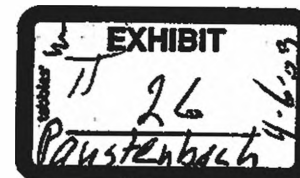


Chem

Clever Deception: Judging Science by Funding Source Instead of Intellectual Content

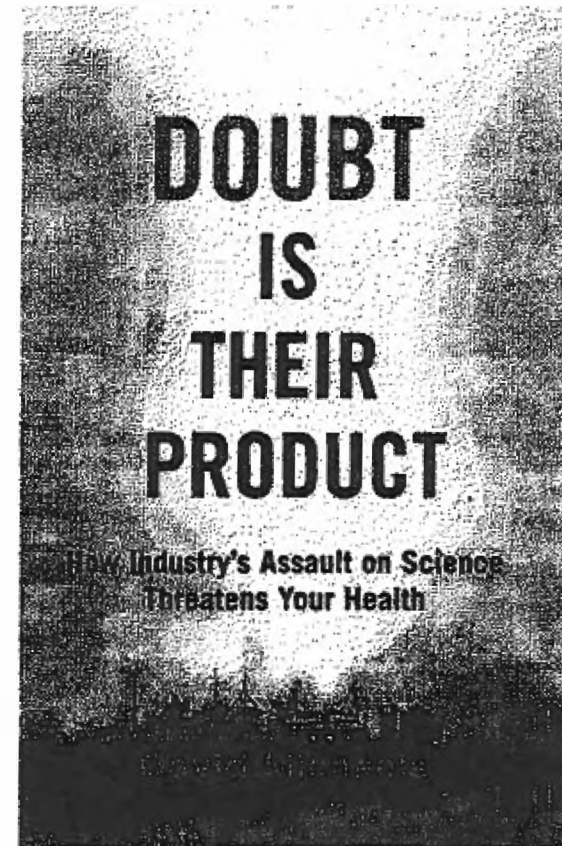


Dennis J. Paustenbach, Ph.D.

DRI Toxic Torts and Environmental Law Seminar
Phoenix, Arizona
March 20, 2009

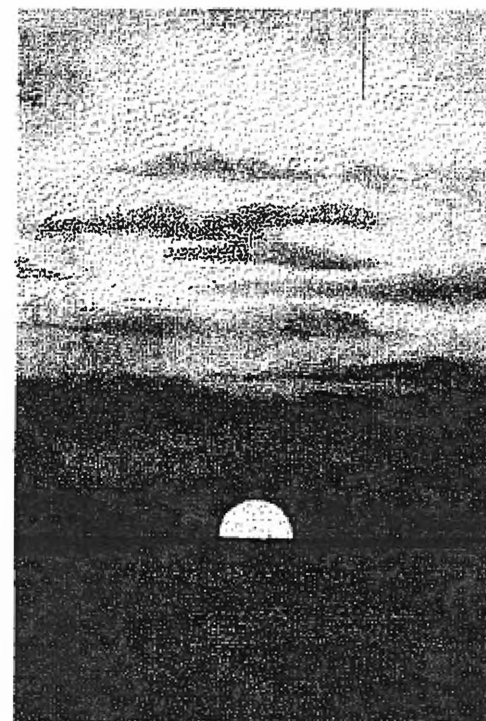
Overview

- Dr. Michaels' claims
- My take on his claims
- Five flaws in his beliefs
- What Michaels avoids
- The impact of Michaels and his book



Initially...

- I thought that putting together this presentation would be straightforward - - it was not !
- I collected Dr. Michaels' written materials and carefully read and reread his book
- He identified nearly 100 persons and organizations to be "manufacturing uncertainty" or "part of the charade"



Deciding the Proper Approach

- My son, a journalism major, confided that I needed to shed the more polite and academic tone in order to stand up to the ferocity of the claims.



How Ferocious Are His Claims?

“They and the larger, wealthier industries for which they work go through the motions we expect of the scientific enterprise, salting the literature with their questionable reports and studies.

Nevertheless, it is all a charade. The work has one overriding motivation; advocacy for the sponsor’s position in civil court....”

- (Michaels, Doubt is Their Product, or, “Michaels’ Book,” p. 460)



How Aggressive is Dr. Michaels?

- “[Product defense companies] ...combine science with public relations to help clients avoid regulation and litigation.”
- “Some of the big ones are Exponent, Gradient, Chem**Risk** and the Weinberg group.”
- When FastCompany asked, “Are there examples of product defense firms rescuing legitimate products?”
- Michaels responded: “Those examples are rare, if they exist at all.”

- Interview with FastCompany, Jan. 14, 2009



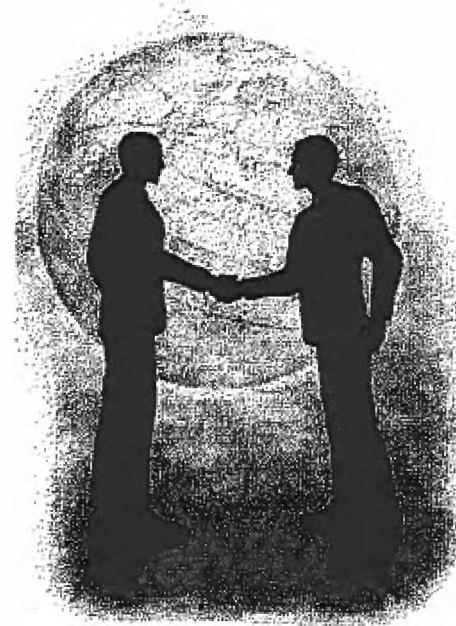
Areas Where Dr. Michaels and I Appear to Disagree:

- The regulated community (including governments and municipalities) is entitled to conduct studies which contribute to the body of scientific knowledge
- Scientific research should be evaluated on the merits of the study, not the source of the funding



Hopeful Areas of Agreement

- More and better studies are NOT always necessary to resolve many issues of science
- It is beneficial for journals to insist that scientists have a high level of disclosure



Other Hopeful Areas of Agreement

- All scientists should be expected to provide an honest and complete presentation of their results
- “The best evidence should be used to regulate chemicals.”

(p. 60, Michaels' Book)



Chem

However...

**I strongly
disagree with
his stream of
accusations**

Industry groups are fighting
government regulation by
fomenting scientific uncertainty

DOUBT

By David Michaels
Photographs by Michael Levenson

Is Their Product

Few scientific challenges are more complex than understanding the health risks of a chemical or drug. How, after all, does one determine if a product is as safe as it seems, or if it is not? Federal scientists' claims that a risk is minimal, or that a chemical is safe, are often challenged by industry groups or by the public. In the case of asbestos, the chemical is known to be a lung irritant, and a long list of other health effects are listed. The U.S. Environmental Protection Agency (EPA) has been challenged by industry groups to challenge a government's claim that a chemical is safe. The



Allegations of Consultant Alchemy

“When product defense specialists cannot get the raw data required for a reanalysis, they have even been known to make them up.”

Michaels' Book, p. 52



My Six General Views

- Michaels, Egilman and other pundits are skilled at telling half the story, providing a misleading, if not deceptive version of the facts
- A dynamic tension in science is to be expected and the struggle is heightened in a courtroom situation



JAMA[®]
The Journal of the American Medical Association

Rothman KJ, JAMA, 1993

Copyright 1993 by the American Medical Association. All Rights Reserved.

Applicable FARS/DFARS Restrictions Apply to Government Use. American Medical Association, 515 N. State St.
Chicago, IL 60610.

Volume 269(21), 2 Jun 1993, pp 2782-2784

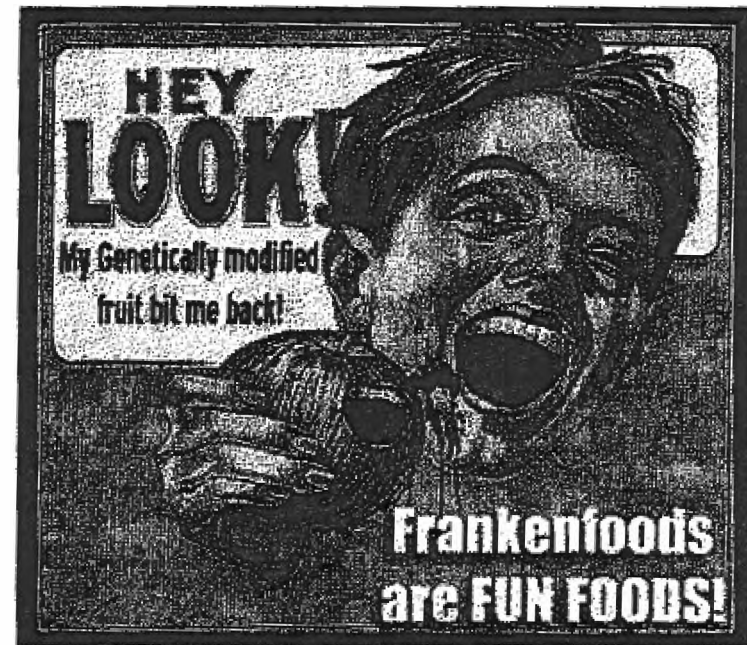
Conflict of Interest: The New McCarthyism in Science

Rothman, Kenneth J.

- But... to question scientists based on affiliation echoes McCarthyism and is inconsistent with honest scientific inquiry

Weird Science

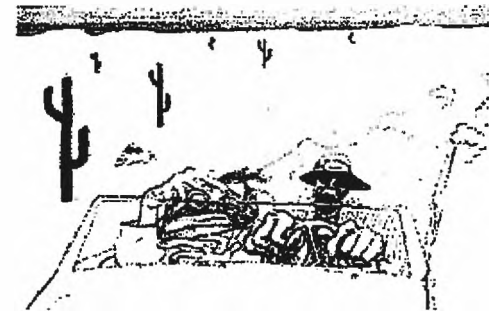
- The pundits fail to acknowledge that very bad science and medicine has been put before juries for decades



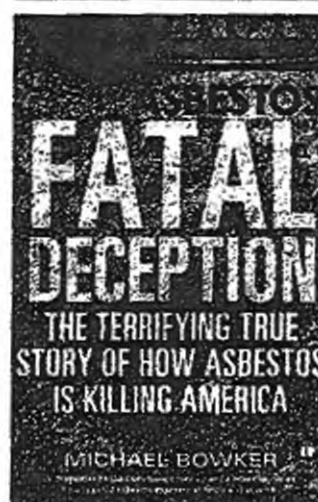
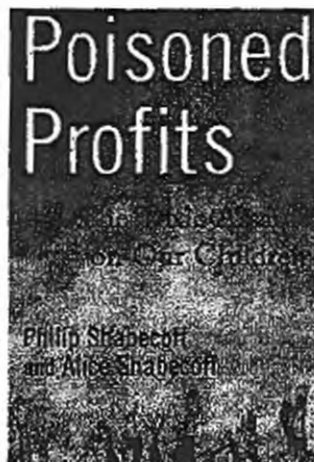
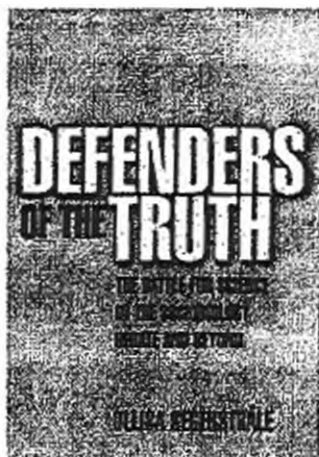
My Six General Views

- Dr. Michaels and his like-minded colleagues employ fear tactics and are not transparent regarding the real uncertainties
- Unfortunately, his claims are often inflammatory and abusive, frequently bordering on libel against those who do not share his views

Hunter S. Thompson
author of *Hell's Angels*
FEAR AND LOATHING
in LAS VEGAS
A Savage Journey to the
Heart of the American Dream
illustrations by Robert Rauschenberg

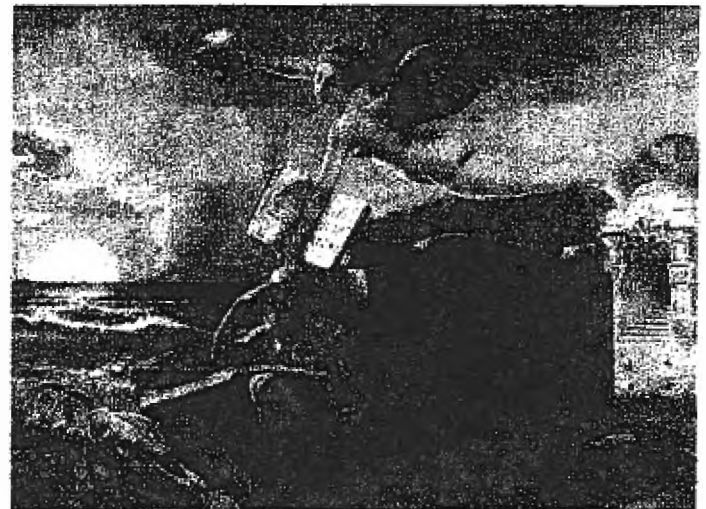


Part of a Coordinated Effort ?



These Pundits Claim to Be on the Side of the Angels...

- Those who question the scientific basis of proposed regulatory standards are, by definition, “mercenaries” whose views are not to be trusted



Dr. Michaels Is Not Just Another Voice - - He Is Quickly Becoming the “Go-To” Spokesman for Environmental Health

I believe he has the
ability to generate a
sea change in the
regulatory and litigation
landscapes



The flaws in his beliefs...



Flawed belief #1: Health effects claimed by plaintiffs are invariably due to chemical exposures

- Claims that every exposure to a single asbestos fiber above background contributes to risk of future disease... excluded!
- Neurologist claiming plaintiff developed multiple chemical sensitivities after exposures during home remodeling because of “limbic kindling”...excluded!

click on the location of your injury



Other Courtroom Claims

- A single exposure to floor wax remover by pregnant woman led to birth defects...excluded!
- Childhood leukemia caused by exposure to chicken manure...excluded!



ChemRisk Publications used to Rebut Plaintiff Expert Claims

Journal of Occupational and Environmental Hygiene, 2002, 79, 1528-1534
 ISSN 1545-9624 print / 1545-9632 online
 Copyright © 2002 JCEH, LLC
 10.1080/00984100290071496

Occupational Exposure to Airborne Asbestos from Phenolic Molding Material (Bakelite) During Sanding, Drilling, and Related Activities

Fionna Mowat,¹ Michael Bono,² R.J. Lee,³ Susan Tamburello,²
 and Dennis Paustenbach¹

¹Exponent, Menlo Park, California

²Exponent, Hudson, Ohio

³RLJ Lee Group, Inc., Monroeville, Pennsylvania
 ChemRisk, San Francisco, California

Journal of Exposure Analysis and Environmental Epidemiology 32(6) 214-234
 © 2004 Nature Publishing Group. All rights reserved. 1061-4268/04 \$15.00

www.nature.com/jee

Occupational exposure to airborne asbestos from coatings, mastics, and adhesives

DENNIS J. PAUSTENBACH,¹ AMY SAGE,² MICHAEL BONO³ AND FIONNA MOWAT¹

¹Exponent, Menlo Park, California, USA

²Exponent, Hudson, Ohio, USA

Journal of Toxicology and Environmental Health, Part A, 65:1965-1979, 2002

Copyright © 2002 Taylor & Francis

1528-7394/02 \$12.00 + .00

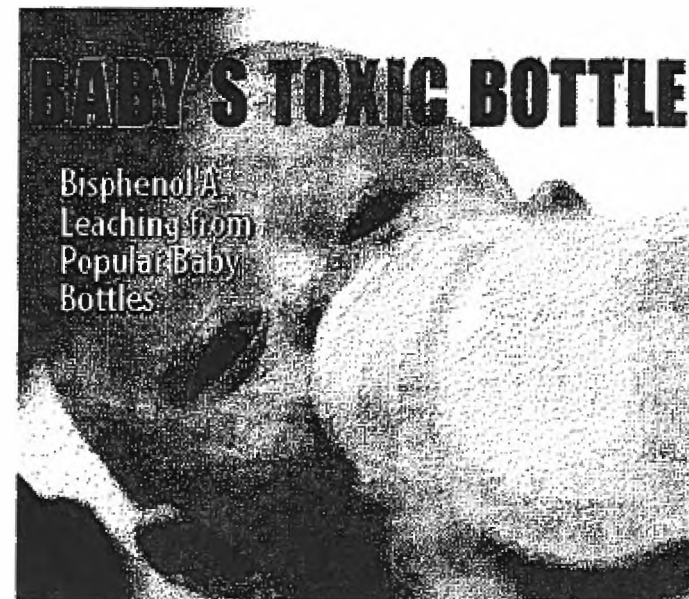
DOI: 10.1080/00984100290071496

Taylor & Francis
 healthsciences

AIRBORNE CONCENTRATIONS OF BENZENE AND MINERAL SPIRITS (STODDARD SOLVENT) DURING CLEANING OF A LOCOMOTIVE GENERATOR AND TRACTION MOTOR

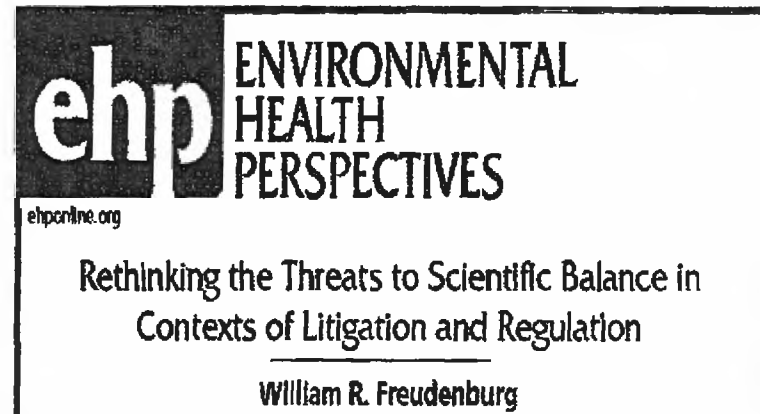
Flawed belief #2: Corporations should not comment on governmental decision-making

- Alas, we are a democratic society - - and corporations are entitled to defend themselves against unwarranted claims
- Michaels and others are attempting an “end-around” to legitimate scientific dialogue by manipulating public sentiment



Flawed belief #3: Published studies authored by companies and consulting firms are, by definition, not to be trusted

- I have seen no indication that scientific research conducted by consulting firms or corporations has been flawed or less valid than research conducted by universities or the government



Flawed belief #4: Studies by Consultants and Professors Supporting Plaintiffs Do Not Require Careful Scrutiny

- One need only review a few of the studies by many plaintiff experts to know this is not true

ATLANTA
Corporate Investigations
2245 Lakeview Court
Savannah, GA 31404
(770) 866-5166 Fax (770) 866-2669



ABRADING OF UNION CARBIDE ASBESTOS-

CONTAINING BAKELITE
FIBER RELEASE STUDY

William E. Longo

AUGUST 2004

My Position

- Since 1988, I have recommended that the consulting community should publish their research in toxicology journals
 - A Radical Position?

ASSESSMENT OF THE DEVELOPMENTAL RISKS RESULTING FROM OCCUPATIONAL EXPOSURE TO SELECT GLYCOL ETHERS WITHIN THE SEMICONDUCTOR INDUSTRY

Dennis J. Paustenbach

McLaren-Chemrisk, Rancho Cordova, California

This risk assessment evaluates the potential human hazards of effects posed by exposure to 2-ethoxyethanol (2-EE), 2-ethoxyethoxyethanol (2-ME), and 2-methoxyethanol acetate (2-MEA) used in semiconductor manufacturing. These glycol ethers are photoresists used in the wafer fabrication process. The available toxicology of these glycol ethers indicates that each can cause offspring of pregnant animals that have been exposed to relatively low doses. For these chemicals, the ratio of the lowest dose which caused effects in pregnant animals (A) and the lowest dose which produced de-

Flawed belief #5: Studies that Question Regulatory Initiatives Are Misdirected

- For decades, the merits of a scientific study were judged on their scientific content...not the source of funding
- Would you rather live in a world where the science is not what is debated - - but rather, what "team" the debater is on

Litigation-Generated Science: Why Should We Care?

Leslie F. Boden and David Ozenoff

Department of Environmental Health, Boston University School of Public Health, Boston, Mass

BACKGROUND: In a 1994 Ninth Circuit decision on the remand of *Danbert v. Merrell Dow Pharmaceuticals, Inc.*, Judge Alex Kozinski wrote that science done for the purpose of litigation should be subject to more stringent standards of admissibility than other science.

OBJECTIVES: We analyze this proposition by considering litigation-generated science as a subset of science involving conflict of interest.

DISCUSSION: Judge Kozinski's formulation suggests there may be reasons to treat science involving conflict of interest differently but raises questions about whether litigation-generated science should be singled out. In particular, we discuss the similar problems raised by strategically motivated science done in anticipation of possible future litigation or otherwise designed to benefit the sponsor and ask what special treatment, if any, should be given to science undertaken to support existing or potential future litigation.

CONCLUSION: The problems with litigation-generated science are not special. On the contrary, they are very general and apply to much or most science that is relevant and reliable in the courtroom setting.

KEY WORDS: biomedical research, conflict of interest, *Danbert*, litigation, peer review, regulatory science, science and litigation, scientific evidence. *Environ Health Perspect* 116:117-122 (2008). doi:10.1289/ehp.116117

My Position

- Bad Science has often found its way into regulations and the courtroom
- Michaels has confused “creating doubt” with “checking against reality”



(A) The “Phantom Epidemic” of Silicosis

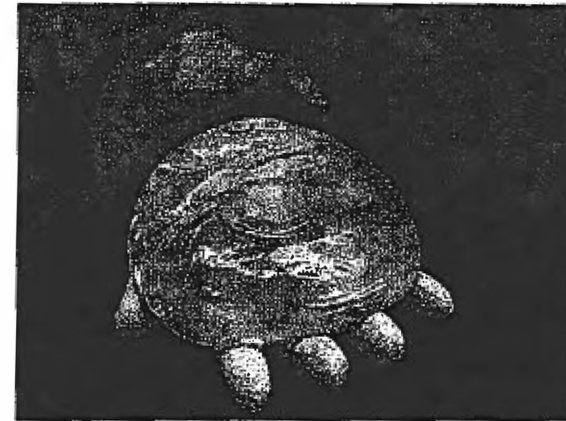
- “A golfer is more likely to hit a hole-in-one than an occupational medicine specialist is to find a single case of both silicosis and asbestosis. [They] parked a van in some parking lots and found over 4,000 such cases.”
- “Dr. Barry Levy diagnosed approximately 1,389 Plaintiffs in this MDL. All told, Dr. Levy performed 1,239 diagnostic evaluations in 72 hours.”
 - Less than 4 minutes per evaluation...
- “These diagnoses were driven by neither health nor justice: they were manufactured for money.”



Judge Janis Jack, In Re:
Silica Products Liability
Litigation, MDL Docket
#1553, Order #29

(B) Silicone Breast Implants and Risk of Disease

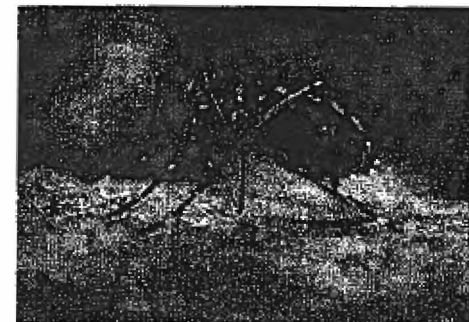
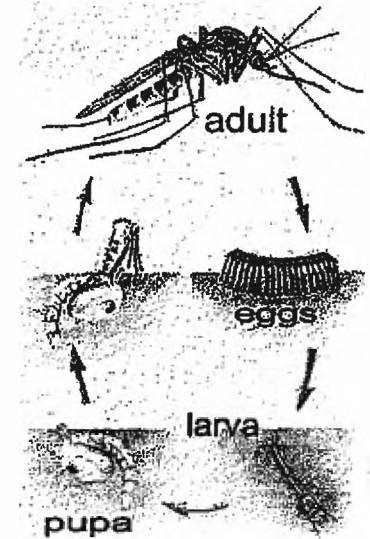
- “Substances known to be in breast implants do not provide a basis for health concerns.”
 - Institute of Medicine, Safety of Silicone Breast Implants, 1999
- Before these studies were released, however, several plaintiffs had won multimillion dollar verdicts, leading to a \$4.25 Billion class action settlement; the largest in history up to that time



Coincidentally...

- SKAPP, headed up by David Michaels and others, is generously funded by the Common Benefit Trust, a fund established pursuant to a court order in the Silicone Gel Breast Implant Products Liability Litigation
- Interestingly, the junk science that led to the collapse of several prominent companies lives on to support SKAPP

...who now advocate repeal of Daubert and Frye



(C) Misleading Testimony Can Influence Judges and Juries

- Some plaintiff experts use “tyndall lighting” to provide an impression of “real” exposures to asbestos
- But, this lighting can not differentiate asbestos from house dust or illuminate respirable particles (as they are too small)



(D) “Popcorn lung” is clearly linked to diacetyl exposure and every claim warrants a multimillion dollar verdict

Int Arch Occup Environ Health
DOI 10.1007/s00420-008-0937-6

© 2008 Springer-Verlag

Popcorn lung and bronchiolitis obliterans: a critical appraisal

David Colburn • David Weill

- Many alternative disease processes are often in play in worker populations...
 - Occupational asthma, hypersensitivity pneumonitis, smoking...
- Michaels does not seem to believe there is any remaining uncertainty... However, NIOSH and OSHA agree that the agent and mechanism of disease is still unclear

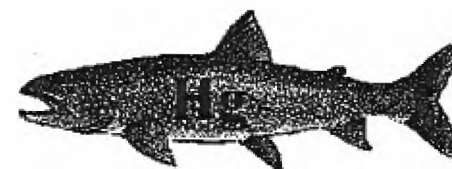
Examples Where Regulatory Agencies or Other Authorities Initially Got it Wrong

- Saccharin increases the risk of several cancers (1969)
- Bendectin and birth defects (1970s)
 - origin of Daubert
- Coffee increases the risk of pancreatic cancer
 - Prof. MacMahon, Harvard 1981



Was “Uncertainty” Warranted?

- Risks of dioxins in breast milk outweigh the benefits of breast feeding (Schechter, 1986)
- Mercury in vaccines increases the risk of autism (2006-2009)
- Mercury in fish outweighs the overall benefits of seafood to human health (2008-2009)



Although Dr. Michaels' book, his articles in the Washington Post, his blog and his lectures focus on "environmental and occupational health," it seems that the real target is the courtroom...





**Egilman “Papers”
and Testimony**



**Michaels’
Book Chapters**

Consultants Corrupting Science

(2005)

Maximizing Profit and Endangering Health:
Corporate Strategies to Avoid Litigation and Regulation

SUSANNA RANKIN BOHME, AM, JOHN ZORABEDIAN, DAVID S. EGILMAN, MD, MPH

INT J OCCUP ENVIRON HEALTH 2005;11:338-348



15

(2008)

*The Bush Administration's
Political Science*

DAVID MICHAELS

DOUBT IS THEIR PRODUCT

Brake Dust

Abuse of Epidemiology:

(2005)

Automobile Manufacturers Manufacture a Defense
to Asbestos Liability

DAVID S. EGILMAN, MD, MPH, MARION A. BILLINGS, MSC

INT J OCCUP ENVIRON HEALTH 2005;11:360-371



2

(2008)

Workplace Cancer before OSHA

WAITING FOR THE BODY COUNT

DAVID MICHAELS

DOUBT IS THEIR PRODUCT

Popcorn Lung

Popcorn-worker Lung Caused by
Corporate and Regulatory Negligence: (2007)
An Avoidable Tragedy

DAVID EGILMAN, MD, MPH, CAROLINE MAILLOUX, CLAIRE VALENTIN

INT J OCCUP ENVIRON HEALTH 2007;13:85-98



10

(2008)

Popcorn Lung

OSHA GIVES UP
DAVID MICHAELS

DOUBT IS THEIR PRODUCT

Beryllium

Anything But Beryllium: The Beryllium Industry's Corruption of Safety Information ⁽²⁰⁰²⁾

DAVID EGILMAN, MD, MPH

AMERICAN JOURNAL OF INDUSTRIAL MEDICINE 42:270-271 (2002)



11

(2008)

Defending the Toxicity Standard

DAVID MICHAELS

DOUBT IS THEIR PRODUCT

Chromium

Corporate Corruption of Science—⁽²⁰⁰⁶⁾
The Case of Chromium(VI)

DAVID EGILMAN, MD, MPH, SCOUT, PHD

INT J OCCUP ENVIRON HEALTH 2006;12:169-176



9

(2008)

Chrome-Plated Mischief

DAVID MICHAELS

DOUBT IS THEIR PRODUCT

Benzene

Manipulated Data in Shell's (2007)

Benzene Historical Exposure Study

Egilman David; Scout; Kol Lerin; Hegg Lea Anne; Bohme Susanna Rankin

International Journal of Occupational and Environmental Health, Vol 13, No (2007)



6

(2008)

Tricks of the Trade

HOW MERCENARY SCIENTISTS

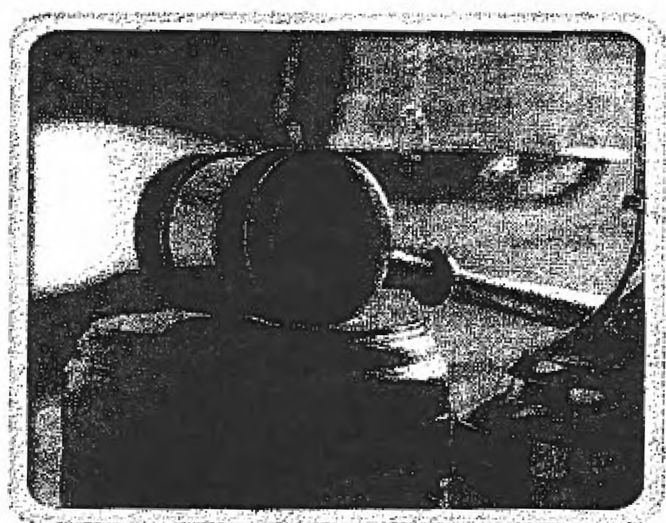
MISLEAD YOU

DAVID MICHAELS

DOUBT IS THEIR PRODUCT

Chem

**Is it any coincidence
that these chemicals
have represented the
lion's share of most
toxics cases?**



Have the Writings And Speaking Engagements of Dr. Michaels Altered The Regulatory and Legal Landscape?



Intimidating Corporations...

- Over the past three years, there has been a precipitous drop in the participation of the regulated community in offering comments or providing scientific input to the rulemaking process
- Might they fear becoming the “new” focus for Dr. Michaels or like-minded NGOs ?



What Is the End Game?

- To intimidate experts and keep them from participating in the regulatory arena and in litigation?
- To “stonewall” legitimate research by corporations and consultants from being published?
- To reverse Daubert and Frye?



Chapter 13 of his book, entitled “Daubert: The most influential supreme court ruling you’ve never heard of”...

- Michaels notes...after having his credibility challenged for testifying in a Daubert challenge...

“These Daubert hurdles were unnecessary.”

[p. 175, Michaels’ Book]



Intimidating Corporations From Participating in Rulemaking

- For example, during the recent EPA Asbestos Science Advisory Board (SAB) meeting...

...guess who submitted letters of outrage regarding the proposed appointment of experts to the asbestos SAB?



Letters Asking EPA to Disqualify Nominated Experts

Name

- Roger Worthington, Esq.
- Mr. Jeffrey Simon
- Ms. Maggie Van Norman
- Ms. Caroline K Shining
- Mr. Christian Hartley
- Mr. James Nevin
- Dr. Jennifer Sass
- Mr. Richard Wiles
- Mr. Robert Paul
- Mr. Tom Lent

Role

- Plaintiff lawyer in asbestos
- Plaintiff lawyer in asbestos
- Plaintiff lawyer in asbestos
- Plaintiff lawyer in asbestos
- Plaintiff lawyer in asbestos
- Plaintiff lawyer in asbestos
- NRDC, coauthor with Egilman
- Environmental Working Group
- Plaintiff lawyer in asbestos
- Health Building Network
- Mr. Victor Schwartz
- Defense attorney, also a Professor

Guess who appeared to deliver oral testimony before the Asbestos SAB?

Hint...it wasn't academic professors, NGOs, or consultants for industry.



Speakers at Convening of EPA SAB

The majority were attorneys for plaintiffs in asbestos cases or their experts



Presented Oral Comments to Asbestos EPA SAB (July 2008)

Name

- Dr. David Egilman
- Mr. Jon Ruckdeschel
- Mr. Rick Nemeroff
- Dr. Richard Lemen
- Mr. Scott Frost
- Ms. Linda Reinstein
- Mr. Terry Lynch
- Ms. Randy Rabinowitz
- Dr. Michael Silverstein
- Dr. Laura Welch
- Dr. Franklin Mirer
- Dr. William Cleveland
- Dr. Barry Castleman
- Mr. James Morris
- Ms. Pat Girtin

- Dr. Suresh Moolgavkar

Role

- Adj Professor and Plaintiff Expert
- Plaintiff Lawyer in Asbestos
- Plaintiff Lawyer in Asbestos
- Professor, Plaintiff Expert in Asbestos
- Plaintiff Lawyer in Asbestos
- Scientist from Labor Union
- Representative of Labor Union
- American Association of Justice
- MD, contributor to the SKAPP blog
- Plaintiff Expert in Asbestos
- Professor, Scientist from Labor Union
- Physician and apparent plaintiff expert
- Plaintiff Expert in Asbestos
- Husband of asbestos plaintiff
- Wife of asbestos plaintiff

- Professor and Defense Expert in Asbestos⁵³

**Have the Writings
And Speaking
Engagements of Dr.
Michaels Altered
The Regulatory and
Legal Landscape?
Absolutely!!**

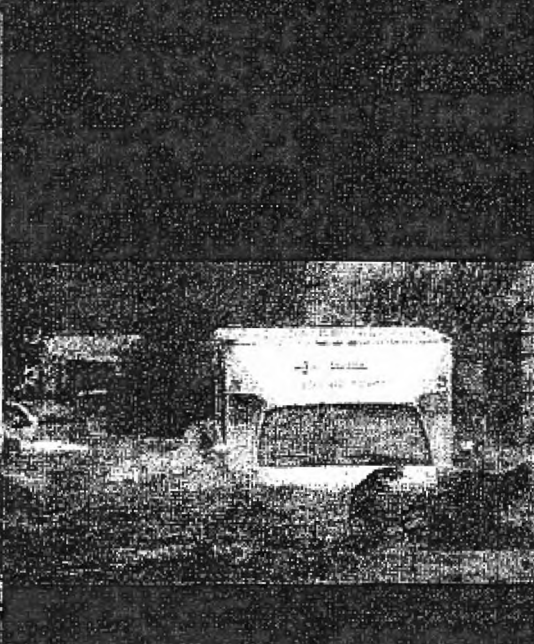
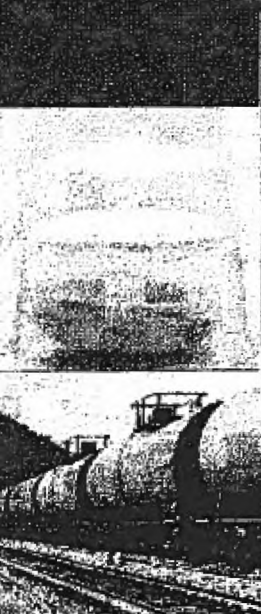


ChemRisk®



"Pioneering innovative human health and environmental risk assessment"

Environmental
Occupational and
Public Health



and ecological risk assessment methods"

Recognizing that Dr. Michaels has often cited statements from the late Senator Moynihan...I will cite one of my favorites:

“Everyone is entitled to his own opinion, but not to his own facts.”

