CORPORATE TIES THAT BIND

An Examination of Corporate Manipulation and Vested Interest in Public Health

---

Edited by Martin J. Walker

Foreword by David O. Carpenter, M.D.

Skyhorse Publishing

CONTENTS

PREFACE

David O. Carpenter

One of the greatest problems in scientific discovery is the perversion that can result due to conflicts of interest. While there are other possible bases for conflicts of interest, most are financial. Individual scientists may have financial conflicts of interest that influence the design of the studies they perform so that they obtain a result similar to that which they, or their funders, want. When funding for scientists comes from an organization or corporation with desires to present a clean bill of health to the public, there is strong motivation to give the funder what they want, if only to continue receipt of funding.

The most egregious epidemiological Judas in modern times is probably Sir Richard Doll, who for years took significant amounts of money from Monsanto, Dow Chemical, and the Chemical Manufacturers Association, in return for making strong public statements denying that chemicals and radiation cause cancer. Because of his distinguished position, his views still have significant influence on public policy, which fail to take into account the impact of hundreds of carcinogenic chemicals in our food, water, and air, and how these exposures increase rates of cancer in the general population.

Corporations themselves have both more power and more money than most individual scientists to influence how scientific and epidemiological results are perceived by the scientific and general public, and especially by the regulatory and political bodies that determine whether restrictions are placed on products and their use. The financial return from development and sale of chemicals and some high-tech products can be enormous, and the temptation to ignore, hide, or deny problems by any means possible is great. This book offers an introduction as to how corporations can, and have, distorted knowledge and actions on health impacts of products in which they had financial interests.

There are a variety of ways that industry can pervert or manipulate knowledge of the toxicity of products in which they have financial interest. Many corporations have their own research units and actively participate in scientific meetings and the publishing of research results. But the outcomes of this research are often, indeed usually, controlled by the corporate management such that adverse effects of their product are not released, even if found by their own research.

Often adverse effects from internal testing are hidden under the ruse that the results are "proprietary." There are numerous examples of disease outcomes where industry-funded research failed to detect hazards but government-funded research show significant adverse health effects. If research is carried out by teams beyond the corporation, they can still to some extent control the outcome by controlling the provision of raw data.

In the laboratory, it is always possible to obtain negative results, if that is the desire. One can manipulate the assay sensitivity so as not to detect an effect. One can study a limited number of animals or people so that any results obtained are not statistically significant. One can fail to follow the animals or the people for a sufficient period of time so as to detect health effects, especially if the effect is something with a long latency, such as cancer. Or one can look for only acute effects, such as LD50, when the real concern is either a subtle change in cognitive function and behavior or a long-term alteration in reproductive function.

There are several common tactics used by industry to pervert or manipulate the results of scientific research and the way in which products are perceived after they come onto the market. Often independent researchers whose studies demonstrate adverse effects of an industrial product in which the corporation has a financial interest are described publicly as being "advocates," "fringe," or even "poor" scientists. This tactic is facilitated by the fact that any responsible scientist will always indicate both the strengths and weaknesses associated with their results in their publications.

Industry often inappropriately takes such "weaknesses" to publicly discredit the investigator while minimizing the importance of the results. When this is not enough, corporations can resort to harassment of independent scientists and others. This may take the form of accusations of misconduct or impropriety, or (at least in the United States) by demanding access to all unpublished data and documents through a Freedom of Information Law (FOIL), and on occasion taking direct legal action against scientists, authors, journalists, or campaigners alleging defamation or loss of income as a result of statements concerning the dangers from the industrial product.

Corporations are often represented on national and international committees that make policy on environmental issues and use their voices on these

committees to promote their own interests. The rationale for including individuals with such clear conflicts of interest on such committees is obscure. Often it is said that these individuals are clearly experts who have great experience of the products or their manufacturer. Such choices are also based on the concept of "balance." The result of such "balance" is usually that public health is compromised by the economic interests of the corporations. This is also common when it comes to comments from the press on environmental health issues. Reporters for newspapers or television often feel obligated to take a "balanced" view on health reports and go to industry for comments that mitigate or minimize the significance of the results showing risk. Corporate interests are used to attack and discredit independent writers and investigators.

Even more powerful interventions can be made by corporations in public health policy at the political levels. The situation in the United States is probably more egregious than elsewhere, but the problem occurs in every country and internationally to various degrees. Except in circumstances where there is public financing of political campaigns, corporations contribute significantly to individuals running for public office who will support their views and corporate interests. These funds effectively buy influence that has impact on budgets for research, regulatory policies, and legislation. In the United Kingdom, money is poured into campaigning committees aligned to Parliament that influence the regulation of and acceptance of questionably toxic products.

The net result of corporate influence on public health policy is that health of the public is inevitably compromised only to protect corporate profits. Through intentional lies, distortion of facts, corruption of individual scientists whose views are for hire to the highest bidder, and influence on the political system to protect profits, industry is responsible for significant morbidity and mortality of the world's citizens.

The history of smoking and cigarette manufacturers is a striking example. There was clear evidence that smoking caused lung cancer as early as the 1930s, but because of the political power of the tobacco industry, aided and abetted by health professionals, many of whom were either addicted to tobacco, held stock in tobacco companies, or were paid as consultants, there was no systemic effort to inform the public of the hazards of smoking or to restrict access to tobacco products until some forty years later. The costs in terms of lives lost and to the global economy are enormous. The World Health Organization states that tobacco kills nearly six million people each year worldwide and costs billions of dollars in excess health-care costs and lost productivity.

Even when developed countries did begin to regulate sale of tobacco products, the producing companies focused on developing countries, using the same

advertising techniques that promoted smoking as something cool and without hazard. The magnitude of adverse health impacts of other chemicals and environmental exposures is less well documented than that of cigarettes and perhaps asbestos, but is increasingly significant.

Most collusive ties to industry in the area of research and the promotion of toxic products begin as secret ties, and by the time they have run their covert course, they have caused considerable damage. Turning around a single case and making even one individual responsible regardless of the damage caused, is exceptionally difficult. Corporations and individually connected scientists have become adept at glossing over a system that can cause immense damage.

Once a product or an industrial process is questioned, the chances are that its defense will get more deeply embedded in the scientific fabric and that the truth about the damage it causes can become less easily challenged over time.

I have chosen to illustrate these phenomena with the story of PCBs, a subject not covered in any of the successive chapters. In point of fact there are now so many such examples that the choice for the editor of this book must have been difficult.

The Monsanto Company manufactured polychlorinated biphenyls (PCBs), sold as "Aroclors," in Anniston, Alabama; and Sauget, Illinois, from 1935 until 1977. While Monsanto had evidence for the toxicity of PCBs as early as 1937, little information on the degree of toxicity was provided to employees, government regulators, or the public even after manufacture and use of PCBs was terminated by federal action in the Unitied States in 1976. As late as 2000, a company spokesperson stated, "The overwhelming weight of scientific evidence suggests there are no chronic human health effects associated with exposure to PCBs." However an internal memo dated September 4, 1953, stated "As I am sure you know, Aroclors cannot be considered nontoxic."

In 1969 an "ad hoc" committee was appointed to "(1) Protect continued sales and profits of Aroclors, (2) Permit continued development of new uses and sales, and (3) Protect the image of the Organic Division and the Corporation as members of the business community recognizing their responsibilities to prevent and/or control contamination of the global ecosystem." A 1975 memo regarding the reporting of results of a two-year study where rats were fed Aroclors made the following recommendation: "In two instances, the previous conclusion of 'slightly tumorigenic' was changed to 'does not appear to be carcinogenic.' The latter phrase is preferable. May we request that the Aroclor 1254 report be amended to say 'does not appear to be carcinogenic.'" While Monsanto had knowledge of the toxicity of PCBs, it was kept hidden. Later a jury found

Monsanto guilty of "suppression of the truth, negligence, trespass, nuisance, wantonness, and outrage," and they were held liable for damages.

One of Monsanto's major clients was the General Electric Corporation (GE), which used PCBs at a large number of sites around the United States, primarily as an insulating fluid in capacitors and transformers. This led to releases into the environment at many plants. In 1976, GE is reported to have purchased about thirteen million pounds of PCBs from Monsanto and used about 5.6 million of those at two plants in Fort Edward and Hudson Falls, New York, communities on the Hudson River. Some five hundred thousand pounds of PCBs were escaping into the river each year, and all two hundred miles down to Manhattan were contaminated. Under threat from the federal government to require cleanup of the river, General Electric mounted an active research program, both internal and in universities, to document that anaerobic bacteria were capable of removing chlorines from the PCB molecule.

They argued that removal and cleanup was unnecessary because natural processes would solve the contamination. The GE publication, *River Watch*, stated in 1991 "GE scientists have announced laboratory findings that could lead to a simpler, cleaner way to get PCBs out of the Hudson River sediments. The findings show that all of the chlorine atoms on a PCB molecule can be removed by anaerobic bacteria." However there was clear evidence that dechlorination did not result in destruction of the PCB molecule, only in a change in the congener distribution. These actions delayed the removal of PCBs from the river for more than thirty years. The upper part of the river is currently being dredged of PCBs; financed by GE, this is the largest and most expensive dredging project in US history.

GE funded a study of over seven thousand capacitor workers at the two plants along the Hudson River. However, to be included in the study required employment for only ninety days and all secretarial staff and others not even working with PCBs were included in the study.

Not surprising under these circumstances, no elevation in cancer risk was found, even though PCBs are known human carcinogens. Later, a GE spokesperson said, "Public perception about the health risks of PCBs and the scientific facts are in conflict. Most scientists agree that PCBs are not the hazard to human health that was feared in the 1970s. PCBs produce tumors in some laboratory animals, but there is no proof—based on human exposure of more than forty years—that PCBs cause cancer or any other serious health problems in people." However, a recent study of 24,865 capacitor plant workers in three states, including those described above, performed by the National Institute of Occupational Safety and Health, found significant elevations in rates of all cancer, intestinal,

brain, prostate, and stomach cancers, and malignant melanoma and multiple myeloma. In 2013 the International Agency for Research on Cancer (IARC) declared all PCBs to be known human carcinogens, based on evidence including the GE-supported study.

In addition to being known human carcinogens, PCBs are known to increase risk of type 2 diabetes, hypertension, cardiovascular disease, hypothyroidism, and chloracne, and they cause cognitive deficits and neurobehavioral changes. If one depended upon Monsanto and GE, none of this information would be known. The length and persistence of arguments in favor of toxic products is demonstrated in the following book.

In 1735, Benjamin Franklin, one of the founders of the United States and authors of the US Constitution, stated, "An ounce of prevention is worth a pound of cure," (or in metric terms, "a gram of prevention is worth a kilogram of cure"). This old phrase captures the concept of the precautionary principle. The majority of chapters in this book show repeatedly that failure in preventing exposures to chemical toxins and various forms of radiation have resulted in human disease that could have been prevented.

The central issue is what level of evidence is necessary before steps are taken by individuals, scientists, and governments to prevent exposure of the public. A closely related question is at what point when there is incomplete information on a danger should the public be informed about the possibility of harm? It is often assumed by regulators as well as scientists that the public cannot deal with uncertainty and wants clear black-and-white statements (i.e., that something is either "safe" or "unsafe.") This condescension is most certainly not justified, as every person deals with uncertainly and risk at various levels all the time.

However, it is much more difficult to explain to the public the level of evidence in support of an issue, as well as the weaknesses in that evidence, than it is to make dogmatic statements about safety or lack thereof. Unfortunately when there is uncertainty, too often the dogmatic statements made by persons in authority turn out in the long run to be wrong, and have negative consequences at multiple levels. The effort to prevent fear of something for which evidence of danger is incomplete is fine when ultimately it turns out not to be dangerous, but is most certainly not okay when the incomplete evidence turns out to be correct or even an underestimation of the actual risk.

There are very different levels of proof used in the world today. In mathematics, it is possible to prove a theorem to an absolute degree of certainty. That is not possible in most other disciplines. Within the medical and scientific community, we use odds or risk ratios with confidence intervals (CI) as indicators of proof. Most epidemiological studies will present results with 95 percent

confidence intervals, and occasionally with 99 percent confidence intervals. This approach acknowledges that there are associations that occur by chance and do not reflect causation. Thus, a 95 percent CI indicates that there is no more than a 5 percent possibility that the associations occurred by chance, whereas a 99 percent CI leaves only a 1 percent possibility of a chance association. However, regardless of the strength of association it is impossible to absolutely prove causation.

The variable one studies may, in fact, be tightly associated with something else that is not being directly studied, and it is the second variable that is causative of the association. Therefore, within the scientific community we rely on the "weight of evidence" from multiple sources and testing multiple variables in an effort, never totally achieved, to reach causation. In addition, we commonly attempt to apply the Hill Criteria (strength, consistency, specificity, temporality, biologic gradient, plausibility, coherence, experimental evidence, and analogy) when trying to distinguish causal from non-causal associations. This is in spite of the fact that Hill himself did not propose these as "criteria" but rather as considerations when drawing conclusions as to causation.

A very different standard of proof is that used in legal circles, which is "more likely than not." This is 50.1 percent level of proof, obviously much less stringent than 95 or 99 percent. Had this level of proof been applied to cigarette smoking and lung cancer and the results reported to the public, literally millions of lives would have been saved.

Scientists at Carnegie Mellon University developed the concept of "prudent avoidance" in the 1980s around concerns related to health effects of magnetic fields associated with power lines and household electricity. They outlined three distinctly different possible approaches for dealing with uncertainty. The first was to do nothing. This could be denial that there was anything of concern, or perhaps providing information in a passive manner. The second was to impose rigid regulation, even though there remains uncertainty as to the magnitude of the risk. This approach may not be in the best interest of society because of costs, inconvenience, and other adverse impacts. The third, intermediate course of action, and the one they recommended, was "prudent avoidance," which meant doing what could be done at both personal and societal levels to reduce exposures without undue costs and inconvenience. This approach involves providing information to the public and the regulators that accurately discloses what is known and what is unknown, allowing individuals to make their own decisions on whether or not to take steps to reduce their exposure.

The concept of "prudent avoidance" is good at a personal level, but it is much weaker than the basic tenants of the precautionary principle at a public

or regulatory level. It should be the responsibility of governments to protect the public from exposure to hazardous exposures, and that decision should not be left to either the general, and often uninformed, public or those with vested interests.

The European Union's REACH regulations are an excellent example of application of the precautionary principle, in that they attempt to be certain that all toxicity of new chemicals is known before the chemical is allowed to be produced. And the possible important toxicities are not only to human and animal health, but also to the ecosystem.

Inevitably corporations have a wide range of arguments about why a precautionary principle should not be invoked: if you scrutinize everything for safety, we will—they say—end up back in the Dark Ages; we will stifle freedom of production and the armchair observers will take control. Application of the precautionary principle does not mean stopping progress with development of new chemicals, new technologies, or new applications. It means only that we do not introduce a new exposure without having first determined exhaustively whether or not it poses harm to the human race or the ecosystem. The harm to human health caused by past mistakes—smoking, PCBs, asbestos, endocrine-disruptive chemicals—should motivate society to learn the tragedies of these errors and practice precaution.

A strong economy and growing economic and technological development are important to all societies, but such growth does not have to be at the expense of public health.

Sibelius Academy, and The Theatre Institute of Advanced Studies (University of the Arts Helsinki). He has worked as a politician, Head of printing works, Head of theatre, and Lecturer at Institute of Advanced Studies (Arts Management). Christian Blom was on sick leave from 2003 to 2008 and is retired since 2008. He has worked since the 1960s and still does as a freelance journalist. He still does research within cultural politics and history.

Dr. David O. Carpenter: David O. Carpenter is a public health physician, the director of the Institute for Health and the Environment, a Collaborating Centre of the World Health Organization, as well as a professor of environmental health sciences at Albany University School of Public Health. He previously served as Director of the Wadsworth Center of the New York State Department of Health, and as Dean of the University at Albany School of Public Health. Carpenter, who received his medical degree from Harvard Medical School, has more than 370 peer-reviewed publications, six books and fifty reviews and book chapters to his credit.

David Egilman: Dr. David Egilman, MD MPH, is Clinical Professor of Family Medicine at the Alpert School of Medicine at Brown University. He received his Bachelors of Science in Molecular Biology and as well as his MD from Brown University. He is board certified in internal medicine and preventive-occupational medicine and graduated from the NIH Epidemiology Training program. He received his Masters in Public Health from Harvard. Dr. Egilman does research on corporate corruption of science and the impact of the manufacture and sale of products on the health of workers and customers. He serves as an expert witness in court cases at the request of injured parties and companies on these issues. He has also published on the duty to test and warn about product hazards. He is the founder and President of the Board of Directors of Global Health through Education, Training and Service (GHETS), a nonprofit organization dedicated to improving health in developing countries through innovations in education and service (www.ghets.org). He has published on warnings, asbestos, US human radiation experiments, benzene, beryllium, Vioxx, and other toxic exposures and medical products.

Devra Davis, PhD, MPH, is President of Environmental Health Trust, a nonprofit scientific and policy think tank. Currently Visiting Professor of Medicine at The Hebrew University, Hadassah Medical Center and Ondokuz Mayis University Medical School, she was Founding Director of the Board on Environmental Studies and Toxicology of the US National Research Council