iWatch News By The Center for Public Integrity

http://www.iwatchnews.org/2012/02/06/8088/landmark-diesel-exhaust-study-stalled-amid-industry-and-congressional-objections

Landmark diesel exhaust study stalled amid industry and congressional objections



Diesel exhaust, which some studies suggest causes lung cancer, spews from a crane loading a ship in Newark, N.J. Mike Derer/AP

Twenty-year investigation of miners exposed to toxic fumes still unpublished

By Jim Morris

February 6, 2012

Publication of a landmark government study probing whether diesel engine exhaust causes lung cancer in miners — already 20 years in the making — has been delayed by industry and congressional insistence on seeing study data and documents before the public does.

A federal judge has affirmed the right of an industry group and a House committee to review the materials and has held the Department of Health and Human Services <u>in contempt</u> for not producing all of them.

The much-anticipated study of 12,000 miners exposed to diesel fumes carries broad implications. If the research suggests a strong link between the fumes and cancer, regulation and litigation could ramp up — with consequences not only for underground mining, but also for industries such as trucking, rail and shipping.

Exposure isn't limited to workers; people who live near ports, rail yards and highways also are subjected to diesel exhaust laced with carcinogens such as benzene, arsenic and formaldehyde.

But for the time being, at least, the results of an \$11.5 million investigation by the National Cancer Institute and the National Institute for Occupational Safety and Health are under lock and key.

<u>Richard Clapp</u>, emeritus professor of environmental health at Boston University, is among several public health experts who called the situation unusual.

"I've never heard of an industry group demanding manuscripts from a government agency before a study has been accepted for publication," Clapp said. "My guess is it would give the industry a chance to prepare their rejoinder early. They want to delay anything that's going to implicate them in liability for lung cancer."

<u>Andrea Hricko</u>, a professor of clinical preventive medicine at the University of Southern California who has followed the saga for years, suspects industry and Republican members of the House Committee on Education and the Workforce want to soften the blow of a statistically powerful government study that could have far-reaching impacts.

"They feel compelled to challenge it because they don't want more regulations on mining equipment and locomotives and trucks," Hricko said.

<u>Henry Chajet</u>, a Patton Boggs lawyer-lobbyist who represents the Mining Awareness Resource Group — known as MARG — declined to comment for this report. But in a recent <u>court filing</u>, Chajet and other lawyers for the group wrote that publication of what they believe to be an "inaccurate and faulty" study, along with government plans to notify the 12,000 subjects of health risks, is "likely to spawn public concerns, regulatory actions, and lawsuits…"

Industry officials say improvements in diesel engine technology are making the issue moot.

"Engine manufacturers have invested enormous resources over the last two decades to reduce emissions from diesel engines by over 99.9 percent," the president of the <u>Truck & Engine</u> <u>Manufacturers Association</u> wrote in a <u>Jan. 23 letter</u> to leaders of the Education and Workforce Committee expressing support for the committee's review powers. "As a result, today's new technology diesel engines produce near-zero levels of particulate matter and toxic air contaminants and, thus, contribute significantly to improving the nation's air quality." Diesel engines are known for their durability, however, and many older ones are still in use.

"It's alarming that special interests appear to be trying to derail independent, peer-reviewed science," <u>Rep. George Miller</u>, a California Democrat and ranking member of the Education and Workforce Committee, said in an emailed statement to the Center for Public Integrity. "Politics and profits should never be allowed to meddle with the scientific process, especially when health and safety are at stake."

The panel's Republican chairman said there is no such agenda. "The committee's ongoing interest is to ensure the results of this research are accurate and meet the highest standards of scientific review," <u>Rep. John Kline</u> of Minnesota said in a statement.

The legal and political tangling over the diesel study began in the mid-1990s, with countless twists and turns since. Last August, MARG won a contempt order against the Department of Health and Human Services, parent of the two institutes that conducted the study. The group alleged that HHS had deliberately withheld study materials from the House committee. <u>U.S.</u> <u>District Judge Richard Haik</u> of Lafayette, La., who had earlier granted the committee, along with mining companies and their scientists, the right to pre-publication review of such materials, agreed.

The Justice Department appealed the contempt order, which required HHS to hand over "all nonconfidential documents, data, draft reports, publications, and draft results" associated with the study and to pay the plaintiffs' court costs and attorneys' fees. The order is stayed while the New Orleans-based U.S. Court of Appeals for the Fifth Circuit ponders the matter; a decision is expected soon.

All told, government researchers have written seven papers on the study, noteworthy not only for its large number of subjects but also because it controls for factors such as cigarette smoking. Four of the papers — describing only the study's methodology — were published in the Annals of Occupational Hygiene in 2010. A fifth paper, also dealing with technical matters, has been accepted for publication by the same journal. Papers six and seven, which detail the study's results, have been accepted by the Journal of the National Cancer Institute.

None of the last three papers can see the light of day until the legal dispute is resolved.

Worst case for the government: Haik's contempt order stands and publication is postponed indefinitely while the House committee and MARG comb through mountains of documents and data. Best case: The order is overturned and the papers are published as soon as March.

In an affidavit filed with the Fifth Circuit, Dr. Robert Hoover, director of epidemiology and biostatistics at the National Cancer Institute, said it would be "unconscionable that there be further delay in publication" and noted that "several major organizations focused on public health are awaiting the results."

Among them is the <u>International Agency for Research on Cancer</u> (IARC), an arm of the World Health Organization, which considers diesel exhaust "probably carcinogenic to humans" and is

scheduled to revisit the science in June. The HHS study could play a major role in the IARC reassessment - assuming the findings are published by then.

Clapp, of Boston University, said the mining industry has an incentive to keep any bad news about diesel under wraps. "When IARC designates something a known human carcinogen, that changes the balance in these liability cases," he said. "It makes it harder for industry to win."

There have long been suspicions about diesel's cancer-causing properties. A study published in Environmental Health Perspectives in 2004, for example, found elevated lung cancer death rates among U.S. railroad workers. "These results indicate that the association between diesel exhaust exposure and lung cancer is real," the authors wrote.

<u>John Froines</u>, a professor of toxicology at UCLA and Hricko's husband, said that more than 90 percent of the particles emitted in diesel exhaust are ultrafine — "smaller than a virus." These diesel particles, coated with toxic chemicals and metals, can penetrate cells and cause cancer and other diseases, said Froines, director of the Southern California Particle Center, a government-funded research institute. The exhaust also contains vapors with "significant toxicity," he said.

Industry experts say the evidence against diesel is far from conclusive. A scientist and a physician employed by Navistar, a manufacturer of diesel engines, wrote in a letter to the American Journal of Respiratory and Critical Care Medicine last year that "available data do not quantitatively link occupational [diesel] exposure to increases in lung cancer."

The HHS study, conceived in 1992, was supposed to help settle the debate. But some early missteps by the government — using what MARG calls three "illegal" advisory groups to design the study, and filing one group's charter with the wrong House committee — opened the door for a mining industry legal challenge in 1996. MARG is a collection of companies that mine salt, limestone and trona — a mineral used to make soda ash, an ingredient in glass, chemicals and other products.

The Education and Workforce Committee inserted itself into the dispute in 1999, when then-Chairman William Goodling, a Pennsylvania Republican, filed an <u>affidavit</u> with Judge Haik. "We have been concerned about the diesel study for several years," Goodling said in the affidavit. He asked that the National Institute for Occupational Safety and Health (NIOSH), over which the committee has jurisdiction, be required to submit all data and drafts to members "for review and approval" prior to publication.

Haik granted the request in a 2000 order. The Justice Department appealed, saying Haik had improperly given the committee veto power over a scientific inquiry. The Fifth Circuit sided with the government, finding that Haik "cannot require Committee approval before publication of the study." Instead, the court said, the committee would have 90 days to review the study data before it could be publicly released. Haik granted MARG the same privilege in a 2001 order.

Last year, as the final three papers were being readied for publication, Kline and another member of the Education and Workforce Committee, <u>Tim Walberg</u>, R-Mich., <u>complained</u> to NIOSH director John Howard that the government wasn't complying with the 2001 order.

"We are troubled by the continued failure of NIOSH to produce the draft publications, data underlying the research reported in those draft publications, and other documents the Committee should be receiving based on instructions from the court," Kline and Walberg wrote on July 8.

Rep. Miller, the Democrat, sent his own <u>letter</u> to Howard on Aug. 16. "The requirement for a pre-publication review by an interested party — and the insinuation of a congressional committee in such review — appears to deviate from the normal scientific process and threatens to undermine the integrity of these studies," Miller wrote.

Two days later Haik granted MARG's motion for contempt. The judge was unmoved by the Justice Department's argument that HHS had complied with his 2001 order and that publication of the last three papers could be significantly delayed while "we have to produce [to MARG and the committee] every single piece of paper in the files of the Department of Health and Human Services having to do with that study."

In a <u>brief</u> filed with the Fifth Circuit in October, the Justice Department characterized the MARG litigation as having been sparked by a "minor, inadvertent violation of the Federal Advisory Committee Act" — filing the HHS advisory panel charter with the wrong House committee — that was quickly corrected.

Compliance with Haik's contempt order, government lawyers argued, "is a burdensome undertaking that will commandeer scarce resources. It would take [HHS] six months to a year to collect, review, and release the documents and data ordered disclosed. Moreover, disclosing the documents and data required by the court has the risk of foreclosing publication of the final results of the study."

In his statement to the Center, Rep. Kline said, "In no way have [the committee's] efforts delayed or compromised the department's work. The results of these studies could have profound consequences for public policy and worker health, and we have a responsibility to ensure the agency gets it right."

http://www.iwatchnews.org/2010/09/27/2492/diesel-dangers-mining-companies-get-first-look-government-cancer-study

Diesel dangers: Mining companies get first look at government cancer study



NIOSH/CDC.gov

By Jim Morris and Chris Hamby

September 27, 2010

A long-delayed government epidemiological study of possible ties between diesel exhaust and lung cancer in miners may finally be published this fall — but only after a mining industry group, represented by the Washington <u>lobbying powerhouse Patton Boggs</u>, finishes a pre-publication review of the study's drafts.

Eighteen years in the making and eagerly awaited by public health officials, the cancer study evaluates more than 12,000 current and former workers from eight mines that produce commodities other than coal. Its goal is to determine whether ultrafine diesel particulate matter — a component of exhaust from diesel-powered machinery — poses a serious hazard to miners in confined spaces.

In a development some experts find alarming, however, Patton Boggs lawyer and partner <u>Henry</u> <u>Chajet</u>, representing a mining industry alliance, the <u>Methane Awareness Resource Group Diesel</u> <u>Coalition</u>, accused the National Cancer Institute and the <u>National Institute for Occupational</u> <u>Safety and Health</u> (NIOSH) of "unfairly, unjustly and unreasonably" depriving mine owners of an advance look at research that could impact their operations.

Providing the latest twist in a nearly 15-year court battle, Chajet's persuasive court filings led to a federal judge's terse, two-page order in June requiring the two Department of Health and Human Services institutes to turn over research to the business coalition's scientific experts 90 days prior to their public release. The same judge had issued a similar order in 2001.

"I think it's outrageous and dangerous," said Francesca Grifo, director of the Scientific Integrity Program at the <u>Union of Concerned Scientists</u>. "It's not a fair fight under any circumstances. The public interest community is so out-funded by the private community, and then on top of that they're getting these materials in advance," she said. "They can spin anything they want any way they want."

Despite critics' charges that Chajet has endangered workers by challenging regulations proposed by the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA) — while attacking the science behind such regulations — the preview was a significant victory for the veteran crisis manager and litigator, who has defended companies in chemical exposure cases, mine disasters, explosions, fires, and construction accidents for more than three decades.

In this clash with the government dating to 1996, Chajet has been a formidable advocate for companies that mine salt, limestone, and an ore used in soda ash, including <u>General Chemical</u> <u>Industrial Products Inc.</u>, Cargill Inc., <u>Detroit Salt Co. LLC</u>, Rohm and Haas Co.'s <u>Morton Salt</u>, FMC Corp., and <u>Mosaic Company</u>.

"People turn to us when they want expertise and they want good lawyering," Chajet explained to the Center. "There are times when problems occur in any business and any enterprise, and we've been honored to help people try to resolve those problems so they can move forward." (According to 2010 disclosure forms filed with the Senate, Chajet was registered to lobby on behalf of General Chemical Corp. and the Methane Awareness Resource Group.)

<u>Celeste Monforton</u>, an assistant research professor at George Washington University who worked at both the occupational and mine safety agencies, has followed the long-running dispute between government health officials and industry interests over diesel. She calls Chajet's challenges "fear-mongering."

"He understands the limitations of science and how to convince people that these agencies are out of control. He really has an appreciation for our dysfunctional regulatory system and has been masterful at capitalizing on that dysfunction," she said.

Monforton believes the mining industry group's demand to see drafts of the cancer study is part of a campaign to delay or discredit the \$9.4 million scientific inquiry. "They've done everything they can to obstruct the study," she said.

"Government researchers do studies all the time and publish them in peer-reviewed journals. This is the only example I know of where an industry group gets access to the information before anybody else does," Monforton said. "I think as soon as the study is published [industry consultants] will already have another paper prepared that will dissect it and explain away any risks that are identified."

The study will be published in the "Annals of Occupational Hygiene," a peer-reviewed British journal, after the court-ordered 90-day review period ends next month.

Representatives of the Centers for Disease Control and Prevention's NIOSH, and the National Cancer Institute, citing ongoing litigation, declined to comment for this story.

Industry may seek more government documents

Chajet said the diesel coalition's only goal is to provide the subjects of the cancer study — both workers and mining companies — with details on how the study was conducted and its results. Even after surrendering edited versions of its unpublished drafts, the government refused to turn over some internal correspondence and raw data, he said. "Our scientists are reviewing what's been given to us," Chajet said, "but we are seriously considering going back [to court] to try to obtain the rest of the documentation." He said the coalition will report its findings to NIOSH and Congress.

"For whatever purpose — whether for litigation, the establishment of public policy, or the establishment of regulatory policy — our goal is to get the information and open the door and let the participants and the public see what the conclusions are based on the science," Chajet said.

But some critics suspect an ulterior motive. Industry scientists, they say, could do their own analysis of the government data and produce papers that minimize the risks posed by diesel. "The bottom line is that this is scientific information in a draft form, and to have that released just provides a superhighway for industry to manipulate those research results," Grifo said.

In arguing for a diesel exposure limit in 2001, the mine safety administration said that diesel particles spewed by front-end loaders, generators, air compressors, and other underground equipment could carry with them up to 1,800 other organic chemicals, including carcinogens. Median diesel concentrations in mines, it said, were up to 180 times higher than the average exposure in heavily polluted urban areas and eight times higher than in other workplaces.

"When there is uncontrolled diesel equipment in an underground mine, it is like working in the tailpipe of a city bus," said Mike Wright, health and safety director for the United Steelworkers, which represents 15,000 miners.

Monforton contends that Chajet sells his clients on the idea that "any characterization of a hazard — particularly a chemical hazard — is a potential liability" to them. His aim, she believes, is to "muck up the works" by challenging the science on toxic compounds such as diesel exhaust and, therefore, help companies fend off litigation or new government rules.

Chajet said he has no such motivation. "We have never conducted any work that put people at risk," he said. "Our clients are committed to protection of health and safety and the environment and are committed to policies that accomplish those goals."

Chajet, 59, has been practicing corporate defense law since 1976. At Patton Boggs, he has testified before Congress on workplace issues; his clients tend to be companies that find themselves in the crosshairs of OSHA and MSHA.

After a Kaiser Aluminum plant in Gramercy, La., blew up in 1999 — injuring 29 workers, showering the neighborhood with residue, and prompting a spate of lawsuits — Chajet and his legal team "resolved all investigations and enforcement actions, helped recover almost the entire financial loss, favorably resolved the tort actions, and recovered denied insurance proceeds to rebuild the plant," according to the Patton Boggs website. In a settlement with the government, Kaiser Aluminum and two of its managers paid more than \$500,000 in fines.

In another notable industry win, OSHA in late 2009 said it would drop chemical exposure limits developed by a nonprofit professional group from hazard disclosure documents that employers are required to maintain. Chajet, representing a range of industries, had pushed for such a move, arguing that the limits — designed to protect workers' health — were developed in secret by "biased" scientists from the <u>American Conference of Governmental Industrial Hygienists</u>. Chajet spent a decade <u>fighting the group</u> in court to stop the government from using the organization's recommended exposure limits.

Delays and frustration

The epidemiological study of workers at so-named metal and nonmetal mines was launched in 1995 by the National Cancer Institute and NIOSH to build on studies that suggested a link between diesel and lung cancer in truck drivers and other workers exposed to diesel particulate matter. The study's results will offer a "state-of-the-art evaluation of diesel," said <u>Kyle Steenland</u>, a professor at Emory University's Rollins School of Public Health and a former NIOSH epidemiologist. "It should provide a very important piece of information about whether diesel is a lung carcinogen. Unfortunately, it has been delayed and delayed for years. It's high time that the public and the scientific community get to see the results of this study."

The delays began in 1996, when the diesel coalition sued NIOSH, arguing that scientific panels established to review the study protocol were potentially biased. Over five years of legal tussling, an appeals court found only one minor violation by NIOSH: providing an advisory panel's charter to the wrong congressional committee. Nevertheless, in a 2001 order, U.S. District Court Judge Richard Haik directed government researchers to share drafts of the study with the House Education and Labor Committee prior to any public release and <u>required</u> that documents explaining the diesel study protocol go to the coalition along with the House committee.

Little of consequence happened after that until March of this year, when the researchers gave drafts of the soon-to-be-published study to the House committee but not to the diesel coalition. In April, Chajet asked Judge Haik to order the government to turn over the drafts to the coalition. The government <u>unsuccessfully argued</u> that releasing the drafts to the group would have constituted public disclosure, in violation of the judge's own 2001 order.

Some observers believe the fight over the cancer study may be a proxy for a bigger objective: Another mining industry challenge to an MSHA rule limiting diesel exhaust.

On Jan. 19, 2001, President Bill Clinton's last day in office, the mine safety administration proposed its first-ever exposure limit for diesel particulate matter in metal and nonmetal mines. The regulation, which was phased in, is designed to cap concentrations of the microscopic

particles, which can work their way deep into the lungs. "Miners should not be required to serve as human guinea pigs in order to remove all doubts about the excess risks of [diesel] exposures," <u>MSHA said</u> at the time.

Although the industry challenged the diesel exposure limit — which MSHA estimated would cost each mine, on average, a relatively paltry \$128,000 per year to adopt — the <u>final version</u> of the regulation took effect in 2008. Companies in the diesel coalition opposed it "because they don't think the science supported what MSHA did," Chajet said, adding that the quarrel over the cancer study has no connection to the MSHA standard. "This is not about a regulation," he said.

Of course, mining companies could in theory ask MSHA to roll back the diesel standard in the face of new scientific evidence, said J. Davitt McAteer, assistant secretary of labor for MSHA from 1993 to 2000. However, it's unlikely such an effort would succeed.

"That would be like finding out that tobacco smoke is actually good for you," McAteer said. "It's not a realistic outcome."