INSTITUTIONAL RESEARCH MISCONDUCT

An Honest Researcher's Worst Nightmare

BY DAVID L. LEWIS, PHD

cientists have implicated environmental pollutants and pediatric vaccines as possible causes behind the rising incidence of autism spectrum disorders (ASDs). Some vaccines may also increase the risks associated with environmental pollutants linked to autism. Government organizations and the pharmaceutical industry, however, are highly motivated to predetermine the outcomes in this area of research by funding scientists to support government policies

and industry practices. Ironically, honest scientists who stand in the way can find *themselves* charged with research misconduct by institutions seeking to discredit their work. Institutional research misconduct, therefore, involves two powerful forces: supporting institutional policies and practices through acts of fraud, and using false allegations of research fraud to eliminate opponents. Science has never offered greater hope than it does now for treating and preventing autism, but that hope diminishes as government and industry surreptitiously mobilize vast resources to protect their own interests.

IMPORTANT CASES RELATED TO AUTISM RESEARCH

Table 1 lists four apparent cases (described in more detail below) of institutional research misconduct related directly or indirectly to autism research. In each case, it appeared that at least one institution was involved in the misconduct to support or protect institutional policies and practices; it was not just individuals acting on their own for their own personal benefit. All of these cases illustrate a common institutional objective: to discredit and suppress unwanted research on adverse

health effects arising from exposure to environmental agents that may trigger autoimmune and neurological diseases. These cases illustrate how government bureaucrats and corporate executives can manipulate and control the scientific enterprise throughout the government, industry, and academic sectors. Their goal, apparently, is to promote scientists who favor their interests and take out scientists who threaten them. As the last case will show, some of the world's leading science and medical journals may also engage in institutional research misconduct.

Table 1.		
Apparent cases of institutional research misconduct		

Case	Institutions involved	Issue
1	USEPA,* USDA,† land grant universities	Biosolids
2	usepa,* cdc‡	Drinking water
3	HHS§	Vaccines
4	British Medical Journal	Vaccines

- US Environmental Protection Agency
- † US Department of Agriculture
- Centers for Disease Control and Prevention
- § US Department of Health and Human Services

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the EPA's Science Achievement Award for his Nature article concerning the effects of climate change on health risks posed by environmental pollutants. Dr. Lewis currently directs the Research Misconduct Project of the National Whistleblowers Center in Washington, DC.

CASE 1

This case involves research I published in the US Environmental Protection Agency's (EPA's) Office of Research and Development (ORD) beginning in 1996. 1-5 It raised public health concerns over the science used to support some of the Agency's regulations, especially the rule (called the 503 Sludge Rule) that regulates land application of processed sewage sludge (biosolids). Sewage sludges, which settle out at municipal wastewater treatment plants, are mainly comprised of human feces. They also contain concentrated levels of a very wide variety of chemical and biological agents found in municipal and industrial wastes.

My research articles linked biosolids to public health problems, including gastrointestinal and respiratory diseases associated with biosolids draining into private wells and blowing into residential neighborhoods from treated fields. From 2000-2002, this work prompted investigations by the EPA's Inspector General, precipitated two hearings by the Committee on Science (now called the Committee on Science, Space, and Technology) in the US House of Representatives, 7,8 and led in 2002 to the passage of the No Fear Act, which requires Federal agencies to be more accountable for violations of whistleblower protection laws.9 One of my papers on chemicals of environmental concern, published in the journal Nature in 1999,2 won the EPA's Science Achievement Award. Notwithstanding these outcomes, the acting head of ORD, who developed the Agency's biosolids regulations, "dead-ended" my job in 1998. While awaiting my termination, he arranged for me to be transferred to the University of Georgia (UGA), where I continued my research on biosolids using my personal funds. The arrangement was part of a deal in which UGA promised to seek a tenured faculty position for me if I transferred to the university.

In 2001, two officials from EPA headquarters met over lunch with executives of a leading biosolids company to discuss my research at UGA. The EPA employees included the director of the Office of Wastewater Management and the Agency's national spokesperson for biosolids. Several months later, the biosolids company sent the EPA officials an anonymous white paper accusing me of research misconduct. Using EPA letterhead, the EPA's biosolids spokesperson then distributed the white paper at public hearings in Georgia where scientists working at UGA, including myself, were speaking about biosolids. The biosolids company reported the allegations to the EPA administrator and then filed them at UGA against me and my primary coauthor, a UGA professor, in a formal petition to investigate our alleged research misconduct.

At UGA, I had assembled a team of scientists to investigate reports of illnesses and deaths linked to biosolids throughout the US and Canada. One case that was particularly troubling to the EPA involved two dairy farms near Augusta, GA. Hundreds of head of cattle died after eating forage crops fertilized with biosolids. To counter my research and lawsuits filed by the farmers, the EPA funded UGA to publish environmental monitoring data, which a federal judge later concluded were widely known to be "fabricated" and "invented." The UGA study was funded through a cooperative agreement in which the EPA claimed that the university—by virtue of its status as a land grant university—had a "unique and trusting relationship" with farmers in the Augusta area. (Government agencies describe grant recipients as "unique" when they want to legally justify not having to open the project to competition.) In this case, the actual "trusting relationship" appeared to have been between the EPA and certain UGA employees, whom the EPA trusted to publish data that were otherwise widely known to be unreliable.

The EPA eventually dismissed the research misconduct allegations against me as having no basis in any facts. UGA's research integrity officer, however, refused to issue any findings. In court proceedings, 10 she cited pressure from a Georgia senator hired by the biosolids company. The EPA and UGA authors who published the fabricated data testified that they knew the data were unreliable when they submitted the paper, but they refused to withdraw it even after city officials in Augusta admitted to making up the data. Although I was the only EPA scientist to publish first-authored articles in the highly regarded journals *Nature* and *The Lancet* and the only EPA scientist working to prevent a deepwater oil spill in the Gulf of Mexico, 13 the Agency terminated me in 2003 as a senior

level research microbiologist with over 31 years of service. My EPA laboratory director issued the following public statement:

Dr. Lewis' involuntary termination over his research articles was not supported by the local lab management in Athens. He was an excellent researcher and an asset to EPA science.

CASE 2

This case is based on award-winning investigations published by Marc Edwards and coworkers at Virginia Tech in Blacksburg. 14 Edwards' investigations focused on the publication of false and misleading data on lead in drinking water by the EPA and the Centers for Disease Control and Prevention (CDC). The investigations by Edwards led to congressional hearings and investigations by the General Accounting Office. 15 According to Nature, 16

Edwards' paper prompted a 2010 congressional probe into the CDC's report that concluded that an author of it had excluded a child from the dataset who had high levels of lead in his blood, as well as that some of the relevant data were missing and that key information suggesting that some of the patients without elevated lead levels had been drinking bottled water, had been withheld.

Although the congressional investigation confirmed Edwards' allegations that data reported in a CDC study do not exist, the CDC and a government-directed journal (*Environmental Health Perspectives*) have refused to withdraw or correct their publications. Other dimensions of this case involve publication of faulty reports funded by the EPA, which hid key data and still steadfastly refuses to properly respond to Freedom of Information Act (FOIA) and other requests. George Washington University also refused to investigate allegations of scientific misconduct after a faculty member involved in the CDC study took early retirement and another scholar took a position elsewhere.

CASE 3

When it passed the National Childhood Vaccine Injury Act of 1986, Congress gave the Vaccine Injury Compensation Program (VICP) under the Department of Health and Human Services (HHS) jurisdiction over all vaccine injury claims. HHS and the CDC have taken the position that autism is unrelated to pediatric vaccines. Mary Holland at New York University (NYU) School of Law and her colleagues, however, discovered 83 cases of acknowledged vaccine injury of "encephalopathy" and "residual seizure disorder" together with autism. ¹⁷ The VICP held the Omnibus Autism Proceeding after autism diagnoses began to skyrocket beginning in the late 1980s and the numbers of petitions mounted. Holland et al. reported that nearly five thousand families filed petitions with the VICP claiming vaccines caused their children's autism. The VICP dismissed all test claims of vaccine-induced autism, and a federal court of appeals upheld the dismissals. Holland and coworkers, however, questioned whether the autism cases dismissed by the VICP are any different from cases of encephalopathy and residual seizure disorder that included autism, which the VICP has been settling before and since the Omnibus Autism Proceeding. These cases span the time since the VICP began in 1988 and suggest that HHS may be systematically disguising a link between autism and vaccination.

CASE 4

Editors at the *British Medical Journal (BMJ)* and Brian Deer, a freelance reporter, alleged that Dr. Andrew Wakefield fabricated the diagnosis of colitis in a 1998 *Lancet* study conducted at the Royal Free Hospital of the University College London (UCL). ¹⁸ The study involved 12 children with ASD and gastrointestinal (GI) problems. In the study, some parents and physicians linked the MMR (measles-mumps-rubella) vaccine to the children's health problems. ¹⁹ The type of MMR vaccine administered to some of the children, which contained live Urabe AM-9 mumps virus, led to outbreaks of meningitis and was withdrawn in the UK in 1992. ²⁰⁻²³

The incidence of autism has risen dramatically in industrialized nations over the past two decades, now affecting an estimated 1 in 110 children in the US and as many as 1 in 38 in South Korea.... The development of ASDs involves both genetic and environmental components. Studies have linked increased risks to neurotoxic agents, including heavy metals, toxic organic chemicals, and viruses. Some researchers have implicated pediatric vaccines.

According to Deer, Wakefield made up the diagnosis by misinterpreting grading sheets from A.P. Dhillon and A. Anthony, the pathologists who reviewed the children's colonic biopsy samples. Grading sheets, Deer wrote, "don't generate clinical diagnoses such as colitis." But the grading sheets I recovered from Wakefield's files after he moved to the United States show that Anthony wrote "colitis" in his marginal notes. Dhillon also included boxes to check for various diagnoses, including Crohn's disease and ulcerative colitis. Consistent with Wakefield's *Lancet* article, both pathologists found that only one child showed no evidence of inflammation. These documents clearly show that Dr. Wakefield did not fabricate the diagnosis of colitis from the pathologists' grading sheets.

Since the *Lancet* study was published, others have confirmed the link between autism and GI disease reported by Wakefield and his coauthors. Williams and coworkers at Columbia University and Harvard Medical School, for example, recently cited papers by Wakefield and his coauthors and concluded that gastrointestinal disturbances are commonly reported in children with autism and may contribute to behavioral impairment.²⁵

In November 2011, Fiona Godlee (editor-in-chief of the *BMJ*) published a highly truncated version of my analysis of Wakefield's documents along with an editorial titled "Institutional Research Misconduct." She now alleges that UCL, the Royal Free Hospital, and all 13 authors of the *Lancet* study conspired to fake the diagnoses of colitis. The reason, she alleges, was to cause public panic over the MMR vaccine so they could profit from their own "autism products." In her disclaimer, Godlee acknowledged for the first time that the *BMJ* is funded by the pharmaceutical companies Merck and GlaxoSmithKline, manufacturers of the MMR vaccine. Several organizations in England dealing with research integrity are reviewing my full report on Wakefield's documents and the *BMJ* s conflicts of interest with manufacturers of the MMR vaccine.

SUPPRESSION OF LEGITIMATE RESEARCH

Inexplicably, the incidence of autism has risen dramatically in industrialized nations over the past two decades, now affecting an estimated 1 in 110 children in the US and as many as 1 in 38 in South Korea. ^{28,29} Populations immigrating from underdeveloped to industrialized countries acquire similarly high incidences. ³⁰ The development of ASDs involves both genetic and environmental components. ³¹ Studies have linked increased risks to neurotoxic agents, including heavy metals, toxic organic chemicals, and viruses. Some researchers have implicated pediatric vaccines. ³² In the following paragraphs, environmental pollutants and vaccines are discussed in greater detail.

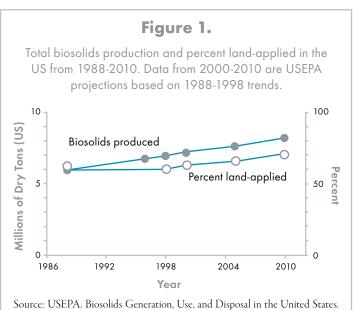
ENVIRONMENTAL POLLUTANTS

When the EPA was created in 1970, chemical and biological wastes generated by municipalities and factories, which contain a wide variety of neurotoxic agents, were flushed into rivers and streams and eventually diluted in the ocean. To clean up the nation's waterways, wastewater treatment plants were constructed to remove water-insoluble (lipophilic) pollutants and concentrate them in sewage sludge. Scientists have noted a "marked correlation" in which neurotoxicity increases as environmental pollutants become more lipophilic. 33

In a 2009 national survey of 74 water treatment plants in 35 states, the EPA found that sewage sludges contained 72 pharmaceuticals, 28 heavy metals, 25 steroids and hormones, 11 flame retardants, and 4 polycyclic aromatic hydrocarbons. The EPA does not regulate or monitor neurotoxic organic chemicals in biosolids and only tested for a small number of these chemicals in its survey. Concentration ranges (mg/kg dry wt) of some of the examples included:

- Bis (2-ethylhexyl) phthalate (DEHP), a widely-used plasticizer (0.66-310)
- Benzo(a)pyrene, a potent carcinogen in coal tar and cigarette smoke (0.06-4.5)
- BDE-47, a brominated flame retardant (0.07-5.0)
- BDE-209, another brominated flame retardant (0.15-17)
- Steroids and hormones, including 0.02-2 mg/kg of testosterone, 0.14-1.3 mg/kg of progesterone, and 0.03-1.9 mg/kg of beta-estradiol 3-benzoate, a synthetic estrogen that promotes thyroid tumors in rats exposed to as little as 0.004 mg³⁵

Prior to Congress enacting the Ocean Dumping Ban Act of 1988, ocean disposal was the preferred method for disposing of biosolids by the world's coastal cities, including in the US where cities along the eastern and western seaboards account for most of the biosolids produced in the country. Biosolids that were not ocean-dumped were landfilled or incinerated. Since 1988, most biosolids in the US are land-applied to forests, farms, parks, school playgrounds, and other public and private lands where people live, work, and grow agricultural products. Following this transition, the amount of biosolids produced in the US and the percentage land-applied have steadily risen (Figure 1).



Source: USEPA. Biosolids Generation, Use, and Disposal in the United State. EPA530-R-99-009. September 1999.

To dispose of sewage sludge as cheaply as possible, the EPA proposed in 1992 that its 503 Sludge Rule regulate only ten of the 28 heavy metals found in biosolids (arsenic, cadmium, chromium, copper, lead, mercury, molybdenum, nickel, selenium, zinc) and no organic pollutants. To convince the public that this approach was based on good science, the EPA established a cooperative agreement with a wastewater industry trade association, the Water Environment Federation (WEF). Under this agreement, the EPA used congressional earmarks to run a National Biosolids Public Acceptance Campaign (funded from 1992-99) to support its 503 rule. 36 After promulgating the rule in 1993, the EPA deregulated chromium in biosolids and dropped cumulative loading limits for molybdenum. According to documents obtained in whistleblower lawsuits I filed against the EPA,³⁷ the purpose of the EPA-WEF cooperative agreement was to develop a network of "gatekeepers" at land grant universities throughout the United States to publish research supporting the 503 rule. The agreement specifically provided federal funding to discredit scientists who reported adverse health effects. Both during and since the EPA's public acceptance campaign, very few studies have questioned the safety of land application of biosolids.

The EPA's national spokesperson for biosolids, who distributed the industry's false allegations of research misconduct against me in Georgia, formed a group at the EPA in 1998, which was called the Biosolids Incident Response Team (BIRT). It was specifically created to investigate the cattle deaths in Augusta. The head of BIRT arranged for the EPA to fund the aforementioned study at UGA, and he supplied the data fabricated by the City of Augusta that were later published in a peer-reviewed journal. These data falsely indicated that Augusta's biosolids generally contained safe levels of heavy metals after the 503 rule was promulgated in 1993. The EPA sent a draft copy of the article to the National Academy of Sciences, which relied on it when concluding that there have been no documented cases of adverse health effects from land application of biosolids under the EPA's 503 rule. 38

To this day, the EPA argues that the same municipal and industrial pollutants that are harmful in air and water have environmental and health benefits when incorporated in biosolids and applied to land. According to the EPA, biosolids containing high concentrations of otherwise toxic heavy metals and hazardous organic chemicals can even be safely ingested by children because they are no longer bioavailable. ³⁹ These conclusions, including the lack of documented cases of adverse health effects, are based upon a body of scientific literature produced through a network of land grant universities apparently engaged in institutional research misconduct.

In an even more disturbing case, the EPA, the US Department of Agriculture (USDA), the US Department of Housing and Urban Development (HUD), and the Kennedy Krieger Institute (KKI) at Johns Hopkins University conducted experiments in which lead-contaminated biosolids were added to lead-contaminated soils in predominantly African-American neighborhoods in Baltimore, Maryland. According to my analysis requested by Maryland's Office of Civil Rights, ⁴⁰ the combined amounts of lead in soil and biosolids to which children were exposed in this study exceeded CDC safety limits; moreover, the study did not follow normal experimental protocols for testing residents and their homes for lead levels. ⁴⁰ Nonetheless, the KKI, USDA, and HUD used this and similar studies to conclude in 2005 that biosolids high in iron and phosphorus can reduce the bioavailability and bioaccessibility of soil lead. ⁴¹ In a previous study involving lead paint, the KKI was sued by parents whose children apparently developed lead poisoning. In 2001, a Maryland appeals court likened

the research to the US Public Health Service's infamous Tuskegee syphilis study and Nazi medical experiments in World War II.⁴²

In 2005, the EPA and state health officials held a public "health fair" in an African-American community in Louisiana to instruct residents in personal hygiene after an outbreak of *Staphylococcus aureus* infections. Residents developed boils when biosolids were applied to sugar cane fields where they lived, but the state health department dismissed biosolids as having any role in the outbreak. In a report summarizing their findings, ⁴³ the EPA and state health officials never mentioned peer-reviewed research articles my coworkers and I had published from 2002-2004 concerning biosolids and *S. aureus* outbreaks. ³⁻⁵ In our research, we found that one-fourth of the cases we studied at ten land application sites, including several deaths, involved *S. aureus* infections associated with chemical irritants in biosolids.

VACCINES

Since the late 1980s, the number of vaccines added to the government-recommended pediatric vaccine schedule has risen dramatically. Currently, over 30 vaccines are administered to children in the United States in the early postnatal period when there is rapid brain growth and the brain and immune system are highly vulnerable to neuroimmunotoxic insults. 44-46 Aluminum compounds and other chemical and biological components of vaccines are known to be neurotoxic and could potentially trigger neurological disorders and autoimmune diseases. 32,47

The CDC and other government organizations assure the public that vaccines do not cause autism and that risks of adverse reactions of any kind are extremely small. As with biosolids, however, the government's reassurances are based on a body of studies funded by government agencies and large corporations with vested interests in downplaying problems with vaccines. And, as with researchers who associate biosolids with adverse health effects, scientists who link vaccines to autism risk losing their jobs and reputations.

POTENTIAL INTERACTIONS BETWEEN ENVIRONMENTAL POLLUTANTS AND VACCINES

It is important that independent research be carried out to determine whether combined exposures to neurotoxic environmental pollutants and vaccines may increase risks associated with autism. Normally, the blood-brain barrier protects the central nervous system from exposure to potentially toxic chemicals present in the bloodstream. Aluminum adjuvants in vaccines, however, can activate microglial cells. ^{48,49} These cells scavenge the brain and spinal cord for damaged neurons, plaques, and infections. But, once activated, they can potentially increase the permeability of the blood-brain barrier to other potentially harmful chemical and biological agents. ⁵⁰ Also, synergistic effects of all kinds are neither uncommon nor unexpected. The sheer number of neurotoxic agents found in biosolids alone is cause for concern, especially when it comes to exposing pregnant women and children during early postnatal brain development.

Christopher Shaw and his coworkers at the University of British Columbia are interested in collaborating on a project aimed at addressing this issue. In the studies we are proposing, pediatric vaccines would be administered on a weight-adjusted basis to groups of rats exposed to biosolids dusts as well as biosolids incorporated into food and drinking water. Biosolids used in the experiments would contain neurotoxic heavy metals and organic chemicals spanning the concentration ranges that the EPA found in its 2009 survey of sewage sludges.

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Pollutants of concern would include the heavy metals cadmium, mercury, lead, manganese, and nickel; and the organic chemicals bis (2-ethylhexyl) phthalate, benzo(a)pyrene, carbamazepine, and beta-estradiol 3-benzoate. If funded, these studies stand a high probability of shedding light on whether vaccines may increase the risks associated with environmental pollutants.

DISCUSSION

So far as public health is concerned, institutional research misconduct may well be the greatest obstacle to scientific progress in our day. If it were not a factor, I am convinced that the body of science published in important areas of public health research would be substantially, if not radically, different. The EPA's biosolids program, for example, is largely supported by institutional research misconduct. It has led to a staggering increase in the complexity of mixtures of pollutants found in soil and water over the past 25 years. Compounding this problem, the Agency's approach to protecting public health rests upon regulating only a small number of pollutants based on the availability of analytical methods and environmental studies. Such a strategy cannot possibly achieve a significant reduction in the numbers of potential environmental triggers for chronic diseases to which populations are exposed. From this perspective, the surge in autism and other environmentally triggered diseases over the past two decades suggests that the EPA may be doing as much harm as good when it comes to protecting public health and the environment.

Research on the causes of autism needs to focus more on exposures to complex mixtures of environmental triggers and less on individual chemical and biological agents. Although risks must always be weighed against benefits, until independent research demonstrates otherwise, we should not assume that highly complex mixtures of contaminants do not trigger adverse outcomes in genetically predisposed individuals, especially in infants from pre-through early postnatal development. As Paracelsus is reputed to have observed in ancient times, dose makes the poison, but when it comes to manifesting genetic predispositions to various diseases, complexity most often pulls the trigger. As the number of potential environmental triggers contained in mixtures of chemicals and biological agents goes up, so does the chance that exposed individuals will encounter the particular agents that trigger the diseases to which they are predisposed.

As just mentioned, the EPA's regulatory approach is based on reducing our exposures only to those pollutants for which analytical methods have been developed and adverse effects demonstrated. This piecemeal approach probably has very little effect at all on the incidence of environmentally triggered diseases of any kind. The number of environmental triggers that the EPA regulates, which may be associated with the current rise in autoimmune and neurological diseases, is unknown, but it almost certainly represents a tiny fraction of the total number of triggers in the environment. Taking into consideration the complexity of mixtures of pollutants is not part of the EPA's regulatory mindset.

The public health implications of this more complex reality are potentially

huge. Consider, for example, the plight of a mother carrying a child she knows is genetically predisposed to develop autism when exposed to certain chromium salts. If research on autism progresses as it should, such a scenario could soon be a reality. In the 1970s, she could have improved her child's chances of a healthy life by choosing not to work at metal plating operations or factories that use chromium salts in tanning operations. The same could be said of someone carrying an infant who is genetically sensitive to organophosphate insecticides. Living near a field where pesticides are sprayed would probably not be a good idea.

Thanks to the EPA, however, public and private lands that include forests, parks, school playgrounds, and home gardens have now become the repository of millions of tons of exceptionally complex mixtures of chemical and biological wastes. We are unknowingly being exposed to an estimated 60,000 different chemical pollutants in biosolids where we live and work. Exposure comes either directly through contaminated soil, water, and air or indirectly from foods grown on farms treated with biosolids. Moreover, the number of chemicals involved multiplies over time by orders of magnitude as the chemicals interact with each other and the environment. Biosolids also include pathogens representative of all of the infections passing through populations living in large cities. Most parasites, fungi, bacteria, and viruses present in sewage sludges can survive the standard disinfection processes that are used to produce biosolids.⁵ Prolonged exposures to such highly complex mixtures of chemical and biological wastes —which include virtually every pollutant that exists in the world today—have a clear potential for triggering a host of neurological disorders and autoimmune diseases in genetically predisposed individuals.

Vaccines contain a similarly daunting array of chemical and biological agents associated with additives, environmental contaminants, and residues from manufacturing processes. Some vaccines, for example, contain traces of antimicrobials, including chlortetracycline, gentamicin, neomycin, polymyxin B, and streptomycin. Amphotericin B, which is used to prevent fungal contamination in rabies vaccines, causes cell membrane damage in human and animal cells. Phenol red, which is used to indicate bacterial contamination in some vaccine media, mimics estrogen. In laboratory experiments, it causes ovarian surface epithelial cells to produce human oocytes (eggs). The CDC dismisses the significance of these contaminants in vaccines because they are only present in trace amounts. Traces of many of the compounds found in vaccines, however, have a demonstrated adverse effect on human health when present in air, water, and soil in the environment.

Other chemical residues commonly found in vaccines include antifoaming agents (polydimethylsilozone), growth media (e.g., hydrocortisone), preservatives (EDTA, benzethonium chloride, phenol, 2-phenoxyethanol, thimerosal), stabilizers (egg albumin, glycine, monosodium glutamate [MSG], potassium glutamate, sorbitol), toxin inactivators (glutaraldehyde, formaldehyde), and viral inactivators (beta-propiolactone, sodium deoxycholate, Triton N-101, octoxynol 9, polysorbates). Vaccines also contain traces of unmonitored environmental and industrial pollutants (e.g., heavy metals, carcinogens, mutagens, neurotoxins,

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endocrine disruptors). Biological residues found in vaccines can include human fetal lung cells (fibroblasts) and viral nucleotides (DNA, RNA), as well as human, equine, and bovine sera and mouse serum protein. Traces of other biological materials from manufacturing sources may include cells and cell components derived from human aborted fetuses, calf skin, mice, and monkeys. Vaccines are also potentially subject to contamination with a wide variety of infectious agents, including viruses, bacteria, fungi, parasites, and prions.

Finally, it is important to understand that unscrupulous scientists wanting to advance their careers are not the only ones who fabricate data and commit other types of research misconduct. As we have seen, institutions do it too. The only difference seems to be that when *individuals* doing it on their own get caught, the consequences are severe, whereas when institutions engage in research misconduct, there are no negative consequences for the scientists who are involved. To the contrary, in all of the cases I have studied, the scientists who support institutional research misconduct are honored with awards and rewarded with promotions. Again, the EPA's biosolids program is a prime example. Although it is a federal crime to falsify the environmental monitoring reports that are required under the Clean Water Act, no one was ever prosecuted when biosolids destroyed two dairy farms in Georgia. Both the EPA and UGA refused to withdraw admittedly unreliable data in Augusta's environmental monitoring reports, even after a federal judge ruled that the data were fabricated. Thus, while institutional research misconduct can even potentially involve national or international criminal activity, these activities may go unpunished because they are institutionally supported.

CONCLUSIONS

Dr. Fiona Godlee, editor-in-chief of the *BMJ*, recently testified to Parliament: "Even on the peer-reviewed side of things, it has been said that the journals are the marketing arm of the pharmaceutical industry. That is not untrue."53 We all suffer when government and industry manipulate and control the peer-reviewed scientific literature for their own purposes. The public needs to demand that government agencies and academic institutions break the back of institutional research misconduct and put safeguards in place to ensure that scientists conducting legitimate research are not targeted for retribution. Government agencies, pharmaceutical companies, and many academic institutions have much at stake when it comes to research on autism. The attacks on Dr. Andrew Wakefield have had an unprecedented chilling effect on vaccine safety research, especially with regard to autism. So long as institutional research misconduct prevails, honest scientists must find ways to get around the system through private funding or other means of support. Otherwise, progress in autism and other important areas of public health research will proceed at a snail's pace for generations to come.

Disclaimer: Opinions expressed in this article are the author's and do not necessarily represent those of the National Whistleblowers Center.

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