

Interview with Boyd E. Haley: Biomarkers supporting mercury toxicity as the major exacerbator of neurological illness, recent evidence via the urinary porphyrin tests

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Abstract

In the recent past, several biological finds have supported the hypothesis that early exposure of infants to Thimerosal was the major exacerbation factor in the increase in autism-related disorders since the advent of the mandated vaccine program. These initially included the observations of a genetic susceptibility impairing the excretion of mercury and the increased retention of mercury by autistic children. This was followed by data indicating that autistics have low levels of the natural compound glutathione that is necessary for the biliary excretion of mercury, possibly explaining the genetic susceptibility. Other observations clearly point out that various biochemical processes are inhibited at exceptionally low nanomolar levels of Thimerosal, including the killing of neurons in culture, the inhibition of the enzyme that makes methyl-B12, the inhibition of phagocytosis (the first step in the innate and acquired immune system), the inhibition of nerve growth factor function at levels not cytotoxic, and the negative effect on brain dendritic cells. It is also now quite clear from primate studies that Thimerosal, or more correctly, the ethylmercury from Thimerosal delivers mercury to the brain, and causes brain inorganic mercury levels higher than equal levels of methylmercury.

Most recently, one study showed that 53 percent of autistic children had aberrant porphyrin profiles similar to mercury toxic individuals. Treatment of these children with a mercury chelator brought these porphyrins back towards normal levels indicating mercury toxicity was the cause, not genetic impairment. Porphyrin profiles are one of the most sensitive methods of measuring toxic mercury exposures. Recently, in a major advance it was shown that about 15 percent of individuals in one population displayed a marked sensitivity to mercury exposure in their porphyrin physiology, again supporting the concept of a genetically susceptible population that is more sensitive to mercury than the general population.

This observation on porphyrin aberrancies brings into consideration other possible effects of mercury toxicity that are secondary to porphyrin depletion. Porphyrins are the precursors to heme synthesis. Heme is the oxygen binding prosthetic group in hemoglobin and depletion of heme would affect oxygen delivery to the mitochondria and decrease energy production. Also, heme is a component of the electron transport system of mitochondria and a prosthetic group in the P450 enzymes which are fundamental in the detox of the body from many organic toxicants including pesticides and PCBs. Just recently, a report was released implying that lack of heme was the major reason why β -amyloid plaques build up in the brains of Alzheimer's diseased subjects. It seems that heme attaches to β -amyloid helping it remain soluble and excretable. Without adequate heme one of the major pathological diagnostic hallmarks of Alzheimer's disease appears. It is well known that mercury rapidly disrupts the normal polymerization of tubulin into microtubulin in brain tissue and aberrant tubulin polymerization is a consistent factor observed in Alzheimer's diseased brain. Therefore, it is the multiple inhibitions of mercury that can cause various neurological and systemic problems and many of these are secondary to the primary site of mercury binding. >>>

Merck's Gardasil Vaccine Not Proven Safe For Little Girls

Main Category: [Immune System / Vaccines News](#)

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The National Vaccine Information Center (NVIC) is calling on the CDC's Advisory Committee on Immunization Practices (ACIP) to just say "no" on June 29 to recommending "universal use" of Merck's Gardasil vaccine in all pre-adolescent girls. NVIC maintains that Merck's clinical trials did not prove the human papillomavirus (HPV) vaccine designed to prevent cervical cancer and genital warts is safe to give to young girls.

"Merck and the FDA have not been completely honest with the people about the pre-licensure clinical trials," said NVIC president Barbara Loe Fisher. "Merck's pre and post-licensure marketing strategy has positioned mass use of this vaccine by pre-teens as a morality play in order to avoid talking about the flawed science they used to get it licensed. This is not just about teenagers having sex, it is also about whether Gardasil has been proven safe and effective for little girls."

The FDA allowed Merck to use a potentially reactive aluminum containing placebo as a control for most trial participants, rather than a non-reactive saline solution placebo. A reactive placebo can artificially increase the appearance of safety of an experimental drug or vaccine in a clinical trial. Gardasil contains 225 mcg of aluminum and, although aluminum adjuvants have been used in vaccines for decades, they were never tested for safety in clinical trials. Merck and the FDA did not disclose how much aluminum was in the placebo.

Animal and human studies have shown that aluminum adjuvants can cause brain cell death and that vaccine aluminum adjuvants can allow aluminum to enter the brain, as well as cause inflammation at the injection site leading to chronic joint and muscle pain and fatigue. Nearly 90 percent of all Gardasil recipients and 85 percent of aluminum placebo recipients reported one or more adverse events within 15 days of vaccination, particularly at the injection site. Pain and swelling at injection site and fever occurred in approximately 83 percent of Gardasil and 73 percent of aluminum placebo recipients. About 60 percent of those who got Gardasil or the aluminum placebo had systemic adverse events including headache, fever, nausea, dizziness, vomiting, diarrhea, myalgia. Gardasil recipients had more serious adverse events such as headache, gastroenteritis, appendicitis, pelvic inflammatory disease, [asthma](#), bronchospasm and arthritis.

"Merck and the FDA do not reveal in public documents exactly how many 9 to 15 year old girls were in the clinical trials, how many of them received hepatitis B vaccine and Gardasil simultaneously, and how many of them had serious adverse events after being injected with Gardasil or the aluminum placebo. For example, if there were fewer than 1,000 little girls actually injected with three doses of Gardasil, it is important to know how many had serious adverse events and how long they were followed for chronic health problems, such as juvenile arthritis."

According to the Merck product manufacturer insert, there was 1 case of juvenile arthritis, 2 cases of rheumatoid arthritis, 5 cases of arthritis, and 1 case of reactive arthritis in 11,813 Gardasil recipients plus 1 case of lupus and 2 cases of arthritis out of 9,701 participants primarily receiving an aluminum containing placebo. Clinical trial investigators dismissed most of the 102 Gardasil and placebo associated serious adverse events, including 17 deaths, that occurred in the clinical trials as unrelated.

"There is too little long term safety and efficacy data, especially in young girls, and too little labeling information on contraindications for the CDC to recommend Gardasil for universal use, which is a signal for states to mandate it," said Fisher. "Nobody at Merck, the CDC or FDA know if the injection of Gardasil into all pre-teen girls -- especially simultaneously with hepatitis B vaccine -- will make some of them more likely to develop arthritis or other inflammatory autoimmune and brain disorders as teenagers and adults. With cervical cancer causing about one percent of all cancer deaths in American women due to routine pap screening, it was inappropriate for the FDA to fast track Gardasil. It is way too early to direct all young girls to get three doses of a vaccine that has not been proven safe or effective in their age group."

The National Vaccine Information Center (NVIC), founded in 1982 by parents of vaccine injured children, has been a leading critic of one-size-fits-all mass vaccination policies and the lack of basic science research into biological mechanisms and high risk factors for vaccine-induced brain and immune system dysfunction. As a member of the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC), Barbara Loe Fisher urged trials include adequate safety data on pre-adolescent children and warned against fast tracking Gardasil at the November 28-29, 2001 VRBPAC meeting.

<http://www.fda.gov/ohrms/dockets/ac/cber01.htm#Vaccines&RelatedBiologic> (scroll down to Vaccines and Related Biologicals For references and more information, go to <http://www.nvic.org>).

National Vaccine Information Center
<http://www.nvic.org>

Drug firms a danger to health - report

International research exposes flaws in £33bn marketing budget

Sarah Boseley, health editor
Monday June 26, 2006
[The Guardian](#)

Photograph: Guardian

Drug companies are accused today of endangering public health through wide scale marketing malpractices, ranging from covertly attempting to persuade consumers that they are ill to bribing doctors and misrepresenting the results of safety and efficacy tests on their products.

In a report that charts the scale of illicit practices by drug companies in the UK and across Europe, Consumers International - the world federation of consumer organizations - says people are not being given facts about the medicines they take because the companies hide the marketing tactics on which they spend billions.

[Article continues](#)

"Irresponsible marketing practices form a serious, persistent and widespread problem among the entire pharmaceutical industry," says the report, which analyses the conduct of

20 of the biggest companies, two of which are British. It calls for tougher government controls and for the companies to put their house in order.

Scandals such as the withdrawal of Vioxx, a drug to relieve pain and inflammation in arthritis, show that unethical drug promotion is a consumer concern, says the report. Merck withdrew the drug in September 2004, but allegedly knew it could increase the chances of heart attacks and strokes from 2000 and has been accused of manipulating study results to play down the risk. More than 6,000 lawsuits have been filed against the company in the United States by people who claim they suffered heart attacks as a result of the drug, or by their families.

Despite regulatory action against drug companies, the malpractice continues, says CI. Many people in the UK may feel they are secure because they trust their doctors to tell them which drug to take, but CI says there is no room for complacency when drug companies spend twice as much on marketing as on research - \$60bn last year (£33bn) - but do not publish information on their drug promotion practices. Of the 20 companies, only Bristol-Myers Squibb provides a marketing code of conduct to consumers.

"One obvious area of concern is about how the promotion of drugs by the pharmaceutical companies to doctors can lead to irrational drug use," says Richard Lloyd, CI's director general. "There is a lot of evidence around of malpractice. This report has found that it is still going on and in a big way and it must be stopped."

More than half the companies looked at were implicated in controversies regarding their relationships to healthcare professionals between 2001 and 2005, says the report.

The British company AstraZeneca, for instance, has been criticised by regulatory bodies: it allegedly organised an event to promote its drug Crestor which included tickets for a musical, and provided flights and hotels for doctors to attend a conference on bipolar disorder on the French Riviera. AstraZeneca says all employees must now pass an exam on its code of conduct.

GlaxoSmithKline, Britain's largest drug manufacturer, is under investigation by German and Italian authorities for alleged corruption of doctors - at least 1,600 in Germany and more than 4,000 in Italy, where the illegal gifts were said to amount to €228m (£156m) from 1999 to 2002. GSK says it has since established marketing codes. New staff have to pass a test on the code of practice. The report points out that in 2004, 87 employees were dismissed or agreed to leave the company voluntarily as a result of breaches of the codes, and that sanctions such as written warnings were imposed in 109 cases.

ADHD, Ritalin

Drugging Children, A Cruel Sign of The Times

by Dr. W. Gifford Jones

Wednesday, June 21, 2006

Would I allow Ritalin or other similar drugs to be prescribed to my children because they fidgeted, squirmed in their seat or were inattentive? Hell would freeze over a thousand times before I'd submit to such idiocy. But today an estimated five million Canadian and U.S. children are prescribed medication for this condition.

This year, a committee of the U.S. Food and Drug Administration (FDA) concluded that a "black box" warning should be placed on ADHD medications, warning about heart attack and other risks. It's the strongest warning possible before a drug is removed from the market. A second advisory panel disagreed so no decision has been reached.

Why the need for a black box warning? It depends on who is giving the opinion. For instance, a report from the Mayo Clinic agrees that ADHD medications can cause heart attack, stroke, hypertension, heart palpitations, an irregular heart beat, psychosis, mania, aggressive behaviour and hallucinations. Some deaths have also been linked to these drugs. This should scare the hell out of any parent. But Mayo claims the risks are small and benefits outweigh these potential problems.

Others, such as Dr. Peter R. Breggin, a renowned researcher in this field, says doctors have become "oblivious to the fact these drugs cause manic and schizophrenic-like disorders." He cites a Canadian study in which a staggering nine per cent of children on this medication developed psychotic symptoms.

He argues that when children on ADHD medication become paranoid and have delusions they're diagnosed with schizophrenia or bipolar disorder. Rather than working them off the drug they are prescribed more drugs to treat these problems.

Dr. Colleen Clements, a psychiatrist at the University of Rochester, in Rochester, N.Y., writes in *The Medical Post* that ADHD is a disease with "dubious scientific merit". She worries that "long term psychoactive medication does not allow the developmental process to continue normally and children may be causally put in this illness category with the implied degrading of their normality and worth."

Adding to these concerns, Dr Nadine Lambert, a developmental psychiatrist at the University of California, reports that children on Ritalin are 3X more likely to develop a taste for cocaine.

So what should parents do when either their doctor or school suggests this medication?

I'd bet if these drugs had been available years ago they would not have been required in

the one-room schoolhouse. I'd also bet there was more discipline in those days when teachers were treated with more respect by parents and children.

As a teenager I had a habit of tapping my pencil on my desk. One day my teacher tossed me down the aisle, then across the room, and finally out the door. I never tapped my pencil again! Nor did I complain I had "rights". Or mention it to my parents. No one suggested Ritalin or medication. And I easily survived this encounter, and in fact the teacher became one of my favourites.

Remember that just because drugs are prescribed does not make them safe. And shouldn't we ask why 90 per cent of ADHD drugs manufactured in the world are used in Canada and the U.S? Isn't it strange that the rest of the world can manage children in the classroom without drugging them.

We should question how and why doctors make the diagnosis of ADHD. There's no test to do so. He may say the child fidgets. Or maybe taps his pen on the desk! But these annoyances are all a matter of degree, so where do you draw the line and start to drug a child?

Dr Breggin says that, "Many facts make a child behave in this manner such as a spirited nature that defies conformity, inconsistent discipline, boredom, oversized classrooms, overstressed teachers, anxiety due to abuse or home problems".

Dr. Laurence Diller, author of the book, "Running on Ritalin" writes, "We prefer to locate our children's problems in their brain rather than in their lives."

Surely it makes more sense to treat the cause, rather than expose children to powerful drugs with drastic side effects. Hell should freeze over before we allow this to happen.
canadafreepress.com

Drugs firm blocks cheap blindness cure

Company will only seek licence for medicine that costs 100 times more

Sarah Boseley, health editor
Saturday June 17, 2006
[The Guardian](http://TheGuardian)

An ophthalmologist prepares a patient's eye for surgery. Photograph: Al Behrman/AP

A major drug company is blocking access to a medicine that is cheaply and effectively saving thousands of people from going blind because it wants to launch a more expensive product on the market.

Ophthalmologists around the world, on their own initiative, are injecting tiny quantities of a colon cancer drug called Avastin into the eyes of patients with wet macular degeneration, a common condition of older age that can lead to severely impaired eyesight and blindness. They report remarkable success at very low cost because one phial can be split and used for dozens of patients.

[Article continues](#)

But Genentech, the company that invented Avastin, does not want it used in this way. Instead it is applying to license a fragment of Avastin, called Lucentis, which is packaged in the tiny quantities suitable for eyes at a higher cost. Speculation in the US suggests it could cost £1,000 per dose instead of less than £10. The company says Lucentis is specifically designed for eyes, with modifications over Avastin, and has been through 10 years of testing to prove it is safe.

Unless Avastin is approved in the UK by the National Institute for Clinical Excellence (Nice) it will not be universally available within the NHS. But because Genentech declines to apply for a licence for this use of Avastin, Nice cannot consider it. In spite of the growing drugs bill of the NHS, it will appraise, and probably approve, Lucentis next year.

Although Nice's role is to look at cost-effectiveness, it says it cannot appraise a drug and

pass it for use in the NHS unless the drug is referred to it by the Department of Health. The department says its hands are tied.

"The drug company hasn't applied for it to be licensed for this use. It wouldn't be referred to Nice until they have made the first move," said a Department of Health spokeswoman. "They need to step up and get a licence. If they are not getting it licensed, why aren't they?"

New drugs for the condition are badly needed: those we have now only slow the progression to blindness. With Avastin, many patients get their sight back with just one or two injections.

Avastin was first used on human eyes by Philip Rosenfeld, an ophthalmologist in the US, who was aware of animal studies carried out by Genentech that showed potential in eye conditions. This unlicensed use of Avastin has spread across continents entirely by word of mouth from one doctor to another. It has now been injected into 7,000 eyes, with considerable success.

Professor Rosenfeld has published his results and a website has been launched in the US to collate the experiences of doctors from around the world. But although the evidence is good, regulators require randomised controlled trials before they grant licences, which generally only the drug companies can afford to carry out.

Prof Rosenfeld said the real issue was drug company profits. "This truly is a wonder drug," he said. "This shows both how good they [the drug companies] are and on the flip side, how greedy they are." He would like to see governments fund clinical trials of drugs such as Avastin in the public interest.

Rising drug bills are a big problem on both sides of the Atlantic. In the UK, said David Wong, chairman of the scientific committee of the Royal College of Ophthalmologists, doctors are fighting battles to persuade primary care trusts to pay for drugs to stop their patients going blind while they wait for Nice to decide on Lucentis and another expensive drug called Macugen. That decision is not expected before the end of next year.

About 20,000 people are diagnosed with age-related macular degeneration in the UK each year. "From the patient's point of view, if they have an eye condition that deteriorates very quickly, there is no question of waiting," said Professor Wong. "We're talking about days and weeks, rather than months. The question is should we do nothing and say there is no randomised controlled trial to prove Avastin is of value?" He called for primary care trusts to agree to pay for the planned phasing-in of new drugs for the condition.

Last night Genentech said its main concern over the use of Avastin to treat eye conditions was patient safety. "While there are some small, single-centre, uncontrolled studies of Avastin being performed, safety data on patients who are treated with Avastin off-label is not being collected in a standard or organised fashion," said a spokeswoman for the

company.

Pharmaceutical firms say they need to launch drugs at high prices because of the hundreds of millions of pounds spent on developing them. Critics point out that the company's calculations also include the marketing budget.

BRIAN A. JOYCE

A shocking form of therapy

By Brian A. Joyce | June 19, 2006

FOR MANY, the term "electric shock" conjures up images of science fiction or horror films. In the movie "One Flew over the Cuckoo's Nest," men in sterile white coats held down terrified patients while affixing metal rods to their heads. Today, shock therapy and other controversial forms of so-called aversive therapy are used in centers across Southeastern Massachusetts on children with mental retardation and autism.

Aversive therapy is the deliberate and controlled induction of some form of physiological state of shock in an individual for the purpose of psychiatric treatment. Its controversial history began in the 1930s, when it was introduced as a possible means to "cure" people of homosexuality and schizophrenia, among other things. The idea was that by associating the patient's mind with an unpleasant stimulus (i.e. pain, nausea, or fear), the patient would be trained to discontinue activities that result in negative consequences.

That behavioral theory is applied to vulnerable children enrolled at the Judge Rotenberg Center -- a school in Canton serving students with conduct, behavior, emotional, and/or psychiatric problems and students with autism. The center operates 46 residences in Attleboro, Mansfield, Rehoboth, Norton, Randolph, Stoughton, Holbrook, and Canton.

To be fair, the objective and methodology is far different from the electric shock horrors depicted in the movies -- and some people swear it is the only effective treatment for those with certain behavioral and emotional problems. However the Judge Rotenberg Center has a troubled history. At least three students have died in its care under various circumstances and the Commonwealth has tried and failed several times to close it down.

Last week, the New York Board of Regents released a damning report following site visits to the center that documented "serious concern" over the school's use of aversive behavioral interventions. The report noted that the background and preparation of staff is not sufficient to oversee the treatment of children with challenging emotional and behavioral problems. It also noted that skin shocks are used for relatively minor behaviors, such as nagging and failing to keep a neat appearance, and were applied to individuals while they bathed or showered, which is inconsistent with FDA regulations.

The Rotenberg Center does not believe in the use of psychotropic drugs to control or regulate behavior. Instead, the school has used water squirts, pinching, spanking, "aromatic ammonia," mechanical restraints, and helmets with visual screens and white noise masks to punish what it considers to be undesirable behavior. In 1989, the center began using skin shocks as well. When the initial device used to deliver the shocks seemed to lose its effectiveness after the first few months, the school developed two new devices that allow instructors to shock more parts of the student's body with increasing voltages. These devices, which are worn constantly by some with mental retardation and autism, deliver shocks by remote control through small backpacks worn by students.

The Rotenberg Center is the only school in the United States known to use electric shock punishment, among other types of aversive therapy, as a means of diminishing violent or otherwise undesirable behaviors. Since the school's creation as the Brain Research Institute in 1971, both Rhode Island and California have withdrawn students and passed legislation banning aversive therapy. New Jersey has suspended any new referrals to the school. Yet Massachusetts is still permitting the center to operate and practice electroshock therapy on mentally disabled children.

I believe aversive therapy amounts to cruel and unusual punishment. We don't allow shock therapy on prisoners, and yet we condone this barbaric practice on children. I filed and helped pass an amendment to the Senate fiscal year 2007 budget that would ban aversive therapy in Massachusetts. The House should pass it also.

All mainstream state and national disability rights organizations oppose the use of painful aversives. The report issued by the New York Board of Regents found the center unsafe, and the board is poised to pull its students from the program. It's time for Massachusetts to do the same, and, more important, to ban aversive therapy.

State Senator Brian A. Joyce represents Norfolk, Bristol and Plymouth.

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Faulty diabetic tests put lives at risk

- 18:11 08 June 2006
- NewScientist.com news service
- Linda Geddes

People with type 1 diabetes are at risk of overdosing on insulin and even slipping into a diabetic coma because of faulty blood glucose meters.

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has warned that some "virtually pain free" meters, widely used by diabetics to check their own blood glucose levels, are giving readings that they may interpret as being far too high.

This could result in them overdosing on insulin while trying to get their blood glucose

under control, causing a sudden drop and, in extreme cases, diabetic coma.

The MHRA says it has received about 100 reports of the problem since February 2005. Most of these came from manufacturers of the meters, who have a legal obligation to inform the MHRA of problems, although some came from concerned diabetics who had noticed the meters malfunctioning.

In a small number of cases, meter users reported feeling unwell or slipped into a hypoglycaemic coma resulting in hospital admission, the MHRA said.

Symptoms of hypoglycaemia, or low blood glucose, include trembling, palpitations, weakness, sweating, intense hunger, drowsiness, confusion, unconsciousness and seizures.

Unit confusion

The problem with the affected meters occurs when the display changes from millimoles per litre (mmol/L) to milligrams per decilitre (mg/dL). This can happen automatically, or when the user accidentally changes the units while in setup mode, in some cases leading to blood glucose readings apparently 18 times as high as the true level of blood glucose.

An MHRA spokesperson said: “We are concerned that this change in unit of measurement could lead users to think that the blood glucose result is high and thus alter the treatment regime. This could lead to patients self-administering an insulin overdose.”

The blood glucose meters affected include FreeStyle and FreeStyle Mini (previously known as TheraSense); MediSense Optium Xceed, manufactured by Abbott Diabetes Care; and LifeScan OneTouch, LifeScan InDuo and LifeScan PocketScan, manufactured by LifeScan.

Both Abbott and LifeScan are recalling affected meters worldwide and have offered to replace them free of charge. A spokeswoman for Abbott told **New Scientist**: “We have had a handful of complaints from customers whose meter units have changed, but there have been no serious injuries in the UK.”

She said meter users should always check which units are displayed on their meters when taking blood glucose readings.

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Big Pharma versus Ontario government no contest Major climbdown on drug reform bill

Jun. 10, 2006. 01:00 AM

[THOMAS WALKOM](#)

No one should be surprised that the Ontario government has backed away from plans to make prescription drugs cheaper. The legal drug trade is big and profitable. By threatening these profits, Health Minister George Smitherman made enemies.

The only question facing Premier Dalton McGuinty's government now is whether it has backed away enough. Pharmacists who had been adamantly opposed appear to be on side, now that the government has agreed they can continue to receive kickbacks (renamed "professional allowances") from the manufacturers of generic, or copycat, drugs. But the most powerful elements of the drug industry, the multinational brand-name manufacturers, have not yet spoken on the government's change of heart. If they aren't satisfied, there will be pressure on Smitherman to humiliate himself further.

In April, when the government first revealed Bill 102, it figured it had this thing finessed. Pharmacists would have to give up kickbacks but would receive higher dispensing fees. Generic firms would face stiffer price controls, but potentially they'd get more market share, thanks to a government plan to give druggists greater scope in dispensing generics.

The biggest problem was always the brand-name industry, sometimes nicknamed Big Pharma. To appease it, Bill 102 would have made it easier for the multinationals to get new products listed with the province's Ontario Drug Benefit plan.

That plan, which subsidizes pharmaceuticals for seniors, welfare recipients and those suffering from certain kinds of catastrophic diseases, is the biggest purchaser of prescription drugs in the country. For manufacturers trying to introduce a new drug into the Canadian market, a listing with the Ontario plan is crucial.

The brand-name companies liked this component of Bill 102. But they were alarmed by others designed to save money.

Prescription drugs are the fastest-growing elements in Canadian health spending, affecting not only governments but individuals who pay out of pocket or through workplace insurance plans. To deal with this, Smitherman proposed a four-pronged attack.

First, he wanted the government to bargain with drug companies over price in an effort to win volume discounts. He also promised to enforce at the wholesale level existing price ceilings on drugs paid for by the province. Currently, many manufacturers charge more than the ceiling price, leaving pharmacists to pick up the difference.

The multinationals didn't like this at all, warning that if the government persisted, they might refuse to invest further in Ontario or even remove their existing processing plants.

In its climbdown this week, the government said it's giving up on plans to enforce price ceilings and, instead, will simply raise these ceilings to the levels already charged by manufacturers. But it still wants to bargain volume discounts.

Second, Bill 102 would have let druggists substitute cheaper generic equivalents for pricey, brand-name drugs in all cases (unless the prescribing doctors specifically objected). Currently, pharmacists are required to do this only for drugs purchased under the provincial plan, or under workplace plans that specifically demand such substitution.

Expanding the use of generics would have saved considerable money for all consumers. But the multinationals hated that, too, arguing that the government should postpone it until further study was done.

This week, the government agreed to do just that.

Third, the original Bill 102 would have given the government the right to expand the definition of generic equivalents to include drugs that, while not chemically identical, were in terms of their active ingredients "similar."

Big Pharma feared the government might use this to get out of paying for new drugs that, while more expensive, aren't any better than existing products. This kind of scheme, in use in British Columbia, is sometimes called therapeutic substitution.

This week, the government agreed to define "similar" more narrowly and ban therapeutic substitution explicitly.

Fourth, Bill 102 would have let bureaucrats make the final decision on which drugs to list with the provincial plan. This week, the government agreed to allow the bureaucracy's decisions to be appealed to an as-yet unspecified board that might include representatives of Big Pharma. It also bowed to the demand of the multinationals that drug policy be dealt with not just as a health issue but as part of an overall economic strategy aimed at promoting investment.

McGuinty government strengthens drug strategy was the headline on the news release announcing this week's climbdown. "Weakens" would have been a more accurate verb. We shall see whether Ontario's vested drug interests think this new version of Bill 102 is weak enough

Real-Life Epilogue To "Erin Brockovich": Medical Journal Retracts Fraudulent Chromium/Cancer Study

EWG Investigation Exposes Fakery of Firm Headed by Bush Appointee

(WASHINGTON, June 2) In a real-life epilogue to "Erin Brockovich," a peer-reviewed medical journal will retract a fraudulent article written and placed by a science-for-hire consulting firm whose CEO sits on a key federal toxics panel. The retraction follows a six-month internal review by the journal, prompted by an Environmental Working Group (EWG) investigation.

The July issue of the Journal of Occupational and Environmental Medicine (*JOEM*), the official publication of the American College of Occupational and Environmental Medicine, will carry a retraction of a 1997 article published under the byline of two Chinese scientists, JianDong Zhang and ShuKun Li.

The article appeared to be a reversal of an earlier study by Zhang that found a significant association between chromium pollution of drinking water and higher rates of stomach cancer in villages in rural northeast China. Since its publication, the fraudulent article has influenced a number of state and federal regulatory decisions on chromium.

"It has been brought to our attention that an article published in *JOEM* in the April 1997 issue by Zhang and Li failed to meet the journal's published editorial policy in effect at that time," says the retraction, written by *JOEM* Editor Dr. Paul Brandt-Rauf and obtained by EWG. "Specifically, financial and intellectual input to the paper by outside parties was not disclosed."

[In an email to the *JOEM* editorial board](#), Brandt-Rauf acknowledged that for legal reasons the retraction is "carefully worded and kept to the barest minimum of facts." But EWG's investigation, confirmed by a Wall Street Journal report in December 2005, found that Zhang and Li were not the actual authors of the article.

Under the state Public Records Act, EWG obtained and posted online documents from California regulators and court records that showed the article was actually the work of ChemRisk, a San Francisco-based consulting firm whose clients include corporations responsible for chromium pollution. The documents and the story they outline are at www.ewg.org.

"In order to ensure continued faith in the scientific process such serious breaches of ethics cannot be tolerated," EWG Senior Vice President Richard Wiles wrote to Brandt-Rauf in December. "The scientific community must be notified that a paper circulating in the published literature is fraudulent, the paper must be retracted, and those responsible for the incident must be appropriately disciplined."

ChemRisk's founder and CEO, Dennis Paustenbach, is a Bush Administration appointee to a U.S. Centers for Disease Control advisory panel on toxic chemicals and environmental health. His firm holds a lucrative contract with the CDC and the Energy Department to investigate radioactive and toxic releases from Los Alamos National Laboratory in New Mexico.

In this case, ChemRisk was working for Pacific Gas & Electric (PG&E), a San Francisco-based utility whose dumping of the industrial chemical chromium-6 had contaminated the drinking water of the small town of Hinkley, Calif. Hinkley residents' lawsuit against the company, which PG&E eventually paid \$333 million to settle, was the basis for the film "Erin Brockovich," starring Julia Roberts as the legal investigator who uncovered the dumping.

PG&E hired ChemRisk to conduct a study to counter Hinkley residents' claims of cancer and other illnesses from chromium-6 in their water. ChemRisk tracked down Zhang, a retired Chinese government health officer, and paid him about \$2,000 for his original data. ChemRisk distorted the data to hide the chromium-cancer link, then wrote, prepared and submitted their "clarification" to *JOEM* under Zhang and Li's byline, and over Zhang's written objection.

Zhang has since died. But *JOEM* located his co-author, ShuKun Li, who agreed that the article should be retracted.

Zhang's original work remains the only study of people ingesting chromium-6 in their drinking water. The *JOEM* article reversing its findings was cited by the U.S. Environmental Protection Agency in allowing continued use of chromium in a wood preservative, and by the Agency for Toxic Substances and Disease Registry in a report that discounted chromium-6 as an oral carcinogen.

Most significantly, the fraudulent article was cited by a scientific panel whose 2001 report forced California health officials to revise a recommendation for how much chromium-6 should be allowed in drinking water. A member of that panel was ChemRisk's Paustenbach, who has made a career out of consulting and testifying on behalf of major industrial polluters including PG&E, ExxonMobil and Dow Chemical.

Independent scientists blasted Paustenbach's 2002 appointment to the Board of Scientific Counselors for CDC's National Center for Environmental Health as part of a Bush Administration pattern of packing environmental panels with industry-friendly experts. EWG has provided CDC with documentation of ChemRisk's fraud in the Zhang case and demanded that Paustenbach be removed from his post when his term expires in June, but

CDC has refused to take action.

"It is abundantly clear that CDC's contractor, ChemRisk, does not have the necessary scientific or ethical integrity to engender public trust," EWG's Wiles wrote to CDC Director Julie Gerberding in March. "It is also clear that ChemRisk founder and president Dennis Paustenbach has been directly involved in the firm's unethical behavior."

EWG has earned a reputation as a watchdog of suspect science. When the group reported to the EPA a failure by DuPont to disclose internal company tests of drinking water and workers for a toxic chemical used to make Teflon, the government sued the company and in 2005 extracted the largest administrative settlement in history for such offenses.

In 2000, EWG caught ABC News' John Stossel reporting nonexistent test results in an "investigation" critical of organic food that was broadcast on the network's 20/20 magazine program. The disclosure forced a rare on-air retraction and apology from Stossel.

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Donations tie drug firms and nonprofits

Many patient groups reveal few, if any, details on relationships with pharmaceutical donors.

By Thomas Ginsberg

Inquirer Staff Writer

The American Diabetes Association, a leading patient health group, privately enlisted an Eli Lilly & Co. executive to chart its growth strategy and write its slogan.

The National Alliance on Mental Illness, an outspoken patient advocate, lobbies for treatment programs that also benefit its drug-company donors.

The National Gaucher Foundation, a supporter of people suffering from a horrific rare disease, gets nearly all its revenue from one drugmaker, Genzyme Corp.

Although patients seldom know it, many patient groups and drug companies maintain close, multimillion-dollar relationships while disclosing limited or no details about the ties.

At a time when people are making more of their own health-care decisions, such coziness raises questions about the impartiality of groups that patients trust for unbiased information. It also poses a challenge for groups trying to hold patients' trust and still raise money to serve them.

An Inquirer examination of six groups, each a leading advocate for patients in a disease area, found that the groups rarely disclose such ties when commenting or lobbying about donors' drugs. They also tend to be slower to publicize treatment problems than breakthroughs. And few openly questioned drug prices.

At the same time, the groups perform an important function by providing services unavailable elsewhere, such as patient education and help in obtaining medications or affording insurance.

They also try to police themselves. For example, each declares it does not endorse or reject products. All formally require that industry grants be "unrestricted," meaning that there are no strings attached. One of them, Children & Adults with Attention Deficit/Hyperactivity Disorder, or CHADD, formally caps pharmaceutical donations.

Combined, the six received at least \$29 million from drug companies last year, according to tax returns and annual reports. The amount ranged from 2 percent to 7 percent of revenue at the Arthritis Foundation, to 89 percent to 91 percent at the much smaller National Gaucher Foundation.

Some health-care experts, although applauding the groups' work, are calling for greater disclosure. And many patients expressed surprise at the ties.

"I don't think that would make a difference as far as taking a drug," said Gloria Antonucci, 65, leader of a Montgomery County pain-support group that relies on Arthritis Foundation advice. "But I think it would make me, maybe, 250 percent more skeptical about what the group is saying."

Jerome Kassirer, a Tufts University and Yale University medical school professor and author of *On the Take: How Medicine's Complicity With Big Business Can Endanger Your Health*, said better disclosure would guard against abuse.

"These organizations are susceptible to industry influence because they have trouble raising money themselves," Kassirer said.

But not all nonprofits are alike, said Marc Boutin, executive vice president of the National Health Council, a standard-setting coalition funded by nonprofits and drug

companies. He said leading nonprofits with "fire walls" against donor influence were worlds apart from questionable organizations.

"We are controlled by volunteers who are living with a condition and the drugs they take, and I guarantee these people would not be influenced by a donor," Boutin said.

Matter of credibility

For drug companies, patient groups carry credibility that the industry sometimes lacks to target patients and "opinion leaders" who drive prescriptions, and hence, sales. Nonprofits also help patients stay on the medicine and push insurers to pay for it.

"Does it help us? Sure," said Matthew Emmens, Wayne-based chief executive officer of Shire PLC, the No. 1 ADHD drugmaker and a major donor to CHADD.

"In the industry, we feel we're doing a pretty good thing while making money, which is even better," said Norm Smith, president of Langhorne-based Viewpoint Consulting Inc. and veteran marketer for Merck & Co. Inc., Johnson & Johnson and others.

The donations are sometimes portrayed by the companies and nonprofits as "giving back" to patients. But the funding usually comes from the companies' marketing or sales divisions, not charity offices, company and nonprofit officials said. Grants often rise with promotional spending as a drug hits the market and fall when sales ebb.

Donations from Merck and Pfizer Inc. to the Arthritis Foundation more than doubled, to at least \$1.65 million combined, in 2000 as they launched Vioxx and Celebrex. The donations fell below \$375,000 by 2004, when safety fears had flattened sales, foundation reports show.

Merck explicitly wove the foundation into sales strategies. A 2001 internal memo, disclosed in product-liability trials, shows that Merck sought to use the foundation's pain-management program to "demonstrate additional benefits" of its products.

Foundation president John Klippel said he was unaware of Merck's plan. But he dismissed it as an example of mutual interests in treatment, not profits. "We envision that as an educational program," he said. "Their marketing folks envision it as marketing."

When interests diverge, however, groups must be ready to face donor pressure. Michael J. Fitzpatrick, president of the National Alliance on Mental Illness, or NAMI, said one donor recently demanded that, in return for funding a TV public-service announcement, the ad include the company's direct contact information. Fitzpatrick said NAMI refused.

The industry also benefits in Washington and state capitals, where nonprofits lobby for issues such as expanded Medicaid drug coverage or treatment programs. That can boost sales.

All six groups are active lobbyists. NAMI, for example, urges and helps states and localities to create special one-on-one "assertive" treatment programs, which include making patients take their medicine.

It acknowledged that drug-company donors may benefit but insisted that's not the goal. "Nobody from the pharmaceutical industry tells us what to do," NAMI president Fitzpatrick said.

Unusual corporate gift

In 2000-2001, the American Diabetes Association did not disclose an unusual gift from Lilly: a lent executive, Emerson "Randy" Hall Jr., who moved into its Alexandria, Va., headquarters and coached it on growth strategies, all paid by Lilly.

Vaneeda Bennett, the ADA vice president for development, denied that the gift compromised the group but conceded that it might look bad. "We always walk a fine line on showing favoritism to one company or another. I would imagine other corporate donors would look askance at it," Bennett said, adding that, if it were offered again, "we'd ask for money."

Hall, a Philadelphia native now retired and living in Princeton, said he never tried to influence the group and merely helped it market itself, including writing its slogan, "Cure. Care. Commitment." He estimated that his work, including diabetes patient research he subsequently shared with Lilly, would have cost "hundreds of thousands" from a contractor.

Asked why it did not cite Hall on its tax returns or annual report, ADA spokeswoman Diane Tuncer said: "There is not a requirement to do so."

Nonprofit experts laud such executive "loans," as long as groups disclose them and limit their authority.

Another group, NAMI, did not disclose that Lilly marketing manager Gerald Radke briefly ran its entire operation. Radke began in 1999 as a Lilly-paid "management consultant," then left Lilly and served as NAMI's paid "interim executive director" until mid-2001. The group acknowledged this only after being shown Radke's resume listing the job.

NAMI's president, Fitzpatrick, said he did not know why his predecessors did not disclose Radke's work. He said using Radke "was a reasonable move to try to increase capacity."

"But there is a perception issue," he said. "So that makes it, in hindsight, a difficult choice."

Radke, of Harrisburg, declined to comment. After NAMI, he ran the Pennsylvania Office

of Mental Health and Substance Abuse, and now serves in the state Health Department.

Indianapolis-based Lilly, which donated at least \$2.5 million to the ADA and \$3 million to NAMI between 2003 and 2005, called its executive loans mutually beneficial. "The primary goal is to assist that organization in developing a needed capacity or function, but it also often serves to assist in the career development of the employee," a Lilly spokesman, Edward G. Sagebiel, said.

Avoiding favoritism

Drug marketers battle hardest over safety and effectiveness, and nonprofits say they strive to avoid favoring one product over another. The six appeared to be cautious on safety scares and rarely took the lead sounding drug-safety alerts, even as they highlighted news of drug breakthroughs and approvals they say members demand, their materials show.

"We don't position ourselves as a watchdog," said Bennett of the ADA.

The ADA, which received 5 percent to 10 percent of its revenue last year from drug companies, reported little initially in 2004 about suspected diabetes risks from antidepressants. Instead, Tuncer, its spokeswoman, said it convened an expert conference - funded by drug companies - and ended up echoing the concerns.

The Arthritis Foundation, which received 2 percent to 7 percent from drug companies, said little in 2000 about early studies raising questions about Vioxx. But when follow-up studies confirmed the concerns in 2001 and 2002, the group highlighted the problems and called for more safety research. A year later, Merck cut off all donations.

Patrick Davish, a Merck spokesman, denied any link between the donation cutoff and criticism, calling it just a "change in funding priorities."

Klippel, the group's president, said he doubted there was a link but said it would not matter anyway. "It's not to say they've not been unhappy with us from time to time," he said. "But it would not influence me."

The ADHD group, while calling itself a science-based information clearinghouse, has not published some critical information about ADHD drugs, including an FDA warning last September about suicide risk from Strattera, made by one of its biggest donors, Lilly.

Its chief executive, E. Clarke Ross, said the group's professional advisory board took time to review all information before posting it. Although the group is an outspoken proponent of ADHD drugs, he said, it has strict fire walls against corporate influence. Indeed, it was alone among the six in publishing an easy-to-find figure on pharmaceutical donations: 22 percent last year, or \$1.01 million.

"We have a number of conflict-of-interest practices that meet industry standards," he

said.

NAMI, like most groups, lists only FDA-confirmed side effects and typically refers people with any questions to the drugmaker.

One outspoken NAMI critic, David Oaks of the support group MindFreedom, described the group as an independent but willing pawn of industry.

"We're not saying there is some conspiracy in a skyscraper by a pharmaceutical executive rubbing his hands together," Oaks said. "It's that the entire paradigm is owned by the drug companies, and that the hazards of the drugs, like brain damage, are not discussed."

NAMI's Fitzpatrick defended its information, but acknowledged that groups were facing demands for fuller drug information. "I think we should be much more like Consumer Reports. We should have transparency on both side effects and benefits," he said.

Close ties on orphan drugs

Ties between drug marketers and patient groups appear closest on so-called orphan diseases, which involve relatively few patients, experts and drugmakers. Financial disclosures by two groups show they used most of the deductible donations to pay the medical bills and insurance premiums of patients using donors' products. That, in effect, spreads around costs while leaving pharmaceutical prices unchanged.

The National Organization for Rare Disorders, a Connecticut-based coalition that tries to spur development of orphan drugs, got \$10.5 million - 68 percent of its revenue - from drug companies last year. It helps pay patients' premiums and bills, administers companies' free-drug programs and helps recruit patients for their clinical trials.

Founder Abbey S. Meyers said that donors did not shape her group's positions and noted that the industry needed the groups as much as they needed it: "I criticize them [donors] all the time. It has never come back to hurt us."

The Gaucher group, according to tax returns, received \$1.77 million of its \$2 million in revenue last year from Boston-based Genzyme, and spent \$1.69 million on medical bills and insurance premiums of patients taking Genzyme's enzyme therapy Cerezyme, which cost insurers as much as \$350,000 a year.

In contrast, the foundation took nothing from Actelion Pharmaceuticals US Inc., of San Francisco, maker of a second-line treatment, Zavesca, to be used when Cerezyme doesn't work. Actelion said the foundation rejected its no-strings grants and gave little or only critical Zavesca information.

"I don't want to say anything nefarious is going on. But it doesn't pass scrutiny," said Actelion's president, Shal Jacobovitz. He portrayed the foundation "almost as a commercial arm" of Genzyme.

Ronda P. Buyers, executive director, denied that the group is biased toward Genzyme. "We're two different organizations. We do get its money, which allows us to do what we do," she said.

Another company, Shire Human Genetic Therapies, formerly Transkaryotic Therapies Inc., which is developing an alternative to Cerezyme, also called the foundation unusually close with Genzyme, even though it had accepted Shire's small donations.

Genzyme "is aggressive, and it's all part of their marketing plan to have a dominant position," said Matt Cabrey, a Shire spokesman in Wayne.

David Meeker, president of Genzyme's lysosomal business unit, said Genzyme had no control over the foundation. He acknowledged that the group was so important for Cerezyme marketing that if it didn't exist, Genzyme would have looked for another.

"This is how we built our business," said Meeker, whose company took in \$932 million last year from Cerezyme, high for an orphan drug. "It's also building a community where patients can get the help they need. It's the ultimate win-win."

Buyers, who did not respond to repeated follow-up calls after an initial interview, said:

"We cannot make them bring the price down. They do make a lot. But without the drug, there would be all these people who would be in such horrible positions. More people would die."

[NEJM Waited Five Years To Report Vioxx Study Data](#)

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