Friends of the Earth

# SICK SCIENCE

## THE CORPORATE FUNDING & CORRUPTION OF SCIENCE

# CONTENTS



# INTRODUCTION

Science is important. It influences most aspects of our lives - including food, energy, medicine and transportation. Over the millennia it has brought us many breakthroughs. Diseases that once killed millions are now easily dispatched thanks to medical developments such as antibiotics. Science is also responsible for a vast array of technological developments. Without science we wouldn't be aware of the global warming impacts of carbon dioxide or of the hole in the ozone layer – and we wouldn't have the tools we need to solve these and other global problems.

However, science is under attack. As public funding has been withdrawn from science, industry has stepped in to fill the gap – with far reaching consequences. This report reviews empirical studies of the ways in which industry shapes and distorts the science upon which important regulations are based and the extent to which this is happening.

"Corporations view science not as a generator of truth but as one among many inputs into production" Krimsky (ND).

Industry funding corrupts science from conception to commercialisation. It corrupts the quality of the science being done and the regulatory regimes that are dependent on science. It also corrupts the media which is regularly inundated with misinformation based on shoddy, corporate-funded science.

Public institutions that enter into corporate partnerships frequently do so secretly and with no public or academic accountability[1]. Universities are compromised, science is corrupted and knowledge becomes a commodity not a shared process of learning.

This report highlights some of the now voluminous literature regarding the corporate corruption of science in many of its forms. It is not a comprehensive review but an indicative one.

At one level, the effect of industry funding of science is obvious and well established – it exercises significant influence over the conclusions of research. But the effects are broader than that and are often insidious or invisible. Industry funding influences what questions get asked - because questions that are not compatible or useful to corporate or political interests are not funded to begin with. Researchers learn not to ask certain kinds of questions, both to get funding and also to avoid pressure and conflict with peers who may feel threatened by a colleague perceived to be questioning their motives or integrity.

Biases in reporting and publication often go undiscovered and negative results may never see the light of public or scientific review. Alteration of data can range from changes in statistical analysis to fabrication of data. Patent or other intellectual property rights may result in knowledge not being shared or access to knowledge being controlled and costly – reducing the likelihood of the research finding benefiting the public.

There is almost no data suggesting that industry data is neutral.

The corporate corruption of science results in unsafe products being put or kept on the market, putting all of us at unnecessary risk and quite literally killing people. This includes tobacco, asbestos and numerous unsafe drugs and chemicals. These are not isolated incidents but part of a systemic problem; part of a problem that continues to get worse as more and more private money dominates R&D budgets - and corporate influence over governments continues to grow.

This corruption of science has profound effects on our regulatory systems, particularly in the case of foods, chemicals and medicines. Not only does it distort the information that forms the basis for regulatory approvals, corrupted science may be the only information considered by regulators in making findings of safety.

Furthermore, government expert panels are often stacked with industry-funded scientists – resulting in questionable advice.

**Three critical and necessary conclusions emerge from these pages:**

1. **Industry-funded science should never form the primary or exclusive basis for regulatory approval;**
2. **As a first step in reducing industry influence over regulatory decision-making, the Government should implement strict measures to avoid conflicts of interest in its advisory committees; and**
3. **Secret contracts between industry and publicly funded research organisations should not be permitted.**

1. For example, in 2016 Friends of the Earth sought contracts between the University of Queensland's Australian Institute of Bioengineering and Nanotechnology (AIBN) and all its corporate partners under Queensland Right to Information laws. 1200 individual contracts were identified. We reduced the scope of the RTI to 6 corporate partners and the request was refused on the basis that the information was confidential. That decision is currently under appeal to the Information Commissioner.

# 1. Corporate influence over science

As  Merrill Goozner, a program director at the Center for Science in the Public Interest, points out "In many precincts of the scientific enterprise, the needs of industry have become paramount," turning science into "a contested terrain" where facts are increasingly contingent on who is funding the research. "The whole scientific revolution, which was a product of the Enlightenment, is threatened when you commercialize science," he warns (Washburn 2007).

The problem of the corporate corruption of science is not a new one. As Mooney (2008) noted in his review of David Michaels' book, *Doubt is Their Product*:

"The sabotage of science is now a routine part of American politics. The same corporate strategy of bombarding the courts and regulatory agencies with a barrage of dubious scientific information has been tried on innumerable occasions - and it has nearly always worked, at least for a time. Tobacco. Asbestos. Lead. Vinyl chloride. Chromium. Formaldehyde. Arsenic. Atrazine. Benzene. Beryllium. Mercury. Vioxx. And on and on. In battles over regulating these and many other dangerous substances, money has bought science, and then science - or, more precisely, artificially exaggerated uncertainty about scientific findings - has greatly delayed action to protect public and worker safety. And in many cases, people have died."

The tactic was pioneered by the tobacco industry to keep its dangerous products on the market. As Schick & Glantz (2007) note:

"Big tobacco funded research for a variety of reasons that still apply across a broad range of industries. This includes building public credibility through what is characterised as independent science, developing industry friendly experts to represent the industry's views, creating controversy in areas where independent science may be conclusive and presenting industry views indirectly and through individuals with greater credibility than the industry itself."

The impacts of the corporate corruption of medical research have been particularly profound. As De Angelis & Fontanarosa (2009) note:

"The profession of medicine, in every aspect — clinical, education, and research—has been inundated with profound influence from the pharmaceutical and medical device industries. This has occurred because physicians have allowed it to happen, and it is time to stop."

The authors argue that:

"Public trust for clinical research is in great jeopardy especially when the extent of how widespread such practices have become is unknown. Although we truly believe that the vast majority of researchers and other authors are honest and have the highest scientific integrity, manipulation of studies and publications by the pharmaceutical and medical device industries is either increasing or there has been more exposure of these practices. Third, in addition to clinical research, clinical practice and medical education also are greatly influenced by for-profit companies. Drastic action is essential" (De Angelis & Fontanarosa 2009).

Light (2013) argues that:

"Over the past 35 years, patients have suffered from a largely hidden epidemic of side effects from drugs that usually have few offsetting benefits. The pharmaceutical industry has corrupted the practice of medicine through its influence over what drugs are developed, how they are tested, and how medical knowledge is created."

Recent research indicates that similar tactics have been used by the sugar industry since the 1960s. Responding to concerns that sugar consumption was implicated in coronary heart disease, the industry commissioned work to point the finger at fats. As a result, even in 2016, coronary heart disease is only "inconsistently cited as a health consequence of added sugar consumption" (Kearns 2016).

The problem of corporate influence over science has worsened in recent decades, as government investment in public interest science has declined and corporations have stepped in to fill the gap. The private sector is now the dominant funding source for R&D. This is true for most G20 countries including Australia. The private sector now outspends the public sector by approximately 2 to 1 (Sciencogram 2013).

## 2. Industry funding and conflicts of interest

Corporate interests dominate clinical drug research. According to Bodenheimer (2000), in 2000 Big Pharma financed approximately 70 per cent of the US's clinical drug research with an estimated 75 per cent of this flowing to for-profit contract research firms.

In 2007, the *San Jose Mercury News* found that one-third of Stanford University's medical school administrators and department heads had reported financial conflicts of interest related to their own research. These included stock options, consulting fees, and patents (Washburn 2007).

Research, published in the journal *Cancer*, found that 29 per cent of cancer research papers published in high-profile journals had authors with conflicts of interest (Jagsi 2009). An earlier study found that reporting of conflicts of interest in major medical journals is low and largely neglected (Papanikolaou 2001).

> ***"Funding arrangements can create networks of dependency that structurally distort the independence of the academic researcher in favour of the funder's interests" (Gray 2013).***

Furthermore, it appears that attempts to improve the declaration of conflicts of interest have been largely unsuccessful. A 2015 review of changed rules and codes of practice (Ruff 2015) found that the largely voluntary measures were "failing to create an effective mechanism to protect the integrity of science from vested interests."

Washburn (2007) observes that the rise in academic patenting and licensing also gives universities and their professors growing financial ties to outside companies, not to mention growing investments in their own research (including patent rights, stockholdings, and royalty shares).


## 3. Study design

As well as distorting research priorities, corporate funding can also affect the study design - and hence research outcomes.

Research published in the journal *Cancer*, found that conflicts of interest appear to have affected how studies were conducted. For example, research that had industry funding focused on treatment 62 per cent of the time, while studies not funded by industry focused on treatment only 36 per cent of the time (Jagsi 2009).

A 2005 study examining the contractual relationships between industry sponsors and academic investigators in more than 100 academic medical centres in the US found that 62 per cent permitted the sponsor to alter the agreed study design (Mello 2005).

Ross *et al.* (2010) revealed that scientists manipulated a study design for the arthritis drug Vioxx by failing to use a placebo and comparing the drug instead to a painkiller. The scientists incorrectly concluded that the drug reduced the risk of heart attack, when, in fact it significantly increased cardiovascular risk.

Another study funded by the chemical industry used small sample sizes and statistical distortion to claim that hexavalent chromium was safe and should be authorised for use in the US, despite its known severe health effects - including links to several types of cancer (Michaels, Monforten & Lurie 2006).

## 4. Industry sponsorship influences research conclusions

Lesser (2007) reviewed a number of studies relating to drinks, juice and milk and the relationship between industry funding and conclusions. 206 articles were investigated - 111 of which declared financial sponsorship. Of these 22 per cent had all industry funding; 47 per cent no industry funding and 32 per cent mixed funding. Lesser found that "funding source was significantly related to conclusions."

Lesser discovered that "among interventional studies, the researchers found that 0 per cent of the studies with any industry funding came to unfavorable conclusions compared with 37 per cent of the studies with no industry funding." Beverage industry-funded studies were also four to eight times more likely to produce results favourable to the industry - in comparison with studies that were independently funded (Lesser 2007).

Lesser concluded that "industry funding of nutrition-related scientific articles may bias conclusions in favor of sponsors' products, with potentially significant implications for public health" (Lesser 2007).

The funding of genetically modified (GM) crop research is particularly dominated by corporate interests. A 2016 study found that ties between researchers and the GM crop industry were common, with 40 per cent of the articles considered to display conflicts of interest (COI). The authors found that, compared to the absence of COI, the presence of a COI was associated with a 50 per cent higher frequency of outcomes favorable to the interests of the GM crop company (Guillemaud *et al.* 2016).

A similar study looking at the pharmaceutical industry, found that industry sponsored studies are biased in favour of the sponsor's products (Lundh 2012). A review published in the *British Medical Journal* (Lexchin *et al.* 2003) found that pharmaceutical-industry-funded research was four times more likely to reflect favourably on a drug than research not financed by industry. Even when other factors are controlled for the effect of industry funding on the research outcome is huge. As Washburn (2007) observes:

"Research on secondhand smoke conducted by researchers with industry ties is 88 times more likely to find no harm; industry-funded studies comparing cholesterol drugs are 20 times more likely to favor the sponsor's drug."

A review of 691 studies of anti-hypertension drugs found that those produced by individuals with ties to drug companies were significantly more likely to report results in the companies' favour (Yank, Rennie & Bero 2007; see also Bekelman, Li & Gross 2003). And a study by Baker *et al.* (2003) found that industry sponsored anti-depressant drug trial results were more favourable than those of non-industry sponsored trials.

> ***"Investigators have demonstrated impressive similarities between the actions of cigarette companies and food companies in protecting and promoting product sales. Consistent with the observation by the IOM [Institute of Medicine], most studies sponsored by food or beverage companies support the benefits of the sponsor's product, whereas most independently funded studies do not" (Nestle 2013).***

Bero (2015) came to the same conclusion in a paper looking at the industry versus non-industry-funded studies of harm caused by the agricultural chemical atrazine.

In an extraordinary review of the literature on bisphenol A (BPA), vom Saal and Welshons (2006) found that 11 of 11 industry-funded studies found no adverse effects from BPA, while 109 of 119 independent studies did show adverse effects.

This distortion of science is quite literally killing people. For example, in 2006, the *New England Journal of Medicine* published a report on the diabetes drug Avandia showing it more effective than other diabetes drugs. The trial was funded by GlaxoSmithKline, and each of the 11 authors had received money from the company. Four authors were company employees with stock holdings. What they missed - or didn't report - is that the drug raised the risk of heart attack. A Food and Drug Administration scientist later estimated that the drug was associated with 83,000 heart attacks and deaths (Nissen 2007; Whoriskey 2012).

## 5. Reporting biases

Reporting biases resulting from industry funding include selective publication, suppression of results, ghost writing by industry and the multiple publication of positive results.

German researchers reviewing reporting bias and selective reporting in published cases identified 40 different types of reporting bias in involving about 50 different pharmaceutical drugs, surgical procedures, diagnostic tools and preventive interventions. The scale of the problem led them to conclude that reporting bias in the pharmaceutical sector is widespread (McGauran *et al.* 2010).

Lexchin *et al.* (2003) observe that the techniques used to bias reported results are remarkably similar: Positive research gets published; negative research doesn't. The sponsor's drug is given at a higher dosage than the competitor's drug. The sponsors control study design, access to data, and statistical analysis. Industry personnel ghostwrite articles and pay prominent academics to sign on as "authors."

Washburn (2007) observes that:

"One 2005 study examining more than 100 academic medical centers found that half would allow the corporate sponsor to write manuscripts reporting on study results and only allow faculty to "suggest revisions"—a policy basically authorizing commercial ghostwriting of academic research. Thirty-five per cent allowed the sponsor to store clinical trial data and release only portions to the investigator; 62 per cent allowed the sponsor to alter the study design after the researchers and the sponsor had signed an agreement."

### Selective publication of data

"Lack of transparency in research, particularly on important biological issues without scientific consensus, may not only jeopardize human/animal health and lead to environmental damage, but is also against the interest of science. This prevents the exchange of results and views between scientists—the lifeline of science, without which no scientific progress is possible. Selective publication of data favourable to the sponsor is serious for society and also distorts science" (Pusztai 2008).

A recent investigation by Greenpeace UK found that chemical giants Bayer and Syngenta suppressed studies that demonstrated the harmful impacts of neonicotinoids on bee colonies. The companies are actively trying to prevent the banning or stricter regulation of these chemicals that have been implicated in the global collapse of bee colonies (Greenpeace 2016).

***"It's been shown that reporting bias is associated with all sorts of funding – government funding, department funding, industry funding – but the worst source of bias is industry-funded"***
***Kay Dickersin, an epidemiologist at Johns Hopkins University (quoted in Hsu 2010).***

A review by Melander (2003) found selective publication, multiple publication of positive results and selective reporting of results from 42 studies of anti-depressants was a "major cause for bias." This study confirmed earlier work showing how publication decisions affected the use of certain drugs.

Turner shook up the medical community in 2008 when he reported that published studies about antidepressants made the drugs appear to work much better than they really did. Of 74 antidepressant studies registered with the FDA, 37 studies that showed positive results ended up being published. By contrast, studies that showed iffy or negative results mostly ended up going unpublished or had their data distorted to appear positive. The missing or skewed studies helped create the impression that 94 per cent of antidepressant trials had produced positive results, according to Turner's analysis, published in the *New England Journal of Medicine*. In reality, all the studies together showed just 51 per cent positive results (Turner 2008).

A past analysis of clinical trials supporting new drugs showed that just 43 per cent of more than 900 trials on 90 news drugs ended up being published (Hsu 2010). Lexchin (2003) found that research funded by drug companies was less likely to be published than research funded by other sources" (Lexchin 2003).

Rising (2008) found that "many trials were still not published 5 years after FDA approval. Discrepancies between the trial information reviewed by the FDA and information found in published trials tended to lead to more favorable presentations of the NDA [new drug application] drugs in the publications."

The results of such a failure to publish research can be serious.

For example, a study conducted by Nissen and Wolski (2007) indicated a significant increase in the risk of death from side effects of a drug where the company did not publish results - including an increase of heart attacks by 31 per cent.

Hsu (2010) argues that "drugs such as Tambocor (flecainide) prescribed in the 1980s to prevent irregular heartbeat may have cost thousands of lives, according to a national study conducted by the National Institutes of Health from 1987 to 1989. That tragedy occurred because early warning signs of dangerous side effects were not published."

Similarly, rosiglitazone - a drug used to treat type 2 diabetes - was approved and first released in 1999. A lawsuit brought against the pharmaceutical giant GlaxoSmithKline resulted in a settlement agreement forcing Glaxo to release all the raw data from its clinical trials relating to rosiglitazone. A review of the data linked the drug's use to increased risk of heart attack. The failure to release the data pre-approval resulted in an increased risk of death from taking the drug (Nissen 2007). It is estimated that up to 100,000 heart attacks are linked to the use of rosiglitazone and at least 5,500 deaths (Drugwatch 2016).

Such behaviour is by no means confined to the drug industry. For example, Bero (2015) found that 91 per cent of industry-funded studies of the chemical atrazine did not report statistically significant results indicating harm as opposed to 67 per cent of non-industry-funded studies.

### Cherry picking results

Another broad example of reporting bias comes from choosing what study outcomes to include in the final publication. Clinical trials are increasingly contracted out to specialist clinical research organisations, which undertake those trials in countries where complete control of the tests, the outcomes and publication of data can occur. This can result in poor trial design and non-publication or cherry picking of results. In 2010, the US Office of the Inspector General found that 80 per cent of the clinical trials for approved drugs took place overseas (Mirowski 2011).

Hsu (2010) argues that comparisons of research protocols and actual journal articles show that results were excluded or the analyses changed in 40-60 per cent of medical studies.

A study conducted by Psaty and Kronmal (2008) highlighted the selective reporting of results on mortality findings in trials of Rofecoxib, an anti-inflammatory drug used to treat pain. This drug, although once approved by the FDA has now been withdrawn from the market due to questionable clinical results (MedicineNet 2004).

GlaxoSmithKline, the pharmaceutical company that manufactures the antidepressant Paxil, commissioned five clinical trials from 1998 to 2002 to assess the drug's efficacy in addressing pediatric and adolescent depression. The company published the results of only one trial, which were mixed. The other four trials had found negative results, including that the drug raised the risk of suicide (McGauran *et al.* 2010; Union of Concerned Scientists 2012).

### Ghostwriting

Healy (2003) observes that "unacknowledged editorial or writing assistants to academic authors – so-called ghostwriters – are often employed by medical communication agencies working for pharmaceutical companies."

McGarity & Wagner (2008) found that scientists have been compensated $3,000 to $5,000 to place their name and title on an article and submit it for publication.

A Union of Concerned Scientists analysis found ghost-authorship of articles on Avandia, Fen-Phen, menopausal hormone therapy, Neurontin, Paxil, Tylenol, Vagus nerve stimulator, Vioxx, Zoloft, and Zyprexa in medical journals (Union of Concerned Scientists 2012).

Ross *et al.* (2008) also revealed that clinical trial articles and review articles related to rofecoxib were frequently written by unacknowledged authors who were employees of for-profit information industries.

## 6. Fabrication, falsification or alteration of data or results

Potentially more serious than the failure to publish test results is evidence that scientists are fabricating, falsifying and altering test results due to pressure from their corporate sponsors. Steen (2010) observes that "levels of misconduct appear to be higher than in the past."

A review of retractions of 742 English language research papers between 2000 and 2010 found that 27 per cent of the retractions were due to fraud (Steen 2010).

Routine data audits conducted by the US Food and Drug Administration between 1977 and 1990 found deficiencies and flaws in 10–20 per cent of studies, and led to 2 per cent of clinical investigators being judged guilty of serious scientific misconduct (Fanelli 2009, Whoriskey 2012).

In 2011, the US Food and Drug Administration (FDA) notified pharmaceutical companies that bioanalytical studies carried out at a lab over a five year period may need to repeated or confirmed because an audit of the lab revealed widespread and serious misconduct - including falsification of documents and manipulation of data (FDA 2011).

A 2005 survey of over 3,000 early and mid-career scientists funded by the National Institutes of Health found that while only 1.5 per cent admitted to falsification and plagiarism, one of every three scientists admitted to questionable research behaviours, such as ignoring a colleague's use of flawed data or questionable interpretation of data. Nearly 16 per cent said they had changed the design, methods or results of a study in response to pressure from a funding source. (Wadman 2005).

In a review of 21 surveys from 1997-2007 Fanelli (2009) strongly corroborated the findings of Wadman's study. When scientists were asked if they had personal knowledge of a colleague who fabricated or falsified research data, or who altered or modified research data between 5.2 per cent and 33.5 per cent responded affirmatively. Furthermore, when surveys defined misconduct in more comprehensive ways (e.g. "experimental deficiencies, reporting deficiencies, misrepresentation of data, falsification of data") between 12 per cent and 92 per cent replied affirmatively.

In a demonstration of the extent to which scientists may have internalised their bias, Fanelli found that scientists admitted more frequently to having "modified research results" than to having reported results they "knew to be untrue" (Fanelli 2009).

## 7. The effect of patents and intellectual property rights

Scientists have argued that the contrary to the current orthodoxy, proliferation of intellectual property (IP) protection has actually had a strongly negative effect on research in their disciplines. In particular they identify problems of delayed or blocked access to needed research tools (Lei 2009).

Some researchers see the patent system as fostering a culture of secrecy – which they characterise as the 'bane' of science (Smith 2016).

The UK Royal Society (2003) found that patents "can encourage a climate of secrecy that does limit the free flow of ideas and information that are vital for successful science."

Mirowski (2011) extensively discusses a number of different problems with patents and intellectual property related to science and R&D. He sees IP as an enclosure movement closely tied to corporate and market forces. He is particularly concerned at the privatising of knowledge. This results in a dangerous level of monopoly control and restricted – and often expensive - access to new technologies and knowledge.

## 8. Industry science is used to shape public perception and culture


Beginning with tobacco and followed by the chemical, pharmaceutical, biotechnology, nuclear, food and fossil fuel industries, corporate interests have paid for and fabricated science that is intended to influence public perception and culture.

Nestle (2013) observes that "financial ties with food and beverage companies are now recognised as influences on federal dietary guidelines, opinions of nutrition professionals, and the interpretation of nutrition studies."

According to Ayoob, Duyff and Quagliani (2002), it is difficult to distinguish between nutrition facts and nutrition misinformation, leading to detrimental consequences that may be harmful to health.

The American Society for Nutrition publishes the American Journal of Clinical Nutrition. Its financial backers include Coca Cola, Monsanto, Cargill, the National Dairy Council and the Sugar Association.

ASN's stances on policy are often at odds with established science and aligned with industry, such as their policy on sugars - "a lack of consensus remains in the scientific evidence of the health effects of added sugars" (Simon 2015).

Similarly, in 2003, the American Academy of Paediatric Dentistry accepted a $1 million donation from Coca-Cola. That year, the group claimed that "scientific evidence is certainly not clear on the exact role that soft drinks play in terms of children's oral disease." The statement directly contradicted the group's previous stance that "consumption of sugars in any beverage can be a significant factor... that contributes to the initiation and progression of dental caries" (Center for Science in the Public Interest 2003).

The climate debate has been significantly affected by the corporate funding of contrary science. What was once a debate about how to address climate change became a debate about whether climate change is occurring at all (Beder 1999b).

## 9. Vilification of scientists

Attacks on scientists are part of the corruption of science. They are part of the battle for legitimacy, in the press and in the political sphere. Scientists are attacked when their science contradicts that of industry.

Dr Herbert Needleman is well known for his commitment to researching the negative effects of lead exposure on children. He has faced constant attacks from the lead industry. The Lead Industries Association and the International Lead Zinc Research Organization published a letter calling Needleman's research "flawed and irrelevant," and labelled him an overemotional, untrustworthy anti-lead fanatic (Denworth 2008).

Tyrone Hayes, a scientist at the University of California Berkeley, was commissioned by Syngenta to undertake a study into atrazine, a widely used agricultural chemical. He found that atrazine negatively affected the sexual development of frogs. Following the publication of his results – long after he had severed ties with Syngenta - the company began to attack his scientific credentials and the integrity of his research. They called him a junk scientist. They commissioned three studies that failed to replicate Hayes' results. Documents later released by Syngenta as a result of a lawsuit arising from Hayes' work showed that Syngenta had, in fact, plotted to discredit him (Aviv 2014

Dr Benjamin Santer, a climate modelling specialist, was asked to draft a portion of the Intergovernmental Panel on Climate Change (IPCC) report in 1995. Two physicists, who had previously worked for the tobacco industry, accused him of doctoring the results to make the science seem more certain than it was. He was accused of 'scientific cleansing' – eliminating views with which he disagreed. They wrote reports, letters to politicians, made public statements, attempted to get Santer fired and even published an op-ed in the *Wall Street Journal* accusing Santer of fraud. Santer was given a limited right of reply in the *Wall Street Journal*, which then allowed a reply letter to be published repeating that Santer had tampered with the IPCC results (Conway and Oreskes 2012; UCS 2012).

In 2001, Dr Ignacio Chapela and David Quist published a study showing that GM corn had contaminated native Mexican corn - despite there being an embargo on the growing of GM crops in Mexico. A public relations firm working for Monsanto circulated online comments from

fictional people attacking Chapela (Monbiot 2002). As Monbiot writes:

> ***"There do appear to be methodological problems with the research Chapela and his colleague David Quist had published, but this is hardly unprecedented in a scientific journal. All science is, and should be, subject to challenge and disproof. But in this case the pressure on Nature was so severe that its editor did something unparalleled in its 133-year history...he published, alongside two papers challenging Quist and Chapela's, a retraction in which he wrote that their research should never have been published."***

Subsequent work by others has confirmed the contamination of Mexican corn and the accuracy of Chapela's and Quist's paper. Chapela was also attacked by academics, including at Berkeley where he taught. These academics, it turns out were associated with a $25 million corporate deal that was in the works between the University of California Berkeley and the biotech giant Novartis. Chapela had actively opposed that deal.

The blowback for Chapela came not only in relation to his work on corn but to his tenure at the University of California at Berkeley. Despite unanimous support for Chapela within his department and a unanimous recommendation that he be granted tenure, he wasn't. That decision was ultimately reversed as a result of the public outcry (GM Watch 2004).

There are a number of other examples of where independent scientists have raised concerns about GM crops and been the subject of ruthless attacks. These include Professor Jack Heinemann, Dr Judy Carman, Dr Arpad Puzstai and Professor Giles-Eric Séralini.

In recent years, Professor Séralini has been perhaps the most consistently and viciously attacked of the scientists whose peer-reviewed work has indicated potential health concerns associated with GM crops.

In September 2012, Séralini published a study in the journal of *Food and Chemical Toxicology* which found evidence of liver and kidney toxicity and hormonal disturbances in rats fed Monsanto's GM maize NK603 and very small doses of the Roundup herbicide (with which it is grown) over a long term period.

Attacks from scientists began almost immediately in the English speaking world and gained significant traction. The push for a retraction was on. More than two dozen scientists – many known to be linked with the biotech industry - signed a letter attacking the paper and its publication, calling for retraction.

Henry I. Miller labelled the study a fraud and accused Séralini of "gross scientific misconduct" in *Forbes* magazine. Miller had previously attempted to discredit research linking tobacco to cancer and heart disease on behalf of the tobacco industry. Since then he has tried to do the same for research critical of GMOs and pesticides (Simon 2012).

In November 2013 the study was retracted by the journal's editor, A. Wallace Hayes, after the appointment of a former Monsanto scientist, Richard E. Goodman, to the editorial board and a non-transparent review process by nameless people that took several months.

Emails released under Freedom of Information laws reveal that Goodman informed his Monsanto correspondent about the publication of Séralini's article and that he "would appreciate" it if the firm could provide him with criticisms. "We're reviewing the paper," the Monsanto correspondent replied. "I will send you the arguments that we have developed." A few days later, Goodman was named "associate editor" of the journal.

On November 2, 2012, Hayes announced in an email to Monsanto employees that from now on Goodman would be in charge of biotechnology at the journal. Hayes added: "My request, as editor, and from Professor Goodman, is that those of you who are highly critical of the recent paper by Séralini and his co-authors volunteer as potential reviewers."

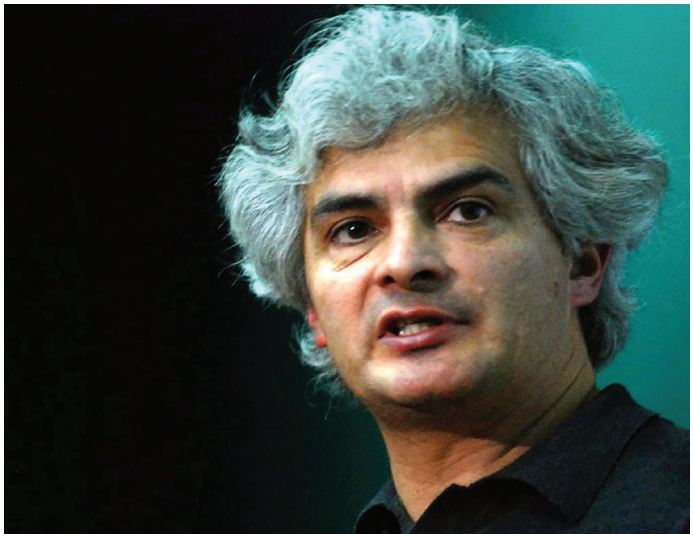
Scientific papers are normally retracted only due to fraud, plagiarism, or honest error. Séralini's study did not fall into any of these categories and was the first to be retracted on grounds of "inconclusiveness". The study was subsequently republished by another journal, *Environmental Sciences Europe* (Seralini 2014, Seralini 2014a, GM Watch 2016).

Seralini has subsequently won two libel cases based on claims he committed scientific fraud. Additionally, in 2016 Marc Fellous the former Chairman of France's Biomolecular Engineering Commission (which has authorised many GM crops for consumption) was convicted of fraud for forging the signature of a scientist in a written attack on Seralini (GMO Seralini 2016). In 2016 Fellous became president of the French Association for Plant Biotechnology, a lobby group set up to promote GM crops.

Food Standards Australia New Zealand joined the attacks, publishing a non-peer reviewed criticism of the paper online (FSANZ 2013). The criticisms are virtually the same as those made by industry-linked academics and have since been thoroughly rebutted both by Seralini and others (Fagan *et al.* 2014).

These are just some examples of the vilification of scientists that occurs when they contradict the prevailing industry position. The pattern is clear. If there is a risk of regulatory intervention, industry will manufacture doubt to prevent or delay regulatory action.

When approvals have been granted, and subsequent studies show legitimate reasons for concern, industry - with the support of regulators - will manufacturer the illusion of scientific consensus - dismissing new scientific findings and insisting their products are safe.



*Ignacio Chapela was publicly vilified after he revealed that native Mexican corn had been contaminated by GM varieties.*

# 10. Industry influence over regulatory agencies

## A systemic problem

Studies of regulatory capture and institutional corruption have demonstrated that the co-option of regulatory agencies is frequent and common (McArdle 2014).

Industry science can help provide a patina of defensibility to decisions that may otherwise be unjustifiable.

Pro-industry science is further supported by certain policy settings that are common in Australian regulatory agencies. This includes refusing to use the precautionary principle because it is "at odds with the principle of minimum necessary regulation." (FSANZ, ND); broad and unscientific conclusions of safety based on analogy or similarity (FSANZ 2007; Ho & Steinbrecher 1998); and making decisions based on available information rather than requiring data gaps to be filled (APVMA 2015a).

Moodie (2013) sees the problem as one of influence, both direct and indirect. "Industries affect public health legislation and avoid regulation with both hard power (i.e., building financial and institutional relations) and soft power (i.e., influence of culture, ideas, and cognitions of people, advocates, and scientists). There is now evidence to show that the food, drink, and alcohol industries use similar tactics and strategies to the tobacco companies to undermine public health interventions."

Unfortunately, industry influence on regulators doesn't stop there. More than half the scientists at the U.S. Fish and Wildlife Service who responded to a survey conducted by the Union of Concerned Scientists in 2005 agreed that "commercial interests have inappropriately induced the reversal or withdrawal of scientific conclusions or decisions through political intervention" (Washburn 2007).

## Reliance on industry data

As this report clearly illustrates, industry data and studies are far more likely to be unreliable, faulty or even fraudulent, yet regulators regularly rely on industry science to allow the introduction of new and potentially unsafe products into the market.

Alarmingly, many regulatory agencies are prepared to give approvals to products based solely on industry data. There is no requirement, for example, when approving a food, a genetically modified crop or a chemical, that regulators secure independent, peer reviewed science in order to make a decision.

Washburn (2007) argues that most government agencies "lack even the most rudimentary tools that a medical journal editor would use to assess the quality and scientific integrity of industry-funded research."

## User fees

Another source of industry influence on regulators is user fees. For example the US Food and Drug Administration (FDA) currently draws more than 50 per cent of its total drug review budget from user fees paid by the pharmaceutical industry. David Kessler, a former head of the FDA, told the *Wall Street Journal*, "There is no doubt that user fees give the industry leverage on setting the agency's priorities. There are significant risks" (Washburn 2007).

Light (2013) argues that "the authorization of user fees in 1992 has turned drug companies into the FDA's prime clients, deepening the regulatory and cultural capture of the agency." Similar conclusions can be drawn regarding our regulators in Australia.

In 2014-15, the Australian Pesticide and Veterinary Medicines Authority, which is responsible for authorising agricultural chemicals received 90 per cent of its 33 million dollar operating expenses from user fees (APVMA 2015). In 2015 the Australian Therapeutic Goods Association (TGA), which is responsible for drug approvals, received $8.5 million in funds from the government and $130.7 million from the sale of goods and provision of services (TGA 2015).

***"Investigations by anti-corruption commissions in Australia "have repeatedly shown that agencies with regulatory functions...are particularly vulnerable to corruption and misconduct" (Adams et al 2007).***

## Advisory committees and conflicts of interest

A study by Neltner (2013) and colleagues examined conflicts of interest among scientific experts serving on panels deciding whether food additives should be deemed generally recognised as safe (GRAS) and exempt from US Food and Drug Administration (FDA) premarket approval requirements. An astonishing 100 per cent of the members of 290 expert panels included in their review worked directly or indirectly for the companies that manufactured the additive in question. Even more alarming, the experts on these panels formed a tight professional cadre. Although 850 people served on the panels, 10 experts served on 27 panels or more, and one of these 10 participated in three-quarters of the panels" (see also Nestle 2013) .

In 2015, Friends of the Earth revealed that an expert panel convened by the Australian food regulator, Food Standards Australia New Zealand (FSANZ) to consider whether and how to regulate a suite of new genetic modification (GM) techniques was comprised entirely of scientists with either direct financial interests in GM or indirect financial interests through their work places. The expert panel recommended that the majority of these techniques should be subject to no or reduced regulation – conclusions strongly disputed by overseas government agencies. FSANZ has denied there was an actual or potential conflict of interest (Friends of the Earth 2015, FSANZ 2015).

Similar conflicts of interest exist in the Office of the Gene Technology Regulator (OGTR)'s Gene Technology Technical Advisory Committee (OGTR 2014), which in 2016 also recommended the deregulation of a range of new GM techniques (OGTR 2016). Despite the Gene Technology Regulations 2001 stipulating that committee members with vested interests in a particular matter should not take part in decision-making, no committee members stood aside during the discussions. The OGTR used the committee's advice as the basis for a discussion paper it released later that year canvassing the potential deregulation of these techniques (OGTR 2016b).

## 11. Corporate science and education – corrupting the next generation

The investment by corporations in education goes well beyond corporate partnerships at Australian universities. While the science that underpins many of these materials is suspect, it is the longer-term indoctrination of students into viewing corporations as part of the solution - not the problem - that is concerning.

Some of the tactics used in primary and secondary schools include free educational materials, school visits, competitions, grants or school projects that reinforce the legitimate role of the corporation in solving environmental or social problems.

The increasing reliance of educators on materials produced by corporations has been heavily criticised by the public and educators alike (e.g. Climate Science and Policy Watch 2010). Beder (2009) for example has accused corporations of taking over schools and creating a "conveyor belt of consumerist conditioning." Unfortunately, government has become increasingly complicit in this process as well.

For example, in Australia the multinational oil company Shell launched an educational program, Carbonkids in 2009 - to subtly inform children that we can have business as usual and protect the climate at the same time. These materials were actively endorsed by the government. One of the ambassadors for the project was Dr Jim Peacock, former chief Australian Scientist and Deputy Director of Plant Industries at CSIRO (Department of Industry, Innovation, Science, Research and Tertiary Education 2009).

Another of CSIRO's educational projects, Sustainable Futures, is sponsored by Bayer – a drug, chemical and GM crop producing corporation (Bayer 2016).

Beder (1999, 2009) observes that a number of educational materials produced by corporate interests are factually inaccurate and misleading. These include materials produced by the chemical, food, paper, plastics, petroleum and nuclear industries.

*The Global Carbon Capture and Storage Institute's CEO, Brad Page with school children from Forrest Primary School at the launch of CarbonKids in Canberra.*

## 12. What needs to happen?

**Three critical and necessary conclusions emerge from these pages:**

1. **Industry-funded science should never form the primary or exclusive basis for regulatory approval;**
2. **As a first step in reducing industry influence over regulatory decision-making , the Government should implement strict measures to prevent conflicts of interest in its advisory committees; and**
3. **Secret contracts between industry and publicly funded research organisations should not be permitted.**

Despite the ubiquitous nature of the corporate corruption of science, there appears to have been relatively little discussion about how to tackle this growing problem. Friends of the Earth believe that implementing the following additional measures would be a step in the right direction.

### Governments should:

1. Implement the precautionary principle with clear guidelines preventing regulatory approvals or declarations of safety when there is significant uncertainty, large data gaps or a lack of peer reviewed science available;
2. Ensure that corrupt or fraudulent science isn't used in making decisions that affect the broader public. This requires not only criminal penalties but significantly greater oversight and enforcement;
3. Require the mandatory reporting of toxicology test results for all chemicals – as has already been implemented by some countries for clinical trial data (Prayle *et al.* 2012);
4. Significantly increase public funding for R&D - particularly to address major data gaps in environment, health and safety (EHS) research across a wide range of scientific fields;
5. Significantly strengthen conflict of interest rules for any research using public monies or facilities - and for any public agency engaging the services, paid or otherwise, of external advisors or experts;
6. Review the patents and other IP held by publicly funded institutions and whether these private interest holdings are conducive to fostering research excellence.

### Public research institutions should:

1. Make transparency a key priority for all science conducted using public funds;
2. Develop strict mandatory guidelines regarding their engagement with industry to ensure that any corporate funding does not distort their research priorities and findings.

### Scientific journals should:

1. Require declarations of vested interests from journal contributors and editors;
2. Require declaration by authors that ghostwriters have not been used.

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