#### DIGITAL NEWSBOOK



More than 80,000 chemicals are on the market in the United States, with hundreds added each year. The Environmental Protection Agency and other regulators are supposed to protect the public from contaminants in air, water and consumer products that can cause cancer and other illnesses. But the chemical industry's sway over science and policy is powerful. Toxic Clout explores how the industry's actions create uncertainty and delay, threatening public health.



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Go online for more on this topic including videos, interactive graphics, supporting documents and related stories at: www.publicintegrity.org/environment/pollution/toxic-clout

### **About the Project**

N Toxic Clout, the Center for Public Integrity unmasked the deep, sometimes hidden, connections entangling the chemical industry, scientists and regulators, revealing the industry's sway and the public's peril.

The series, born of a year of reporting, took Center journalists from Washington, D.C., to the state capital of Connecticut, the research triangle in North Carolina, an aging blue-collar plant in Niagara Falls, N.Y., the academic hub of Berkeley, California, and beyond. These ground-level reports revealed the consequences of industry power and government inaction in a world of chemical safety relying largely on an honor system.

Our reporting prompted tangible reform. In May, following a Center investigation revealing how the Environmental Protection Agency was unaware of potential conflicts of interest on its own cancer review panels,



Part of this investigation was produced in partnership with the PBS NewsHour. The images at right link to videos produced by PBS.



#### Video: Science for Sale

In part one of a two-part series, PBS News-Hour Science Correspondent Miles O'Brien travels to Hinkley, Calif. — the town whose multi-million dollar settlement for ground-water contamination was featured in the movie *Erin Brockovich*. Now, almost 30 years later, O'Brien explores the reasons why the ground-water in Hinkley still has dangerous levels of the chemical chromium and its link to cancer.



#### Video: Decision Delayed on Dangerous Chemical in Drinking Water

In part two, Miles O'Brien talks to scientists, members of the chemical industry and representatives from Pacific Gas and Electric about chromium-6 contamination in American drinking water.

the EPA adopted tighter rules regulating conflicts. "Increasing transparency will lead to stronger science," an EPA executive said, announcing the changes.

That reporting was one piece of a body of work exploring the power of industry and the deepseated, sometimes conflicting ties of scientists expected to help safeguard the public from dangerous chemicals.

Toxic Clout informed the public about how and why toxic chemicals continue to imperil them amid the red tape of government and escalating power of industry. The reports not only led to immediate changes in EPA conflict rules, they may help trigger lasting reform.

#### A Center Environmental Team Investigation

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The Center for Public Integrity was founded in 1989 by Charles Lewis. We are one of the country's oldest and largest nonpartisan, nonprofit investigative news organizations. Our mission: To enhance democracy by revealing abuses of power, corruption and betrayal of trust by powerful public and private institutions, using the tools of investigative journalism.

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A Pacific Gas & Electric pipeline operations station is seen in Hinkley, Calif., in the Mojave Desert northeast of Los Angeles. Reed Saxon/AP

## EPA unaware of industry ties on cancer review panel

By David Heath and Ronnie Greene Published Online: February 13, 2013

N SEPTEMBER 2010, scientists at the Environmental Protection Agency came to a startling conclusion: Even a small amount of a chemical compound commonly found in tap water may cause cancer.

The compound, hexavalent chromium, gained infamy in the Oscar-

winning film *Erin Brockovich*, based on the David-vs.-Goliath legal duel between desert dwellers in Hinkley, Calif., and Pacific Gas & Electric Co. The film ends in Hollywood fashion, with the corporate polluter paying \$333 million to people suffering from illnesses.

But in real life, the drama continues. More than 70 million Americans drink traces of chromium every day, according to the Environmental Working Group, a nonprofit research organization.

And now, more than a decade after the film, EPA scientists cite "clear evidence" that the chemical compound, also known as chromium (VI), can cause cancer. The federal agency was poised to announce its findings in 2011, a step almost certain to trigger stricter drinkingwater standards to prevent new cancers and deaths.

The chemical industry's trade association and chief lobbyist, the American Chemistry Council, urged the EPA to wait for more research, a common practice to delay action on toxic chemicals. However, Vincent Cogliano, the soft-spoken head of EPA's chemical-assessment program, rebuffed the powerful group, writing in an April 2011 letter that "strong" new research was already available.

Ten months later, the EPA reversed itself, quietly posting a notice on the Internet that it was pushing back the release of its findings for at least four more years. Environmentalists were stunned at the reason: The agency would wait for the re-

## **Key Findings**

- In 2011, the Environmental Protection Agency was poised to cite evidence of cancer risks in hexavalent chromium, a chemical compound found in tap water likely presaging stricter drinking water standards.
- Yet a special EPA panel urged the agency to delay action — citing, among other issues, pending research by the American Chemistry Council, a trade association. The EPA agreed to put off action.
- Three of the EPA panelists urging delay had worked on behalf of PG&E, a California power company accused of polluting waters with hexavalent chromium, The Center for Public Integrity found.
- The EPA panelists were selected by a private company under contract with the agency. Under its own rules, the EPA does not see conflict of interest forms filed by prospective panelists — potentially leaving it in the dark.
- As she leaves office, EPA Administrator Lisa Jackson is pushing new rules to allow more public input on panelists for the agency's peer review committees.

sults of new studies costing \$4 million and paid for by the American Chemistry Council.

The EPA decided to wait at the urging of a panel of scientists chosen to give an unbiased review of the chromium findings. But the EPA doesn't vet these scientists directly, instead handing the task over to outside contractors. An investigation by the Center for Public Integrity found that several of the panelists had worked on behalf of PG&E to defend the company in the Brockovich lawsuits.

President Obama pledged during his 2008 campaign to halt meddling and interference in government science. The president put restoring integrity to science on his short list of priorities in his first inaugural address, right after fixing the economy and before health care reform. "We'll restore science to its rightful place," he said.

The story of chromium (VI), full of twists and turns, offers a case study in how the Obama administration has failed to shield science at the EPA from industry influence.

Companies with a stake in chromium have borrowed from the Big Tobacco playbook, using science to create doubt. Ever since the brassy Brockovich knocked on doors in Hinkley to organize a class-action

lawsuit, scientists paid by industry have tried to convince the courts and regulators that chromium (VI) poses no health risk.

Some of those scientists ended up on the panel chosen to review the EPA's chromium findings, the Center for Public Integrity found:

- Three of the five panelists who urged delay had worked on industry's behalf in the Hinkley court cases.
- One of those scientists was retained by PG&E in the company's ongoing chromium cleanup in Hinkley at the same time he was serving on the EPA panel.
- Another scientist who urged the EPA to wait for the American Chemistry Council studies served as a consultant on those studies.

"You don't have to be a rocket scientist to realize that this is corrupt and unacceptable," contends Rena Steinzor, a law professor at the University of Maryland and president of the Center for Progressive Reform, a think tank that recently published a report on the chemical industry's influence.

Those members served on the EPA's toxic-chemical-assessment program, the Integrated Risk Information System. IRIS, as it is known, is

the pure science upon which clean air and water rules are based. But IRIS has become a major bottleneck, delaying new federal and state air and water standards amid industry influence and other factors. Critics say the EPA has only itself to blame.

Since October, EPA Administrator Lisa Jackson has declined interview requests to discuss IRIS or loopholes that open the door for potential conflicts of interest. Yet Jackson is pushing reform before she leaves office this week that would



Law professor Rena Steinzor, an expert at corporate interference in government science, said industry hogties scientists at the EPA with a flood of last-minute research as a way of escaping new regulation.

PBS Newshour

address some of the conflicts unearthed in the Center's review, and cited by environmental activists.

And recently the EPA decided to move up its timetable to complete its chromium assessment to later this year.

#### Case study of industry's muscle

The issue of scientists with industry ties serving on special EPA peer review panels goes beyond chromium. One out of every six scientists appointed to such panels since Obama took office had been a primary author of research articles funded by the American Chemistry Council over the past dozen years.

In all, 11 of the 68 members appointed to EPA panels assessing chemical health hazards were significant authors on studies funded by the ACC, a review of the council's research database reveals. That number does not capture all scientists backed by industry, just those with work funded by the ACC. The authors of the hexavalent chromium studies, for example, are not included.

One scientist who has served on several EPA panels and co-written more than a dozen ACC-funded studies said that working with industry does not necessarily suggest a conflict.

"Scientists by and large want to get at the truth, so this really becomes more a matter of a perception of a problem than a real problem, in my opinion," said Frederick J. Miller, an independent consultant who once worked at the Hamner Institutes for Health Sciences, a North Carolina research institute formed in the 1970s by leaders from 11 major chemical companies.

"The people that serve on these panels ... know if somebody is trying to make an argument that doesn't hold water," said Miller, who began his career in government.

However, studies have shown that when industry pays for research, it may influence the outcome. A 1998 analysis of more than 100 articles published on secondhand smoke reported that 37 percent found no health risk. At least 74 percent of the articles exonerating cigarette smoke were written by scientists with ties to the tobacco industry.

The American Chemistry Council has a stake in the outcome of research. Lobby disclosure forms from 2011 reveal that the ACC lobbied the EPA on its assessments of three highly controversial chemicals: dioxin, formaldehyde and chromium (VI).



David Fischer, a senior director at the American Chemistry Council, defended the trade association's funding of research on toxic chemicals. PBS Newshour

The group boasts on its Web site that "in 2012, we helped defeat or amend 281 chemical regulation and product ban proposals."

The ACC, whose members such as ExxonMobil, Dow Chemical, Merck and Procter & Gamble are a who's who of the Fortune 500, is one of the freest-spending lobby groups on Capitol Hill. In 2011, it laid out \$12.6 million on lobbying, four times the amount spent by the National Rifle Association.

David Fischer, a senior director at the ACC, defended the group's research program. "We feel we have an obligation to step up and fund studies to assist the agency — whether it's EPA or others — to answer questions that might be posed about chemicals that we manufacture," he said.

Asked if any of the ACC's studies had ever shown that a chemical was more toxic than previously thought, Fischer replied, "I'm not aware of one right at this moment."

The ACC said it was not involved in selecting the peer reviewers studying chromium (VI). "EPA's peer reviewers were selected by EPA. They were vetted in the normal peer review process from EPA and we from the ACC do not have any direct links to these people," said Ann Mason, the ACC scientist who commissioned the group's new studies on chromium.

However, few scientists in the world specialize in chromium, a compound used to add color to paints, make stainless steel, add finish to chrome and inhibit rust. During its lawsuits, PG&E hired several of these scientists as expert witnesses; some say the debate over the compound's toxicity caused lasting splits in the tight-knit scientific world.

One of PG&E's key experts was Steven Patierno, a former professor of pharmacology at the George Washington University School of Medicine and Health Sciences who had conducted numerous studies on the metal. Patierno, now the deputy director of the Duke Cancer Institute, has been an expert defense witness in seven chromium lawsuits. He hasn't wavered in his view that drinking low doses of chromium (VI) does not cause cancer.

By early 2011, Patierno was selected for the peer review panel critiquing the EPA's chromium (VI) findings. At a public meeting on May 12, 2011, he revealed a potential conflict of interest. There's no recording or transcript of the meeting. Nothing in the EPA's public record reveals the conflict. Two EPA officials who were there say they cannot recall what Patierno said. Patierno himself declined requests for an interview.

Jennifer Sass, a senior scientist at the nonprofit Natural Resources Defense Council, took notes at the meeting and said that Patierno revealed he was an investigator — though not a principal investigator — on the American Chemistry Council studies.

The ACC's Mason disputes that Patierno was involved. But Travis O'Brien, one of the principal investigators on the studies and a former colleague of Patierno's at George Washington University, told the Center for Public Integrity that Patierno was a consultant on the research.

Max Costa, now a professor at New York University's medical school, knows Patierno well. When Costa taught at the University of Texas Medical School, Patierno worked in his laboratory. The two published research together. Costa said they became rivals when they took opposite sides in the PG&E lawsuit.

He argues that Patierno's opinions are not credible because he works for the chrome industry. "He's been a paid a large amount of money by them, and he's totally biased because of that."

Patierno levels the same charge against Costa, attacking his conclusions in a lawsuit as "unsubstantiated" and "severely flawed." Patierno criticized the EPA for even citing Costa's papers among hundreds of others in its report. In his peer review comments, Patierno said two of Costa's articles should not be taken seriously because "they were written and published at a time when the senior author was actively engaged as an expert witness for the plaintiffs in high-profile hexavalent chromium lawsuits."

Patierno was an expert witness for PG&E in the same lawsuits. When

he was asked in a 2006 lawsuit if he discloses his expert-witness work for industry when submitting articles on chromium (VI), he answered no. Patierno said his articles were based on laboratory studies that were not relevant to his legal work.

Costa was originally listed as a candidate for the EPA peer review panel, according to documents obtained by the Center through a Freedom of Information Act (FOIA) request. Costa says he disclosed his work in the PG&E lawsuit but doesn't know if that work disqualified him. An EPA official said privately said that Costa's work as an expert witness may have kept him off the panel.

#### **Industry ties and EPA panel**

Patierno was not the only defense litigation expert who served on the EPA's IRIS panel. Two others were John P. Wise Sr., a toxicology professor at the University of Southern Maine, and Joshua Hamilton, a chief academic and scientific officer at the Marine Biological Laboratory in Woods Hole, Mass., which is affiliated with Brown University.

Wise, who worked in Patierno's laboratory as a graduate student, said that in 1997 he worked for a



John P. Wise Sr. shows PBS NewsHour correspondent Miles O'Brien his Portland, Maine, laboratory where he studies hexavalent chromium. PBS Newshour

consulting firm and was assigned to do research for an industry client in the Hinkley lawsuit — but that he has not accepted industry money in the past 15 years. Wise added that he was never told the identity of the client and that he does not believe "such limited contact so long ago" influenced his opinion.

Hamilton was a defense expert in a PG&E chromium lawsuit that settled in 2006 and worked for the company as a consultant again starting in 2009, according to PG&E. PG&E acknowledged that it hired Hamilton in May 2011 — the same month the EPA panel met — to consult on the ongoing chromium cleanup in Hinkley. PG&E said it paid him \$110,000.

Hamilton appeared before a California Regional Water Quality Control Board on June 8, 2011, to speak on behalf of PG&E about its cleanup of Hinkley. The EPA peer review panel issued its final comments one month later, on July 6, 2011.

Hamilton's consulting work in-

cluded criticism of the California EPA's own scientific assessment of chromium (VI), which was nearly identical to the EPA's.

In an eight-page statement to the water board dated July 9, 2011, Hamilton wrote that the state agency's findings did not represent "established science." He described California's regulations as "overly protective."

The PG&E director in charge of the Hinkley cleanup, Sheryl Bilbrey, said Hamilton's work should not have affected his objectivity. "PG&E expects all of our experts to give us unbiased advice," she said. "So we would never ask anyone to change their scientific opinion to fit something that we would want."

Asked whether it was appropriate for an EPA peer reviewer to be working simultaneously for PG&E, the ACC's Fischer said, "That sounds like a conflict of interest to me. Generally, the way you get around it is you just — you don't appoint that particular scientist to that particular panel."

It was not the first time Hamilton had been paid a substantial sum by PG&E. In 2001, Hamilton said he was surprised to get a \$100,000 check in the mail before doing any work as an expert witness. Accord-

ing to his deposition, Hamilton talked to PG&E's lawyers about the check and learned that it was on top of his hourly fee. PG&E ultimately paid Hamilton nearly \$300,000 for his work on the lawsuit.

(Hamilton has since disclosed that he repaid the \$100,000; see editor's note on page 19.)

"That's completely outrageous," said Francesca Grifo, director of scientific integrity at the nonprofit Union of Concerned Scientists. "I don't know how anybody could stand up logically and say I got \$100,000 but it didn't affect how I handled this."

Hamilton declined interview requests.

## EPA farms screening to consultants

Working for a chemical company appears to violate the EPA's guidelines on conflicts of interest. The EPA's Peer Review Handbook says peer reviewers should appear to be impartial, defined as not having anything that "may cause a reasonable person with knowledge of the relevant facts to question the expert's ability to carry out official duties without bias or influence."

The handbook offers, as an ex-

ample of a conflict, a scientist paid to be an expert witness for a chemical company in a class-action lawsuit.

Yet, the EPA doesn't ask scientists if they've worked as expert witnesses or have taken money from industry. Instead, it turns that job over to private companies, which handle conflict-of-interest reviews in secret. All of the information the vendors collect, including financial disclosure forms, is "considered private and non-disclosable to EPA or outside entities except as required by law," the EPA policy says.

The contractor examines candidates' published work, and prospective panelists fill out a questionnaire detailing potential conflicts. Once the panel is picked, the contractor certifies to the EPA that "no unresolved actual or potential conflict of interest issues" remain.

What's more, the ethics guidelines are not binding on contractors, and the EPA handbook says the agency should not override decisions on conflicts of interest. "EPA should not attempt to make any changes in the contractor's conclusions as this would compromise the independence of the peer review conducted by the contractor," the handbook says.

The EPA said it set the system up

this way to ensure impartiality. But, the Center found, this structure helps shield the very conflicts the agency aims to avoid.

A year ago, the Center sought information on the screening of IRIS panelists through a FOIA request. The EPA withheld most documents, including emails between the vendors and agency.

Officials at Eastern Research Group Inc., the Massachusetts firm that vetted the peer reviewers on the chromium (VI) panel, did not return emails and phone calls. An official at another company handling peer reviews, Versar Inc., said he was prohibited by EPA from talking.

The EPA's administrator, Jackson, and its chemical-assessment officials declined requests for onthe-record interviews. But an EPA official acknowledged privately that the agency was not fully aware of the chromium (VI) peer reviewers' ties to PG&E. The official defended the use of private vendors, contending that if the EPA chose peer reviewers, it could pick scientists it knew would be friendly.

However, the EPA routinely selects scientists for other advisory panels. Critics said it's not clear how checking financial disclosure forms would taint the process. The Peer

Review Handbook does note that checking disclosure forms would activate the Federal Advisory Committee Act, a law meant to make panels more open.

"It's bizarre," Grifo said of the EPA's secretive screening process. "At its core it's supposed to increase the public trust in the system. If it looks like the whole system is rigged to begin with, then why should a citizen trust it?"

The EPA said it was working to reduce the potential for conflicts. "We are exploring the best ways to provide for public review of contractmanaged peer review panels and ensure that contractors are held accountable for their assessment of any conflicts of interest," the agency said in a statement.

#### The 'pure science' bottleneck

Some 700 new chemicals hit the market each year, adding to the tens of thousands already in use. Yet the EPA has assessed only 557 chemicals since the IRIS program began in 1985. A typical review takes six to eight years, sometimes much longer. It took 27 years for the agency to issue a partial assessment of dioxin, a byproduct of plastics manufacturing and burning.

The Government Accountability Office (GAO) concluded in 2008 that the IRIS program was so bogged down that it was in danger of becoming obsolete.

In 2009, EPA Administrator Jackson made bold promises within her first weeks in office to fix the program. She pledged to finish many more assessments and to try to complete each one within two years. Since May 2009, the EPA said it completed 24 IRIS assessments, "double the number" completed in the same time period prior to May 2009.

Yet its overall progress remains slow, and in the past two years, the program produced as few assessments as ever. Last year, the EPA planned to complete 40 assessments. It finished three.

The reasons for the logjam are complex. But it has become common for industry and its allies inside the federal government to push for delay. "Even a single delay can have far-reaching, time-consuming consequences, in some cases requiring that the assessment process essentially start over," the GAO reported.

In the case of chromium (VI), evidence shows that industry worked closely with the EPA as the agency conducted its assessment. On Oct. 8, 2009, a scientist at a law firm rep-

resenting chemical companies complained in an email that the EPA was pushing ahead on its assessments without waiting for studies to address "gaps" in the science.

"EPA moved Chrom VI up by about two years after 'we' entered into a process of planning research with them to address gaps," wrote Richard Canady, a former scientist at the White House's Office of Management and Budget (OMB), who was then working at the private law firm of McKenna, Long & Aldridge. "I'd like to make a case for EPA planning ahead in cooperation with industry."

Canady's email was sent to Nancy Beck, a toxicologist at OMB who reviewed the EPA's findings. Beck referred Canady to an American Chemistry Council official for help in gathering data. A 2009 investigation by a subcommittee of the House Science and Technology Committee criticized Beck for improperly interfering with IRIS assessments during the George W. Bush administration. Beck now works for the ACC. She did not return a call last week seeking comment; an ACC spokesman said Tuesday he would seek her perspective.

In a recent interview, Canady said he could not recall the precise details from his email and declined to reveal clients for which he was working. But Canady said he thought the process of planning research with the EPA "wasn't that formal." Instead, industry scientists would call EPA scientists to find out what new data would help them in their chromium (VI) assessment, he said.

His 2009 email also said, "Peter made a point to me the other day about how boron and methylene chloride were good examples of working together on developing data ahead of assessments in ways that influenced the outcome."

Canady said this was a reference to Peter Preuss, then the director of the EPA's National Center for Environmental Assessment, which oversees IRIS.

The EPA originally planned to issue its chromium (VI) assessment last summer, giving the ACC time to finish its new studies. However, under Jackson's imperative to quicken assessments, the EPA moved up its timeline by six to nine months.

When the EPA's Cogliano rebuffed the ACC's request for a delay, the trade association turned its attention to the peer review panel.

Critics say the industry uses comments on chemicals that are under review to overwhelm the agency.

"There's a very elaborate process

that involves multiple opportunities for industry to pick away and blast away and confuse and overload the staff of IRIS, and the IRIS staff reacts by trying to address each and every one of industry's concerns," said law professor Steinzor.

"The chemical industry has made IRIS its leading target, one of its leading targets, for spoil in the current age of greed," Steinzor said

Of the 49 public comments submitted to the EPA on chromium before the peer-review panel met, the American Chemistry Council and its research partners authored 29 of them, totaling 1,661 pages. In addition, 10 other comments totaling 137 pages came from industry urging the EPA to wait for the ACC studies.

As the EPA stood poised to announce potential new safeguards for chromium (VI), the ACC had hired a scientific consulting firm, ToxStrategies, to manage the \$4 million studies of mice and rats given the chemical for 90 days.

The panel met May 12, 2011, at a Hilton hotel near Reagan National Airport. Patierno was highly critical of the EPA's findings and suggested the agency "absolutely consider the extensive new data being provided." Hamilton and Wise agreed.

In a recent interview, Wise said

he wasn't entirely familiar with Tox-Strategies' findings, which hadn't yet been published. But he assumed the delay would be short, only a few months. The EPA initially said the delay would take four years. Later, the agency said the assessment would be done this year.

Anatoly Zhitkovich, a professor at Brown University who chaired the EPA peer review panel, was upset with the results and wrote his own review published in the journal *Chemical Research in Toxicology*, according to Costa, a close colleague. Zhitkovich declined an interview request, but his article supported the findings of the EPA.

In lobbying for delay, the American Chemistry Council quietly enlisted the help of a small office within the U.S. Small Business Administration.

SBA Chief Counsel for Advocacy Winslow Sargeant, an electrical engineer by training, submitted a comment to the EPA on Oct. 5, 2011, challenging its scientific conclusions and urging it to delay its chromium assessment pending completion of the ACC studies. Winslow cited the peer review comments from Hamilton and Wise to support his argument.

But emails obtained through FOIA by the advocacy group Center for Effective Government revealed that the ACC helped shape the SBA letter. An ACC lobbyist, Randy Schumacher, sent an email to Sargeant's office on June 28, 2011, asking for its help.

"Administrator Jackson calling upon her to stop the Cr6 risk assessment process to do exactly as EPA's peer reviewers deemed advisable," Schumacher wrote. "Since it appears EPA needs to hear from more constituents for it to listen to its own peer review team, would SBA be willing to send a letter to Ms. Jackson to weigh in on this matter?"

Later emails from Schumacher suggested editing changes to Sargeant's letter. The SBA official has not responded to interview requests.

## Frustration prompts push for reform

Now the EPA is in the process of revamping its IRIS program once more. Cogliano has proposed releasing the names of prospective peer reviewers in advance, giving the public an opportunity to explore conflicts. "This will improve transparency in the peer review process," the EPA said in a statement. The changes could be formally announced this week, as Jackson departs.

The ACC's Fischer says he's in favor of a conflict-of-interest policy that allows industry to participate on peer review panels. "Bias in and of itself should not necessarily disqualify a particular scientist from serving on the panel," he said. "Industry perspective is a bias but so [is] every other perspective."

The EPA is also weighing whether to set "stopping points" for new research, a deadline after which no additional studies would be considered. Kenneth Olden, a senior EPA official who oversees IRIS, has proposed announcing assessments two years in advance, giving industry time to complete new studies.

Such proposals drew criticism at an EPA meeting in November, with an environmental group's scientist stating bluntly that industry seeks delays because it wants IRIS to fail. His comments drew faint gasps from a conference room filled almost entirely with industry consultants.

"The practice of waiting for one more study to be completed, as has happened repeatedly under IRIS — especially when that study is to be conducted by an entity with a vested financial interest in tilting the outcome — simply must stop," said the scientist, Richard Denison, with the nonprofit Environmental

Defense Fund. "Simply put, a decision delayed is health protection denied."

This story has been clarified to reflect that, as an employee of a consulting firm, John P. Wise Sr. worked for an industry client in the PG&E lawsuit but that he was never told the identity of the client. After the story was published, Joshua Hamilton provided proof that he repaid a \$100,000 check from PG&E more than three years after

he received it. Hamilton now says he was confused about the July 2001 check at the time he was deposed in August 2002. A 2001 letter he provided from PG&E that came with the check says it was prompted by the company's Chapter 11 reorganization and was meant as "security for additional work you may be asked to perform on this matter." The letter says that Hamilton could keep the full amount of the check until his final invoice, but he was expected to repay the \$100,000 when his work was done.

#### SIDEBAR

# Ouster of scientist from EPA panel shows industry clout

By Ronnie Greene and David Heath
Published Online: February 13, 2013

N 2007, when Deborah Rice was appointed chair of an Environmental Protection Agency panel assessing the safety levels of flame retardants, she arrived as a respected Maine toxicologist with no ties to industry.

Yet the EPA removed Rice from the panel after an intense push by the American Chemistry Council (ACC), an industry lobbying group that accused her of bias. Her supposed conflict of interest? She had publicly raised questions about the safety of a flame retardant under EPA review.

Rice's travails through the EPA's Integrated Risk Information System, or IRIS, program reveal the flip side of industry's sway. Not only

does the ACC back many scientists named to IRIS panels, it also has the power to help remove ones it doesn't favor.

The ruckus over the Maine scientist surfaced six years ago, but its lesson echoes today.

To Rice, her removal points up an irony borne out by a Center for Public Integrity investigation: Scientists with deep ties to industry are

allowed to continue on IRIS panels. But she with no financial link to industry — was booted.

"It wasn't like I was a consultant, saying this stuff is really bad because someone is paying me to do it. I was the toxicologist working for the state of Maine asked by my department to do these reviews," she said. "That



**Deborah Rice** 

was the basis on which they said I was in conflict."

Another irony: Rice's assessment was on target. Two years later, the EPA moved to cease production of decaBDE, a chemical it views as a possible carcinogen. In Maine, Rice's research had supported a state ban on the chemical.

Rice was with the Maine Center for Disease Control and Prevention when she was appointed to the EPA panel convened to study the safety of brominated flame retardants used in products ranging from building materials to electronics and plastics. The panel was tasked to assess the safe reference doses of four forms of polybrominated diphenyl ethers (PBDEs) — including decaBDE, which Rice had studied for several years in Maine.

A former EPA toxicologist, Rice had been honored by the agency in 2004 for outstanding scientific work.

Her undoing came after she made public comments about a compound that was under EPA review.

Before her appointment to the IRIS panel, Rice, like other members, was asked whether she had taken public positions on the chemicals being studied. She answered "No" — but reported that in 2004 and 2005, as a toxicologist for the Maine CDC, she had written a review of the health effects of PBDEs.

With the IRIS panel due to convene Feb. 22, 2007, members were asked on Feb. 16 if any of their information had changed. "No changes," Rice reported.

A day earlier in Maine, Rice had testified before the Legislature supporting a ban of decaBDE. "Deborah Rice with the Maine CDC's Environmental and Occupational Health Program told lawmakers there is no question in her mind that deca should be eliminated because it is a persistent toxin that accumulates in the food chain," the Bangor Daily News reported.

The ACC seized on those public statements and, in May 2007, dispatched a 10-page letter to the EPA urging that she be stricken from the panel. The chemistry council cited "certain information that has come to light that could suggest the potential for bias exists on the part of the Peer Review Chairperson."

The ACC cited her comments in Maine and in articles she had written. "Thus, EPA staff had to know *or should have known* that the Chairperson has been a fervent advocate of banning deca-BDE — the very sort of policy predisposition that has no place in an independent, objective peer review," wrote an ACC vice president.

Rice's inclusion on the panel, the ACC said, "ultimately calls into question the overall integrity of the entire IRIS database."

An EPA official met with the ACC that June. In the end, the agency sided with industry, concluding that Rice's statements created a "perception of bias." Reviewers found, however, that her comments did not influence others — "because her comments were echoed by the other panelists."

In August 2007, the EPA deleted Rice's comments from its website.

A day later, an IRIS official called Rice to tell her the news.

The EPA site today says: "The final report includes only four of the five reviewers' comments. One reviewer's comments were excluded from the report and were not considered by EPA due to the perception of a potential conflict of interest."

Rice had already completed her IRIS service when the EPA took its action. She said she was simply reporting her findings as a toxicologist and had no conflict. "All of a sudden my comments disappeared as if I had never been part of this panel," she said.

Rice wonders whether industry targeted her as part of a larger plan to discredit attempts to ban deca. At the time, several states were raising concerns over the retardant's safety. The EPA itself had raised concerns — ones so significant that in late 2009 the agency and several chemical companies agreed to phase out its production.

"I think the motivation just has been to discredit me personally," Rice surmised. "To say, 'She's biased, she has a conflict, she's discredited. These other states shouldn't pay attention to what Maine has done.' And it seemed to me they saw a good opportunity to do this."

The ACC said it sought Rice's removal to ensure the peer review was independent.

Her ouster triggered a dustup. Groups ranging from the Environmental Working Group to the Center for Science in the Public Interest chastised the EPA for removing Rice while, in other cases, keeping panelists with ties to industry. "The actions taken by EPA against Dr. Rice call into question the credibility of EPA management," the groups wrote in 2008, urging the EPA to reinstate Rice as panel chair. "When it allows itself to serve the interests of the polluting industries that it is charged with regulating, it has perverted its mission."

Rep. John Dingell, D-Mich., then-chairman of the Energy and Commerce Committee, pressed the chemistry council to explain why panelists with industry ties "have not been targeted by the ACC as also having conflicts of interest that would disqualify them from serving on EPA panels."

The EPA's Office of Inspector General investigated, and found no

wrongdoing in the agency's actions. "We conclude that EPA did not violate existing federal law, regulations, guidance or other relevant requirements in its actions," an IG official wrote in January 2009.

Still, the removal of Rice shone a light on the system — for a time. The EPA "kind of promised to clean things up," said Rice, who recently retired. "Once the spotlight shifts to something else, it's business as usual."

#### **FOLLOW-UP**

# EPA adds safeguards to spotlight conflicts on scientific panels

By David Heath and Ronnie Greene

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HE Environmental Protection Agency announced new safeguards Friday to prevent conflicts of interest or bias from tainting its science, including efforts to assess the dangers of toxic chemicals.

The reforms, targeting scientific review panels selected for EPA by outside contractors, follow a Center for Public Integrity-PBS News-Hour examination revealing ties between scientists and industry on a panel reviewing hexavalent chromium, a compound commonly found in drinking water that may cause cancer.

In that case, three panelists who urged the EPA to delay potentially stricter drinking water standards had been expert witnesses for industry in hexavalent chromium litigation. The scientists denied any conflict and said their input was based on research, but the case study revealed how the EPA is unaware of potential conflicts on its own panels.

Under its own process, the Center reported, the agency turns over the job of selecting panelists to private companies, which handle conflict-of-interest reviews in secret. All information the vendors collect, including financial disclosure forms, is "considered private and nondisclosable to EPA or outside entities except as required by law," the EPA policy says.

The changes announced Friday add more layers of review — and provide more public disclosure — to the process.

Environmental watchdogs, who had questioned EPA's existing process, say the steps are overdue.

"It brings transparency to a process that wasn't there before," said Francesca Grifo, a senior policy fellow and expert on scientific integrity at the Union of Concerned Scientists.

One key change: After an EPA-hired contractor selects members of a scientific review panel, "the contractor will consult with EPA to review whether the contractor followed existing conflicts of interest guidance and requirements, and identify and provide input on any issues."

That step adds an extra layer of review by EPA.

Also, the agency said, the names of chosen panelists will be publicly posted before any meetings take place.

The new steps do not change EPA's existing standards for assessing conflicts, the agency said, but instead add sunshine to the process.

"This process will ensure that existing conflicts of interest guidance and requirements are applied correctly and where a potential conflict of interest is identified, allow EPA to determine whether the contractor's plan to address the conflict is acceptable," the agency said.

The EPA's acting administrator, Bob Perciasepe, said Friday the new steps show the agency is "committed to scientific integrity."

"Improving the contract-managed peer review process and increasing transparency will lead to stronger science at the agency," Perciasepe said in a statement.

Richard Denison, a senior scientist at the Environmental Defense Fund, has been outspoken about industry influence at the EPA. Denison praised the EPA for bringing more openness to the process.

"The hexavalent chromium example was the major impetus for this revision," he said.

Hexavalent chromium, best known as the toxic chemical compound from the hit film Erin Brockovich, is found in the drinking water of more than 70 million Americans, according to the Environmental Working Group.

New animal studies published in 2008 showed that mice and rats given high doses of the compound developed large numbers of tumors. The National Toxicology Program, part of the National Institutes of Health, cited the compound as a "clear carcinogen."

The EPA planned to revise its assessment of the compound in 2011, even as a trade group, the American Chemistry Council, urged the agency to wait for industry funded studies. Several members of the peer review panel also urged the EPA to wait.

One was Steven Patierno, then a scientist at George Washington University, who was a consultant on ACC studies.

Another was Joshua Hamilton, a scientist at the Marine Biological Laboratory in Woods Hole, Mass., which is affiliated with Brown University. Pacific Gas & Electric Co., the company that polluted the water in Hinkley, Calif., with chromium, hired Hamilton as a consultant in 2009.

Hamilton said that just before the EPA peer-review panel met, PG&E asked him if he would go back to Hinkley to discuss the health effects of hexavalent chromium. PG&E said it paid Hamilton \$110,000 for his work in Hinkley. Hamilton said he revealed the PG&E work to the private contractor hired by EPA, Eastern Research Group, and that the firm concluded it was not a conflict.

Officials with Eastern Research Group, based in Massachusetts, have not responded to interview requests.

Meanwhile, some members of Congress are pushing potential change to support industry. The House science committee recently approved a bill to change the rules at the EPA for setting up scientific advisory panels. It would prevent the EPA from excluding people from panels with industry ties, as long as those ties are disclosed. It would also exclude panelists whose research is incorporated in the assessment. The bill is awaiting action by the full House.

# Lauded public health researcher also worked for industry, revealing entanglements of science

By David Heath
Published Online: December 20, 2013

BERKELEY, Calif. — At a memorial service held last month in her favorite classroom, Patricia Buffler was hailed as a champion of children.

While dean of the School of Public Health at the University of California, Berkeley, Buffler started the nation's largest program researching the causes of childhood leukemia. She expanded her study of this rare disease after stepping down as dean in 1998, continuing the work until she died unexpectedly in late September at the age of 75.

Buffler's research, backed by more than \$35 million in federal grants, could save lives. Her team concluded that sending your child to daycare might reduce the risk of getting leukemia, perhaps by bolstering the immune system. It found strong



Patricia Buffler was a highly esteemed public-health scientist and former dean of the University of California, Berkeley, School of Public Health. She also worked extensively for the chemical industry. Jim Block/UC Berkeley News Center

evidence suggesting that preschoolers should stay away from wet paint. One of her graduate students at the memorial was struck by something Buffler once said: "Children are fragile, so it is our role to protect them."

Yet now some of her peers are torn to learn that, in the past three years, Buffler was paid more than \$360,000 to work as an expert witness on behalf of companies that used to sell lead-based paint. Ten California communities, including the county where Buffler lived, this week won a \$1.1 billion judgment against the companies. The money will be used to remove lead paint from older homes. Even minute amounts of lead in a child's blood can cause permanent brain damage.

According to a court filing, Buffler concluded — to the astonishment of other experts — that lead-based paint in older homes poses little risk to children. The judge rejected that argument in his written decision.

"She may be an expert in some areas but lead poisoning in children is definitely not one of them," said Dr. Bruce Lanphear, a professor at Simon Fraser University in Canada and lead author of widely cited studies on the effects of lead poisoning on children.

Lanphear, who testified against the paint companies, considered Buffler's views so indefensible that, days before she died, he talked to fellow directors of the International Society for Children's Health and the Environment about removing her from the group, of which she was a founding member.

Buffler was one of the nation's most revered and influential public health scientists. But researchers familiar with her chemical industry consulting question whether she bent to the wishes of her corporate sponsors — a criticism she denied when questioned in lawsuits.

Her dual career arc — as public health researcher and consultant for private industry — opens a window into the deeply entrenched influence of the chemical industry on academics.

College campuses have embraced collaborating with industry for research as a way to produce innovative products and cure disease. But in public health, influential academics are often sought instead to defend potentially toxic chemicals.

While the Food and Drug Administration treats new drugs as unsafe until clinical trials prove otherwise, the Environmental Protection Agency does just the op-

Even as Buffler led research into whether pesticides and herbicides may cause leukemia, she served for 17 years on the board of directors of a \$3 billion pesticide and herbicide company, FMC Corp.

posite with chemicals: By law, it presumes a chemical is safe unless scientific evidence shows otherwise. The burden of determining whether a chemical is harmful or deadly falls largely on academic scientists such as Buffler.

Working for industry can be lucrative for researchers, but can also pose conflicts. Even as Buffler led research into whether pesticides and herbicides may cause leukemia, she served for 17 years on the board of directors of a \$3 billion pesticide and herbicide company, FMC Corp.

In 2010, FMC paid Buffler nearly \$200,000 in cash and stock. Securities and Exchange Commission records show that when she sold the stock the company gave her, mostly in 2010, Buffler made more than \$2 million.

A review of public records shows that in publishing her results in scientific journals or in applying for government funding from the National Institutes of Health, Buffler did not disclose that she owned stock in FMC or served as one of its directors.

UC Berkeley officials knew that Buffler served on FMC's board, said Graham Fleming, the school's vice chancellor for research. But he said that until federal rules changed recently, it was up to researchers to decide whether their financial ties posed a conflict. The university limited its own review to potential conflicts the researchers disclosed before forwarding the grant application to the NIH.

Fleming wasn't willing to say whether Buffler serving on the board of FMC posed a conflict.

"We have no way to know," he said. "She herself must have determined that there was none. And given her record of integrity throughout her career, I would say that the default would be to accept that as the appropriate judgment."

Since 1995, the NIH has approved more than \$28 million for Buffler's research, money that went directly to UC Berkeley. The NIH wouldn't comment on whether Buffler violated its rules.

Yet Hugh Tilson, the executive editor of NIH's Environmental Health Perspectives, which published some of Buffler's pesticide research, said the journal is now reviewing whether she violated its disclosure rules.

Sheldon Krimsky, a Tufts University professor and an expert in conflicts of interest in scientific research, said after reviewing Buffler's case. "This is the worst case of conflict of interest I've seen in years."

Sen. Charles Grassley, R-Iowa, pushed for recent changes at NIH, requiring more financial disclosure and lowering the standard for a conflict of interest. But after recently reviewing documents on Buffler, he said more changes are needed.

"It appears NIH doesn't have a means of auditing or enforcing the rules," Grassley said. "Research institutions that look the other way on conflicts of interest appear free to do so knowing NIH will take them at their word."

The recent changes in the NIH rules stemmed from concerns

about the integrity of taxpayerfunded science. Studies show, for example, that researchers making money from drug companies publish scientific articles more favorable to those companies than do independent researchers. In 2007, more than half of life sciences faculty at the top 50 research universities reported financial connections to industry.

Yet scant data exist on the influence of industry money on public health.

"There are lots of people who are working as academics who are making lots of money from industry," said Jennifer Sass, a senior scientist at the Natural Resources Defense Council, an environmental group. "A lot of the research that the industry funds is made to muddy the waters. It's designed specifically to create uncertainties."

Stanford University historian Robert Proctor draws parallels between chemical manufacturers today and the tobacco industry in years past, which he says quietly paid thousands of academics to influence the science.

"There's a long history of academic corruption, of people becoming very heavily involved with industry: testifying, writing expert reports and becoming directors and not disclosing this. Their colleagues don't know about it, and they are able to zoom under the radar," Proctor said. "It's not just a conflict of interest. It's worse than that"

#### An activist at Berkeley

Buffler earned her master's degree in public health at UC Berkeley and became a teaching assistant there during the 1960s, an era when the school became an icon of liberal activism.

Some of that activist spirit may have rubbed off on her. Her son, Martyn Buffler, recalled at her memorial service that when he was a child, his mother fought successfully to stop construction of an oil terminal in their hometown of Galveston, Texas, because it endangered shrimp in the Gulf of Mexico.

In 2004, Buffler published an article with colleague Paul Brennan reporting that nonsmokers can get cancer from secondhand smoke. One night, Brennan recalled, Buffler dragged him to a Berkeley theater to pass out leaflets because it was accepting money from the tobacco industry. Buffler wanted people to know this.

Buffler is remembered by many for criticizing the FDA for delays in requiring warning labels on aspirin bottles. Giving aspirin to children is linked to Reye's syndrome, a disease that can be deadly.

In 1992, Buffler coauthored an article calculating that 1,470 children died because, at industry's urging, the FDA delayed the warning-label rule. Drug companies argued that the science linking aspirin to Reye's syndrome was weak.

Buffler rejected that argument, telling The New York Times, "The Reagan administration and the Bush administration have been marked by a commitment to deregulation. When it occurs in an area where it has a health impact, the consequences are profound — profoundly adverse."

Devra Lee Davis, who coauthored the article while working at the National Academy of Sciences, called Buffler's stance "courageous."

Davis and Buffler were friends as well as colleagues. It wasn't until after Buffler died of a stroke that Davis realized how much work her friend had done for industry. She didn't know that by the time they worked together in 1992, Buffler already had a long history of consulting for companies, including Dow

Chemical, DuPont, Union Carbide, Shell Oil, Goodyear and Atlantic Richfield.

## Leukemia focus, and industry work, in Woburn, Mass.

Buffler said her interest in leukemia stemmed in part from her work in 1984 in Woburn, Mass., site of a toxic tort case made famous by the best-selling book and hit film, *A Civil Action*.

Twenty children in this Boston suburb of 37,000 were diagnosed with leukemia between 1964 and 1983 — twice the normal rate. Six of the children lived within a few blocks of one another, a cancer cluster highly unlikely to be a coincidence.

Tests showed that two of the wells supplying water for the town were heavily polluted with several chemicals, including trichloroethylene, commonly known as TCE. Eight families sued, alleging that industry contaminated the wells. In 1986, a jury cleared Beatrice Foods of wrongdoing. W.R. Grace later settled with the families for \$8 million. A third company, UniFirst, had settled out of court for slightly over \$1 million.

Years later, Buffler reminisced about her work in Woburn, saying that there was never proof that the chemicals caused the cancers. "The people of Woburn won eventually; yet, we could not answer their questions," she said.

Her remarks intrigued Harvard statistician Marvin Zelen, who had conducted a study, with two colleagues, showing a statistical association between the polluted water and leukemia.

Buffler never participated in the Woburn study. Instead, she and three other academics were hired by the chemical industry to critique the findings of Harvard researchers Zelen, Barbara Wessen and Stephen Lagakos.



Harvard researcher Marvin Zelen said Patricia Buffler was paid by industry to critique his study of a childhood leukemia cluster in Woburn, Mass. Courtesy of American University

Buffler's work was sponsored by the American Industrial Health Council, whose board was composed of chemical company executives, including a senior executive of W.R. Grace. Her committee concluded that while the Harvard study was "sophisticated," its results couldn't be trusted because the people who volunteered to help collect information for a telephone survey were biased.

About half of the 235 unpaid volunteers lived in Woburn, where there had been ample news coverage of the lawsuit. The volunteers called Woburn residents to collect medical information about fetal deaths, birth defects and childhood diseases. Ultimately, they got information from nearly 60 percent of the town's homes.

Figuring out how much polluted water each household drank became a complicated task for the researchers. Water from the polluted wells was blended with other well water and piped into houses throughout Woburn, but not in equal amounts. The Harvard researchers were able to calculate the amount each household consumed and compare it to the medical data.

The numbers were striking. They showed significantly higher rates of some types of birth defects as well as deaths of fetuses and newborns. There was also a statistical link between children with leukemia and the polluted water.

The industry panel led by Buffler, then a professor at the University of Texas Health Science Center at Houston, cast doubt on the medical data collected, given that Woburn residents might be tempted to blame their diseases on industrial pollution. The "potential for reporting biases is alarmingly high," the review committee said.

Zelen didn't know about Buffler's report until a year later, with an interviewer from a PBS show shared it with him. Zelen said it was full of factual errors.

For example, the review speculated that the volunteers might know who they were calling. But Zelen said they were assigned random phone numbers and trained not to ask for names. The review also speculated that the volunteers could guess where people lived from the telephone number. Zelen said that was impossible.

The data collected on birth defects was verified with doctors' records, Zelen said. What's more, the data showed that once the two wells were shut down, the higher rates of birth defects disappeared.

The Harvard researchers sent a letter to Buffler and other panelists, but said they never got a response. They did hear back from the journalist at PBS. He said that after Buffler received their letter, she changed her mind about being interviewed for the program.

Since then, similar studies in Toms River, N.J., and Camp Lejeune, N.C., have found links between water polluted with TCE and leukemia.

## From Clinton Superfund panel to pesticide board member

A few years later, Buffler left Houston to become dean at the UC Berkeley School of Public Health, one of the most prominent jobs in her field. Within her first two years, she was elected president of two professional associations as well as a member of the National Academy of Sciences and the Institute of Medicine.

She was also selected to serve on a panel during the Clinton administration to recommend reforms to the Superfund law. The law was intended to require businesses to clean up old industrial waste sites, but big businesses complained it went after deep pockets unfairly, and environmentalists complained it was too ponderous.

It was on this panel, in December

1992, that Buffler met Robert Burt, the chairman and chief executive officer of FMC. Burt and Buffler represented opposing interests on the panel. Burt was also a director of the Chemical Manufacturers Association, the chemical industry's chief lobby group. He asked Buffler to serve on his company's board.

"Mr. Burt convinced me that the company really was committed to doing the very best — doing the right thing in terms of the environment and occupational health and safety and needed that kind of independent voice on their board of directors," Buffler explained in a court deposition in 2007.

"I was very outspoken during the deliberations of the Superfund commission, and apparently that did not alarm him as a CEO of a specialty chemical company. ... After quite a prolonged due diligence, I became very comfortable with the — what was being requested," Buffler said.

In 1994, Buffler joined a board with several political heavyweights, including former Gov. James Thompson of Illinois, Clayton Yeutter, former chairman of the Republican National Committee, and Jean A. Francois-Poncet, former Minister of Foreign Affairs in France. All four were appointed to a committee to



The Justice Department levied a \$11.9 million penalty against FMC Corp. for illegally dumping phosphorus into an open pond near a plant on an Indian reservation in Pocatello, Idaho. Phosphorus spontaneously ignites when exposed to air, causing fires by the pond and spewing poisoning gases. Buffler joined the board of directors of FMC in 1994, shortly after an EPA inspection found the illegal dumping.

review FMC's dealings with government as well as its environmental efforts. Buffler would eventually chair that committee.

Buffler's objectivity is beyond question, FMC said in a statement to the Center for Public Integrity.

"Dr. Buffler was nominated to the FMC Board of Directors due to her expertise in health and environmental issues," the company said. "She served as chairperson of our board's Public Policy Committee and supported the eventual evolution of that committee to a new Sustainability Committee that focuses primarily on sustainability and health, safety and environmental matters."

In 1996, Buffler was appointed to an EPA panel to advise the agency

of scientific matters related to pesticides.

FMC at the time was facing scrutiny from the EPA and the Justice Department. In 1993, the EPA inspected FMC's phosphorus plant in Pocatello, Idaho, and found the company was illegally dumping phosphorus residue into an open pond.

When exposed to air, phosphorus spontaneously ignites. The plant had a history of fires along the banks of its pond. Phosphine gas is also poisonous, which authorities reported may have caused the deaths of migratory birds attracted to the pond. In 1998, the Justice Department reached a settlement with FMC to cap the pond and fined FMC almost \$11.9 million, which at the time was the largest penalty ever imposed under the Resource Conservation and Recovery Act. Since then, FMC has been named as potentially liable for 28 other Superfund sites.

A year after joining the board, Buffler launched her leukemia research program at Berkeley, a collaboration with five institutions focused on leukemia cases in the Bay Area. "These projects cover a wide range of Superfund related areas and chemicals," the grant application begins. In 1999, she expanded to other parts of California and strengthened

the focus on children's exposure to household chemicals and pesticides.

In 2002, Buffler co-authored an article in Environmental Health Perspectives showing a link between household pesticides and leukemia. The article explicitly reported no link to agricultural pesticides or herbicides, the products sold by FMC. At the time, Buffler was on the editorial board of the journal.

The lead author of that study, Xiaomei Ma, now an associate professor at Yale University, said she doesn't believe Buffler's ties to FMC had an impact on the study's findings. Ma said she had high regard for Buffler's integrity and was offended anyone would question it.

A later study, published by Buffler and her team in 2009, showed a possible link between some pesticides used on farms and childhood leukemia, including a class of pesticides known as organophosphates. FMC's Web site shows that two of its 15 brands of pesticides fall into this class.

The article said, however, that children exposed to the highest levels of organophosphates did not show higher rates of leukemia.

A year earlier, Buffler co-authored a review funded by Dow AgroSciences that was favorable to organophosphates. Several studies, including some done by Buffler's colleagues at the UC Berkeley School of Public Health, had already linked exposure of organophosphates in fetuses to problems with mental development. But in her review, Buffler challenged those findings.

FMC said organophosphates account for "a very minor part of our crop protection portfolio. ... These two premix products, while important to help farmers combat crop destroying insects, account for less than 1 percent of our Agricultural Solutions sales in the United States."

During her career, Buffler co-authored 15 articles in scientific journals paid for by companies or industry groups that asked her to evaluate chemical and other risks. In one article, her findings were unfavorable to her sponsor. In 1990, she and others found an unusually high number of colon cancers among workers at General Motors who made early vehicle prototypes. In three articles, the results were mixed. And in 11 articles. her findings were favorable to her sponsors, a Center for Public Integrity analysis found.

The favorable findings included studies on the herbicides paraquat and Agent Orange.

Buffler also served as an expert witness in toxic tort lawsuits. When asked in depositions, she could not recall ever testifying against indus-

Buffler was criticized in a 2004 law review article for views the article equated with giving chemicals the same presumption as criminal defendants: nontoxic unless proven toxic beyond a reasonable doubt. "The expert's assertions represent a view of the scientific method which came under strenuous attack long ago, and a view of statistical testing that was rejected even earlier," wrote Sander Greenland, a former professor at UCLA, and co-author of a textbook on epidemiology.

For her legal work, Buffler charged \$600 an hour.

She and her husband split time between homes in Berkeley and a house they built in the mountains of Santa Fe, N.M. Property records show they also owned a house in Austin, Texas, where a relative lived, and four timeshares. She routinely used a limousine service to get around, according to her deposition testimony in the lead-paint lawsuit.

She was also one of UC Berkeley's largest donors, giving the school \$245,000.

Buffler volunteered to help in-

dustry groups challenging scientists who published studies unfavorable to the chemical industry or who testified against chemical companies. She served as an advisor to the industry-funded American Council on Science and Health. And she put her name on legal briefs generated by the Atlantic Legal Foundation.

Some of Buffler's pro-industry testimony came in cases in which plaintiffs said toxins were sickening or killing them.

#### An asbestos case in Maryland

Struggling to catch her breath, Joan Dixon drove 35 miles to a Morgantown, W.Va., emergency room. There, in March 2008, she learned that her left lung was soaked in fluid. The doctor revealed that she had a rare form of lung cancer, one Dixon had never heard of: mesothelioma.

There is no cure. The doctor said there was only one known cause exposure to asbestos.

Starting in the late 1960s, Dixon's husband Bernard spent three or four nights a week in a friend's garage fixing brakes for neighbors. The Dixons lived in Friendsville, Md., a speck of a town of 142 families a few miles from the borders of Pennsylvania and West Virginia. Dixon charged \$10 or

\$20 for his brake jobs. Sometimes he accepted a six-pack of beer instead.

The job was dirty. Dixon would spray the exposed brake with an air gun, sending clouds of dust particles into the air and onto his clothes. The dust was full of asbestos. Sometimes Joan would help. Other times she was the one who threw her husband's dirty clothes into the wash.

Joan was adamant about suing Ford Motor Co. for warning employees and dealers — but not others — about the dangers of asbestos in its brakes. She died in February 2009, before her case went to trial. Her husband said he was against taking action at first, thinking it futile and mostly for the benefit of attorneys. But he promised his wife he would carry out her wish.

At the end of a trial in April 2010, a Baltimore jury sided with the Dixons with a \$15 million verdict. The court reduced it to \$6 million.

Buffler became involved on appeal. She and 12 other scientists, including two Nobel laureates, signed a "friend of the court" brief. It was filed by the Atlantic Legal Foundation, a nonprofit whose board includes current and former executives of companies grappling with their own asbestos lawsuits.

The foundation said in one report

that it has a "deep commitment to redressing the bias against business which manifests itself in favor of narrow consumer or environmental concerns." When asked during the 2007 deposition if she agreed with that goal, Buffler said, "My understanding in the role that I play is — trying to find the right way to express it. Best way I can express it in terms of my understanding and the role that I play is advancing the role of science in litigation."

Buffler said she would receive briefs from the Atlantic Legal Foundation, review them, edit them and, if she agreed, sign them. She did this in several asbestos cases as well as others, but said she didn't get paid. FMC, on whose board she served, has over the years faced nearly 100,000 asbestos claims, the company reports in recent financial statements.

In the Dixon case, the "friend of the court" brief signed by Buffler argued that the testimony of the family's scientific expert, Dr. Laura Welch, shouldn't have been allowed because it was "unacceptable" sci-



Joan Dixon of Friendsville, Md., died from a rare lung cancer linked to asbestos. She sued Ford Motor Co., because for years she washed her husband Bernard's dusty clothes after he fixed brakes full of asbestos. After a Baltimore jury awarded the Dixon family \$6 million, Patricia Buffler and others filed a legal brief on appeal arguing it was highly unlikely anyone could get cancer from brakes. Maryland's highest court disagreed.

ence. Welch is the medical director of the Center to Protect Workers' Rights in Silver Spring, Md.

There are no studies proving that people get mesothelioma from doing brake work, let alone that wives of brake mechanics are at risk, the brief said. It added that Welch "ignored the overwhelming evidence that chrysotile asbestos, the type used in automobile brakes and that Mr. Dixon and Mrs. Dixon were exposed to, has far less, and maybe nil, potential to cause mesothelioma than other types of asbestos."

In June 2012, the Maryland Court of Special Appeals threw out the jury's verdict. Citing the brief's argument that Welch never quantified how much asbestos Dixon was exposed to, the court said Welch couldn't know if it was enough to cause the cancer.

In an earlier lawsuit, Welch filed her own "friend of the court" brief responding to Buffler's arguments, signed by 51 scientists. She quoted a U.S. Public Health Service report citing "general agreement among scientists and health agencies" that chrysotile asbestos can cause mesothelioma. In addition, "there is sufficient evidence in humans for the carcinogenicity of all forms of asbestos," says the latest report of the World Health Organization's International Agency for Research on Cancer.

In July, Maryland's highest court reversed the appeals court ruling, saying it has been established in previous cases that chrysotile asbestos can cause cancer. The court also ruled that Welch had quantified Dixon's exposure.

Bernard Dixon said he never understood why Buffler got involved in the case.

## Expert witness in lead-paint lawsuit

Several of Buffler's friends and acquaintances say they were most surprised by her work as an expert witness in the lead-paint lawsuit.

Ten miles south of the Berkeley campus, Tamara Moore lives with her three children on the second floor of a cramped three-room duplex more than a century old. A single mother, she can barely afford the \$1,700-a-month rent.

When they moved in, the dull teal paint outside on the windows and stairs was peeling badly, especially in the backyard. It's a common problem in Alameda County, where 80 percent of homes still have lead paint.

When she applied for welfare, Moore was required to get blood tests for her children. The results for her two-year-old daughter were disturbing: Erica had lead in her blood, a level so high it nearly required emergency medical treatment.

Now eight, Erica struggles with a learning disability and takes special-education classes.

Lead can cause permanent brain damage. Studies have shown that even tiny amounts are linked to lower IQ test scores and may trigger attention-deficit/hyperactivity disorder and learning disabilities.

The Centers for Disease Control and Prevention now says there's no safe level of lead in a child's blood. But to focus resources on children with the highest exposures, the CDC defines a "level of concern" at five micrograms of lead per deciliter of blood. For a typical two-yearold girl, that's just 1.4 millionths of an ounce of lead in her whole body.

Friction from opening a window can create lead dust, according to the National Safety Council. The dust sticks to the fingers and can end up in a child's mouth.

The CDC estimates that during an eight-year period that ended in 2010, there were 535,000 children under the age of six with this much lead or more in their blood.

The Healthy Homes Department in Alameda County is notified whenever a child has a blood test with a level of concern. Erica's test reading was eight times that level. In her case, the agency was able to



Blood tests showed Erica Moore at age two had high levels of lead in her body, most likely from the paint peeling at her apartment. She now has a learning disability. Buffler served as an expert witness for lead paint companies, saying in a court filing that lead paint poses little risk to children like Erica.

remove some of the old lead paint and paint over the rest. That was five years ago. But on a recent visit, some of the paint on the front and back stairs was peeling again, exposing the underlying lead.

Julie Twichell, a spokesperson for the county agency, said there's little money available to remove lead paint from homes. While driving through Moore's neighborhood in Alameda, she pointed out house after house with peeling lead paint.

Alameda County is among 10 communities in California that just won a \$1.1 billion judgment against the lead-paint companies Buffler defended.

Buffler was not called as a witness during the trial, but revealed her opinions on lead in a disclosure form filed in the lawsuit.

"There are many indicators that the risk of injury to children living in homes with lead-based paint is low, and that the risk to children from lead-based paint in homes is not probable or imminent," according to the document.

Yet in his ruling, Superior Court Judge James P. Kleinberg rejected that claim. "Leading experts in the field of lead poisoning are virtually unanimous in concluding that lead paint is the primary cause of lead poisoning in young children," he wrote.

Buffler said the average likelihood of a child under the age of three being harmed by lead is 1 in 58,400, citing a report from the

U.S. Department of Housing and Urban Development. But Warren Friedman, a senior advisor for the HUD division that published the report, said this number is not accurate for the United States. Friedman said the real risk is 1 in 40.

Kim Dietrich, a professor of environmental health at the University of Cincinnati who specializes in lead research, said the statistic is an obvious error that any epidemiologist should have challenged.

After reading Buffler's opinions on lead, Dietrich said, "The doctor reveals a stunning and perhaps deliberate ignorance of the problem, but typical of those the lead industry pays very well to give this kind of testimony."

# Drawing the line on corporate interference

Buffler once spoke candidly about her views on financial ties and attempts by funders to interfere with research. While testifying in the 2007 deposition, Buffler cited cases where she objected to a sponsor's intrusion on her work. Without offering details, she recalled one situation where a sponsor objected to her analysis. "That's not appropriate," Buffler said she told them.

Without elaborating, she added, "I mean, there are many instances."

Buffler said UC Berkeley adopted guidelines to assure the independence of research, and she followed them. "Research involves a great deal of public trust. The research enterprise is such that if we don't have those kinds of [guidelines], then how could the public trust the work that we do? I feel very strongly about that."

But now, fully understanding her

ties to industry, some close friends are torn by questions.

"I admired and loved her," said one, Devra Davis. "I had never dreamed, never imagined that she would have put her expert opinion up for sale .... It sends me into a tail-spin of reflection as I try to fathom what the hell she could have been thinking."

Jim Morris and Sam Pearson contributed to this report.

#### **SIDEBAR**

# Berkeley training helps researchers 'work around' potential conflicts

By David Heath

Published Online: December 20, 2013

**ERKELEY**, Calif. — A faculty member at the University of California, Berkeley, wanted to secure a National Institutes of Health grant to benefit his startup company.

That might be a problem, university officials in charge of complying with NIH's conflict-of-interest rules said. Their solution? Resubmit the application and list another faculty member as the researcher. The academic withdrew the application instead.

This real example was presented in a September 2011 training video, posted on YouTube, showing how university officials help researchers avoid having to disclose possible financial conflicts of interest to the federal agency funding their research.

Records detail another case this year in which a professor said it was "highly likely" his company would license any technology produced from his NIH-funded research. Berkeley officials saw no conflict.

To some, such cases raise questions about how stringently UC Berkeley enforces NIH's conflict-of-interest rules. Sen. Charles

Grassley, R-Iowa, said they also raise questions about whether the NIH should leave enforcement to universities.

Concerns that financial entanglements can taint research prompted the NIH in August 2011 to strengthen its rules requiring disclosure of financial conflicts. The new rules expanded the definition of such conflicts and required more reporting to NIH.

"NIH can continue to rewrite conflict of interest rules, but the rules



Sen. Charles Grassley, R-Iowa speaks on Capitol Hill in Washington in May 2013.

J. Scott Applewhite/AP

won't do any good unless there's a way to make them stick," Grassley told the Center for Public Integrity. "Research institutions that look the other way on conflicts of interest appear free to do so knowing NIH will take them at their word."

The NIH declined to comment on UC Berkeley's practices or to respond to Grassley's comments. In a written statement, a spokesperson said, "NIH strengthened the key provisions of the regulations and added accountability and transparency to send a clear message that NIH is committed to promoting objectivity in the research it funds."

The issue of conflicts of interest in research is complex. Congress passed the Bayh-Dole Act in 1980, allowing nonprofit organizations and small businesses with federal research grants to own the patents on their discoveries. Yet studies suggest financial conflicts can bias research findings.

The theory in the scientific community is that you can manage conflicts to reduce bias, and a common way to do that is to require public disclosure. NIH requires schools to investigate and manage possible conflicts; under the new rules, it directs schools to explain how it is managing the conflicts.

Graham Fleming, UC Berkeley's vice chancellor for research, said the very nature of research is to make discoveries that aid the public.

"Conflict of interest is something we take very seriously. We don't aim to eliminate it. In fact that would be counterproductive. What we aim to do is to manage the conflict of interest," he said.

A standard way to manage a conflict is to name another professor without a financial stake as the lead researcher, something that the school would disclose to NIH, Fleming said. By naming a new researcher, he said, the conflict is eliminated.

In the UC Berkeley training video, Jyl Baldwin, coordinator of the university's conflict-of-interest committee, says situations like this are "rare." The committee's goal, she says, is to help researchers so "the research can go on the way it's proposed without causing any headlines in the San Francisco Chronicle."

Baldwin also said, "For certain programs, [the Department of Energy] also has a financial disclosure requirement. We've found a way to work around that — I shouldn't say that; it sounds negative, or sounds manipulative. We found a way to handle the DOE disclosure requirements."

The school's website and the training video suggest that in some

cases the university determines there is no conflict of interest even when the professor has a financial stake in the research.

"Is a financial interest automatically a conflict of interest? Not necessarily," says UC Berkeley's website. "This may be a matter of semantics. Some argue that any financial interest in a company au-

tomatically puts the individual into a situation where there is a conflict with his or her research responsibilities."

NIH rules say a researcher has a significant conflict of interest if the researcher is paid more than \$5,000 or owns stock in a private company with interest in the research. Sometimes, that standard is put to the test.

In April, genetics professor Andrew Dillin disclosed to UC NIH rules say a researcher has a significant conflict of interest if the researcher is paid more than \$5,000 or owns stock in a private company with interest in the research.

Berkeley officials that he gets paid \$90,000 a year and owns 2 million shares — valued at \$200,000 — of Proteostasis Therapeutics, a company he co-founded to develop new drugs for people with cystic fibrosis and Alzheimer's disease. Dillin said it was "highly likely" the company would license any technology arising from the \$387,000 research grant he was seeking from NIH.

The school's conflict-of-interest committee concluded there was no conflict and that no disclosure needed to be made to NIH. The research was not within the current "focus" of the company, the head of the committee wrote.

Even so, the committee said it would be "prudent" for Dillin to disclose his company ties to students in his laboratory and when presenting his research in talks or publications.

Asked why the committee suggested Dillin disclose ties to his students but not to the NIH, Fleming referred the question to university spokesman Dan Mogulof. Because the committee found no conflict of interest, Mogulof explained in an email, there was no requirement for Dillin to disclose his company ties to anyone.

"In other words, the Committee recommended that Prof. Dillin take steps beyond those required by federal regulations," Mogulof wrote. Dillin did not respond to an interview request.

NIH rules say that even in cases where the university has more stringent conflict of interest rules than NIH, it must still disclose how it will manage the conflict.

The NIH had initially proposed that schools post all financial disclosures from researchers on university websites. But in the final rules, that proposal was changed to releasing the records, when requested, within five business days.

It took UC Berkeley more than two months to release Dillin's disclosures following a Center for Public Integrity public records request. The school's public-records officer said NIH's five-day rule didn't apply because the school determined there was no conflict.

Universities have their own conflict in trying to police researchers because they get a cut of research dollars, said Paul Thacker, a fellow at Harvard University and a former investigator for Grassley specializing in conflicts of interest in research.

School officials don't fear retaliation from the NIH, Thacker believes, because the agency doesn't have a history of cracking down.

The Center requested interviews with conflict-of-interest officials at NIH for weeks, but the agency declined. The NIH would not talk about its history of enforcing conflict-of-interest rules and said it had no data on how many times it had taken action against researchers or universities for failing to disclose conflicts.

Grassley said that despite the recent changes in NIH rules, more needs to be done.

"An effective enforcement mechanism might require legislation," he said, "since NIH either can't or won't get tough enough on its own."



The American Chemistry Council is located in Washington, D.C. just blocks away from Capitol Hill. Sarah Whitmire/Center for Public Integrity

# In new battleground over toxic reform, American Chemistry Council targets the states

By Ronnie Greene
Published Online: September 9, 2013

ARTFORD, Conn. — In the bare-knuckle war over toxic chemicals, the fight between industry and activists has shifted noticeably from Washing-

ton, D.C., to state venues such as the golden-domed Capitol that rises over Hartford, like a lordly manse.

What happened this year in Hartford shows how industry — fueled by the American Chemistry Council, a \$100-million-a-year advocacy group glittered with Fortune 500 partners — is flexing its muscles from statehouse to statehouse to beat back efforts to disclose harmful chemicals or remove them from the shelves.

In Connecticut, grassroots activists worked with state Rep. Diana Urban, a former professor of economics and politics, to craft a bill they viewed as little more than a baby step toward reform. The measure — An Act Concerning Children's Products and Chemicals of High Concern — would have allowed the state Public Health Department to identify and list chemicals that posed dangers to children.

The bill came at zero cost to state government.

This session, it was snuffed out by an aggressive lobbying push from the ACC and state business groups, and an outcry from Republican members portraying the bill as an attack on business and duplication of federal efforts. Urban couldn't even get it to a vote: legislative critics literally talked the three-page bill to death for more than four hours one afternoon, killing it on an appropriations deadline day with question after question that kept the clock ticking to zero.

"It would have been, honestly, a very small first step," said Anne Hulick, coordinator for the nonprofit Coalition for a Safe & Healthy Connecticut. "The bill we were proposing was not revolutionary. All it was, was a report. Even that — even a report every two years — was something that was very unpalatable to them."

Her organization has an annual budget of \$100,000 — one thousandth of the ACC's — funding one full-time employee, one part-timer and support for other nonprofits. On the last day of session in June, Hulick found herself literally surrounded by industry lobbyists as she grabbed coffee in the legislative cafeteria, accidentally taking a seat normally filled by an ACC lobbyist and then, after moving, having a toy industry lobbyist sit at the next table. She stepped outside to talk with a journalist.

"I'm pretty beaten down," Hulick admitted. "Our primary goal was in protecting children's health. I don't think we ever got the opportunity to see that."

For the American Chemistry Council, it was another in a string of victories in state houses from Maine to Washington State — and part of a vigorous campaign to smother toxics reform bills filed in states fed up

The ACC "helped defeat, amend or postpone the passage of more than 300 flawed bills dealing with chemicals and plastics in 44 states," the organization said in its tax return for 2010.

with logjams at the Environmental Protection Agency. Connecticut is just one snapshot of a larger picture in state capitals across the U.S., a Center for Public Integrity examination found.

"It's becoming the new battle-ground for a lot of this work," said Steve Lester, science director for the Center for Health, Environment & Justice, a nonprofit headquartered in Falls Church, Va., and founded by Love Canal activist Lois Gibbs.

Defeating state bills ranks among the ACC's notable accomplishments, the group's tax returns say.

The ACC "helped defeat, amend or postpone the passage of more than 300 flawed bills dealing with chemicals and plastics in 44 states," the organization said in its tax return for 2010, echoing its other Form 990 reports.

The chemistry council doesn't shy away from — or apologize for — its lobbying efforts.

"We're an advocacy organiza-

tion," said spokesman Scott Openshaw. "We're in business to advocate for our industry to ensure that public policy is balanced and formulated in the right way for all Americans, and for the value of our industry to ensure that we can continue to be a global leader. That's what we do. We advocate for our members."

The ACC's influence sometimes reaches deep into the fine print of state rules, the Center found.

In Iowa, a legislator proposed a resolution urging Congress to crack down on dangerous chemicals — only to see his measure diluted to mirror, nearly word for word, the ACC's own model legislation before being killed. That ACC model, targeting reform of the Toxic Substances Control Act, says a "robust" federal system precludes the need for state laws that could trigger "negative impacts on the national economy." The ACC model has been introduced in at least five other statehouses from New Jersey to Oregon, the Center

found by analyzing a Sunlight Foundation database of bills.

When the Council of State Governments met for a conference on product safety last year, the session was sponsored by ACC member Procter & Gamble at its Cincinnati headquarters, with industry scientists leading talks.

From city halls to state houses, the ACC sometimes maintains strikingly close ties to political power. In Baltimore, where the chemistry council helped delay a potential city ban on Styrofoam cups and containers, the mayor officiated at the wedding of an ACC lobbyist.

In Maine, the commissioner of the Department of Environmental Protection, Patricia Aho, was an ACC lobbyist before taking office in 2011. In the 2011-12 session, Aho registered as the ACC's principal lobbyist on 10 different bills before her ascension to state office, records show. Her support for the organization is clear.

"The ACC represents the companies that make the products that make modern life possible, while working to protect the environment, public health, and the security of our nation," said Aho's lobbyist registration form for 2010. Aho declined an interview request from

the Center, but her office said any potential conflicts were "thoroughly vetted" before she took office.

Now, as DEP chief, she oversees an agency that this April testified in opposition to a bill seeking to keep toxic chemicals away from pregnant women and children, on the same day as did the ACC.

The ACC and its allies, Lester said, use their resources to build doubt over claims that company products cause harm. "That's what they're good at, creating this element of doubt, questioning our science, our speakers, our information," Lester said. "They see these rules are making progress, and I think they are feeling threatened."

#### Big money, big connections — and results

The American Chemistry Council has resources to push back, representing members such as Dow, Procter & Gamble Chemicals Division and ExxonMobil Chemical Company, and listing annual revenue from \$100 million to \$135 million in recent years.

The ACC spends \$8 million to \$10 million a year in annual federal lobbying, and raised nearly half a million dollars in recent election cyFrom 2005 through part of 2012, the chemical industry "gave \$39 million to candidates for federal office" and "spent \$333 million on lobbying at the federal level," a Common Cause report noted.

cles supporting federal campaigns. Over the last decade it has backed candidates of both parties, but more often favored Republicans over Democrats. Yet the industry's financial muscle is many times greater, as those figures represent just ACC contributions. From 2005 through part of 2012, the chemical industry "gave \$39 million to candidates for federal office" and "spent \$333 million on lobbying at the federal level," a Common Cause report noted.

In waging state campaigns, the D.C.-based group retains statehouse lobbyists to fight bills from Maine to Connecticut, from Iowa to Minnesota, Oregon to Washington State.

In the states, the ACC has developed a playbook that is at once boilerplate and effective: Convincing decision-makers that bills aimed at identifying, and potentially banning, chemicals would only kill businesses. And, stressing that state bills would merely duplicate federal efforts and add layers of government.

"The chemical industry keeps their message simple. Chemicals: Good. Business: Good. Banning chemicals: Bad," said Connecticut's Urban, who witnessed that success first-hand this session.

In killing bills from coast to coast, legislative critics sometimes echo power points developed by the ACC and its lobbyists. "It's an onslaught," said Urban, a Democrat. "It's very hard for me to fight that. You go into a committee and they're out here grabbing legislators one after another."

In Washington State, the ACC helped kill the Toxic-Free Kids and Families Act. The 2013 bill would have banned two toxic flame retardants from children's products and furniture, and prevented manufacturers from replacing them with retardants identified by the state Department of Ecology "as a high priority chemical of high concern for children." The bill was weakened in the Senate to ban retardants already

being phased out by industry — but failing to grant the larger state powers. Then, as supporters tried to revive the original measure, it died.

"They do an all-out confrontation when these bills are drawn up," said state Sen. Sharon Nelson, a Washington State Democrat. "They nitpick. 'This isn't quite ready. We are not quite there.' So they just delay, delay, delay,"

In Oregon this session, the ACC helped defeat a bill that would have allowed the Oregon Health Authority to maintain a list of "high priority chemicals of concern for children's health." The bill remained deadlocked in the Senate, 15-15, in the session's final day. "We never got a commitment from a 16th person, so it was not heard in the Senate," said Democratic Rep. Alissa Keny-Guyer, a co-sponsor. "I was really disappointed."

In Maine, the bill Aho's office fought — An Act To Further Strengthen the Protection of Pregnant Women and Children from Toxic Chemicals — was also watered down before winning approval, with the ACC among the critics pushing back. The initial bill would have identified products using the 49 "worst of the worst" chemicals and sought to remove them from reaching children. The

final version would have effectively required \$1 billion companies to disclose their use of Bisphenol A (BPA), a chemical that some studies suggest can impact the brain and behavior of children, in food packaging.

Then, in July, Gov. Paul LePage, who appointed Aho as commissioner, vetoed the bill over the objections of protesting parents.

## D.C. red tape prompts states to act

The tussle in the states is fallout from the slug-like pace of reform in Washington, D.C., embodied by the Toxic Substances Control Act. TSCA was passed in 1976, granting the EPA power to require testing of dangerous compounds. But in the nearly four decades since, the EPA has rarely used that power — and for years has been tied up in a protracted effort to update TSCA.

"We're not getting much leadership at the federal level," said North Carolina Rep. Pricey Harrison, who has attempted reform efforts in her state for six years. "It's a little bit frightening to think there are 80,000 chemicals out there in commerce that haven't been studied. It's frustrating for those of us who have public health as a priority to have the lack of leadership in the federal level, so we need to do it in the states."

In state after state, officials echoed Harrison: The federal government is stuck in time, forcing states to act. The Government Accountability Office has also raised questions about the pace of EPA reform. Even with some changes, "it is unclear whether EPA's new approach to managing chemicals will position the agency to achieve its goal of ensuring the safety of chemicals," the GAO concluded in June.

The EPA reports modest progress under TSCA: Under the act, the agency said, it has "only been able to require testing on a little more than 200 existing chemicals," and banned five.

In September 2009, the EPA announced a set of principles to "update and strengthen" TSCA. "Restoring confidence in EPA's existing chemicals chemical management program is a priority for EPA and the Administration," the agency said in a statement, saying it aims to "modernize and strengthen the tools available in TSCA to increase confidence that chemicals used in commerce, which are vital to our Nation's economy, are safe and do not endanger the public health."

In large measure, the ACC is fighting both the states and the feds. Even as it tells the states to leave the job to Washington, the chemistry council has attacked the fine print of some proposals to reform TSCA.

The group, for instance, cited "fundamental flaws" in legislative proposals to strengthen the act. In a November 2011 press release titled "ACC Expresses Concern with Safe Chemicals Act," the group wrote: "We believe we can develop legislation that will give consumers confidence, learns from the success and missteps of reforms undertaken by other countries, and fosters innovation and job creation."

Meanwhile, to states, the chemistry council cites "EPA's Actions to Strengthen the Chemical Management Safety Net," as the group wrote in correspondence opposing Connecticut's bill. "ACC urges this committee to consider this information and, in light of it, to ask itself whether HB 6526 is even necessary and whether it would provide significant public health benefit to the children of Connecticut."

It's an argument the ACC had made elsewhere, providing fuel for legislative critics to douse state bills.

The chemistry council is not in conflict by challenging both states and Washington, spokesman Openshaw said. Instead, he said, the ACC supports tangible reform to TSCA through the Chemical Safety Improvement Act, one of the last bills filed by Sen. Frank Lautenberg, the venerable New Jersey Democrat who died earlier this year.

"Our No.1 priority is to see the Toxic Substances Control Act, the national law that regulates chemicals in commerce, we want to see that reformed. It's time to do that now," Openshaw said. "It's an approach that will benefit all states when it comes to ensuring the safety of chemicals for consumers and workers and also ensuring that the U.S. remains a leader in innovation around the globe."

The chemistry council's model plan said consumers should have confidence the products they buy are safe, and that federal rules should "preserve America's role as the world's leading innovator and employer" in the chemical field.

While Lautenberg's bill has gained momentum and awaits congressional hearings, some environmental groups and states worry that the measure, cemented after compromise with critics, could weaken standards in some instances. The ACC said it strikes the right balance.

"It was the first time in 40 years we actually have a bipartisan approach to reform TSCA," Openshaw said.

From Washington to the states, the ACC makes one thing clear: It supports reform — but only on its terms.

#### Iowa: The ACC lends a hand

In Iowa, Representative Charles Isenhart filed a proposed resolution in 2011 that would have prodded Congress to mandate reforms to TSCA, "the only major federal environmental statute that has never been updated or reauthorized," his proposal said.

"There was not an effort at the national level to address these issues in a meaningful way in Washington, so some of us ... decided to take a run at those issues," Isenhart said in an interview.

His resolution included strong language, saying "children and developing fetuses are uniquely vulnerable to the health threats of toxic chemicals," and noting that "a growing body of peer-reviewed scientific evidence links exposure to toxic chemicals to many diseases and health conditions." The General Assembly resolution would have put the onus on chemical manufac-

turers to "prove that all existing and new chemicals are not harmful to human health."

"The toxics resolution in particular was opposed by the American Chemistry Council," Isenhart wrote the Center.

When his resolution came out of Iowa's Committee on Commerce, it was noticeably altered. Gone was language citing chemical dangers to children and fetuses. Gone was language forcing industry to prove its chemicals weren't harmful.

Instead, the substituted language adopted a clear concern for industry. It said the EPA's chemical management program "should preserve the role of the United States as the world's leading innovator and employer in the manufacture, processing, distribution, and use of chemicals." Federal reforms "should encourage companies and the EPA to work together to enhance public access to chemical health and safety information."

The substitute language mirrors, nearly verbatim, the ACC's model TSCA legislation.

What happened? Isenhart said the commerce committee member assigned the legislation, Republican Rep. Ralph Watts, introduced the ACC language. State legislative records show an ACC lobbyist, John Easter, registered as "for" the final version, after originally registered as "undecided."

Isenhart said he tried to change the language back, but to no avail. The resolution never came for a vote. "The bill was dead," he said. "They weren't interested in having a debate. I have a feeling Representative Watts just wanted to curry favor with the chemistry council, taking their language."

The initial proposal was "totally unacceptable," Rep. Watts countered in an interview. "As I recall, the proposal that Representative Isenhart made went way too far in adding more toxicity regulations," he said.

Initially, Watts said he didn't recall the ACC playing a role. Told lobbyist Easter registered on the item, Watts said: "As I recall John might have offered some suggestions on the bill, on the resolution."

Lobbyist Easter, reached in August, said he was at lunch and couldn't talk. He later said his office was preparing a statement, but the office did not follow up.

Iowa's experience was not unique. The ACC model was introduced in state houses in Oregon, Illinois, Iowa, New Jersey, Michigan and Texas — and adopted, in some form, in Michigan, New Jersey and Illinois but not in other states, the Center found.

In Iowa, several other toxic reform bills failed to move forward in recent sessions, an environmental health legislation database maintained by the National Conference of State Legislatures shows. "Iowa is an Ag economy," Rep. Watts said. "We're sensitive to over-regulation that sometimes is proposed that is damaging to industry and has no sound science background."

How much sway does the chemistry council hold in the state? "I think probably people will listen to them, just like a lot of other lobbyists," Watts said. "We listen to lobbyists of all stripes. Some we agree with: some we don't."

#### Maine: ACC lobbyist-turnedenvironmental chief

In Maine, the ACC's connection to the top is decidedly direct: The state's environmental chief was, until her arrival to the Maine department in 2011, a registered ACC lobbyist.

Lawyer Patricia Aho was the principal lobbyist for the ACC on multiple bills in the 2011 session, her filings show, after representing the

chemistry council and other clients for years. Among the bills she registered on behalf of the ACC in the 2011-12 session:

- An Act To Ensure That Children's Products Are Free of Cadmium
- An Act To Provide the Department of Environmental Protection with Regulatory Flexibility Regarding the Listing of Priority Chemicals
- An Act To Amend the Process for Prioritizing Toxic Chemicals in Children's Products

Aho joined the Maine Department of Environmental Protection in early 2011; that September, Gov. LePage named her commissioner. Aho has long touted her connection to business. Her official bio on the governor's website, for instance, notes that the Kennebec County Chamber of Commerce honored her "advocacy on behalf of the business community."

Under her watch. Maine has been slow to adopt toxics reform.

This session, the ACC was among organizations opposing the proposal to "further strengthen" protections for pregnant women and children from chemicals. In filings to the state, the ACC cited TSCA reform as one reason the bill was not needed. "In sum, TSCA's New Chemicals program is considered one of TSCA's major regulatory successes," the organization wrote.

As it had in Connecticut, the ACC asked whether the proposal was "even necessary and whether it would have any public health benefit to the children of Maine."

Advocates were trying to build upon earlier progress. Already, Maine had adopted a list of 49 chemicals of high concern, making it one of the few states to publicize such a list. But, heading into the 2013 session, supporters said, the state had not taken steps to remove products tainted with those same toxins.

"The bill will identify which products contain the 49 'worst of the worst' chemicals and set priorities for action to get those chemicals out of household products that Maine children encounter every day," wrote the Maine Conservation Voters. The bill would have pushed the state DEP to each year prioritize two chemicals, from the 49, and set about studying alternatives to replace them.

With the ACC and business leaders fighting the bill, it was seriously scaled back.

By session's end, the bill was narrowed to effectively require companies with \$1 billion in annual sales to disclose their use of BPA in food packaging. But it would not require the state to keep adding high priority chemicals to the list.

"There was a clear shift ... to more of a transparency bill, but it's important that we make progress," said the bill sponsor, then-Senate Majority Leader Seth Goodall. "And in the current climate here in Maine we had to be realists and pragmatic and move forward."

Aho's department had voiced objections, damaging the bill's chances.

"This bill is complex and includes many interwoven components that would greatly expand the reach of the current program, the consequence of which would be a big government program focused on churning out rules and processing paperwork, rather than engaging in meaningful analysis and informed decision-making," a DEP director testified in April.

Three months later, the governor vetoed it.

Aho's revolving door from industry lobbyist to state regulator drew scrutiny in a recent series in the *Portland Press Herald/Maine Sunday Telegram*, entitled "The Lobbyist in the Henhouse." It described how environmental regulation and en-

forcement has slowed considerably under her watch.

The Center for Public Integrity, exploring Aho's dual roles, sought an interview with the commissioner. Aho declined the request, but a spokeswoman said Aho had been an attorney in Maine since 1982, practicing government and regulatory affairs.

"And her background is no different than many other attorneys who have or are serving in agencies or departments in the state of Maine," said the statement from DEP spokeswoman Jessamine Logan. "And any questions about her potential conflicts of interest were thoroughly vetted when she joined state government over two years ago and later during her confirmation process as commissioner, where she was confirmed with overwhelmingly bipartisan support, 35-0."

The attention over her dual roles triggered a firestorm, with the Sierra Club pressing Republican Gov. Le-Page to oust her. LePage's anger, instead, turned toward the press — not

his director, who remains in office.

Following the critical reports, Aho dispatched an email to staffers in June, with the subject line 'Welcome to Summer.' It said the agency was moving to protect Maine's natural environment. "I remain committed to taking my responsibilities of environmental stewardship seriously and am proud that our DEP is a resourceful, respectful, and responsive agency," she wrote.

Aho added, "The protection of our environment and natural resources and a robust economy do not have to conflict."

Beth Ahearn, political director for the Maine Conservation Voters, said Aho had been respected as a lobbyist for being reasonable to deal with and having "a lot of integrity."

But her rise to the top environmental post raises larger questions.

"How do we separate our background from the decisions we make? And that's a tougher question," Ahearn said in an interview. "Obviously she knows those companies or worked with those companies really well, and has that perspective, the company's perspective.

"We want the commissioner of environmental protection to be all about environmental protection."

#### Reform bills filed, and fought, from Florida to **Washington State**

Across the country, a pattern has emerged: State officials pitch proposals to identify and potentially ban toxic chemicals, grassroots groups rally behind the proposals and the bills die in committee or get watered down, with the ACC, business groups and legislative critics pushing back.

To many, Washington State is a leader in toxics reform. The state adopted a "Chemicals of High Concern to Children" list, 66 chemicals from formaldehyde to benzene to BPA the state considers potentially hazardous. Other states have tried to follow suit and create their own lists — the first step, advocates say, in ultimately removing products that can sicken children.

This session in Washington State, advocates filed the Toxic-Free Kids and Families Act, a bill aimed at banning two forms of toxic flame retardants from reaching children - and barring manufacturers from replacing them with similarly dangerous products. Even there, the larger reform butted up against opposition.

"The main opposition is the American Chemistry Council. It's a well-funded, well organized force and they are able to come in, organize in-state business and outof-state businesses — Wal-Mart and Target come to mind," said Ivy Sager-Rosenthal, with the nonprofit Washington Toxics Coalition. Opponents are "able to sow enough doubt in legislators' minds that some put the brakes on this type of legislation."

"The ACC and their allies," she added, "their main tactic is to delay any meaningful reform."

In the Senate, the bill was weakened to target only products already being phased out. It failed to revive in the House and died entirely, said bill co-sponsor Sen. Nelson.

"Once again the chemical industry won the fight in Washington State," Nelson said in August. "We had the chemical industry and Association of Washington Business, the usual suspects, sitting in the gallery making sure once again protections

for children die in the state."

Lobbyist Mark Greenberg, who represents the ACC in Washington State, routed a Center interview request to the chemistry council. The AWB, the state's "premiere advocate for the business community," said it pushes an economic climate benefiting "all citizens."

Nelson, trying for three years to adopt the change, said she won't give up. "I'm a mom and I'm going to be a grandma possibly this week," she had said in May. "It just makes me more committed to have something that is this clear that we need to ban. To have corporate interests continue to try to roll us on it makes me more committed to wanting to get it done."

In Oregon this session, House Bill 3162 would have required the state to list "high priority chemicals of concern" present in children's products from car seats to toys, jewelry and pacifiers. Under the initial bill, manufacturers would have to disclose if they used potentially toxic chemicals, and then phase them out in certain products.

Bill co-sponsor Keny-Guyer said she targets public health issues involving women and children. "I'm also very concerned about toxics in our environment, because we've

had an explosion in chemical development over the decades, and our regulatory system has not kept up," she said.

She quickly encountered sistance. In public hearings, the ACC and Toy Industry Association squared off against bill public health backers including Oregon "The American Chemisnurses. try Council, the Toy Association of America, the Associated Oregon Industries, Procter & Gamble, the pulp and paper industry, the International Fragrance Association ... have all opposed the bill and they are putting up a really pretty big fight," Keny-Guyer said in June, with the bill still in play.

"Their arguments are it's a slippery slope, they think it's an undue burden on business, and it should be done at the federal level." Her reply: "The feds have not kept up with the development of chemicals and are not adequately addressing this."

By session's end the next month, the bill never made it to the Senate for a vote, even as sponsors scrambled to save the measure by cutting out some elements. "In order to try to gain support in the Senate, we pared back the bill," said Keny-Guyer. "The amendment was to take out the entire phase-out piece and only have disclosure. And even that could not get the 16th vote."

Industry pushback, she said, doomed it. "I mean they brought in lobbyists in the end who kind of banded together and fought it tooth and nail," the representative said.

In other states, some legislators are finding it hard to muster enthusiasm reforms will ever take root.

In Texas, Rep. Carol Alvarado, a Houston Democrat, tried for three years to push a bill banning the sale of children's products containing "bisphenol-A or certain other substances identified as known human carcinogens or banned hazardous substances." BPA is an industrial chemical found in plastic bottles and metal cans that federal agencies, including the Food and Drug Administration, say have "potential effects ... on the brain, behavior, and prostate gland in fetuses, infants, and young children."

Alvarado's proposals never came for a vote. "I wasn't surprised," Alvarado said, knowing politics in Texas. "With these type of issues you keep pressing and moving forward, you can't get bogged down. ... You have to keep it moving forward and hopefully get some public discussion going on."

In Florida, Rep. Mark Danish

co-sponsored a bill this session to identify chemicals of high concern. The idea was to let consumers know which products contain potentially toxic chemicals, with Florida's Department of Environmental Protection posting the information online.

As in Texas, his bill never came for a vote — one of a string of toxic reform bills extinguished in the Sunshine State, the state legislative database shows.

"My bill got absolutely no traction whatsoever. People took notice of it, said 'nice bill.' I could not even get it to its first committee. Never even saw the light of day," Danish said in an interview.

After he proposed the bill, he said, Florida's agricultural industry called a meeting, worried he was targeting pesticides. Danish said he tried to calm nerves by saying he aspired only to inform the public about household chemicals of potential concern to pregnant women and children. No matter. The bill did not move forward — the victim, he believes, of legislative pushback against new regulations, along with resistance in the Republican controlled House to bills pitched by Democrats.

"It was kind of a shame, because I thought it was a good bill," Danish said.

In North Carolina, Democratic Rep. Harrison proposed the Toxic Free Kids Act this session. Its aim: Protecting children "from harmful chemicals in their toys, furniture, car seats and other products that children touch, lick, inhale and snuggle up with every day," advocates said.

It, too, failed to come for a vote, but instead was deemed by the House Commerce Committee to be a "study bill," meaning it was going back for more study and could return next year.

"This is a legislature that's highly anti-regulatory and there's very little support for enacting stricter regulations on anything. This time around we had a Republican lead sponsor, we recruited a couple of Republicans to be on the bill," Harrison said. "But unfortunately we couldn't get the bill moved into the session, so we turned it into a study.

"I've been trying to get this issue studied forever."

In other states, some reform measures have moved forward — after compromise with industry.

In Minnesota, State Sen. Katie Sieben helped sponsor a bill this session that bans BPA in toddler and infant food. It passed.

"It certainly took some negotiat-

ing with industry. One thing that helped was that BPA was already banned in Minnesota in sippy cups, and we were the first state in the nation to do that," Sieben said in July, a baby bouncing on her lap during a phone interview. "And there are manufacturers who produce baby food without BPA in it, so there was a viable and known alternative."

The final version was scaled back from an earlier proposal, which could have applied to any food targeted to children, to focus solely on toddler and infant food and formula. "There was a lot of pushback from food manufacturers. 'It was too sweeping. Anything could be defined as children's product,' " Sieben said. "Ultimately we had to take a more measured approach."

#### Connecticut: 'Baby step' bill falls flat

In Connecticut, advocates thought they, too, had taken a measured approach.

Their bill, they thought, was simple: An Act Concerning Children's Products and Chemicals of High Concern. Initially the bill would have followed the leads of Washington state and Maine, which already compile lists of chemicals of high concern.

Citing states that had made strides in toxic reform struck some the wrong way in Connecticut.

"When we reference the list in Maine and Washington, the minute we reference those lists it becomes a huge red flag with industry," said Urban, who later deleted reference to the states and scaled the bill back to simply allow the state to compile a list, every two years, of potentially harmful chemicals. It was crafted so it would not cost the state a penny.

Critics, led by the ACC, turned the conversation away from the potential harm to kids to the potential harm to Connecticut businesses. portraying the bill as an intrusion by state government into a job already held by the feds.

"They can't win on science," said Hulick, of the Connecticut advocacy group. "It became not about the health of kids. Somehow, that became second."

She added, "Obviously, they are afraid of something."

And opponents put lobbyists into play in a state with 187 legislators and more than 1,000 registered lobbyists. "The lobbyists for the toy and chemical industry are much better funded," said Noele Kidney, project coordinator for the Connecticut Public Health Association. "They have a huge presence here, all day long, every day."

Hughes & Cronin, "Connecticut's Oldest Contract Lobbying Firm," represents the ACC in the state. Founder Carroll J. Hughes did not respond to a July interview request. The ACC said its lobbying push is centered on supporting change at the federal level — change it said would aid the states.

For bill advocates, the low point was a four-hour hearing before the Connecticut Appropriations Committee April 23, the deadline day for the committee to move bills forward. In a hearing room filled with mostly empty chairs, Urban opened with a brief overview.

"The purpose behind this bill," she said, is to "start to get a handle on what kind of chemicals are out there that might be a problem for our children."

Republican opponents didn't see it that way, probing the three-page bill for hours, sometimes asking Urban to define words in the proposal, or explain how it compared with practices in Europe. Critics pitched their own amendments, each one triggering more questions - and more delay. Seventeen Republican critics took turns picking the bill apart word by word.

Twice, legislators invoked the ACC by name in challenging the proposal. Several echoed the chemistry council's chief argument, saying the EPA was already on the case.

"I know the implications and the harm that come to commerce when we as a state start to nitpick into issues that very frankly we are not the ultimate authorities in. We should leave this to the EPA," said Republican Rep. Mitch Bolinsky, citing "very, very deep concerns."

Connecticut businesses "are not feeling reassured by the openness of our state government to doing everything possible to make it easy to do business in this state. In fact, quite the contrary," said Republican Rep. Gail Lavielle, who asked, among other questions, how the word 'biological' was used as a noun, and for the definition of 'polyester resins.'

Lavielle did not respond to an interview request. During the hearing, she said her multiple questions were necessary "due diligence" for a measure drawing supporters and detractors.

"We're just putting too many restrictions on businesses," added Republican Rep. Jay Case. "From what our governor tells us, we are open for business and we need to keep the tax rolls coming in."

Nearing hour four, Republican Rep. Al Adinolfi noted that the proposed list could include chemicals of high concern "after considering a child's or developing fetus' potential for exposure."

He asked: "Now, what would be the definition of developing fetus?"

Urban, taken aback, replied: "I'm not the person to make a definition of what is or is not a fetus."

"Many of us believe that a fetus is formed immediately after conception," Adinolfi continued. "So does that mean if this bill becomes real ... that when these lists are given to us by these commissions ... that we can amend that and add the morning after pill as not legal?" Adinolfi, rehabbing from surgery, was not available for comment, his office said.

Urban became flustered at times — "Madam chair, I believe that we are really getting into minutiae at this point," she said after the first wave of questions from a half dozen legislators — and focused at others, trying to shift discussion to the bill's focus. "This is the first baby step toward protecting our children and getting a handle on these chemicals" that could be carcinogenic, she said as the final minutes ticked away. "It's merely creating a list."

In a statehouse controlled by Democrats, Republican critics held sway that day. At hearing's end, with continuous criticism of a "one-sided" bill opponents said gave industry no voice, the gavel was pounded. Discussion over, bill dead. Another victory for the ACC. "It was a filibuster," Urban said later. "It was very clear they were killing the bill. They decided to talk it until 5 o'clock."

Republican State Sen. Rob Kane, ranking member of the Appropriations Committee, was among opponents holding the floor with amendments, questions and more amendments. In an interview on the session's last day in Hartford, Kane said the intent was not purposeful delay, but to drill down into the bill's particulars.

"We have a great deal of questions with regard to the policy, the science and the economic impact," he said, noting that "proponents of the bill certainly are in the majority of both houses."

Why did the committee spend so much time focused on the impact to businesses? "That's because it was the appropriations committee," Kane said, where the focus is on finances. "Anytime you add more hurdles, it makes it more and more difficult for businesses."

Legislators' fear over toxics reform could be felt in other bills, too. This session, Connecticut pushed a bill creating a Mental Health Task Force to deal with emotional issues following the school shooting in Newtown, Conn., in December 2012. Among other issues, the task force will study the impact of nutrients, genetics and psychotropic drugs on the mental health of children.

Urban, one of the bill's prime backers, said she initially included the phrase "environmental toxins" among the issues to be studied. She said the leadership told her to strike the phrase. Initially enraged, she said she closed the door for 30 minutes by herself "and used four-letter words as a stress reliever." Then she looked at the "greater good" — a measure to help children.

That bill passed. Her toxics bill did not. "It's dead," Urban said in the exhaustion of the session's final day. "Night, night. Bye, bye."

The bill died even though the Connecticut Department of Public Health supported the final version, which came at no cost to state government.

"The legislation could have helped the Legislature understand what our research is showing, and opened communication a little bit more in this area," said Gary Ginsberg, a state toxicologist. "So I think it's a loss in that regard that the Legislature doesn't have that automated reporting mandated. But there are other ways for us to get our message out to the public."

When she crafts a bill, Urban said, she is mindful of how industry and critics will attack. So she wrote a bill targeting the most vulnerable. "And I'm thinking, how do you say no to babies?" she asked, in an interview at the Capitol. "But guess what? They were able to say no to babies."

Visibly worn, Urban admitted she

"didn't realize the extent of their negativity early enough."

She has learned, she said, that critics engage in what she calls "The Ali Rope-A-Dope" — bobbing and weaving, doing anything to avoid a hit, just as heavyweight boxing champion Muhammad Ali used rope-a-dope to frustrate foes in the ring.

"It's rope-a-dope, and I know it's rope-a-dope."

She sighed. "I don't know how to get this done just yet. But I will." ■

Chris Zubak-Skees contributed to this report.

#### **SIDEBARS**

# Best of friends: Baltimore mayor, chemical lobbyist

By Ronnie Greene

Published Online: September 9, 2013

**HE** American Chemistry Council's influence is so deeply entwined with local and state government, it sometimes feels like a marriage. Sometimes, it is.

In Baltimore, Mayor Stephanie Rawlings-Blake is so close to ACC lobbyist Lisa Harris Jones, the city leader officiated at Jones' Nevada wedding to a partnering lobbyist. The Harris Jones & Malone law firm doesn't shy from such connections — it boasts about them. "Power

Couple's Vegas Nuptials Draw Host of MD Political Notables," said a May headline formerly linked on the firm's website.

Another link cited a report listing Jones as the 3rd top earning lobbyist in Maryland in a recent six month period, with \$864,625 in compensation.

The website lists political fundraisers and spells out the firm's long list of corporate clients, including the ACC. The links between mayor and lobbyist have drawn attention in local media, including the Baltimore Brew website. Another account detailed how the mayor visited the lobbyist's Rehoboth Beach getaway.

There's also scrutiny of how the ACC lobbyist helped beat back city reform. In June, Jones helped the ACC delay a proposed bill that would have made Baltimore the first East Coast city to ban foam cups and containers for carryout food. The ACC testified against the ban, which was postponed the same day Jones lobbied against it in City Hall.

Mayor Rawlings-Blake did not respond to four interview requests made with her office by the Center for Public Integrity.

Reached for comment, Jones asked the Center for questions in writing. She did not respond to written questions about the ACC's Baltimore bill opposition or her ties to the mayor.

The closeness between mayor and lobbyist raises significant questions, ethics advocates say.

"The most striking thing is, it's not just a lobbyist. It's a lobbyist who represents maybe 40 to 50 percent of the lobbying business in the city," said James Browning, Regional Director for State Operations for Common Cause. "The worrying thing is you have no way of knowing if that agenda is checked at the door when they are on vacation or doing these other things together."

Session for state officials 'intended to educate,' not influence, corporate sponsor says

### Session for state officials 'intended to educate,' not influence, corporate sponsor says

By Ronnie Greene

Published Online: September 9, 2013

**HEN** the Council of State Governments met last year to discuss product safety, the session was sponsored by Procter & Gamble at its corporate headquarters in Cincinnati, with all presentations led by company scientists and members.

The government council said it took strides to avoid a "one-sided" agenda, and the company said it merely set out to inform, not influence, decision makers. But the session shows the closeness between industry and government in shaping environmental health agendas — and the stage industry is given in framing dialogue.

"The audience was a lot of us who sponsored toxic state legislation at the state level," said North Carolina Rep. Pricey Harrison, who has encountered hurdles securing reform in her state. "They were trying to show us what industry was doing to keep us safe."

The two-day session, held July 7 and 8, 2012, drew 25 Council of State Governments members from across the country, who heard P&G-led talks titled "Fundamentals of Human Safety," "Fundamentals of Environmental Safety," and "Regulatory Compliance of Consumer Products." The closing day explored "Current Issues with Safety Science and Public Policy," with a focus on the Environmental Protection Agency's chemical policy program.

"The purpose of the event was to provide an educational curriculum to policymakers regarding their use of scientific data, studies and reports when considering policy in their home states," the council wrote the Center for Public Integrity. "P&G provided access to members of their scientific community who in turn served as speakers and resources during the event."

Why did the council, founded in 1933 to foster "the exchange of insights and ideas to help state officials shape public policy," turn to a Fortune 500 company to sponsor the event for its Policy Academy on Consumer Product Safety?

Finances were one factor, the council said. "Given the limited budget for the event, it was de-

"We weren't trying to influence decisions other than giving state legislators the tools they need to evaluate issues from a scientific standpoint."

— Tim Long, P&G spokesman

termined that the best option would be to take the policy academy event to the resources/speakers, rather than incurring additional travel costs for the speakers to travel to another location," the CSG said. The council — headquartered in Lexington, Kentucky, with offices from D.C. to California — stayed at a Cincinnati hotel whose meeting space was booked. "Therefore, P&G agreed to house our event on their nearby campus utilizing their conference facilities."

As it planned the event, the council acknowledged "concerns that such a program could be perceived as one-sided." To address the issue, the group said it convened a bipartisan council of state leaders to help develop the agenda. "The Council of State Governments hosted the event with material and in-kind support provided by P&G," the council said. "At no time did P&G have control over the program."

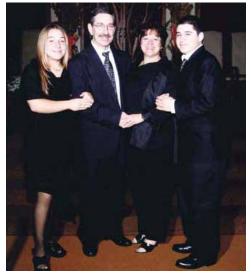
For its part, Procter & Gamble said its intent was to educate. "We weren't trying to influence decisions other than giving state legislators the tools they need to evaluate issues from a scientific standpoint," said spokesman Tim Long, who took part in the forum. "It was intended to educate them on the process used by industry in general to evaluate safety in ingredients in products."

# Facing lawsuits over deadly asbestos, paper giant launched secretive research program

By Jim Morris
Published Online: October 21, 2013

N the spring of 2005, Georgia-Pacific Corp. found itself facing nearly \$1 billion in liability from a product it hadn't made in nearly three decades: a putty-like building material, known as joint compound, containing the cancer-causing mineral asbestos.

Named in more than 60,000 legal claims, Atlanta-based Georgia-Pacific sought salvation in a secret research program it launched in hopes of exonerating its product as a carcinogen, court records obtained by the Center for Public Integrity show. It hired consultants known for their defense work to conduct studies and publish the results, with input from the company's legal de-



Daniel Stupino with his wife, Anna, daughter Dana and son Daniel. Stupino died last year of mesothelioma, a cancer almost always linked to asbestos exposure. Courtesy of the Stupino family

partment — and is attempting to keep key information hidden from plaintiffs.

The Consumer Product Safety Commission had banned all asbestos-containing joint compound as of 1978, and Georgia-Pacific, maker of a widely used version called Ready-Mix, had raised no objection. But in 2005, as asbestos-related diseases with long latency periods mounted, the company revisited the issue with one aim: to defend lawsuits filed by people like Daniel Stupino, a parttime renovation worker who died last year of mesothelioma, a form of cancer virtually always caused by asbestos exposure.

Under its research program, Georgia-Pacific paid 18 scientists a collective \$6 million, documents show. These experts were directed by Georgia-Pacific's longtime head of toxicology, who was "specially employed" by the company's inhouse counsel to work on asbestos litigation and was under orders to hold "in the strictest confidence" all information generated.

This framework, taking a page from the tobacco industry playbook hatched years earlier, allowed Georgia-Pacific to control the science and claim all communications as privileged — not subject to discovery in litigation. A New York appeals court held recently that the communications "could have been in furtherance of a fraud," an allegation the company has denied.

Some of the researchers hired by Georgia-Pacific sought to re-create versions of Ready-Mix and a dry joint compound that contained asbestos in the 1970s. Others tried to estimate historical worker exposures to dust from sanded compound. Still others exposed laboratory rats to the reformulated materials, employing suspect protocols; they reported that asbestos fibers were cleared quickly from the rodents' lungs and posed no cancer threat, a theory many experts reject.

Thirteen company-funded articles were published in scientific journals. A Georgia-Pacific lawyer offered pre-publication comments, casting doubt on the objectivity of the science.

The Atlanta-based company's research program fits into a broader pattern chronicled by the Center for Public Integrity: Industry's use of well-paid experts to minimize the hazards of toxic chemicals and fend off liability, regulation, or both.

A spokesman for Georgia-Pacific, Greg Guest, declined to answer questions about the project, referring a reporter to court pleadings. In one document, the company says it "properly commissioned studies to explore scientific issues that repeatedly arise in joint compound litigation, disclosed its role in the studies themselves, and submitted them to the technical rigors of scientific peer review by qualified scientists who were neither affiliated with nor selected by Georgia-Pacific."

Now owned by Koch Industries Inc., Georgia-Pacific has refused to turn over certain study-related documents to plaintiffs in thousands of asbestos cases from the five boroughs of New York City, which have been consolidated in a Manhattan court. The company contends the materials are protected under attorney-client privilege and as attorney work product. These protections can be forfeited, however, amid evidence that a client engaged in a "fraudulent scheme."

In a unanimous decision in June, a New York appeals court found reason to believe Georgia-Pacific had perpetrated such a scheme and ordered the company to hand over the documents to a judge for in camera inspection. Guest said Georgia-Pacific had not decided whether to appeal.

"There's something extremely



The Georgia-Pacific Tower in downtown Atlanta. Frank Kehren, Flickr CC

smelly about claiming attorney-client privilege for something that is being claimed at the same time as good science," said Sheila Jasanoff, a professor at Harvard University's John F. Kennedy School of Government who has written extensively

about litigation-driven research. "Legal confidentiality protections should not be placed around good science."

The company is trying to "rewrite history," said Linda Reinstein, co-founder of the Asbestos Disease Awareness Organization, a victims' advocacy group. "Georgia-Pacific funded junk science in an attempt to contest the known facts about asbestos and negate its culpability in this man-made disaster," said Reinstein, whose husband, Alan, died of mesothelioma.

## Decades later, a deadly killer

The dangers of asbestos were first noted more than a century ago by British factory inspectors. In the 1920s, writes Barry Castleman, an asbestos historian and environmental consultant, "The lung-scarring disease asbestosis was named and described in detail in reports of totally disabling and fatal cases." Reports of lung cancer among asbestos workers surfaced in the 1930s and mesotheliomas —incurable malignancies usually found in the membrane surrounding the lungs —began to appear in the 1940s.

It was around this time that drywall —and, by extension, joint compound —became exceedingly popular among builders trying to meet the demands of the post-war boom in America. "Low cost housing went into mass production in 1947-1948," researchers with New York's Mt. Sinai School of Medicine wrote in a 1979 article, "Wallboard sections were soon manufactured to fit standard room dimensions, enabling a worker to construct living quarters within a few hours. Drywall construction was also considered superior [to lathing and plastering] because of its adaptation to soundproofing and fire codes."

Manufacturers began fire- and heat-resistant asbestos to joint compound as a reinforcing agent. The practice continued well into the 1970s, even as evidence of the mineral's carcinogenicity mounted.

Georgia-Pacific got into the joint compound business relatively late, acquiring Bestwall Gypsum Co. in 1965. It sold Ready-Mix, a paste that could be applied directly to walls, as well as a dry mix, to which water had to be added. The products contained between 2 and 7 percent chrysotile -white -asbestos, mined in Canada. Both products were asbestos-free by 1977.

By the mid-1960s, investigators

like Mt. Sinai's Irving Selikoff had proved conclusively that asbestos was a cruelly efficient, though slowacting, killer. Having already found high rates of lung cancer, asbestosis and mesothelioma among asbestos insulation workers, Selikoff and his colleagues began looking at drywall installers.

In a series of papers published from 1975 to 1979, they reported that sanding, sweeping or mixing joint compound could yield fiber counts up to 12 times higher than what was allowed under federal law. "Fiber concentrations generated by sanding were similar to those measured in the work environment of asbestos insulation workers," they wrote.

In July 1977, having found "an unreasonable risk of injury of certain types of cancer, such as mesothelioma and lung cancer," the Consumer Product Safety Commission said it intended to ban asbestos-containing joint compound. In a letter to the commission's chairman, a Georgia-Pacific vice president said the company supported the ban, noting that "we ceased using asbestos in our product and switched to a substitute."

The ban became effective in January 1978. The damage inflicted by

asbestos, however, can take decades to appear. Microscopic fibers sent airborne by activities such as sanding dried joint compound can trigger lung cancer, asbestosis and mesothelioma. "There is no safe level of exposure known," says the Environmental Protection Agency.

The government crackdown came too late for Daniel Stupino, a transplanted Uruguayan who began renovating New York apartments part time in 1974 and earned extra cash that way for nine years.

In a 2011 trial, Stupino testified that he regularly used Georgia-Pacific joint compound, among other brands, to seal joints between sheets of drywall. When he sanded it, he said, it was "like a snow ... that penetrate[d] all over ... in my body, my head, you know, my clothes."

"What would you have done if you had seen a warning back then that breathing the dust from the joint compound is dangerous?" asked Stupino's lawyer, Jerry Kristal.

"Not use it," Stupino replied.

In the spring of 2010 Stupino began feeling "weak, tired," he testified. "I didn't know what [it] was, no idea. I thought it was stress."

A CT scan revealed fluid in his lungs. "He make a hole between two ribs and he put [in] a drain,"

Stupino said of his pulmonologist. What came out looked "almost like blood "

The spirit-breaking news came shortly thereafter. The doctor told Stupino, "You have cancer, and it's malignant. And I say, 'My God.' And [the doctor said], 'Remember what you did 20, 30 years ago. Remember what you did."

Stupino had a lung removed in January 2011, then endured chemotherapy and radiation treatments that were "like hell," he testified. "I have almost permanent pain."

He said he'd once dreamed of retiring at 65 and traveling with his wife. Anna.

"Can you tell us what your dreams are now?" Kristal asked.

"I don't have them," Stupino said. Stupino's case against Georgia-Pacific settled mid-trial. He died of mesothelioma on Dec. 14, 2012, just shy of his 64th birthday.

More than 107,000 people die of asbestos-related diseases each year, the World Health Organization estimates. "All types of asbestos cause lung cancer, mesothelioma, cancer of the larynx and ovary, and asbestosis (fibrosis of the lungs)," it warns.

In all, 55 countries — but not the United States — have banned all forms of the mineral.

Big business is still pushing back.

"Unfortunately," said John Dement, a professor at the Duke University School of Medicine who has studied the lung-ravaging effects of asbestos for 40 years, "litigationdriven research has really corrupted a lot of the science by presenting unbalanced information."

#### Tobacco playbook revised

The model for Georgia-Pacific's plan to lock away the details of scientific studies in its lawyers' offices had been developed decades earlier by the tobacco industry.

Cigarette manufacturers Brown Williamson Tobacco British American Tobacco Co., among others, were "very concerned about the threat of products liability lawsuits," researchers wrote in the Journal of the American Medical Association in 1995, and took steps to "avoid the discovery of documents that might be useful to a plaintiff ... These steps included efforts to control the language of scientific discourse on issues related to smoking and health [and] to bring all potentially damaging internal scientific documents under attorney work product and attorney-client privilege."

The so-called crime-fraud exception to attorney-client privilege played a key role in the \$6.6 billion settlement of Minnesota v. Philip Morris et al., in 1998. The case, one of several brought by state attorneys general attempting to recoup public funds spent on smoking-related illnesses, accused the tobacco companies of deceptive marketing and suppression of science. The Minnesota settlement was reached shortly after the judge ordered the defendants to release some 40,000 documents over which they'd claimed privilege.

In April 2005, Georgia-Pacific, which would be acquired by Koch Industries for \$21 billion later that year, hired John Childs as its chief litigation counsel. Childs had been in private practice in Chicago and Minneapolis and decided to "repot" himself in Atlanta, he told the publication Corporate Counsel in 2008. "My role," Childs said, "was to develop and design an in-house defense to the asbestos litigation."

On Aug. 22, 2005, Childs sent a letter to Stewart Holm, then Georgia-Pacific's director of toxicology and chemical management, who had been with the company since 1992. The letter confirmed that Holm had been "specially employed ... to perform expert consulting services in connection with pending and anticipated litigation concerning alleged exposure to asbestos."

Holm's duties, Childs explained, would be "separate and distinct from your duties as a regular employee of GP, and your work will be directed solely by GP's in-house counsel." Holm was to mark all his notes, memoranda and reports "PRIVILEGED AND CONFIDEN-TIAL — PREPARED AT DIREC-TION OF COUNSEL IN ANTICI-PATION OF LITIGATION."

In a court filing, Georgia-Pacific said there was nothing improper about the arrangement. "It is simply sound practice to insure that an inhouse consulting expert is aware of the protections available under the law and his duty to maintain the confidentiality of litigation-related work," the company said.

Holm, who'd done no previous work on asbestos, set about designing a research strategy. He began by reviewing the medical literature. "I found virtually no material whatsoever on worker exposure to joint compound resulting in disease," he testified in a 2011 deposition.

Now chief scientist for the American Forest & Paper Association, Holm declined an interview request, as did Childs.

At Childs's behest, Holm conceived a plan that required outside help to implement.

In January 2006, Georgia-Pacific contracted with David Bernstein, an American-born toxicologist based in Switzerland, to oversee animal tests. It also hired the consulting firms Exponent and Environ to gauge the accuracy of decades-old studies, like those done by Mt. Sinai, showing high fiber counts associated with the sanding and sweeping of joint compound.

The consultants were known for their litigation defense work. Exponent and Environ — paid \$3.3 million and \$1.5 million, respectively, by Georgia-Pacific — specialized in exposure reconstruction in product-liability lawsuits. Exponent scientists, for example, had been retained by automakers in litigation with mesothelioma victims who claimed they'd gotten sick after being exposed to asbestos during brake work. The scientists' position: grinding or otherwise tinkering with brakes couldn't produce enough fiber-laden dust to cause disease.

Bernstein, who declined to comment for this article, had directed asbestos inhalation experiments on rats for Union Carbide and a Brazilian mining company. The tests, he reported, had shown that fibers found in chrysotile, the only type of asbestos sold in recent years, were cleared quickly by the rats' lungs and therefore unlikely to cause cancer.

Bernstein, who had been a tobacco industry consultant before



Chrysotile asbestos, the only type imported to the United States. More than 2.3 million pounds entered the country from Brazil in 2012. Wikimedia Commons

turning to asbestos, discussed his "biopersistence" theory in a 2007 trial. There are two families of asbestos, he explained: chrysotile and amphiboles. Under the microscope, chrysotile fibers look like flimsy, rolled sheets of paper; amphibole fibers like solid rods. "The work I've done shows that [chrysotile] rap-

idly disintegrates in the lung, goes away, whereas the amphibole fibers persist and stay and cause disease," Bernstein said.

His findings have been welcomed not only by asbestos defendants, including Georgia-Pacific, but also by producers seeking to maintain or expand sales in developing countries, as the Center for Public Integrity reported in 2010.

By 2007, the Georgia-Pacific research program, approved by Childs, was in full swing. The first step was to try to re-create both wet and dry asbestos-containing joint compound since, Holm said in his deposition, no usable amounts of actual product could be located.

The re-created compound was applied to wallboard, allowed to dry and then sanded. The dust was shipped to a laboratory near Geneva, where Bernstein supervised a series of rat experiments. Lab workers wore "moon suits" to protect themselves from asbestos fibers.

In a pilot study, the rats were divided into three groups of 14 and confined in tubes for five days, six hours a day. The control group breathed filtered air. The second group breathed chrysotile fibers, the third a mixture of chrysotile and aerosolized joint compound particles.

The rats were killed after exposure and their lungs and pleural tissue were examined. The "chrysotile exposed lungs had the same appearance as the filtered-air controls," Bernstein and his co-investigators reported. No obvious lung damage, in Bernstein's view, translated to little or no cancer risk.

In a later experiment, one group of rats inhaled re-created Ready-Mix containing chrysotile. Another group inhaled amosite asbestos, part of the amphibole family. The rats exposed to chrysotile showed "no pathology in either the lung or the pleural cavity," Holm testified in his deposition. Those that breathed amosite showed "both inflammation as well as fibrosis in the lung, and showed inflammation also in the pleura."

In field and chamber studies, Exponent and Environ researchers tried to determine if intense worker dust exposures reported in the 1970s had been overstated.

Exponent scientists prepared and analyzed airborne samples of re-created joint compound using what they described as more modern methods than were available decades ago. Samples prepared with the older technique yielded fiber counts "significantly greater" than

those prepared with the newer one, they reported.

The implication: conditions for drywall workers in the 1970s may not have been as dire as the Mt. Sinai team indicated. An Exponent vice president, Angela Meyer, declined to comment on the firm's work for Georgia-Pacific.

Environ was hired to develop and validate models predicting breathing-zone concentrations of dust, Fred Boelter, a Chicago-based principal with the firm, said in a telephone interview. Such exposure estimates couldn't be made from data found in the 1970s-era literature and constituted an "important, missing piece of the puzzle," he said.

Environ's work "helped address questions about where the exposures occurred historically so we can answer questions today about disease or claimed injury," Boelter said, adding that "I don't really care whether I'm working for one side or the other" in litigation.

Asked whether Environ had been chosen to generate pre-determined results and infuse them into the scientific literature, Boelter said: "I can tell you that motivation would fall on deaf ears in my case and was not the motivation that influenced

what we sought to publish. Nobody had ever done what we had done, and that filled a gap within the literature."

The goal, he said, is to protect workers from hazards. "Bad science does not protect anybody," he said.

## Company research into scientific journals

The Georgia-Pacific consultants began publishing their findings in peer-reviewed journals in 2008. Jerry Kristal, a lawyer with New York-based plaintiff's firm Weitz & Luxenberg, noticed that Holm, the Georgia-Pacific toxicologist, was listed as a co-author on the first paper, in Inhalation Toxicology.

Kristal, who'd been trying asbestos cases since 1987, already knew of Bernstein's animal experiments on chrysotile, which had yielded good results for industry. Kristal served notice on Georgia-Pacific to depose Holm and produce documents underlying the joint compound studies.

The Holm deposition took place in Atlanta over three days in June 2011. Here, details of the secret research program were revealed.

Under Kristal's questioning, Holm acknowledged that the pre-

ferred method of testing fibers for carcinogenicity in humans is a twoyear animal inhalation study -not a five-day study of the sort overseen by Bernstein in Switzerland. Although the two-year test was endorsed by an expert government panel —of which Bernstein was a member —in the mid-1990s, Bernstein decided with the company's blessing that the five-day test would be "predictive of causing disease," Holm said.

He declined, on advice of his lawyer, to say why the longer study wasn't done.

Holm and Kristal debated whether proper disclosure had been made in the journal articles. The first paper on Bernstein's animal work, for example, said the research had been "sponsored by a grant" from Georgia-Pacific. In fact, Holm admitted, Bernstein was under contract with the company —initially for 350 and later for 400 Swiss francs an hour and ultimately was paid the equivalent of \$850,000.

There was no indication in the first paper and the three that followed, moreover, that Bernstein had testified as an expert witness for Georgia-Pacific in 2007. This led to a clarification, submitted by Holm to Inhalation Toxicology in

October 2011, and a public apology from the journal's publisher. Holm's clarification stated that the studies described in the articles had been commissioned by the company in response to joint compound litigation.

One Bernstein's papers, Kristal learned, was twice rejected by the journal Toxicological Sciences. A reviewer wrote, "The report will be helpful for those wanting to use or sell the commercial product (if such people still exist); otherwise, there is little new information provided by the paper."

Outside the legal arena, scientists were picking away at Bernstein's biopersistence theory, which holds that chrysotile fibers are removed so quickly from the lungs that they can't cause cancer.

David Egilman, editor-in-chief of the International Journal of Occupational and Environmental Health and a consultant for asbestos plaintiffs, wrote in 2011 that "the key question is not how long the fibers remain in the target organ, but rather, do the fibers persist long enough to induce the disease (e.g., induction of mutations when cancer is the outcome of interest)? The answer to this question is clearly yes."

an interview. Dement. of

Duke, said it's wrong to assume that cancer must be presaged by fibrosis, or scarring, of the lung, which Bernstein said he hadn't found in the rats. It's possible that chrysotile is less potent than amphiboles for production of mesothelioma, as Bernstein contends, but this doesn't mean chrysotile is safe, said Dement, who has testified for plaintiffs in asbestos cases. There doesn't appear to be any meaningful difference between the two in terms of causing lung cancer, he said.

In the late 1980s and early 1990s, while performing animal inhalation tests on man-made fibers for the North American Insulation Manufacturers Association, Bernstein and other investigators needed a "positive control" —a substance likely to produce harmful effects.

Their choice: chrysotile, which, according to a 1993 paper, triggered pulmonary fibrosis in the rats as well as mesothelioma and "significant increases in lung tumors."

Nonetheless, Bernstein maintains today that white asbestos is all but harmless if used under controlled conditions. After the Georgia-Pacific project, he was paid about \$200,000 by the International Chrysotile Association, a trade group for asbestos producers, to re-

visit the issue, the group's treasurer testified in a 2013 deposition.

His conclusion, which the association shared with skeptical health authorities, was published in *Critical Reviews in Toxicology* in January. While "heavy and prolonged exposure to chrysotile can produce lung cancer," Bernstein and his coauthors wrote, "low exposures ... do not present a detectable risk to health."

## Legal push to unveil secret research

The discovery battle stemming from the Georgia-Pacific research program began in April 2011, when plaintiff's lawyer Kristal sought a broad range of documents in connection with the upcoming Stewart Holm deposition. Georgia-Pacific produced some but withheld others, claiming they were privileged. Kristal pressed to get everything.

The matter went before Special Master Laraine Pacheco, who handled discovery disputes and pretrial settlement conferences in the New York City asbestos litigation. On June 15, 2011, Pacheco recommended that the trial judge, Sherry Klein Heitler, hold an *in camera review* of internal communications

and raw data underlying studies identified on a "privilege log" by Georgia-Pacific.

The company moved to vacate the recommendation. Heitler denied the motion.

"Georgia-Pacific cannot use its experts' conclusions as a sword while at the same time attempting to shield the public from information which affects the veracity of its experts' conclusions," the judge wrote in her decision on Dec. 7, 2011.

Heitler noted that a Georgia-Pacific lawyer, Mary McLemore, had offered input on some, and possibly all, of the 13 published articles. "The court is concerned that Georgia-Pacific's attorney would be involved in any discussions concerning the content of these purportedly objective scientific studies by Georgia-Pacific's consulting experts," she wrote.

Georgia-Pacific continued to resist. In a brief filed with the appeals court on Nov. 8, 2012, it called Kristal's fraud allegations "baseless" and accused him of embarking on a "boundless fishing expedition.

"There is no rule anywhere that would preclude a lawyer from reviewing, commenting on, or discussing the research of her scientific consultants," outside lawyers for Georgia-Pacific wrote. "Nor is there anything untoward about the fact that such research was eventually published in the scientific literature ... Publication in the scientific literature subjects work-product studies to the scrutiny of the independent scientific community, a process helpful to judges, juries, and the search for scientific truth."

Writing for the plaintiffs on Dec. 10, Weitz & Luxenberg lawyer Alani Golanski alleged that Georgia-Pacific had attempted to "seed" the literature with papers spawned by "methodologically skewed, litigation-driven research."

The company hired a "small army of pre-screened defense consultants," whose disclosures in their publications failed to note the major roles "special employee" Holm and lawyer McLemore had played in the shaping of the studies, Golanski wrote. Bernstein's characterization of his hourly contract as a "grant," he wrote, was intended to "perpetuate a fraud upon the public."

On June 6 of this year, the appeals court sided with Heitler in a 5-0 decision. Despite Holm's and McLemore's "extensive participation" in their development, "none of the [published] articles dis-

closed that [Georgia-Pacific's] inhouse counsel had reviewed the manuscripts before they were submitted for publication," the court found. "Two articles falsely stated that '[Georgia-Pacific] did not participate in the design of the study, analysis of the data, or preparation of the manuscript.'"

Holm's clarification to *Inhalation Toxicology* in October 2011 "failed to acknowledge its in-house counsel's participation and did not make clear" that Bernstein had testified as an expert witness for Georgia-Pacific prior to publication of his first joint compound paper in 2008, the court said. "The foregoing constitutes a sufficient factual basis for a finding that the relevant communications could have been in furtherance of a fraud."

Jonathan Ruckdeschel, a lawyer from Ellicott City, Md., who has sued Georgia-Pacific in Maryland and Florida on behalf of asbestos victims, called the court's ruling "incredibly rare. In my 16 years of practicing law, I have never seen a court enter an order like this."

The decision prompted an editorial this month in the *Annals of Occupational Hygiene*, which published two of the Exponent papers funded by Georgia-Pacific. "While

these revelations do not in any way prove that the data used in the two Annals papers were fraudulent or that the authors' conclusions were not legitimately based on the data, they do challenge the principles of free and open scientific inquiry," chief editor Noah Seixas wrote, noting that the journal was reviewing its conflict-of-interest policies for authors.

Thus far, Georgia-Pacific hasn't used any of the 13 published articles in the New York asbestos litigation, nor has it asked any of the authors to testify about them.

The extent of the company's asbestos liabilities no longer can be found in Securities and Exchange Commission filings; Georgia-Pacific was taken private after being acquired by Koch Industries almost eight years ago. Spokesman Guest declined to say how many cases are pending.

Ultimately, Georgia-Pacific may be forced to share everything with the New York plaintiffs. Should that happen, its effort to "deny the undeniable," as Ruckdeschel put it, could come into sharper focus.

The appeals court "ordered that the rock be lifted up," he said, "so we can see the true extent of the manipulation of science."



The Goodyear chemical plant in Niagara Falls, N.Y., has been plagued for decades by high rates of bladder cancer within its workforce. Matthew Leonard/WXXI

# High bladder cancer rate shrouds New York plant, exposing chemical hazards in the workplace

By Jim Morris
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Ray Kline, it's said, bled Goodyear blue. Compact and laconic, Kline signed on as an operator at the Goodyear chemical plant here in 1960 and logged just

short of 40 years. He routinely worked six days a week, 12 hours a day, retiring in 1999 as head of maintenance.

"I made a good living," Kline said in the dining room of his comfortable home in Lewiston, N.Y., two Workers at the Goodyear plant came to fear "the ginch" — bladder cancer. Federal officials have confirmed 50 cases of the disease through 2007 — nearly three times the number expected for the general population of New York State.

The unofficial tally to date is 58 cases.

blocks from the Niagara River — betraying little bitterness over the price his family paid for economic stability.

Kline, 75, has endured two bouts of bladder cancer. Strong evidence suggests the disease was work-related.

In a yet-to-be published study, federal health investigators have confirmed 50 cases of bladder cancer among plant employees through 2007, nearly three times the number that would have been expected in the general population of New York State. The unofficial tally to date, compiled by a lawyer for some of the cancer victims, is 58 cases.

The likely trigger in most instances, investigators concluded, was a chemical, still used by Goodyear and others, called ortho-toluidine.

The disease made its appearance in 1972 and continues to plague this decaying pocket of western New York. Workers at the 67-yearold plant, a collegial place that sustained generations, called it "the ginch." Those who survived it fear its return. Those who avoided it wonder when their luck will run out. Many question why the chemical's most prominent manufacturer, Du-Pont, took so long to issue warnings.

The long-running episode underscores the limits of regulation and points up the insidious nature of occupational illnesses, which by one estimate take more than 50,000 lives in America each year.

It's a cautionary tale at a time when more than 80,000 chemicals, many carrying unknown or little-understood health effects, are on the market in the United States. Workers can become unwitting test subjects, made vulnerable by employers that fail to act on scientific knowledge or, in extreme cases, suppress the truth.

Three years before Kline landed at Goodyear, the plant began making Nailax, an antioxidant that keeps tires from cracking. Three U.S. companies supplied a key ingredient, ortho-toluidine, at various times from the 1950s into the 1990s; DuPont supplied Goodyear for the longest period, almost four decades.

By 1955, records show, DuPont knew the chemical caused bladder cancer in laboratory animals and protected its own workers from it. But it didn't issue warnings to Goodyear and other customers until 1977, the year Kline's son-in-law, Harry Weist, started at the Niagara Falls plant.

It would be another 13 years before Goodyear would take significant steps to reduce exposures to ortho-toluidine in the plant. By then, the outbreak of bladder cancer was under way.

Kline was case No. 21, diagnosed in 1997. Weist was No. 37, diagnosed in 2004.

"None of us are simple-minded," said Weist, 57, who worked at the plant for 34 years. "If we knew this stuff was bad and we were getting exposed to it back in the day, we would have protected ourselves."

In a statement to the Center for Public Integrity, Goodyear said it

"takes the issue of ortho-toluidine exposure at the Niagara Falls plant very seriously. We are deeply concerned and continue to be committed to actions to address the issue."

DuPont said it "conducts its business in accordance with the highest ethical standards and in compliance with all applicable laws to ensure the safety and health of our employees, our customers, and the people of the communities in which we operate. Our experience with orthotoluidine was no exception."

Its communications about the chemical were, DuPont said, "commensurate with the state of scientific knowledge" at the time.

Steve Wodka, a lawyer in Little Silver, N.J., maintains DuPont could have told Goodyear how to use ortho-toluidine safely by 1957, when Goodyear's rubber chemicals division opened in Niagara Falls.

"There were so many warning signals," said Wodka, who has sued DuPont and other ortho-toluidine suppliers on behalf of 24 bladder cancer victims from Goodyear and three from the now-shuttered Morton International chemical plant in Paterson, N.J. "If people had simply heeded them, there would have been a lot of lives saved."

The disease cluster "wouldn't

have been detected by the medical community" had the Oil, Chemical and Atomic Workers union not pushed for a federal investigation at Goodyear, Wodka said. "It would have just blended into the background."

#### Goodyear 'social club'

The Goodyear plant in Niagara Falls opened in 1946 as the city, blessed with cheap hydroelectric power from the Niagara River, was becoming a manufacturing behemoth. Factories lined Buffalo Avenue—B.F. Goodrich, Olin Mathieson, International Paper. By the 1950s, word was, you could quit a job in the morning and be working in a new place that afternoon.

Ray Kline came to Goodyear in January 1960, having migrated north from Pennsylvania a year or so earlier and knocked around places like Nabisco and Autolite Battery. Kline was hired as an operator in Department 145, where polyvinyl chloride (PVC) resin was made in reactors. He helped clean the reactors, chipping away at the hard, white plastic with a hammer and chisel. He also helped bag the PVC powder.

Nine years later Kline transferred

to maintenance, which frequently took him into Department 245, the rubber chemicals division. Here ortho-toluidine, a yellowish liquid, was pumped into reactors from tanks outside and used to make Nailax, which came out looking like dark chocolate chips and was bagged for shipment to Goodyear tire plants.

"The 245 reactors — after all the mixture had taken place, you always had sludge and crap in the bottom," Kline said. "You had to go in and clean it out." The company's method of determining overexposure was crude, he said: Workers were told to go outside when their fingernails and lips turned blue.

Harry Weist, Kline's gregarious son-in-law, said Goodyear was like a "social club," where fathers got jobs for sons, workers tormented one another with practical jokes, football pools were managed and hockey outings organized. At its peak the plant employed about 300 union workers, who earned solidly middleclass wages, sometimes better. People stayed.

The plant was also a breeding ground for disease.

By the early 1970s, three workers from Department 145 — the PVC unit, which closed in 1996 — had died of a rare form of liver cancer

angiosarcoma, which researchers blamed on a sweet-smelling chemical called vinvl chloride.

When Kline worked in Department 145 in the 1960s, his wife, Dottie, bore two children, John and Donna, with severe birth defects in consecutive years. John, who was missing much of his brain and skull, condition called anencephaly, lived for one day. Donna, born with a brain fluid buildup known as hydrocephalus and spina bifida, a spinal cord defect, survived six weeks.

Dottie Kline believes her husband's work around vinyl chloride caused both children's defects, a theory with some scientific support.

In 1975, Peter Infante, then an epidemiologist with the Ohio Department of Health, reported significant excesses of birth defects in three Ohio cities with PVC production sites. His study, he wrote, "demonstrated that malformations involving the central nervous system in those three communities were particularly high," though they couldn't be pinned to a particular chemical.

Infante, who went on to work for two federal agencies, later emphasized that it was important to assess "not only the effects of [vinyl chloride] as transmitted through the female, but also the potential for any

In 1975, Peter Infante, then an epidemiologist with the Ohio Department of Health, reported significant excesses of birth defects in three Ohio cities with PVC production sites.

adverse effect that may be transmitted through the male."

The research didn't come in time for the Klines. "It still hurts to talk about it." Dottie said.

In 1986, Ray Kline nearly died of a heart attack at 48 after being struck in the chest by a piece of equipment at work. Bladder cancer came on in 1997 and reappeared a year later. "He is still getting suspicious cells to this day," Dottie said.

Ray said he considers it all "water under the bridge. I don't get too excited about it." He had to be coaxed by his family into bringing a lawsuit against DuPont, thinking it might reflect badly on Goodyear.

"Honestly, there's drawbacks to any place you work," he said. "You just need to be aware of them, and we weren't aware of them at the time."

His wife is not as forgiving.

"He's been through a lot because of Goodyear," Dottie said. "Sure gave us a good living, but I don't know that it was worth what we went through with our kids and what he's been through."

Asked about the Klines' ordeal, Goodyear said, "The health and safety of our associates has always been at the top of our agenda. That includes all operations at the Niagara Falls facility."

## Recipe for cancer

After nearly three years in the Air Force, Harry Weist started in Department 145 — vinyl — at Goodyear in December 1977. "My mom was a switchboard operator there and I said, 'Give me a job.'"

Weist, who married Ray Kline's daughter, Diane, in 1980, spent a decade in Department 145. He ventured at times into Building C-2, the recycling area of the rubber chemicals division. Here liquid waste drained from the Nailax reactors, including ortho-toluidine, was collected. Weist's path to becoming bladder cancer case No. 37 may have begun in C-2.

In those days, and for years after, some workers handled the vilest of compounds wearing only T-shirts, jeans, ball caps and cotton gloves. The most-despised task was cleaning the Sparkler filters, which removed iron filings from the batches of Nailax. "You'd open it and you'd have orange fumes coming off it," Weist said. "It was really nasty." The fumes were rich with ortho-toluidine.

There were other, bigger sources of exposure. For 31 years, Goodyear weighed ortho-toluidine — pumped into Building 32, the Nailax production area —in open tanks, posing an inhalation risk. There were frequent spills, allowing for direct contact with the chemical and absorption through the skin.

In the late 1970s, amid mounting worries about chemicals in the workplace, the Oil, Chemical and Atomic Workers —since absorbed by the United Steelworkers —hired physicians to investigate conditions in union plants. Dr. Christine Oliver of Boston arrived at Goodyear in Niagara Falls in March 1979; once inside the plant, she learned of an apparent cluster of premature deaths from heart disease in Department 245. There also seemed to be a bladder cancer problem, Oliver was told.

Two years after Oliver's visit, Rod Halford, then president of OCAW Local 8-277, wrote a letter to plant manager James Pearson. "It has

come to our attention that four current Goodyear employees have developed cancer of the urinary bladder," Halford's letter began. He identified two chemicals of concern: ortho-toluidine and aniline, a raw material in Kagarax, which helped speed the rubber curing process and is no longer made by Goodyear.

Both were suspected animal carcinogens, Halford wrote, though only ortho-toluidine appeared to target the bladder. He asked Pearson for air monitoring and worker mortality data, among other things.

Pearson replied that worker exposures to the chemicals were "well below" allowable limits, and that neither of the two mortality studies conducted in the plant to date had addressed "cancer of the urinary tract specifically."

More than three years before Pearson wrote this letter, DuPont had informed Goodyear managers that while there was no evidence ortho-toluidine had caused cancer in any DuPont employees, it had induced tumors in rats and mice during a study by the National Cancer Institute.

Attached to DuPont's letter was a material safety data sheet it planned to begin using. It included the following warnings: "O-toluidine is

cyanogenic [turns the lips and nails blue] and can be absorbed through the skin & respiratory tract, exposure symptoms may include bluish lips or fingernails, headache, nausea, or fatigue. Product may cause cancer in animals. Direct body exposure to fumes or liquid must be prevented."

Current and former Goodyear workers say this information wasn't shared with them at the time. Halford would become bladder cancer case No. 18 in 1992.

There was limited activity in the seven years following Halford's 1981 letter. Wodka, who'd been a legislative assistant and staff representative in the OCAW's Washington office for 12 years, left the union to get his law degree.

By 1988, after Harry Weist had transferred to maintenance, local OCAW officials knew of eight workers in Niagara Falls with bladder cancer. Wodka alerted the OCAW international, which requested an investigation by the National Institute for Occupational Safety and Health -NIOSH, part of the Centers for Disease Control and Prevention.

Things were worse than expected. NIOSH epidemiologists found 13 cases of bladder cancer in the plant, nearly four times the incidence rate in the general population. They documented a 27-fold increase in the disease among workers who had spent at least 10 years in Department 245. Suspicion fell on ortho-toluidine and, to a lesser extent, aniline.

Elizabeth Ward was the lead NIOSH investigator for five years. Now national vice president for intramural research at the American Cancer Society, Ward believes the cancer surge at Goodyear was largely preventable.

"There was evidence of the carcinogenicity of ortho-toluidine in animals, but the plant had not really taken sufficient precautions to reduce exposures to the workforce," Ward said. "It really was a case of not heeding the evidence."

Goodyear said, "We have followed effective industrial hygiene practices for decades in regard to this chemical." Only one case of bladder cancer, it said, involved a worker who started at the plant after 1990.

#### Casualties

This is small comfort to people like Dick Prato. Prato started at Goodyear in 1963 and worked in Department 245 for 39 years. He was diagnosed with bladder cancer after urinating blood on a camping trip in 1995, making him case No. 19. The ginch came back in 1997 and 2007.

Prato rode out six weeks of chemotherapy in 1995 and another round two years later. "Every Monday I'd get the [drugs] shot up in my bladder," he said. "You'd get that stuff at 8 in the morning and urinate it out by 1. You were wrapped up in a blanket, freezing to death, and yet sweat was just pouring off you. It was like the flu."

The cancer lay dormant for a decade. "Then I went in to have my regular check-up," Prato said, "and there it was."

He underwent more chemo. At 72, he harbors a persistent, low-grade anxiety. "Sometimes," he said, "I don't even wait a year" to get a cystoscopy, an exploratory procedure, usually done annually, in which a tube fitted with a lens is inserted into the urethra. "I get scared and get scoped after nine months." The aim, for anyone in his position, is to keep the cancer from breaching the bladder wall and metastasizing.

Bladder cancer is often survivable if caught early. Once unleashed, it's horrific.

During the last year of his life, Joseph Nicastro, a retired Morton International worker who died in 2010, was punctured with tubes and perpetually sickened by chemo and radiation treatments.

"It was pure hell," said his wife, Pam, who lives in Ocean Township, N.J.

Pam and Joe had met in 1993 and were married a year later. Joe was an operator at the Morton plant in Paterson, where ortho-toluidine was used to make dyes for gasoline. "He used to speak every once in a while about [co-workers] who had cancer," Pam recalled. "I'd say, 'I hope you're wearing your protective gear.' And he'd say, 'Oh yeah, I'm wearing it.' He showered every day before he left that plant. I think you had to."

Joe was a "big, strong guy," his wife said. "He had a presence about him." In late 2007, when he was 64, Joe began complaining of leg and shoulder pain. "We just thought it was the aches and pains of aging," Pam said. By early 2008, he was having trouble urinating. One day a "big blood clot" came out, Pam said. A cystoscopy detected "a mass so large it was outside the bladder wall. It was in his muscle."

The cancer had spread to Joe's bones. He lived another 22 months and weathered treatments that sometimes seemed worse than the disease itself. Steroids made him anxious

and aggressive; chemo made him violently ill. At one point "the skin was literally peeling off his butt" from radiation therapy, a condition exacerbated by chronic diarrhea, Pam said. "The man was trying to sit on a toilet with open wounds." Joe fell one time when Pam was out; she returned to the couple's townhouse to find him on the floor, covered in feces.

Pam became Joe's full-time caretaker, flushing the nephrostomy tubes that drained his kidneys and emptying the bags that collected his urine. She helped him go to the bathroom, gave him sponge baths, took him to countless doctor visits and tried to boost his flagging spirits. "He was so scared. His mind was racing," she said. "He would always say he was sorry to me. I would say, 'Why are you sorry? You had to make a living.' "

Joe spent the last week and a half of his life in hospice care. He died at 3 a.m. on March 4, 2010. He was 66.

Pam sued DuPont, claiming it failed to warn Morton —which closed the Paterson plant in 2002 —about the cancer-causing properties of ortho-toluidine. The case was settled for an undisclosed sum just before a scheduled trial in October 2012.

Pam said she used to be "furious" at DuPont, though her anger has

abated somewhat. "I just felt like every time I would see [DuPont's] lawyers, it was no big deal to them," she said. "It made me sick."

DuPont said it "settled lawsuits related to ortho-toluidine in order to avoid a long and drawn-out litigation process. DuPont's decision was not, nor should it be construed as, an admission of liability."

## Decades of alerts, DuPont's knowledge

DuPont began making ortho-toluidine -part of a family of compounds known as aromatic amines, used in the rubber and dye industries —at its sprawling Chambers Works in southern New Jersey in 1919. More than two decades earlier, in 1895, a German physician named Ludwig Rehn had reported finding bladder cancer in three workers at a dye factory. Rehn had documented 38 cases in seven factories by 1906; German law eventually would force such operations to improve ventilation, provide workers with protective clothing and mandate post-shift hot baths.

In a 1921 paper, the International Labour Office in Geneva summarized the findings of Rehn and others in Europe, deeming it "absolutely necessary that in factories in which workers are exposed to the dangerous action of aromatic bases, the most rigorous application of hygienic precautions should be required." Such precautions, it predicted, "will assure at the end of a few years the diminution and even the disappearance of the disease."

Yet hundreds of bladder cancer cases emerged from DuPont and another early manufacturer of aromatic amines, Allied Chemical in Buffalo, in the coming years. Chambers Works, which opened in 1917, had recorded 489 cases by 1991, 453 of which DuPont viewed as "occupational" in nature, according to a company memo.

The alerts kept coming.

In 1934, G.H. Gehrmann, then DuPont's medical director, noted the importance of giving highly exposed employees at Chambers Works annual cystoscopies. Medical examinations, he wrote, should "continue all through the entire period of employment, and in the case of men exposed to bladder tumorforming chemicals, continue until death removes the final possibility of tumor development."

In 1940, two researchers at Osaka Imperial University in Japan reported that ortho-toluidine caused benign tumors in the bladders of rabbits that had been injected with the chemical and rats whose skin had been painted with small amounts of it. They took this as evidence that the development of cancer in humans "can be prevented by keeping the skin as clean as possible."

In 1948, Wilhelm Hueper of the National Cancer Institute warned in a review of occupational carcinogens that ortho-toluidine was "capable of producing bladder tumors" in animals. Hueper had published on the subject as early as the 1930s, when he was a toxicologist at Du-Pont's Haskell Laboratory for Toxicology and Industrial Medicine.

In a deposition a half-century later, the lab's retired director, John Zapp, dismissed Hueper, a German immigrant, as a "difficult, troublesome employee wherever he worked."

Zapp admitted knowing by 1955 that ortho-toluidine had caused tumors in rodents. "Look, I don't care if a chemical gives cancer to rats if it doesn't bother the humans," he testified in his deposition. "And I think that the rat is a poor indicator for bladder tumors."

Zapp acknowledged that DuPont had the capacity to perform its own study of ortho-toluidine at the time but elected not to. It already had flagged another aromatic amine It was also in 1955 that
Monsanto, which had
been buying orthotoluidine from DuPont for
at least 15 years, reported
that some exposed
workers had seen blood
in their urine. Neither
this development nor the
animal studies created a
stir at DuPont.

made at Chambers Works, betanaphthylamine, as the biggest cancer threat to workers; that chemical, Zapp said, was gone from the plant by 1957.

It was also in 1955 that Monsanto, which had been buying ortho-toluidine from DuPont for at least 15 years, reported that some exposed workers had seen blood in their urine. Neither this development nor the animal studies created a stir at DuPont. Ortho-toluidine already was classified as a "no-contact chemical" at Chambers Works based on its acute effects, Zapp explained.

"Even if we had proved that orthotoluidine was a carcinogen, I think our workers would have been protected," he said. Indeed, a photograph in Modern Occupational Medicine, a 1954 textbook edited by Zapp and two other DuPont employees, shows a worker in a "Chem-Proof Air Suit" developed at Chambers Works.

Goodyear began buying orthotoluidine from DuPont and Allied (later acquired by Honeywell) in 1957. A third supplier, Mississippibased First Chemical, entered the picture in 1967. Three years later a Russian study found an excess of bladder cancer among workers exposed to the chemical; the study was translated into English for both Allied and DuPont.

In the United States, the National Cancer Institute found that orthotoluidine triggered bladder tumors in rats and mice. DuPont followed the work closely. In a confidential 1975 memo, Haskell Lab's assistant director, Blaine McKusick, wrote that faults could be found with the NCI experiment but suggested DuPont "regard ortho-toluidine as a suspected carcinogen" nonetheless.

DuPont waited another two years to send a letter to Goodyear and other customers, alerting them to a "possible carcinogen problem" with the chemical. The letter had little impact at Goodyear, said the president of the company's bargaining unit at Steelworkers Local 4-277, Ed

Polka, who started at the Niagara Falls plant in 1979, the year the NCI study was published.

Workers had "no inkling" of ortho-toluidine's potency, said Polka, who bagged Nailax his first five years. "DuPont knew beaucoup years earlier. None of this information ever came to us. It was a dirty little secret." Goodyear's position, he said, was, "You don't need to worry about it."

In its statement, DuPont said it was on the "cutting edge of the available toxicology and epidemiology studies conducted with orthotoluidine" during the 90 years it and its wholly owned subsidiary, First Chemical, made the compound. "DuPont's communications for orthotoluidine were commensurate with the state of scientific knowledge, the applicable laws and regulatory standards and consistently reflected the scientific community's consensus on the potential health effects associated with the product."

## 'Still a question' for Goodyear

When did Goodyear know? In a 1991 deposition, the company's former medical director, Dr. Clifford Johnson, testified that when the union alerted the company to the four bladder cancers in Niagara Falls in 1981,

there was "still a question" in his mind about whether ortho-toluidine caused bladder cancer in humans.

"Did you notify any of the suppliers of ortho-toluidine to the Niagara Falls plant of this incidence of bladder cancer?" union lawyer Wodka asked.

"No, I did not," Johnson replied. He hadn't been convinced there was a looming crisis in Department 245. "I had no way of knowing whether four cases was a high number," Johnson testified; he said he'd made no attempt to find out.

Dr. Steven Markowitz, a Steel-workers and former OCAW consultant, said Goodyear should have acted after the 1979 NCI study was published.

"Bells should have gone off about restricting exposure and about looking at human epidemiology — is there a problem?" said Markowitz, a professor of occupational and environmental medicine at New York's Queens College, a medical expert in Wodka's litigation and a co-author of the first NIOSH paper on the outbreak. "That was very strong evidence because it wasn't just any old animal carcinogen. The NCI study showed tumors in the same organ as in humans — the bladder — in female rats."

Goodyear said it "adjusted its systems and processes" when it learned ortho-toluidine might be problematic.

In fact, it made improvements at the Niagara Falls plant in the 1980s, upgrading exhaust systems and encouraging workers to wear protective gear instead of T-shirts and jeans. The policy was loosely enforced, Polka said. "The older guys were like, 'You know what? I don't want to be bothered with it. I've worked with it all this time and I got no problems. Leave me alone.' Goodyear's attitude was, 'We're making it available to you. Put it on if you want.'"

When NIOSH came into the plant in 1988 and confirmed the bladder cancer excess, people took notice. Goodyear clamped down in the early 1990s, making mandatory the wearing of chemical-barrier suits and respirators for workers performing certain jobs and fortifying pipes and pumps to keep orthotoluidine from leaking. Workers who had to clean the rancid Sparkler filters were required to put on air-fed "astronaut" suits, not unlike the ones DuPont began supplying to its own people decades earlier.

Despite these measures, enormous harm already had been done. Dozens of workers developed bladder cancer from the 1970s on. Among them was a maintenance worker known for his obsession with cleanliness.

"That guy was so meticulous he'd wipe his chair in the lunchroom before he sat down," Goodyear retiree Bob Dutton said. "Later on we find out he's got the ginch. He's gone. He died of a brain tumor."

## 'Antiquated' standards, few inspections

Ortho-toluidine is no longer made in the United States. The four domestic users —Goodyear, Monsanto, Lanxess Corp. of Pittsburgh and AC&S Inc. of Nitro, W.Va., according to the Environmental Protection Agency — import it from countries such as Germany, China and India. The compound is on the European Chemicals Agency's version of a blacklist, along with 143 other "substances of very high concern." The International Agency for Research on Cancer considers it a Group 1 — known — human carcinogen.

Monsanto brought in more than 23 million pounds of ortho-toluidine last year to make herbicides in Muscatine, Iowa. In a statement, spokesman Thomas Helscher wrote that the company is "aware that orthotoluidine is classified as a probable human carcinogen by OSHA" — the Occupational Safety and Health Administration.

The raw chemical, he wrote, "is not handled at any of Monsanto's facilities." It's shipped first to an intermediate manufacturer in Texas, which converts it to a more benign material that then goes to Iowa.

Both Monsanto and the intermediate manufacturer — which Helscher declined to name, citing a confidentiality agreement — take care to protect workers from ortho-toluidine exposure, he wrote. Levels of the chemical in the Texas plant were "undetectable" during air monitoring earlier this year.

Still, air concentrations of orthotoluidine in Goodyear's Department 245, even at the height of the cancer scourge, were mere fractions of the federal limit of 5 parts per million, according to NIOSH. That limit, like hundreds of others, hasn't been updated by OSHA since 1971.

In 1974, OSHA issued a broad standard covering 14 carcinogens, including aromatic amines such as beta-naphthylamine. The standard required a long list of protective measures; impervious gloves, boots and air-supplied hoods had to be worn by workers in case of spills or

during maintenance, for example, to keep the chemicals from soaking through the skin.

Ortho-toluidine wasn't included. Workers kept dying.

In an unusually candid news release in October, OSHA, boxed in by industry legal challenges, restrictive court decisions and hostile politicians, acknowledged that its "exposure standards are out of date and inadequately protective for the small number of chemicals that are regulated in the workplace." It urged employers to switch to safer alternatives or voluntarily adopt more stringent limits "since simply complying with OSHA's antiquated [ones] will not guarantee that workers will be safe."

Rigid policing seems out of the question. OSHA and its state partners must monitor nearly 8 million workplaces; together they have about 2,400 inspectors. "It would take us close to 100 years to inspect every workplace once," OSHA chief David Michaels said in November.

Goodyear, for its part, said it has "systems and procedures in place for the safe handling of ortho-to-luidine, which include double seal pumps, dedicated shower rooms, ventilation, and the required use of personal protective equipment."

The company said it does biannual bladder screening for all active and retired employees. It also does pre- and post-shift urine testing for workers to gauge how much orthotoluidine is being absorbed through the skin during the workday.

Wodka, however, had to bring a class-action lawsuit to force Goodyear to extend the screening program to retirees and other former employees. And urine testing for workers is infrequent, with no guarantee it will continue.

Older members of Steelworkers Local 4-277 speak of Wodka — 64, with a salt-and-pepper beard — with reverence. "Ask Steve," they say when their memories fail them.

Wodka remains a union stalwart, representing the local. He joined the staff of the Oil, Chemical and Atomic Workers as an intern in 1969. He and a *New York Times* reporter were to meet nuclear whistle-blower and union organizer Karen Silkwood in Oklahoma the night she died in a car accident in 1974. Many believe Silkwood, an employee of Kerr McGee Corp. who'd been contaminated with plutonium, was deliberately run off the road.

In 1983, as a legal assistant in the Washington office of the plaintiffs' firm Baron & Budd, Wodka worked

on the first bladder cancer case out of Goodyear —Henry "Hank" Schiro, who was diagnosed in 1972 and died at 57 in 1986. He filed his first lawsuit against DuPont, Allied and First Chemical in 1987 on behalf of Goodyear worker Richard Sullivan, victim No. 3. (Workers' compensation laws generally bar employees from suing their employers).

"My goal," Wodka said, "is to see things through to the end ... to make sure that workplace is made safe before my career is up."

Today the Goodyear plant has only 43 union workers. Part of Department 145 — the old PVC section — has been torn down; the rest is used as a warehouse.

The plant still moves a lot of product with its stripped-down crew, Harry Weist said. A sign outside reads: "TAKE SAFETY TO THE EXTREME. WE MUST. WE WILL."

## A town in decline, fear of 'the ginch'

Niagara Falls itself is in decline, a seedy cousin to its tourist-mecca namesake across the river in Ontario. Gone are Great Lakes Carbon, Electro Metallurgical and other plants that provided middle-class jobs for decades.

Downtown is mostly bereft of life, save for the Seneca Niagara Casino and Hotel on 4th Street. A half-mile west of the tower, mist rises from the 180-foot-high American Falls and, beyond that, the slightly lower but much wider Horseshoe Falls in Canada. "You've got this beautiful attraction," Weist said during a drive through the city. "I can't believe you can't do something with this."

Weist and his father-in-law, Ray Kline, deliver auto parts to keep busy in retirement and make extra money — especially important for Kline, whose health benefits, like those of other former managers, were eliminated by Goodyear.

Both have settled claims against DuPont. Both have their bladders scoped annually for cells that could signal the ginch's return.

"You always worry," Weist said. "Is it going to come back?" ■

This story was reported in collaboration with WXXI Public Broadcasting and the Innovation Trail in Rochester, N.Y.

# Industry muscle targets federal 'Report on Carcinogens'

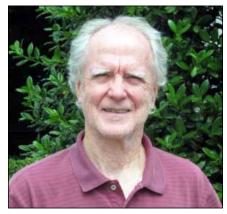
By Jim Morris and Chris Hamby Published Online: July 30, 2013

RESEARCH TRIANGLE PARK, N.C. — In the 1980s, toxicologist James Huff was a bane of industry's existence.

A blunt Philadelphian, Huff helped supervise animal tests here at the National Institute of Environmental Health Sciences, part of the National Institutes of Health. Mice and rats were dosed with chemicals, and Huff and his colleagues publicized the results when tumors sprouted. People needed to know about "blowout" carcinogens, Huff said. He didn't care who was upset.

Now, three decades later, Huff cites industry's growing and "perverse" influence on science. "They're more clever, more sophisticated," said Huff, 75, who retired this year but remains a guest researcher at NIEHS. "They spend a lot of time in Congress."

Increasingly, industry is targeting Huff's former employer and its par-



James Huff cites industry's growing and "perverse" influence on science.
Jim Morris/Center for Public Integrity

ent, the Department of Health and Human Services — in particular, HHS's *Report on Carcinogens*. Two lobby groups sued the agency after two widely used chemicals were listed in the report. In a victory for

industry, lawmakers mandated additional, ongoing scientific reviews of the document. And, a trade association representing makers of fiberreinforced plastics claimed credit for a congressional hearing last year that evolved into an open airing of industry grievances.

All this comes while the chemical industry is building muscle: In the midst of a prodigious expansion due to the availability of cheap natural gas, it spent \$55.7 million on lobbying in 2012 — twice what it spent 10 years earlier, according to the Center for Responsive Politics.

The push may be having an effect. In June, for instance, two Republican members of the House Committee on Science, Space and Technology sent a letter to the director of the NIH, complaining about a journal article by NIEHS Director . Linda Birnbaum.

The article — "When environmental chemicals act like uncontrolled medicine" - was published in the peer-reviewed Trends in Endocrinology & Metabolism. Birnbaum cited striking increases in diseases such as prostate cancer and breast cancer over the past 40 years and concluded, "Clearly we must look to the environment as the primary cause of such increases because the



NIFHS Director Linda Birnbaum National Institute of Environmental Health Sciences

human genome has not changed over the same time period."

Her conclusion did not sit well with Reps. Paul Broun of Georgia and Larry Bucshon of Indiana. "Some of Dr. Birnbaum's statements sound less like a presentation of scientific data and more like an opinion," Broun, who chairs the Science Committee's Subcommittee on Oversight, and Bucshon, who chairs the Subcommittee on Research, wrote in a June 13 letter to Birnbaum's boss, NIH Director Francis Collins.

It was unclear, they contended, "whether the article represents Dr.

"The tenor of the hearings in the last two years has been to attack scientists — particularly environmental scientists like Linda Birnbaum on behalf of the industries that are affected."

- Brad Miller, a former congressman who served on the Science Committee for a decade until January 2013

Birnbaum's personal views or reflects Administration policy," raising "questions about the NIH commitment to transparency."

The Republican-controlled Science Committee is facing transparency questions of its own. Critics, including a former member, say the committee has become a surrogate for industries that feel threatened by researchers like Birnbaum, who told the Center for Public Integrity her article was "appropriately cleared" by NIH officials.

"The tenor of the hearings in the last two years has been to attack scientists — particularly environmental scientists like Linda Birnbaum on behalf of the industries that are affected," said Brad Miller, a former Democratic congressman from North Carolina who served on the committee for a decade until January 2013. "I think it does affect the

agencies' conduct. They try to do their analyses in a defensive crouch because they are anticipating criticism for everything they do."

Birnbaum, who oversees NIEHS's National Toxicology Program, which has tested nearly 2,900 chemicals for carcinogenicity and other health effects, has become a favorite target. Miller, now with the liberal Center for American Progress, said he suspects Broun and Bucshon wrote their letter "because her scientific work has caused some discomfort" in industry circles.

Broun is a physician and U.S. Senate candidate who has called manmade climate change a "hoax" and characterized evolution and the Big Bang theory of the universe's early development as "lies straight from the pit of hell." Bucshon, also a physician, is a self-described "long-term friend of coal." Since 2010, each has

received donations from political action committees for coal, oil and chemical companies.

Both declined interview requests from the Center.

In a written statement, Science Committee Chairman Lamar Smith, R-Texas, said the committee "invites a balanced panel of witnesses from across the spectrum" to hearings and encourages "an open, public and full discussion of issues." Smith has received contributions from oil and chemical company PACs; the money, he said, had no impact on his actions.

#### 'Show trials'

Miller maintained that a number of committee hearings since the GOP takeover of the House in 2011 have been "show trials" designed to intimidate government scientists and promote pro-business positions.

On April 25, 2012, for example, the Subcommittee on Oversight (then called Investigations and Oversight) and the House Committee on Small Business's Subcommittee on Healthcare and Technology convened to examine the science behind the Report on Carcinogens, a congressionally mandated document updated every few years by the National Toxicology Program.

The hearing turned into a gripe session for proponents of styrene, a chemical used in automobile and boat parts, rubber carpet backing, disposable cups and other products, that had appeared for the first time in the report the year before. Styrene had been listed as "reasonably anticipated to be a human carcinogen," based on studies that found excesses of leukemia and lymphoma among workers exposed to the chemical and mouse studies that produced lung tumors. An industry group, the Styrene Information and Research Center. already had sued the Department of Health and Human Services over the listing, and its allies were eager to vent in Room 2318 of the Rayburn House Office Building.

Broun opened the hearing by saying that "concerns have been raised about how the [Report on Carcinogens] is developed and how its findings are communicated." He called it a "highly influential" document used by regulatory agencies to make policy and cautioned against "arbitrary or capricious" condemnation of chemicals. "When concerns and fear are promoted with little actual risk," Broun said, "commerce, small businesses and everyday citizens are impacted with no appreciable benefit to their safety."

"In theory, we are examining the National Toxicology Program's 12th Report on Carcinogens. In reality, we are hearing the objections of one industry to the listing of one chemical. There is virtually no balance here, in my opinion, today."

- Rep. Paul Tonko, D-N.Y.

Rep. Paul Tonko, D-N.Y., deemed the witness lineup "very disappointing. In theory, we are examining the National Toxicology Program's 12th Report on Carcinogens. In reality, we are hearing the objections of one industry to the listing of one chemical. There is virtually no balance here, in my opinion, today."

Birnbaum explained that preparation of the report, which lists 240 substances as either known or probable cancer-causing agents, was a multistep process that "included expert advisory reviews, independent external peer review and drew upon the scientific expertise" of agencies such as the Centers for Disease Control and Prevention. Public comments were solicited six times, she said.

Critics were not persuaded.

A toxicologist with Dow Chemical Co., speaking on behalf of the styrene research group, questioned

the scientific rigor of the National Toxicology Program. The vice president of a small manufacturer of custom showers and vanity tops said the listing of styrene "could make it very difficult for us to stay in business."

The environmental affairs manager of a company that makes ballistic panels for the military said the firm had been receiving "anonymous phone calls saying things like 'You do know that styrene causes cancer, don't you?' "An official with the Small Business Administration warned that users of styrene faced tort lawsuits, higher insurance costs and more regulations.

Then-Congressman Miller, who'd chaired the Investigations and Oversight subcommittee before Broun took over, reminded his colleagues that "the styrene industry's lobbyists do take credit for having scheduled this hearing."

The American Composites Manufacturers Association later reported in its newsletter that it had convinced Congress to hold two hearings and a roundtable discussion on styrene and had "built a record" against the National Toxicology Program. "Unlike the industries that conceded after their product was listed," the association said, "ACMA continues to work to remove styrene" from the report.

## 'Truth in testimony'

"When substances are found to be harmful, we should make every reasonable effort to minimize the public's exposure," Rep. Smith wrote to the Center. He noted, however, that witnesses testifying before the Science Committee had seen room for improvement in the *Report on Carcinogens*, whose classifications "have the potential to be confusing."

All witnesses sign "truth in testimony" agreements, Smith wrote, in which they disclose "relevant financial information. This agreement includes all information that is required to be disclosed under House Rules."

Those rules allow wiggle room. A witness is asked, for example, whether he or she has received federal grants or contracts — but not whether they're a paid consultant

for, say, a chemical company. Democrats on the Science Committee tightened the rules to require such disclosure, but Republicans undid the change after they assumed control. Smith explained that the current rules maintain a "fair balance," allowing the public to view the witness forms online without revealing too much "personal or sensitive financial information."

Witnesses' bonds to industry aren't always obvious. At a May 2011 hearing, for instance, Michael Economides, identified as a professor of chemical and biomolecular engineering at the University of Houston, testified against stricter regulation of the controversial oil and gas drilling technique known as hydraulic fracturing. Under questioning from Miller, Economides said he was paid \$1 a year by the university as an adjunct professor but made about \$1 million annually from his oil and gas consulting firm.

In a telephone interview, Economides said, "I'm independent. I don't belong to the oil companies. I just happen to know the technology and I teach it." His résumé is publicly available, he said: "I don't have anything to hide."

Other witnesses who presented themselves as independent scien-

tists or testifying on their own behalf turned out to have strong industry ties.

At a hearing in June, Jeffrey Holmstead, head of the Environmental Protection Agency's air office under George W. Bush and now a partner at Bracewell & Giuliani, a Washington lobbying firm, said he was speaking in his personal capacity when he argued against a tougher EPA standard for ozone, a form of smog generated by industrial operations and motor vehicles. Holmstead's firm has brought in nearly \$24 million in fees from electric utilities and oil and gas companies since he took over its Environmental Strategies Group in 2006, records show.

"I didn't consult with any clients before preparing my testimony or give anyone a chance to look at it, so it's not as if I'm representing anyone's point of view other than my own," Holmstead said by phone. "I actually think [ozone regulation] is a very important issue, and it kind of trivializes it if you're just talking about disclosure stuff."

But Science Committee member Donna Edwards, D-Md., said, "It seems to us that there were instances that people appeared before our committee as independent experts when in fact they were industry lobbyists. We need to know that in advance."

When Miller was its chairman, it was not uncommon for the Investigations and Oversight subcommittee to go after research and regulatory agencies for doing too little to protect public health, not too much. The Agency for Toxic Substances and Disease Registry, part of the CDC, was skewered at hearings on high levels of formaldehyde in trailers supplied to victims of hurricanes Katrina and Rita by the federal government, and on a cancer cluster linked to tainted well water at the Marine Corps' Camp Lejeune in North Carolina.

Now, Miller said, hearings are constructed to "attack science as being incomplete, haphazard, halfassed. You're never going to get a scientist to say, 'No, we don't need more research, we're certain of this result.' We need to have action on environmental exposures on the basis of the science we have at this point. We're pretty sure there are chemicals that are doing bad stuff to adults and especially children."

## Tangling with industry

Birnbaum, director of the NIEHS and the National Toxicology Program since 2009, believes industry attacks on public health research

"There's nothing that has been as successful as the bioassay [for identifying human carcinogens]. The problem is, it's expensive, and it takes a long time, and then you have to fight industry when it's one of their chemicals"

- James Huff, retired NIEHS researcher

have become more strident. She disputes allegations that her agency cherry-picks science to build cases against certain chemicals.

"We are the one federal agency that is not only developing new tests but conducting new tests and evaluating the potential toxicity of a variety of environmental chemicals and other kinds of public health hazards," Birnbaum said. "Our evaluations are extremely transparent."

James Huff joined the National Toxicology Program as it was ramping up in 1980 and remains an ardent defender.

Huff tangled repeatedly with industry over the branding of chemicals as confirmed or likely carcinogens following animal tests, known as bioassays. NIEHS had inherited the nascent bioassay program from the National Cancer Institute.

"They had a slew of publications

that were sitting around," Huff said of the NCI. "One of the things I was asked to do was scientifically beef up the technical reports that came out from each bioassay on rats and mice. We started knocking them out and presenting them at national meetings."

Between 800 and 1,000 animals are used for each experiment; they eat, drink, inhale or absorb through the skin the chemical being tested. After two years, the animals that are still alive are killed and their organs examined for tumors.

"There's nothing that has been as successful as the bioassay [for identifying human carcinogens]," Huff said. "The problem is, it's expensive, and it takes a long time, and then you have to fight industry when it's one of their chemicals."

This happened, for instance, with 1,3-butadiene, a chemical used to make synthetic rubber that was tested by the National Toxicology Program in the 1980s. "It was so carcinogenic that there were hardly any animals left after 50 weeks, so we cut the experiment down to 60 weeks instead of 104," Huff said.

Representatives of the rubber industry asked Huff and his colleagues not to present or publish their results until the industry did its own studies. "We said, 'Hell no, we're not waiting,' " Huff recalled. "They were just devastated that we were coming out with this stuff."

At the time, the workplace exposure limit for the chemical was 1,000 parts per million. It was lowered to 1 ppm in 1997, largely "because of our studies," Huff said. Even that limit may be too high: "We still don't know at what dose in animals butadiene is not a carcinogen."

Some industry-backed scientists are dismissive of bioassays, saying tumors in rodents don't necessarily portend tumors in humans. Huff, whose name appears on some 400 peerreviewed papers, says industry has become more "formidable" in challenging such tests. "They know more. Government, likewise, seems to be more receptive to their arguments."

As of August 2011, the American Chemistry Council, a trade associa-

tion that represents companies such as Dow and ExxonMobil, had 53 panels devoted to chemicals from acetone to vinyl chloride, the council's CEO and president, Cal Dooley, wrote in responses to questions from Rep. Edwards. The panels spring into action — with research and advocacy — when regulations are proposed or products otherwise come under scrutiny. They and other council divisions spent a combined \$45.5 million on research from 2008 to mid-2011, Dooley wrote.

Years ago, Huff said, "You either got funded from the National Academy [of Sciences] or NIH or you didn't get any money. The whole thing has shifted. There's been a ton of money coming in from industry."

This phenomenon carries risks, a 2012 report by the Union of Concerned Scientists, a nonprofit environmental advocacy group, concluded: "When funding their own studies, corporations may terminate or fail to report research with negative findings, tailor study designs to lead to desired outcomes, and overreport positive results. Companies may rely on the names of respected academics to publish corporate-funded research. And they may attack scientists whose research proves inconvenient."

There is no reason to anticipate a letup. The natural gas drilling boom under way in Texas and other states, made possible by hydraulic fracturing of shale deposits, has prompted expansion plans by a host of chemical companies that use ethane — a natural gas liquid — as a feedstock. In a recent report, the American Chemistry Council said that nearly 100 projects, valued at \$71.7 billion, had been announced as of the end of March.

# Backlash against carcinogens report

Birnbaum, a toxicologist with more than 600 peer-reviewed publications on her curriculum vitae, spent 19 years with the EPA —"the federal government's worst offender when it comes to overreaching regulations," according to Congressman Smith — before coming to NIEHS.

She was sorely tested by the 12th Report on Carcinogens, the 2011 document that listed styrene as "reasonably anticipated" to cause cancer and bumped up formaldehyde —used in adhesives for pressed-wood products and as a preservative in mortuaries and medical laboratories — from "reasonably anticipated" to "known to be a human carcinogen," mainly on evidence that it can trigger leu-

kemia. Two years earlier, a working group of the International Agency for Research on Cancer, part of the World Health Organization, had found "sufficient evidence" that formaldehyde caused leukemia.

The Report on Carcinogens' 462page styrene background document had 551 scientific references; the 512page formaldehyde background document had 798. "We followed a very detailed process, which had been vetted extensively," Birnbaum said.

Nonetheless, the report's publication touched off a burst of activity. In June 2011, the Styrene Information and Research Center sued the Department of Health and Human Services, contending the styrene listing was "contrary to the weight of scientific evidence and opinion" and asking that it be struck from the report. This May, the U.S. District Court for the District of Columbia ruled in HHS's favor, saying the report's conclusions were well-documented and decrying the styrene group's "scattershot approach in attacking [HHS's] listing decision."

The styrene research center — whose lobbying expenditures went from zero in 2009 to \$570,000 in 2011, records show —did not appeal. Scientific evidence available to the National Toxicology Program

while the Report on Carcinogens was under review "supported a conclusion that styrene does not represent a human carcinogen concern at any levels of exposure which the workers or the public might reasonably experience," the group wrote the Center.

The American Chemistry Council twice sued HHS, seeking to obtain data underlying a federally funded study out of the University of California, Berkeley, linking formaldehyde to leukemia. The study helped inform the listing in the Report on Carcinogens. Dissatisfied with what it received through a Freedom of Information Act request, the chemistry council claimed HHS had violated federal law by refusing to release information. HHS said it had turned over all the pertinent records it could find.

This month, the D.C. district court granted an HHS motion for summary judgment dismissing one of the council's cases; the second is pending.

In a statement to the Center, the council said it is seeking the raw Berkeley data "in order to analyze inconsistencies in the published report and to carefully evaluate the potential implications [of] the authors' conclusion." It added. "The federal government is denying open access to data that was funded by the American taxpayer and is preventing a comprehensive analysis of the data through time-consuming and expensive litigation."

Marianne Engelman Lado, an attorney with the nonprofit environmental law firm Earthjustice, which intervened in the styrene case, suspects another motive: A "fishing expedition" for data that can be reanalyzed to create uncertainty. "They have turned things upside down so that industry science is somehow objective and academic science that is in part funded by the government but is independent is somehow less reliable," Lado said.

Although industry litigation has had no discernible effect, lawmakers did attach a rider to a 2012 appropriations bill setting aside \$1 million for reviews of the styrene and formaldehyde listings by two National Academy of Sciences panels. The results aren't expected until August 2014.

"I think the whole thing is unnecessary," Birnbaum said. "That was money that came out of the assistant secretary of health's budget which, I think, probably could have been better spent."

The aim, Huff said: "Delay the game."

Sam Pearson contributed to this story.



For the past 60 years, water polluted with chromium (VI) has plagued Hinkley, Calif., the desert town made famous by the film *Erin Brockovich*. Although residents there won their lawsuit against the polluter, Pacific Gas & Electric Co., there's still a debate over whether the compound causes cancer in drinking water. The Environmental Protection Agency says yes, but industry scientists disagree. Miles O'Brien, PBS NewsHour

# How industry scientists stalled action on carcinogen

By David Heath
Published Online: March 13, 2013

INKLEY, Calif. — Ten days before Christmas 1965, Pacific Gas & Electric Co. station chief Richard Jacobs walked a half-block on a dusty road lined with scraggly creosote shrubs to check out a neighbor's toilet.

Jacobs carried with him a secret, something he referred to as the "chromate problem."

Starting in 1952, the power company began mixing a toxic form of chromium with water to prevent rust at a new pipeline pumping station

in Hinkley, a remote desert community united by a single school and a general store. PG&E dumped the chromium-laced water into a pond.

Lately there had been reports of problems with the neighbors' wells. PG&E had just drawn greenish water from one well and discovered high levels of chromium. Now, retired farmer John Speth was complaining of greenish deposits in his toilet bowl.

Jacobs took a look in the bowl but assured Speth that PG&E had nothing to do with it. "When I left Mr. Speth," Jacobs later wrote in longhand, "he was satisfied but still concerned about his water." Speth died of stomach cancer in 1974.

It wasn't until Dec. 7, 1987 —

#### **Key Findings**

- Tens of millions of Americans drink water contaminated with chromium (VI), a compound the Environmental Protection Agency was poised in 2011 to conclude likely causes cancer. That finding would set the stage for setting stricter drinking-water standards.
- The National Toxicology Program, part of the National Institutes of Health, published a major rodent study in 2008 that concluded there was "clear evidence" chromium (VI) in water was a carcinogen.
- The EPA's assessment of chromium was delayed to wait for new studies paid for by the American Chemistry Council, the chemical industry's main trade group and lobbyist.
- Some of the same industry-paid scientists involved in past efforts to stall government action on chromium worked on the studies delaying the EPA.
- After delays of nearly a decade, the California Environmental Protection Agency declined to wait for the industry studies and issued its own finding in 2011 that chromium was a carcinogen in drinking water.
- The EPA initially planned to complete its chromium (VI) assessment in 2015.
   After the Center for Public Integrity and PBS NewsHour started asking questions about the delay, EPA posted a revised timetable for completing the assessment this year.

22 years after that visit to Speth's house — that PG&E finally told the local water board that it had contaminated the underground water. The company claimed it had discovered the problem just one week earlier.

From here, the story is familiar to anyone who saw the hit film Erin Brockovich. The corporate polluter was taken to court. The victims got millions of dollars, Problem solved.

But in reality, the "chromate problem" has not gone away. Today, tens of millions of Americans drink chromiumtainted tap water. Yet the controversy over whether people like Speth are dying of cancer from it is still being hotly debated.

Some of the most powerful voices in the debate are companies with a stake in the outcome. They've hired scientists to convince regulators that the chemical compound is safe. The lawsuit that Brockovich championed was merely the beginning of an intriguing tale about corporate manipulation of science.

In 2008, the National Toxicology Program, part of the National Institutes of Health, published groundbreaking research detailing how mice and rats that drank heavy



In the early 1990s, PG&E bought up homes in the Hinkley neighborhood most affected by contaminated water. The company razed and burned some of the homes, but some boarded-up and abandoned buildings remain. Miles O'Brien, PBS NewsHour

doses of a toxic form of chromium called chromium (VI) developed cancerous tumors. The findings prompted the Environmental Protection Agency to act.

EPA scientists evaluated hundreds of studies and concluded that chromium (VI) likely causes cancer in people who drink it. The agency in 2011 was on the verge of making its scientists' findings official — a first step toward forming more stringent clean-water rules. But last year it bowed to pressure and announced it was going to wait for new studies being paid for by the chemical industry.

To lead those studies, the American Chemistry Council, the industry's main trade group and lobbyist, hired ToxStrategies Inc., a Texas-based firm with scientists experienced in poking holes in research that links chromium to cancer. The company describes its business this way on its website: "We often interact and collaborate with regulatory, academic and industrial professionals to ensure that the most appropriate science is incorporated into each assessment."

Mark Harris and Deborah Proctor, two principal scientists at Tox-Strategies, have a history of attempting to delay regulatory action on chromium. Starting in 1996, they were both leaders in the chrome industry's efforts to dissuade the Occupational Safety and Health Administration from setting stricter rules for airborne chromium in the workplace. OSHA pushed back action for years despite decades of research showing that workers exposed to chromium were dying at higher-than-expected rates of lung cancer. The agency finally adopted a stricter standard in 2006 under pressure from a court order.

Proctor also worked on revising a 1987 study that concluded that Chinese villagers who drank water polluted with chromium (VI) had higher than normal rates of stomach cancer. With funding from PG&E, Proctor's employer, ChemRisk, paid the Chinese author to help publish a new analysis of the data. In contrast to the earlier article, the new one concluded that chromium wasn't the likely culprit. The revised study which did not reveal the involvement of PG&E or its scientists helped persuade California health officials to delay new drinking water standards for chromium.

Finally, with industry funding, Proctor worked to try to influence the makeup and findings of a scipanel deciding whether entific California needed stricter drinking water standards for chromium. The panel concluded — to the surprise of many - that there was no scientific basis for believing that drinking chromium causes cancer. One-third of Californians have chromium in their water.

Proctor and Harris declined to respond to requests for interviews.

The use of science to delay regulation is part of a familiar pattern in the field of environmental science. Industry pays for research to address "data gaps." Even when animals or people are believed to be getting cancer from exposure, industry scientists argue that the chemical in question is dangerous only at extremely high doses. Finally, they argue that you can't determine a safe dose of a chemical unless you understand precisely how it causes cancer. Until all the questions are answered, they say, it's not fair to ask industry to bear the cost of stricter rules.

"So now what is happening is the industry is trying to get scientists to slow down the EPA," said Gary Praglin, one of the lawyers who sued PG&E on behalf of Speth and hundreds of others who had lived near the Hinkley pumping station.

David Michaels, an epidemiologist who now heads OSHA, has written extensively about this brand of science.

"Their business model is straightforward," Michaels wrote in his book, "Doubt Is Their Product." "They profit by helping corporations minimize public health and environmental protection and fight claims of injury and illness. In field after field, year after year, this same handful of individuals come up again and again."

# Overwhelming evidence of lung cancer

Suspicions that chromium might cause cancer emerged in the late 19th century. In the 1950s, studies of factory workers exposed to airborne chromium showed much higher rates of lung cancer than expected. Thomas Mancuso, a pioneer in occupational medicine, continued to follow the workers at a chromate plant in Painesville, Ohio, for decades. In his final account in 1997, he reported that 23 percent of them had died of lung cancer. Other studies elsewhere confirmed Mancuso's findings.

Given the overwhelming evidence that chromium particles in the air were killing people, PG&E's challenge in the Hinkley case was to persuade judges on an arbitration panel that chromium traces in water were different. The company hired academic scientists, such as Steven Patierno at George Washington University, who testified that saliva and stomach acid render toxic chromium harmless, at least at levels that any human would drink.

Still, a few troubling studies at the time suggested that humans and animals may have developed cancer from drinking chromium. To address those studies, PG&E hired ChemRisk, a scientific firm that helped companies with legal or regulatory issues. The chief executive officer of ChemRisk was Dennis Paustenbach, a San Francisco scientist who has become the undisputed star of product defense.

Paustenbach declined interview requests. In a 2009 profile written by two University of Virginia professors, Paustenbach explains that he's been driven since his modest upbringing to be financially successful, putting in 65-hour work weeks.

His work as a scientist has included advocacy from the start. Each week as a young toxicologist at a chemical company in Connecticut, he flew to the nation's capital to lobby regulatory agencies such as the EPA. His relationship with the agency evolved and he later sat on numerous EPA advisory panels. For the past four years, he's served on a panel overseeing EPA research.

A rare inside look at what Paustenbach does can be found in the minutes of a 1996 meeting in Pittsburgh of the Chrome Coalition, then the industry's trade group. At the time, OSHA was proposing a big reduction in the amount of chromium dust allowed in the workplace. Paustenbach outlined a plan to prevent that from happening.

"Dr. Paustenbach suggested that ... the Coalition may wish to approach the regulators with a program designed to fill a 'data gap' ... to forestall the rulemaking," the minutes read.

There was a discussion of Chem-Risk possibly providing "confidential" and "pro bono" assistance to researchers at Johns Hopkins University to finish analyzing data for an EPA study of a Baltimore chromate plant. The EPA study was designed to answer questions left from Mancuso's earlier work. At the same time, Paustenbach proposed writing an "anti-Mancuso manuscript" and critiquing all relevant workplace studies in an "effort of convincing OSHA not to go forward with what they presently have."

Also attending the meeting were Proctor, who worked for Paustenbach at ChemRisk, and Harris, a former ChemRisk employee who at the time worked for Chemical Land Holdings, a company involved in a costly chromium cleanup. Both Proctor and Harris now work for ToxStrategies.



Residents of Hinkley meet to discuss the contamination of their drinking water, a jug of which is seen here. PG&E is offering from buy scores of homes affected. Many of the townspeople don't trust the giant utility despite a massive cleanup effort. The meetings are often punctuated by angry outbursts.

Miles O'Brien, PBS NewsHour

Paustenbach said in a recent statement to CPI and PBS NewsHour. "There is no evidence supporting any unethical conduct by ChemRisk scientist in regards to past work for the Chrome Coalition. The focus of ChemRisk scientists was solely on expanding the body of knowledge on which OSHA and other scientists could evaluate Chromium 6."

In the end, the EPA study confirmed Mancuso's findings that workers exposed to chromium were

at a substantially higher risk of dying from lung cancer. Still, OSHA would wait more than a decade to tighten workplace standards for chromium under pressure from federal appeals court decision.

For the PG&E lawsuit, Paustenbach decided to conduct original research. Environmental science often lacks good human studies. Few people would volunteer to drink something potentially toxic to see if it would make them sick. Yet, that is

precisely what Paustenbach did.

He and other scientists at Chem-Risk sat for hours in Jacuzzis filled with chromium-laced water. They also drank chromium-contaminated water by the jug and then ran tests on their blood and urine.

ChemRisk scientist Brent Finley appeared on ABC News in 1996 to drink some of the yellow water, prompting correspondent Cynthia McFadden to say, "There are those who would say you drinking a gallon of this chromium-laced water doesn't prove anything except that you — in some people's minds — may be foolish."

Paustenbach explained in his business school profile that he's motivated in his work by what he sees as greedy lawyers using bad science to take advantage of corporations.

"Without a doubt, a large percentage of environmental and occupational claims are simply bogus," he said, "intended only to extract money from those who society believes can afford to 'share the wealth.'"

## Secrets of the 'Blue-Ribbon Panel'

Before the film Erin Brockovich even came out, the state of California was already taking steps to strengthen drinking-water standards for chromium. In 1999, scientists at the California Office of Environmental Health Hazard Assessment concluded that it was safe to assume that drinking chromium may cause cancer. They reasoned that breathing chromium was just another way the metal got into the body and caused damage. Plus, a 1968 study showed that 11 out of 66 female mice developed tumors after drinking chromium-laced water.

OEHHA's next task was to figure out how much chromium a person could drink each day without exceeding a one-in-a-million chance of getting cancer from it. The agency computed a number that was 40 times lower than the existing U.S. drinking-water limit.

One industry consultant warned that if this standard became law, it would cost \$11 billion to clean up California's water, plus another \$1.7 billion every year to keep chromium out of the water.

Before a new drinking-water standard could take effect, the state asked the University of California to set up a "blue-ribbon panel" of scientists to review the science. In August 2001, the panel issued a report that said there was "no basis" for concluding that chromium-contaminated water could cause cancer.

The panel dismissed the rodent study because an unrelated virus had killed many of the mice. It barely addressed the mounds of research on lung cancer.

The state agency concluded that it had little choice but to retract its chromium "public health goal" and wait. The state had asked the National Toxicology Program to do multimillion-dollar rodent studies on chromium. But the results wouldn't be published for another seven years.

Questions soon arose about whether the blue-ribbon panel was biased. When the group held its only public hearing in July 2001, a lawyer for Hinkley residents, Brian Depew, attended. Depew said an environmental activist approached him afterward and later sent him a binder of documents that touched off months of investigation by Depew's law firm.

The lawyers soon documented that Paustenbach initially served on the panel even though PG&E had paid ChemRisk at least \$1.5 million during the lawsuits. Paustenbach said he didn't appear at the public hearing and his name is not on the report.

The lawyers also learned from invoices and testimony that Exponent, the company where Paustenbach served as vice president and its most senior scientist, was being paid by an industry group focusing attention on the blue-ribbon panel. The Alliance for Responsible Water Policy was bankrolled by General Electric Co. and Lockheed Martin Corp., two companies entangled in chromium cleanups.

A strategic action plan for the Alliance dated April 6, 2001, and later disclosed in court records, listed as its strategy to "participate in state panel's review of chromium 6, influence selection of panelists [and] provide input and information to panel."

Proctor acknowledged in a deposition that she drew up a wish list of panelists and gave it to a lobbyist, Eric Newman. One of her colleagues, Brent Finley, also asked how he could get on the panel. Newman, who declined to comment for this story, responded to Finley in a March 31, 2001, email: "We will be lobbying hard for balanced representation. ... It is critical that we get you, Deborah Proctor and/or other folks on the non-alarmist side of things."

According to Proctor's testimony, one of the names on her list was Joshua Hamilton, a Dartmouth professor working as an expert witness for PG&E. In 2011, Hamilton would be named to an EPA peer review panel for chromium (VI) and urge the agency to wait for new industry-funded studies led by Proctor. Hamilton, in a statement, has denied that he had any conflicts of interest while he served on the EPA panel.

When Paustenbach was named to the panel, Finley sent an email to Newman saying, "So, it looks like we got 'one of our own' on the panel."

When asked whether Exponent was being paid by an industry-funded group for work related to the blue-ribbon panel, Paustenbach told CPI through a public-relations firm, "I have heard that this is true, but I do not know specific details because I did not participate in any work for the Alliance."

Proctor, Paustenbach and other Exponent scientists quickly penned a review article that could serve as a blueprint for the panel, and Paustenbach shared it with the group. The article was paid for by Merck, another company involved in a chromium cleanup. The panel chairman, Jerold Last, sent an email to the group on June 14, 2001, saying, "I copied the third chapter pretty much verbatim from a review Dennis and his colleagues have in press, so we will

want to do some revisions to eliminate the verbatim aspect."

Paustenbach denied that blue-ribbon panel's report merely copied from Proctor's article. He told a California Senate committee investigating the panel that only "4 percent - exactly 4 percent - of the report was, in part, borrowed from a published paper by my colleague," Proctor. Last, who did not respond to requests for comment, told the committee that what "started out as cutting and pasting ... ended up being material that one or all of us reviewed thoroughly before we put it into the report."

The major conclusions reached in the ChemRisk article and the state report were the same.

Paustenbach said that he disclosed his involvement in the PG&E lawsuit to Last but that neither he nor Last considered the PG&E work to be a conflict of interest. Still, because of concerns raised by an advocacy group, Paustenbach said he stepped down from the panel before the panel held its public hearing.

When the blue-ribbon panel report came out, Paustenbach attached it to an email to a colleague at Exponent saying, "Buy a good bottle of wine, pull up a chair, and then read this. Then say to yourself, 'Yep, I really finally did something good for society...' The world is now a better place to live."

When a lawyer read the email aloud during a deposition, another scientist who served on the panel called it "sad."

"This [is] about winning. It's not about truth," John Froines, a toxicologist at the University of California, Los Angeles, testified. "The world isn't a better place to live. The world is actually a poorer place to live because of this. It makes people cynical about trusting in the science, and I think that's really too bad."

Froines quit the panel before it finished its report, saying he was concerned about panelists with ties to industry. But also, Froines simply didn't believe the panel's findings.

#### Chinese study revisited

Meanwhile, the California Environmental Protection Agency also had suspicions about the blue-ribbon panel.

Two studies highlighted in the panel report came from China's Liaoning province, northeast of Beijing, where a smelter began contaminating the water with chromium (VI) in 1965. A doctor in the area cared for the sick for years and eventually counted the deaths from cancer. He published an article in 1987 in a Chinese journal, concluding that villagers who drank the tainted water suffered higher rates of stomach cancer.

A decade later, the same doctor published a new article in an American journal concluding that chromium most likely wasn't the culprit.

The head of California EPA's Office of Environmental Health Hazard Assessment, George Alexeeff, asked a new epidemiologist on staff, Jay Beaumont, to look into the studies. In recent interviews, Beaumont said he quickly found things that didn't seem to add up.

For example, the revised ticle said stomach-cancer rates for the province weren't available. But Beaumont had a colleague quickly track down the data at the University of California, Berkeley, library. Beaumont said the numbers came from the same source the Chinese doctor used for other comparisons.

Within a few days, Beaumont ran his own analysis and found that villagers who drank chromium-laced water were 85 percent more likely to have stomach cancers than were those who lived in the surrounding province.

### "I don't know what Dr. Zhang was paid to do by McLaren/Hart, but republishing his study with different conclusions seems a possibility."

Jay Beaumont, an EPA epidemiologist

Beaumont tried to reach the Chinese author, Dr. Zhang JianDong, but he had died in 1999. However, there was still a website promoting a book Zhang had written. Something caught Beaumont's attention. The site revealed that Zhang was a consultant to McLaren/Hart Environmental Engineering Corp., the company that at the time owned ChemRisk.

Putting the pieces together, Beaumont wrote an email to his boss, saying that "the money to pay Dr. Zhang likely came from the industrial clients of McLaren/Hart who have a strong financial interest in the health effects evidence for Cr6. I don't know what Dr. Zhang was paid to do by McLaren/Hart, but republishing his study with different conclusions seems a possibility."

PG&E now acknowledges it paid for the revised analysis, though records show only about \$2,000 went to Zhang.

Two ChemRisk documents describe Zhang's role as "research assistance" and "document review and consultation." Meanwhile, ChemRisk scientist named project coordinator was budgeted to be paid \$13,500 to "interpret data" and "write reports" that were then to be edited by Paustenbach and Finley. The ChemRisk proposal linked the research to the PG&E lawsuit by saying that the new article "can be used as the foundation of a number of trial exhibits that summarize the absence of the association between cancer and groundwater exposure to Cr6."

Proctor, the same scientist who recently conducted studies for the American Chemistry Council, billed for her time on the Chinese article as well, according to a deposition.

"What was important to PG&E at the time is that the science was accurate," said Sheryl Bilbrey, now in charge of the cleanup in Hinkley for PG&E. "So we did fund that work, and I think it's unfortunate that when it was republished they didn't acknowledge PG&E's involvement, because it really took away from the focus of the science and had more to do with the disclosure issue.

"PG&E's intention on any project is to make sure that we have the best science," Bilbrey said. "These projects are incredibly important to us, and we want to get it right. So we looked to Dr. Paustenbach and his experts to make sure that the science was accurate."

Paustenbach, through a public-relations firm, released a 9-page statement acknowledging that ChemRisk approached Zhang and another author to point out that "there were shortcomings in how these physicians interpreted their data." The statement said that Zhang was surprised by the new ChemRisk analysis but agreed with it. The firm also released hundreds of pages of documents that included one signed by Zhang saying he agreed to the "editing and expanding of the original manuscript."

Paustenbach's recent statement says, "The record makes clear not only that Zhang prepared the report, but also that Zhang, fearful of political pressure from his government, indicated that acknowledgment of American researchers was not appropriate since it was his study." Paustenbach testified in 2002, "We asked Dr. Zhang, in fact, to be coauthors on that paper for sake of transparency ... Dr. Zhang, on his own decision, chose to keep that as a singular authorship."

None of the documents Paustenbach provided CPI indicate that Zhang explicitly objected to other names being listed as authors.

Despite the question of authorship, scientists at California's OEHHA said they took the new study at face value. Still, they rejected its findings.

"The '97 study basically concluded that there was no association between chromium (VI) in the drinking water and cancer cases among the Chinese villagers, in large part because the villages that were more distant from the source of the drinking water contamination had higher cancer rates," said Allan Hirsch, OEHHA's deputy director, in a recent interview. "People closest to the facility may not have been drinking the water, because it was yellow and unpalatable."

In a recent statement, Paustenbach characterized the California EPA's analysis as "flawed and incorrect."

The Journal of Occupational and Environmental Medicine retracted the article. Journal editor Paul Brandt-Rauf said in a recent interview with CPI that the article violated its policies by not revealing all of the significant authors or the funding.

Paustenbach said through a spokesman that the rules did not require disclosure because the amount paid Zhang was so small. However, Brandt-Rauf rejected that explanation.

The Environmental Working Group, an advocacy organization, did its own investigation of the Zhang study and was troubled by what it found. "I mean, this really is a story about science for sale," said Heather White, executive director of the group. "It's shocking."

#### **EPA** faces industry pressure

In 2008, the National Toxicology Program published the results of its rodent studies. High numbers of the mice and rats developed tumors in their oral cavities and small intestines. The NTP concluded that there was "clear evidence" that drinking chromium (VI) causes cancer. At about the same time, the California EPA took the nearly unprecedented step of publishing its own findings on the Chinese study.

Both the federal and California EPAs began preparing scientific assessments based on the new research. Both would come to the same conclusion. Hexavalent chromium is safe only in miniscule doses.

Yet the American Chemistry Council planned to have a number of new studies ready just before the EPA was scheduled to issue its final assessment. The ACC urged the EPA to wait until the agency could digest the new data. The scientists at Tox-Strategies proposed studies to address "data gaps" in the NTP study.

It was a move harkening back to the Chrome Coalition meeting in 1996 that Proctor and Harris attended. When she worked for Paustenbach, Proctor published a series of articles about workers in the same plant that Mancuso studied for decades, but her conclusion was quite different. Her studies concluded that OSHA did not need to tighten its standard to protect workers.

In the end, OSHA adopted a stricter standard, but critics argue that it's still too high. By OSHA's own calculations, 10 to 45 workers out of 1,000 are expected to get lung cancer in their lifetimes from the current exposure limit.

The California EPA, which had already delayed a chromium assessment for a decade, refused to wait for ToxStrategies' studies, saying, "It would be very difficult for OEHHA to justify further delay."

California's assessment of chromium went through not one, but two peer-review panels. Some of the independent scientists questioned whether the safe-dose level was actually too high, so OEHHA lowered it. The agency issued its public-health goal on chromium (VI) in July 2011.

At first, the head of the EPA's chemical-assessment program, Vincent Cogliano, also refused to wait for the ToxStrategies studies. But five of nine peer reviewers selected by a private contractor urged delay. One of the reviewers was Steven Patierno, a former PG&E expert witness who served as a consultant on the ToxStrategies' studies.

In January, the NTP published new research from its rodent studies that challenges Patierno's contention that saliva and stomach acids render chromium (VI) completely harmless, undermining the theory that chromium is dangerous only in high doses.

Celeste Monforton, a professorial lecturer at George Washington University's School of Public Health who has written about industry scientists' influence on chromium policy, said that, based on her own experience working with agencies, regulators are aware that research done by industry is often an attempt to delay.

"Some people at EPA understand that and know that," she said. "It takes the political will to stand up to that."

In the Hinkley lawsuit, judges more 16 years ago considered the scientific arguments and ruled against PG&E. In essence, they concluded that the contaminated water in Speth's toilet was capable of causing cancer.

Froines, the UCLA scientist who resigned from the blue-ribbon panel, said it's time for public health agencies to do the same.

"At this point, we shouldn't be debating the carcinogenicity. ... We should be at a place where we're looking for alternatives to the use of chromium," said Froines, who has evaluated more than 400 chemicals for a California advisory panel he chairs. "You're dealing with people's lives."

Miles O'Brien, science correspondent for the PBS NewsHour, contributed to this story