William D. Travis, Regina G. Ziegler, Sholom Wacholder, Michael D. Attfield

Manuscript received February 15, 2011; revised June 3, 2011; accepted October 21, 2011.

**Correspondence to:** Debra T. Silverman, ScD, Occupational and Environmental Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, Room 9108, 6120 Executive Blvd, Bethesda, MD 20895 (e-mail: silvermd@mail.nih.gov).

**Background** Most studies of the association between diesel exhaust exposure and lung cancer suggest a modest, but consistent, increased risk. However, to our knowledge, no study to date has had quantitative data on historical diesel exhaust exposure coupled with adequate sample size to evaluate the exposure-response relationship between diesel exhaust and lung cancer. Our purpose was to evaluate the relationship between quantitative estimates of diesel exhaust exposure and lung cancer mortality after adjustment for smoking and other potential confounders.

**Methods** We conducted a nested case-control study in a cohort of 12 315 workers in eight non-metal mining facilities, which included 198 lung cancer deaths and 562 incidence density-sampled control subjects. For each case subject, we selected up to four control subjects, individually matched on mining facility, sex, race/ethnicity, and birth year (within 5 years), from all workers who were alive before the day the case subject died. We estimated diesel exhaust exposure, represented by respirable elemental carbon (REC), by job and year, for each subject, based on an extensive retrospective exposure assessment at each mining facility. We conducted both categorical and continuous regression analyses adjusted for cigarette smoking and other potential confounding variables (eg, history of employment in high-risk occupations for lung cancer and a history of respiratory disease) to estimate odds ratios (ORs) and 95% confidence intervals (CIs). Analyses were both unlagged and lagged to exclude recent exposure such as that occurring in the 15 years directly before the date of death (case subjects) or reference date (control subjects). All statistical tests were two-sided.



2012: The World Health Organization/  
International Agency for Research on Cancer  
Classifies Diesel Engine Exhaust  
as Carcinogenic to Humans



# How did the Diesel Industry Respond?



Critical Reviews in Toxicology



ISSN: 1040-8444 (Print) 1547-6898 (Online) Journal homepage: <http://www.tandfonline.com/loi/itx20>

## A Critical Assessment of Studies on the Carcinogenic Potential of Diesel Exhaust

Thomas W. Hesterberg, William B. Bunn III, Gerald R. Chase, Peter A. Valberg, Thomas J. Slavin, Charles A. Lapin & Georgia A. Hart

## Reanalysis of the DEMS Nested Case-Control Study of Lung Cancer and Diesel Exhaust: Suitability for Quantitative Risk Assessment

Kenny S. Crump,<sup>1,\*</sup> Cynthia Van Landingham,<sup>2</sup> Suresh H. Moolgavkar,<sup>3</sup> and Roger McClellan<sup>3</sup>

## Reanalysis of Diesel Engine Exhaust and Lung Cancer Mortality in the Diesel Exhaust in Miners Study Cohort Using Alternative Exposure Estimates and Radon Adjustment

Ellen T. Chang<sup>\*</sup>, Edmund C. Lau, Cynthia Van Landingham, Kenny S. Crump, Roger O. McClellan, and Suresh H. Moolgavkar

\* Correspondence to Dr. Ellen T. Chang, Center for Health Sciences, Exponent, Inc., 149 Commonwealth Drive, Menlo Park, CA 94025 (e-mail: [echang@exponent.com](mailto:echang@exponent.com)).

## Research and regulation of diesel exhaust: an overview focused on lung cancer risk

Hesterberg<sup>1</sup>, Christopher M. Long<sup>2</sup>, William B. Bunn<sup>1</sup>, Charles A. Lapin<sup>1</sup>, Slavin<sup>1</sup>, and Peter A. Valberg<sup>2</sup>

<sup>1</sup>Illinois, USA, <sup>2</sup>Gradient, Cambridge, Massachusetts, USA, and <sup>3</sup>Institute for Occupational and Environmental Health, University of Illinois at Chicago

## Lung cancer and diesel exhaust: an updated critical review of the occupational epidemiology literature

John F. Gamble<sup>1</sup>, Mark J. Nicolich<sup>2</sup>, and Paolo Boffetta<sup>3,4</sup>

<sup>1</sup>National Institute for Environmental Health Sciences, Durham, NC, USA, <sup>2</sup>Department of Environmental Health Sciences, University of Illinois at Chicago, Chicago, IL, USA, <sup>3</sup>International Agency for Research on Cancer, Lyon, France, and <sup>4</sup>INSERM U1052, Lyon, France

<sup>1</sup>566 Elizabeth Avenue, Somerset, NJ 08873, USA, <sup>2</sup>COGIMET, Lambertville, NJ, USA, <sup>3</sup>The Tisch Cancer Institute and Institute for Translational Epidemiology, Mount Sinai School of Medicine in New York, NY, USA, and <sup>4</sup>International Prevention research Institute, Lyon, France

Abstract

## Influence of Alternative Exposure Estimates in the Diesel Exhaust Miners Study: Diesel Exhaust and Lung Cancer

Van Landingham,<sup>2</sup> and Roger O. McClellan<sup>3</sup>

The landmark Diesel Exhaust in Miners Study (DEMS) studied the relationship between diesel engine exhaust (DEE) and lung cancer mortality of workers at eight nonmetal mines were followed from beginning of dieselization of the mines (1947–1967) through December 1, 1997. The original analyses quantified DEE exposures using exposure to respirable particulate carbon (REC) to represent DEE, and CO as a surrogate for REC. However, this

that additional includes seven trends between bounding. Those inconsistent E-R

# The PROBLEMS with PFAS



HOW DOES IT GET INTO OUR BODIES?



Cooking with nonstick pans



Products containing PFAS



PFAS-contaminated food and water



PFAS in air and dust



HEALTH PROBLEMS LINKED TO PFAS



Kidney and testicular cancer

High blood pressure and pre-eclampsia

Higher cholesterol

Lower infant birth weights

Decreased vaccine response in children

## PFAS

- Short for **per- and polyfluoroalkyl substances**, chemicals used in products such as non-stick cookware, food packaging, water-resistant clothing, and stain-resistant carpeting
- Also called **'forever chemicals,'** they can take up to 1,000 years to break down in nature

## WHAT CAN WE DO?



INDIVIDUALS – **avoid products with PFAS** and ask policymakers to limit or ban its use

HEALTH PROFESSIONALS – **advise patients on how to avoid PFAS** and support limits on its use

BUSINESSES – **phase out use of PFAS** and avoid non-essential uses

POLICYMAKERS – **limit or ban PFAS**

# Defending PFAS: 2002

Following initial C8 lawsuits, at DuPont's recommendation, West Virginia hires product defense firm **Toxicology Excellence for Risk Assessment (TERA)** to calculate safe level of PFAS in drinking water.

TERA recommends 150 parts per billion as **150** times DuPont's internal safe level.

# Defending PFAS: 2006

DuPont hires **ChemRisk** to estimate risk among population who drink PFAS-contaminated water. ChemRisk's conclusion:

“the likelihood of adverse health effects due to exposure to PFOA, based on currently available information, is **extremely low.**”

Paustenbach DJ, Panko JM, Scott PK, Unice KM. A methodology for estimating human exposure to perfluorooctanoic acid (PFOA): A retrospective exposure assessment of a community (1951–2003). *Journal of Toxicology and Environmental Health, Part A.* 2006;70(1):28-57.

# Defending PFAS: 2014

In 2012, independent investigators leading DuPont-funded C8 study conclude “PFOA exposure was associated with kidney and testicular cancer in this population.”

Barry V, Winqvist A, Steenland K. Perfluorooctanoic acid (PFOA) exposures and incident cancers among adults living near a chemical plant. *Environ Health Perspect.* 2013 Nov-Dec;121(11-12):1313-8.

3M hires **Exponent** to prepare a strategic literature review, which found:

“the epidemiologic evidence does not support the hypothesis of a causal association between PFOA or PFOS exposure and cancer in humans.”

Ellen T. Chang, Hans-Olov Adami, Paolo Boffetta, Philip Cole, Thomas B. Starr & Jack S. Mandel (2014) A critical review of perfluorooctanoate and perfluorooctanesulfonate exposure and cancer risk in humans, *Critical Reviews in Toxicology*, 44:sup1, 1-81, DOI: 10.3109/10408444.2014.905767

# Defending PFAS: 2016

In response to US National Toxicology Program review and hazard assessment, scientists at **Gradient**, 3M's product defense consultant, assert:

NTP's analysis is biased and “much of the human and animal evidence **does not support NTP's conclusions**, and the hazard ratings for both PFOA and PFOS should be downgraded.”

Gradient. Comments Regarding the Systematic Review of Immunotoxicity Associated with Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS): Prepared on behalf of 3M. July 5, 2016

# Defending PFAS: 2017

2017: 3M's product defense consultant **Exponent** issues report in Minnesota litigation asserting:

“The overall weight of the relevant epidemiologic evidence is not sufficient to demonstrate causal associations between exposure to specific PFAS... and the development of specific adverse health outcomes in humans, whether in general communities, PFAS-contaminated communities, or occupational settings.”

Chang ET (Exponent). Expert Report. In the matter of State of Minnesota, et al., vs. 3M Company. 7 Nov. 2017

# Selected Glassdoor Reviews by Product Defense Firm Employees

- “This is a law consulting company, not a science consulting company. Don’t expect to be a ‘scientist.’” [**Cardno ChemRisk**]
- “Some of the principal scientists have questionable ethics (and have been called out for it).” [**Gradient**]
- “Sometimes you will be working for the evil do-ers and trying to make it seem like they did nothing wrong.” [**Exponent**]



# Manufactured Uncertainty Threatens Public Health

- Clean Air
- Clean Water
- The Opioid Epidemic
- The Obesity Epidemic
- Pediatric Neurological Development
- Alcohol-Related Diseases
- US Football and Chronic Traumatic Encephalopathy (CTE)

# The Work of Mercenary Scientists Hurts the Credibility of All Scientists



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# How to Avoid Repeating Our Mistakes

- Build structures that deter both “agency capture” and the revolving door
- Recognize the inevitability of real uncertainty (as distinguished from manufactured uncertainty) and that decisions must be made using the best evidence available at the time.
- Acknowledge that the absence of evidence of harm is not the evidence of absence of harm
- Build the evidence base with research produced by unconflicted scientists

# Unconflicted Research?

- Polluters and producers of hazardous chemicals must pay for the research, but not control it.
- Research must be directed by independent, unconflicted scientists.

## What Other Past Mistakes to Avoid?

- Regulate toxic chemicals by class, not one by one.
- Chemicals are not innocent until proven guilty:

*End the Presumption of Innocence!*

Thank You for Listening